

Case Number: 92839

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

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

Seq: 1

	994				V	Veight:		
spitalisation:						Age : 23Y	•	
Onset Date: 08/04/19	94		DOB:					
Outcome: Not yet r	ecovered				Са	usality: Cau	sality possible	
action Details:								
Preferred Term	S	Severity	Rep	ort De	scription		Treatment	
lyperkinesia								
nsomnia								
lausea								
Somnolence								
ledicine Details:	Othor dure)		Do.					
BENZTROPINE MESYLATE (C	Jiner arug)	2.0	Ke Milligram	ason: Daily	,	Oral		
Batch:	!	Started:	wiiiigiaiii	Daily	Stopped:	Jiai		
NITRAZEPAM (Other drug)	•	Starteu.	Re	ason:	Specific disorde	rs of sleep		
Tablet		10.0	Milligram	Daily		Oral		
Batch:	;	Started:	g	,	Stopped:			
ALCOHOL (Suspected)			Re	ason:				
, ,		0.0						
Batch:	•	Started:			Stopped:			
RISPERDAL (Suspected)			Re	ason:	Unspecified sch	izophrenia		
Oral application		4.0	Milligram	Daily	(Oral		
Batch:	:	Started: 05/0	4/1994		Stopped: 2	26/04/1994		
ala a wata wa 1 kawa ati wa								
aboratory Investiga	Range	Date Teste	ed Result			Details		

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 1 of 554



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

se Number: 93418 Seq: 1 Gender: M Reported: 02/06/1994 Weight: pitalisation: Age: 27Y Onset Date: 19/05/1994 DOB: Outcome: Recovered Causality: Causality: Causality probable ction Details: Preferred Term Severity Report Description Treatment culation failure dicine Details: MOTIDINE (Other drug) Reason: 20.0 Milligram Daily Batch: Started: 18/05/1994 Stopped: CONTIN SPERIDONE (Suspected) Reason: 4.0 Milligram Daily Batch: Started: 12/05/1994 Stopped: 26/05/1994	•	ails:							
Ction Details: Preferred Term Severity Report Description Treatment Culation failure Color	Reported Iospitalisation Onset Date	d: 02/06/199 n: e: 19/05/199	94	1				Weight: Age: DOB:	27Y
Preferred Term Severity Report Description Treatment dicine Details: MOTIDINE (Other drug) Reason: 20.0 Milligram Daily Batch: Started: 18/05/1994 Stopped: CONTIN SPERIDONE (Suspected) Reason: 4.0 Milligram Daily Batch: Started: 12/05/1994 Stopped: 26/05/1994			·u				0.	ausanty.	Causanty probable
dicine Details: MOTIDINE (Other drug) Batch: Started: 18/05/1994 Reason: 20.0 Milligram Daily Batch: Started: 18/05/1994 Stopped: CONTIN Reason: 4.0 Milligram Daily Batch: Started: 12/05/1994 Stopped: 26/05/1994			Se	verity	Repo	ort Descr	iption		Treatment
MOTIDINE (Other drug) 20.0 Milligram Daily Batch: Started: 18/05/1994 Stopped: CONTIN Reason: 4.0 Milligram Daily Batch: Started: 12/05/1994 Stopped: 26/05/1994 Stopped: 26/05/1994	Ejaculation fail	lure			•		•		
MOTIDINE (Other drug) 20.0 Milligram Daily Batch: Started: 18/05/1994 Stopped: CONTIN Reason: 4.0 Milligram Daily Batch: Started: 12/05/1994 Stopped: 26/05/1994 Stopped: 26/05/1994									
Batch: Started: 18/05/1994 Stopped: CONTIN Reason: 4.0 Milligram Daily Batch: Started: 12/05/1994 Stopped: 26/05/1994 Doratory Investigations:					Rea	son:			
SPERIDONE (Suspected) 4.0 Milligram Daily Batch: Started: 12/05/1994 Stopped: 26/05/1994 Doratory Investigations:						Daily			
Batch: Started: 12/05/1994 Stopped: 26/05/1994 Doratory Investigations:			St	arted: 18/05/1			Stopped:		CONTIN
Batch: Started: 12/05/1994 Stopped: 26/05/1994	RISPERIDONE ((Suspected)		4.0 Milli					
boratory Investigations:	Batch:		St			Daily	Stopped:	26/05/1994	
Date Total T				Date Tested	Result			Detail	9
		туре	Range	Date Tested	Resuit			Detail	S
				Date Tested	Result			Detail	S

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 2 of 554



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

Case Numb						
	er : 94396	Seq:	1		Gend	ler: M
Report	ed: 14/07/1994				Weig	ht: 90.00
ospitalisatio						ge : 82Y
Onset Da	nte: 01/07/1994					OB:
	ne: Not yet reco	overed			Causal	ity: Causality possible
action De						
	ferred Term	Sev	erity	Repo	ort Description	Treatment
epatitis cho	lestatic					
ladiaira F	Notaile:					
LEGICINE E				Reas	son:	
	J. Glug/		0.0	i veas	JOII.	
Batch	1:	Sta	rted:		Stopped:	CONTIN
ATENOLOL (C		Jia		Reas		30.11.114
			0.0	11001		
Batch	:	Sta	rted:		Stopped:	CONTIN
SINEMET (Oth				Reas		
(3	3 ,		0.0			
	ı:	Sta	rted:		Stopped:	CONTIN
Batch				Reas		-
	(Other drug)				5011.	
	(Other drug)		0.0		SOII.	
INSULIN NOS		Sta	0.0			CONTIN
INSULIN NOS Batch	:				Stopped:	CONTIN
Batch	: / Investigation	ons:	rted:		Stopped:	
INSULIN NOS Batch	:	ons:		Result	Stopped:	CONTIN

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 3 of 554



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number:	94396	Seq: 1			(Gender:	M	
	14/07/1994	•				Weight:		
ospitalisation:						Age:		
Onset Date:	01/07/1994					DOB:		
	Not yet recovered				Ca		Causality	possible
action Detai	=					-	•	
Medicine Deta	aile							
	TRATE (Other drug)			Reason:				
Cream	ζ,		0.0			Transderma	al	
Batch:		Started			Stopped:			
					• • •			
RISPERIDONE (Su	ispected)			Reason:	Unspecified psy	/chosis		
RISPERIDONE (Su	ispected)		0.5 Milligram	Reason: Daily	Unspecified psy	/chosis		
RISPERIDONE (Su	ispected)		0.5 Milligram	Reason: Daily				
Batch:	ispected)		0.5 Milligram : 20/06/1994		Unspecified psy Stopped:			
	ispected)							
	ispected)							
	ispected)							
	ispected)							
	ispected)							
	ispected)							
	ispected)							
Batch:								
Batch:	uvestigations:							
Batch:								
Batch:								
Batch:								
Batch:								
Batch:								
Batch:								
Batch:								
Batch:	vestigations:							
Batch: aboratory In	evestigations:							
Batch:	evestigations:							
Batch: aboratory In	evestigations:							
Batch: aboratory In	evestigations:							

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 4 of 554



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

ase Number:		Seq:	1			Gende	
spitalisation:	: 09/09/199	/4				Weight	: 76Y
Onset Date		14				DOE	
	Recovere						: Causality probable
e.ction Deta		u				Causanty	. Causality probable
	red Term	Se	everity	Ren	ort Descriptior	1	Treatment
uroleptic mal			J. C. I.L.	1.00	ort Becompaier	'	Trodunone
edicine De SPERIDONE (S			1.0 Milli		i son: Daily		
Batch:		s	tarted:		Stop	ped:	
<u>boratory l</u>	nvestigat						
Date	Туре	Range	Date Tested	Result		Det	ails
dditional Ir	ıformatio	n:					
	007 11:01AN	/ Database: pi			ADRS004		Page 5 of 554



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

Report	Details:
--------	----------

Case Number: 96855 Seq: 1 Gender: F
Reported: 01/11/1994 Weight:

Hospitalisation: Age: 47Y
Onset Date: 15/10/1994
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

١,	Caction Details.				
	Preferred Term	Severity	Report Description	Treatment	1
	Increased appetite			Commenced on fluphenazine.	1
	Weight increased				i

Medicine Details:

TEMAZEPAM (Other drug) Reason: Specific disorders of sleep

20.0 Milligram

Batch: Started: 25/08/1994 Stopped:

METHOTREXATE (Other drug) Reason: Other psoriasis

10.0 Milligram Weekly

Batch: Started: Stopped:

IMIPRAMINE HYDROCHLORIDE (Other drug) Reason: Depression

150.0 Milligram Daily

Batch: Started: 22/09/1994 Stopped:

CLONAZEPAM (Other drug) Reason:

2.0 Milligram Daily

Batch: Started: 11/10/1994 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 6 of 554



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number:	96855	Seq: 1				Gender:	F
Reported:	01/11/1994					Weight:	
Hospitalisation:						Age:	
Onset Date:	15/10/1994					DOB:	
	Recovered				С	ausality:	Causality probable
Reaction Detai	ls:						
Medicine Det	ails:						
	YDROCHLORIDE (Oti	her drug)		Reason:			
			40.0 Milligram	Daily			
Batch:		Start	ed: 11/10/1994		Stopped:		
RISPERDAL (Susp	ected)			Reason:	Unspecified ps	ychosis	
			6.0 Milligram	Daily			
Batch:		Start	ed: 22/09/1994		Stopped:	25/10/1994	
I aboratory In	vestigations:						
Laboratory III	vootigationo.						
A alakata a a la d							
Additional Inf	formation:						
Additional Inf	formation:						
Additional Inf	formation:						
Additional Inf	formation:						
Additional Inf	formation:						

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 7 of 554



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

eq : 1				
			Gender: Weight:	
			Age:	
		•	DOB:	Causality possible
		C	ausanty.	Causality possible
Severity	Reno	ort Description		Treatment
Ocventy		or Becomption		Treatment
	Camba rong			
	Rea	son: Unspecified ps	sychosis	
5.0			Oral	
		Stopped:		CONTIN
	Reas	son:		
4.0	Dose Unspecified	Daily	Inhalation	
Started:	L TERM	Stopped:		
Date Test	ed Result		Detail	s
	4.0 Started:	Reas 5.0 Milligram Started: 25/09/1994 Reas 4.0 Dose Unspecified Started: L TERM	Severity Report Description Gained 10kg Reason: Unspecified ps 5.0 Milligram Daily Started: 25/09/1994 Stopped: Reason: 4.0 Dose Unspecified Daily Started: L TERM Stopped:	Reason: Unspecified psychosis 5.0 Milligram Daily Oral Started: 25/09/1994 Stopped: Reason: Unspecified psychosis Oral Started: L TERM Stopped:

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 8 of 554



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

Report Details:

 Case Number:
 97134
 Seq: 1
 Gender:
 F

 Reported:
 17/11/1994
 Weight:

Hospitalisation: Age: 55

Onset Date: 08/07/1994 **DOB**: 17/02/1939

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia			

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 9 of 554



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number: 97134 Reported: 17/11/1994 Hospitalisation: Onset Date: 08/07/1994 Outcome: Recovered Reaction Details:	Seq: 1			
Medicine Details:				
ZOLOFT (Suspected)	FO O Milliana	Reason: Depression	01	
Tablet Batch:	50.0 Milligram Started: 13/05/1994		Oral	
Batcii.	Started: 13/03/1994	Stopped:	00/07/1994	<u>'</u>
Laboratory Investigations:				
Additional Information:				

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 10 of 554



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

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

Case Number: 97579 Seq: 1 Gender: F

Reported: 05/12/1994 Weight: 56.00 Hospitalisation: Age: 77Y

Onset Date: 21/11/1994 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

Tablet 2.0 Milligram Total Oral

Batch: **Started**: 20/11/1994 **Stopped**: 22/11/1994

RISPERIDONE (Suspected) Reason: Unspecified psychosis

500.0 Microgram As necessary

Batch: Started: Stopped: 23/11/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 11 of 554



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

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

Case Number: 97960 Seq: 1 Gender: M

Reported: 19/12/1994 Weight: 105.00 Hospitalisation: Age: 47Y

Onset Date: DOB:

Outcome: Death Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			
Sudden death			

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient died on the 9/12/94.

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 12 of 554



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Reported: 19/12/1994 Weight: 105.00 Sopitalisation:		97960	Seq: 1			Ge	ender:	M	
Age: 47Y Onset Date: Outcome: Death Causality: Causality possible action Details: Causality possible Causality	Reported:		-						
Onset Date: Outcome: Death Causality: Causality possible action Details: Causality possible Causality	-						_		
Redicine Details: VERAPAMIL HYDROCHLORIDE (Other drug) Batch: Started: Stopped: Reason: VStopped: Reason: Voral									
240.0 Milligram Daily Batch: Started: Stopped: RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 6.0 Milligram Daily Oral	Outcome:	Death				Caus	sality:	Causality pos	ssible
VERAPAMIL HYDROCHLORIDE (Other drug) Reason: 240.0 Milligram Daily Batch: Started: Stopped: RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 6.0 Milligram Daily Oral	action Detail	s:							
Reason: 240.0 Milligram Daily Batch: Stopped: RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 6.0 Milligram Daily Oral									
Reason: 240.0 Milligram Daily Batch: Started: Stopped: RISPERDAL (Suspected) Oral application 6.0 Milligram Daily Oral									
VERAPAMIL HYDROCHLORIDE (Other drug) Reason: 240.0 Milligram Daily Batch: Started: Stopped: RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 6.0 Milligram Daily Oral									
VERAPAMIL HYDROCHLORIDE (Other drug) Reason: 240.0 Milligram Daily Batch: Started: Stopped: RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 6.0 Milligram Daily Oral									
VERAPAMIL HYDROCHLORIDE (Other drug) Reason: 240.0 Milligram Daily Batch: Started: Stopped: RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 6.0 Milligram Daily Oral									
VERAPAMIL HYDROCHLORIDE (Other drug) Reason: 240.0 Milligram Daily Batch: Started: Stopped: RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 6.0 Milligram Daily Oral									
VERAPAMIL HYDROCHLORIDE (Other drug) Reason: 240.0 Milligram Daily Batch: Started: Stopped: RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 6.0 Milligram Daily Oral									
VERAPAMIL HYDROCHLORIDE (Other drug) Reason: 240.0 Milligram Daily Batch: Started: Stopped: RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 6.0 Milligram Daily Oral									
VERAPAMIL HYDROCHLORIDE (Other drug) Reason: 240.0 Milligram Daily Batch: Started: Stopped: RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 6.0 Milligram Daily Oral									
VERAPAMIL HYDROCHLORIDE (Other drug) Reason: 240.0 Milligram Daily Batch: Started: Stopped: RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 6.0 Milligram Daily Oral									
VERAPAMIL HYDROCHLORIDE (Other drug) Reason: 240.0 Milligram Daily Batch: Started: Stopped: RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 6.0 Milligram Daily Oral									
VERAPAMIL HYDROCHLORIDE (Other drug) Reason: 240.0 Milligram Daily Batch: Started: Stopped: RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 6.0 Milligram Daily Oral	ladiaina Data	.:							
Batch: Started: Stopped: RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 6.0 Milligram Daily Oral			rua)		Rosson:				
Batch: Started: Stopped: RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 6.0 Milligram Daily Oral	VEIXAFAIIIL III DIX	OCHEONIDE (Other di		n Milligram					
RISPERDAL (Suspected) Oral application Reason: Unspecified schizophrenia Daily Oral	Batch:			o iviiliigiaiii	Daily	Stopped:			
Oral application 6.0 Milligram Daily Oral		acted)	Otartea.						
					Reason:	Unspecified schize	onnrenia		
			6.0	n Milligram					
Suiton Control Copped	Oral applica					Or			
	Oral applica					Or			
	Oral applica					Or			
	Oral applica					Or			
	Oral applica					Or			
	Oral applica					Or			
	Oral applica Batch:	tion				Or			
aboratory Investigations:	Oral applica Batch:	tion				Or			
aboratory Investigations:	Oral applica Batch:	tion				Or			
aboratory Investigations:	Oral applica Batch:	tion				Or			
aboratory Investigations:	Oral applica Batch:	tion				Or			
aboratory Investigations:	Oral applica Batch:	ition				Or			
aboratory Investigations:	Oral applica Batch:	ition				Or			
aboratory Investigations:	Oral applica Batch:	ition				Or			
aboratory Investigations:	Oral applica Batch:	ition				Or			
	Oral applica Batch: aboratory inv	vestigations:				Or			
dditional Information:	Oral applica Batch: aboratory Inv	vestigations:				Or			
additional Information:	Oral applica Batch: aboratory Inv	vestigations:				Or			
dditional Information:	Oral applica Batch: aboratory Inv	vestigations:				Or			
aboratory Investigations: Additional Information: atient died on the 9/12/94.	Oral applica Batch: aboratory Inv	vestigations:				Or			

Page 13 of 554



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

Report Details:

Case Number: 98554 Seq: 1 Gender: M

Reported: 23/01/1995 Weight: 76.00 Hospitalisation: Age: 73

Onset Date: 16/01/1995 DOB: 22/02/1921

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 14 of 554



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

Report Details:

Case Number: 98554 Seq: 1 Gender: M

Reported: 23/01/1995 Weight: 76.00 Hospitalisation: Age: 73

Onset Date: 16/01/1995 **DOB**: 22/02/1921

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected) Reason: Manic-depression psycho,manic

4.0 Milligram Daily

Batch: Started: 09/01/1995 **Stopped:** 16/01/1995

Laboratory Investigations:

Additional Information:

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

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 15 of 554



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

eport De	tails:								
	oer: 98628 ed: 05/12/199	Seq: 1					Gender: F Weight:	=	
pitalisatio							Age:		
	ate: 20/11/199						DOB:		
	ne: Death, ma	ybe drug				C	ausality:(Causality possible	
ction De									
	ferred Term	Seve	erity	Rep	ort Desc	ription		Treatment	
diac arres	<u>st</u>								
aliaiaa F	2-4-11								
dicine [Details: E (Suspected)			Pos	ıson: U	Inspecified sc	hizophronia		
			4 O Milli			mspecilled sc			
Tablet		•	4.0 Milligram			Daily Oral Stopped: 20/11/1994			
Batch	1:	Star	rted: 15/11/19	994		Stopped:	20/11/1994		
aboratory	y Investigat	ions:							
Date	Type		Date Tested	Result			Details		
ditional	Informatio	า:							
- D 04/0	G/2007 11:04 A N	Database: pusi	me0?		ADRS004			Page 16 of	<i></i>

Page 16 of 554



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

Report Details:

Case Number: 98929 Seq: 1 Gender: F

Reported: 13/02/1995 Weight: 110.00 Hospitalisation: Age: 52Y

Onset Date: 25/01/1995 **DOB:**

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

DEPTRAN (Other drug)			Reason:	Depression	
	200.0	Milligram	Daily		
Batch:	Started:	L	. TERM	Stopped:	CONTIN
LITHIUM CARBONATE (Other drug)			Reason:	Depression	
	1.2	Gram	Daily		
Batch:	Started: 23	/08/1994		Stopped:	CONTIN
THYROXINE SODIUM (Other drug)			Reason:	Myxedema	
	200.0	Microgram	Daily		
Batch:	Started:	L	. TERM	Stopped:	CONTIN
RISPERDAL (Suspected)			Reason:	Unspecified psychosis	
	10.0	Milligram	Daily		
Batch:	Started: 03	/08/1994		Stopped: 05/02/1995	5

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 17 of 554



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

Report Details:

Case Number: 98929 Seq: 1 Gender: F

Reported: 13/02/1995 Weight: 110.00 Hospitalisation: Age: 52Y

Onset Date: 25/01/1995 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

DEPTRAN (Other drug) Reason: Depression

200.0 Milligram Daily

Batch: Started: L TERM Stopped: CONTIN

LITHIUM CARBONATE (Other drug) Reason: Depression

1.2 Gram Daily

Batch: Started: 23/08/1994 Stopped: CONTIN

THYROXINE SODIUM (Other drug) Reason: Myxedema

200.0 Microgram Daily

Batch: Started: L TERM Stopped: CONTIN

RISPERDAL (Suspected) Reason: Unspecified psychosis

10.0 Milligram Daily

Batch: Started: 03/08/1994 **Stopped:** 05/02/1995

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 18 of 554



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

Report Details:

Case Number: 98929 Seq: 1 Gender: F

Reported: 13/02/1995 Weight: 110.00 Hospitalisation: Age: 52Y

Onset Date: 25/01/1995 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

DEPTRAN (Other drug)		Reason:	Depression	
	200.0 Millio	gram Daily	•	
Batch:	Started:	L TERM	Stopped:	CONTIN
LITHIUM CARBONATE (Other drug)		Reason:	Depression	
	1.2 Grar	n Daily	•	
Batch:	Started: 23/08/19	94	Stopped:	CONTIN
THYROXINE SODIUM (Other drug)		Reason:	Myxedema	
	200.0 Micro	ogram Daily	•	
Batch:	Started:	L TERM	Stopped:	CONTIN
RISPERDAL (Suspected)		Reason:	Unspecified psychosis	
	10.0 Millio	gram Daily	•	
Batch:	Started: 03/08/19	94	Stopped: 05/02/1995	

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 19 of 554



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

tails:				
on: ate: 24/02/199	5		Weight: Age: DOB	22Y
etails:				
	Severity	Report Des	scription	Treatment
Details: E (Suspected)		Reason:	Unspecified schizophreni	a
t	6.0	Milligram Daily	Oral	
ո։	Started: 26/0	1/1995	Stopped : 28/02/199	5
y Investigati		d Result	Deta	ils
y Investigati _{Type}	ONS: Range Date Teste	d Result	Deta	ils
	per: 100021 ped: 04/04/1998 pon: pate: 24/02/1998 pee: Recovered petails: pered Term pate: 24/02/1998 petails: pered Term pate: 24/02/1998	per: 100021 Seq: 1 red: 04/04/1995 con: rate: 24/02/1995 me: Recovered retails: referred Term Severity red: Severity red: 04/04/1995 red: 24/02/1995 red: Recovered retails: referred Term Severity red: Recovered retails: Recovered reta	per: 100021 Seq: 1 red: 04/04/1995 ron: rate: 24/02/1995 rne: Recovered retails: referred Term Severity Report Design of the second of the sec	per: 100021 Seq: 1 Gender: ped: 04/04/1995 Weight: petaile: 24/02/1995 DOB: petails:

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 20 of 554



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

Report Details:

Case Number: 100889 Seq: 1 Gender: M

Reported: 18/05/1995 Weight:

Hospitalisation: Age: 20Y
Onset Date: 08/05/1995
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria		White papular rash	

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Eczema and itchy before risperidone therapy worsened after starting rispersone

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 21 of 554



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

Report Details:

Case Number: 100915 Seq: 1 Gender: M

Reported: 19/05/1995 Weight:

Hospitalisation: Age: 39Y
Onset Date: 10/05/1995
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

? nms in the past secondary to largactil and haloperidol.

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 22 of 554



Case Number: 102217

Reported: 17/07/1995

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight:

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

Seq: 1

Onset Date: 08/07/199			A	.ge: 31Y
O	95			OB:
Outcome: Recovere	ed .		Causa	lity: Causality probable
eaction Details:				
Preferred Term	Severity	Repor	Description	Treatment
Hypokinesia		Psychomotor retar	dation.	
Anorexia				
Anxiety				
Depression				
atigue				
nsomnia				
Pyrexia				
hinking abnormal				
Medicine Details: RISPERDAL (Suspected)		Reaso	n: Unspecified psychos	is
Batch:		05/07/1995	Stopped: 11/07	7/1995
		Tooled Doorth		Dotaila
_aboratory Investigat Date Type		Tested Result		Details
	Range Date	Tested Result		Details



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

Report Details:

Case Number: 102651 Seq: 1 Gender: M

Reported: 02/08/1995 Weight: 92.00 Hospitalisation: Age: 32Y

Onset Date: 15/04/1995 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

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

Medicine Details:

Medicine Details.			
LITHICARB (Other drug)		Reason:	
Tablet	1.7 Gram	Daily Ora	al
Batch:	Started: 01/02/1995	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schize	phrenia
Tablet	4.0 Milligram	Daily Ora	al
Batch:	Started: 04/04/1995	Stopped: 20/	07/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 24 of 554



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

eport De	tails:					
Report spitalisatio Onset Da	ate: 02/08/199	5			Weig A <u>q</u> D0	ler: M ht: 74.00 ge: 26Y DB:
	ne: Not yet re	covered			Causal	ity: Causality possible
action De		Cayani	4.	Danart	Description	Transferent
skinesia	ferred Term	Severi	ıy	Report	Description	Treatment
edicine I	Details: E (Suspected)		4.0 Millig	Reasor gram Da	ı: Billy	
Batch	1:	Starte	d: 30/11/19	94	Stopped:	CONTIN
aborator Date	y Investigat Type		e Tested	Result	C	Details
	,,	ű				
.dditional	Informatio	1:				
ort Run · 04/0	6/2007 11·01AM	Database: pusime		ADR	S004	Page 25 of 554

Page 25 of 554



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

Reported: 23/0 spitalisation:		q : 1		Gende	
spitalisation:	08/1995				t: 75.00
	·			_	e: 30Y
Onset Date: 14/				DO	
Outcome: Red				Causalit	y: Causality probable
action Details:		O a a with .	Daniel Dee		Tue above and
Preferred T	erm	Severity	Report Des	cription	Treatment
jaculation failure lausea					
ledicine Details			Reason:	Unspecified schizophre	nia
Tablet		5.0 Milli	igram Daily	Oral	
Batch:		Started: 30/06/1	995	Stopped: 01/08/19	995
.aboratory Inves		Date Tested	Result		tails

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 26 of 554



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

Case Number: 103382 Reported: 06/09/1995 ospitalisation: Onset Date: 31/07/1995	Seq: 1		We	ender: M eight: Age: 57Y DOB:
Outcome: Not yet recovere	d		Caus	sality: Causality possible
eaction Details: Preferred Term	Severity	Reno	rt Description	Treatment
jaculation failure	Ocventy	Поро	Tt Description	Treatment
Medicine Details: RISPERIDONE (Suspected) Tablet	6.0 Mil	Reas	on: Unspecified schizo	
Batch:	Started: 19/06/1		Stopped: 19	
_aboratory Investigations:				
Date Type Rar	nge Date Tested	Result		Details
Additional Information:				

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 27 of 554



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

Report Details:

Case Number: 103464 Seq: 1 Gender: M

 Reported:
 11/09/1995
 Weight:
 65.00

 Hospitalisation:
 Age:
 25Y

 Onset Date:
 31/08/1995
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			
Hyperkinesia			

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

6.0 Milligram Daily

Batch: Started: 03/07/1995 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 28 of 554



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

Report Details:

Case Number: 103580 Seq: 1 Gender: M

Reported: 15/09/1995 Weight: 77.00 Hospitalisation: Age: 41Y

Onset Date: 05/08/1995 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

WARFARIN SODIUM (Other drug)	Reason: F	Peptic ulcer nos w/o ment perf
------------------------------	-----------	--------------------------------

0.0

Batch: Started: 01/07/1995 Stopped:

PRO-BANTHINE (Other drug) Reason: Other diseases of bladder

6.0 Dose Unspecified Daily

Batch: Started: 01/04/1995 Stopped:

PROZAC (Other drug) Reason: Depression

20.0 Milligram Daily

Batch: Started: 01/01/1995 Stopped:

ZANTAC (Other drug) Reason:

300.0 Milligram Daily

Batch: Started: L TERM Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 29 of 554



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

Report Details:

Case Number: 103580 Seq: 1 Gender: M

Reported: 15/09/1995 Weight: 77.00 Hospitalisation: Age: 41Y

Onset Date: 05/08/1995 **DOB:**

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

Additional Information:

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

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 30 of 554



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

Report Details:

Case Number: 103738 Seq: 1 Gender: M

Reported: 28/09/1995

Hospitalisation:
Onset Date:

Weight: 82.00
Age: 28Y
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			

Medicine Details:

RISPERIDONE (Suspected) Reason: Schizophrenia

8.0 Milligram Daily

Batch: Started: 01/04/1995 **Stopped:** 28/08/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 31 of 554



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

Report	Details:
--------	----------

 Case Number:
 104163
 Seq: 1
 Gender: M

 Reported:
 25/10/1995
 Weight:

Hospitalisation: Age: 73Y
Onset Date: 10/10/1995
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			

Medicine Details:

AMOXIL (Other drug)		Rea	son:	Bronchitis,unq	ualified
Oral application	1.5	Gram	Daily		Oral
Batch:	Started: 09/	/10/1995		Stopped:	16/10/1995
SINEMET (Other drug)		Reas	son:	Paralysis agita	ins
Tablet	3.0	Dose Unspecified	Daily		Oral
Batch:	Started:	L TERM		Stopped:	
PROPYLTHIOURACIL (Other drug)		Rea	son:	Myxedema	
Tablet	100.0	Milligram	Daily		Oral
Batch:	Started:	L TERM		Stopped:	
BETOPTIC (Other drug)		Reas	son:	Unspecified gla	aucoma
Eye Drops	2.0	Dose Unspecified	Daily		Ophthalmic
Batch:	Started:	L TERM		Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 32 of 554



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

	104163	Seq: 1				Gender:	141	
Reported: 2	25/10/1995					Weight:		
ospitalisation:						Age:	73Y	
Onset Date:	10/10/1995					DOB:		
Outcome: F	Recovered				C	ausality:	Causality	possible
action Details	s:							
Medicine Deta	ils:							
RISPERDAL (Suspe				Reason:	Hallucinations			
Tablet		1.0	Milligram	Daily		Oral		
Batch:		Started: 09		·	Stopped:	15/10/1995		
MODURETIC (Suspe	actod)							
MICDOINE HIC (Cuspe	ecteu)			Reason:	Essential benic	an hypertens	sion	
MODURETTO (Odspr	ecteu)	0.5	Dose Unspe	Reason:	Essential beniq	n hypertens	sion	
	ecieuj			ecified Daily				
Batch:	ecteu)	0.5 Started:				gn hypertens 13/10/1995		
	ecteu)			ecified Daily				
	ecteu)			ecified Daily				
	ecteu)			ecified Daily				
	ecteu)			ecified Daily				
	ecteu)			ecified Daily				
	scieu)			ecified Daily				
Batch:		Started:		ecified Daily				
Batch:		Started:		ecified Daily				
Batch:		Started:		ecified Daily				
Batch:		Started:		ecified Daily				
Batch:		Started:		ecified Daily				
Batch:		Started:		ecified Daily				
Batch:		Started:		ecified Daily				
Batch:		Started:		ecified Daily				
Batch:		Started:		ecified Daily				
Batch:	estigations:	Started:		ecified Daily				
	estigations:	Started:		ecified Daily				
Batch:	estigations:	Started:		ecified Daily				
Batch:	estigations:	Started:		ecified Daily				
Batch:	estigations:	Started:		ecified Daily				
Batch:	estigations:	Started:		ecified Daily				

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 33 of 554



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

Report Details:

Case Number: 104460 Seq: 1 Gender: F

Reported: 07/11/1995 Weight:
Hospitalisation: Age: 31Y

Onset Date: 17/10/1995 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

,	caction Details.				
	Preferred Term	Severity	Report Description	Treatment	
	Blood creatine phosphokinase incr				1
	Neuroleptic malignant syndrome			Fluids, bromocriptine.	

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 34 of 554



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

Report De				
	tails:			
Case Numb	oer: 104478	Seq: 1	Gender	: F
Report	ted: 08/11/1995		Weight:	
-lospitalisati	on:		Age	30Y
Onset Da	ate: 29/09/1995		DOB	:
Outcor	ne: Recovered		Causality	: Causality probable
eaction De	etails:			
Pre	eferred Term	Severity	Report Description	Treatment
Urticaria			Rash around hips, tops of legs, chest,	
Angiaadama			neck	
Angioedema				
Medicine I	Details:			
RISPERDAL (Reason: Unspecified schizophreni	a
Oral a	application	4.0	Milligram Daily Oral	
Batch	h:	Started: 29/0	09/1995 Stopped : 06/10/199	5
	y Investigatio		od L Dooult	.ilo
Laborator Date	y Investigatio	P NS: Range Date Test	ed Result Deta	iils

Report Run: 04/06/2007 11:01AM Database: pusime02 ADRS004 Page 35 of 554



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

Report Details:

 Case Number:
 104702
 Seq: 1
 Gender:
 F

 Reported:
 20/11/1995
 Weight:
 80.00

Hospitalisation: Age: 67

Onset Date: 10/10/1995 **DOB**: 28/09/1928

Outcome: Recovered Causality: Causality probable

Reaction Details:

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

Medicine Details:

PANAMAX (Other drug)			
	2.0 Dose U	Inspecified As necessary	
Batch:	Started:	Stopped:	
THYROXINE SODIUM (Other drug)		Reason:	
	200.0 Microg	ram Daily	
Batch:	Started:	Stopped:	
TOLVON (Other drug)		Reason:	
	60.0 Milligra	ım Daily	
Batch:	Started:	Stopped:	
LORAZEPAM (Other drug)		Reason:	
	2.0 Milligra	ım Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 36 of 554



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

Report Details:			
Case Number: 104702	Seq: 1	Gender:	F
Reported: 20/11/1995	•	Weight:	
Hospitalisation:		Age:	
Onset Date: 10/10/1995		_	28/09/1928
Outcome: Recovered			Causality probable
Reaction Details:		•	, , , , , , , , , , , , , , , , , , ,
Medicine Details:			
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	10.0 Milligram	Daily	
Batch:	Started: 01/05/1995	Stopped: 10/10/1995	j
Laboratory Investigations:			
Laboratory investigations.			
Additional Information:	manahadia dimensi diserbis di	an atom data in material and	unda huitindinetee tiest of o
Past history of side effects to many anti occurred sometime during the month.	psycholic drugs. The dosa	ge start date is not necessarily acct	irale dul indicates that start

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 37 of 554



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

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

Case Number: 105609 Seq: 1 Gender: M

Reported: 02/01/1996 Weight:
Hospitalisation: Age: 19Y

Onset Date: 16/12/1995 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Face oedema	Severe		

Medicine Details:

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

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 38 of 554



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

Report Details:

 Case Number:
 106327
 Seq: 1
 Gender:
 F

 Reported:
 07/02/1996
 Weight:

Hospitalisation:
Onset Date: 31/01/1996
Age: 64Y
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Severe		
Extrapyramidal disorder			
Hyperkinesia			

Medicine Details: COGENTIN (Other drug)

Batch:	Started:	Stopped:	
	2.5 Milligram	Daily	
DIAZEPAM (Other drug)	ı	Reason:	
Batch:	Started: 12/12/1995	Stopped: 28/01/1996	
	0.5 Milligram	Daily	

Reason:

Paralysis agitans

RISPERIDONE (Suspected) Reason: Presenile dementia

0.5 Milligram Daily

Batch: Started: 01/12/1995 **Stopped:** 28/01/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 39 of 554



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

Report	Details:
--------	----------

Case Number: 106525 Seq: 1 Gender: F
Reported: 19/02/1996 Weight:
Hospitalisation: Age: 86Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness			
Dysphagia			
Face oedema			

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 40 of 554



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

Re	port	Det	tail	s:

 Case Number:
 106525
 Seq: 1
 Gender:
 F

 Reported:
 19/02/1996
 Weight:

Hospitalisation: Age: 86Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 41 of 554



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

Report Details:		
Case Number: 106699	Seq: 1	Gender: M
Reported: 26/02/1996		Weight: 72.00

Hospitalisation:
Onset Date: 03/02/1996
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bronchospasm			

Medicine Details:

RISPERDAL (Suspected)

Tablet

2.0 Milligram

Daily

Oral

Batch: Started: 30/01/1996 **Stopped:** 12/02/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 42 of 554



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

Report Details:

Case Number: 106805 Seq: 1 Gender: M

Reported: 01/03/1996 Weight:
Hospitalisation: Age: 22Y

Onset Date: 18/08/1995 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified schizophrenia

Tablet 4.0 Milligram Daily Oral

Batch: Started: 08/08/1995 Stopped:

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Patient has allergy to largactil.

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 43 of 554



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

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

Case Number: 106956 Seq: 1 Gender: M

Reported: 08/03/1996 Weight: 66.00 Hospitalisation: Age: 74Y

Onset Date: 01/03/1996 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Blood creatine phosphokinase incr			

Medicine Details:

IMDUR (Other drug)	Reason:	Angina pectoris w/o hyperten
--------------------	---------	------------------------------

60.0 Milligram Daily

Batch: Started: Stopped:

MADOPAR Q (Other drug) Reason: Paralysis agitans

3.0 Dose Unspecified Daily

Batch: Started: Stopped:

RISPERIDONE (Suspected) Reason: Hallucinations

Tablet 1.5 Milligram Daily Oral

Batch: Started: 28/02/1996 **Stopped:** 01/03/1996

CHLORMETHIAZOLE (Suspected) Reason: Otr spec symp psychopathol nec

192.0 Milligram Daily

Batch: Started: 15/02/1996 Stopped:

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 44 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Repor Hospitalisati Onset D			: 1			Gende Weight Age DOB Causality	: :
Reaction D							, , , , , , , , , , , , , , , , , , ,
	eferred Term	Se	everity	Repo	ort Desc	ription	Treatment
Confusional	state						
Madiaina	Dotoilo						
Medicine PEPCIDINE (Rea	son:		
(g,		40.0 Milli		Daily		
Batc	h:	s	tarted:		•	Stopped:	
THYROXINE	SODIUM (Other d	rug)		Rea	son:		
			150.0 Micr	rogram	Daily		
Batc	h:	S	tarted:			Stopped:	
THIAMINE (O	ther drug)			Rea	son:		
			10.0 Milli	gram	Daily		
Batc		S	tarted:			Stopped:	
ZOLOFT (Sus	spected)				son:		
D-4-	L	•	50.0 Milli	_	Daily	Otamanada	
Batc	n:	8	tarted: 03/02/19	996		Stopped:	
Laborator	y Investigat	tions:					
Date	Type	Range	Date Tested	Result		Det	ails
Additiona	l Informatio	n:					

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 45 of 554



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

Report Details:				
Case Number: 107160 Reported: 20/03/1996 Hospitalisation: Onset Date: Outcome: Unknown Reaction Details:	Seq: 1		Gender: F Weight: Age: DOB: Causality: Causality possible	
Medicine Details: RISPERIDONE (Suspected)		Reason:		7
Batch:	1.0 Milligram Started: 09/02/1996	Daily	Stopped: 16/02/1996	
Laboratory Investigations:				
Additional Information:				

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 46 of 554



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

Reported: 28/03/1996 ospitalisation: Onset Date: 29/02/1996 Outcome: Unknown eaction Details: Preferred Term Galactorrhoea	Seq: 1	Rep	ort Dogorinti	Age DOI	t: 71.00 e: 17Y
Ospitalisation: Onset Date: 29/02/1996 Outcome: Unknown eaction Details: Preferred Term Galactorrhoea	Severity	Rep	ort Dogorinti	Age DOI	e: 17Y B:
Outcome: Unknown eaction Details:	Severity	Rep	ort Dogorinti	DO	В:
Outcome: Unknown eaction Details: Preferred Term Galactorrhoea	Severity	Rep	art Descripti		
Preferred Term Galactorrhoea	Severity	Rep	art Dagarinti	Causalit	y: Causality possible
Preferred Term Galactorrhoea	Severity	Rep	art Descripti		
Salactorrhoea	Seventy	Rep			Trootingont
			ort Descripti	OH	Treatment
Type: protactina critic					
ledicine Details:		Re:	ason:		
Tablet	1.0 G		Daily	Oral	
Batch:	Started:		-	opped:	
VALPRO (Other drug)		Rea	ason:		
Tablet	1.0 G	ram	Daily	Oral	
Batch:	Started:		Ste	opped:	
RISPERIDONE (Suspected)			ason:		
Tablet	6.0 M	•	Daily	Oral	
Batch:	Started: 14/12/	1995	Sto	opped:	
_aboratory Investigations: Date Type Range	e Date Tested	Result			tails
Pharmacokinetics			4/3/96 lithium prolactin 1786	<0.1 mmol/l 6 miu/l (32-420)	valproate 253 mmol/l hcg < 2 (0-5)

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 47 of 554



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

Report Details:

Case Number: 107695 Seq: 1 Gender: F

 Reported:
 03/04/1996
 Weight:
 50.00

 Hospitalisation:
 Age:
 27Y

 Onset Date:
 20/03/1996
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 48 of 554



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

Report Details:

Case Number: 107730 Seq: 1 Gender: M
Reported: 04/04/1996 Weight:
Hospitalisation: Age: 70Y

Onset Date: 03/11/1995 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 49 of 554



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

Report	Details:
--------	----------

Case Number: 107730 Seq: 1 Gender: M
Reported: 04/04/1996 Weight:
Hospitalisation: Age: 70Y

Onset Date: 03/11/1995 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

LITHIUM CARBONATE (Other drug)		R	eason:		
Tablet	1.0	Gram	Daily		Oral
Batch:	Started:	L TER	М	Stopped:	
NITRAZEPAM (Other drug)		R	eason:		
Oral application	2.0	Dose Unspecifie	d Daily		Oral
Batch:	Started:	L TER	М	Stopped:	
RISPERIDONE (Suspected)		R	eason:		
	5.0	Milligram	Daily		
Batch:	Started: 01	/08/1995		Stopped:	

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 50 of 554



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

Report Details:

Case Number: 107912 Seq: 1 Gender: M
Reported: 15/04/1996 Weight:
Hospitalisation: Age: 23Y

Onset Date: 16/11/1995 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

Medicine Details.					
CHLORPROMAZINE HYDROCHLO	Reason:				
	300.0 Milligram	Daily			
Batch:	Started: 07/11/1995		Stopped:	15/11/1995	
RISPERIDONE (Suspected)		Reason:			
	4.0 Milligram	Daily			
Batch:	Started:		Stopped:		

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 51 of 554



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

Report D	_4_:						
Cooo Nium	etalis:						
	nber: 107912	Seq: 1	I			Gender:	M
_	orted: 15/04/1996					Weight:	
ospitalisa						Age:	
	Date: 16/11/1995					DOB:	
	ome: Not yet recovere	ed			C	ausality:	Causality possible
action l	Details:						
	D. ()						
	e Details: DMAZINE HYDROCHLORID	E (Suspec	tod)	Reaso	n.		
CHLOKPK	DWIAZINE HTDROCHLORID	c (Suspec	300.0 Milli		oily		
Ba	tch:	Sta	ted: 07/11/19		Stopped:	15/11/1995	5
	NE (Suspected)			Reaso			
			4.0 Milli	gram [Daily		
Ba	tch:	Sta	ted:		Stopped:		
	ory Investigations:		Date Tracket I	Down I		Data	
.aborato	Type Ra	nge [Date Tested	Result		Detai	is
	Type Ra Eosinophils	nge [20/11/1995	0.55		Detai	İs
	Type Ra Eosinophils Erythrocyte	nge [20/11/1995 18/11/1995	0.55 29		Detai	ls
	Type Ra Eosinophils	nge [20/11/1995	0.55		Detai	is
	Type Ra Eosinophils Erythrocyte	nge [20/11/1995 18/11/1995 17/11/1995	0.55 29 341		Detai	ls
	Type Ra Eosinophils Erythrocyte	nge [20/11/1995 18/11/1995 17/11/1995	0.55 29 341		Detai	ls
	Type Ra Eosinophils Erythrocyte	nge [20/11/1995 18/11/1995 17/11/1995	0.55 29 341		Detai	İs
Date	Type Ra Eosinophils Erythrocyte GGT = SGGT = GGT = SGGT =	nge [20/11/1995 18/11/1995 17/11/1995	0.55 29 341		Detai	ls
Date	Type Ra Eosinophils Erythrocyte	nge [20/11/1995 18/11/1995 17/11/1995	0.55 29 341		Detai	Is
Date	Type Ra Eosinophils Erythrocyte GGT = SGGT = GGT = SGGT =	nge [20/11/1995 18/11/1995 17/11/1995	0.55 29 341		Detai	İs
Date	Type Ra Eosinophils Erythrocyte GGT = SGGT = GGT = SGGT =	nge [20/11/1995 18/11/1995 17/11/1995	0.55 29 341		Detai	ls
Date	Type Ra Eosinophils Erythrocyte GGT = SGGT = GGT = SGGT =	nge [20/11/1995 18/11/1995 17/11/1995	0.55 29 341		Detai	S

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 52 of 554



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

Report Detail	s:			
Case Number:	108212	Seq: 1	Gender:	M
Reported:	06/05/1996		Weight:	90.00
Hospitalisation:			Age:	27Y
Onset Date:	01/04/1996		DOB:	
Outcome:	Not yet recovered		Causality:	Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Flushing			
Hyperhidrosis			

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 53 of 554



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

Report Details:

Case Number: 108829 Seq: 1 Gender: F

Reported: 30/05/1996 Weight: 70.00 Hospitalisation: Age: 54

Onset Date: 07/04/1996 **DOB**: 04/08/1941

Outcome: Recovered Causality: Causality probable

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 54 of 554



Report Details:

Case Number: 108935

Reported: 03/06/1996

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight:

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

Seq: 1

					Age : 8Y		
Onset Date: 17/12/199	95	DOB:					
Outcome: Recovere	ed		ality: Ca	usality probable			
ction Details:					ı		
Preferred Term	Se	everity	Report De	escription		Treatment	
rapyramidal disorder							
ulogyration							
nary incontinence							
edicine Details:							
EXAMPHETAMINE SULPHAT	ΓE (Other drug)		Reason:				
		0.0					
Batch:	S	tarted:	L TERM	Stopped:			
PILIM (Other drug)			Reason:	Other&unspecified	epilepsy		
Databa		0.0	LTEDM	04			
Batch: SPERIDONE (Suspected)	S	tarted:	L TERM Reason:	Stopped:			
Tablet		1.5 Millig		, Ora			
	c						
Batch:	S	tarted: 16/12/19		Stopped: 20/1	2/1995		
h 4							
	tions:	Date Tested	Result		Details		
boratory Investigat		Date Tested	Result		Details		



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number:	109274	Seq:	. 1		Ge	ender: F
Reported	18/06/199	6			We	eight:
lospitalisation:						Age: 26Y
Onset Date:	19/04/199	6				DOB:
Outcome:	Recovere	d			Caus	sality: Causality probable
eaction Deta	ils:					
Prefer	red Term	Se	everity	Rep	ort Description	Treatment
Headache		Sevei	re			
Nausea						
Medicine De						
RISPERIDONE (S	uspected)		4 O M:III:		son: Unspecified psych	osis
Batch:		•	4.0 Milli	gram	Daily Stopped: 20.	10.4.14.000
Laboratory I			Date Tested	Desult		Details
Date	Туре	Range	Date Tested	Result		Details
Additional In	formatio	n:				
eport Run: 04/06/20	007 11:02AN	1 Database։ pւ	usime02	ļ	ADRS004	Page 56 of 554



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

Report Details:

 Case Number:
 109383
 Seq: 1
 Gender:
 F

 Reported:
 20/06/1996
 Weight:
 55.00

 Hospitalisation:
 Age: 76Y

Onset Date: 12/04/1996 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion botano							
Preferred Term	Severity	Report Description	Treatment				
Renal failure acute			Prednisolone 60mg orally daily, gradually decreasing				
Nephritis interstitial							

Medicine Details:

MONOPRIL (Suspected)		Reason:	Essential benign	hypertension
Tablet	5.0 Milligram	Daily	C	Oral
Batch:	Started: 01/04/1996		Stopped: 2	23/04/1996
VOLTAREN (Suspected)		Reason:		
Tablet	100.0 Milligram	Daily	C	Oral
Batch:	Started:		Stopped: 3	30/04/1996
COGENTIN (Suspected)		Reason:		
Tablet	1.0 Milligram	Daily	C	Oral
Batch:	Started: 12/04/1996		Stopped:	
MACRODANTIN (Suspected)		Reason:	Othr diseases of	urinary tract
Capsule	50.0 Milligram	Daily	C	Oral
Batch:	Started: L	TERM	Stopped: 1	4/05/1996

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 57 of 554



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

Report Details:							
Case Number: 109	383	Seq: 1			Gend	er: F	
Reported: 20/0	06/1996				Weigh	nt: 55.00	
Hospitalisation:					Ag	e: 76Y	
Onset Date: 12/0	04/1996				DO		
Outcome: Not	yet recovered	i			Causali	ty: Causality possible	Э
Reaction Details:						•	
Medicine Details				Bassani	Unanasified ashizonbro	nia	
RISPERDAL (Suspected	a)		0.0. Milliana	Reason:	Unspecified schizophre	enia	
Tablet		0441	3.0 Milligram	Daily	Oral		
Batch:		Started	d: 12/04/1996		Stopped:		
l abaratary layes	tiaatiana						
Laboratory Inves	digations.						
Additional Inform	nation:						
See original report for o		dosage sta	art date is not ne	cessarily acc	curate but indicates the	hat start occurred some	time
during the month.	3	J 1-		,			

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 58 of 554



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

Report Details:

 Case Number:
 110066
 Seq: 1
 Gender:
 M

 Reported:
 19/07/1996
 Weight:
 90.00

 Hospitalisation:
 Age:
 26Y

Onset Date: 09/07/1996 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 59 of 554



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

Report Details:

Case Number: 110303 Seq: 1 Gender: F

Reported: 29/07/1996 Weight: 58.00 Hospitalisation: Age: 54Y

Onset Date: 28/06/1996 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	towotton botton:								
	Preferred Term	Severity	Report Description	Treatment					
	Orthostatic hypotension		Bp 90/50						
	Dizziness								

Medicine Details:

VALIUM (Other drug)		Reason: Otr spec symp psychop	athol nec
Tablet	2.0 Milligram	As necessary Oral	
Batch:	Started: 12/06/1996	Stopped: 19/06/19	996
COGENTIN (Other drug)		Reason:	
Tablet	2.0 Milligram	As necessary Oral	
Batch:	Started: 22/06/1996	Stopped: 05/07/19	996
TEMAZE (Other drug)		Reason: Otr spec symp psychop	athol nec
	20.0 Milligram	Daily	
Batch:	Started: 12/06/1996	Stopped:	CONTIN
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	2.0 Milligram	Daily	
Batch:	Started: 19/06/1996	Stopped:	CONTIN

Laboratory Investigations:

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

Additional Information:

Report Run : 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 60 of 554



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

Re	port	Detai	ls:
----	------	-------	-----

Gender: F Case Number: 110304 Seq: 1

Weight: 58.00 Reported: 29/07/1996 **Hospitalisation:** Age: 54Y

Onset Date: 10/07/1996 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

icaction Details.							
Preferred Term	Severity	Report Description	Treatment]			
Dystonia				1			
Oculogyration			Cogentin iv stat.				

Medicine Details: TEMAZE (Other drug)

	20.0 Milligram	Daily		
Batch:	Started: 12/06/1996	Stopped:	CONTIN	
LARGACTIL (Suspected)		Reason: Otr spec symp psych	opathol nec	
	100.0 Milligram	As necessary		
Batch:	Started: 04/07/1996	Stopped:	CONTIN	

Reason:

Specific disorders of sleep

RISPERDAL (Suspected)

Reason: Unspecified psychosis

2.0 Milligram Daily

Batch: Started: 19/06/1996 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

ADRS004 Report Run: 04/06/2007 11:02AM Database: pusime02 Page 61 of 554



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

Re	por	t D	etai	ils:
	Ρ-			

 Case Number:
 110314
 Seq: 1
 Gender: M

 Reported:
 29/07/1996
 Weight:
 80.00

 Hospitalisation:
 Age: 54Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Ι,	teaction Details.			
Preferred Term		Severity	Report Description	Treatment
Rash			Acneiform eruption anterior chest	
	Abscess		Has abscesses groin and axillae	

Medicine Details:

HALDOL DECANOATE (Suspected)			Reason:	Unspecified so	chizophrenia	
Injection	100.0	Milligram	Week	dy	Intramuscular	
Batch:	Started:		L TERM	Stopped:		CONTIN
HALOPERIDOL (Suspected)			Reason:	Unspecified so	chizophrenia	
	20.0	Milligram	Daily			
Batch:	Started:		L TERM	Stopped:		CONTIN
RISPERIDONE (Suspected)			Reason:			
	8.0	Milligram	Daily			
Batch:	Started:			Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 62 of 554



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

Report Details:

Case Number: 110316 Seq: 1 Gender: F

Reported: 29/07/1996 Weight:
Hospitalisation: Age: 49Y

Onset Date: 25/06/1996 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Cachon Details.			
Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction	
Oculogyration			

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drugs

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 63 of 554



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

eport Details:			
Case Number: 110316	Seq: 1	Gender	F
Reported: 29/07/1996	-	Weight:	
espitalisation:		Age:	49Y
Onset Date: 25/06/1996		DOB	
Outcome: Recovered		Causality:	Causality possible
action Details:			
edicine Details:	500.0 Microgram	Reason: Otr spec symp psychopat	hol nec
Ratch:		·	â
	Started: 20/00/1990		
Tablet	2.0 Milligram		
Batch:	Started: 19/06/1996		CONTIN
Batch: RISPERDAL (Suspected) Tablet	500.0 Microgram Started: 20/06/1996 2.0 Milligram Started: 19/06/1996	Reason: Otr spec symp psychopat As necessary Stopped: 26/06/199 Reason: Unspecified schizophrenia Daily Oral Stopped:	6
Laboratory Investigations:			

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 64 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number:	110494	Seq:	1				Gender	: M	
	05/08/199	-					Weight:		
ospitalisation:							_	: 19Y	
Onset Date:	19/07/199	16					DOB		
Outcome:	Recovere	d				С	ausality	: Causality proba	able
action Deta	ils:								
Preferi	red Term	Se	everity	Repo	ort Desc	ription		Treatmen	ıt
izziness		Sevei	re						
pistaxis									
ledicine Det		han dura)		Doo					
BENZTROPINE M	ESTLATE (U	iner arug)	2.0 Milli		son: Daily				
Batch:		s	tarted:	igrain	Daily	Stopped:			
RISPERIDONE (S	uspected)		turtou.	Rea	son:	Otoppou.			
,	,		3.0 Milli		Daily				
Batch:		s	tarted: 05/07/1			Stopped:	26/07/199	96	
_aboratory li	nvestigat								
Date	Туре	Range	Date Tested	Result			Deta	ails	
Additional In	formatio	n:							
oort Run: 04/06/20)07 11:02AN	1 Database: ni	usime02	Δ	ADRS004			Page 65	of 554

Rep



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

Report Details:

 Case Number:
 110669
 Seq: 1
 Gender: M

 Reported:
 09/08/1996
 Weight:
 92.00

Hospitalisation: Age: 25Y

Onset Date: 01/07/1996 **DOB**:

Outcome: Recovered with sequelae Causality: Causality possible

Reaction Details:

•	todotion Botano.			
	Preferred Term	Severity	Report Description	Treatment
	Blood creatine phosphokinase incr			
	Pyrexia			

Medicine Details:

CLOZAPINE (Suspected) Reason: Unspecified psychosis

275.0 Milligram Daily

Batch: Started: 28/06/1996 Stopped: 03/07/1996

FLUOXETINE HYDROCHLORIDE (Suspected) Reason: Depression

20.0 Milligram Daily

Batch: Started: Stopped: 26/06/1996

RISPERIDONE (Suspected) Reason: Unspecified schizophrenia

6.0 Milligram Daily

Batch: Started: Stopped: 25/06/1996

TETRACYCLINE (Suspected) Reason:

500.0 Milligram Daily

Batch: Started: Stopped: 25/06/1996

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 66 of 554



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

Report Details:

 Case Number:
 110878
 Seq: 1
 Gender:
 F

 Reported:
 15/08/1996
 Weight:
 61.00

Hospitalisation: Age: 27

Onset Date: 22/07/1996 **DOB**: 23/04/1969

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

	Reason:	Othr&unspec metaboli	c diseases
4.0 Milligram	Daily	Oral	
Started: 01/11/1995		Stopped:	CONTIN
	Reason:	Othr&unspec metaboli	ic diseases
1.0 Gram	Daily		
Started: 01/03/1995		Stopped:	CONTIN
	Started: 01/11/1995	4.0 Milligram Daily Started: 01/11/1995 Reason: 1.0 Gram Daily	4.0 Milligram Daily Oral Started: 01/11/1995 Stopped: Reason: Othr&unspec metaboli 1.0 Gram Daily

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 67 of 554



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

Re	por	t D	etai	ils:
	Ρ-			

Case Number: 111442 Seq: 1 Gender: M

Reported: 05/09/1996 Weight:
Hospitalisation: Age: 29

Onset Date: 12/08/1996 **DOB**: 12/08/1967

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			Benztropine

Medicine Details:

RISPERIDONE (Suspected) Reason: Schizophrenia

Tablet 2.0 Milligram Daily Oral

Batch: Started: 05/08/1996 **Stopped:** 12/08/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run : 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 68 of 554



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

Report	per : 111598	Seq	j: 1				Occupio	r. C		
Report			j : 1					r. E		
_	ted: 13/09/19	O.C.		Gender: F						
ospitalisati	Reported: 13/09/1996				Weight:					
ospitalisation:							Age	: 20Y		
Onset Da	ate:				DOB:					
	ne: Recovere	ed				(Causality	: Caus	sality probat	ble
eaction De							1			
	eferred Term	S	Severity	Repo	rt Desc	cription			Treatment	
Galactorrhoe	ea									
Obesity										
/ledicine [Details:									
	Details:	IDE (Other drug	1)	Reas	on:					
	HYDROCHLOR	IDE (Other drug	i) 60.0 Mil		on: Daily		Oral			
	HYDROCHLOR					Stopped:		C	CONTIN	
PAROXETINE Tablet Batch	HYDROCHLOR	;	60.0 Mil		Daily	Stopped		C	CONTIN	
PAROXETINE Tablet Batch	HYDROCHLOR t h: RBONATE (Other	;	60.0 Mil	igram Reas	Daily	Stopped		C	CONTIN	
PAROXETINE Tablet Batch LITHIUM CAR Tablet Batch	E HYDROCHLOR t h: RBONATE (Other t h:	· drug)	60.0 Mill	igram Reas	Daily on: Daily	Stopped	Oral	C	CONTIN	
PAROXETINE Tablet Batch LITHIUM CAR Tablet Batch	HYDROCHLOR t h: RBONATE (Other	· drug)	60.0 Mill Started: 1.0 Gra	igram Reas	Daily on: Daily		Oral	C	CONTIN	
PAROXETINE Tablet Batch LITHIUM CAR Tablet Batch	E HYDROCHLOR t h: RBONATE (Other t h: E (Suspected)	· drug)	60.0 Mill Started: 1.0 Gra	igram Reas nm Reas	Daily on: Daily	Stopped	Oral	C	CONTIN	
PAROXETINE Tablet Batch LITHIUM CAR Tablet Batch	t HYDROCHLOR th: RBONATE (Other this) E (Suspected)	drug)	60.0 Mill Started: 1.0 Gra Started:	Reas m Reas igram	on: Daily on: Con:	Stopped	Oral osychosis Oral	C	CONTIN	
PAROXETINE Tablet Batch LITHIUM CAR Tablet Batch RISPERIDONI	t HYDROCHLOR th: RBONATE (Other this) E (Suspected)	drug)	60.0 Mill Started: 1.0 Gra Started: 6.0 Mill	Reas m Reas igram	on: Daily on: Con:	Stopped: Inspecified p	Oral osychosis Oral	C	CONTIN	
Tablet Batch LITHIUM CAR Tablet Batch RISPERIDONI Tablet	t HYDROCHLOR th: RBONATE (Other this) E (Suspected)	drug)	60.0 Mill Started: 1.0 Gra Started: 6.0 Mill	Reas m Reas igram	on: Daily on: Con:	Stopped: Inspecified p	Oral osychosis Oral	C	CONTIN	
Tablet Batch LITHIUM CAR Tablet Batch RISPERIDONI Tablet	t HYDROCHLOR th: RBONATE (Other this) E (Suspected)	drug)	60.0 Mill Started: 1.0 Gra Started: 6.0 Mill	Reas m Reas igram	on: Daily on: Con:	Stopped: Inspecified p	Oral osychosis Oral	C	CONTIN	
Tablet Batch LITHIUM CAR Tablet Batch RISPERIDONI Tablet	t HYDROCHLOR th: RBONATE (Other this) E (Suspected)	drug)	60.0 Mill Started: 1.0 Gra Started: 6.0 Mill	Reas m Reas igram	on: Daily on: Con:	Stopped: Inspecified p	Oral osychosis Oral	C	CONTIN	
Tablet Batch LITHIUM CAR Tablet Batch RISPERIDONI Tablet	t HYDROCHLOR th: RBONATE (Other this) E (Suspected)	drug)	60.0 Mill Started: 1.0 Gra Started: 6.0 Mill	Reas m Reas igram	on: Daily on: Con:	Stopped: Inspecified p	Oral osychosis Oral	C	CONTIN	
PAROXETINE Tablet Batch LITHIUM CAR Tablet Batch RISPERIDONI Tablet Batch	HYDROCHLOR t h: RBONATE (Other t h: E (Suspected) t	· drug)	60.0 Mill Started: 1.0 Gra Started: 6.0 Mill	Reas m Reas igram	on: Daily on: Con:	Stopped: Inspecified p	Oral osychosis Oral	C	CONTIN	
PAROXETINE Tablet Batch Tablet Batch RISPERIDONI Tablet Batch	t HYDROCHLOR th: RBONATE (Other this) E (Suspected)	· drug)	60.0 Mill Started: 1.0 Gra Started: 6.0 Mill	Reas m Reas igram	on: Daily on: Con:	Stopped: Inspecified p	Oral osychosis Oral	C	CONTIN	

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 69 of 554

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



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

Report Details:

Case Number: 111636 Seq: 1 Gender: F

Reported: 16/09/1996 Weight: 70.00 Hospitalisation: Age: 60Y

Onset Date: 01/09/1996 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 70 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Onset Date: Outcome: Unknown eaction Details:			Gender: M Weight: Age: DOB: Causality: Causality possible		
Preferred Term	Severity	Report Description	Treatment		
Anxiety Hyperkinesia Increased appetite Paranoia					
Medicine Details: RISPERIDONE (Suspected)		Reason:			
	0.0				
Batch:	Started:	Stopped:			
		Dogult	Detaile		
Laboratory Investigatio Date Type	Range Date Tested	Result	Details		

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 71 of 554



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

Report Details:

Case Number: 112239 Seq: 1 Gender: F

 Reported: 14/10/1996
 Weight: 70.00

 Hospitalisation:
 Age: 55Y

Onset Date: 26/09/1996 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Rash erythematous		Punctate red rash on lower limbs	
Headache			

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Onset two days after starting risperidone.

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 72 of 554



Case Number: 112293

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

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

Seq: 1

Reported: 16/10/1996				We	eight: 90.00	
lospitalisation:					Age: 50Y	
Onset Date: 10/10/1996		DOB:				
Outcome: Unknown				Caus	sality: Causality possible	
eaction Details:						
Preferred Term	Severity	Rep	ort Des	cription	Treatment	
lot flush		Felt hot.			Maxolon.	
Headache						
Hyperacusis						
Nausea						
/omiting						
Medicine Details:						
RISPERIDONE (Suspected)		Re	ason: [Depression		
Tablet	2	.0 Milligram	Daily	Ora		
Batch:		10/10/1996	- ,	Stopped:		
_aboratory Investigation	ns:					
Date Type	Range Date T	ested Result			Details	
Additional Information:						



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number: 112961 Reported: 08/11/1996 Dispitalisation: Onset Date: Outcome: Unknown	Seq: 1		Gende Weigh Ag DO Causalit	t: e:
action Details:				y. Gaddanty possible
Preferred Term	Severity	Report De	escription	Treatment
ledicine Details:		Reason:		
Tablet	0.0		Oral	
Batch:	Started:		Stopped:	3M
aboratory Investigation				
Date Type	Range Date Tested	Result	De	etails
Additional Information:		·		
ort Run: 04/06/2007 11:02AM	Database: pusime02	ADRSO	004	Page 74 of 554

Rep



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

Preferred Term Severity Report Description Treatment Sepression Sertraline Bedicine Details:
Spitalisation: Onset Date: 26/09/1996 Outcome: Recovered Causality: Causality possination Preferred Term Pression Pression Severity Report Description Sertraline Pedicine Details: BEPERIDONE (Suspected) Tablet 1.0 Milligram Paley Age: 37Y DOB: Causality: Causality possination Report Description Treatmen Sertraline Prestruction Teatmen Tablet Reason: Schizophrenia Tablet Oral
Onset Date: 26/09/1996 Outcome: Recovered Causality: Causality possi action Details: Preferred Term Severity Report Description Treatmen expression Sertraline edicine Details: ISPERIDONE (Suspected) Tablet 1.0 Milligram Daily Oral
Outcome: Recovered Causality: Causality possinaction Details: Preferred Term Severity Report Description Treatment Sertraline Sertraline Details: Redicine Details: RISPERIDONE (Suspected) Tablet 1.0 Milligram Daily Oral
Preferred Term Severity Report Description Treatment epression Sertraline Preferred Term
Preferred Term Severity Report Description Treatment Sertraline Bedicine Details: RISPERIDONE (Suspected) Tablet 1.0 Milligram Daily Oral
edicine Details: RISPERIDONE (Suspected) Tablet 1.0 Milligram Daily Oral
RISPERIDONE (Suspected) Tablet 1.0 Milligram Daily Oral
Tablet 1.0 Milligram Daily Oral
· · · · · · · · · · · · · · · · · · ·
Batch: Started: 23/05/1996 Stopped:
.aboratory Investigations: Date Type Range Date Tested Result Details
Date Type Range Date rested Result Details

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 75 of 554



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

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

Case Number: 113119 Seq: 1 Gender: F

 Reported:
 13/11/1996
 Weight:
 52.00

 Hospitalisation:
 Age:
 74Y

 Onset Date:
 01/11/1996
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

SORBITOL (Other drug)		Reason:	
Oral application	20.0 Millilitre	Daily Oral	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 14/08/1996	Stopped: 04/11/19	96

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 76 of 554



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

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

Case Number: 113181 Seq: 1 Gender: M

 Reported:
 15/11/1996
 Weight:
 70.00

 Hospitalisation:
 Age:
 36Y

 Onset Date:
 31/10/1996
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 77 of 554



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

Report Details:

Case Number: 113205 Seq: 1 Gender: M
Reported: 18/11/1996 Weight:

Hospitalisation: Age: 55

 pitalisation:
 Age: 55Y

 Onset Date: 07/08/1996
 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (S	Suspected)	Reason:		
Oral application	100.0 Mil	lligram As neces	sary	Oral
Batch:	Started:		Stopped:	
LITHIUM CARBONATE (Suspected)		Reason:		
Tablet	1.2 Gra	am Daily		Oral
Batch:	Started:		Stopped:	07/08/1996
RISPERIDONE (Suspected)		Reason:		
Tablet	6.0 Mil	lligram Daily		Oral
Batch:	Started: 01/06/1	1995	Stopped:	07/08/1996
THIOPENTONE SODIUM (Suspected)		Reason:		
	200.0 Mil	lligram Daily		
Batch:	Started:		Stopped:	

Laboratory Investigations:

	. <u>,</u>				
Date	Туре	Range	Date Tested	Result	Details
	Creatine		08/08/1996	3004	
	Creatine		12/08/1996	1746	
	White blood cells		08/08/1996	15.1	

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 78 of 554



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

Report Detail	s:					
Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detai	18/11/1996 07/08/1996 Recovered	Seq: 1			Gender: Weight: Age: DOB: Causality:	55Y
Medicine Deta						
SUXAMETHONIUN	I CHLORIDE (Suspec			Reason:		
Batch:		70.0 Started:	Milligram	Daily	Stopped:	
Laboratory In	vestigations:					
Additional Inf		/ accurate but i	ndicates that	start occurred	d sometime during the	month.

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 79 of 554



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

Report Details:

Case Number: 113240 Seq: 1 Gender: F

Reported: 19/11/1996 Weight: 70.00
Hospitalisation: Age: 70Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		1	Stop risperidone, re-instate stelazine

Medicine Details:

STELAZINE (Suspected)		Reason:				
	0.0					
Batch:	Started:	L	TERM	Stopped:		
RISPERIDONE (Suspected)			Reason:	Unspecified schizophrenia		
	1.0	Milligram	Daily			

Batch: Started: 23/07/1996 **Stopped:** 07/11/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 80 of 554



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

Report Details:

Case Number: 113426 Seq: 1 Gender: F

Reported: 26/11/1996 Weight: 64.00
Hospitalisation: Age: 24Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified psychosis

4.0 Milligram Daily

Batch: Started: 01/09/1996 Stopped:

BENZTROPINE MESYLATE (Suspected) Reason:

4.0 Milligram Daily

Batch: Started: 01/09/1996 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 81 of 554



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

Report Details:

Case Number: 113533 Seq: 1 Gender: M

Reported: 29/11/1996 Weight: 101.00 Hospitalisation: Age: 40Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

•	todotion Botano.			
	Preferred Term	Severity	Report Description	Treatment
	Face oedema			
	Periorbital oedema			

Medicine Details:

RISPERIDONE (Suspected) Reason:

Tablet 12.0 Milligram Daily Oral

Batch: Started: 01/09/1996 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 82 of 554



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

Report Details:

Case Number: 113781 Seq: 1 Gender: F

Reported: 09/12/1996 Weight: 75.00 Hospitalisation: Age: 27Y

Onset Date: 08/10/1996 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

104011011 20141101			-
Preferred Term	Severity	Report Description	Treatment
Confusional state		Acute brain syndrome	Cogentin 2mg im, 1mg orally
Dystonia		Dystonia of lower limbs and oral muscles	

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

Tablet 2.0 Milligram Daily Oral

Batch: Started: 04/10/1996 **Stopped:** 09/10/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has history of problems being stabilised on any antipsychotics.

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 83 of 554



Case Number: 113865

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

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

Seq: 1

Batch: Started: M (Other drug) Batch: Started: M CARBONATE (Other drug) 75 Batch: Started: RDAL (Suspected) Batch: Started: ratory Investigations:	Severity	Report I	Cau: Description	Age: DOB: sality: Causality probable Treatment Risperdal ceased
ed	Severity	Report I		sality: Causality probable Treatment
	Severity	Report I		Treatment
S	Severity	Report I	Description	
	beveniy	Report	Description	
				Risperual ceaseu
		Reason	:	
	0.0			
;	Started:	L TERM	Stopped:	
	0.0	Reason	:	
;		L TERM	Stopped:	
	750.0 Millig	gram Da	aily	
;	Started:	L TERM	Stopped:	
		Reason	:	
;	Started:		Stopped:	
tions:				
Range	Date Tested	Result		Details
	r drug)	750.0 Millig Started: 0.0 Started:	0.0 Started: L TERM r drug) Reason 750.0 Milligram Da Started: L TERM Reason 0.0 Started:	Started: L TERM Stopped: r drug) Reason: 750.0 Milligram Daily Started: L TERM Stopped: Reason: 0.0 Started: Stopped:

ADRS004 Page 84 of 554



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

Report Details:

Case Number: 113867 Seq: 1 Gender: F
Reported: 12/12/1996 Weight:
Hospitalisation: Age: 79Y

Onset Date: 10/10/1996 **DOB**:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Hypercalcaemia			
Stupor			

Medicine Details:

ROCALTROL (Suspected)		Reason:	Osteoporosis	
	0.5 Micro	ogram Daily		
Batch:	Started:		Stopped:	10/10/1996
CALTRATE (Suspected)		Reason:	Osteoporosis	
	1.2 Gram	n Daily		
Batch:	Started:		Stopped:	10/10/1996
SODIUM VALPROATE (Suspected)		Reason:	Otr&unsp verte	ebrogen pain synd
	200.0 Millig	ram Daily		
Batch:	Started:		Stopped:	20/10/1996
RISPERIDONE (Suspected)		Reason:	Unspecified so	chizophrenia
	1.0 Millig	ram Daily		
Batch:	Started:		Stopped:	28/11/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 85 of 554



DOB: 24/08/1924

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

Report Details:

 Case Number:
 114152
 Seq:
 1
 Gender:
 M

 Reported:
 23/12/1996
 Weight:

Hospitalisation: Age: 72

Outcome: Recovered Causality: Causality possible

Reaction Details:

Onset Date: 18/11/1996

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 86 of 554



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

Report Details:

 Case Number:
 114152
 Seq: 1
 Gender: M

 Reported:
 23/12/1996
 Weight:

Hospitalisation: Age: 72

Onset Date: 18/11/1996 **DOB**: 24/08/1924

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

MYLANTA (Suspected) Reason: Other diseases of esophagus

20.0 Millilitre As necessary

Batch: Started: 18/11/1996 **Stopped:** 19/11/1996

RISPERIDONE (Suspected) Reason: Otr spec symp psychopathol nec

1.0 Milligram Daily

Batch: Started: 15/11/1996 **Stopped:** 17/11/1996

RISPERIDONE (Suspected) Reason: Otr spec symp psychopathol nec

2.0 Milligram Daily

Batch: Started: 17/11/1996 **Stopped:** 20/11/1996

FUNGILIN (Suspected) Reason: Moniliasis

Lozenge 4.0 Dose Unspecified Daily Oral

Batch: Started: 11/11/1996 **Stopped:** 19/11/1996

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 87 of 554



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

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

 Case Number:
 114152
 Seq: 1
 Gender: M

 Reported:
 23/12/1996
 Weight:

Hospitalisation: Age: 72

Onset Date: 18/11/1996 **DOB**: 24/08/1924

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

MYLANTA (Suspected) Reason: Other diseases of esophagus

20.0 Millilitre As necessary

Batch: Started: 18/11/1996 **Stopped:** 19/11/1996

RISPERIDONE (Suspected) Reason: Otr spec symp psychopathol nec

1.0 Milligram Daily

Batch: Started: 15/11/1996 Stopped: 17/11/1996

RISPERIDONE (Suspected) Reason: Otr spec symp psychopathol nec

2.0 Milligram Daily

Batch: Started: 17/11/1996 Stopped: 20/11/1996

FUNGILIN (Suspected) Reason: Moniliasis

Lozenge 4.0 Dose Unspecified Daily Oral

Batch: Started: 11/11/1996 **Stopped:** 19/11/1996

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 88 of 554



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

Report Det	ails:							
Case Numbe	er: 114520	Seq:	: 1			(Gender:	M
Reporte	ed: 13/01/19	97				V	Neight:	
ospitalisatio	n:						Age:	88
Onset Da	te: 15/07/19	96					DOB:	14/09/1907
Outcom	ne: Unknowr	ı				Ca	usality:	Causality possible
action De	tails:							
Pref	ferred Term	Se	everity	Repo	ort De	scription		Treatment
euroleptic m	nalignant synd	drome						
–								
ledicine D				D		Otrana a a como a		and man
RISPERIDONE	(Suspected)		F00 C		son:	Otr spec symp p	sycnopatr	101 NEC
			500.0 Mic	rogram	As ne	cessary		
Batch:		S	tarted:			Stopped:		2D
PERICYAZINE	(Suspected)			Rea	son:	Otr spec symp p	sychopath	nol nec
Tablet			3.0 Dos	se Unspecified	Daily	(Oral	
Batch:	:	s	started:			Stopped:		3D
THIORIDAZINE	HYDROCHLO	RIDE (Suspected	(k	Rea	son:	Otr spec symp p	sychopath	nol nec
			30.0 Mill	ligram	Daily			
Batch:		9	started:	·9·•···	24,	Stopped:		5D
Batcii			tarteu.			Stoppeu.		3D
	<u> Investiga</u>							
Date	Туре	Range	Date Tested	Result			Detai	ls
dditional	Information	on:						

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 89 of 554



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

R	Δ١	n	n	rt	ח	Δí	a	il	e	•
\mathbf{r}	CI	ш.	•	IL	ப	G I	a		3	

Case Number: 114690 Seq: 1 Gender: M
Reported: 23/01/1997 Weight:
Hospitalisation: Age: 82Y

Onset Date: 15/01/1997 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			

Medicine Details:

AGAROL (Other drug)		Reason: C	Constipation	
Oral Liquid	20.0 Millilitre	Daily	Oral	
Batch:	Started:		Stopped:	
RISPERIDONE (Suspected)		Reason:		
	1.0 Milligram	Daily		
Batch:	Started: 24/12/1996		Stopped:	
RISPERIDONE (Suspected)		Reason:		
	2.0 Milligram	Daily		
Batch:	2.0 Milligram Started: 06/01/1997	Daily	Stopped:	
Batch: COLOXYL WITH SENNA (Suspected)	· ·	•	Stopped:	
	· ·	Reason: C		

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 90 of 554



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

Report Details:

 Case Number:
 114776
 Seq: 1
 Gender: M

 Reported:
 28/01/1997
 Weight:

Hospitalisation: Age: 32Y
Onset Date: 03/10/1996
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

<u> </u>	ij mitoonga				
Date	Туре	Range	Date Tested	Result	Details
	Pharmacokinetics				Carbamazepine level=32umol/l, lithium level=1.23umol/l both therapeutic levels

Additional Information:

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 91 of 554



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number: 17 Reported: 28 Hospitalisation: Onset Date: 03 Outcome: U Reaction Details	8/01/1997 3/10/1996 nknown	Seq: 1			C	Gender: Weight: Age: DOB: ausality:	32Y	
Medicine Detail								
AROPAX (Suspected))			Reason:	Depression			
Tablet			Milligram	Daily		Oral	CONTIN	
Batch:		Started: 26	/09/1996		Stopped:		CONTIN	
Laboratory Inve	estigations:							
Additional Info	rmation:							

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 92 of 554



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

Report Details:

Case Number: 114911 Seq: 1 Gender: M
Reported: 03/02/1997 Weight:
Hospitalisation: Age: 24Y

Onset Date: 20/01/1997 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Monitor bloods.

Medicine Details:

TEGRETOL (Suspected)		Reason:	Other&unspec	cified epilepsy
Tablet	1.0 Gram	Daily		Oral
Batch:	Started: 01/01/1995		Stopped:	22/01/1997
RISPERDAL (Suspected)		Reason:	Unspecified ps	sychosis
Tablet	6.0 Milligran	n Daily		Oral
Batch:	Started: 01/01/1996		Stopped:	
RIVOTRIL (Suspected)		Reason:		
Tablet	1.5 Milligran	n Daily		Oral
Batch:	Started:	L TERM	Stopped:	

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 93 of 554



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

Report Details:

 Case Number:
 114911
 Seq: 1
 Gender: M

 Reported:
 03/02/1997
 Weight:

Hospitalisation: Age: 24Y
Onset Date: 20/01/1997
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

TEGRETOL (Suspected)		Reason:	Other&unspeci	fied epilepsy
Tablet	1.0 Gra	am Daily		Oral
Batch:	Started: 01/01/1	995	Stopped:	22/01/1997
RISPERDAL (Suspected)		Reason:	Unspecified psy	ychosis
Tablet	6.0 Milli	igram Daily		Oral
Batch:	Started: 01/01/1	996	Stopped:	
RIVOTRIL (Suspected)		Reason:		
Tablet	1.5 Milli	igram Daily		Oral
Batch:	Started:	L TERM	Stopped:	

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 94 of 554



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

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

 Case Number:
 114919
 Seq: 1
 Gender: M

 Reported:
 03/02/1997
 Weight: 85.00

Hospitalisation: Age: 28Y
Onset Date: 28/12/1996 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

RISPERIDONE (Suspected)

Tablet

5.0 Milligram
Daily
Oral

Batch: Started: 18/08/1996
Stopped:

PAROXETINE HYDROCHLORIDE (Suspected) Reason: Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started**: 19/12/1996 **Stopped**: 16/01/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 95 of 554



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

D	4 1	D - 4 -	
Repo	ort i	Jeta	IIS:

Case Number: 114927 Seq: 1 Gender: M
Reported: 03/02/1997 Weight:
Hospitalisation: Age: 71Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run : 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 96 of 554



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

Report Details:

Case Number: 115051 Seq: 1 Gender: M

 Reported:
 07/02/1997
 Weight:
 83.00

 Hospitalisation:
 Age:
 40Y

Onset Date: 31/01/1997 DOB:
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•				1
	Preferred Term	Severity	Report Description	Treatment
	Periorbital oedema	Puffy inflamed eyelids		
	Rhinitis		Stuffy nose	

Medicine Details:

AROPAX (Other drug)		Reason: De	epression	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 07/01/1997		Stopped:	CONTIN
RISPERDAL (Suspected)		Reason: Ur	nspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral	
Batch:	Started: 30/01/1997		Stopped: 02/02/1997	
VALIUM (Suspected)		Reason: An	nxiety neurosis	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 29/01/1997		Stopped: 04/02/1997	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History of allergy to stelazine - swollen tongue

Report Run : 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 97 of 554



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

Report Details:

Case Number: 115192 Seq: 1 Gender: M

Reported: 13/02/1997 Weight: 95.00 Hospitalisation: Age: 37

Onset Date: 29/12/1996 **DOB:** 06/03/1959

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 98 of 554



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

Report Details:

Case Number: 115370 Seq: 1 Gender: F

Reported: 18/02/1997 Weight: 100.00 Hospitalisation: Age: 18Y

Onset Date: 07/02/1997 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

6.0 Milligram Daily

Batch: Started: 01/01/1996 **Stopped:** 13/02/1997

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 99 of 554



Case Number: 115917

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

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

Seq: 1

ospitalisation:	Reported: 12/03/1997					
				Age: 7	0Y	
Onset Date: 22/01/1997					DOB:	
Outcome: Not yet recov	ered			C	ausality: C	Causality possible
action Details:						
Preferred Term	Severity	<u>′</u>	Report D	escription		Treatment
adykinesia						
drapyramidal disorder						
eadache						
alivary hypersecretion						
emor						
edicine Details:						
EMAZEPAM (Suspected)	-		Reason:			
	2	0.0 Milligra	m 1 tir	ne		
Batch:	Started:	21/01/1997		Stopped:	22/01/1997	
ISPERIDONE (Suspected)			Reason:	Otr spec sym	o psychopathol	nec
		1.0 Milligra	m Dail	y		
Batch:	Started:	22/01/1997		Stopped:	23/01/1997	
ALOPERIDOL (Suspected)			Reason:			
		6.0 Milligra	m Dail	y		
Batch:	Started:	05/01/1997		Stopped:	19/01/1997	
				оторрош.		
aboratory Investigation	s:					
aboratory Investigation		Tested	Result		Details	



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Outcome: Recover eaction Details: Preferred Term Pancytopenia	red		Gender: M Weight: Age: 78 DOB: 31/10/1918				
Preferred Term				Cau	sality: Causality probable		
Danautanania	Sev	erity	Repo	ort Description	Treatment		
	•				•		
Medicine Details:							
DIGOXIN (Other drug)		60 F M:III		son:			
Batch:	Star	62.5 Milli	igram L TERM	Daily Stopped:			
RANITIDINE (Other drug)	Stat	rtea:		son:			
KANTIDINE (Other drug)		300.0 Milli		Daily			
Batch:	Star	rted:	L TERM	Stopped:			
FRUSEMIDE (Other drug)				son:			
, ,,		40.0 Milli	igram	Daily			
Batch:	Sta	rted:	L TERM	Stopped:			
ENALAPRIL MALEATE (Other	r drug)		Rea	son:			
		5.0 Milli	igram	Daily			
Batch:	Star	rted: 22/01/1	997	Stopped:			
aharatan, Invastiga	tional						
<u>aboratory Investiga</u> Date Type		Date Tested	Result		Details		
7,1	- 3-						

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 101 of 554



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

Report Details:			
Case Number: 115934 Reported: 12/03/1997 Hospitalisation: Onset Date: Outcome: Recovered Reaction Details:	Seq: 1		
Medicine Details: RISPERIDONE (Suspected)		Reason:	
Batch:	1.0 Milligram Started: 05/02/1997	Daily Stopped:	
Laboratory Investigation	s:		
Additional Information:			

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 102 of 554



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number:	116075	Seq:	1			Gende	r: F	
Reported:	18/03/199	97				Weigh	t: 58.00	
ospitalisation:						Age	e: 36Y	
Onset Date:	08/03/199	97				DOI	3:	
Outcome:	Recovere	d				Causality	y: Causality prob	able
eaction Deta								
Prefer	ed Term	Se	everity	Rep	ort Descriptior	1	Treatmer	nt
Ageusia								
Somnolence								
Medicine Det				Rea	son:			
			2.0 Milli	gram	Daily			
Batch:		St	tarted: 07/03/19	997	Stop	ped: 09/03/19	97	
Laboratory lı								
Date	Type	Range	Date Tested	Result		De	tails	
Additional In	formatio	n:						
port Run: 04/06/20	007 11:02AN	И Database: pu	usime02	,	ADRS004		Page 103	of 554



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

_	ed: 10/04/19	997				Weight:	75V	
lospitalisati	on: ate: 08/03/19	007				Age: 7	751	
	ne: Not yet i				•		Causality possi	hle
		ecovered			`	Jausanty. V	Causanty possi	oi c
eaction De	eferred Term	Se	everity	Repo	ort Description		Treatmen	<u> </u>
Gait disturba			,					
Medicine I			3.0 Dos	Rea e Unspecified	son:			
Batch	١٠	s	tarted:	o 0op 00ou	Stopped		CONTIN	
Laborator	v Investiga	ations:						
Date	Туре	Range	Date Tested	Result		Details		
Additional	Informatio	on:						



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Reason: O.3 Milligram Daily Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.5 Dose Unspecified Daily Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: Stopped: Stopped: Reason: 2.0 Milligram Daily Stopped: Out/04/1997	spitalisation: Age: 69Y Onset Date: 04/04/1997 Outcome: Recovered Causality: Causality probable action Details: Preferred Term Severity Report Description Treatment gression reperkinesia Batch: Started: Started: Stopped: Started: Started: Stopped: Started: Stopped: Stopped:	ase Nulliber. 110004	Seq. 1			Gender. M	
Causality: Causality probable Reason: O.3 Milligram Daily Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.5 Dose Unspecified Daily Stopped: Reason: 2.6 Milligram Daily Stopped: Reason: 2.7 Reason: 2.8 Stopped: Reason: 2.9 Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.0 Milligram Daily Stopped:	Onset Date: 04/04/1997 Outcome: Recovered Causality: Causality: Causality probable action Details: Preferred Term Severity Report Description Treatment aggression pperkinesia Gedicine Details: RemAX (Other drug) Batch: Started: Stopped: Reason: 2.0 Milligram Daily Batch: Started: Stopped: Reason: 2.0 Milligram Daily Batch: Started: Stopped: Reason: 2.0 Milligram Daily Batch: Started: Stopped: Reason: 2.0 Milligram Daily Batch: Started: Stopped: Reason: 2.0 Milligram Daily Batch: Started: Stopped: Reason: 2.0 Milligram Daily Batch: Started: Stopped: Reason: 2.0 Milligram Daily Batch: Started: Stopped: Reason: 2.0 Milligram Daily Batch: Started: Stopped: Reason: 2.0 Milligram Daily Batch: Started: Reason: 2.0 Milligram Daily Batch: Started: Reason: 2.0 Milligram Daily Batch: Started: Reason: 2.0 Milligram Daily Batch: Started: Reason: 2.0 Milligram Daily Batch: Started: Reason: 2.0 Milligram Daily Batch: Reason: 2.0 Milligram Daily Batch: Started: Reason: 2.0 Milligram Daily Batch: Started: Result Details	•	7			_	
Reason: O.3 Milligram Daily Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.5 Dose Unspecified Daily Stopped: Reason: 2.6 Milligram Daily Stopped: Reason: 2.7 Dose Unspecified Daily Stopped: Reason: 2.8 Stopped: Reason: 2.9 Milligram Daily Stopped: Reason: 2.0 Milligram Daily Stopped:	Outcome: Recovered Cousality: Causality: Causality probable Cotion Details: Preferred Term Severity Report Description Treatment gression perkinesia Dedicine Details: RMAX (Other drug) Reason: Batch: Started: Stopped: RTANE (Other drug) Reason: 2.0 Milligram Daily Batch: Started: Stopped: ADOPAR (Other drug) Reason: 2.5 Dose Unspecified Daily Batch: Started: Stopped: ADOPAR (Other drug) Reason: 2.0 Milligram Daily Batch: Started: Stopped: ADOPAR (Other drug) Reason: 2.5 Dose Unspecified Daily Batch: Started: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Stopped: Daily Stopped: Stopped: Daily Stopped: Da	spitalisation:				_	Υ
Reason: 2.0 Milligram Daily Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.5 Dose Unspecified Daily Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.0 Milligram Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.0 Milligram Daily Stopped:	Preferred Term Severity Report Description Treatment gression perkinesia Reason: 0.3 Milligram Daily Batch: Started: Stopped: RTANE (Other drug) Reason: 2.0 Milligram Daily Batch: Started: Stopped: RADOPAR (Other drug) Reason: 2.5 Dose Unspecified Daily Batch: Started: Stopped: REASON: 2.5 Dose Unspecified Daily Batch: Started: Stopped: Reason: 2.6 Milligram Daily Batch: Started: Stopped: Reason: 2.7 Milligram Daily Batch: Started: Stopped: Reason: 2.8 Dose Unspecified Daily Batch: Started: Reason: 2.9 Milligram Daily Batch: Reason: 3.0 Milligram Daily Batch: Reason: 3.1 Milligram Daily Batch: Reason: 3.2 Milligram Daily Batch: Reason: 3.3 Milligram Daily Batch: Reason: 3.4 Milligram Daily Batch: Reason: 3.5 Dose Unspecified Daily Batch: Reason: 3.6 Milligram Daily Batch: Reason: 3.7 Milligram Daily Batch: Reason: 3.8 Milligram Daily Ba	Onset Date: 04/04/1997	7				
Reason: O.3 Milligram Daily Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.5 Dose Unspecified Daily Stopped: Reason: 2.6 Milligram Daily Stopped: Reason: 2.7 Stopped: Reason: 2.8 Stopped: Reason: 2.9 Milligram Daily Stopped: 04/04/1997	Preferred Term Severity Report Description Treatment gression perkinesia Policine Details: ERMAX (Other drug) Batch: Started: Started: Started: Stopped: ADOPAR (Other drug) Batch: Started: Started: Stopped:	Outcome: Recovered	ł		(Causality: Ca	ausality probable
Reason: O.3 Milligram Daily Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.5 Dose Unspecified Daily Stopped: Reason: 2.6 Milligram Daily Stopped: Reason: Stopped: Stopped: Stopped: Stopped: Reason: 2.0 Milligram Daily 20/03/1997 Stopped: 04/04/1997	gression perkinesia Pedicine Details: ERMAX (Other drug) Batch: Started: Stopped: READOPAR (Other drug) Batch: Started: Stopped: ADOPAR (Other drug) Batch: Started: Stopped: Batch: Started: Stopped: ADOPAR (Other drug) Batch: Started: Stopped: Batch: Started: Stopped: ADOPAR (Other drug) Batch: Started: Stopped: ADOPAR (Other drug) Batch: Started: Stopped: ADOPAR (Other drug) Batch: Started: Stopped: Daliy Batch: Started: Stopped: ADOPAR (Other drug) Batch: Started: Stopped: Daliy Batch: Started: Stopped: Daliy Batch: Daliy Batch: Stopped: O4/04/1997 ADOPAR (Other drug) Batch: Started: Stopped: O4/04/1997 ADOPAR (Other drug) Batch: Started: Stopped: Daliy Batch: Da	ection Details:					
Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.5 Dose Unspecified Daily Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.0 Milligram Daily 20/03/1997 Stopped: 04/04/1997	edicine Details: ERMAX (Other drug) Batch: Started: Stopped: REASON: 2.0 Milligram Daily Batch: Started: Stopped: RADOPAR (Other drug) Batch: Started: Stopped: RADOPAR (Other drug) Reason: 2.5 Dose Unspecified Daily Batch: Started: Stopped: REASON: 2.0 Milligram Daily Batch: Started: Stopped: REASON: 2.0 Milligram Daily Batch: Started: Stopped: REASON: 2.0 Milligram Daily Batch: Started: Reason: 2.0 Milligram Daily Batch: Started: Reason: 2.0 Milligram Daily Batch: Started: Reason: 2.0 Milligram Daily Batch: Da		Severity	Repo	ort Description		Treatment
Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.5 Dose Unspecified Daily Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.0 Milligram Daily Stopped: 04/04/1997	PERMAX (Other drug) Batch: Started: Stopped: ARTANE (Other drug) Batch: Started: Stopped: 2.0 Milligram Daily Batch: Started: Stopped: AADOPAR (Other drug) Batch: Started: Stopped: AADOPAR (Other drug) Batch: Started: Stopped: ABOPAR (Other drug) Ba	ggression					
Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.5 Dose Unspecified Daily Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.0 Milligram Daily Stopped: 04/04/1997	Reason:	yperkinesia					
Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.5 Dose Unspecified Daily Stopped: Reason: 2.0 Milligram Daily Stopped: Reason: 2.0 Milligram Daily Stopped: 04/04/1997	Batch: Started: Stopped: ARTANE (Other drug) Batch: Started: Stopped: 2.0 Milligram Daily Batch: Started: Stopped: MADOPAR (Other drug) Batch: Started: Stopped: 2.5 Dose Unspecified Daily Batch: Started: Stopped: RESPERIDONE (Suspected) Reason: 2.0 Milligram Daily Batch: Started: Stopped: ARTANE (Other drug) Reason: 2.5 Dose Unspecified Daily Stopped: Stopped: ARTANE (Other drug) Reason: 2.0 Milligram Daily Batch: Started: 20/03/1997 Stopped: 04/04/1997 ABDOPATORY Investigations: Date Type Range Date Tested Result Details						
Reason: 2.0 Milligram Daily Stopped: Reason: 2.5 Dose Unspecified Daily Stopped: Reason: 2.0 Milligram Daily 20/03/1997 Stopped: 04/04/1997	Batch: Started: Stopped: ARTANE (Other drug) Batch: Started: Stopped: ARTANE (Other drug) Batch: Started: Stopped: MADOPAR (Other drug) Batch: Started: Stopped: 2.5 Dose Unspecified Daily Batch: Started: Stopped: Reason: 2.0 Milligram Daily Batch: Started: 20/03/1997 Stopped: 04/04/1997 Batch: Started: 20/03/1997 Stopped: Details	PERMAX (Other drug)					
Reason: 2.0 Milligram Daily Stopped: Reason: 2.5 Dose Unspecified Daily Stopped: Reason: 2.0 Milligram Daily 20/03/1997 Stopped: 04/04/1997	ARTANE (Other drug) 2.0 Milligram Daily Batch: Started: Stopped: MADOPAR (Other drug) Reason: 2.5 Dose Unspecified Daily Batch: Started: Stopped: RISPERIDONE (Suspected) Reason: 2.0 Milligram Daily Batch: Started: 20/03/1997 Stopped: 04/04/1997 Aboratory Investigations:			/lilligram	-		
2.0 Milligram Daily Reason: 2.5 Dose Unspecified Daily Stopped: Reason: 2.0 Milligram Daily 20/03/1997 Stopped: 04/04/1997	Batch: Started: Stopped:		Started:				
Stopped: Reason: 2.5 Dose Unspecified Daily Stopped: Reason: 2.0 Milligram Daily 20/03/1997 Stopped: 04/04/1997	Batch: Started: Stopped:	ARTANE (Other drug)					
Reason: 2.5 Dose Unspecified Daily Stopped: Reason: 2.0 Milligram Daily 20/03/1997 Stopped: 04/04/1997				Milligram	-		
Stopped: Reason: 2.0 Milligram Daily 20/03/1997 Stopped: 04/04/1997	Batch: Started: Stopped: RISPERIDONE (Suspected) Batch: Started: 2.0 Milligram Daily Batch: Started: 20/03/1997 Stopped: 04/04/1997 Baboratory Investigations: Date Type Range Date Tested Result Details		Started:				
Stopped: Reason: 2.0 Milligram Daily 20/03/1997 Stopped: 04/04/1997	Batch: Started: Stopped: Reason: 2.0 Milligram Daily Batch: Started: 20/03/1997 Stopped: 04/04/1997 Aboratory Investigations: Date Type Range Date Tested Result Details	MADOPAR (Other drug)	0.5.5				
Reason: 2.0 Milligram Daily 20/03/1997 Stopped: 04/04/1997	RISPERIDONE (Suspected) 2.0 Milligram Daily Batch: Started: 20/03/1997 Stopped: 04/04/1997 aboratory Investigations: Date Type Range Date Tested Result Details	Patah:		Jose Unspecified			
2.0 Milligram Daily 20/03/1997 Stopped: 04/04/1997	Batch: Started: 20/03/1997 Stopped: 04/04/1997 Aboratory Investigations: Date Type Range Date Tested Result Details		Started:	Dan			
20/03/1997 Stopped : 04/04/1997	Batch: Started: 20/03/1997 Stopped: 04/04/1997 aboratory Investigations: Date Type Range Date Tested Result Details	VIOLEKIDONE (Onsbected)	20 N				
	Aboratory Investigations: Date Type Range Date Tested Result Details Details	Batch:		_	-	04/04/1997	
Tested Result Details	Date Type Range Date Tested Result Details	Daton.	Starteu. 20/00	J. 1001	оторреа.	ו פטו ודטודט	
Tested Result Details							
	dditional Information:	Date Type	Range Date Tester	d Result		Details	
		_aboratory Investigation	Started: 20/03 ions: Range Date Tester	3/1997	-		

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 105 of 554



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

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

Case Number: 116968 Seq: 1 Gender: M

Reported: 21/04/1997 Weight: 40.00 Hospitalisation: Admitted to hospital Age: 12

Onset Date: 22/03/1997 **DOB**: 22/07/1984

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		Excessive sedation	

Medicine Details:

RISPERIDONE (Suspected) Reason:

Tablet 1.0 Milligram Daily Oral

Batch: Started: 06/03/1997 **Stopped:** 22/03/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 106 of 554



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

Case Number: 117343 Reported: 08/05/1997				
ospitalisation: Onset Date: Outcome: Unknown	Seq: 1		Gender: Weight: Age: DOB: Causality:	25Y
eaction Details:			-	
Preferred Term	Severity	Report De	scription	Treatment
∃ypoaesthesia Pain				
Medicine Details: RISPERDAL (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	0.0	Daily	Oral	
Batch:	Started:		Stopped:	
Laboratory Investigations:	<u> </u>			
	nge Date Tested	Result	Detai	ls
		Neurol	ogist review: no alteration in ion right little finger, no sen	n tone, minor weakness
Other data		obduct	ion right little linger, no sen	sory disturbance.
		obduct	on nghi iliue ilinger, no sen	sory distance.

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 107 of 554



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

Re	port	Deta	ails:
----	------	------	-------

Case Number: 117489 Seq: 1 Gender: M
Reported: 12/05/1997 Weight:

Hospitalisation: Age: 45

Onset Date: 14/02/1997 **DOB**: 27/07/1951

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term Severity		Report Description	Treatment
Priapism			

Medicine Details:

PARACETAMOL (Other drug)			Reason:	Other disturba	nce of sensation
Oral application	1.0	Gram	As ne	cessary	Oral
Batch:	Started:		L TERM	Stopped:	
FLUPHENAZINE NOS (Other drug)			Reason:	Unspecified ps	sychosis
Oral application	10.0	Milligram	Daily		Oral
Batch:	Started:		L TERM	Stopped:	
RISPERIDONE (Suspected)			Reason:	Unspecified so	chizophrenia
Tablet	4.0	Milligram	Daily		Oral
Batch:	Started: 20/	01/1997		Stopped:	14/02/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 108 of 554



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

Report Details:

 Case Number:
 117527
 Seq: 1
 Gender: M

 Reported:
 13/05/1997
 Weight:
 80.00

 Hospitalisation:
 Age: 62Y

Onset Date: 11/04/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 109 of 554



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

Report Details:

Case Number: 117527 Seq: 1 Gender: M

 Reported: 13/05/1997
 Weight: 80.00

 Hospitalisation:
 Age: 62Y

 Onset Date: 11/04/1997
 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

GLIBENCLAMIDE (Other drug) Reason: Diabetes mellitus

5.0 Milligram Daily

Batch: Started: 01/01/1997 Stopped: CONTIN

QUININE (Suspected) Reason: Pain in limb

300.0 Milligram Daily

Batch: Started: 04/04/1997 Stopped: 13/04/1997

RISPERIDONE (Suspected) Reason:

Tablet 6.0 Milligram Daily Oral

Batch: Started: 07/03/1997 Stopped: 13/04/1997

SODIUM VALPROATE (Suspected) Reason:

800.0 Milligram Daily

Batch: Started: 04/04/1997 **Stopped:** 13/04/1997

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 110 of 554



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

Report Details:

Case Number: 117527 Seq: 1 Gender: M

Reported: 13/05/1997 Weight: 80.00 Hospitalisation: Age: 62Y

Onset Date: 11/04/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

GLIBENCLAMIDE (Other drug) Reason: Diabetes mellitus

5.0 Milligram Daily

Batch: Started: 01/01/1997 Stopped: CONTIN

QUININE (Suspected) Reason: Pain in limb

300.0 Milligram Daily

Batch: Started: 04/04/1997 Stopped: 13/04/1997

RISPERIDONE (Suspected) Reason:

Tablet 6.0 Milligram Daily Oral

Batch: Started: 07/03/1997 Stopped: 13/04/1997

SODIUM VALPROATE (Suspected) Reason:

800.0 Milligram Daily

Batch: Started: 04/04/1997 **Stopped:** 13/04/1997

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 111 of 554



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

Report Details:

Case Number: 117527 Seq: 1 Gender: M

Reported: 13/05/1997 Weight: 80.00 Hospitalisation: Age: 62Y

Onset Date: 11/04/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

GLIBENCLAMIDE (Other drug) Reason: Diabetes mellitus

5.0 Milligram Daily

Batch: Started: 01/01/1997 Stopped: CONTIN

QUININE (Suspected) Reason: Pain in limb

300.0 Milligram Daily

Batch: Started: 04/04/1997 Stopped: 13/04/1997

RISPERIDONE (Suspected) Reason:

Tablet 6.0 Milligram Daily Oral

Batch: Started: 07/03/1997 Stopped: 13/04/1997

SODIUM VALPROATE (Suspected) Reason:

800.0 Milligram Daily

Batch: **Started**: 04/04/1997 **Stopped**: 13/04/1997

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 112 of 554



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

Report Details:

Case Number: 117527 Seq: 1 Gender: M

Reported: 13/05/1997 Weight: 80.00 Hospitalisation: Age: 62Y

Onset Date: 11/04/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

GLIBENCLAMIDE (Other drug) Reason: Diabetes mellitus

5.0 Milligram Daily

Batch: Started: 01/01/1997 Stopped: CONTIN

QUININE (Suspected) Reason: Pain in limb

300.0 Milligram Daily

Batch: Started: 04/04/1997 Stopped: 13/04/1997

RISPERIDONE (Suspected) Reason:

Tablet 6.0 Milligram Daily Oral

Batch: Started: 07/03/1997 Stopped: 13/04/1997

SODIUM VALPROATE (Suspected) Reason:

800.0 Milligram Daily

Batch: Started: 04/04/1997 **Stopped:** 13/04/1997

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 113 of 554



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

Report Details:

Case Number: 117527 Seq: 1 Gender: M

 Reported: 13/05/1997
 Weight: 80.00

 Hospitalisation:
 Age: 62Y

 Onset Date: 11/04/1997
 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

GLIBENCLAMIDE (Other drug) Reason: Diabetes mellitus

5.0 Milligram Daily

Batch: Started: 01/01/1997 Stopped: CONTIN

QUININE (Suspected) Reason: Pain in limb

300.0 Milligram Daily

Batch: Started: 04/04/1997 Stopped: 13/04/1997

RISPERIDONE (Suspected) Reason:

Tablet 6.0 Milligram Daily Oral

Batch: Started: 07/03/1997 Stopped: 13/04/1997

SODIUM VALPROATE (Suspected) Reason:

800.0 Milligram Daily

Batch: **Started**: 04/04/1997 **Stopped**: 13/04/1997

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 114 of 554



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

Report Details:

Case Number: 117527 Seq: 1 Gender: M

Reported: 13/05/1997 Weight: 80.00 Hospitalisation: Age: 62Y

Onset Date: 11/04/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

GLIBENCLAMIDE (Other drug)Reason: Diabetes mellitus

5.0 Milligram Daily

Batch: Started: 01/01/1997 Stopped: CONTIN

QUININE (Suspected) Reason: Pain in limb

300.0 Milligram Daily

Batch: Started: 04/04/1997 Stopped: 13/04/1997

RISPERIDONE (Suspected) Reason:

Tablet 6.0 Milligram Daily Oral

Batch: Started: 07/03/1997 Stopped: 13/04/1997

SODIUM VALPROATE (Suspected) Reason:

800.0 Milligram Daily

Batch: **Started**: 04/04/1997 **Stopped**: 13/04/1997

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 115 of 554



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

Re	port	Det	tail	s:

Case Number:117605Seq: 1Gender:FReported:15/05/1997Weight:Hospitalisation:Age:

Onset Date: DOB:
Outcome: Unknown Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 116 of 554



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

Re	port	t De	tail	ls:
----	------	------	------	-----

Case Number: 117605 Seq: 1 Gender: F
Reported: 15/05/1997 Weight:
Hospitalisation: Age:

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

OMEPRAZOLE (Suspected)		Reason:		
Oral application	20.0 Millig	ram Daily	Oral	
Batch:	Started:	Stop	pped:	
CLOBAZAM (Suspected)		Reason:		
Tablet	20.0 Millig	ram Daily	Oral	
Batch:	Started:	Stop	pped:	
DUPHALAC (Suspected)		Reason:		
Oral Liquid	20.0 Millilit	re Daily	Oral	
Batch:	Started:	Stop	pped:	
PREDNISOLONE (Suspected)		Reason:		
Oral application	5.0 Millig	ram Alternate days	Oral	
Batch:	Started:	Stor	pped:	

Laboratory Investigations:

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 117 of 554



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

Report Details:

Case Number: 117804 Seq: 1 Gender: F

Reported: 23/05/1997 Weight: 70.00 Hospitalisation: Age: 37Y

Onset Date: 10/03/1997 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botans.			
Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			
Hyperprolactinaemia			

Medicine Details:

RISPERIDONE (Suspected) Reason: Schizophrenia

Tablet 2.0 Milligram Daily Oral

Batch: Started: 01/01/1995 Stopped:

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 118 of 554



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

Report Details:

Case Number: 117897 Seq: 1 Gender: F

Reported: 27/05/1997 Weight: 60.00 Hospitalisation: Age: 12Y

Onset Date: 21/05/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Continuing risperidone with cogentin

Medicine Details:

modifile Botalie:				
SERTRALINE HYDROCHLORIDE (Ot	her drug)	Reason:		
Tablet	25.0 Milligram	Daily	Oral	
Batch:	Started: 20/05/1997	;	Stopped:	
RISPERIDONE (Suspected)		Reason: Sch	izophrenia	
Tablet	500.0 Microgram	Daily	Oral	
Batch:	Started: 21/05/1997	;	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 119 of 554



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

Report Details:

 Case Number:
 117973
 Seq: 1
 Gender:
 F

 Reported:
 30/05/1997
 Weight:
 65.00

 Hospitalisation:
 Age: 70Y

Onset Date: 19/05/1997 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 120 of 554



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

Report Details:

Case Number: 117978 Seq: 1 Gender: M

Reported: 30/05/1997 Weight: 75.00 Hospitalisation: Age: 53Y

Onset Date: 31/03/1997 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Flatulence			
Insomnia			
Nausea			

Medicine Details:

RISPERIDONE (Suspected) Reason: Schizophrenia

0.0

Batch: Started: 12/03/1997 **Stopped:** 12/04/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 121 of 554



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

Report Details:

Case Number: 118020 Seq: 1 Gender: F

Reported: 03/06/1997 Weight: 60.00 Hospitalisation: Age: 32Y

Onset Date: 14/05/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	todotion Botans.			
	Preferred Term	Severity	Report Description	Treatment
	Hypertonia		Stiffness	Artane
	Dizziness			

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 122 of 554



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

Case Number:118102Seq: 1Gender:FReported:05/06/1997Weight:Hospitalisation:Admitted to hospitalAge:

Onset Date: DOB:

Outcome: Recovered with sequelae Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypoventilation			Risperidone course ceased

Medicine Details:

EPILIM (Other drug)		Reason:	
	800.0 Milli	igram Daily	
Batch:	Started:		Stopped:
LASIX (Other drug)		Reason:	
	40.0 Milli	igram Daily	
Batch:	Started:		Stopped:
TRANSIDERM-NITRO (Other drug)		Reason:	
	25.0 Milli	igram Daily	
Batch:	Started:		Stopped:
THYROXINE SODIUM (Other drug)		Reason:	
	50.0 Micr	rogram Daily	
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Sensiive to serenace/risperidone.

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 123 of 554



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

Report Details:		
Case Number: 118 Reported: 05/0 Hospitalisation: Adr Onset Date: Outcome: Rec Reaction Details:	06/1997	Gender: F Weight: Age: DOB: Causality: Causality probable
Medicine Details		
RISPERIDONE (Suspec	o.0	Reason:
Batch:	Started:	Stopped:
Laboratory Inves	stigations:	
Additional Inform Sensiive to serenace/ris		

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 124 of 554



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

Report Details:

Case Number: 118149 Seq: 1 Gender: F

Reported: 06/06/1997 Weight: 30.00 Hospitalisation: Age: 79Y

Onset Date: 25/05/1997 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 125 of 554



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

Report Details:			
Case Number: 118149 Reported: 06/06/19 Hospitalisation: Onset Date: 25/05/19 Outcome: Recover Reaction Details:	997	Gender: Weight: Age: DOB: Causality:	30.00 79Y
Medicine Details:		Reason:	
Batch:	0.0 Started:	Stopped:	
Laboratory Investiga	ations:		
Additional Information the dosage start date is not reached as a second start date in the dosage start date is not reached as a second start date in the dosage start date	On: necessarily accurate but indicates that	start occurred sometime during the	month.

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 126 of 554



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

Report Details:

Case Number: 118176 Seq: 1 Gender: F

Reported: 11/06/1997 Weight:
Hospitalisation: Age: 48Y

Onset Date: 04/04/1997 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea		Dyspnoea with minimal exertion	

Medicine Details:

MODECATE (Other drug) Reason: Unspecified psychosis

37.5 Milligram Monthly

Batch: Started: L TERM Stopped:

BENZTROPINE MESYLATE (Other drug) Reason:

4.0 Milligram Daily

Batch: Started: L TERM Stopped:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

4.0 Milligram Daily

Batch: **Started**: 24/03/1997 **Stopped**: 11/04/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Breathlessness investigated - no cause found.

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 127 of 554



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

Report De	etails:				
Case Num	nber: 118370	Seq: 1		Gender:	М
Repor	rted: 18/06/199	7		Weight:	79.00
ospitalisat	tion:			Age:	17Y
Onset D	Date: 08/04/199	7		DOB:	
Outco	ome: Not yet red	covered		Causality:	Causality possible
eaction D					
Pr	referred Term	Severity	Repoi	t Description	Treatment
Synaecoma	astia				
	Details:				
RISPERIDOR	NE (Suspected)	12.0 1	Reas	·	l
Bato				Daily	
	cn:	Started: 05/02	2/1997	Stopped:	CONTIN
			2/1997	Stopped:	CONTIN
	ry Investigat			Stopped: Deta	
Laborato	ry Investigati	ions:			

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 128 of 554



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

Repor Ospitalisat Onset D	nber: 118427 rted: 20/06/199 tion: Date: 07/06/199 ome: Recovered	7				c	Gender: Weight: Age: DOB: ausality:	33Y	orobable
eaction D			-						
	referred Term	Severity	/	Repo	rt De	scription		Trea	tment
Jrinary inco	nunence								
<i>l</i> edicine	Details:								
ZOLOFT (Ot				Reas	on:	Depression			
		5	0.0 Milli	gram	Daily				
Bate	ch:	Started:	11/12/19	996		Stopped:			
RISPERDAL	(Suspected)			Reas	on:	Unspecified ps	sychosis		
RISPERDAL	(Suspected)		1.0 Milli	gram	on: Daily				
RISPERDAL Bate			1.0 Milli 26/05/19	gram			sychosis 12/06/1997	,	
Bato		Started:		gram					
Bate Laborato	_{ch:} ry Investigat	Started:	26/05/19	gram 997			12/06/1997		

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 129 of 554



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

Report Details:

Case Number: 118428 Seq: 1 Gender: F

Reported: 20/06/1997 Weight: 53.00 Hospitalisation: Age: 67Y

Onset Date: 02/06/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia	Severe		

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 130 of 554



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

Report Details:

Case Number: 118491 Seq: 1 Gender: F

Reported: 24/06/1997 Weight:
Hospitalisation: Age: 47Y

Onset Date: 04/05/1997 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

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

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified psychosis

1.0 Milligram Daily

Batch: Started: 07/04/1997 **Stopped:** 27/05/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 131 of 554



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

Report Details:

 Case Number:
 118537
 Seq: 1
 Gender:
 F

 Reported:
 25/06/1997
 Weight:

Hospitalisation: Age: 32Y
Onset Date: 11/06/1997
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Other drug) Reason: Unspecified psychosis

0.0

Batch: Started: Stopped:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

 Tablet
 4.0 Milligram
 Daily
 Oral

 Batch:
 Started: 01/06/1997
 Stopped: 19/06/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:02AM Database: pusime02 ADRS004 Page 132 of 554



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

Report Details:

 Case Number:
 118680
 Seq: 1
 Gender: M

 Reported:
 30/06/1997
 Weight:

Hospitalisation: Age: 61Y
Onset Date: 23/02/1997
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dementia		Organic brain syndrome	

Medicine Details:

LITHIUM CARBONATE (Other drug)			Reason:	Unspecified so	hizophrenia	
Tablet	750.0 M	Iilligram	Daily		Oral	
Batch:	Started:	l	L TERM	Stopped:		
CLONAZEPAM (Suspected)			Reason:	Otr spec symp	psychopathol ne	ec
Tablet	1.0 M	Iilligram	Daily		Oral	
Batch:	Started: 21/12	2/1996		Stopped:		CONTIN
SODIUM VALPROATE (Suspected)			Reason:	Other&unspec	ified epilepsy	
Tablet	400.0 N	1illigram	Daily		Oral	
Batch:	Started: 13/11	/1996		Stopped:	05/02/1997	
BENZHEXOL HYDROCHLORIDE (Suspect	ed)		Reason:			
Tablet	10.0 N	Iilligram	Daily		Oral	
Batch:	Started: 08/02	2/1997		Stopped:	07/05/1997	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Clopixol-acuphase taken at 50mg every 3 days.

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 133 of 554



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

Reported: 30/06/1997	leport Details:				
Action Details: Action Details: Risperibone (Suspected) Tablet Batch: Started: 24/06/1996 Reason: Unspecified psychosis Oral Stopped: 04/02/1997 CLOPIXOL-ACUPHASE (Suspected) Reason: Unspecified psychosis Stopped: 04/02/1997 CLOPIXOL-ACUPHASE (Suspected) Reason: Unspecified psychosis Stopped: 04/02/1997 CLOPIXOL-Batch: Started: 07/02/1997 Stopped: 01/03/1997	Reported: 30/06/1997 ospitalisation:	Seq: 1		Weight: Age:	61Y
Reason: Unspecified psychosis Reason: Unspecified psychosis	Outcome: Not yet recovered		С	ausality:	Causality possible
Tablet 2.0 Milligram Daily Oral Batch: Started: 24/06/1996 Stopped: 04/02/1997 CLOPIXOL-ACUPHASE (Suspected) Reason: Unspecified psychosis Injection 50.0 Milligram Cyclical Intramuscular Batch: Started: 07/02/1997 Stopped: 01/03/1997	eaction Details:				
Reason: Unspecified psychosis Tablet 2.0 Milligram Daily Oral Batch: Started: 24/06/1996 Stopped: 04/02/1997 CLOPIXOL-ACUPHASE (Suspected) Reason: Unspecified psychosis Injection 50.0 Milligram Cyclic Intramuscular Batch: Started: 07/02/1997 Stopped: 01/03/1997					
Batch: Started: 24/06/1996 Stopped: 04/02/1997 CLOPIXOL-ACUPHASE (Suspected) Reason: Unspecified psychosis Injection 50.0 Milligram Cyclical Intramuscular Batch: Started: 07/02/1997 Stopped: 01/03/1997			Reason: Unspecified ps	sychosis	
CLOPIXOL-ACUPHASE (Suspected) Injection 50.0 Milligram Cyclical Intramuscular Batch: Started: 07/02/1997 Stopped: 01/03/1997		2.0 Milligram	Daily	Oral	
Injection 50.0 Milligram Cyclical Intramuscular Batch: Started: 07/02/1997 Stopped: 01/03/1997	Batch:	Started: 24/06/1996	Stopped:	04/02/1997	7
Batch: Started: 07/02/1997 Stopped: 01/03/1997	CLOPIXOL-ACUPHASE (Suspected)		Reason: Unspecified ps	sychosis	
	Injection	_	•		
aboratory Investigations:	Batch:	Started: 07/02/1997	Stopped:	01/03/1997	7
	Laboratory Investigations:	Control (1702)	Сторрош		

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 134 of 554



DOB:

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

Report Details:

Case Number: 118835 Seq: 1 Gender: M

Reported: 04/07/1997 Weight: 90.00 Hospitalisation: Age: 33Y

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Onset Date: 31/05/1997

Preferred Term	Severity	Report Description	Treatment
Palpitations			

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified schizophrenia

6.0 Milligram Daily

Batch: Started: Stopped: 02/07/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 135 of 554



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

Report Details:

 Case Number:
 119015
 Seq: 1
 Gender:
 F

 Reported:
 10/07/1997
 Weight:

Hospitalisation:
Onset Date: 25/06/1997
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

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

Medicine Details:

RISPERIDONE (Suspected) Reason: Schizophrenia

6.0 Milligram Daily

Batch: **Started**: 17/06/1997 **Stopped**: 27/06/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 136 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

-		119230	U	Seq: 1					Gender:	IVI
ospitalisation Onset Dat	d:	17/07/199	9 7						Weight:	
Onset Dat	n:								Age:	83
	e:								DOB:	: 04/09/1913
Outcome	e:	Not yet re	covered					С	ausality:	Causality possible
action Det										
Prefe	erre	d Term		Severity		Repo	ort Des	cription		Treatment
Neuroleptic ma	alig	nant synd	rome						Ris	speridone ceased
Medicine Do			drug)			Rea	son:			
				400.0	Milliç	gram	Daily			
Batch:				Started:				Stopped:		
AMOXYCILLIN-	POT	ASSIUM CI	LAVULANA [.]	TE (Other druເ	J)	Rea	son:			
				3.0	Dose	e Unspecified	Daily			
Batch:				Started: 16	/06/19	97		Stopped:	20/06/199	7
NYSTATIN (Oth	er d	lrug)				Rea	son:			
					Millili		Daily			
Batch:				Started: 16	/06/19			Stopped:		
AMPICILLIN (Of		drug)					son:			
Injection					Gran		Daily		Intravenou	
Batch:				Started: 13	06/19	997		Stopped:	16/06/199	7
aboratory	In	vestigat	tions:							
Date		Туре	Range	Date Tes	ted	Result			Detai	ils

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 137 of 554



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

Report Details	5 :					
Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detail	17/07/1997 Not yet recovered	Seq: 1				
Medicine Deta				Reason:		
1	, pootou,		1.0 Milligram	Daily		
Batch:		Started:			Stopped:	
Laboratory In	vestigations:					
Additional Info	ormation:					

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 138 of 554



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

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

Case Number: 119353 Seq: 1 Gender: M
Reported: 23/07/1997 Weight:

Hospitalisation: Age: 19Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Face oedema		Puffy face	

Medicine Details:

Micaicine Details.			
ALCOHOL (Interaction)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
RISPERIDONE (Interaction)		Reason: Unspecified schizophrer	ia
Tablet	2.0 Milligram	Daily Oral	
Batch:	Started: 01/12/1996	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 139 of 554



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

Report Details:

 Case Number:
 119381
 Seq: 1
 Gender:
 F

 Reported:
 23/07/1997
 Weight:

Hospitalisation: Age: 11Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

١,	Caction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Skin discolouration		Transient unusual discolouration of skin	
	Constipation			
	Epistaxis			

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

1.0 Milligram Daily

Batch: Started: 01/12/1996 **Stopped:** 28/07/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 140 of 554



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

Report Details:

 Case Number:
 119442
 Seq:
 1
 Gender:
 M

 Reported:
 25/07/1997
 Weight:
 103.00

Hospitalisation: Age: 67Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

100011011 20101101			
Preferred Term	Severity	Report Description	Treatment
Myopathy		Moderately severe proximal muscle weakness	
Extrapyramidal disorder			

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 141 of 554



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

Report Details:

Case Number: 119754 Seq: 1 Gender: F

Reported: 08/08/1997 Weight:
Hospitalisation: Age: 81Y
Onset Date: 25/07/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)

0.0

Batch: Started: Stopped:

RISPERIDONE (Suspected) Reason:

2.0 Milligram Daily

Batch: Started: 09/07/1997 **Stopped:** 28/07/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 142 of 554



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

Report Details:

Case Number: 119760 Seq: 1 Gender: M

Reported: 08/08/1997 **Weight:** 60.00

Hospitalisation: Age:
Onset Date: 23/07/1997
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment	l
Urinary retention			Cessation of risperidone	l

Medicine Details:

RISPERIDONE (Suspected) Reason:

Tablet 2.0 Milligram Daily Oral

Batch: Started: 01/01/1997 **Stopped:** 21/07/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 143 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number: 119963	Seq: 1		Gen	der: F		
Reported: 15/08/1	-		Weight:			
ospitalisation:		Age: 32Y				
Onset Date:				OB:		
Outcome: Unknow	vn		Causality: Causality possible			
action Details:		_				
Preferred Term	Severity	Repor	t Description	Treatment		
rug ineffective						
Iodioino Dotoilo:						
ledicine Details: RISPERIDONE (Suspected)		Reaso	on: Unspecified psychos	is		
Tablet	0.0		Oral			
Batch:	Started:		Stopped:			
aboratory Investig	ations:					
Date Type	Range Date Test	ted Result		Details		
Additional Informat	ion:					
oort Run: 04/06/2007 11:03	BAM Database: pusime02	AE	RS004	Page 144 of 554		



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

case Number. 120324	Seq. 1		Gender. W
Reported: 26/08/1997	7		Weight:
spitalisation:			Age: 76Y
Onset Date:			DOB:
Outcome: Recovered	1		Causality: Causality probable
ction Details:			
Preferred Term	Severity	Report Descri	ption Treatment
ticaria			Ceased risperidone.
edicine Details:	0.0	Reason:	
Batch:	Started:		Stopped:
aboratory Investigati	ons:		
Date Type	Range Date Tested	Result	Details
dditional Informatior	1:		
ort Run : 04/06/2007 11:03AM	Database: pusime02	ADRS004	Page 145 of 554

ADRS004 Page 145 of 554



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

Repo	rt D	etai	ls:
------	------	------	-----

Case Number: 120325 Seq: 1 Gender: M

Reported: 26/08/1997 Weight:

Hospitalisation: Age: 76Y
Onset Date: 14/07/1997
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus			Pinetarsol

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

Tablet 3.0 Milligram Daily Oral

Batch: Started: 09/07/1997 **Stopped:** 13/07/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 146 of 554



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

Report Details:

Case Number: 120581 Seq: 1 Gender: F

Reported: 05/09/1997 Weight: 84.00
Hospitalisation: Admitted to hospital Age: 37Y
Onset Date: 16/05/1997 DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fielelieu ieiiii	Seventy	Report Description	Healment
Hypotension			
Hypothermia			Amitted to icu, ventilation and
			ionotropes, risperdone ceased.

Medicine Details:

Medicine Details.				
SERTRALINE HYDROCHLORIDE (O	ther drug)	Reason:		
Tablet	50.0 Milligram	Daily	Oral	
Batch:	Started: 09/05/1997	Stoppe	d: 16/05/1997	
RISPERDAL (Suspected)		Reason: Unspecified	psychosis	
Tablet	4.0 Milligram	Daily	Oral	
Batch:	Started: 21/04/1997	Stoppe	d: 04/07/1997	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 147 of 554



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

Report Details:

 Case Number:
 120723
 Seq: 1
 Gender: M

 Reported:
 12/09/1997
 Weight:
 65.00

 Hospitalisation:
 Age: 23Y

Onset Date: 18/05/1997 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 148 of 554



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

Report Details:

Case Number: 120723 Seq: 1 Gender: M

Reported: 12/09/1997 Weight: 65.00 Hospitalisation: Age: 23Y

Onset Date: 18/05/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

Medicine Details.			
PARVOLEX (Suspected)		Reason: Adv effect an	iline derivatives
Injection	20.0 Gram	Daily	Intravenous
Batch:	Started: 17/05/1997	Stopped	20/05/1997
RISPERIDONE (Suspected)		Reason: Schizophreni	a
Tablet	8.0 Milligram	Daily	Oral
Batch:	Started: 01/03/1997	Stopped	: 12/05/1997

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 149 of 554



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

•	ils:								
Case Numbe			Seq: 1					Gend Weig	ler: F ht:
lospitalisatior	1:							Ą	ge:
Onset Date	e: 15/09	/1997						DO	OB:
Outcome	: Not ye	et recovered					С	ausali	ity: Causality possible
eaction Det	ails:								
Prefe	rred Terr	n	Severity		Repo	rt De	scription		Treatment
Seborrhoea				Greasy chest &	skin ovei back	scalp	/forehead/upp	oer	
Pruritus									Ceased risperdal.
Rash				1					I.
Medicine De									
TRIPHASIL (Oth	er drug)				Reas		Contraception		
Tablet				Dose Un	specified	Daily		Oral	
Batch:			Started:				Stopped:		CONTIN
RISPERDAL (Su	spected)				Reas		Schizophrenia		
Tablet				Milligram		Daily		Oral	
Batch:			Started: 09	/09/1997			Stopped:	18/09/	1997
Laboratory	Investi	gations:							
Date	Туре	Range	e Date Tes	sted F	Result			С)etails
Additional I	nform-	tion							
Additional I	nforma	tion:							
Additional I	nforma	tion:							
Additional I	nforma	ition:							
Additional I	nforma	ition:							

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 150 of 554



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

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

 Case Number:
 121453
 Seq: 1
 Gender: U

 Reported:
 09/10/1997
 Weight:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

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

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	Other&unspecified epi	ilepsy
	0.0			
Batch:	Started:		Stopped:	CONTIN
PHENYTOIN SODIUM (Other drug)		Reason:	Other&unspecified epi	ilepsy
Capsule	0.0		Oral	
Batch:	Started:		Stopped:	CONTIN
RISPERDAL (Suspected)		Reason:	Unspecified psychosis	3
Tablet	4.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 151 of 554



Report Details:

Case Number: 121569

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

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

Seq: 1

Reported: 13/10/1997				We	eight: 50.00
lospitalisation:					Age: 13Y
Onset Date: 29/09/1997					DOB:
Outcome: Recovered				Caus	ality: Causality probable
eaction Details:					
Preferred Term	Se	everity	Rep	ort Description	Treatment
sthenia					
Confusional state					
epersonalisation					
rug withdrawal syndrome					
atigue					
Sensory disturbance					
Medicine Details: RISPERIDONE (Suspected)		2.0 Milli		son:	
Batch:		2.0 Nilli Started: 20/08/19		Daily Stopped: 28/	00/4007
aboratory Investigation		1		T	
Date Type	Range	Date Tested	Result		Details
Additional Information	:				
ort Run: 04/06/2007 11:03AM	Database: pi	usime02	,	ADRS004	Page 152 of 554



Causality: Causality possible

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

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

Case Number:121680Seq: 1Gender: MReported:16/10/1997Weight:Hospitalisation:Age:

Onset Date: 10/09/1997 **DOB**:

Outcome: Death, maybe drug

Reaction Details:

caction Details.			
Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation			
Left ventricular failure			

Medicine Details:

ZANTAC (Suspected)			Reason:	
	300.0	Milligram	Daily	
Batch:	Started:	L -	ΓERM	Stopped:
PREDNISOLONE (Suspected)			Reason:	
	5.0	Milligram	Daily	
Batch:	Started:	L -	ΓERM	Stopped:
PARACETAMOL (Suspected)			Reason:	
	6.0	Gram	Daily	
Batch:	6.0 Started:		Daily FERM	Stopped:
Batch: PROGOUT (Suspected)			,	Stopped:
		L.	ΓERM	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 153 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number:	121680	Seq:	1				Gender:	M
Reported:	16/10/1997						Weight:	
Hospitalisation:							Age:	
Onset Date:	10/09/1997						DOB:	
Outcome:	Death, maybe dru	g					Causality:	Causality possible
Reaction Detai	ls:							
Marillata Dat	- *1 -							
Medicine Det					Reas	son:		
Diooxiii (ouspect	.cu)		20	Dose Uns				
Batch:		Sta	rted:		L TERM	Daily	Stopped:	
RISPERIDONE (Su	spected)				Reas	son:	Otoppoul	
140. 214.20142 (00	opostou,		1.0	Milligram	11041	Daily		
Batch:		Sta		3/09/1997		Dany	Stopped:	
							оторрош.	
Laboratory In	vestigations:							
Additional Inf								
	iormation:							
Paneni nao iono-si	formation:	patier	nt died	10/9/97				
Patient had long-st	formation: anding stable ihd/af	patier	nt died	10/9/97.				
Patient had long-si		patier	nt died	10/9/97.				
Patient nad long-si		patier	nt died	10/9/97.				
Patient had long-si		patier	nt died	10/9/97.				

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 154 of 554



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

Case Numb							
· · ·		Sec	q : 1			Gender:	
_	ed: 24/10/199	1				Weight:	
ospitalisatio						Age:	
Onset Da						DOB:	
	ne: Unknown				•	Jausanty:	Causality possible
eaction De		1 6	Coverity	Don	art Description		Tractment
Hypertonia	erred Term	3	Severity	Slow onset of m	ort Description	0.0	Treatment gentin, valium.
Medicine D			50.0 A		son:		
CAPTOPRIL (C	Other drug)			Milligram	Daily		
CAPTOPRIL (C	Other drug) :	;	50.0 M Started:	Milligram L TERM	Daily Stopped:		
CAPTOPRIL (C	Other drug) :		Started:	Milligram L TERM Rea	Daily Stopped:		
CAPTOPRIL (C Batch LASIX (Other c	Other drug) : drug)		Started:	Milligram L TERM Rea Milligram	Daily Stopped: son: Daily		
CAPTOPRIL (C Batch LASIX (Other c	Other drug) : drug)		Started:	Villigram L TERM Re a Villigram L TERM	Daily Stopped:		
CAPTOPRIL (C Batch LASIX (Other c	Other drug) : drug) :		Started: 40.0 M Started:	Villigram L TERM Re a Villigram L TERM	Daily Stopped: son: Daily Stopped:		
Batch LASIX (Other of Batch) RISPERIDONE	other drug) : drug) : (Suspected)		Started: 40.0 M Started:	Ailligram L TERM Rea Ailligram L TERM Rea Milligram	Stopped: son: Daily Stopped: son: Daily		7
Batch LASIX (Other of Batch RISPERIDONE Tablet	Other drug) : drug) : (Suspected)		Started: 40.0 M Started:	Ailligram L TERM Rea Milligram L TERM Rea Milligram	Stopped: son: Daily Stopped: son: Daily	Oral	7
Batch LASIX (Other of Batch RISPERIDONE Tablet Batch	Other drug) : drug) : (Suspected)		Started: 40.0 M Started:	Ailligram L TERM Rea Ailligram L TERM Rea Ailligram 2/1995 Rea	Daily Stopped: Son: Daily Stopped: Son: Daily Stopped: Stopped:	Oral	7
Batch LASIX (Other of Batch RISPERIDONE Tablet Batch	Other drug) : drug) : (Suspected) : ected)		40.0 M Started: 1.0 M Started: 07/12	Ailligram L TERM Rea Milligram L TERM Rea Milligram 2/1995 Rea Milligram	Daily Stopped: Son: Daily Stopped: Son: Daily Stopped: Son: Daily Daily	Oral	
Batch LASIX (Other of Batch RISPERIDONE Tablet Batch EPILIM (Suspe	Other drug) : drug) : (Suspected) : ected)	:	\$\$tarted: 40.0 M \$\$tarted: 1.0 M \$\$tarted: 07/12 200.0 M	Ailligram L TERM Rea Milligram L TERM Rea Milligram 2/1995 Rea Milligram	Daily Stopped: Son: Daily Stopped: Son: Daily Stopped: Son: Daily Daily	Oral 28/02/1997	
Batch LASIX (Other of Batch RISPERIDONE Tablet Batch EPILIM (Suspe	Other drug) : drug) : (Suspected) : ected)	:	\$\$tarted: 40.0 M \$\$tarted: 1.0 M \$\$tarted: 07/12 200.0 M	Ailligram L TERM Rea Milligram L TERM Rea Milligram 2/1995 Rea Milligram 2/1995	Daily Stopped: Son: Daily Stopped: Son: Daily Stopped: Son: Daily Daily	Oral 28/02/1997	7

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 155 of 554



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

Report Details:

Case Number:121969Seq: 1Gender: MReported:28/10/1997Weight: 67.00Hospitalisation:Admitted to hospitalAge: 26Y

Onset Date: 08/09/1997 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 156 of 554



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

Report Details:

 Case Number:
 122269
 Seq: 1
 Gender:
 F

 Reported:
 11/11/1997
 Weight:
 70.00

 Hospitalisation:
 Age: 86Y

Onset Date: 14/10/1997 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 157 of 554



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

Report Details:

Case Number: 122269 Seq: 1 Gender: F

Reported: 11/11/1997 Weight: 70.00
Hospitalisation: Age: 86Y

Onset Date: 14/10/1997 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 158 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Reported:	122269	Seq	: 1			Gender:	F
	11/11/199	7				Weight:	70.00
lospitalisation:						Age:	86Y
Onset Date:	14/10/199	7				DOB:	
Outcome:	Not yet red	covered				Causality:	Causality possible
eaction Deta	ils:						
Medicine Det	tails:						
PARACETAMOL (Re	ason:		
			4.0 Gran	m	Daily		
Batch:		5	Started:			Stopped:	
ASPIRIN (Other d	rug)			Re	ason:		
			100.0 Millig	gram	Daily		
Batch:		5	Started:			Stopped:	
RISPERIDONE (S	uspected)			Re	ason:		
Oral applic	cation		1.0 Milli	gram	Daily	Oral	
Batch:		5	Started: 03/10/19	97		Stopped: 21/10/1997	,
METOLAZONE (S	uspected)			Re	ason:		
Tablet			1.2 Milli	gram	Daily	Oral	
Batch:		5	Started:			Stopped: 17/09/1997	,
Laboratory lı			 				
Date	Type = ALP	Range	Date Tested 24/10/1997	Result 114		Detai	is .

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 159 of 554



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

Repo	rt D	etai	ls:
------	------	------	-----

Case Number: 122641 Seq: 1 Gender: M

Reported: 20/11/1997 Weight: 100.00 Hospitalisation: Age: 30Y

Onset Date: 24/10/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified schizophrenia

0.0

Batch: Started: Stopped: 22/10/1997

ZYPREXA (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 23/10/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 160 of 554



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

	etails:						
Case Numl	ber: 122765	Seq: 1				Gend	er: M
Repor	ted: 25/11/1997					Weigl	nt: 51.00
Hospitalisati						_	je: 34Y
	ate: 17/11/1997						DB:
	me: Recovered				С	ausali	ty: Causality possible
Reaction D							
	eferred Term	Severity		ort Desc			Treatment
Dystonia			Dystonic tongue protruding	e, curling	upwards ar	nd 	Cogentin imi 2mg.
Medicine RISPERDAL			Rea	ison:			
Table		2.0	Gram	Daily		Oral	
Batc	h:	Started: 14	/11/1997		Stopped:		
RISPERDAL	(Suspected)		Rea	ison:			
		4.0	Milligram	Daily			
Batc	h:	Started: 16	/11/1997		Stopped:		
Laborator Date	r y Investigatio Type	ns: Range Date Tes	sted Result			D	etails
			sted Result			D	etails

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 161 of 554



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

Re	port	Detai	ls:
----	------	-------	-----

 Case Number:
 122913
 Seq: 1
 Gender:
 F

 Reported:
 01/12/1997
 Weight:
 50.00

 Hospitalisation:
 Age: 68Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 162 of 554



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

Report Details:				
Case Number: 12	22913	Seq: 1	Gender:	F
Reported: 01	1/12/1997		Weight:	50.00

Hospitalisation: Age: 68Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 163 of 554



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

Report Details:

Case Number: 123544 Seq: 1 Gender: M
Reported: 18/12/1997 Weight:

Hospitalisation: Treated in outpatient department only. Age: 51

Onset Date: 15/08/1997 **DOB**: 11/07/1946

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Priapism			Risperdal ceased.

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified neurosis

3.0 Milligram Daily

Batch: Started: 14/08/1997 **Stopped:** 15/08/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Priapism developed after the second dose of risperdal.

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 164 of 554



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

Report Details:

Case Number: 123771 Seq: 1 Gender: F

Reported: 05/01/1998 Weight: 77.00
Hospitalisation: Age: 46Y
Onset Date: DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

,	caction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Pneumonia	Bronchopneumonia		
	Pulmonary oedema			

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient died in october 1997.

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 165 of 554



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

Re	port	Detail	ls:
----	------	--------	-----

 Case Number:
 123771
 Seq: 1
 Gender:
 F

 Reported:
 05/01/1998
 Weight:
 77.00

 Hospitalisation:
 Age: 46Y

Onset Date: DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Medicine Details:

COGENTIN (Other drug)		Reason:	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ALODORM (Other drug)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ANTENEX (Other drug)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
Moi Lindal (Guspecteu)		Reason.	
Tablet	2.0 Milligram	Daily	Oral

Laboratory Investigations:

Additional Information:

The patient died in october 1997.

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 166 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number: 123 Reported: 05/ Hospitalisation: Onset Date: Outcome: Dea	/01/1998 ath, maybe drug	Seq: 1		Gender: Weight: Age: DOB: Causality:	77.00 46Y
Medicine Details	S:				
RISPERDAL (Suspecte	ed)	4.O. MUU aaraa	Reason:	01	
Tablet		4.0 Milligram	Daily	Oral	
Batch:		Started: 05/10/1997	3	topped:	
Laboratory Inves	stigations:				
Additional Information The patient died in octo					

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 167 of 554



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

Report Details:

Case Number:123810Seq: 1Gender: MReported:05/01/1998Weight: 25.00Hospitalisation:Admitted to hospitalAge: 7Y

Onset Date: 06/09/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 168 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number:	123910	Seq:	1			Gend	er: M	
Reported:	13/01/199	98				Weigl	nt:	
lospitalisation:						Ag	je:	
Onset Date:	:					DC	B:	
Outcome:	Recovere	ed				Causali	ty: Causality poss	ible
eaction Deta		1						
	red Term		everity		ort Desc	ription	Treatmer	nt
Electrocardiogra	ım QT prol	onged	Pro	olonged qt in	erval			
Tachycardia							Atenolol	
Medicine Det				Rea	ıson:			
Tablet			6.0 Milli	igram	Daily	Oral		
Batch:		S	tarted: 15/05/19	997		Stopped:		
Laboratory li				Devel				
Date	Туре	Range	Date Tested	Result		D	etails	
Additional In	formatio	n:						
eport Run: 04/06/20	007 11:03AI	И Database: рі	usime02		ADRS004		Page 169	of 554



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

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

Case Number: 124574 Seq: 1 Gender: F

Reported: 02/02/1998 Weight:
Hospitalisation: Age: 18Y

Onset Date: 22/10/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

-				
	Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Elevated prolactin		
	Galactorrhoea			

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified psychosis

2.0 Milligram Daily

Batch: Started: 15/09/1997 Stopped: CONTIN

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 170 of 554



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

Report Details:

 Case Number:
 124579
 Seq: 1
 Gender: F

 Reported:
 02/02/1998
 Weight:

Hospitalisation: Age: 36

Onset Date: 15/07/1997 **DOB**: 23/11/1960

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast pain			
Hyperprolactinaemia			

Medicine Details:

CYCLOPHOSPHAMIDE (Suspected)		Reason:	Systemic lupus erythematosus	3
	0.0			
Batch:	Started:		Stopped:	
MOCLOBEMIDE (Suspected)		Reason:	Depression	
Tablet	450.0 Milligram	Daily	Oral	
Batch:	Started: 01/10/1996		Stopped:	CONTIN
RISPERDAL (Suspected)		Reason:	Unspecified psychosis	
Tablet	500.0 Microgram	Daily	Oral	
Batch:	Started: 01/10/1996		Stopped:	CONTIN
PREDNISONE (Suspected)		Reason:	Systemic lupus erythematosus	3
	50.0 Milligram	Daily		
Batch:	Started:		Stopped:	CONTIN

Laboratory Investigations:

Laborator	iy ilivcətiga				
Date	Туре	Range	Date Tested	Result	Details
	Prolactin	(46-622)	15/07/1997	838	

Additional Information:

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 171 of 554



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

Report Details:

Case Number: 124586 Seq: 1 Gender: F

Reported: 02/02/1998 Weight: 72.00 Hospitalisation: Age: 29

Onset Date: 15/04/1996 **DOB**: 08/11/1966

Outcome: Unknown Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Prolactin increased	
Amenorrhoea			

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified schizophrenia

Tablet 4.0 Milligram Daily Oral

Batch: Started: 01/04/1996 Stopped: CONTIN

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 172 of 554



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

Report Details:						
Case Number: 124673	Seq: 1		Gende	er: M		
Reported: 04/02/1998	-		Weigh	t : 56.00		
Hospitalisation:			Ag	e: 17Y		
Onset Date:			DO			
Outcome: Recovered			Causalit	y: Causality possible		
Reaction Details:						
Preferred Term	Severity	Report De	scription	Treatment		
Tachycardia		Hr - 160				
Dyskinesia		Tongue protruding fror	n mouth			
Dizziness				Benztropine 1mg		
Dyspnoea						
Dystonia						
Medicine Details: RISPERDAL (Suspected)		Reason:	Unspecified psychosis			
Oral application	2.0	2.0 Milligram Daily Oral				
Batch:	Started: 07/					
Laboratory Investigations:						
Date Type Ran	ge Date Test	ed Result	De	etails		
Additional Information:						

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 173 of 554



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

Report Details:

 Case Number:
 125013
 Seq: 1
 Gender:
 F

 Reported:
 16/02/1998
 Weight:

Hospitalisation: Age: 37

Onset Date: 31/03/1997 **DOB**: 03/04/1959

Outcome: Unknown Causality: Causality possible

Reaction Details:

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
Alopecia		Hair loss	
Dry skin			
Visual disturbance			

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

Oral application 1.0 Milligram Daily Oral

Batch: Started: 15/03/1997 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 174 of 554



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

Damast Data!					
Report Detail	s:				
Case Number:	125140	Seq: 1		Gender:	F
Reported:				Weight:	
lospitalisation:				Age:	28Y
Onset Date:	15/08/199	7		DOB:	
Outcome:					Causality probable
eaction Detai		4		Oausanty.	Causanty probable
	ed Term	Severity	Report Description		Treatment
Menstrual disord			Increased and prolonged menstru	ıal	
			bleeding		
Medicine Det			Reason: Unspecified	I schizophrenia	1
Tablet	,	0.0	·	Oral	
Batch:		Started: 15/0	8/1997 Stoppe	d:	CONTIN
_aboratory In	ıvestigati	ions:			
Laboratory In	ivestigat i Type	ions: Range Date Teste	ed Result	Detai	is
Laboratory In			ed Result	Detai	ls

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 175 of 554



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

Report Details:

 Case Number:
 125317
 Seq: 1
 Gender:
 F

 Reported:
 23/02/1998
 Weight:

Hospitalisation: Age: 47

Onset Date: DOB: 21/06/1950

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

METOCLOPRAMIDE HYDROCHLORIDE (O	ther drug)		Reason:			
Tablet	10.0	Milligram	As nece	essary	Oral	
Batch:	Started:			Stopped:		CONTIN
THIORIDAZINE HYDROCHLORIDE (Other of	drug)		Reason:			
Tablet	50.0	Milligram	As nece	essary	Oral	
Batch:	Started:			Stopped:		CONTIN
OESTROGENS CONJUGATED (Other drug	1)		Reason:	Menopausal s	ymptoms	
Tablet	625.0	Microgram	Daily		Oral	
Batch:	Started:			Stopped:		CONTIN
MS CONTIN (Other drug)			Reason:	Pain		
Tablet	30.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:		CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 176 of 554



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

Report Details:

 Case Number:
 125317
 Seq: 1
 Gender: F

 Reported:
 23/02/1998
 Weight:

Hospitalisation: Age: 47

Onset Date: DOB: 21/06/1950

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 177 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Туре		מוכ ו כאופט	INCOUR		Det	ana
ry Investigatio		eate Tested	Result		Det	ails
:n:	Star	iea:		51	oppea:	
et				Daily	Oral	
Details:			Rea	son: Other	atyp forms schizo	ohrenia
CICITCO TCITII	0000			-	011	rreaunent
etails:		arity	Pen	ort Descript		Treatment
	vered					B: r: Causality possible
rted: 27/02/1998 ion:					_	: 4Y
	Details: Det	Details: Details: Details: Details: Details: Details: Details: Start Start	Details: Det	Details: Details: Eferred Term Details: Details: Severity Recurrent nose Recurrent nose Details: SE (Suspected) Et 1.0 Milligram Started:	Details: Details: Details: Details: Details: Details: Details: Details: Details: Details: Details: Details: Details: Securrent nose bleeds Details: Details: Details: Details: Details: Securrent nose bleeds Details: Securrent nose bleeds Details: Securrent nose bleeds Details: Securrent nose bleeds Details: Securrent nose bleeds Details: Securrent nose bleeds Details: Securrent nose bleeds	Details: Details: Details: Details: Deferred Term



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

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

Case Number: 125484 Seq: 1 Gender: M

Reported: 03/03/1998 Weight: 65.00 Hospitalisation: Age: 19Y

Onset Date: 19/06/1997 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

<u>leaction Details.</u>			
Preferred Term	Severity	Report Description	Treatment
Gynaecomastia		Gynaecomastia bilateral	
Breast pain			

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified psychosis

4.0 Milligram Daily

Batch: Started: 20/03/1996 **Stopped:** 19/06/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 179 of 554



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

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

Case Number: 125543 Seq: 1 Gender: U

Reported: 05/03/1998 Weight:
Hospitalisation: Age:
Onset Date: 31/01/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure	

Medicine Details:

<u>Medicine Details.</u>			
ZYPREXA (Suspected)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stonned:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 180 of 554



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

Report Details:

Case Number: 125601 Seq: 1 Gender: F

 Reported:
 06/03/1998
 Weight:
 61.00

 Hospitalisation:
 Age:
 46Y

 Onset Date:
 31/01/1998
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 181 of 554



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

Report Details:

Case Number: 125658 Seq: 1 Gender: M

Reported: 09/03/1998 Weight:
Hospitalisation: Age: 79Y

Onset Date: 31/12/1998 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 182 of 554



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

Report Details:

Case Number: 125879 Seq: 1 Gender: F
Reported: 17/03/1998 Weight:
Hospitalisation: Admitted to hospital Age: 77Y

Onset Date: DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 183 of 554



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

Report Details:

Gender: F Case Number: 125879 Seq: 1 Weight: Reported: 17/03/1998

Hospitalisation: Admitted to hospital Age: 77Y

Onset Date: DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)		Reason:
	0.0	
Batch:	Started:	Stopped : 25/02/1998
TRYPTANOL (Suspected)		Reason:
TRYPTANOL (Suspected)	0.0	Reason:

HALOPERIDOL (Suspected) Reason: Reactive confusion

2.0 Milligram Daily

Batch: Started: 25/02/1998 Stopped: 26/02/1998

Laboratory Investigations:

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

Additional Information:

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

ADRS004 Report Run: 04/06/2007 11:03AM Database: pusime02 Page 184 of 554



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

Report Details:

 Case Number:
 125879
 Seq: 1
 Gender:
 F

 Reported:
 17/03/1998
 Weight:

Hospitalisation: Admitted to hospital Age: 77Y

Onset Date: DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected) Reason:

0.0

Batch: Started: Stopped: 25/02/1998

TRYPTANOL (Suspected) Reason:

0.0

 Batch:
 Started:
 Stopped:
 25/02/1998

HALOPERIDOL (Suspected) Reason: Reactive confusion

2.0 Milligram Daily

Batch: Started: 25/02/1998 **Stopped:** 26/02/1998

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 185 of 554



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

Report Details:

Case Number: 125879 Gender: F Seq: 1 Reported: 17/03/1998 Weight:

Hospitalisation: Admitted to hospital Age: 77Y

Onset Date: DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Medicine Details:

Batch:

RISPERIDONE (Suspected) Reason:

0.0

Batch: Started: Stopped: 25/02/1998

TRYPTANOL (Suspected) Reason:

0.0

Reactive confusion

HALOPERIDOL (Suspected) Reason:

Started:

2.0 Milligram Daily

Started: 25/02/1998 Batch: Stopped: 26/02/1998

Laboratory Investigations:

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

Stopped: 25/02/1998

Additional Information:

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

ADRS004 Report Run: 04/06/2007 11:03AM Database: pusime02 Page 186 of 554



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

Report Details	S:				
Case Number:	125952	Seq: 1		Gender	M
Reported:	20/03/1998			Weight:	76.00
Hospitalisation:				Age:	21Y
Onset Date:				DOB	
Outcome:	Not yet recovere	ed		Causality	Causality possible
Reaction Detai				•	, ,
	ed Term	Severity	Report De	escription	Treatment
Dyskinesia			Chewing movements		
Medicine Deta			Pagani	Unapposition achizophropi	,
RISPERDAL (Susp	ected)	2.0	Reason:	Unspecified schizophrenia Oral	i
Batch:		3.0 Started: 30/0	Milligram Daily	Stopped:	
Laboratory In	vestigations:				
Laboratory In		nge Date Teste	ed Result	Deta	ils
			ed Result	Deta	ils

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 187 of 554



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

Rep	ort	Detail	ls:
-----	-----	--------	-----

Case Number: 126363 Seq: 1 Gender: M

Reported: 01/04/1998 Weight:
Hospitalisation: Age: 69Y

Onset Date: 30/03/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradycardia		Bradyarrhythmia	

Medicine Details:

TRANSIDERM-NITRO (Other drug)		Reason: Chron isch heart dis no hyper
	25.0 Milligram	Daily
Batch:	Started:	Stopped:
ASPIRIN (Other drug)		Reason:
Tablet	150.0 Milligram	Daily Oral
Batch:	Started:	Stopped:
PERMAX (Other drug)		Reason:
Tablet	150.0 Milligram	Daily Oral
Batch:	Started:	Stopped:
TEGRETOL (Other drug)		Reason:
	750.0 Milligram	Daily
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 188 of 554



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

9Y ausality possible
)

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 189 of 554



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

Report Details:

Case Number: 126765 Seq: 1 Gender: M

Reported: 17/04/1998 Weight:
Hospitalisation: Age: 19

Onset Date: 21/03/1998 **DOB**: 05/12/1978

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Clonic tonic seizure	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)		Reason:			
	100.0 Milligram	Daily			
Batch: S	started: 01/03/1997		Stopped:	CONTIN	
DISDEDIDONE (Supported)		Pagagni	Unapposition psychopia		_

RISPERIDONE (Suspected) Reason: Unspecified psychosis

2.0 Milligram Daily

Batch: Started: 15/03/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 190 of 554



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

Report Details:

 Case Number:
 127152
 Seq: 1
 Gender: M

 Reported:
 05/05/1998
 Weight:

Hospitalisation: Age: 27Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Tardive dyskinesia		,	Risperdal ceased and olanzapine commenced

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified schizophrenia

6.0 Milligram Daily

Batch: Started: 01/10/1997 **Stopped:** 13/03/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 191 of 554



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

Report Details:

Case Number: 127200 Seq: 1 Gender: F

 Reported:
 06/05/1998
 Weight:
 98.00

 Hospitalisation:
 Age:
 29Y

Onset Date: 31/08/1997 **DOB:**

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

100:01:01: = 010:::01			
Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Grossly raised prolactin levels.	
Menstrual disorder		Oligomenorrhoea	
Weight increased			

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified schizophrenia

4.0 Milligram Daily

Batch: **Started**: 01/02/1997 **Stopped**: 28/03/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 192 of 554



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

Report Details:

Case Number: 127208 Seq: 1 Gender: M

Reported: 06/05/1998 **Weight:** 123.00

Hospitalisation: Age: 31Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

100.00.00.00.00.			
Preferred Term	Severity	Report Description	Treatment
Genital ulceration		Penile meatus	
Hypertonia		Spasm in left leg and arm.	
Rash			

Medicine Details:

OLANZAPINE (Suspected)Reason:Unspecified schizophreniaTablet20.0 MilligramDailyOralBatch:Started: 24/04/1998Stopped: 25/04/1998

RISPERIDONE (Suspected) Reason: Unspecified schizophrenia

2.0 Milligram Daily

Batch: Started: 01/01/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 193 of 554



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

Report D	etails:
----------	---------

 Case Number:
 127345
 Seq: 1
 Gender: M

 Reported:
 13/05/1998
 Weight:

Hospitalisation: Age: 22

Onset Date: 25/03/1998 **DOB**: 28/07/1975

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	,		Benztropine 2mg and imi cogentin 2 mg regularly

Medicine Details:

SALBUTAMOL (Other drug) Reason:

Inhalation 2.0 Dose Unspecified As necessary Inhalation

Batch: Started: Stopped:

ZUCLOPENTHIXOL ACETATE (Suspected) Reason:

150.0 Milligram 1 time

Batch: Started: 23/03/1998 Stopped:

RISPERIDONE (Suspected) Reason:

6.0 Milligram Daily

Batch: Started: 18/03/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 194 of 554



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

Report Details:

Case Number: 127395 Seq: 1 Gender: F
Reported: 12/05/1998 Weight:
Hospitalisation: Age: 23Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified schizophrenia

3.0 Milligram Daily

Batch: Started: 01/01/1996 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 195 of 554



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

Report Details:

 Case Number:
 127398
 Seq: 1
 Gender: M

 Reported:
 12/05/1998
 Weight:

Hospitalisation: Admitted to hospital Age: 37Y
Onset Date: 31/12/1997
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

RISPERIDONE (Suspected)

4.0 Milligram

Daily

Batch: Started: 01/11/1996

Stopped: CONTIN

PAROXETINE HYDROCHLORIDE (Suspected) Reason: Depression

10.0 Milligram Daily

Batch: Started: 29/09/1997 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 196 of 554



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

Report Details:

 Case Number:
 127399
 Seq: 1
 Gender: M

 Reported:
 12/05/1998
 Weight:

Hospitalisation: Admitted to hospital Age: 28Y
Onset Date: 31/01/1998
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Details.	action betails.							
Preferred Term	Severity	Report Description	Treatment					
Abdominal pain								
Anorexia								
Nausea								

Medicine Details:

RISPERIDONE (Suspected) Reason: Paranoia

1.0 Milligram Daily

Batch: Started: 17/01/1996 Stopped: CONTIN

SERTRALINE HYDROCHLORIDE (Suspected) Reason: Depression

25.0 Milligram Daily

Batch: Started: 11/02/1997 Stopped: CONTIN

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 197 of 554



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

Report Details:

Case Number: 127403 Seq: 1 Gender: M

Reported: 13/05/1998 Weight:
Hospitalisation: Age: 86Y

Onset Date: 23/10/1997 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 198 of 554



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

Report Detail	s:				
Case Number:	127403	Seq: 1		Gender:	M
	13/05/1998			Weight:	
Hospitalisation:				Age:	
Onset Date:				DOB:	
	Recovered			Causality:	Causality probable
Reaction Detai	ils:				
Medicine Det					
RISPERDAL (Susp	pected)	0.0	Reason:	Unspecified psychosis	
Batahi		0.0		Stannadi	
Batch:		Started : 16/10/1997		Stopped:	
l abayatayı lya					
Laboratory in	vestigations:				
A alaliti a mal lm4					
Additional Int		/ accurate but indicates that	stoppage (occurred sometime durin	a the month
and dodage stop de		, accurate par maiorico triat	Stoppage (securio de de la constitución de	y are monan.

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 199 of 554



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

Report De	etails:							
Case Num	ber: 127450	Seq:	1				Gender:	F
Repor	ted: 15/05/199	8					Weight:	65.00
Hospitalisat							Age:	
	Date: 28/04/199						DOB:	
	me: Recovere	d				С	ausality:	Causality probable
Reaction D		Cov	o with a	Dani				Transferent
	eferred Term	Sev	erity			scription		Treatment
Hyperprolac Galactorrho			Ra	ised prolactin				
	ction abnormal							
Madialaa	Detelle:							
Medicine RISPERDAL				Rea	son:	Unspecified ps	sychosis	
	application		2.0 Mill		Daily	oopooou po	Oral	
Bato		Sta	rted: 12/04/1	_	Í	Stopped:	05/05/1998	3
Laborator	ry Investigat	ions:						
Date	Type	Range [Date Tested	Result			Detai	ls
Additiona	ıl Informatio	n:						

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 200 of 554



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

Report Details:

 Case Number:
 127461
 Seq: 1
 Gender: M

 Reported:
 18/05/1998
 Weight:
 80.00

 Hospitalisation:
 Age: 17Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

RISPERDAL (Suspected) Reason: Other atyp forms schizophrenia

4.0 Milligram Daily

Batch: Started: 01/01/1994 **Stopped:** 28/05/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 201 of 554



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

Report Details:

Case Number: 127608 Gender: F Seq: 1

Reported: 20/05/1998 Weight: 90.00 Hospitalisation: **Age:** 18Y

Onset Date: 08/11/1997 DOB: Causality: Causality possible

Outcome: Not yet recovered

Reaction Details:

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

Medicine Details:

RISPERIDONE (Suspected) Reason:

1.0 Milligram Daily

Batch: Started: 01/10/1997 Stopped: 28/12/1997

Laboratory Investigations:

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

Additional Information:

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

ADRS004 Report Run: 04/06/2007 11:03AM Database: pusime02 Page 202 of 554



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

port Details:				
ase Number: 127731 Reported: 25/05/199	Seq: 1		Gender: Weight:	55.00
pitalisation:	_		Age:	
Onset Date: 07/05/199			DOB:	
Outcome: Recovere	ea ea		Causanty:	Causality possible
action Details: Preferred Term	Severity	Report De	escription	Treatment
epersonalisation	- Covering	Depersonalised feelin		madrin 5mg bd.
edicine Details:		Reason:		
Batch:	0.0 Started:		Stopped:	
RISPERDAL (Suspected)	Starteu.	Reason:	Unspecified schizophrenia	1
,	3.0	Milligram Daily		
	0.0	willigram Dally		
Batch:	Started: 05/0	-	Stopped:	
Batch: _aboratory Investigat Date Type	Started: 05/0	05/1998		ls

Page 203 of 554



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

Report Details:

 Case Number:
 127734
 Seq: 1
 Gender:
 F

 Reported:
 25/05/1998
 Weight:

Hospitalisation: Age: 18Y
Onset Date: 08/11/1997
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)	Reason:		
Tablet	60.0 Milligram	Daily	Oral	
Batch:	Started:	Sto	pped:	CONTIN
KEMADRIN (Other drug)		Reason:		
Tablet	20.0 Milligram	Daily	Oral	
Batch:	Started:	Sto	pped:	CONTIN
RISPERDAL (Suspected)		Reason: Other a	typ forms schizop	hrenia
Tablet	1.0 Milligram	Daily	Oral	
Batch:	Started: 01/10/1997	Sto	pped: 28/12/199	97

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 204 of 554



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

Case Number: 127736 Seq: 1 Gender: F
Reported: 25/05/1998 Weight:
Hospitalisation: Age: 50Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

caction Details.			
Preferred Term	Severity	Report Description	Treatment
Menstrual disorder			
Metrorrhagia			

Medicine Details:

RISPERIDONE (Suspected) Reason:

0.0

Batch: Started: 01/01/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 205 of 554



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

Report Details:

Case Number: 127738 Seq: 1 Gender: M

Reported: 25/05/1998 Weight:

Hospitalisation: Age: 16Y
Onset Date: 15/01/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amnesia			

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

0.0

Batch: Started: 01/10/1997 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 206 of 554



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

Case Number: 12785 Reported: 27/05/ ospitalisation: Onset Date: 19/05/ Outcome: Not ye	/1998	: 1			С	Ag DC	er: F nt: 82.00 e: 54 B: 04/07/1943 ty: Causality possible
eaction Details: Preferred Terr	m S	everity	Reno	ort Desc	rintion		Treatment
Rash	" 3		Rash over abdo			У	Benadryl 50mg po tds
		1	redish rash.		•	•	3 31
Pruritus							
Medicine Details: LITHIUM CARBONATE (Ot	ther drug)		Rea	son:			
Tablet		1.0	Gram	Daily		Oral	
Batch:		Started:			Stopped:		
AMOXYCILLIN SODIUM (S	iuspected)				thr diseases		y tract
Tablet		1.5 (Daily	04	Oral	000
Batch:		Started: 19/0		son:	Stopped:	20/05/1	998
RISPERDAL (Suspected) Tablet		40 !	кеа : Milligram	son: Daily		Oral	
		Started:	9	Daily	Stopped:	Olui	
Batch:							
Batch: Laboratory Investi	gations:	Date Teste	d Result			D	etails
Batch: Laboratory Investi		Date Teste	d Result			D	etails

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 207 of 554



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

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

Case Number: 127898 Seq: 1 Gender: M

Reported: 28/05/1998 Weight: 54.00 Hospitalisation: Age: 18Y

Onset Date: 15/05/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 208 of 554



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

	128010	Seq:	1			Gende	r: M
Reported:	01/06/199	08				Weigh	t:
spitalisation:						Age	e : 30
Onset Date:						DO	B : 10/10/1967
Outcome:	Recovere	d				Causalit	y: Causality probable
action Detail			1				
Preferre		Se	everity	Repo	rt Description		Treatment
epatic function a	abnormal					F	Risperidone ceased
edicine Deta				Reas	on: Unenocific	ed schizophre	nia
Tablet	ecteu)		0.0	Reas	on. Onspecifie	Oral	IId
Batch:		S	tarted:		Stonn	ed: 26/02/19	998
obovotov. In	vooti ant	iana.					
aboratory In	vestigat _{Type}	i ons: Range	Date Tested	Result		De	tails

Rep



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

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

Case Number: 128052 Seq: 1 Gender: M

Reported: 03/06/1998 Weight:

Hospitalisation: Age: 44Y
Onset Date: 04/06/1997
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

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

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified schizophrenia

Tablet 4.0 Milligram Daily Oral

Batch: **Started**: 22/04/1997 **Stopped**: 08/07/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 210 of 554



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

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

 Case Number:
 128269
 Seq: 1
 Gender: M

 Reported:
 10/06/1998
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 09/09/1997
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal disorder			Total colestomy with formation of an ileostomy.

Medicine Details:

RISPERDAL (Suspected)

Tablet

12.0 Milligram

Daily

Oral

Batch: Started: 07/05/1997 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Run : 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 211 of 554



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

Report Details:

 Case Number:
 128350
 Seq: 1
 Gender: F

 Reported:
 11/06/1998
 Weight:

Hospitalisation: Admitted to hospital **Age:** 27

Onset Date: 28/03/1998 **DOB**: 14/12/1970

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 212 of 554



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

Report Details:

 Case Number:
 128350
 Seq: 1
 Gender:
 F

 Reported:
 11/06/1998
 Weight:

Hospitalisation: Admitted to hospital Age: 27

Onset Date: 28/03/1998 **DOB**: 14/12/1970

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal impairment			

Medicine Details:

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

Laboratory Investigations:

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 213 of 554



DOB: 17/10/1922

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

Report	Details:
--------	----------

 Case Number:
 128492
 Seq: 1
 Gender:
 F

 Reported:
 18/06/1998
 Weight:

Hospitalisation: Age: 75

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Onset Date:

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

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Suspected)	Reason:	Unspecified psychosi	s
Batch:	Started:		Stopped:	
TEMAZEPAM (Suspected)		Reason:	Specific disorders of	sleep
	10.0 Milligram	As ne	ecessary	
Batch:	Started:		Stopped:	
ATENOLOL (Suspected)		Reason:	Otr&nos disord of hea	art rhythm
	50.0 Milligram	Daily	,	
Batch:	Started:		Stopped:	CONTIN
CARTIA (Suspected)		Reason:	Otr&nos disord of hea	art rhythm
	100.0 Milligram	Daily	•	
Batch:	Started:		Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 214 of 554



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

Report Details	:							
Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detail	18/06/1998 Not yet recovered	Seq: 1			(
Medicine Deta	ils:							
RISPERIDONE (Sus			1.0 Milligram	Reason: Daily	Paranoia			
Batch:		Started:			Stopped	:	CONTIN	
Laboratory Inv	estigations:							
Additional Info	ormation:							

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 215 of 554



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

Report Details:

Case Number: 128646 Seq: 1 Gender: F
Reported: 23/06/1998 Weight:

Hospitalisation:
Onset Date:

DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

,	teaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Hyperprolactinaemia		Raised prolactin: 2169	
	Amenorrhoea			

Medicine Details:

RISPERDAL (Suspected) Reason: Schizophrenia

3.0 Milligram Daily

Batch: Started: 01/01/1996 Stopped:

Laboratory Investigations:

	. <u>,</u>				
Date	Туре	Range	Date Tested	Result	Details
	Radiololgy				Ct scan indicated possibility of 5mm. microadenoma in pituitary.

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 216 of 554



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

Report Details:

Case Number: 128783 Seq: 1 Gender: M
Reported: 24/06/1998 Weight:
Hospitalisation: Age: 62Y

Onset Date: 10/06/1998 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 217 of 554



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

Report Details:

Case Number: 129097 Seq: 1 Gender: M

Reported: 10/07/1998 Weight: 72.00 Hospitalisation: Age: 58Y

Onset Date: 14/06/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Prothrombin level increased			

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 218 of 554



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

Report Details:

 Case Number:
 129719
 Seq: 1
 Gender:
 F

 Reported:
 30/07/1998
 Weight:

Hospitalisation:
Onset Date: 27/07/1998
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

PANADEINE FORTE (Other drug)	Reason:			
	2.0 Dose Unspecif			
Batch:	Started: 01/01/1996	Stoppe	d:	
PROZAC (Other drug)		Reason:		
	60.0 Milligram	Daily		
Batch:	Started: 01/01/1996	Stoppe	d:	
VALIUM (Other drug)		Reason:		
	60.0 Milligram	Daily		
Batch:	Started: 01/01/1996	Stoppe	d:	
RISPERIDONE (Suspected)		Reason:		
	8.0 Milligram	Daily		
Batch:	Started: 21/07/1998	Stoppe	d: 27/07/1998	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 219 of 554



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

Re	ро	rt I	Det	tail	ls:
----	----	------	-----	------	-----

Case Number: 129853 Seq: 1 Gender: F
Reported: 03/08/1998 Weight:
Hospitalisation: Age: 32Y

Onset Date: 28/01/1998 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea			
Galactorrhoea			
Hyperprolactinaemia			

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 220 of 554



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

Report Details:

 Case Number:
 130287
 Seq: 1
 Gender:
 F

 Reported:
 17/08/1998
 Weight:

Hospitalisation: Admitted to hospital Age: 37Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality certain

Reaction Details:

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

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

4.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 221 of 554



DOB:

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

Report Details:

Case Number: 130655 Seq: 1 Gender: F

Reported: 31/08/1998 Weight:
Hospitalisation: Age: 31Y

Outcome: Recovered Causality: Causality possible

Reaction Details:

Onset Date:

Preferred Term	Severity	Report Description	Treatment
Mania			Zoloft ceased

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 222 of 554



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

Report Details:

 Case Number:
 130794
 Seq: 1
 Gender: M

 Reported:
 02/09/1998
 Weight:

Hospitalisation: Age: 77

Onset Date: 24/06/1998 **DOB**: 06/09/1920

Outcome: Recovered Causality: Causality probable

Reaction Details:

,	caction Details.				
	Preferred Term	Severity	Report Description	Treatment	
	Coordination abnormal				
	Extrapyramidal disorder			Risperidone ceased.	l

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:03AM Database: pusime02 ADRS004 Page 223 of 554



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

Report Details	s:						
Case Number:	130794	Seq: 1				Gender:	M
Reported:	02/09/1998					Weight:	
Hospitalisation:						Age:	77
Onset Date:	24/06/1998					DOB:	06/09/1920
	Recovered					Causality:	Causality probable
Reaction Detai	ls:						
Medicine Deta	ails:						
RISPERDAL (Susp	pected)				Reason:	Unspecified psychosis	
			500.0	Microgram	Daily		
			000.0	Microgram	Daliy		
Batch:		Start		Wildrogram	Daily	Stopped:	2M
Batch:				- Wilding and	Daily	Stopped:	2M
Batch:				- Wild Ogram	Daily	Stopped:	2M
Batch:				Microgram	Daily	Stopped:	2M
Batch:				Miorogram	Daily	Stopped:	2M
Batch:				Mioregram	Daily	Stopped:	2M
Batch:				Microgram	Daily	Stopped:	2M
Batch:				Mioregram	Daily	Stopped:	2M
Batch:				- Mioregram	Daily	Stopped:	2M
				Mioregram	Daily	Stopped:	2M
Batch:	vestigations:			- Wild or Grant	Daily	Stopped:	2M
	vestigations:			Mioregram	Daily	Stopped:	2M
	vestigations:			- Mioregram	Daily	Stopped:	2M
	vestigations:			Mioregram	Daily	Stopped:	2M
	vestigations:				Daily	Stopped:	2M
	vestigations:				Daily	Stopped:	2M
	vestigations:				Daily	Stopped:	2M
Laboratory In					Daily	Stopped:	2M
Laboratory In	formation:	Start	ed:				
Laboratory In Additional Inf	formation:	Start	ed:	start occur	red sometim	Stopped:	

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 224 of 554



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

Report Details:

 Case Number:
 130823
 Seq: 1
 Gender: M

 Reported:
 04/09/1998
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 18/05/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

TEMAZEPAM (Other drug)		Reason:	
Oral application	20.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped:	CONTIN
PARACETAMOL (Other drug)		Reason: Headache	
Oral application	4.0 Gram	As necessary	Oral
Batch:	Started:	Stopped:	CONTIN
CHLORPROMAZINE HYDROCHLORIDE (Of	ther drug)	Reason: Schizophrenia	1
Oral application	125.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
RISPERDAL (Suspected)		Reason: Schizophrenia	1
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 27/02/1998	Stopped:	17/06/1998

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 225 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

	eq: 1			Gender:	
04/09/1998				Weight:	
Admitted to hospital				Age:	32Y
18/05/1998				DOB:	
Not yet recovered			С	ausality:	Causality possible
ls:					
ROCHLORIDE (Suspect			Depression		
		Daily			
	Started: 18/05/1998		Stopped:	17/06/1998	
vestigations:					
vestigations: ormation:					
	18/05/1998 Not yet recovered Is:	18/05/1998 Not yet recovered Is:	18/05/1998 Not yet recovered Is: ails: ROCHLORIDE (Suspected) Solve Milligram Reason: Daily	Not yet recovered C Is: Ails: ROCHLORIDE (Suspected) Solve Milligram Reason: Depression Daily	18/05/1998 DOB: Not yet recovered Causality: Is: Ails: ROCHLORIDE (Suspected) Reason: Depression 50.0 Milligram Daily Oral

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 226 of 554



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

Report Details:

Case Number: 130921 Seq: 1 Gender: M

Reported: 08/09/1998 Weight: 76.00 Hospitalisation: Age: 65Y

Onset Date: 12/08/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Neuroleptic malignant syndrome			
Tremor			

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine				Ck - 1960

Additional Information:

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

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 227 of 554



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

Repo	ort.	Deta	ile.
IZEDI	<i>-</i>		1115.

Case Number: 131013 Seq: 1 Gender: M

Reported: 04/09/1998 Weight: 68.00 Hospitalisation: Age: 34Y

Onset Date: 29/07/1998 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

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

Medicine Details:

RISPERIDONE (Suspected) Reason:

2.0 Milligram Daily

Batch: Started: 27/07/1998 **Stopped:** 28/07/1998

RISPERIDONE (Suspected) Reason:

4.0 Milligram Daily

Batch: Started: 29/07/1998 **Stopped:** 31/07/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 228 of 554



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

Report Details:

Case Number: 131143 Seq: 1 Gender: M
Reported: 11/09/1998 Weight:
Hospitalisation: Age: 35Y

Onset Date: 01/06/1998 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	teaction Betails.			
	Preferred Term	Severity	Report Description	Treatment
	Orthostatic hypotension		110/80 bp	
	Tachycardia			

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 229 of 554



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

Report Details:

 Case Number:
 131328
 Seq: 1
 Gender: M

 Reported:
 16/09/1998
 Weight:
 60.00

 Hospitalisation:
 Age: 77Y

Onset Date: 01/09/1998 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 230 of 554



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

Report Details:

Case Number: 131328 Seq: 1 Gender: M

 Reported:
 16/09/1998
 Weight:
 60.00

 Hospitalisation:
 Age:
 77Y

 Onset Date:
 01/09/1998
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 231 of 554



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

Report Details:

Case Number: 131328 Seq: 1 Gender: M

 Reported:
 16/09/1998
 Weight:
 60.00

 Hospitalisation:
 Age:
 77Y

 Onset Date:
 01/09/1998
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 232 of 554



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

Report Details:

Case Number: 131328 Seq: 1 Gender: M

 Reported:
 16/09/1998
 Weight:
 60.00

 Hospitalisation:
 Age:
 77Y

 Onset Date:
 01/09/1998
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 233 of 554



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

Report Details:

Case Number: 131458 Seq: 1 Gender: F

Reported: 23/09/1998 Weight: 59.00 Hospitalisation: Age: 27

Onset Date: 16/09/1998 **DOB**: 14/08/1971

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

Oral application 2.0 Milligram Daily Oral

Batch: Started: 12/09/1998 **Stopped:** 18/09/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient allergy to aspirin.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 234 of 554



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

Report Details:

Case Number: 131598 Seq: 1 Gender: F

Reported: 30/09/1998 Weight: 52.00 Hospitalisation: Age: 71Y

Onset Date: 31/12/1998 **DOB:**

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

i toaction Botano.			
Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			
Hypertonia			

Medicine Details:

RISPERIDONE (Suspected) Reason: Nervousness

3.0 Milligram Daily

Batch: Started: 09/12/1997 **Stopped:** 03/09/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 235 of 554



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

Re	por	t D	etai	ils:
	Ρ-			

Case Number: 131713 Seq: 1 Gender: M

Reported: 28/09/1998 Weight: 76.00 Hospitalisation: Age: 21

Onset Date: 08/09/1998 **DOB**: 26/04/1977

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

4.0 Milligram Daily

Batch: Started: 31/08/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 236 of 554



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

Report Details:

Case Number: 131934 Seq: 1 Gender: M
Reported: 12/10/1998 Weight:

Hospitalisation: Age: 36

Onset Date: 15/06/1997 **DOB**: 08/10/1960

Outcome: Recovered Causality: Causality probable

Reaction Details:

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

Medicine Details:

RISPERDAL (Suspected)

Tablet

5.0 Milligram
Daily
Oral

Batch:
Started: 15/03/1997
Stopped: 15/07/1997

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 237 of 554



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

Re	port	Deta	ails:
----	------	------	-------

 Case Number:
 131982
 Seq: 1
 Gender:
 F

 Reported:
 13/10/1998
 Weight:

Hospitalisation: Age: 13Y
Onset Date: 26/08/1998
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 238 of 554



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

Reported: 15 ospitalisation: Onset Date: 16 Outcome: Ur	5/09/1998 nknown	Seq	: 1		c	Gender: F Weight: Age: 71 DOB: 08/02/1927 causality: Causality possible
Preferred		Se	everity	Repo	ort Description	Treatment
Dystonia				rozen state	, , , , , ,	Cogentin 2mg imi given on 11/09/98 pt felt better. risperidone reduced on 21/09/98 to 1mg at night.
ledicine Detail:	s:					
FAMOTIDINE (Other d	lrug)			Reas	son:	
		_	40.0 M	_	Daily	
						CONTINI
Batch:	drug)	S	Started:	S TERM	Stopped:	CONTIN
	drug)	S		Reas	son:	CONTIN
SALBUTAMOL (Other	drug)	_	30.0 M	Reas	son: Daily	
SALBUTAMOL (Other Batch:		s		Reas	son: Daily Stopped:	CONTIN
SALBUTAMOL (Other Batch:		s	30.0 M	Reas Iilligram S TERM Reas	Son: Daily Stopped:	
SALBUTAMOL (Other Batch: GLYCERYL TRINITRA		s J)	30.0 M	Reas Iilligram S TERM Reas	son: Daily Stopped:	CONTIN
SALBUTAMOL (Other Batch: GLYCERYL TRINITRA Cream Batch:	TE (Other drug	s J)	30.0 M Started: 50.0 M	Reas Iilligram S TERM Reas Iilligram	Son: Daily Stopped: Daily Daily Stopped:	CONTIN Transdermal
SALBUTAMOL (Other Batch: GLYCERYL TRINITRA Cream	TE (Other drug	s J)	30.0 M Started: 50.0 M	Reas Iiilligram S TERM Reas Iiilligram S TERM Reas	Son: Daily Stopped: Daily Daily Stopped:	CONTIN
SALBUTAMOL (Other Batch: GLYCERYL TRINITRA Cream Batch:	TE (Other drug	s 3) S	30.0 M Started: 50.0 M Started:	Reas Iiilligram S TERM Reas Iiilligram S TERM Reas	Son: Daily Stopped: Son: Daily Stopped: Son:	CONTIN Transdermal
Batch: Batch: GLYCERYL TRINITRA Cream Batch: SODIUM BICARBONA Batch:	TE (Other drug	s (3) (3) (3)	30.0 M Started: 50.0 M Started: 40.0 M	Reas S TERM Reas Iiilligram S TERM Reas Reas Iiilligram	Son: Daily Stopped: Son: Daily Stopped: Son: Daily Stopped:	CONTIN Transdermal CONTIN
SALBUTAMOL (Other Batch: GLYCERYL TRINITRA Cream Batch: SODIUM BICARBONA	TE (Other drug	s (3) (3) (3)	30.0 M Started: 50.0 M Started: 40.0 M	Reas Iiilligram S TERM Reas Iiilligram S TERM Reas Iiilligram S TERM Reas Iiillilitre S TERM	Son: Daily Stopped: Son: Daily Stopped: Son: Daily Stopped:	CONTIN Transdermal CONTIN

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 239 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number:	131992	Seq: 1				Gender:	F	
Reported:	15/10/1998					Weight:		
Hospitalisation:						Age:	71	
Onset Date:	16/09/1998					DOB:	08/02/1927	
Outcome:	Unknown				С	ausality:	Causality possible	е
Reaction Detai	ils:							
Marilla Dat	- 11 -							
Medicine Det			Reas	2001	Constipation			
SORBILAX (Other	arug)	40.0	Millilitre	Daily	Constipation			
Batch:		Started:	S TERM	Dally	Stopped:		CONTIN	
SENOKOT (Other	drug)	Starteu.	Reas	on:	Constipation		CONTIN	
Oral applic		2.0	Dose Unspecified		Constipation	Oral		
Batch:	auon	Started:	S TERM	Daily	Stopped:	Olai	CONTIN	
RISPERIDONE (Su	isnected)	Starteu.	Reas	son:	эторрец.		CONTIN	
THOI ENDONE (OF	aspected,	20	Milligram	Daily				
Batch:		Started:	S TERM	Daily	Stopped:			
Duton.		Otarica.	O TERM		оторреа.			
Laboratory In	vestigations:							
A 1 11/41 1 1 1								
Additional Inf	formation:							

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 240 of 554



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

Report Details:

Case Number: 132117 Seq: 1 Gender: F
Reported: 19/10/1998 Weight:
Hospitalisation: Age: 38Y

Onset Date: 06/10/1998 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

Pt currently has a urinary tract infection

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 241 of 554



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

Report Details:

 Case Number:
 132117
 Seq: 1
 Gender:
 F

 Reported:
 19/10/1998
 Weight:

Hospitalisation: Age: 38Y
Onset Date: 06/10/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

LARGACTIL (Suspected)

Reason: Otr spec symp psychopathol nec

100.0 Milligram As necessary

Batch: **Started**: 26/09/1998 **Stopped**: 06/10/1998

RISPERDAL (Suspected) Reason: Manic-depression psycho,manic

 Tablet
 2.0
 Milligram
 Daily
 Oral

 Batch:
 Started: 26/09/1998
 Stopped: 07/10/1998

Laboratory Investigations:

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

Additional Information:

Pt currently has a urinary tract infection

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 242 of 554



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

Report Details:

 Case Number:
 132117
 Seq: 1
 Gender:
 F

 Reported:
 19/10/1998
 Weight:

Hospitalisation: Age: 38Y
Onset Date: 06/10/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ		SAP = ALP		08/10/1998	143	
ı		SAP = ALP		14/10/1998	118	

Additional Information:

Pt currently has a urinary tract infection

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 243 of 554



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

Report Details:			
Case Number: 132117 Reported: 19/10/1998 Hospitalisation: Onset Date: 06/10/1998 Outcome: Not yet recovered Reaction Details:	Seq: 1	V	Gender: F Veight: Age: 38Y DOB: usality: Causality possible
Medicine Details: LARGACTIL (Suspected)	100.0 Milligram	Reason: Otr spec symp p As necessary	sychopathol nec
Batch:	Started: 26/09/1998	Stopped: 0	6/10/1998
RISPERDAL (Suspected)		Reason: Manic-depression	
Tablet Batch:	2.0 Milligram Started: 26/09/1998	Daily C)ral
Laboratory Investigations:			
Additional Information: Pt currently has a urinary tract infection			

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 244 of 554



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

Report Details:

 Case Number:
 132315
 Seq: 1
 Gender:
 F

 Reported:
 22/10/1998
 Weight:

Hospitalisation: Age: 36

Onset Date: 15/04/1998 **DOB**: 16/02/1962

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	todotion Details.			
	Preferred Term	Severity	Report Description	Treatment
	Amenorrhoea			
	Hyperprolactinaemia			

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

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

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 245 of 554



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

Report Details:

 Case Number:
 132398
 Seq: 1
 Gender:
 F

 Reported:
 29/10/1998
 Weight:

Hospitalisation: Age: 37Y
Onset Date: 06/10/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

See original report for more drugs.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 246 of 554



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

Report Details:

 Case Number:
 132398
 Seq: 1
 Gender:
 F

 Reported:
 29/10/1998
 Weight:

Hospitalisation:
Onset Date: 06/10/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecifid affective psychosis

 Tablet
 2.0 Milligram
 Daily
 Oral

 Batch:
 Started: 26/09/1998
 Stopped: 07/10/1998

Laboratory Investigations:

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

Additional Information:

See original report for more drugs.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 247 of 554



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

Report Details:

 Case Number:
 132398
 Seq: 1
 Gender:
 F

 Reported:
 29/10/1998
 Weight:

Hospitalisation:
Onset Date: 06/10/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

See original report for more drugs.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 248 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

	132398	Seq: 1			Gender:	
Reported: 2					Weight:	
spitalisation:					Age:	37Y
Onset Date:	06/10/1998				DOB:	
	Not yet recovered			С		Causality possible
action Detail					-	
ledicine Deta	ils:					
RISPERIDONE (Sus			Reason:	Unspecifid affe	ective psycho	osis
Tablet		2.0 Milligram	Daily		Oral	
Batch:		Started: 26/09/1998		Stopped:	07/10/1998	}
aboratory Inv	vestigations:					
aboratory Inv	vestigations:					
aboratory Inv	vestigations:					
aboratory Inv	vestigations:					
aboratory Inv	vestigations:					
aboratory Inv	vestigations:					
aboratory Inv	vestigations:					
aboratory Inv	vestigations:					
additional Info	ormation:					
additional Info	ormation:					
aboratory Inv	ormation:					
dditional Info	ormation:					

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 249 of 554



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

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

Case Number: 132914 Seq: 1 Gender: M

Reported: 06/11/1998 Weight:
Hospitalisation: Age: 76Y
Onset Date: 03/11/1998 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Urticaria		Raised red whelts on back & thighs for 2 days	Risperidone ceased

Medicine Details:

LARGACTIL (Other drug)		Reason:	Otr spec symp psychopathol ned	
	1.0 Dos	e Unspecified As ne	ecessary	
Batch:	Started: 29/10/19	998	Stopped:	
MADOPAR M (Other drug)		Reason:	Paralysis agitans	
Oral application	4.0 Dos	e Unspecified Daily	Oral	
Batch:	Started:		Stopped:	
ATROMID-S (Other drug)		Reason:		
Oral application	1.0 Gra	m Daily	Oral	
Batch:	Started:		Stopped:	
ZYLOPRIM (Other drug)		Reason:	Gout	
	300.0 Milli	gram Daily		
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 250 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

	132914	Seq: 1			Gende	
	06/11/1998				Weight	
Hospitalisation:	00/44/4000					: 76Y
Onset Date:	Recovered				DOI	
Cutcome. Reaction Detai					Causant	: Causality probable
Reaction Detai	15.					
Medicine Deta	ails:					
ZOCOR (Other dru			Re	ason:		
			.0 Dose Unspecified	Daily		
Batch:		Started:			Stopped:	
RISPERIDONE (Su	spected)			ason:		
			.0 Milligram	Daily	• • • • • • • • • • • • • • • • • • • •	
Batch:		Started:	29/10/1998		Stopped: 03/11/19	98
Laboratory In	voetigations:					
Laboratory In	vestigations:					
Laboratory In	vestigations:					
Laboratory In	vestigations:					
Laboratory In	vestigations:					
Laboratory In	vestigations:					
Laboratory In	vestigations:					
Laboratory In	vestigations:					
Laboratory In						

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 251 of 554



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

Report Details:

Case Number: 132918 Seq: 1 Gender: M

Reported: 02/11/1998 **Weight:**

Hospitalisation: Age: 77Y
Onset Date: 21/08/1998
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
Ne	uroleptic malignant syndrome			Risperdal ceased

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Principal diagnosis: extrapyranudal disorder

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 252 of 554



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

Report Details:

Case Number:133033Seq: 1Gender: MReported:02/11/1998Weight:Hospitalisation:Admitted to hospitalAge: 39

Onset Date: 19/10/1998 DOB: 27/12/1958

Outcome: Unknown Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 253 of 554



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

Report Details:

 Case Number:
 133033
 Seq: 1
 Gender: M

 Reported:
 02/11/1998
 Weight:

Hospitalisation: Admitted to hospital Age: 39

Onset Date: 19/10/1998 **DOB**: 27/12/1958

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)Reason:Unspecified schizophreniaTablet700.0MilligramDailyOralBatch:Started: 14/08/1996Stopped: 19/10/1998

Laboratory Investigations:

<u>Laborato</u>	i y ilittootiga				
Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		22/10/1998	1.01	
	Platelets		22/10/1998	275	
	Platelets		25/11/1998	21	
	White blood cells		03/07/1998	9.6	
	White blood cells		19/10/1998	1.0	
	White blood cells		22/10/1998	1.2	
	White blood cells		25/11/1998	2.1	

Additional Information:

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 254 of 554



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

Report Details:

Case Number: 133135 Seq: 1 Gender: M
Reported: 12/11/1998 Weight:
Hospitalisation: Age: 68Y

Onset Date: 17/10/1998 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

All drugs started on admission

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 255 of 554



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

Case Number: 133135 Seq: 1 Gender: M		etails:						
Age: 68Y DOB:			-	: 1				М
Causality Caus	_		98				=	
Outcome: Not yet recovered caction Details: Medicine Details: SALBUTAMOL (Other drug) Reason: Inhalation 800.0 Milligram Daily Inhalation Batch: Started: Stopped: METFORMIN HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: GLICLAZIDE (Other drug) Reason: 320.0 Milligram Daily Stopped: GLICLAZIDE (Other drug) Reason: 320.0 Milligram Daily Stopped: LITHIUM CARBONATE (Other drug) Reason: 500.0 Milligram Daily Stopped: LITHIUM CARBONATE (Other drug) Reason: 500.0 Milligram Daily Stopped: LITHIUM CARBONATE (Other drug) Reason: 500.0 Milligram Daily Stopped: LITHIUM CARBONATE (Other drug) Reason: 500.0 Milligram Daily Stopped: LITHIUM CARBONATE (Other drug) Reason: 500.0 Milligram Daily Stopped: LITHIUM CARBONATE (Other drug) Reason: 500.0 Milligram Daily Stopped:	-						_	
Paction Details: Foliable Pacific Pacif								
Reason:		=	ecovered				Causality:	Causality possible
Neason:	action D	Details:						
SALBUTAMOL (Other drug) Reason: Inhalation 800.0 Milligram Daily Inhalation Batch: Started: Stopped: Batch: Started: Stopped: GLICLAZIDE (Other drug) Reason: 320.0 Milligram Daily Batch: Started: Stopped: LITHIUM CARBONATE (Other drug) Reason:								
SALBUTAMOL (Other drug) Reason: Inhalation 800.0 Milligram Daily Inhalation Batch: Started: Stopped: Batch: Started: Stopped: GLICLAZIDE (Other drug) Reason: 320.0 Milligram Daily Batch: Started: Stopped: LITHIUM CARBONATE (Other drug) Reason:								
Neason:								
Neason:								
SALBUTAMOL (Other drug) Reason: Inhalation 800.0 Milligram Daily Inhalation Batch: Started: Stopped: Batch: Started: Stopped: GLICLAZIDE (Other drug) Reason: 320.0 Milligram Daily Batch: Started: Stopped: LITHIUM CARBONATE (Other drug) Reason:								
SALBUTAMOL (Other drug) Reason: Inhalation 800.0 Milligram Daily Inhalation Batch: Started: Stopped: Batch: Started: Stopped: GLICLAZIDE (Other drug) Reason: Batch: Started: Stopped: LITHIUM CARBONATE (Other drug) Reason: 500.0 Milligram Daily Batch: Stopped: Batch: Started: Stopped: LDH Date Tested Result Details								
SALBUTAMOL (Other drug) Reason: Inhalation 800.0 Milligram Daily Inhalation Batch: Started: Stopped: Batch: Started: Stopped: GLICLAZIDE (Other drug) Reason: 320.0 Milligram Daily Batch: Started: Stopped: LITHIUM CARBONATE (Other drug) Reason:	/ledicine	Dotaile:						
Inhalation					Rea	son:		
Batch: Started: Stopped: METFORMIN HYDROCHLORIDE (Other drug) Reason: Batch: Started: Stopped: GLICLAZIDE (Other drug) Reason: Batch: Started: Stopped: LITHIUM CARBONATE (Other drug) Reason: 500.0 Milligram Daily Batch: Stopped: Batch: Stopped: Daily Batch: Stopped: Batch: Stopped:				800.0 M	illigram	Daily	Inhalation	
Reason:	Bato	ch:	S		Ü	,		
Started: Stopped:	METFORMIN	N HYDROCHLORIE	DE (Other drug)		Rea	son:		
Started: Stopped:				1.0 G	ram	Daily		
Started: Stopped:	Bato	ch:	S	Started:			Stopped:	
Batch: Started: Stopped: LITHIUM CARBONATE (Other drug) Reason: 500.0 Milligram Daily Batch: Stopped: .aboratory Investigations: Date Type Range Date Tested Result Details LDH 19/10/1998 268	GLICLAZIDE	(Other drug)			Rea	son:		
Reason:				320.0 M	illigram	Daily		
Started: Stopped:	Bato	ch:	S	started:			Stopped:	
Batch: Started: Stopped: .aboratory Investigations:	LITHIUM CA	RBONATE (Other	drug)		Rea	son:		
.aboratory Investigations: Date Type Range Date Tested Result Details LDH 19/10/1998 268				500.0 M	illigram	Daily		
Date Type Range Date Tested Result Details LDH 19/10/1998 268	2							
LDH 19/10/1998 268		ch:	s				Stopped:	
	Bato						Stopped:	
White blood cells 17/10/1998 16.1	Bato aborato	ry Investiga Type	tions:	Started: Date Tested				s
	Bato _aborato	ry Investiga Type	tions:	Started: Date Tested				is .
	Bato _aborato Date	ry Investiga Type LDH	tions:	Date Tested 19/10/1998	268			's
	Bato _aborato Date	ry Investiga Type LDH	tions:	Date Tested 19/10/1998	268			S
	Bato _aborato Date	ry Investiga Type LDH	tions:	Date Tested 19/10/1998	268			S
	Bato _aborato Date	ry Investiga Type LDH	tions:	Date Tested 19/10/1998	268			S
Additional Information:	Bato _aborato Date	ry Investiga Type LDH White blood cells	tions: Range	Date Tested 19/10/1998	268			S
Additional Information: All drugs started on admission	Bate Date	ry Investiga Type LDH White blood cells	tions: Range	Date Tested 19/10/1998	268			S
	Bate Date	ry Investiga Type LDH White blood cells	tions: Range	Date Tested 19/10/1998	268			S

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 256 of 554



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Hospitalisation: Onset Date: Outcome: Reaction Detai	12/11/1998 17/10/1998 Not yet recovered Is:	Seq: 1		Gender: Weight: Age: DOB: Causality:	68Y
Medicine Deta			D		
RISPERIDONE (Su	spectea)	1.0 Milligram	Reason: Daily		
Batch:		Started:	Bully	Stopped: 14/10/1998	3
Laboratory In	vestigations:				
Additional Inf All drugs started or					

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 257 of 554



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

Report Details:

 Case Number:
 133231
 Seq: 1
 Gender: M

 Reported:
 13/11/1998
 Weight:

Hospitalisation: Age: 30

Onset Date: 31/07/1997 **DOB**: 16/05/1967

Outcome: Unknown Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	n Severity	Report Description	Treatment
Hypertonia		Increased muscle tone	
Chest pain			
Hyperkinesia			Ceased risperidone

Medicine Details:

RISPERIDONE (Suspected) Reason: Schizophrenia

0.0

Batch: Started: Stopped: 28/07/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 258 of 554



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

Report Details:

Case Number: 133295 Seq: 1 Gender: M

Reported: 18/11/1998 Weight: 75.00 Hospitalisation: Age: 33Y

Onset Date: 23/10/1998 **DOB**:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction		Sexual dysfunction	

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	Unspecific affective psychosis	
Tablet	750.0 Milligram	Daily	/ Oral	
Batch:	Started: 23/10/1998		Stopped: 25/10/1998	
RISPERDAL (Suspected)		Reason:	Unspecifid affective psychosis	

Tablet 2.0 Milligram Daily Oral

Batch: Started: 13/10/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 259 of 554



Case Number: 133522

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

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

Seq: 1

Reported: 20/11/1998	8 Weight:				
ospitalisation:			Age : 78Y		
Onset Date: 09/10/1998				OB:	
Outcome: Recovered			Causal	ity: Causality probable	
eaction Details:					
Preferred Term	Severity	Report Des	cription	Treatment	
elusion					
Extrapyramidal disorder					
Paranoia				Ceased risperidone.	
Psychotic disorder					
Madiaina Dataila:					
Medicine Details: TENOPT (Other drug)		Reason:			
Eye Drops	2.0 Γ	Dose Unspecified Daily	Ophth	almic	
Batch:	Started:	,	Stopped:	CONTIN	
RISPERIDONE (Suspected)		Reason:	• •		
	1.0 N	/lilligram Daily			
Batch:	Started: 01/10	0/1998	Stopped: 09/10/	1998	
	S: Range Date Tester	d Result		Details	
_aboratory Investigation Date Type I		d Result	[Details	
Additional Information:					
port Run: 04/06/2007 11:04AM D	atabase: pusime02	ADRS004	1	Page 260 of 55	



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

Report Details:

Case Number: 133574 Seq: 1 Gender: F
Reported: 23/11/1998 Weight:

Hospitalisation: Age: 16Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	<u> </u>			1
	Preferred Term	Severity	Report Description	Treatment
	Micturition disorder		Urinary urgency	Zoloft was discontinued.
	Urinary incontinence			

Medicine Details:

Medicine Details.			
ZOLOFT (Suspected)		Reason: Schizo-affective type psychos	
Tablet	50.0 Milligram	Daily Oral	
Batch:	Started:	Stopped: 28/11/1998	
RISPERDAL (Suspected)		Reason: Schizo-affective type psychos	
Tablet	3.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient with schizo-affective disorder for 1 year. no other cause of her urinary symptoms could be identified. no urinary infection was found. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 261 of 554



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

Report Details:

Case Number: 133629 Seq: 1 Gender: M

Reported: 23/11/1998 Weight: 75.00 Hospitalisation: Age: 50Y

Onset Date: 31/08/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•								
	Preferred Term	Severity	Report Description	Treatment				
	Thrombosis mesenteric vessel			Operaton and small bowel resection.				

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified psychosis

0.0

Batch: Started: 01/01/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 262 of 554



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

Report Details:

Case Number: 133659 Seq: 1 Gender: F

Reported: 24/11/1998 Weight: 64.00
Hospitalisation: Age: 33Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

caction betains.								
Preferred Term	Severity	Report Description	Treatment					
Amenorrhoea								
Hyperprolactinaemia								

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug) Reason: Depression

100.0 Milligram Daily

Batch: Started: L TERM Stopped:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

8.0 Milligram Daily

Batch: Started: L TERM Stopped:

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
I		Biochemistry				Prolactin 4000 ml/l.
Histology Microadenoma of pituritary gland.		Microadenoma of pituritary gland.				

Additional Information:

Sequalae: patient has reduced bone density.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 263 of 554



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

case Number. 13370	•			iender. F
Reported: 27/11	/1998		W	/eight:
spitalisation:				Age: 40Y
Onset Date:				DOB:
Outcome: Unkno	own		Caı	usality: Causality possible
action Details:				
Preferred Terr	n Sever		Report Description	Treatment
enstrual disorder		Menstrual dis	sturbances.	
edicine Details:	1)	0.0	Reason:	
Batch:	Starte		Stopped:	
aboratory Investi	nations:			
Date Type		ite Tested Result		Details
Additional Informa	tion:			
port Run : 04/06/2007 11:	04AM Datahase: nusim	e02	ADRS004	Page 264 of 55/

ADRS004 Page 264 of 554



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

Report Details:

 Case Number:
 133822
 Seq: 1
 Gender: F

 Reported:
 30/11/1998
 Weight:

Hospitalisation: Age: 38Y
Onset Date: 13/10/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

	todotion Botano.			
	Preferred Term	Severity	Report Description	Treatment
	Pruritus		Itching on the arm and thighs.	
Rash		Rash and general redness on the arm and thighs.		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Uns	pecified psychosis	
Tablet	4.0 Milligram	Daily	Oral	
Batch:	Started: 15/02/1998	5	Stopped: 28/10/1998	8
PHENYTOIN SODIUM (Suspected)		Reason: Othe	er&unspecified epileps	Sy
Oral application	330.0 Milligram	Daily	Oral	
Batch:	Started:	5	Stopped:	CONTIN
VENLAFAXINE HYDROCHLORIDE (Sus	pected)	Reason:		
Tablet	225.0 Milligram	Daily	Oral	
Batch:	Started: 15/03/1998	5	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 265 of 554



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

Reported: 30/11/1998 spitalisation: Onset Date: 15/11/1998 Outcome: Not yet recovered	Seq: 1			c	Gender: Weight: Age: DOB:	12Y
ection Details:	I			· ·	ausanty.	Causanty possible
Preferred Term	Severity	<u> </u>	Report De	scription		Treatment
rinary incontinence		Nocturnal e	enuresis			
edicine Details: RISPERIDONE (Suspected) Tablet	500.0	Microgram	Reason: Daily	Obsessive cor	mpulsive neu Oral	ırosis
Batch:	Started:	Microgram	Dally	Stopped:	Olai	1W
RISPERIDONE (Suspected)	otal tour		Reason:	Alcoholism		
Tablet	1.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:		CONTIN
	I Duk Tu	sted Resu	alt I		Detail	s
_aboratory Investigations: Date Type Rang	ge Date Tes	ica rest	IIL		Detail	
	ge Date Les	iled Resc			Betan	

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 266 of 554



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

Report Details:

Case Number: 133825 Seq: 1 Gender: F

Reported: 30/11/1998 Weight:
Hospitalisation: Age: 17

Open 15 Potes 45/04/4000

Onset Date: 15/01/1998 **DOB**: 25/07/1980

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence			

Medicine Details:

RISPERIDONE (Suspected) Reason: Schizophrenia

Tablet 4.0 Milligram Daily Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms some months after starting risperidone. when risperidone was stopped and replaced by olanzapine, symptoms continued. it also continued when risperidone was restarted.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 267 of 554



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

Report Details:

Case Number: 133843 Seq: 1 Gender: F

Reported: 02/12/1998 Weight:
Hospitalisation: Age: 24Y

Onset Date: 15/10/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Dotanoi			
Preferred Term	Severity	Report Description	Treatment
Neurosis			28 oct 97 thioridazine 100mg/day and risperidone gradually discontinued.

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified schizophrenia

8.0 Milligram Daily

Batch: Started: 01/10/1997 **Stopped:** 28/10/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

While the patient was taking risperidone she developed obsessional thoughts and images (no rituals). the risperidone dose varried from 1mg/day to 6mg/day. olanzapine was started jan 98 in addition to thioridazine and was increased gradually to a dose of 20mg/day. olanzapine was ceased 28 sep 98. ocd symptons also occurred during olanzapine treatment. periciazine was started once olanzapine had been ceased. ssri started 3 weeks ago for ocd symptoms. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 268 of 554



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

Report Details:

 Case Number:
 134007
 Seq: 1
 Gender:
 F

 Reported:
 04/12/1998
 Weight:
 88.00

Hospitalisation: Age: 71Y
Onset Date: 11/06/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lichenoid keratosis			
Oedema peripheral			
Weight increased			Ceased risperidone

Medicine Details:

ASPIRIN (Other drug)		Rea	son:		
Tablet	0.5	Dose Unspecified	Daily	Oral	
Batch:	Started:	L TERM		Stopped:	
DIGOXIN (Other drug)		Rea	son:		
	125.0	Microgram	Daily		
Batch:	Started:	L TERM		Stopped:	
LASIX (Other drug)		Rea	son:		
LASIX (Other drug)	1.0	Rea Dose Unspecified	son: Daily		
LASIX (Other drug) Batch:	1.0 Started:		Daily	Stopped:	
, ,		Dose Unspecified L TERM	Daily	Stopped:	
Batch:		Dose Unspecified L TERM	Daily	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Ongoing oedema, lichen-planus, weight gain.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 269 of 554



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Hospitalisation: Onset Date: Outcome: Reaction Detai	04/12/1998 11/06/1998 Not yet recovered Is:	Seq: 1		Gender: Weight: Age: DOB: Causality:	88.00 71Y
Medicine Deta			B		
RISPERIDONE (Su	spected)	0.0	Reason:		
Batch:		Started:		Stopped:	
Laboratory In	vestigations:				
Additional Inf Ongoing oedema,	formation: lichen-planus, weigh	nt gain.			

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 270 of 554



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

Reported: 22/ pspitalisation: Onset Date: 08/ Outcome: Re	/12/1998 /12/1998 covered	: 1		С	Gender: Weight: Age: DOB: ausality:	26Y
action Details: Preferred T		everity	Report De	scription		Treatment
Respiratory depressi						
ledicine Details RISPERDAL (Interaction			Reason:	Unspecified ps	svchosis	
Tablet	,	4.0 Millig			Oral	
Batch:	:	Started: 24/09/19		Stopped:		
METHADONE HYDRO	CHLORIDE (Interaction)	Reason:			
Oral Liquid		10.0 Millig	gram Daily		Oral	
Batch:		Started: 04/12/19	98	Stopped:	08/12/1998	3
		Date Tested	Result		Detail	s
Laboratory Inves		Date Tested	Result		Detai	s

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 271 of 554



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

Report Details:

Case Number: 134507 Seq: 1 Gender: F

Reported: 23/12/1998 Weight: 73.00 Hospitalisation: Age: 27Y

Onset Date: 01/12/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

outlion botaile:							
Preferred Term	Severity	Report Description	Treatment				
Pruritus		Ears & neck at hairline & waist, thigh area.					
Urticaria		Including palms, soles of feet & face.					
Angioedema		Severe facial & mild on rest of body.					
Bronchospasm							
Face oedema							

Medicine Details:

<u>Medicine Details.</u>			
RISPERIDONE (Suspected)		Reason: Depression	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 24/11/1998	Stopped:	01/12/1998
ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 27/11/1998	Stopped:	01/12/1998

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Allergic to pethidine. risperidone 2mg po nocte 20/10/98 to 29/10/98 the 1mg nocte till 2/11/98. no previous exposure to zoloft.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 272 of 554



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

•	2/1998	q: 1			Gend Weig		М	
ospitalisation: Adm					_	.ge: 4	13	
Onset Date: 21/1	•					_	01/06/1955	
Outcome: Reco							Causality po	ssible
action Details:								
Preferred Te	erm S	Severity	Repo	ort Des	scription		Treatm	nent
ystonia			Dystonic reactio	n	·	21/1	1/98 benztro	pine(oral)
						then	cogentin (im	ıi)
Chest pain								
yspnoea								
ledicine Details: FOLIC ACID (Other drug			Poo	son:				
OLIC ACID (Other drug)	50 N	Rea ⁄Iilligram	Daily				
		5.0 N	miligram	Dally				
Ratch:		Startod:			Stopped:			
Batch:		Started:	Rea	son:	Stopped:			
				son: Daily	Stopped:			
DILANTIN (Other drug)		400.0 N		son: Daily			CONTIN	
DILANTIN (Other drug) Batch:	TATE (Suspected)		/lilligram		Stopped:	opatho	CONTIN I nec	
DILANTIN (Other drug) Batch:	TATE (Suspected)	400.0 N Started:	/lilligram	Daily	Stopped: Otr spec symp psych	opatho		
DILANTIN (Other drug) Batch:	TATE (Suspected)	400.0 N Started:	Ailligram Rea Aicrogram	Daily	Stopped: Otr spec symp psych	opatho		
DILANTIN (Other drug) Batch: ZUCLOPENTHIXOL ACE Batch:		400.0 M Started:	Ailligram Rea Aicrogram 1/1998	Daily	Stopped: Otr spec symp psych			
DILANTIN (Other drug) Batch: ZUCLOPENTHIXOL ACE		400.0 M Started: 100.0 M Started: 20/11	Ailligram Rea Aicrogram 1/1998	Daily son: 1 time	Stopped: Otr spec symp psych Stopped:			
DILANTIN (Other drug) Batch: ZUCLOPENTHIXOL ACE Batch:	ed)	400.0 M Started: 100.0 M Started: 20/11	Ailligram Rea Aicrogram 1/1998 Rea Ailligram	Daily son: 1 time son:	Stopped: Otr spec symp psych Stopped:			
Batch: Batch: Batch: Batch: Batch: Batch: Batch: Batch: Batch: Batch:	ed)	400.0 M Started: 100.0 M Started: 20/11	Ailligram Rea Aicrogram 1/1998 Rea Ailligram	Daily son: 1 time son:	Stopped: Otr spec symp psych Stopped: Unspecified psychosi			
Batch: Batch: Batch: Batch: Batch: Batch:	ed)	400.0 M Started: 100.0 M Started: 20/11	Ailligram Rea Aicrogram 1/1998 Rea Ailligram 1/1998	Daily son: 1 time son:	Stopped: Otr spec symp psychological Stopped: Unspecified psychosical Stopped:			

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 273 of 554



DOB:

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

Report Details:

Case Number: 134866 Seq: 1 Gender: M

Reported: 06/01/1999

Hospitalisation:

Weight: 96.00
Age: 17Y

Outcome: Recovered Causality: Causality possible

Reaction Details:

Onset Date:

Preferred Term	Severity	Report Description	Treatment
Fatigue		Tiredness	Changed to zyprexa

Medicine Details:

ZOLOFT (Other drug)		R	eason:	Other atyp forms schizophrenia	
	100.0	Milligram	Daily		
Batch:	Started:	L TER	² M	Stopped:	
CLARATYNE (Other drug)		R	eason:		
	1.0	Dose Unspecifie	d Daily		
Batch:	Started:			Stopped:	
RISPERDAL (Suspected)		R	eason:		
	2.0	Milligram	Daily		
Batch:	Started: 01	/02/1997		Stopped: 10/12/1998	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 274 of 554



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

Re	port	Detail	ls:
----	------	--------	-----

 Case Number:
 134974
 Seq: 1
 Gender:
 F

 Reported:
 07/01/1999
 Weight:

Hospitalisation:
Onset Date: 08/12/1998
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Respiratory depression			

Medicine Details:

METOCLOPRAMIDE HYDROCHLORIDE (Suspected) Reason:

0.0

Batch: Started: Stopped:

NALTREXONE HYDROCHLORIDE (Suspected) Reason:

0.0

Batch: Started: Stopped:

RISPERDAL (Suspected) Reason: Unspecified psychosis

4.0 Milligram Daily

Batch: Started: 01/08/1998 Stopped: CONTIN

METHADONE HYDROCHLORIDE (Suspected) Reason:

10.0 Milligram Daily

Batch: Started: 04/12/1998 **Stopped:** 08/12/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details	
	Pharmacokinetics				Urinary drug screen collected of dec 98=methadone, metoclopramide and naltre- xone.	

Additional Information:

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

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 275 of 554



DOB:

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

Report Details:

Case Number: 135206 Seq: 1 Gender: F

 Reported:
 18/01/1999
 Weight:
 64.00

 Hospitalisation:
 Age:
 50Y

Outcome: Unknown Causality: Causality possible

Reaction Details:

Onset Date:

Preferred Term	Severity	Report Description	Treatment
Weight increased		14kg gained in 18/12.	

Medicine Details:

Micalcinic Details.			
NORMISON (Other drug)		Reason: Specific disorders of sleep	
Tablet	5.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 01/06/1997	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 276 of 554



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

	Seq: 1			Gender: F
Reported: 01/02/199	99		,	Weight:
ospitalisation:				Age: 81Y
Onset Date: 22/12/199	98			DOB:
Outcome: Recovere	ed		Ca	ausality: Causality possible
action Details:				
Preferred Term	Severity	Rep	ort Description	Treatment
ravitational oedema		Bilateral leg oe	dema	Ceased respiridone and kefle
ash				
edicine Details:				
VARFARIN SODIUM (Other dr			ason:	
Batch:	0. Started:	0	Stopped:	
DESTRADIOL (Other drug)	Otartea.	Re	ason:	
LOTINADIOL (Other drug)				
-	0		u3011.	
	0. Started:			
Batch:	0. Started:	0	Stopped:	
Batch:	Started:	0 Re	Stopped:	
Batch: AMLODIPINE (Other drug)	Started:	0	Stopped: ason: Daily	
Batch: AMLODIPINE (Other drug) Batch:	Started:	0 Re 0 Milligram	Stopped: ason: Daily Stopped:	
Batch: AMLODIPINE (Other drug) Batch:	Started: 10. Started:	0 Re 0 Milligram	Stopped: ason: Daily Stopped:	
Batch: AMLODIPINE (Other drug) Batch: CALTRATE (Other drug)	Started: 10. Started: 3.	0 Re 0 Milligram	Stopped: ason: Daily Stopped: ason: Daily	
Batch: AMLODIPINE (Other drug) Batch: CALTRATE (Other drug) Batch:	Started: 10. Started: 3. Started:	0 Re 0 Milligram	Stopped: ason: Daily Stopped:	
Batch: AMLODIPINE (Other drug) Batch: CALTRATE (Other drug) Batch: aboratory Investigat	Started: 10. Started: 3. Started:	Re 0 Milligram Re 0 Dose Unspecified	Stopped: ason: Daily Stopped: ason: Daily	Dotoilo
Batch: AMLODIPINE (Other drug) Batch: CALTRATE (Other drug) Batch:	Started: 10. Started: 3. Started:	Re 0 Milligram Re 0 Dose Unspecified	Stopped: ason: Daily Stopped: ason: Daily	
Batch: AMLODIPINE (Other drug) Batch: CALTRATE (Other drug) Batch:	Started: 10. Started: 3. Started:	Re 0 Milligram Re 0 Dose Unspecified	Stopped: ason: Daily Stopped: ason: Daily	Details
Batch: AMLODIPINE (Other drug) Batch: CALTRATE (Other drug) Batch: aboratory investigat	Started: 10. Started: 3. Started:	Re 0 Milligram Re 0 Dose Unspecified	Stopped: ason: Daily Stopped: ason: Daily	Details
Batch: AMLODIPINE (Other drug) Batch: CALTRATE (Other drug) Batch: aboratory investigat	Started: 10. Started: 3. Started:	Re 0 Milligram Re 0 Dose Unspecified	Stopped: ason: Daily Stopped: ason: Daily	Details
Batch: AMLODIPINE (Other drug) Batch: CALTRATE (Other drug) Batch: aboratory Investigat	Started: 10. Started: 3. Started:	Re 0 Milligram Re 0 Dose Unspecified	Stopped: ason: Daily Stopped: ason: Daily	Details
Batch: AMLODIPINE (Other drug) Batch: CALTRATE (Other drug) Batch: aboratory Investigat Date Type	Started: 10. Started: 3. Started: tions: Range Date To	Re 0 Milligram Re 0 Dose Unspecified	Stopped: ason: Daily Stopped: ason: Daily	Details
Batch: AMLODIPINE (Other drug) Batch: CALTRATE (Other drug) Batch: Batch:	Started: 10. Started: 3. Started: tions: Range Date To	Re 0 Milligram Re 0 Dose Unspecified	Stopped: ason: Daily Stopped: ason: Daily	Details
Batch: AMLODIPINE (Other drug) Batch: CALTRATE (Other drug) Batch: Batch: Type	Started: 10. Started: 3. Started: tions: Range Date To	Re 0 Milligram Re 0 Dose Unspecified	Stopped: ason: Daily Stopped: ason: Daily	Details
Batch: AMLODIPINE (Other drug) Batch: CALTRATE (Other drug) Batch: aboratory Investigat Date Type	Started: 10. Started: 3. Started: tions: Range Date To	Re 0 Milligram Re 0 Dose Unspecified	Stopped: ason: Daily Stopped: ason: Daily	Details
Batch: AMLODIPINE (Other drug) Batch: CALTRATE (Other drug) Batch: aboratory Investigat Date Type	Started: 10. Started: 3. Started: tions: Range Date To	Re 0 Milligram Re 0 Dose Unspecified	Stopped: ason: Daily Stopped: ason: Daily	Details
Batch: AMLODIPINE (Other drug) Batch: CALTRATE (Other drug) Batch: aboratory investigate Date Type	Started: 10. Started: 3. Started: tions: Range Date To	Re 0 Milligram Re 0 Dose Unspecified	Stopped: ason: Daily Stopped: ason: Daily	Details

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 277 of 554



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Reported: 01/02/1999	le
Onset Date: 22/12/1998 Outcome: Recovered Causality: Causality possible caction Details: Medicine Details:	le
Outcome: Recovered action Details: Iedicine Details:	le
AMIODARONE HYDROCHLORIDE (Other drug) Batch: Started: Stopped: FERRO-GRADUMET (Other drug) Batch: Started: Stopped: 2.0 Dose Unspecified Daily Batch: Started: Stopped: Reason: 2.0 Dose Unspecified Daily Batch: Started: Stopped: Stopped: RISPERIDONE (Suspected) Reason: 1.0 Milligram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 KEFLEX (Suspected) Reason: 1.5 Gram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 Aboratory Investigations:	le
Reason: 200.0 Milligram Daily Batch: Started: Stopped: Sto	
AMIODARONE HYDROCHLORIDE (Other drug) Batch: Started: 200.0 Milligram Daily Reason: FERRO-GRADUMET (Other drug) Batch: Started: 2.0 Dose Unspecified Daily Batch: Started: Reason: 1.0 Milligram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 KEFLEX (Suspected) Reason: 1.5 Gram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 AMIODARONE HYDROCHLORIDE (Other drug) Milligram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 AMIODARONE HYDROCHLORIDE (Other drug) Milligram Daily Stopped: 22/12/1998 AMIODARONE HYDROCHLORIDE (Other drug) Milligram Daily Stopped: 22/12/1998 AMIODARONE HYDROCHLORIDE (Other drug) Milligram Daily Stopped: 22/12/1998 AMIODARONE HYDROCHLORIDE (Other drug) Milligram Daily Stopped: 22/12/1998	
AMIODARONE HYDROCHLORIDE (Other drug) Batch: Started: 200.0 Milligram Daily Reason: FERRO-GRADUMET (Other drug) Batch: Started: 2.0 Dose Unspecified Daily Batch: Started: Reason: 1.0 Milligram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 KEFLEX (Suspected) Reason: 1.5 Gram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 AMIODARONE HYDROCHLORIDE (Other drug) Milligram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 AMIODARONE HYDROCHLORIDE (Other drug) Milligram Daily Stopped: 22/12/1998 AMIODARONE HYDROCHLORIDE (Other drug) Milligram Daily Stopped: 22/12/1998 AMIODARONE HYDROCHLORIDE (Other drug) Milligram Daily Stopped: 22/12/1998 AMIODARONE HYDROCHLORIDE (Other drug) Milligram Daily Stopped: 22/12/1998	
Reason:	
Reason:	
Reason:	
AMIODARONE HYDROCHLORIDE (Other drug) Batch: Started: 200.0 Milligram Daily Beason: FERRO-GRADUMET (Other drug) Batch: Started: 2.0 Dose Unspecified Daily Batch: Reason: 1.0 Milligram Daily Batch: Started: 21/12/1998 KEFLEX (Suspected) Reason: 1.5 Gram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 KEFLEX (Suspected) All Batch: Started: 21/12/1998 Stopped: 22/12/1998 Stopped: 22/12/1998 All Batch: Started: 21/12/1998 Stopped: 22/12/1998	
AMIODARONE HYDROCHLORIDE (Other drug) Batch: Started: 200.0 Milligram Daily Beason: FERRO-GRADUMET (Other drug) Batch: Started: 2.0 Dose Unspecified Daily Batch: Reason: 1.0 Milligram Daily Batch: Started: 21/12/1998 KEFLEX (Suspected) Reason: 1.5 Gram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 KEFLEX (Suspected) All Batch: Started: 21/12/1998 Stopped: 22/12/1998 Stopped: 22/12/1998 All Batch: Started: 21/12/1998 Stopped: 22/12/1998	
AMIODARONE HYDROCHLORIDE (Other drug) Batch: Started: 200.0 Milligram Daily Beason: FERRO-GRADUMET (Other drug) Batch: Started: 2.0 Dose Unspecified Daily Batch: Reason: 1.0 Milligram Daily Batch: Started: 21/12/1998 KEFLEX (Suspected) Reason: 1.5 Gram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 KEFLEX (Suspected) All Batch: Started: 21/12/1998 Stopped: 22/12/1998 Stopped: 22/12/1998 All Batch: Started: 21/12/1998 Stopped: 22/12/1998	
AMIODARONE HYDROCHLORIDE (Other drug) Batch: Started: 200.0 Milligram Daily Beason: FERRO-GRADUMET (Other drug) Batch: Started: 2.0 Dose Unspecified Daily Batch: Reason: 1.0 Milligram Daily Batch: Started: 21/12/1998 KEFLEX (Suspected) Reason: 1.5 Gram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 KEFLEX (Suspected) All Batch: Started: 21/12/1998 Stopped: 22/12/1998 Stopped: 22/12/1998 All Batch: Started: 21/12/1998 Stopped: 22/12/1998	
AMIODARONE HYDROCHLORIDE (Other drug) Batch: Started: COUNTIED TO BE STATE	
Raison:	
AMIODARONE HYDROCHLORIDE (Other drug) Batch: Started: COUNTIED TO BE STATE	
AMIODARONE HYDROCHLORIDE (Other drug) Batch: Started: COUNTIED TO BE STATE	
Batch: Started: Stopped:	
Batch: Started: Stopped: FERRO-GRADUMET (Other drug) Batch: Started: Stopped: 2.0 Dose Unspecified Daily Batch: Started: Stopped: Reason: 1.0 Milligram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 KEFLEX (Suspected) Reason: 1.5 Gram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 Aboratory Investigations:	
FERRO-GRADUMET (Other drug) 2.0 Dose Unspecified Daily Batch: Started: Stopped: Reason: 1.0 Milligram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 KEFLEX (Suspected) Reason: 1.5 Gram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 Aboratory Investigations:	
Batch: Started: Stopped: RISPERIDONE (Suspected) Batch: Started: Paily Batch: Started: 21/12/1998 Stopped: 22/12/1998 KEFLEX (Suspected) Batch: Started: 21/12/1998 Stopped: 22/12/1998 KEFLEX (Suspected) Batch: Started: 21/12/1998 Stopped: 22/12/1998 Stopped: 22/12/1998 Stopped: 22/12/1998	
Risperidone (Suspected) Reason:	
RISPERIDONE (Suspected) 1.0 Milligram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 KEFLEX (Suspected) 1.5 Gram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 Aboratory Investigations:	
Started: 21/12/1998 Stopped: 22/12/1998 KEFLEX (Suspected) Reason:	
Reason: 1.5 Gram Daily Batch: Started: 21/12/1998 Stopped: 22/12/1998 Aboratory Investigations:	
Batch: Started: 21/12/1998 Stopped: 22/12/1998 -aboratory Investigations:	
Batch: Started: 21/12/1998 Stopped: 22/12/1998 .aboratory Investigations:	
aboratory Investigations:	
	_
Additional Information:	
Additional Information:	
Additional Information:	
Additional Information:	
Additional Information:	
Additional Information:	
Additional Information:	
Additional Information:	

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 278 of 554



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number: 136172	2 Seq: 1		Gende	er: M
Reported: 15/02/			Weigh	t:
ospitalisation:			Age	e: 16
Onset Date:				B : 13/08/1982
Outcome: Unkno	wn		Causalit	y: Causality possible
action Details:				
Preferred Term	n Severity	Report De	scription	Treatment
/eight increased				
ledicine Details: RISPERIDONE (Suspected)		Reason:		
	0.0			
Batch:	Started:		Stopped:	
CLOZARIL (Suspected)		Reason:	Unspecified schizophre	nia
Tablet	275.0 M			
Batch:	Started: 07/07	/1998	Stopped:	
aboratory Investic	ations:			
Date Type	Range Date Tested	d Result	De	etails
Additional Informat	ion:			
port Run: 04/06/2007 11:0	4AM Database: pusime02	ADRS0	04	Page 279 of 554



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

Report Details:

 Case Number:
 136528
 Seq: 1
 Gender:
 F

 Reported:
 23/02/1999
 Weight:

Hospitalisation:
Onset Date: 09/02/1999
DOB:

Onset Date: 09/02/1999

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			
Gynaecomastia			

Medicine Details:

PULMICORT (Other drug) Reason:

Inhalation 4.0 Dose Unspecified Daily Inhalation

Batch: Started: 21/01/1999 Stopped:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

4.0 Milligram Daily

Batch: Started: 04/02/1999 Stopped: 09/02/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt had been on 1mg bd of risperidone 21/1/99 to 4/2/99.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 280 of 554



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

Report Details:

 Case Number:
 136573
 Seq: 1
 Gender: M

 Reported:
 24/02/1999
 Weight:

Hospitalisation: Age: 71

Onset Date: 29/01/1999 **DOB**: 22/07/1927

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

100011011 D 0101101			
Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			Ceasing risperidone ck decreased.

Medicine Details:

Medicine Details.			
ASPIRIN (Other drug)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started: 29/01/1999	Stopped:	CONTIN
RISPERIDONE (Suspected)	1	Reason: Depression	
Tablet	0.5 Milligram	Daily	Oral
Batch:	Started: 29/01/1999	Stopped:	31/01/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient originally on 0.5mg nocte. increased to 1mg nocte from 01/02/99 to 04/02/99. increased again to 2mg nocte from 05/02/99 to 09/02/99.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 281 of 554



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Onset Date: Outcome: Unknown Causality: Causality possible eaction Details: Preferred Term Severity Report Description Treatment Dyspnoea Breathlessness, first on exertion, & later at rest Medicine Details: LITHIUM CARBONATE (Other drug) Oral application 1.5 Gram Daily Oral Batch: Started: Stopped: CONTIN	Case Number: 136862	Seq: 1		Gende	r: M
Onset Date: Outcome: Unknown Causality: Causality possible Preferred Term Preferred Term Oyspnoea Breathlessness, first on exertion, & later at rest Medicine Details: LITHIUM CARBONATE (Other drug) Oral application Batch: Started: Reason: Unspecified schizophrenia Oral application Oral oral application Oral oral oral oral oral oral oral oral o	Reported: 01/03/1999			Weight	:
Outcome: Unknown Preferred Term Severity Report Description Breathlessness, first on exertion, & later at rest Medicine Details: LITHIUM CARBONATE (Other drug) Oral application 1.5 Gram Daily Oral Batch: Started: Reason: Unspecified schizophrenia CONTIN RISPERDAL (Suspected) Oral application 2.0 Milligram Daily Oral Reason: Unspecified schizophrenia CONTIN Reason: Unspecified schizophrenia CONTIN	ospitalisation:			Age	e: 40Y
Preferred Term Severity Report Description Treatment Dyspnoea Breathlessness, first on exertion, & later at rest Medicine Details: LITHIUM CARBONATE (Other drug) Oral application 1.5 Gram Daily Oral Batch: Started: Stopped: CONTIN Reason: Unspecified schizophrenia Oral application 2.0 Milligram Daily Oral	Onset Date:			DO	3:
Preferred Term Severity Report Description Treatment Dyspnoea Breathlessness, first on exertion, & later at rest Medicine Details: LITHIUM CARBONATE (Other drug) Oral application 1.5 Gram Daily Oral Batch: Started: Reason: Unspecified schizophrenia Oral application 2.0 Milligram Daily Oral	Outcome: Unknown			Causality	: Causality possible
Dyspnoea Breathlessness, first on exertion, & later at rest Breathle	eaction Details:				
rest rest	Preferred Term	Severity	Report D	escription	Treatment
LITHIUM CARBONATE (Other drug) Reason: Unspecified schizophrenia Oral application 1.5 Gram Daily Oral Batch: Started: Stopped: CONTIN RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 2.0 Milligram Daily Oral	yspnoea			on exertion, & later at	
LITHIUM CARBONATE (Other drug) Reason: Unspecified schizophrenia Oral application 1.5 Gram Daily Oral Batch: Started: Stopped: CONTIN RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 2.0 Milligram Daily Oral					
LITHIUM CARBONATE (Other drug) Reason: Unspecified schizophrenia Oral application 1.5 Gram Daily Oral Batch: Started: Stopped: CONTIN RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 2.0 Milligram Daily Oral					
Oral application 1.5 Gram Daily Oral Batch: Started: Stopped: CONTIN RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 2.0 Milligram Daily Oral					
Batch: Started: Stopped: CONTIN RISPERDAL (Suspected) Reason: Unspecified schizophrenia Oral application 2.0 Milligram Daily Oral					
RISPERDAL (Suspected) Oral application 2.0 Milligram Daily Oral	LITHIUM CARBONATE (Other drug)			·	nia
Oral application 2.0 Milligram Daily Oral	LITHIUM CARBONATE (Other drug) Oral application	1.5		y Oral	
	LITHIUM CARBONATE (Other drug) Oral application Batch:	1.5	Gram Dai	y Oral Stopped:	CONTIN
Statted: 07/12/1990 Stopped: 30/01/1999	Oral application Batch: RISPERDAL (Suspected)	1.5 Started:	Gram Dai	y Oral Stopped: Unspecified schizophrer	CONTIN
	Oral application Batch: RISPERDAL (Suspected) Oral application	1.5 Started: 2.0	Gram Dai Reason: Milligram Dai	y Oral Stopped: Unspecified schizophrer y Oral	CONTIN
	Oral application Batch: RISPERDAL (Suspected) Oral application	1.5 Started: 2.0	Gram Dai Reason: Milligram Dai	y Oral Stopped: Unspecified schizophrer y Oral	CONTIN
	Batch: RISPERDAL (Suspected) Oral application Batch:	1.5 Started: 2.0 Started: 07/	Gram Dai Reason: Milligram Dai	y Oral Stopped: Unspecified schizophrer y Oral	CONTIN
_aboratory Investigations: Date Type Range Date Tested Result Details	Oral application Batch: RISPERDAL (Suspected) Oral application Batch:	1.5 Started: 2.0 Started: 07/	Reason: Milligram Dai /12/1998	y Oral Stopped: Unspecified schizophrer y Oral Stopped: 30/01/19	CONTIN nia 99

Additional Information:

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 282 of 554



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

Report Details:

 Case Number:
 136932
 Seq: 1
 Gender:
 F

 Reported:
 05/03/1999
 Weight:

Hospitalisation: Age: 35Y
Onset Date: 28/03/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

vieuicine Delans.			
LITHICARB (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
OROXINE (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Schizophrenia	
	2.0 Milligram	Daily	
Batch:	Started: 01/11/1997	Stopped: 28/02/1999	

Laboratory Investigations:

ı	Date	Type	Range	Date Tested	Result	Details
ĺ		ALT = SGPT		01/04/1998	233	
١		GGT = SGGT =		01/04/1998	477	
ı		SAP = ALP		01/04/1998	135	

Additional Information:

Progressive increased in lfts whilst on risperidone, which seems to reverse when risperidone ceased.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 283 of 554



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

Report Details:

Case Number: 138655 Seq: 1 Gender: F

Reported: 22/04/1999 Weight:
Hospitalisation: Age: 81

Onset Date: 08/03/1999 **DOB**: 26/10/1917

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment	
Salivary hypersecretion			Ceased risperidone	

Medicine Details:

RISPERDAL (Suspected) Reason: Hallucinations

1.0 Milligram Daily

Batch: Started: 04/03/1999 Stopped: 12/03/1999

MORPHINE SULPHATE (Suspected) Reason: Otr spec symp psychopathol nec

4.0 Millilitre Daily

Batch: Started: Stopped: 08/03/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

? bradykinesia. no known allergies. see original report for details of other drugs - amiodarone, sodium valproate, ramipril, famotidine.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 284 of 554



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

Report Details:

Case Number: 139514 Seq: 1 Gender: M

Reported: 14/05/1999

Hospitalisation:
Onset Date:

Weight: 85.00
Age: 25Y
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Hyperprolactinaemia		Increased prolactin levels	
	Gynaecomastia			

Medicine Details:

<u> Wiedicine Details:</u>				
RISPERIDONE (Suspected)		Reason:	_	
	2.0 Milligram	Daily		
Batch:	Started: 01/01/1999		Stopped:	
SODIUM VALPROATE (Suspected)		Reason:		
	200.0 Milligram	Daily		
Batch:	Started: 01/01/1999		Stopped:	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

No history other drugs. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 285 of 554



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

ase Number:	139645	Seq: 1					Gende	er: F	
Reported:	19/05/1999						Weigh	it:	
spitalisation:							Ag	e : 20Y	
Onset Date:							DO	B:	
Outcome:	Unknown					С	ausalit	y: Causality poss	ible
action Detai	ls:								
Preferre	ed Term	Severi	ty	Repo	rt Des	scription		Treatmer	nt
perprolactinae	mia						ı	Zoloft ceased, cipra commenced.	mil
edicine Deta				Reas	on:	Unspecified so		nia	
Tablet			0.0				Oral		
Batch:		Starte	d:			Stopped:			
OLOFT (Suspecte	ed)			Reas		Anxiety neuros			
Tablet Batch:		1 Starte	100.0 Milligra	am	Daily	Stopped:	Oral		
aboratory In									
Date	Туре	Range Dat	te Tested	Result			De	etails	
dditional Inf			e resteu	Nesuit			De	zians	



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

Report Details:

Case Number: 139656 Seq: 1 Gender: F

Reported: 24/05/1999

Weight: 85.00

Hospitalisation: Admitted to hospital

Age: 70Y

Onset Date: 01/04/1999 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

-				
	Preferred Term	Severity	Report Description	Treatment
	Blood creatine phosphokinase incr			
	Confusional state			Ceased risperidone

Medicine Details:

RISPERIDONE (Suspected) Reason:

4.0 Milligram Daily

Batch: Started: 01/03/1999 **Stopped:** 01/04/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine				Ck increased to 1002.

Additional Information:

See original report for details on other drug therapy: sertraline. patient history of depression and obsessive compulsive disorder. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 287 of 554



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number:		Seq: 1		Gender: M
Reported:	07/06/1999			Weight:
spitalisation:				Age: 20Y
Onset Date:				DOB:
Outcome:	Recovered			Causality: Causality probable
action Deta				
	ed Term	Severity	Report Description	Treatment
lood creatine p	hosphokinase incr			
Medicine Det		0.0	Reason:	
Batch:		Started:	Stopp	ed:
	nvestigations:	na Data Tastad	Recult	Details
_aboratory Ir	nvestigations:	ge Date Tested	Result	Details

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 288 of 554



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

Report Details:

Case Number: 140401 Seq: 1 Gender: M

Reported: 10/06/1999 Weight:
Hospitalisation: Age: 30Y

Onset Date: 18/05/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Dyspnoea		Difficulty breathing.	
Dysphagia		Difficuly in swallowing.	
Rash		Rash on hands.	Calamine lotion & phenergan oral
Face oedema		Swollen lip & eyelids.	

Medicine Details:

Micalcinic Details.			
HALOPERIDOL (Suspected)		Reason:	
Tablet	5.0 Milligram	1 time	Oral
Batch:	Started: 18/05/1999	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 18/05/1999	Stopped:	18/05/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient developed rash on 18.5.99. unsure if is due to risperidone or haloperidol.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 289 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number: 140581	Seq: 1		Ge	nder: F			
Reported: 23/06/1999	_	Weight:					
spitalisation:				Age: 60Y			
Onset Date:				DOB:			
Outcome: Unknown			Caus	ality: Causality possible			
ction Details:				1			
Preferred Term	Severity	Report Des	scription	Treatment			
perkinesia				Risperidone discontinued.			
edicine Details: ISPERIDONE (Suspected)		Reason:					
Batch:	8.0 Millig Started:	gram Daily	Stopped:				
							
aboratory Investigatio	DNS: Range Date Tested	Result		Details			
Date Type	Natige Date resteu	Result		Details			
dditional Information	:						
ort Run: 04/06/2007 11:04AM	Database: pusime02	ADRS00)4	Page 290 of 554			



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

Report Details:

Case Number: 140898 Seq: 1 Gender: F

 Reported: 28/06/1999
 Weight: 62.00

 Hospitalisation:
 Age: 75Y

 Onset Date: 08/06/1999
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	toaction Botanoi			
	Preferred Term	Severity	Report Description	Treatment
	Hyponatraemia			Risperadone ceased & fluid restriction.
	Inappropriate antidiuretic hormone			

Medicine Details:

RISPERIDONE (Suspected)Reason:Unspecified psychosisTablet2.0 MilligramDailyOral

Batch: **Started**: 18/05/1999 **Stopped**: 09/06/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Serum osmolality				Sos 254
	Sodium		18/05/1999	131	
	Sodium		24/05/1999	136	
	Sodium		08/06/1999	123	
	Sodium		09/06/1999	121	
	Sodium		13/06/1999	124	
	Sodium		17/06/1999	126	

Additional Information:

Please see original report for details of other drugs - indapamide, enalapril, amlodipine, pravastatin, quinine bisulfate, imdur.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 291 of 554



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

Report Details:

Case Number: 140898 Seq: 1 Gender: F

Reported: 28/06/1999 Weight: 62.00 Hospitalisation: Age: 75Y

Onset Date: 08/06/1999 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

Tablet 2.0 Milligram Daily Oral

Batch: Started: 18/05/1999 **Stopped:** 09/06/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Sodium		21/06/1999	130	
	Urine osmolality				Vos 308

Additional Information:

Please see original report for details of other drugs - indapamide, enalapril, amlodipine, pravastatin, quinine bisulfate, imdur.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 292 of 554



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

Repo	ort D	etai	ls:
------	-------	------	-----

Case Number: 141299 Seq: 1 Gender: M
Reported: 08/07/1999 Weight:
Hospitalisation: Age:

Onset Date: 21/06/1999 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			
Myositis			
Respiratory depression			

Medicine Details:

RISPERDAL (Suspected) Reason:
Oral application 2.0 Milligram Daily Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine kinase				4000-5000

Additional Information:

Patient history of mild chronic renal failure, diabetes, hypertension.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 293 of 554



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

Report Details:

Case Number: 141362 Seq: 1 Gender: M

Reported: 09/07/1999 Weight:

Hospitalisation: Age: 18Y
Onset Date: 31/12/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Pt began to experience epileptic fits everyday.	Zoloft discontinued.

Medicine Details:

Batch:

TEGRETOL (Interaction)		Reason:	Other&unspecified epilepsy
	0.0		
Batch:	Started:		Stopped:

Stopped:

Stopped:

SODIUM VALPROATE (Interaction) Reason: Other&unspecified epilepsy

0.0

VODEDDAL (Internation)

RISPERDAL (Interaction) Reason: Unspecified schizophrenia

0.0 Batch: Started:

ZOLOFT (Interaction) Reason: Depression

Started:

Tablet 50.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 294 of 554



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

Report Details:

Case Number: 141467 Seq: 1 Gender: M

Reported: 13/07/1999 **Weight:** 82.00

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia			

Medicine Details:

vieulcine Details.				
FLUPHENAZINE HYDROCHLORIDE	Reason:			
	0.0			
Batch:	Started:	L TERM	Stopped:	28/07/1994
CHLORPROMAZINE HYDROCHLORIDE (Suspected)		Reason:		
	0.0			
Batch:	Started:	L TERM	Stopped:	28/07/1994
RISPERIDONE (Suspected)		Reason:		
	6.0 Milli	igram Daily		
Batch:	Started: 01/02/1994		Stopped:	08/07/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - metoprolol. had previous tardive dyskinesia 1993-1994 which seemed to resolve after change to clozapine, then reappeared. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 295 of 554



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

Report Details:

 Case Number:
 141728
 Seq: 1
 Gender:
 F

 Reported:
 19/07/1999
 Weight:

Hospitalisation: Age: 16

Onset Date: 31/03/1999 **DOB:** 14/05/1982

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction Betails.	saction betails:								
Preferred Term	Severity	Report Description	Treatment						
Galactorrhoea									
Hyperprolactinaemia									

Medicine Details:

RISPERDAL (Suspected)

Tablet

Reason: Unspecified psychosis

Oral

Batch: Started: 01/03/1999 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Prolactin	(50-500)	19/04/1999	3500	Prolactin level=3737 mlu/l

Additional Information:

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

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 296 of 554



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

Report Details:

Case Number: 141774 Seq: 1 Gender: F

Reported: 21/07/1999 Weight:
Hospitalisation: Age: 84Y

Onset Date: 17/06/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Risperidone ceased.

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

11.0 Milligram Total

Batch: Started: 24/05/1999 **Stopped:** 08/07/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details: frusemide, chlorvescent, coloxyl with senna, digoxin, & warfarin.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 297 of 554



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

Report Details:

Case Number: 141886 Seq: 1 Gender: M

Reported: 23/07/1999 Weight:
Hospitalisation: Age: 54

pitalisation: Age: 54Y
Onset Date: 13/07/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence		Nocturnal urinary incontinence	

Medicine Details:

RISPERIDONE (Suspected) Reason: Schizophrenia

3.0 Milligram Daily

Batch: Started: 06/07/1999 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for details on other drugs: nitrazepam, clonazepam. risperidone was started at 1mg on 30/6/99, increased to 3mg 6/7/99 reduced to 2mg on 13/7/99.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 298 of 554



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

Report Details:

Case Number: 141934 Seq: 1 Gender: F

 Reported: 26/07/1999
 Weight: 73.00

 Hospitalisation:
 Age: 58Y

Onset Date: 31/03/1999 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

,	caction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Weight increased		Gained 9 kg.	
	Alopecia		Hair falling out	

Medicine Details:

RISPERDAL (Suspected) Reason:

Tablet 1.0 Milligram Daily Oral

Batch: Started: 01/11/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 299 of 554



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

Report Details:

 Case Number:
 142427
 Seq: 1
 Gender: F

 Reported:
 05/08/1999
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 10/06/1999
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lymphadenopathy		Enlarged lymphnodes	
Hepatomegaly		Liver mildly tender and edge palpable.	
Abdominal pain		Tender I upper quadrant	
Dizziness			
Hepatic function abnormal			
Nausea			Recovery with supportive measures and cessation of risperidone.
Pyrexia			
Vomiting			

Medicine Details:

Medicine Details.		
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia
Tablet	1.0 Milligram	Daily Oral
Batch:	Started: 04/06/1999	Stopped: 07/06/1999
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia
Tablet	2.0 Milligram	Daily Oral
Batch:	Started: 07/06/1999	Stopped : 10/06/1999

Laboratory Investigations:

	<u> </u>				
Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		17/06/1999	241	
	Bilirubin		17/06/1999	76	
	GGT = SGGT =		17/06/1999	135	
	SAP = ALP		17/06/1999	305	

Additional Information:

See original report for details of other drug therapy: luvox, voltaren, nitrazepam and paracetamol.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 300 of 554



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

Report Details:

 Case Number:
 142428
 Seq: 1
 Gender: M

 Reported:
 05/08/1999
 Weight:

Hospitalisation: Age:

Onset Date: 28/03/1999 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia			
Hyperprolactinaemia			

Medicine Details:

RISPERDAL (Suspected) Reason: Obsessive compulsive neurosis

 Tablet
 2.0 Milligram
 Daily
 Oral

 Batch:
 Started: 01/03/1999
 Stopped: 12/05/1999

Laboratory Investigations:

Edbordtory invoctigations:						
	Date	Туре	Range	Date Tested	Result	Details
		Prolactin	24 - 467	12/05/1999	568	
		Prolactin	24 - 467	02/06/1999	NORMAL	

Additional Information:

Patient was also on valproate. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 301 of 554



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

Report Details:

 Case Number:
 142453
 Seq: 1
 Gender: M

 Reported:
 06/08/1999
 Weight:
 50.00

 Hospitalisation:
 Age: 82Y

Onset Date: 23/07/1999 **DOB**:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

eaction betails.							
Preferred Term	Severity	Report Description	Treatment				
Leukopenia							
Pneumonia							
Respiratory failure							
Sepsis							

Medicine Details:

RISPERDAL (Suspected)	Reason:				
	3.0 Milligram	Weekly			
Batch:	Started:	Stopped:	6M		
DIAZEPAM (Suspected)		Reason:			
	2.5 Milligram	As necessary			
Batch:	Started:	Stopped:			
SINEMET (Suspected)		Reason: Paralysis agitans			
	3.0 Dose Unspe	cified Daily			
Batch:	Started:	Stopped:			
ZOLOFT (Suspected)		Reason:			
	25.0 Milligram	Daily			
Batch:	Started:	Stopped:			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells				White cell count of 1.5

Additional Information:

Date of death: 23/7/99.

Report Run : 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 302 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Hospitalisation: Onset Date:	06/08/1999 23/07/1999 Death, maybe dru	Seq: 1		Gender: Weight: Age: DOB: Causality:	50.00 82Y
Medicine Deta					
NORMISON (Susp	ected)	10.0 Milligram	Reason: Daily		
Batch:		Started:	Dany	Stopped:	
Laboratory In	vestigations:				
Additional Inf Date of death: 23/7					

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 303 of 554



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

Report Details:

Case Number: 142459 Seq: 1 Gender: M

Reported: 09/08/1999 Weight:

Hospitalisation: Age: 23Y
Onset Date: 12/10/1998
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment	
Hepatic function abnormal		Abnormal lft.	Risperdal therapy ceased.	

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified psychosis

Tablet 3.0 Milligram Daily Oral

Batch: Started: 21/09/1998 **Stopped:** 18/10/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry Alt 2		Alt 277 units/l (n<50) ast 112 u/l (n<41)		

Additional Information:

See original report for details of other drug. - antenex.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 304 of 554



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

Report Details:

Case Number: 142502 Seq: 1 Gender: M

Reported: 09/08/1999 Weight:
Hospitalisation: Age: 20Y

Onset Date: 31/12/1999 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Macular degeneration			

Medicine Details:

Medicine Details.					
ZOLOFT (Suspected)			Reason: D	Depression	
Tablet	50.0	Milligram	Daily		Oral
Batch:	Started:	L TE	ERM	Stopped:	
RISPERDAL (Suspected)			Reason:		
Tablet	4.0	Milligram	Daily		Oral
Batch:	Started:	L TE	ERM	Stopped:	
COGENTIN (Suspected)			Reason:		
Tablet	1.0	Milligram	Daily		Oral
Batch:	Started:	L TE	ERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 305 of 554



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

Report Details:

Case Number: 142947 Seq: 1 Gender: F

Reported: 24/08/1999 Weight: 65.00 Hospitalisation: Age: 42Y

Onset Date: 17/05/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Prolactin rise	Risperidone ceased
Galactorrhoea			

Medicine Details:

RISPERIDONE (Suspected) Reason:

0.0

Batch: Started: Stopped:

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
Ī		Prolactin		17/05/1999	993	
		Prolactin		20/06/1999	3238	
		Prolactin		27/07/1999	4710	
Į		Prolactin		04/08/1999	128	

Additional Information:

Patient has a long psych history. has had 2 overdose attempts with the drugs ducene, zoloft, codeine phos and brufen on 31/5/99 and 12/6/99.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 306 of 554



DOB:

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

Report Details:

Case Number: 142948 Seq: 1 Gender: M

Reported: 24/08/1999 Weight: 0.00 Hospitalisation: Age: 22Y

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Onset Date: 31/07/1999

Preferred Term	Severity	Report Description	Treatment
Breast mass		Nodular breast lump	

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

3.0 Milligram Daily

Batch: Started: 01/06/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 307 of 554



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

Report Details:

Case Number: 143260 Seq: 1 Gender: M
Reported: 31/08/1999 Weight:

Hospitalisation: Age: 50Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Retinal disorder		See additional information for description.	

Medicine Details:

Medicine Details.		
RISPERDAL (Suspected)		Reason: Unspecified psychosis
	0.0	
Batch:	Started:	Stopped:
GLIMEL (Suspected)		Reason: Diabetes mellitus
	0.0	
Batch:	Started:	Stopped:
CYANOCOBALAMIN (Suspected)		Reason:
Injection	0.0	Intravenous
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Mild hypopigmentation and punctate choroiditis within 1 disc diameter of left macula in retina.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 308 of 554



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

se Number: 14	IONAO	0	1			Camala	N/
		Seq:	I			Gende	
Reported: 23	709/1999					_	t: 65.00
pitalisation:	1/00/4000					_	9: 35Y
Onset Date: 11						DOI	
Outcome: Ro						Causality	: Causality possible
ction Details		1 0-	vority:	D -	nort Dari	vrintian T	Tue et a a a t
Preferred apism	rerm	Se	verity	Re	port Desc	cription	Treatment
dicine Detail SPERIDONE (Suspe				Re	eason:		
Oral applicatio			2.0 Milli		Daily	Oral	
Batch:		St	arted: 01/09/19			Stopped:	CONTIN
lboratory Inve		IS: Range	Date Tested	Result			tails

Rep



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

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

Case Number: 143950 Seq: 1 Gender: U

Reported: 23/09/1999 Weight:
Hospitalisation: Age: 72

Onset Date: 15/08/1999 DOB: 11/08/1927

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Bp has dropped from 160/100 to 60/40.	

Medicine Details:

Medicine Details.			
RISPERIDONE (Suspected)	1	Reason:	
Oral application	500.0 Microgram	Daily	Oral
Batch:	Started: 15/08/1999	Stopped:	15/08/1999
PHENERGAN (Suspected)	ı	Reason:	
Oral application	30.0 Milligram	Daily	Oral
Batch:	Started: 14/08/1999	Stopped:	15/08/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 310 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

-	r: 144024	оеч	: 1		G	ender: F
	i : 24/09/199	_			-	
spitalisation						Age: 67Y
Onset Date						DOB:
	: Recovere	ed .			Cau	sality: Causality probable
action Deta						
	rred Term		everity	Repo	ort Description	Treatment
yspnoea		Seve	ere			Ceased risperdal
Medicine De				Rea	son:	
Potob		c	0.0		Stannadi	
Batch: ASIG (Other drug	a)		Started:	Reas	Stopped:	
ASIG (Other dru	9)		0.0	Neas	5011.	
Batch:		٤	Started:		Stopped:	
ENDEP (Other di	rug)			Reas		
			0.0			
Batch:		8	Started:		Stopped:	
RISPERDAL (Su	spected)			Reas	son: Unspecified schiz	ophrenia
Tablet			2.0 Milli	gram Daily Oral		
Batch:			Started: 20/08/1	999	Stopped: 17	7/09/1999
Daton.		tione:				
	INVACTIMAI					
aboratory l	I nvestiga i Type	Range	Date Tested	Result		Details

Report Run : 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 311 of 554



Report Details:

Case Number: 144140

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

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

Seq: 1

ospitalisatio Onset Da	Reported: 28/09/1999				Weig	ght:		
-					Age:			
						OB:		
Outcom	ne: Unknown				Causa	lity: Causality possible		
action De								
Pref	ferred Term	Se	everity	Repor	t Description	Treatment		
gitation								
ledicine D				Reasc	n:			
			0.0					
Batch:		S	Started: Stopped:					
CLOZARIL (Su				Reaso	•	ırenia		
Tablet Batch:		_	600.0 Milli tarted:	gram [Oaily Oral Stopped:	CONTIN		
aboratory	/ Investigat	ions:	Date Tested	Result		Details		

ADRS004 Page 312 of 554



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

Report Details:

Case Number: 144594 Seq: 1 Gender: F

Reported: 12/10/1999 Weight:
Hospitalisation: Age: 35Y

Onset Date: 03/09/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus		Patient complaied of itch (without rash).	Risperidone ceased.

Medicine Details:

RISPERIDONE (Suspected) Reason:

4.0 Milligram Daily

Batch: **Started**: 27/08/1999 **Stopped**: 03/09/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - clonazepam, haloperidol & temazepam.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 313 of 554



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

Report Details:

Case Number: 144894 Seq: 1 Gender: M

Reported: 19/10/1999 Weight:
Hospitalisation: Age: 23Y

Onset Date: 11/06/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash			Cease risperidone, changed to olanzapine then clopixol depot 400mg.

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified schizophrenia

Oral application 3.0 Milligram Daily Oral

Batch: Started: 07/06/1999 **Stopped:** 11/06/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Nil previous adr's.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 314 of 554



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

Report Details:

 Case Number:
 144937
 Seq: 1
 Gender: M

 Reported:
 20/10/1999
 Weight:

Hospitalisation: Age: 41Y
Onset Date: 26/08/1999
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

touction betains.			
Preferred Term	Severity	Report Description	Treatment
Oedema		Oedema in hands.	Clozapine dose had been reduced from 550mg/day to 525mg/day in 6/99 and then further reduced to 500mg/day in 7/99.

Medicine Details:

AMITRIPTYLINE HYDROCHLORIDE (Oti	ner drug)	Reason:			
	25.0 Milligram	Daily			
Batch:	Started: 01/01/1998		Stopped: 28/0	7/1999	
LIPEX (Suspected)		Reason:	Othr&unspec metab	olic diseases	
Tablet	10.0 Milligram	Daily	Oral		
Batch:	Started: 01/03/1999		Stopped:	CONTIN	
CLOZAPINE (Suspected)		Reason:	Schizophrenia		
	550.0 Milligram	Daily			
Batch:	Started: 01/02/1998		Stopped:		
RISPERDAL (Suspected)		Reason:	Schizophrenia		
	8.0 Milligram	Daily			
Batch:	Started: 01/10/1998		Stopped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 315 of 554



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

Report	Details:
--------	----------

 Case Number:
 145436
 Seq: 1
 Gender: F

 Reported:
 04/11/1999
 Weight:

Hospitalisation: Age: 19Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			Stopped risperidone and changed to olanzapine 5mg.

Medicine Details:

RISPERIDONE (Suspected) Reason: Manic-depression psycho,manic

2.0 Milligram Daily

Batch: Started: 02/09/1999 **Stopped:** 16/09/1999

RISPERIDONE (Suspected) Reason: Manic-depression psycho,manic

4.0 Milligram Daily

Batch: Started: 16/09/1999 Stopped: 28/10/1999

Laboratory Investigations:

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

Additional Information:

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 316 of 554



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

Report Details:

Case Number: 145442 Seq: 1 Gender: M

Reported: 04/11/1999

Hospitalisation:
Onset Date:

Weight:
Age: 6Y

DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

٠,	touction Dotailor			
	Preferred Term	Severity	Report Description	Treatment
	Tardive dyskinesia		Mother and teacher noticed oral-buccal movements	

Medicine Details:

RISPERDAL (Suspected) Reason:

Oral application 0.5 Milligram Daily Oral

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Risperdal given for adhd. when risperdal was discontinued, reaction occurred. reaction stopped when risperdal was started again. patient has developmental delay. see original report for details of other drug - ritalin.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 317 of 554



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

Report Details:

Case Number: 145446 Seq: 1 Gender: F

Reported: 04/11/1999 Weight:
Hospitalisation: Age: 22Y

Onset Date: 31/01/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	todotion Details.			
	Preferred Term	Severity	Report Description	Treatment
	Amenorrhoea			
	Hyperprolactinaemia			

Medicine Details:

RISPERDAL (Suspected)

Oral application

2.0 Milligram

Daily

Oral

Batch:

Started: 01/07/1998

Stopped: 01/03/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Prolactin				Patient's prolactin level was 2838 miu/l.

Additional Information:

Dose has been reduced on 2/3/99, to 1mg daily. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 11:04AM Database: pusime02 ADRS004 Page 318 of 554



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

Report Details:

 Case Number:
 145447
 Seq: 1
 Gender:
 F

 Reported:
 04/11/1999
 Weight:

Reported: 04/11/1999

Hospitalisation:
Onset Date:

Weight:
Age: 38Y

DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Amenorrhoea			
Hyperprolactinaemia			Risperdal dose has been reduced.

Medicine Details:

RISPERDAL (Suspected)Reason:Unspecified psychosisOral application4.0 MilligramDailyOralBatch:Started: 01/09/1998Stopped: 28/06/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Prolactin				Prolactin level at the end of june 99 was 2683 miu/l.

Additional Information:

Dose reduced to 3mg daily. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 319 of 554



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

asa Numba							
Reported	r: 145448 d: 04/11/199	Seq: 9	1			Wei	nder: F ght:
spitalisation							Age: 26Y
Onset Date							OOB:
	: Unknown					Causa	ality: Causality possible
action Det	alls: rred Term		a va wita v	Don	a = 1 Da		Transferent
	rrea rerm	56	everity	Tenderness	on De	scription	Treatment
reast pain reast enlargei	ment			renderness			
alactorrhoea	illont						
ollakiuria							
rinary incontir	nence						
edicine De	etails: Gesterone A	CETATE (Susp	ected)	Rea	ison:		
			0.0				
Batch:		S	tarted:			Stopped:	CONTIN
RISPERDAL (Su	spected)			Rea	son:	Unspecified psychol	sis
Oral app	lication			Milligram	Daily	Oral	
Oral app Batch :			tarted:	_		Oral Stopped:	CONTIN
Oral app Batch:			tarted:	Rea	ison:		CONTIN
Oral app Batch :		IDE (Suspected	tarted:	_			CONTIN
Oral app Batch: DOXYCYCLINE Batch:	HYDROCHLOR	IDE (Suspected	tarted: d) 100.0 tarted:	Rea Milligram	ison:	Stopped:	
Oral app Batch: DOXYCYCLINE	HYDROCHLOR	IDE (Suspected	tarted: d) 100.0	Rea Milligram	ison:	Stopped:	

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 320 of 554



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

Report Details:

Case Number: 145576 Seq: 1 Gender: F

 Reported:
 09/11/1999
 Weight:

 Hospitalisation:
 Age:
 20Y

 Onset Date:
 23/04/1998
 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Bizaqrre movements/gestures.	Risperidone ceased and changed to olanzepine and melleril.
Depersonalisation		Patient states she felt strange.	
Speech disorder		Speech slow and childlike.	
Hypertonia			

Medicine Details:

Medicine Details.			
PROZAC (Suspected)		Reason: Depression	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 20/04/1998	Stopped:	30/04/1998
RISPERIDONE (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 21/04/1998	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - lithium. patient history: older brother has scz, abused by father and husband, depression.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 321 of 554



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

Repo	rt D	etai	ls:
------	------	------	-----

 Case Number:
 145929
 Seq: 1
 Gender: M

 Reported:
 16/11/1999
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 30/10/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Cachon Details.				
Preferred Term	Severity	Report Description	Treatment	
Dystonia				
Hypertonia			Cogentin 2mg orally.	

Medicine Details:

Micalcinic Details.					
ZUCLOPENTHIXOL ACETATE (Suspected	ed)	Reason: Unspec	ified psychosis		
Injection	150.0 Milligram	1 time	Intramuso	ular	
Batch:	Started: 27/10/1999	Sto	pped:		
RISPERIDONE (Suspected)		Reason:			
Tablet	2.0 Milligram	Daily	Oral		
Batch:	Started: 27/10/1999	Sto	pped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 322 of 554



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

Report Details:

Case Number: 145961 Seq: 1 Gender: M

Reported: 18/11/1999 Weight:
Hospitalisation: Age: 33Y

Onset Date: 28/12/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis			

Medicine Details:

RISPERDAL (Suspected)

Tablet

4.0 Milligram

Daily

Oral

Batch:

Started: 28/12/1998

Stopped: 30/04/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells	4 - 11	28/12/1998	17.5	
	White blood cells	4 - 11	20/01/1999	20.4	
	White blood cells	4 - 11	10/05/1999	14.8	

Additional Information:

Medical conditions include asthma. risperdal reduced to 1mg then ceased 5/99. see original report for details of other drug therapy: moclobemide

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 323 of 554



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

Report Details:

Case Number: 146443 Seq: 1 Gender: M
Reported: 02/12/1999 Weight:
Hospitalisation: Age: 26Y

Onset Date: 08/10/1999 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

104011011 20141101			
Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Elevation of prolactin serum level	
Blood testosterone decreased		Reduction of the serum testosterone level	Risperdal dose reduced to 2mg.
Mastitis			

Medicine Details:

RISPERDAL (Suspected)		Reason:	Unspecified schizophrenia
Oral application	3.5 Milligram	Daily	Oral
Batch:	Started : 12/02/1998		Stopped: 10/09/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data	9.5 - 35.0	08/09/1999	6.6	Testosterone level
	Prolactin	50 - 300MIU/L	08/09/1999	704	

Additional Information:

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 324 of 554



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

Report Details:

Case Number: 146836 Seq: 1 Gender: M

Reported: 13/12/1999 **Weight:**

Hospitalisation: Age: 61

Onset Date: 20/11/1999 **DOB**: 24/10/1938

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation			Cogentin

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

4.0 Milligram Daily

Batch: Started: 06/11/1999 Stopped: CONTIN

ZUCLOPENTHIXOL DECANOATE (Suspected) Reason: Unspecified psychosis

100.0 Milligram Daily

Batch: Started: 18/11/1999 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt also taking sodium valproate, salbutamol, clonazepam, benztropine.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 325 of 554



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

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

Case Number: 147034 Seq: 1 Gender: M

Reported: 16/12/1999 Weight: 75.00 Hospitalisation: Age: 58

Onset Date: 16/09/1999 **DOB**: 15/09/1941

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			Benzthropine, diazapam, indoral 40mg bd.

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

12.0 Milligram Daily

Batch: Started: 30/03/1999 **Stopped:** 04/11/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 326 of 554



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

Report De	etails:						
Case Num Repor Hospitalisat Onset D	ber: 147084 rted: 17/12/199 ion: Date: 08/12/199 rme: Recovered	9		Gender: Weight: Age: DOB: Causality:	44.00 17Y		
	eferred Term	Severity	Repo	ort Description	Treatment		
Agitation Coordination Hallucination	n abnormal	Coroniy	Increased irritab Very unsteady, i	ility			
Medicine RISPERIDON	Details:		Rea	son:			
	(<i>Caopolica</i>)	1.0	Milligram	Daily			
Bato	ch:	Started: 08/	Started: 08/12/1999 Stopped: 08/12/1999				
Laborato Date	ry Investigat	ions: Range Date Test	ed Result	Deta	is		
	,	•	•				

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 327 of 554



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

Report Details:

Case Number: 147308 Seq: 1 Gender: M

Reported: 23/12/1999

Hospitalisation:
Onset Date:

Weight: 51.00
Age: 14Y
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertrichosis		Fine hair on face and neck	

Medicine Details:

Miculcine Details.				
LITHIUM CARBONATE (Suspected)	Reason:			
	1.0 Gram	Daily		
Batch:	Started: 01/04/1999	Stopped:	CONTIN	
RISPERIDONE (Suspected)		Reason:		
	1.0 Milligram	Daily		
Batch:	Started: 01/05/1998	Stopped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 328 of 554



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

Report Details:

Case Number: 147317 Seq: 1 Gender: F

Reported: 23/12/1999 Weight:
Hospitalisation: Age: 43Y

Onset Date: 31/10/1999 **DOB**:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea		No menstruation	

Medicine Details:

Medicine Details.					
RISPERDAL (Suspected)		Reason: Unspec	cified psychosis		
Tablet	2.0 Milligram	Daily	Oral		
Batch:	Started: 01/04/1999	Sto	pped: 28/10/1999	1	
RISPERDAL (Suspected)		Reason: Specifi	c disorders of sleep		
Tablet	1.0 Milligram	Daily	Oral		
Batch:	Started: 01/10/1999	Sto	pped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 329 of 554



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

Report Details:

Case Number: 147505 Seq: 1 Gender: M

Reported: 24/12/1999 Weight: 90.00
Hospitalisation: Age: 18Y

Onset Date: 31/08/1999 **DOB:**

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pharyngitis			Antibiotic therapy amoxil, rulide, abbocillin.

Medicine Details:

RISPERDAL (Suspected) Reason: Explosive personality disorder

Oral application 1.0 Milligram Daily Oral

Batch: Started: 01/08/1999 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 330 of 554



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

Report Details:

Gender: F Case Number: 148015 Seq: 1

Reported: 14/01/2000 Weight: 71.00 Hospitalisation: Age: 61Y

Onset Date: 31/10/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperventilation			Dose of risperdal reduced from 4mg to 2mg daily.

Medicine Details:

RENITEC (Other drug)		Reason: Essential benign hypertension
	10.0 Milligram	Daily
Batch:	Started: 01/06/1999	Stopped:
RISPERDAL (Suspected)		Reason: Unspecified psychosis

4.0 Milligram Daily

Batch: Started: 01/09/1999 **Stopped:** 28/12/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month, the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that stoppage occurred to mental the month. The dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

ADRS004 Report Run: 04/06/2007 11:05AM Database: pusime02 Page 331 of 554



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

Report Details:

Case Number: 148239 Seq: 1 Gender: F

Reported: 20/01/2000 Weight:
Hospitalisation: Age: 49Y

Onset Date: 20/10/1999 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hair texture abnormal		Hair has become very hard and like straw.	

Medicine Details:

	Reason:		
2.0 Milligram	Daily	Oral	
Started: 20/10/1999	Stoppe	ed:	CONTIN
	Reason:		
150.0 Milligram	Daily	Oral	
Started: 01/01/1999	Stoppe	ed:	CONTIN
	2.0 Milligram Started: 20/10/1999 150.0 Milligram	Started: 20/10/1999 Stoppe Reason: 150.0 Milligram Daily	2.0 Milligram Daily Oral Started: 20/10/1999 Stopped: Reason: 150.0 Milligram Daily Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 332 of 554



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

Report Details:

Case Number: 148240 Seq: 1 Gender: F

Reported: 20/01/2000 Weight:
Hospitalisation: Age: 30Y

Onset Date: 28/06/1999 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia			

Medicine Details:

RISPERDAL (Suspected) Reason:

0.0

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Prolactin		28/06/1999	1670	

Additional Information:

Patient also taking modecate, temazepam, serepax, benztropine and diane 35.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 333 of 554



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

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

Case Number: 148274 Seq: 1 Gender: F

Reported: 24/01/2000 Weight:
Hospitalisation: Age: 86Y

Onset Date: 31/12/1999 **DOB:**

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness			Zoloft reduced

Medicine Details:

	RISPERDAL (Suspected)		Reason:	
		0.0		
Ì	Batch:	Started:	Stopped:	
	701 OFT (0(1)		December Democracies	

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 334 of 554



Report Details:

Case Number: 148454

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

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

Seq: 1

Reported: 31/01/2000	Weight:							
ospitalisation:			Age: 20Y					
Onset Date: 02/07/1999					DC	DB:		
Outcome: Unknown			Causality: Causality possible					
action Details:						Γ		
Preferred Term	Sev	verity	Rep	ort Descri	ption	Treatment		
lepharospasm						The patient had some relief with benztropine and a reduction of the dose of risperidone.		
ledicine Details:	Other drua)		Re	ason:				
Tablet	other drug,	20.0 Mill		Daily	Oral			
Batch:	Sta	arted: 08/09/1			Stopped:	CONTIN		
RISPERIDONE (Suspected)				ason:				
Tablet		2.0 Mill	igram	Daily	Oral			
Batch:	Sta	arted: 01/08/1	-	-	Stopped:	CONTIN		
_aboratory Investigation		Date Tested	Result	1	D	etails		
Additional Information:								
port Run: 04/06/2007 11:05AM I	Database: pus	sime02		ADRS004		Page 335 of 554		



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

Report Details:

Case Number: 148836 Seq: 1 Gender: F

Reported: 11/02/2000 Weight: 75.00 Hospitalisation: Age: 20

Onset Date: 02/07/1999 **DOB**: 08/06/1979

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Jaw tightness	Cogentin

Medicine Details:

Medicine Details.				
RISPERDAL (Suspected)		Reason:		
	2.0 Milligram	Daily		
Batch:	Started: 01/07/1999		Stopped:	
HALOPERIDOL (Suspected)		Reason:		
	5.0 Milligram	Daily		
Batch:	Started: 01/07/1999		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking zoloft and panamax.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 336 of 554



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

Report Details:

Case Number: 148981 Seq: 1 Gender: M

 Reported: 14/02/2000
 Weight: 50.00

 Hospitalisation:
 Age: 09Y

Onset Date: 31/10/1999 **DOB:**

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased			

Medicine Details:

RISPERDAL (Suspected) Reason: Otr spec symp psychopathol nec

2.0 Milligram Daily

Batch: Started: 01/10/1999 **Stopped:** 03/02/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Increase in weight from 30-40kg over four months. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 337 of 554



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

Report Details:

Case Number: 149751 Seq: 1 Gender: F

Reported: 29/02/2000 Weight:
Hospitalisation: Age: 32Y

Onset Date: 20/01/2000 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.	action betails.									
Preferred Term	Severity	Report Description	Treatment							
Galactorrhoea		Creamy discharche from nipples.	Risperidone ceased.							
Hyperprolactinaemia										

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

Oral application 2.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking aropax.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 338 of 554



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

Report Details:

Case Number: 150369 Seq: 1 Gender: M

Reported: 10/03/2000 Weight:

Hospitalisation: Age: 16Y
Onset Date: 01/02/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Risperidone and diazepam ceased.

Medicine Details:

Medicine Details.			
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily Oral	
Batch:	Started: 20/01/2000	Stopped: 01/02/2000	
DIAZEPAM (Suspected)		Reason: Specific disorders of sleep	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

-						
	Date	Туре	Range	Date Tested	Result	Details
		Biochemistry				Increased Ift's detected about 10 days after commencing risperidone. drugs ceased and Ift's repeated in 2 days - levels decreased.

Additional Information:

Amobarbited 0.1mg ?frequency and bromoual erylurea 0.15mg ?frequency - reported on discharge summary when he first became psychotic on 20.1.00. allergies to some foods.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 339 of 554



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

• • •	ils:						
Case Number	r: 150836	Seq: 1				Gender:	F
Reported	d: 27/03/2000	0				Weight:	
lospitalisatior						Age:	
	e: 24/02/2000					DOB:	
	e: Recovered	d			C	Causality:	Causality possible
eaction Det			.,		5		- , ,
	erred Term	Seve	erity	Report	Description	0-	Treatment
Erythema multi	lioittie					Ce	eased zoloft and risperidone
Medicine De							
ZOLOFT (Suspe	ected)		EO O Milli	Reaso	•	Orol	
Batch:		Star	50.0 Milli	gram D	aily Stopped:	Oral	
RISPERIDONE (Suspected)	Otal	teu.	Reaso			
(, cacpetten,		4.0 14:11:				
Tablet			1.0 MIIII	gram D	aily	Oral	
Tablet Batch:		Star	1.0 Milli	gram D	aily Stopped:		
		Star		gram D			
		Star		gram D			
		Star		gram D			
		Star		gram D			
		Star		gram D			
		Star		gram D			
Batch:	Investigati			gram D			
Batch:	Investigati	ions:		gram D			ils
Batch:		ions:	ted:				ils
Batch:		ions:	ted:				ils
Batch:		ions:	ted:				ils
Batch:		ions:	ted:				ils
Batch:		ions:	ted:				ils
Batch:		ions:	ted:				ils
Laboratory Date	Туре	i ons: Range [ted:				ils
Batch:	Туре	i ons: Range [ted:				ils
Laboratory Date	Туре	i ons: Range [ted:				ils
Laboratory Date	Туре	i ons: Range [ted:				ils
Laboratory Date	Туре	i ons: Range [ted:				ils

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 340 of 554



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

Report Details:

Case Number: 150906 Seq: 1 Gender: F

Reported: 28/03/2000 Weight: 105.00 Hospitalisation: Age: 30

Onset Date: 20/10/1999 **DOB**: 02/07/1969

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	todotion Dotanoi			
	Preferred Term	Severity	Report Description	Treatment
	Diabetes mellitus			
	Weight decreased			

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psy	rchosis
Oral application	1.0 Milligram	Daily	Oral
Batch:	Started: 31/03/1998	Stopped:	
ALDAZINE (Suspected)		Reason: Specific disorde	rs of sleep
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 24/06/1998	Stopped:	
AROPAX (Suspected)		Reason: Depression	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 31/03/1998	Stopped:	
SODIUM VALPROATE (Suspected)		Reason:	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started: 07/04/1998	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data				Lost a lot of weight 15-20 kgs.

Additional Information:

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 341 of 554



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

Report Details:

 Case Number:
 150939
 Seq: 1
 Gender: M

 Reported:
 28/03/2000
 Weight:

Hospitalisation: Admitted to hospital **Age:** 78

Onset Date: 15/02/2000 DOB: 27/11/1921

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypokinesia		Decreased mobility.	
Confusional state		Increased confusion.	
Fatigue		Increased lethargy.	
Urinary incontinence		Increased urinary incontinence.	
Dizziness			
Hypotension			Ceasing risperidone. madopar dose has since been decreased to 5 x day ceasing last dose of the day. chlormethiazole been introduced.

Medicine Details:

RISPERIDONE (Suspected)

Reason: Hallucinations

3.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking warfarin, ranitidine, madopar and paroxetine.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 342 of 554



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

Report Details:

 Case Number:
 150992
 Seq: 1
 Gender:
 F

 Reported:
 28/03/2000
 Weight:

Hospitalisation: Age: 78Y
Onset Date: 04/01/2000 DOB:

Onset Date: 04/01/2000 DOB:
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

toaction Botano.			
Preferred Term	Severity	Report Description	Treatment
Confusional state			
Disturbance in attention			Risperdal decreased then ceased, aricept ceased and started on olanzapine therapy.
Somnolence			

Medicine Details:

ARICEPT (Suspected) Reason: Presenile dementia

0.0

Batch: Started: 01/06/1999 Stopped: 28/09/1999

RISPERDAL (Suspected) Reason: Paranoia

3.0 Milligram Daily

Batch: Started: 01/06/1999 Stopped: 04/01/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 343 of 554



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

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

 Case Number:
 151049
 Seq: 1
 Gender: M

 Reported:
 28/03/2000
 Weight:

Hospitalisation: Age: 20Y
Onset Date: 27/10/1998
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Saliva altered		Difficulty with salivation and tongue movements.	
Dystonia			Benztropine 2mg given orally. thioridazine reduced to 150mg/d.

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Suspected)			Unspecified psych	osis	
Tablet	300.0 Milligram	Daily	Ora	al	
Batch:	Started: 26/10/1998		Stopped: 27	10/1998	
RISPERIDONE (Suspected)		Reason:	Unspecified psych	osis	
Tablet	1.0 Milligram	Daily	Ora	al	
Batch:	Started: 23/10/1998		Stopped:	CONTIN	
DIAZEPAM (Suspected)		Reason:	Anxiety neurosis		
Tablet	15.0 Milligram	Daily	Ora	al	
Batch:	Started: 24/10/1998		Stopped:	CONTIN	

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 344 of 554



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

Report Details:

Case Number: 151287 Seq: 1 Gender: F

Reported: 06/04/2000 Weight: 72.00 Hospitalisation: Age: 81Y

Onset Date: 21/02/2000 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion botano			
Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating		Altered mental state	
Convulsion		Clonic tonic seizure	Phenytoin
Urinary incontinence			

Medicine Details:

RISPERIDONE (Suspected) Reason:

2.0 Milligram Daily

Batch: Started: 10/02/2000 **Stopped:** 21/02/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking thyroxine, temazeapm, lactulose, paracetamol.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 345 of 554



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

Report Details:

Case Number: 151790 Seq: 1 Gender: M

Reported: 18/04/2000 Weight:

Hospitalisation: Age: 16Y
Onset Date: 09/07/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tongue oedema		Tongue feeling increasingly swollen.	Benztropine. risperidone slowly withdrawn over 1 week. olanzapine slowly introduced in place of risperidone.

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified schizophrenia

Oral application 6.0 Milligram Daily Oral

Batch: Started: 01/05/1999 **Stopped:** 12/07/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient found it difficult to speak properly and move tongue. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 346 of 554



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

Case Number: 151811 Seq: 1 Weight: Reported: 17/04/2000 Weight: Iospitalisation: Age: 52Y Onset Date: DOB: Outcome: Unknown Causality: Causality possible eaction Details: Preferred Term Severity Report Description Treatment Oedema peripheral Swollen feet. Risperdal therapy ceas more than 5 years ago. Weight increased Weight gain. Medicine Details: RISPERDAL (Suspected) Reason: 0.0 Batch: Started: Stopped:						
Onset Date: Outcome: Unknown Baction Details: Preferred Term Dedema peripheral Dedina peripheral Weight increased Medicine Details: RISPERDAL (Suspected) Batch: Started: Age: 52Y DOB: Causality: Causality possible Report Description Treatment Risperdal therapy ceas more than 5 years ago. Weight gain.		Seq: 1				
Onset Date: Outcome: Unknown Causality: Causality: Causality possible saction Details: Preferred Term Severity Report Description Treatment Dedema peripheral Swollen feet. Risperdal therapy cease Weight increased Weight gain. Medicine Details: RISPERDAL (Suspected) Reason: 0.0 Batch: Started: Stopped:						
Outcome: Unknown Peaction Details: Preferred Term Severity Report Description Treatment Dedema peripheral Swollen feet. Risperdal therapy ceas more than 5 years ago. Weight increased Weight gain. Medicine Details: RISPERDAL (Suspected) Reason: 0.0 Batch: Started: Stopped:				_		
Preferred Term Severity Report Description Treatment Dedema peripheral Swollen feet. Risperdal therapy ceas more than 5 years ago. Weight increased Weight gain. Medicine Details: RISPERDAL (Suspected) Reason: 0.0 Batch: Started: Stopped:						
Preferred Term Severity Report Description Treatment Dedema peripheral Swollen feet. Risperdal therapy ceas more than 5 years ago. Weight gain. Medicine Details: RISPERDAL (Suspected) Reason: 0.0 Batch: Started: Stopped:				Causality: Causality possible		
Medicine Details: RISPERDAL (Suspected) Batch: Swollen feet. Risperdal therapy ceasmore than 5 years ago. Reason: 0.0 Started: Stopped: Reason: 0.0 Batch: Started: Stopped:		T - T				
Medicine Details: RISPERDAL (Suspected) Batch: Started: Stopped: Action of than 5 years ago. Medicine Details: Reason: 0.0 Started: Stopped:						
Medicine Details: RISPERDAL (Suspected) Batch: Started: Stopped:	Dedema peripheral		Swollen feet.	Risperdal therapy ceased more than 5 years ago.		
Medicine Details: RISPERDAL (Suspected) 0.0 Batch: Started: Stopped:	Veight increased	,	Weight gain	more than 6 years age.		
Batch: Started: Stopped: aboratory Investigations:			Page 2000			
Batch: Started: Stopped:	KISPERDAL (Suspected)	0.0				
aboratory Investigations:	Batch:					

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 347 of 554



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

			4 1	_		
$\mathbf{\nu}$	Δn	\sim 1	**	ם ו	taı	ls:
1	CN	vi	L	UG	Lai	13.

Gender: M Case Number: 152154 Seq: 1 Reported: 26/04/2000 Weight:

Hospitalisation: Admitted to hospital **Age:** 37

Onset Date: 19/04/2000 **DOB:** 31/10/1962

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			

Medicine Details:

Batch:

OLANZAPINE (Other drug)		Reason:	
	0.0		
Batch:	Started:		Stopped:

RISPERIDONE (Suspected) Reason:

0.0

Started: Stopped: Batch:

Started:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason:

0.0

Stopped: CLOZARIL (Suspected) Reason: Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: Started: 01/01/1997 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

ADRS004 Report Run: 04/06/2007 11:05AM Database: pusime02 Page 348 of 554



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

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

Case Number: 152326 Seq: 1 Gender: M

Reported: 03/05/2000 Weight:
Hospitalisation: Age: 29Y

Onset Date: 02/03/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
C	convulsion		Generalised tonic-clonic movements.	

Medicine Details:

McGicilic Details.				
CLOPIXOL (Suspected)		Reason: Uns	pecified schizophrenia	
Injection	50.0 Milligram	Daily	Intramuscula	r
Batch:	Started: 29/02/2000	;	Stopped:	CONTIN
RISPERDAL (Suspected)		Reason: Uns	pecified schizophrenia	
Tablet	1.0 Milligram	Daily	Oral	
Batch:	Started: 21/02/2000	;	Stopped: 21/02/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 349 of 554



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

Report Details:

Case Number: 152327 Seq: 1 Gender: F

Reported: 03/05/2000 Weight:
Hospitalisation: Age: 84Y

Onset Date: 04/02/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash erythematous			Sorbolene cream, oatmeal baths and olive oil to scalp.

Medicine Details:

RISPERDAL (Suspected) Reason:

Tablet 0.5 Milligram Daily Oral

Batch: Started: Stopped: 07/02/2000

Laboratory Investigations:

<u> </u>	i ji iii tootiga	invocagationor					
Date	Type Range Date		Date Tested	Result	Details		
	Histology				Biopsy was taken, which suggested toxic pustuloderma or agep (acute generalised exanthematous pustulosis).		

Additional Information:

Patient was also taking ssri which was discontinued on 7.2.00, verapamil, folic acid, atorvastatin, aspirin and coloxyl with senna. reaction: the patches commenced in the intramammary regions, spreading over the next few days to trunk, neck, back, arms, groin, thighs and legs, sparing the face. it progressed to skin exfoliation and redness of skin, but no oedema.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 350 of 554



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

Report Details:

 Case Number:
 152438
 Seq: 1
 Gender: M

 Reported:
 08/05/2000
 Weight:

Hospitalisation: Admitted to hospital

Age: 82Y

Onset Date: 17/04/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion botano.			
Preferred Term	Severity	Report Description	Treatment
Hypotension		Bp 56/38	
Tachycardia			Dose reduced to 0.5mg and slowly increased on subsequent nights.

Medicine Details:

RISPERIDONE (Suspected) Reason:

2.0 Milligram Daily

Batch: Started: 17/04/2000 Stopped: 17/04/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking oxazepam, temazepam, droperidol, panadeine, lactulose, olanzapine.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 351 of 554



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

Report Details:

Case Number: 152716 Seq: 1 Gender: F
Reported: 18/05/2000 Weight:
Hospitalisation: Admitted to hospital Age: 33Y

Onset Date: 14/02/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Syncope		Loss of consciousness.	Treated with sodium valproate
Amnesia			
Arrhythmia			
Convulsion			
Palpitations			

Medicine Details:

Medicine Details.						
MELLERIL (Other drug)	Reason:					
	1.0 Dose Unspeci	fied As necessary				
Batch:	Started:	Stopped:				
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia				
Tablet	1.0 Milligram	Daily Oral				
Batch:	Started: 13/11/1998	Stopped: 22/08/2000				

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Electrographics				Ecg showed qtc from 0.47 to 0.45. ct scan in mar-00 showed no abnormalities. eeg on 8/3/00 showed temporal lobe activity.

Additional Information:

Patient history of palpitations whilst taking risperidone.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 352 of 554



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

Report Details:

Case Number: 153176 Seq: 1 Gender: F

Reported: 10/05/2000 Weight: 72.00 Hospitalisation: Age: 16Y

Onset Date: 17/04/2000 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle spasms		Cramping legs/feet>spasms	
Drug withdrawal syndrome			
Dysphagia			
Headache			
Insomnia			
Nausea			
Nervousness			
Tremor			
Vomiting			

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified psychosis

0.2 Milligram Daily

Batch: Started: 18/02/1999 **Stopped:** 17/04/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking luvox. doctors comment: withdrawal syndrome to risperdal unusual.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 353 of 554



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

Report Details:

 Case Number:
 153333
 Seq: 1
 Gender:
 F

 Reported:
 01/06/2000
 Weight:
 0.00

 Hospitalisation:
 Age: 30Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Pituitary tumour		Pituitary neoplasm	
Diplopia	Severe		
Headache	Severe		
Hyperprolactinaemia			

Medicine Details:

Medicine Details:			
LITHIUM CARBONATE (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	3.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1996	Stopped: 28/05/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
17/12/2002	Other data				Prolactin level of 50,000 miu/l. ct scan showed an enlarged pituitary.

Additional Information:

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

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 354 of 554



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

Report Details:

 Case Number:
 153461
 Seq: 1
 Gender: F

 Reported:
 07/06/2000
 Weight:

Hospitalisation: Age: 16Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

caction Details.						
Preferred Term	Severity	Report Description	Treatment			
Galactorrhoea			Ceased risperidoen and reduced venlafaxine dose. commenced high dose cabergoli ne 0.5mg bd.			
Hyperprolactinaemia						

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other	er drug)		Reason:	Depression	
Oral application	600.0	Milligram	Daily		Oral
Batch: Started:		Stopped:			
RISPERIDONE (Suspected)			Reason:	Depression	
Oral application	3.0	Milligram	Daily		Oral

Laboratory Investigations:

		. <u>,</u>	• • .			
	Date	Туре	Range	Date Tested	Result	Details
I		Other data				Prolactinaemia diagnosed on 22/12/1999.
		Prolactin	66 - 490 MU/L	08/11/1999	1096	
		Prolactin	66 - 490 MU/L	30/11/1999	759	
		Prolactin	66 - 490 MU/L	10/01/2000	11MU/L	
		Prolactin	66 - 490 MU/L	17/04/2000	209MU/L	

Additional Information:

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 355 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number:	153543	Seq:	1		Ge	ender: M
	09/06/2000	_				eight: 85.00
ospitalisation:						Age: 18Y
Onset Date:	25/05/2000					DOB:
Outcome:	Unknown				Cau	sality: Causality possible
eaction Detai						
	ed Term	Se	everity	Repo	ort Description	Treatment
Anaphylactoid re	action					
Madiaina Dat	alla.					
Medicine Det				Rea	son:	
1401 21412 0142 (00	iopootou,		0.0	1100		
Batch:		S	tarted:		Stopped:	
_aboratory In			[]			
Date	Туре	Range	Date Tested	Result		Details
	I					
Additional Inf	formation					
additional III	omation.					
port Run: 04/06/20	07 11:05AM	Database: pu	usime02	A	DRS004	Page 356 of 554



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

Reporte ospitalisatio Onset Da Outcon eaction De	oer: 153609 :ed: 13/06/200	0 1		
ospitalisation Onset Da Outcon eaction De		Seq: 1	Geno	ler: M
ospitalisation Onset Da Outcone eaction De		-	Weig	ht:
Onset Da Outcon eaction De	on:		_	ge : 60
eaction De	ate: 05/06/200	00		OB : 15/07/1939
	ne: Unknown		Causal	ity: Causality possible
_	etails:			
Pre	ferred Term	Severity	Report Description	Treatment
Hypothermia			Temps of 35.4 and 34.8 degrees c.	
3lood creatin	ne phosphokina	ase incr		
<u>Medicine E</u>				
DIAZEPAM (S	suspected)		Reason:	
		0.0		
Batch		0.0 Started:	Stopped:	
Batch RISPERIDONE		Started:	Stopped: Reason:	
	E (Suspected)			
RISPERIDONE	E (Suspected)	Started: 0.0 Started:	Reason:	
RISPERIDONE Batch	E (Suspected) n: y Investigat	0.0 Started:	Reason: Stopped:	Netails
Batch Batch Laboratory Date	E (Suspected)	Started: 0.0 Started:	Reason: Stopped:	Details 2 days was 635 and 359

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 357 of 554



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

Report Details:						
Case Number: 153764	Seq: 1	Gender: M				
Reported: 19/06/2000		Weight: 77.00				

Hospitalisation: Age: 29Y
Onset Date: 20/05/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Rigidity in limbs	
Asthenia			
Blood creatine phosphokinase incr			
Chills			
Headache			
Hyperhidrosis			
Leukocytosis			
Malaise			
Neuroleptic malignant syndrome			
Pyrexia			
Visual disturbance			

n,	-	101	ne	-	+0:	10:
ıv		16 - 1			141	•

RISPERDAL (Suspected)

4.0 Milligram

Daily

Daily

Batch: Started: Stopped: 20/05/2000

Laboratory Investigations:

Euboratory invoctigations.						
	Date	Туре	Range	Date Tested	Result	Details
		Creatine		20/05/2000	685	
		White blood cells		20/05/2000	13.2	

Additional Information:

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 358 of 554



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

Report Details:

Case Number: 154013 Seq: 1 Gender: M

Reported: 22/06/2000 Weight:
Hospitalisation: Age: 35Y

Onset Date: 06/06/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Respiratory disorder		Restricted breathing.	
Dystonia	Required Specialist Consultation	Very mild dystonia.	
Libido decreased			

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified schizophrenia

2.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Oculomotor muscles neck, masseters, upper and lower trunk. chronic paranoid schizophrenia well controlled on risperdal 2mg/day. some treatment emergent dystonia (very mild), reduced libido and persistence of negative schizophrenic symptoms - affective blunting, disturbances in concentration.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 359 of 554



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

Report Details:

Case Number: 154038 Seq: 1 Gender: F

Reported: 23/06/2000 Weight:
Hospitalisation: Age: 52Y

Onset Date: 16/03/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electroencephalogram abnormal			

Medicine Details:

RISPERDAL (Suspected) Reason: Presenile dementia

Tablet 1.0 Milligram Daily Oral

Batch: Started: 09/03/2000 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Symptoms occurred within one week of starting risperdal therapy. medical history alzheimer's disease with a range of psychiatric symptoms.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 360 of 554



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

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

Gender: F Case Number: 154039 Seq: 1

Weight: Reported: 23/06/2000 **Hospitalisation:** Age: 40Y Onset Date: 31/05/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

LIPEX (Suspected)

III In (Gaopootoa)		110000111	
	0.0		
Batch:	Started:	Stopped:	
ASPIRIN (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
QUINAPRIL HYDROCHLORIDE (Suspected)	Reason:	

Reason:

0.0

Batch: Started: Stopped:

RISPERDAL (Suspected) Reason:

> 6.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	(30-40)IU/L	03/05/2000	121	
	Bilirubin	(3)UMOL/L	03/05/2000	12	
	GGT = SGGT =	(<40)IU/L	03/05/2000	112	

Additional Information:

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

ADRS004 Report Run: 04/06/2007 11:05AM Database: pusime02 Page 361 of 554



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Report Details:					
Case Number: 154078	Seq: 1	Gen	Gender: M		
Reported: 26/06/2000		Weig	ght:		
Hospitalisation:		Age : 25			
Onset Date: 05/06/2000		DOB : 28/08/1974			
Outcome: Recovered		Causality: Causality possible			
Reaction Details:					
Preferred Term	Severity	Report Description	Treatment		
Leukopenia			Clozaril and risperidone treatment ceased.		

	-				
М	edi	icii	ne	Deta	ails:

CLOZARIL (Suspected)		Reason: Unspecifi	ed schizophrenia	
Tablet	300.0 Milligram	Daily	Oral	
Batch:	Started: 08/03/2000	Stopp	ped: 10/06/2000	
RISPERIDONE (Suspected)		Reason:		
	1.0 Milligram	Daily		
Batch:	Started:	Stop	ned:	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

ADRS004 Report Run: 04/06/2007 11:05AM Database: pusime02 Page 362 of 554



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

Report Details:

Case Number: 154474 Seq: 1 Gender: M
Reported: 06/07/2000 Weight:
Hospitalisation: Age: 13Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Headache		Bad headaches.	
Muscle twitching		Mouth twitching.	
Dyskinesia			
Extrapyramidal disorder			Cogentin.
Extrapyramidal disorder			
Syncope			
Tardive dyskinesia			
Tremor			

Medicine Details:

RISPERDAL (Suspected)			Reason:	Unspecified schizophrenia	
Tablet	4.0	Milligram	Daily	Oral	
Batch:	Started:	S	STERM	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Tardive dyskinesia symptoms such as tremors, arm and leg jerkiness, rigidity of muscles, teeth chattering, body vibrations, eyes rolling in the head and mouth staying open. reactions occur throughout the day and the evening and have interferred with schooling and hygiene (such as showering).

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 363 of 554



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

Report Details:

 Case Number:
 155023
 Seq: 1
 Gender: F

 Reported:
 19/07/2000
 Weight:

Hospitalisation: Age: 40

Onset Date: 28/06/2000 **DOB**: 25/02/1960

Outcome: Recovered Causality: Causality probable

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Amenorrhoea			
Hyperprolactinaemia			Changed to olanzapine 7.5mg.

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified schizophrenia

1.5 Milligram Daily

Batch: **Started**: 18/12/1999 **Stopped**: 28/06/2000

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ľ		Prolactin				Prolactin level 1621 (n:619).

Additional Information:

Date of recovery 12.7.00.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 364 of 554



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

Report Details:

Case Number: 155243 Seq: 1 Gender: F

Reported: 20/07/2000 Weight:
Hospitalisation: Age: 81Y

Onset Date: 18/01/2000 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension			Risperidone ceased, commenced clozapine.

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

1.0 Milligram Daily

Batch: Started: 12/01/2000 Stopped: 19/01/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking citalopram, oxazepam, paracetamol, aspirin, imdur, coloxyl with senna, duralax, vit b12. previous adr on haloperidol - delusions.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 365 of 554



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

Report Details:

Case Number: 155271 Seq: 1 Gender: F

Reported: 20/07/2000 Weight: 50.00
Hospitalisation: Age: 75Y

Onset Date: 16/12/1999 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash			Diprosone oint, phenergan tds. omeprazole and perindopril ceased.

Medicine Details:

OMEPRAZOLE (Suspected)		Reason:	Other disease	s of esophagus
Oral application	40.0 Milligram	Daily		Oral
Batch:	Started: 01/11/1999		Stopped:	16/12/1999
PERINDOPRIL (Suspected)		Reason:		
Oral application	2.0 Milligram	Daily		Oral
Batch:	Started: 01/01/1997		Stopped:	16/12/1999
CITALOPRAM HYDROBROMIDE (Sus	pected)	Reason:	Depression	
Oral application	20.0 Milligram	Daily		Oral
Batch:	Started: 01/10/1999		Stopped:	22/12/1999
RISPERIDONE (Suspected)		Reason:	Otr spec symp	psychopathol nec
Oral application	0.5 Milligram	Daily		Oral
Batch:	Started: 30/11/1999		Stopped:	21/12/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History of bulous pemphigoid. patient also taking panadol, oxazepam. previous adr to prednisolone, haloperidol, frusemide, flucloxacillin, ethasymic acid, olanzapine, diazepam. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 366 of 554



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

Report Detail	S:					
Case Number:	155271	Seq: 1			Gender:	
	20/07/2000				Weight:	
ospitalisation:					Age:	
Onset Date:					DOB:	
	Not yet recovered			C	ausality:	Causality possible
eaction Detai	ils:					
Medicine Det	d)	11	Reas	·		
	d)	1. Started:	Reas 0 Dose Unspecified L TERM	Daily	nemia Oral 22/12/1999)
FEFOL (Suspected Oral applic	d)		0 Dose Unspecified	Daily	Oral	

Additional Information:

History of bulous pemphigoid. patient also taking panadol, oxazepam. previous adr to prednisolone, haloperidol, frusemide, flucloxacillin, ethasymic acid, olanzapine, diazepam. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 367 of 554



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

Report Details:

 Case Number:
 155823
 Seq: 1
 Gender:
 F

 Reported:
 04/08/2000
 Weight:

Hospitalisation: Age: 52

Onset Date: 14/06/2000 **DOB**: 10/10/1947

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

<u> </u>			1
Preferred Term	Severity	Report Description	Treatment
Pancreatitis	Life threatening	Life threatening acute pancreatitis.	

Medicine Details:

RISPERDAL (Suspected) Reason:

0.0

Batch: Started: 01/06/2000 Stopped: 14/06/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Risperdal given for behaviour changes, patient also taking gopten, norvasc and melleril. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 368 of 554



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

Report Details:

Case Number: 155898 Seq: 1 Gender: M

Reported: 07/08/2000 Weight:
Hospitalisation: Age: AD

Onset Date: 31/07/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapeutic response decreased			

Medicine Details:

Medicine Details.				
LAMISIL (Interaction)	R	Reason: Cellulitis of fing	er and toe	
Tablet	250.0 Milligram	Daily	Oral	
Batch:	Started: 01/06/2000 S TER	RM Stopped:		
RISPERIDONE (Interaction)	R	Reason: Unspecified sc	nizophrenia	
Tablet	2.0 Milligram	Daily	Oral	
Batch:	Started: 01/10/1999	Stopped:	CONTIN	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patients psychoses was not managed as well and this decrease in effecy was note 4 weeks after starting lamisil. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 369 of 554



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

Report Details:

Case Number: 156028 Seq: 1 Gender: F

Reported: 10/08/2000 Weight: 90.00 Hospitalisation: Admitted to hospital Age: 33

Onset Date: 23/07/2000 DOB: 13/11/1966

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating		Altered conscious state.	
Blood creatine phosphokinase incr			
Myopathy			Patient hospitalised. date of recovery 07/08/00. treatment ceased.

Medicine Details:

vieulcine Details.		
RISPERDAL (Suspected)		Reason:
	4.0 Milligram	Daily
Batch:	Started: 04/07/2000	Stopped: 28/07/2000
QUININE (Suspected)		Reason: Pain in limb
	300.0 Milligram	Daily
Batch:	Started: 20/07/2000	Stopped: 28/07/2000
TEMAZEPAM (Suspected)		Reason: Specific disorders of sleep
	10.0 Milligram	Daily
Batch:	Started: 04/07/2000	Stopped: 28/07/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		28/07/2000	3072	
	Creatine		02/08/2000	134	

Additional Information:

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 370 of 554



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

Report Details:

 Case Number:
 156060
 Seq: 1
 Gender: M

 Reported:
 11/08/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 44Y
Onset Date: 04/08/2000 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction betails.			
Preferred Term	Severity	Report Description	Treatment
Confusional state			
Hypertonia			
Neuroleptic malignant syndrome			Risperdal ceased. patient was hospitalised.
Pyrexia			

Medicine Details:

Medicine Details.			
RISPERDAL (Suspected)		Reason:	
	1.0 Milligram	Daily	
Batch:	Started: 01/05/2000	Stopped:	08/08/2000
EPILIM (Suspected)		Reason:	
	500.0 Milligram	Daily	
Batch:	Started: 02/08/2000	Stopped:	04/08/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking lithium. long history of melleril use prior to risperdal. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 371 of 554



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

Report Details:		
Case Number: 157229	Seq: 1	Gender: F

Reported: 31/08/2000 Weight:
Hospitalisation: Age: 18Y

Onset Date: 19/06/2000 **DOB:**

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			Risperdal ceased.

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified schizophrenia

 Oral application
 4.0 Milligram
 Daily
 Oral

 Batch:
 Started: 02/06/2000
 Stopped: 26/06/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 372 of 554



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

Report Details:

 Case Number:
 157331
 Seq: 1
 Gender: U

 Reported:
 04/09/2000
 Weight:

Hospitalisation: Age:
Onset Date: 31/08/2000 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal impairment		Interstitial nephritis	

Medicine Details:

RISPERDAL (Suspected) Reason:

Oral application 1.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 373 of 554



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

Re	port	Detail	ls:
----	------	--------	-----

 Case Number:
 157738
 Seq: 1
 Gender: M

 Reported:
 15/09/2000
 Weight:
 110.00

Hospitalisation: Weight: 110.00

Onset Date: 09/09/2000 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	todotion Dotails.			
	Preferred Term	Severity	Report Description	Treatment
	Hepatic function abnormal			
	Weight increased			

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified schizophrenia

2.5 Milligram Daily

Batch: Started: 10/02/2000 Stopped: CONTIN

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ		Biochemistry				Ggt 77 (<51), alt 61 (<51).

Additional Information:

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 374 of 554



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

Report Details:

Case Number: 157739 Seq: 1 Gender: M
Reported: 15/09/2000 Weight:
Hospitalisation: Age: 88Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion Botanoi			
Preferred Term	Severity	Report Description	Treatment
Pyrexia		Temp of 39.2 degrees	Date of recovery 11/09/00
Blood creatine phosphokinase incr			
Somnolence			

Medicine Details:

RISPERIDONE (Suspected) Reason:

2.5 Milligram Daily

Batch: Started: 01/08/2000 **Stopped:** 09/09/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine				Cpk 1330.

Additional Information:

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

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 375 of 554



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

Report Details:

 Case Number:
 157742
 Seq: 1
 Gender: M

 Reported:
 15/09/2000
 Weight:

Hospitalisation: Age: 45

Onset Date: 06/07/2000 **DOB**: 27/12/1954

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating			
Hypertonia			Bromocritpine then electroconvulsive therapy.
Pyrexia			

Medicine Details:

NORVIR (Suspected)		Reason:	Hiv infection	
	800.0 Milligram	Daily		
Batch:	Started: 01/01/2000		Stopped:	08/07/2000
FORTOVASE (Suspected)		Reason:	Hiv infection	
	400.0 Milligram	Daily		
Batch:	Started: 01/01/2000		Stopped:	08/07/2000
COMBIVIR (Suspected)		Reason:	Hiv infection	
	2.0 Dose Unspec	cified Daily		
Batch:	Started: 01/01/2000		Stopped:	08/07/2000
RISPERDAL (Suspected)		Reason:	Unspecified ps	sychosis
	4.0 Milligram	Daily		
Batch:	Started: 01/03/2000		Stopped:	08/07/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatinine				Small rise in creatinine kinase levels

Additional Information:

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

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 376 of 554



DOB: 27/12/1954

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

Report Details:

 Case Number:
 157742
 Seq: 1
 Gender: M

 Reported:
 15/09/2000
 Weight:

Hospitalisation: Age: 45

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Onset Date: 06/07/2000

Medicine Details:

ZIAGEN (Suspected) Reason: Hiv infection

2.0 Dose Unspecified Daily

Batch: Started: 01/01/2000 **Stopped:** 08/07/2000

VALIUM (Suspected) Reason: Unspecified psychosis

10.0 Milligram Daily

Batch: Started: 03/07/2000 Stopped: 08/07/2000

Laboratory Investigations:

Additional Information:

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

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 377 of 554



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

Severity	Report De	DOI Causality scription	e: 36 B: 24/04/1964 y: Causality possible Treatment Pramin 1q6h prn, required visit to doctor.
Severity	Report De	Causality scription	y: Causality possible Treatment Pramin 196h prn, required
Severity	Report De	scription F	Treatment Pramin 1q6h prn, required
Severity	Report De	F	Pramin 1g6h prn, required
Severity	Report De	F	Pramin 1g6h prn, required
		F	Pramin 1q6h prn, required visit to doctor.
	Posson:	Unenocified nevelocie	
1.0 Millia		Orispecified psychosis	
		Stopped:	
I Data Tasked I	Decision I		A. :10-
ge Date Tested	Result	De	tails
		Reason: 1.0 Milligram Daily Started: 11/10/2000	1.0 Milligram Daily Started: 11/10/2000 Stopped:

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 378 of 554



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

Report Details:

 Case Number:
 158723
 Seq: 1
 Gender: F

 Reported:
 20/10/2000
 Weight:

Hospitalisation: Age: 25Y
Onset Date: 30/07/2000 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia			Risperdal ceased

Medicine Details:

Medicine Details.					
RISPERDAL (Suspected)		Reason:	Manic depressive	psycho, depre	
Tablet	2.0 Milligram	Daily	0	ral	
Batch:	Started: 25/07/2000		Stopped: 2	1/09/2000	
VENLAFAXINE HYDROCHLORIDE	(Suspected)	Reason:			
Oral application	225.0 Milligram	Daily	0	ral	
Batch:	Started: 18/07/2000		Stopped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Lymphocytes	1-4 X10E9/L	25/07/2000	1.0	
	Lymphocytes	1-4 X10E9/L	30/07/2000	0.9	
	Lymphocytes	1-4 X10E9/L	07/09/2000	0.9	
	Neutrophils	1.8-8 X10E9/L	25/07/2000	5.4	
	Neutrophils	1.8-8 X10E9/L	30/07/2000	2.0	
	Neutrophils	1.8-8 X10E9/L	07/09/2000	1.3	
	White blood cells	4-11 X10E9/L	25/07/2000	7	

Additional Information:

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 379 of 554



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

Report Details:

 Case Number:
 158723
 Seq: 1
 Gender: F

 Reported:
 20/10/2000
 Weight:

Hospitalisation: Age: 25Y
Onset Date: 30/07/2000 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

MEGICINE DETAILS.				
RISPERDAL (Suspected)		Reason: Manic d	epressive psycho, o	depre
Tablet	2.0 Milligram	Daily	Oral	
Batch:	Started: 25/07/2000	Stop	oped: 21/09/2000	
VENLAFAXINE HYDROCHLORIDE	Reason:			
Oral application	225.0 Milligram	Daily	Oral	
Batch:	Started: 18/07/2000	Stop	oped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells	4-11 X10E9/L	30/07/2000	3.5	
	White blood cells	4-11 X10E9/L	07/09/2000	2.5	
	White blood cells	4-11 X10E9/L	25/09/2000	5.4	
	White blood cells	4-11 X10E9/L	29/09/2000	3.1	
	White blood cells	4-11 X10E9/L	06/10/2000	2.7	
	White blood cells	4-11 X10E9/L	13/10/2000	3.6	

Additional Information:

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 380 of 554



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

Report Details:

 Case Number:
 158867
 Seq: 1
 Gender: M

 Reported:
 27/10/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 36Y
Onset Date: 31/10/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Dotano.			
Preferred Term	Severity	Report Description	Treatment
Dystonia		Worsening of dystonia.	
Blood creatine phosphokinase incr			Patient hospitalised.

Medicine Details:

RISPERDAL (Suspected)		Reason:	Unspecified schizophrenia
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started:		Stopped: 11/10/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		11/10/2000	5000	Ck levels mormalised to <200u/l.
	Creatine		12/10/2000	1000	Ck levels mormalised to <200u/l.
	Creatine		23/10/2000	<200	Ck levels mormalised to <200u/l.

Additional Information:

Patient also taking lithium carbonate. patient refuses treatment with any other antipsychotic. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 381 of 554



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

Report Details:

Case Number: 158896 Seq: 1 Gender: M

Reported: 31/10/2000 Weight:

Hospitalisation: Age: 86Y
Onset Date: 31/08/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			Risperdal ceased.

Medicine Details:

RISPERDAL (Suspected)

0.5 Milligram Daily

Batch: Started: Stopped: 4D

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells				Slighty elevated wcc.

Additional Information:

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

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 382 of 554



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

Report Details:

Case Number: 159301 Seq: 1 Gender: M

Reported: 16/11/2000 Weight:

Hospitalisation: Age: 18Y
Onset Date: 04/10/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Tongue was stiff & protruding, then curled up.	Given im benztropine

Medicine Details:

Medicine Details.				
HALOPERIDOL (Suspected)	OPERIDOL (Suspected) Reason:			
Injection	10.0 Milligram	1 time Intramuscular		
Batch:	Started:	Stopped:		
RISPERIDONE (Suspected)		Reason: Unspecified psychosis		
Tablet	2.0 Milligram	Daily Oral		
Batch:	Started: 03/10/2000	Stopped:		

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Patient also taking midazolam, diazepam.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 383 of 554



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

Report Details:

Case Number: 159355 Seq: 1 Gender: F

Reported: 16/11/2000 Weight:
Hospitalisation: Age: 22Y

Onset Date: 12/06/2000 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Tongue oedema		Swollen tongue.	
Dyskinesia		Tongue darting.	

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

Tablet 2.0 Milligram Daily Oral

Batch: Started: 12/06/2000 Stopped: 13/06/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking diane 35. no previous exposure but further exposure (one off dose) caused no further effects. this was the first exposure to antipsychotics - prevously neuroleptic naive.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 384 of 554



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

Report Details:

 Case Number:
 159674
 Seq: 1
 Gender: M

 Reported:
 01/12/2000
 Weight:

Hospitalisation: Admitted to hospital **Age:** 76

Onset Date: 10/11/2000 DOB: 30/06/1924

Outcome: Recovered Causality: Causality possible

Reaction Details:

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
Hypoglycaemia			Patient was hospitalised. discharged 3 days later.

Medicine Details:

viedicine Details:				
RISPERIDONE (Suspected)		Reason:	Unspecified schizophrenia	a
Tablet	6.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	CONTIN
SODIUM VALPROATE (Suspected)		Reason:	Otr spec symp psychopat	hol nec
Oral application	200.0 Milligram	Daily	Oral	
Batch:	Started: 01/10/2000		Stopped:	CONTIN
RANITIDINE (Suspected)		Reason:	Other diseases of esopha	gus
Tablet	300.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Serum glucose				Bsl prior to admission 1.3 mmol/l.

Additional Information:

No previous history of hypoglycaemia. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 385 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number		Seq	: 1			Gende		
_	: 20/11/200	00				Weigh		
spitalisation						_	e: 28Y	
Onset Date	:					DO	В:	
Outcome	: Recovere	d				Causalit	y: Causality possi	ble
action Deta								
Prefer	red Term	S	everity	Rep	ort Descrip	otion	Treatmen	t
ood creatine p	phosphokina	ase incr				<u> </u>	Risperidone ceased	
edicine De			2.0 Milli		son:			
Batch:			2.0 Milli Started:	gram	Daily	Stopped:		
ala avata w I		:						
aboratory I	nvestigat Type	Range	Date Tested	Result	I	De	tails	
Date	Турс	range	Date Tested	rtoduit			iuii o	
dditional Ir	nformatio	n:						
ort Run: 04/06/2	007 11:05AN	И Database: р	usime02	,	ADRS004		Page 386	of 554



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

Report Details:

 Case Number:
 159796
 Seq: 1
 Gender: M

 Reported:
 07/12/2000
 Weight:

Hospitalisation: Age: 29Y
Onset Date: 09/11/2000 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

,	Cachon Details.			
	Preferred Term	Severity	Report Description	Treatment
	Oedema		Oedema hands, feet, face.	Patient already in hospital
	Weight increased			

Medicine Details:

Medicine Details.			
RISPERDAL (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 06/11/2000	Stopped:	09/11/2000
RISPERDAL (Suspected)		Reason:	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 09/11/2000	Stopped:	13/11/2000

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Patient was also taking clonazeapm, flupenthixol decanoate.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 387 of 554



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

Report Details:

 Case Number:
 159805
 Seq: 1
 Gender: M

 Reported:
 08/12/2000
 Weight:

Hospitalisation: Age: 38

Onset Date: 02/12/2000 **DOB**: 18/04/1962

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		High temp 38.3 degrees.	
Blood creatine phosphokinase incr			
Neuroleptic malignant syndrome	Life threatening		lv hydration, alkaline urine.
Renal failure acute	Life threatening		
Rhabdomyolysis	Severe		

Medicine Details:

RISPERIDONE (Suspected)		Reason:	Schizophrenia	
Tablet	3.0 Milligram	Daily		Oral
Batch:	Started: 01/01/1999		Stopped:	02/12/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatinine		02/12/2000	240,000	

Additional Information:

Patient history of schizophrenia and intellectual retardation. sequelae: renal failure. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 388 of 554



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

Report Details:

 Case Number:
 159814
 Seq: 1
 Gender:
 F

 Reported:
 08/12/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 48

Onset Date: 27/10/2000 **DOB**: 17/08/1952

Outcome: Unknown Causality: Causality possible

Reaction Details:

١,	reaction Details.				
	Preferred Term	Severity	Report Description	Treatment	
	Dystonia			Patient hospitalised	
	Suicide attempt				
	Tremor				

Medicine Details:

Medicine Details.		
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia
Tablet	10.0 Milligram	Daily Oral
Batch:	Started: 01/02/2000	Stopped : 20/10/2000
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia
Tablet	6.0 Milligram	Daily Oral
Batch:	Started: 20/10/2000	Stopped: 01/11/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking epilim, seroquel. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 389 of 554



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

Report Details:

Case Number: 159945 Seq: 1 Gender: F

Reported: 13/12/2000 Weight: 60.00 Hospitalisation: Age: 26

Onset Date: 06/12/2000 DOB: 23/09/1974
Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

todotion botailor			
Preferred Term	Severity	Report Description	Treatment
Angioedema			Respiridone ceased. required a visit to doctor.
Pruritus			
Urticaria			

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified schizophrenia

1.0 Milligram Daily

Batch: Started: 05/12/2000 Stopped: 06/12/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Same reaction occurred on rechallenge with risperidone.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 390 of 554



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

Report Details:

 Case Number:
 160356
 Seq: 1
 Gender: M

 Reported:
 02/01/2001
 Weight:

Hospitalisation:
Onset Date:

DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

,	caction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Blepharospasm		Uncontrollable eye shutting.	
	Tardive dyskinesia			

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified schizophrenia

8.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Australian and new zealand journal of psychiatry 2000, 34 (5): 879-80.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 391 of 554



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

Report Details:

 Case Number:
 160357
 Seq: 1
 Gender:
 F

 Reported:
 02/01/2001
 Weight:

Hospitalisation: Age: 25

Onset Date: 31/10/2000 **DOB**: 29/10/1975

Outcome: Unknown Causality: Causality possible

Reaction Details:

-				
	Preferred Term	Severity	Report Description	Treatment
	Hyperprolactinaemia		Elevated prolactin level.	
	Thrombocytopenia			

Medicine Details:

Medicine Details.						
LITHIUM CARBONATE (Other drug)			Reason:			
Tablet	1.0	Gram	Daily		Oral	
Batch:	Started:			Stopped:		CONTIN
RISPERDAL (Suspected)			Reason:	Unspecified pa	sychosis	
Oral application	7.0	Milligram	Daily		Oral	
Batch:	Started: 01/0	3/1999		Stopped:	28/11/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Platelets		14/07/2000	169X10?9/L	
	Platelets		26/10/2000	123X10?9/L	
	Platelets		24/11/2000	102X10?9/L	
	Prolactin		26/10/2000	114.8MIU/L	
	Prolactin		24/11/2000	113.1MIU/L	

Additional Information:

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

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 392 of 554



Report Details:

Case Number: 160468

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

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

Seq: 1

Medicine Details: RISPERDAL (Suspected) Tablet 3.0 Milligram Dally Oral Batch: Started: Stopped:	Reported: 09/01/2001			V	veignt:
Onset Date: Outcome: Unknown action Details: Preferred Term Severity Report Description Treatment euroleptic malignant syndrome enal impairment Patient was admitted to hospital. Patient was admitted to hospital. Patient was admitted to hospital. Patient was admitted to hospital. Patient was admitted to hospital. Patient was admitted to hospital. Patient was admitted to hospital. Patient was admitted to hospital. Patient was admitted to hospital. Patient was admitted to hospital. Patient was admitted to hospital. Patient was admitted to hospital. Patient was admitted to hospital. Patient was admitted to hospital. Patient was admitted to hospital. Patient was admitted to hospital. Patient was admitted to hospital.	ospitalisation: Admitted to	hospital			Age:
Action Details: Preferred Term	Onset Date:				
Preferred Term Severity Report Description Treatment leuroleptic malignant syndrome lenal impairment Patient was admitted to hospital. Patient was admitted to hospital.	Outcome: Unknown			Cau	usality: Causality possible
Preferred Term Severity Report Description Treatment leuroleptic malignant syndrome lenal impairment Patient was admitted to hospital. Patient was admitted to hospital.	eaction Details:				
Renal impairment Patient was admitted to hospital. Redicine Details: RISPERDAL (Suspected) Tablet 3.0 Milligram Daily Oral Batch: Started: Stopped:		Severity	Report Do	escription	Treatment
Medicine Details: RISPERDAL (Suspected) Tablet 3.0 Milligram Daily Oral Batch: Started: Stopped:	leuroleptic malignant syndro	me			
Medicine Details: RISPERDAL (Suspected) Tablet 3.0 Milligram Daily Oral Batch: Started: Stopped:	Renal impairment				Patient was admitted to
Tablet 3.0 Milligram Daily Oral Batch: Started: Stopped: Aboratory Investigations:					
Tablet 3.0 Milligram Daily Oral Batch: Started: Stopped: Aboratory Investigations:					
Tablet 3.0 Milligram Daily Oral Batch: Started: Stopped: Aboratory Investigations:					
Tablet 3.0 Milligram Daily Oral Batch: Started: Stopped: Aboratory Investigations:			Pagagoni		
Batch: Started: Stopped:		3.0		, .)ral
aboratory Investigations:			Willigram Dally		nai
	aboratory Investigatio	ons:			
			ted Result		Details
	A daliti a u al lusta uma ati a u .				
	Additional Information:				
Additional Information:					



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

Report Details:

Case Number: 160773 Seq: 1 Gender: F

Reported: 18/01/2001 Weight: 89.00
Hospitalisation: Age: 37Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Hallucination		Hearing voices and visual hallucinations.	
	Psychotic disorder		Slashed wrists and breasts.	

Medicine Details:

ALDAZINE (Interaction)	Reason:			
	50.0 Milligram	As necessary		
Batch:	Started:	Stopped:		
ZYBAN SR (Interaction)		Reason:		
	300.0 Milligram	Daily		
Batch:	Started: 13/11/2000	Stopped: 04/01/2001		
RISPERDAL (Interaction)		Reason:		
	4.0 Milligram	Daily		
Batch:	Started:	Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking adventan, akineton, aldazine, betnovate, depo-ralovera, diazepam, difflam, efexor-xr, ergodryl mono, metoclopramide and panadeine forte. allergies to cephalexin, cortisone im, cotrimoxazole, doxycycline, erythromycin, gentamicin, lincomycin, neomycin, septrin, sodium, streptomycin and theophylline.

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 394 of 554



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

Report Details:

Case Number: 160797 Seq: 1 Gender: M
Reported: 22/01/2001 Weight:

Hospitalisation: Admitted to hospital **Age**: 35

Onset Date: 04/01/2001 **DOB**: 25/05/1965

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Patient hospitalised. patient diagnosed with hep c.

Medicine Details:

Medicine Details.				
RISPERDAL (Suspected)		Reason: Unspecified schize	phrenia	
	4.0 Milligram	Daily		
Batch:	Started: 27/12/2000	Stopped: 03/	01/2001	
LITHICARB (Suspected)		Reason: Unspecified schize	phrenia	
	1.2 Gram	Daily		
Batch:	Started:	Stopped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		04/01/2000	689	
	ALT = SGPT		05/01/2001	540	
	ALT = SGPT		10/01/2001	555	
	ALT = SGPT		08/01/2001	562	
	ALT = SGPT		11/01/2001	595	
	AST = SGOT		04/01/2000	211	
	AST = SGOT		05/01/2001	181	

Additional Information:

Report Run: 04/06/2007 11:05AM Database: pusime02 ADRS004 Page 395 of 554



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

Report Details:

Case Number: 160797 Seq: 1 Gender: M
Reported: 22/01/2001 Weight:

Hospitalisation: Admitted to hospital Age: 35

Onset Date: 04/01/2001 **DOB**: 25/05/1965

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified schizophrenia

4.0 Milligram Daily

Batch: Started: 27/12/2000 **Stopped:** 03/01/2001

LITHICARB (Suspected) Reason: Unspecified schizophrenia

1.2 Gram Daily

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

<u> </u>	, ,				
Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT		08/01/2001	173	
	AST = SGOT		11/01/2001	177	
	AST = SGOT		10/01/2001	174	
	GGT = SGGT =		04/01/2000	84	
	GGT = SGGT =		10/01/2001	68	
	GGT = SGGT =		08/01/2001	61	
	GGT = SGGT =		05/01/2001	76	

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 396 of 554



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

Report Details:

Case Number: 160797 Seq: 1 Gender: M
Reported: 22/01/2001 Weight:

Hospitalisation: Admitted to hospital Age: 35

Onset Date: 04/01/2001 **DOB**: 25/05/1965

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified schizophrenia

4.0 Milligram Daily

Batch: Started: 27/12/2000 **Stopped:** 03/01/2001

LITHICARB (Suspected) Reason: Unspecified schizophrenia

1.2 Gram Daily

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

<u> </u>	i ji iii tootiga				
Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =		11/01/2001	72	
	SAP = ALP		04/01/2000	146	
	SAP = ALP		05/01/2001	128	
	SAP = ALP		08/01/2001	117	
	SAP = ALP		10/01/2001	112	
	SAP = ALP		11/01/2001	117	

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 397 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

ospitalisati Onset D	ate: 24/11/200 me: Recovered	0	: 1			DOE	
	eferred Term	Se	everity	Repo	ort Description	n	Treatment
aggression ardive dysk	inesia					F c	tisperdal and cogentin eased.
l odicina	Dotoilo						
ledicine ZANTAC (Oth				Rea	son:		
			2.0 Dos	e Unspecified			
Batc	h:	S	Started:			pped:	
PANAMAX (C	ther drug)			Rea	son:		
			4.0 Dos	e Unspecified	-		
Batc		S	Started:			pped:	
RISPERDAL ((Suspected)		50 t		son:		
Batc	h·	c	5.0 Milli Started: 02/11/20		Daily	pped: 05/12/20	00
COGENTIN (S			naiteu. UZ/11/20		son:	ppsu. 00/12/20	
(0			2.0 Milli		Daily		
		Started: 14/11/2000			-	pped: 05/12/20	00
Batc	h:						
Batc							
Batc	y Investigat		Date Tested	Result		Det	oilo

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 398 of 554



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

Report Details:

 Case Number:
 161118
 Seq: 1
 Gender:
 F

 Reported:
 01/02/2001
 Weight:

Hospitalisation: Age: 23

Onset Date: 24/01/2001 **DOB**: 25/05/1977

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion botanoi			
Preferred Term	Severity	Report Description	Treatment
Dystonia	Life threatening	Severe dystonia reaction	Given cogentin im.
Oculogyration			

Medicine Details:

CLOPIXOL-ACUPHASE (Suspected)		Reason:	Unspecified p	sychosis
Injection	100.0 Milligram	1 time	е	Intramuscular
Batch:	Started: 22/01/2001		Stopped:	22/01/2001
CHLORPROMAZINE HYDROCHLORIDE	(Suspected)	Reason:		
	100.0 Milligram	Daily		
Batch:	Started: 22/01/2001		Stopped:	23/01/2001
RISPERIDONE (Suspected)		Reason:		
	1.0 Milligram	Daily		
Batch:	Started: 23/01/2001		Stopped:	24/01/2001
DIAZEPAM (Suspected)		Reason:		
	15.0 Milligram	Daily		
Batch:	Started: 22/01/2001		Stopped:	22/01/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Allergic to penicillin. patient recovered 24/01/01.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 399 of 554



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

Report Details:

Case Number: 161533 Seq: 1 Gender: F

Reported: 14/02/2001 Weight: 50.00 Hospitalisation: Age: 48Y

Onset Date: 20/02/2000 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	todotion Botans.			
	Preferred Term	Severity	Report Description	Treatment
	Oedema		Pedal oedema - moderately severe.	
	Hypoproteinaemia			

Medicine Details:

Medicine Details.			
RISPERIDONE (Suspected)			
	2.0 Milligram	Daily	
Batch:	Started: 03/02/2000	Stopped	: CONTIN
TEMAZEPAM (Suspected)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started: 03/02/2000	Stopped	l:
ZOLOFT (Suspected)		Reason:	
	50.0 Milligram	Daily	
Batch:	Started: 01/01/2000	Stopped	l :

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ſ		Albumin				Albumin fell to 31.

Additional Information:

Patient also taking lithium and thioridazine. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 400 of 554



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

Report Details:

Case Number: 161558 Seq: 1 Gender: M

Reported: 10/02/2001 **Weight:** 100.00

Hospitalisation: Age: 84

Onset Date: 23/01/2001 **DOB**: 17/05/1916

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal		Thought disorder	Required a visit to doctor.

Medicine Details:

RISPERDAL (Suspected)

1.0 Milligram

Daily

Batch: Started: 25/12/2000 Stopped: 25/01/2001

ZOLOFT (Suspected) Reason:

50.0 Milligram Daily

Batch: **Started**: 24/10/2000 **Stopped**: 25/01/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking aldactone, astrix, lanoxin, lasix. patient recovered 28/1/01.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 401 of 554



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

Report Details:

Case Number: 161582 Seq: 1 Gender: F

Reported: 16/02/2001 Weight: 85.00 Hospitalisation: Admitted to hospital Age: 74

Onset Date: 15/01/2001 **DOB**: 29/07/1926

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Aggression			Cessation of drugs, patient hospitalised
Thinking abnormal		Thought disorder	

Medicine Details:

 RISPERDAL (Suspected)
 Reason:

 2.0
 Milligram
 Daily

 Batch:
 Started: 12/02/2000
 Stopped: 20/01/2001

ZOLOFT (Suspected) Reason: Depression

100.0 Milligram Daily

Batch: Started: 19/10/2000 **Stopped:** 20/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking fosamax, augmentin forte, astrix.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 402 of 554



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

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

 Case Number:
 161616
 Seq: 1
 Gender: M

 Reported:
 16/02/2001
 Weight:

Hospitalisation: Age: 76

Onset Date: 10/11/2000 **DOB**: 30/06/1924

Outcome: Recovered Causality: Causality possible

Reaction Details:

	I _		
Preferred Term	Severity	Report Description	Treatment
Hypoglycaemia			Glucose infusion. patient hospitalised

Medicine Details:

RISPERIDONE (Suspected)		Reason:	Unspecified schizophren	ia
	6.0 Milligram	Daily		
Batch:	Started:		Stopped:	CONTIN
SODIUM VALPROATE (Suspected)		Reason:	Otr spec symp psychopa	thol nec
	200.0 Milligram	Daily		
Batch:	Started:		Stopped:	CONTIN
RANITIDINE (Suspected)		Reason:		
	300.0 Milligram	Daily		
Batch:	Started:		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Serum glucose				Bsl - 1.3mmol/l

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 403 of 554



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

Report Details:

Case Number: 162004 Seq: 1 Gender: M

Reported: 28/02/2001 **Weight**: 110.00

 Hospitalisation:
 Age: 16

 Onset Date: 08/02/2001
 DOB: 26/08/1984

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction Details.				
Preferred Term	Severity	Report Description	Treatment	l
Weight increased		Weight gain 25kg.		ĺ
Drug withdrawal syndrome				l
Dyskinesia			Required a visit to doctor.	l

Medicine Details:

RISPERIDONE (Suspected) Reason: Otr spec symp psychopathol nec

6.0 Milligram Daily

Batch: Started: 01/10/1999 **Stopped:** 04/02/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking fluvoxamine, quetiopine. reaction occurred 4 days after the cessation of risperidone and 4 days into quetiopine therapy. patient has asperger's and mildly intellectually impaired. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 404 of 554



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

Report Details:

Case Number: 162258 Seq: 1 Gender: M

Reported: 07/03/2001 Weight:

Hospitalisation: Age: 19Y
Onset Date: 02/01/2001 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus		Itchy all over.	Ceased phenytoin.
	Required Specialist Consultation	Rash on face	

Medicine Details:

RISPERIDONE (Suspected) Reason: Otr spec symp psychopathol nec

Tablet 1.0 Milligram Daily Oral

Batch: Started: 13/12/1999 **Stopped:** 21/12/2000

PHENYTOIN SODIUM (Suspected) Reason: Prophylaxis

Capsule 400.0 Milligram Daily Oral

Batch: Started: 13/02/2000 **Stopped:** 21/12/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking lacrilube, rhinocort. patient recovered 22/12/00.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 405 of 554



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

Report Details:

Case Number: 162375 Seq: 1 Gender: F

Reported: 08/03/2001 Weight: 60.00 Hospitalisation: Age: 44Y

Onset Date: 14/12/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Treatment	
Hyperkinesia	·		Cease risperidone on 14/12/2000. restarted on 20/12/2000.

Medicine Details:

RISPERIDONE (Suspected) Reason: Otr spec symp psychopathol nec

Tablet 0.5 Milligram As necessary Oral

Batch: Started: 12/11/2000 **Stopped:** 14/12/2000 CONTIN

Laboratory Investigations:

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

Additional Information:

Relevant medical history - alzheimer's disease - agitated. patient also taking - donepezil and sertraline.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 406 of 554



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

Report Details:

Case Number: 162384 Seq: 1 Gender: F

Reported: 08/03/2001 Weight: 38.00 Hospitalisation: Age:

Onset Date: 11/01/2001 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Convulsion		Involuntary jerking movements.	
Anorexia			
Confusional state			
Dry mouth			
Fatigue			
Hypertension			
Neuropathy peripheral			

Medicine Details:

BACLOFEN (Suspected)		Reason:	Abnormal invo	luntary movement
Tablet	60.0 Milligram	Daily		Oral
Batch:	Started: 07/01/2001		Stopped:	12/01/2001
QUININE (Suspected)		Reason:	Pain in limb	
Oral application	300.0 Milligram	Daily		Oral
Batch:	Started: 10/01/2001		Stopped:	11/01/2001
AMITRIPTYLINE HYDROCHLORIDE (Su	spected)	Reason:	Pain	
Oral application	25.0 Milligram	Daily		Oral
Batch:	Started: 07/01/2001		Stopped:	10/01/2001
AMITRIPTYLINE HYDROCHLORIDE (Su	spected)	Reason:	Pain	
Oral application	50.0 Milligram	Daily		Oral
Batch:	Started: 10/01/2001		Stopped:	11/01/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking trimethoprim, digesic, heparin.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 407 of 554



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

Report Detail	s:							
Case Number: Reported: Hospitalisation: Onset Date:	08/03/2001	Seq:	1				Gender: Weight: Age: DOB:	38.00
	Not yet recovered					C		Causality possible
Reaction Detai						·	ausanty.	Causanty possible
Medicine Deta	ails:							
PERSANTIN SR (S					Reason:			
Capsule	. ,		200.0	Milligram	Daily		Oral	
Batch:		Sta	arted:			Stopped:	11/01/2001	
RISPERIDONE (Su	spected)				Reason:	Abdominal pai	n	
				Milligram	Daily			
Batch:		Sta	arted: 10/	01/2001		Stopped:	11/01/2001	
Laboratory In	vestigations:							
Additional Inf Patient was also ta	ormation: king trimethoprim, d	igesic,	heparin.					

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 408 of 554



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

Re	port	Det	tail	s:

 Case Number:
 162385
 Seq: 1
 Gender:
 F

 Reported:
 08/03/2001
 Weight:

Hospitalisation: Admitted to hospital Age: 35Y
Onset Date: 22/02/2001
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botanoi								
Preferred Term	Severity	Report Description	Treatment					
Pneumonia			Treated with antibiotics, ceased quietiapine. was admitted to hospital.					
Somnolence								

Medicine Details:

CIPRAMIL (Suspected)			Reason:	
	20.0	Milligram	Daily	
Batch:	Started:			Stopped:
RISPERIDONE (Suspected)			Reason:	
	2.0	Milligram	Daily	
Batch:	Started:			Stopped:
QUETIAPINE (Suspected)			Reason:	
	50.0	Milligram	Daily	
Batch:	Started:			Stopped: 22/02/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 28/2/01.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 409 of 554



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

Ren	ort	Deta	ils:
-----	-----	------	------

Case Number: 162499 Seq: 1 Gender: F

Reported: 13/03/2001 Weight: 30.00 Hospitalisation: Age: 9

Onset Date: 01/12/2000 **DOB**: 29/09/1991

Outcome: Recovered Causality: Causality possible

Reaction Details:

touction bottom			
Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia			Required a visit to doctor. date of recovery 22/01/01

Medicine Details:

RISPERIDONE (Suspected) Reason:

Oral application 250.0 Microgram 1 time Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Prolactin		01/12/2000	131	

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 410 of 554



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

Report Details:

Case Number: 162682 Seq: 1 Gender: M

Reported: 16/03/2001 Weight:
Hospitalisation: Age: 41

Onset Date: 05/01/2001 **DOB**: 16/02/1959

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Risperidal ceased. date of recovery 16.1.01.

Medicine Details:

RISPERDAL (Suspected) Reason: Otr spec symp psychopathol nec

 Tablet
 2.0 Milligram
 Daily
 Oral

 Batch:
 Started: 03/01/2001
 Stopped: 12/01/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		30/12/2000	6.14	
	Neutrophils		05/01/2001	5.14	
	Neutrophils		08/01/2001	1.65	
	Neutrophils		11/01/2001	1.47	
	Neutrophils		12/01/2001	1.44	
	Neutrophils		13/01/2001	2	
	Neutrophils		15/01/2001	1.65	

Additional Information:

Patient also taking dilantin, coloxyl with senna, nilstat and heparin. patient history: 3.12.00 pushbike accident, multiple fractures, chi (multi focal haemorrhage with oedema), small intraventricular sub-dural bleed, splenic lacerations and post traumatic amnesia.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 411 of 554



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

Report Details:

 Case Number:
 162682
 Seq: 1
 Gender: M

 Reported:
 16/03/2001
 Weight:

Hospitalisation: Age: 41

Onset Date: 05/01/2001 **DOB**: 16/02/1959

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

RISPERDAL (Suspected) Reason: Otr spec symp psychopathol nec

 Tablet
 2.0 Milligram
 Daily
 Oral

 Batch:
 Started: 03/01/2001
 Stopped: 12/01/2001

Laboratory Investigations:

	<u>,</u>	• • .			
Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		16/01/2001	4.78	
	Neutrophils		18/01/2001	2.17	
	Neutrophils		29/01/2001	3.55	

Additional Information:

Patient also taking dilantin, coloxyl with senna, nilstat and heparin. patient history: 3.12.00 pushbike accident, multiple fractures, chi (multi focal haemorrhage with oedema), small intraventricular sub-dural bleed, splenic lacerations and post traumatic amnesia.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 412 of 554



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

Report Details:

Case Number: 163013 Seq: 1 Gender: M

Reported: 22/03/2001 Weight:
Hospitalisation: Age: 78

Onset Date: 20/03/2001 DOB: 09/07/1922

Outcome: Recovered Causality: Causality probable

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Dermatitis bullous		Blistering lower lip.	
	Face oedema		Swelling of lower lip.	Required a visit to doctor.

Medicine Details:

RISPERIDONE (Suspected) Reason: Otr spec symp psychopathol nec

 Tablet
 0.5 Dose Unspecified Daily
 Oral

 Batch:
 Started: 19/02/2001
 Stopped: 17/03/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No other recent change in treatment.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 413 of 554



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

Report Details:

Case Number: 163278 Seq: 1 Gender: F

Reported: 02/04/2001 Weight:
Hospitalisation: Age: 78Y

Onset Date: 01/03/2001 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

-				
	Preferred Term	Severity	Report Description	Treatment
	Tardive dyskinesia			

Medicine Details:

RISPERIDONE (Suspected) Reason: Paranoia

1.0 Milligram Daily

Batch: Started: 01/05/1997 **Stopped:** 28/01/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking diazepam, aspirin, thyroxine, hrt. the date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start and stop date is not necessarily accurate but indicates the drug was started sometime in the month.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 414 of 554



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

Report Details:

 Case Number:
 163344
 Seq: 1
 Gender: M

 Reported:
 28/03/2001
 Weight:

Hospitalisation: Age: 20

Onset Date: DOB: 29/03/1980

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

Medicine Details:

RISPERDAL (Suspected)

Tablet

3.0 Milligram

Daily

Oral

Batch:

Started: 22/09/2000

Stopped: 28/02/2001

Laboratory Investigations:

	<u> </u>				
Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		08/09/2000	3.7	
	Neutrophils		08/02/2001	1.4	
	Neutrophils		15/02/2001	1.9	
	Neutrophils		01/03/2001	1.3	

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 415 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Onset Date: Outcome: Recovered eaction Details: Preferred Term Urinary incontinence Choking Coma Constipation Salivary hypersecretion	Sev	verity	Bedwe	Report	: Desc		Weight: Age: DOB ausality:	: Causality	possible
Outcome: Recovered eaction Details: Preferred Term Urinary incontinence Choking Coma Constipation Salivary hypersecretion	Sev	rerity	Bedwe		: Desc		DOB	: Causality	
Outcome: Recovered eaction Details: Preferred Term Urinary incontinence Choking Coma Constipation Salivary hypersecretion	Sev	verity	Bedwe		: Desc			Causality	
Preferred Term Urinary incontinence Choking Coma Constipation Salivary hypersecretion	Sev	rerity	Bedwe		: Desc		ausality:		
Urinary incontinence Choking Coma Constipation Salivary hypersecretion	Sev	verity	Bedwe		Desc	ription		Trea	atment
Preferred Term Urinary incontinence Choking Coma Constipation Salivary hypersecretion	Sev	verity	Bedwe		Desc	ription		Trea	atment
Choking Coma Constipation Salivary hypersecretion			Bedwe	tting					
Coma Constipation Salivary hypersecretion									
Coma Constipation Salivary hypersecretion Vomiting									
Salivary hypersecretion									
Vomiting	<u> </u>								
Medicine Details:									
CLOZARIL (Suspected)				Reaso					
Tablet			Gram		Daily		Oral		
Batch:	Sta	rted:				Stopped:			
AROPAX (Suspected)				Reaso					
			Milligran	n [Daily				
Batch:	Sta	rted:				Stopped:			
RISPERIDONE (Suspected)		0.0	N 4:11:	Reaso					
Parkets.	04-		Milligrar	n L	Daily	04			
Batch:	Sta	rted:				Stopped:			
Laboratory Investigation Date Type		Date Test	ted	Result			Deta	ils	
Additional Information:				L					
Additional Information:									

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 416 of 554



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

Report Details:

 Case Number:
 163762
 Seq: 1
 Gender:
 F

 Reported:
 17/04/2001
 Weight:

Hospitalisation: Age: 57

Onset Date: 03/04/2001 **DOB**: 23/10/1943

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			
Neuroleptic malignant syndrome			Dantrolene, cogentin, bromocriptine, sinemet.

Medicine Details:

CEFTRIAXONE (Other drug)		Reason:	
	0.0		
Batch:	Started:		Stopped: 30/03/2001
GENTAMICIN SULPHATE (Other drug)		Reason:	
	0.0		
Batch:	Started: 27/03/2001		Stopped:
AMOXYCILLIN SODIUM (Other drug)		Reason:	
	0.0		
Batch:	Started:		Stopped: 04/04/2001
PROTAPHANE (Other drug)		Reason:	
	44.0 Unit	Daily	
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		26/03/2001	52	
	Creatine		03/04/2001	333	
	Creatine		04/04/2001	316	
	Creatine		05/04/2001	252	
	Creatine		06/04/2001	1347	
	Creatine		06/04/2001	1623	
	Creatine		07/04/2001	1367	

Additional Information:

Previous nms secondary to haloperidol.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 417 of 554



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

Report Details:

 Case Number:
 163762
 Seq: 1
 Gender:
 F

 Reported:
 17/04/2001
 Weight:

Hospitalisation: Age: 57

Onset Date: 03/04/2001 **DOB**: 23/10/1943

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE	(Other drug)	Reason:			
	0.5 Milligram	Daily			
Batch:	Started: 26/03/2001		Stopped:		
CLONAZEPAM (Other drug)		Reason:			
	75.0 Milligram	Daily			
Batch:	Started: 26/03/2001		Stopped:		
HALOPERIDOL (Suspected)		Reason:			
Injection	0.5 Milligram	1 time		Intramuscular	
Batch:	Started: 28/03/2001		Stopped:		
RISPERIDONE (Suspected)		Reason:			
Oral application	1.0 Milligram	Daily		Oral	
Batch:	Started: 30/03/2001		Stopped:	04/04/2001	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		09/04/2001	403	

Additional Information:

Previous nms secondary to haloperidol.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 418 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number:	163762	Seq: 1		Gender:	F
Reported:	17/04/2001			Weight:	
Hospitalisation:				Age:	
Onset Date:					23/10/1943
	Not yet recovered	d		Causality:	Causality possible
Reaction Detail	ls:				
Madiaina Data					
Medicine Deta	ROCHLORIDE (Suspe	acted)	Reason: Diabe	etes mellitus	
	COOTILOTABL (Ouspo	2.0 Gram	Daily	otes memas	
Batch:		Started: 29/03/2001		topped: 04/04/2001	
				••	
Laboratory In	vestinations:				
Euboratory III	vestigations.				
Additional Info	ormation:				
Previous nms seco		I.			

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 419 of 554



Report Details:

Case Number: 163982

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

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

Seq: 1

Repor	ted: 26/04/2001				Wei	ght:		
lospitalisati	ion:		Age: 52 DOB: 03/03/1949					
Onset D	ate:							
Outco	me: Unknown			Causality: Causality pos				
eaction D								
	eferred Term	Se	everity	Rep	oort Description	Treatment		
Choking								
Dysphagia T								
Tongue oed	етта							
Medicine	Dotoilo							
	IE (Suspected)			Re	ason:			
INIOI ENIDOI	ie (Gaspesica)		1.0 Milli		Daily			
Batc	.h.		tarted:	gram	Stopped:			
Date	411.		iarieu.		Stopped.			
Laborator	y Investiga <u>ti</u>	ons:						
Date	Туре	Range	Date Tested	Result		Details		
_			-					
Additiona	I Information):						
eport Run: 04/0	06/2007 11:06AM	Database: p	usime02		ADRS004	Page 420 of 554		



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

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

 Case Number:
 164332
 Seq: 1
 Gender:
 F

 Reported:
 07/05/2001
 Weight:
 81.00

Hospitalisation: Admitted to hospital Age: 52

Onset Date: 06/11/2000 **DOB**: 20/03/1948

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Hallucination		Hallucinations of spiders on my back.	Symptoms settled by decreasing risperidal to 2mg daily, patient was hospitalised.

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug) Reason: Otr disord amino-acid transprt

150.0 Milligram Daily

Batch: Started: L TERM Stopped: 05/03/2001

RISPERDAL (Suspected) Reason:

0.0

Batch: Started: Stopped:

LITHIUM CARBONATE (Suspected) Reason: Schizophrenia

1.2 Gram Daily

Batch: Started: L TERM Stopped: 05/03/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 421 of 554



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

Report Details:

Case Number:164333Seq: 1Gender:FReported:07/05/2001Weight:81.00Hospitalisation:Admitted to hospitalAge: 52

Onset Date: 04/01/2001 **DOB**: 20/03/1948

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		Extremely sleepy.	Required a visit to doctor, was hospitalised. dose of riperidone was increased to 3mg.
Catatonia			
Hyponatraemia			
Red blood cell sedimentation rate i			

Medicine Details:

Medicine Details:					
VENLAFAXINE HYDROCHLORIDE (O	ther drug)		Reason:	Schizophrenia	
	150.0	Milligram	Daily		
Batch:	Started:		L TERM	Stopped:	05/03/2001
RISPERIDONE (Suspected)			Reason:		
	2.0	Milligram	Daily		
Batch:	Started:			Stopped:	
LITHIUM CARBONATE (Suspected)			Reason:	Schizophrenia	
	1.2	Gram	Daily		
Batch:	Started:		L TERM	Stopped:	05/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		24/10/2000	74	
	ALT = SGPT		05/03/2001	94	
	AST = SGOT		24/10/2000	40	
	AST = SGOT		05/03/2001	34	
	Creatinine		05/03/2001	0.321	
	Creatinine		19/03/2001	0.134	
	Creatinine		27/03/2001	0.147	

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 422 of 554



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

Report Details:

Case Number: 164333 Seq: 1 Gender: F

Reported: 07/05/2001 Weight: 81.00
Hospitalisation: Admitted to hospital Age: 52

Onset Date: 04/01/2001 **DOB**: 20/03/1948

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)

Batch: Started: L TERM Stopped: 05/03/2001

RISPERIDONE (Suspected) Reason:

Reason:

Schizophrenia

Stopped:

2.0 Milligram Daily

Batch: Started:

LITHIUM CARBONATE (Suspected) Reason: Schizophrenia

1.2 Gram Daily

Batch: Started: L TERM Stopped: 05/03/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatinine		03/04/2001	0.159	
	Creatinine		01/05/2001	0.146	
	Creatinine		19/04/2001	0.122	
	Creatinine		10/04/2001	0.143	
	Erythrocyte		05/03/2001	96	
	Erythrocyte		19/03/2001	91	
	Erythrocyte		27/03/2001	84	

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 423 of 554



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

Report Details:

Case Number: 164333 Seq: 1 Gender: F

Reported: 07/05/2001 Weight: 81.00 Hospitalisation: Admitted to hospital Age: 52

Onset Date: 04/01/2001 **DOB**: 20/03/1948

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug) Reason: Schizophrenia

150.0 Milligram Daily

Batch: Started: L TERM Stopped: 05/03/2001

RISPERIDONE (Suspected) Reason:

2.0 Milligram Daily

Batch: Started: Stopped:

LITHIUM CARBONATE (Suspected) Reason: Schizophrenia

1.2 Gram Daily

Batch: Started: L TERM Stopped: 05/03/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Erythrocyte		03/04/2001	81	
	Erythrocyte		10/04/2001	74	
	Erythrocyte		19/04/2001	60	
	Erythrocyte		01/05/2001	45	
	GGT = SGGT =		24/10/2000	50	
	GGT = SGGT =		05/03/2001	131	
	Haemoglobin		19/03/2001	10.2	

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 424 of 554



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

Report Details:

Gender: F Case Number: 164333 Seq: 1

Reported: 07/05/2001 Weight: 81.00 Hospitalisation: Admitted to hospital Age: 52

Onset Date: 04/01/2001 **DOB**: 20/03/1948

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Batch:

VENLAFAXINE HYDROCHLORIDE (Other drug)

	150.0 Millig	gram Daily				
Batch:	Started:	L TERM	Stopped: 05/03/2001			
RISPERIDONE (Suspected)		Reason:				
	2.0 Millio	oram Daily				

Reason:

Schizophrenia

Stopped:

2.0 Milligram Daily

Started: LITHIUM CARBONATE (Suspected) Schizophrenia

Reason:

1.2 Gram Daily

Started: L TERM Batch: Stopped: 05/03/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haemoglobin		27/03/2001	10.1	
	Haemoglobin		03/04/2001	10.0	
	Prolactin		03/04/2001	5467	
	Prolactin		10/04/2001	1058	
	Prolactin		01/05/2001	488	
	Prolactin		19/04/2001	627	
	SAP = ALP		24/10/2000	104	

Additional Information:

ADRS004 Report Run: 04/06/2007 11:06AM Database: pusime02 Page 425 of 554



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

Report Details:

Case Number: 164333 Seq: 1 Gender: F

Reported: 07/05/2001 Weight: 81.00 Hospitalisation: Admitted to hospital Age: 52

Onset Date: 04/01/2001 **DOB**: 20/03/1948

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)

	150.0 Milli	igram Daily		
Batch:	Started:	L TERM	Stopped: 05/03/2001	
RISPERIDONE (Suspected)	Reason:			

Reason:

Schizophrenia

2.0 Milligram Daily

Batch: Started: Stopped:

LITHIUM CARBONATE (Suspected) Reason: Schizophrenia

1.2 Gram Daily

Batch: Started: L TERM Stopped: 05/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP		05/03/2001	113	
	Serum drug level	LITHIUM	05/03/2001	1.40	
	Serum glucose		05/03/2001	10.0	
	Serum glucose		19/03/2001	8.0	
	Serum glucose		03/04/2001	4.9	
	Serum glucose		27/03/2001	5.7	
	Sodium		05/03/2001	124	

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 426 of 554



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

Report Details:

Gender: F Case Number: 164333 Seq: 1

Weight: 81.00 Reported: 07/05/2001 Hospitalisation: Admitted to hospital Age: 52

Onset Date: 04/01/2001 **DOB**: 20/03/1948

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)

	150.0 Milli	igram Daily	1			
Batch:	Started:	L TERM	Stopped: 05/03/2001			
RISPERIDONE (Suspected)	Reason:					
2.0 Milligram Daily						

Reason:

Schizophrenia

2.0 Milligram Daily

Batch: Started: Stopped:

LITHIUM CARBONATE (Suspected) Reason: Schizophrenia

> 1.2 Gram Daily

Batch: Started: L TERM Stopped: 05/03/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Urate		05/03/2001	0.85	
	Urate		03/04/2001	0.34	
	Urate		27/03/2001	0.33	
	Urate		19/03/2001	0.37	
	Urea		05/03/2001	2.7	
	Urea		19/03/2001	10.2	
	Urea		27/03/2001	7.9	

Additional Information:

ADRS004 Report Run: 04/06/2007 11:06AM Database: pusime02 Page 427 of 554



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

Report Details:

Case Number: 164333 Seq: 1 Gender: F

Reported: 07/05/2001 Weight: 81.00
Hospitalisation: Admitted to hospital Age: 52

Onset Date: 04/01/2001 **DOB**: 20/03/1948

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)			Reason:	Schizophrenia	
	150.0	Milligram	Daily		
Batch:	Started:		L TERM	Stopped:	05/03/2001
RISPERIDONE (Suspected)			Reason:		
	2.0	Milligram	Daily		
Batch:	Started:			Stopped:	
LITHIUM CARBONATE (Suspected)			Reason:	Schizophrenia	
	1.2	Gram	Daily		
Batch:	Started:		L TERM	Stopped:	05/03/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Urea		03/04/2001	6.2	
	Urea		10/04/2001	5.2	
	Urea		19/04/2001	3.5	
	Urea		01/05/2001	6.6	

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 428 of 554



Report Details:

Case Number: 164334

Reported: 07/05/2001

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 81.00

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

Seq: 1

Onset Date: 19/03/2001 Outcome: Recovered eaction Details: Preferred Term Insomnia						
Preferred Term				DOB : 20/03/1948		
Preferred Term nsomnia		Causality: Causality possible				
nsomnia						
	Severity	Rep	ort Description	Treatment		
		Can not sleep.				
Thirst		Drinking litres of thirsty.	f water, dry mouth,	very		
Hyperprolactinaemia		Prolactin extrem	nely high.			
Thinking abnormal		Weird thoughts	etc.			
Anaemia				Ceased risperidone.		
Diabetes mellitus						
Drug level increased						
Polydipsia						
Renal failure acute						
LITHIUM CARBONATE (Interaction Batch:		.2 Gram L TERM	ason: Daily Stopped:	05/03/2001		
RISPERIDONE (Interaction)	Starteu.		ason: Schizophreni			
Mor EMBONE (interaction)	3	.0 Milligram	Daily	u .		
Batch:		06/11/2000	-	05/03/2001		
	ns:					
aboratory Investigation		ested Result		D 4 3		
_aboratory Investigation Date Type	Range Date T	esteu Resuit		Details		

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 429 of 554



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

Report Details:

 Case Number:
 164502
 Seq: 1
 Gender: M

 Reported:
 14/05/2001
 Weight:

Hospitalisation:
Onset Date: 28/09/2000
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure		Nothing comes out.	

Medicine Details:

vieuicine Details.					
SEREPAX (Other drug)	Reason:				
	7.5 Millig	ram As r	necessary		
Batch:	Started:	L TERM	Stopped:	CONTIN	
RISPERDAL (Suspected)		Reason:	Unspecified schizop	hrenia	
	0.0 Millig	ram 6 tin	nes		
Batch:	Started: 01/08/200	00	Stopped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date is not necessarily accurate but indicates the drug was started sometime in the month. patient had been on modecate for 30 years before switching to risperdal. weaned off it over 3/12.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 430 of 554



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

Report Details:

Case Number: 164601 Seq: 1 Gender: U

Reported: 18/05/2001 Weight:
Hospitalisation: Age: 21Y

Onset Date: 28/12/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			

Medicine Details:

RISPERDAL (Suspected) Reason:

Tablet 4.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. 2 years of use of risperdal. pt developed tarditive dyskinesia. dystonia cease d with reduction in dose but psychotic relapse necessitated reinstitution of risperidone.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 431 of 554



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

Report Details:

Case Number: 164602 Seq: 1 Gender: M

Reported: 18/05/2001 Weight:
Hospitalisation: Age:
Onset Date: 15/05/2001 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pericarditis			

Medicine Details:

RISPERDAL (Suspected) Reason:

Tablet 2.0 Milligram Daily Oral

Batch: Started: 25/04/2001 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset in not necessarily accurate but indicates onset sometime in the month.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 432 of 554



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

Case Number: 164913 Seq: 1 Gender: M
Reported: 28/05/2001 Weight: 75.00

Hospitalisation: Age: 36

Onset Date: 17/03/2001 DOB: 02/08/1964
Outcome: Recovered Causality: Causality probable

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Urticaria	Severe	Rash on face, arms, trunk, legs, feet, ears, scalp	
Face oedema			
Oedema genital			
Oedema peripheral			
Periorbital oedema			

Medicine Details:

RISPERIDONE (Suspected)

Tablet

4.0 Milligram

Daily

Oral

Batch: Started: 16/02/2001 Stopped: 17/02/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 433 of 554



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

Report Details:

Case Number: 165069 Seq: 1 Gender: F

Reported: 01/06/2001 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 35Y
Onset Date: 28/05/2001
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular disorder			

Medicine Details:

RISPERDAL (Suspected)		Reason:		
Tablet	500.0 Microgram	Daily	Oral	
Batch:	Started:	Sto	pped: 28/05/2001	
RISPERDAL (Suspected)	!	Reason:		
	1.5 Milligram	Daily		
Batch:	Started: 01/05/2001	Sto	pped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. The dose start and stop dates are not accurate but indicates risperidal was started and stopped sometime in the month.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 434 of 554



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

Report Details:

Case Number:165276Seq: 1Gender: MReported:12/06/2001Weight: 76.00Hospitalisation:Admitted to hospitalAge: 79

Onset Date: 19/02/2001 **DOB**: 24/11/1921

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Bp 70-90.	
Aphasia		Mutism.	
Arrhythmia		Pulse very slow and irregular.	
Neuroleptic malignant syndrome	Severe	Severe neuroleptic nalignant syndrome.	
Bradycardia			
Hypertonia			Patient was hospitalised. required a visit to doctor. reaction was life threatening. treated with baclofen 1 bd. melleril ceased.

n	// a al	: _:		Det:	.:
n	/IPA	ıcı	ne	I JATS	anc.

·	100.0 Milligram	Daily		
CARTIA (Other drug)		Reason:		
Batch:	Started:		Stopped:	
	25.0 Milligram	Daily		
TENORMIN (Other drug)		Reason:		
Batch:	Started:		Stopped:	
	0.0			
VITAMINS (Other drug)		Reason:		
Batch:	Started:		Stopped:	
	0.0			
GINKGO BILOBA (Other drug)		Reason:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start date for risperdal is not accurate but indicates the drug was started sometime in the year. patient had been taking melleril 10mg regularly at 5pm instead of only prn.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 435 of 554



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

Report Details:

Case Number: 165276 Seq: 1 Gender: M

Reported: 12/06/2001 Weight: 76.00
Hospitalisation: Admitted to hospital Age: 79

Onset Date: 19/02/2001 DOB: 24/11/1921

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

ARICEPT (Other drug)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	
FOLIC ACID (Other drug)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	
MELLERIL (Suspected)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Otr spec symp psychopathol nec	
	0.5 Milligram	Daily	
Batch:	Started: 01/01/2000	Stopped: 22/02/2001	

Laboratory Investigations:

Additional Information:

The dose start date for risperdal is not accurate but indicates the drug was started sometime in the year. patient had been taking melleril 10mg regularly at 5pm instead of only prn.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 436 of 554



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

Report Details:

Case Number: 165391 Seq: 1 Gender: M
Reported: 13/06/2001 Weight:

Hospitalisation: Age: 44

Onset Date: DOB: 06/03/1957

Outcome: Recovered Causality: Causality possible

Reaction Details:

Des faces of Taxon	0	Demand Demandation	Torontorout
Preferred Term	Severity	Report Description	Treatment
Psychotic disorder			Zyban ceased. date of recovery 3/2001.

Medicine Details:

JEZIL (Other drug)		Reason:		Othr&unspec	netabolic diseases
	2.0	Dose Unspecified	Daily		
Batch:	Started:	L TERM		Stopped:	
ASPIRIN (Other drug)		Reason:			
	0.5	Dose Unspecified	Daily		
Batch:	Started:	L TERM		Stopped:	
ZYBAN SR (Suspected)		Rea	son:	Smoker	
	2.0	Dose Unspecified	Daily		
	2.0	Dose Orispecified	Daily		
Batch:	Started: 01	·	Daily	Stopped:	28/03/2001
Batch: RISPERIDONE (Suspected)		/03/2001	son:	Stopped:	28/03/2001
1 11		/03/2001	,	Stopped:	28/03/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The start and stop dates for zyban are not necessarily accurate but indicates the drug was started and stopped sometime in the month. increased "voices" schizophrenic symptoms.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 437 of 554



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

Report Details:

Case Number: 165405 Seq: 1 Gender: F

Reported: 14/06/2001 Weight: 70.00 Hospitalisation: Age: 20

Onset Date: 08/06/2001 **DOB**: 12/04/1981

Outcome: Unknown Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Required visit to doctor, stopped risperdone, treated with cogentin

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

1.0 Milligram Daily

Batch: Started: 15/05/2001 **Stopped:** 10/06/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime of the month

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 438 of 554



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

Report Details:

Case Number: 165936 Seq: 1 Gender: M

Reported: 29/06/2001 **Weight:** 100.00

Hospitalisation: Age: 34

Onset Date: 28/06/2000 **DOB**: 05/03/1966

Outcome: Recovered Causality: Causality probable

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Erectile dysfunction			No medication given. risperidone ceased. date of recovery 06/2001
	Salivary hypersecretion			

Medicine Details:

SODIUM VALPROATE (Other drug) Reason: Unspecifid affective psychosis

2.0 Gram Daily

Batch: Started: Stopped:

RISPERIDONE (Suspected) Reason: Unspecified affective psychosis

4.0 Milligram Daily

Batch: Started: 01/06/2000 Stopped: 01/06/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 439 of 554



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

Report Details:

Case Number: 166064 Seq: 1 Gender: F

Reported: 04/07/2001 Weight: 40.00 Hospitalisation: Age: 15

Onset Date: 20/06/2001 **DOB**: 10/07/1985

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	,	Dystonic reaction affecting r extensors of hand	Cogentin given and stopped risperdal.

Medicine Details:

Medicine Details.			
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	1.0 Milligram	Daily	
Batch:	Started: 14/05/2001	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	2.0 Milligram	Daily	
Batch:	Started: 24/05/2001	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	3.0 Milligram	Daily	
Batch:	Started: 11/06/2001	Stopped: 28/06/2001	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 440 of 554



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

Report Details:

 Case Number:
 166153
 Seq: 1
 Gender:
 F

 Reported:
 05/07/2001
 Weight:

Hospitalisation: Age: 36

Onset Date: 15/06/2001 **DOB:** 03/04/1965

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia			

Medicine Details:

Medicine Details.			
LITHIUM CARBONATE (Other drug)		Reason: Unspecified schizophrenia	
Oral application	1.0 Gram	Daily Oral	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily Oral	
Batch:	Started: 01/04/2001	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start date of risperdal is not necessarily accurate but indicates the drug was started sometime in the month.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 441 of 554



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

Report Details:

Case Number: 166344 Seq: 1 Gender: F
Reported: 11/07/2001 Weight:

Hospitalisation:
Onset Date: 28/02/2001
Age: 30Y
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Amenorrhoea		Patient has not mensturated for the past year.	Plans to cease zoloft if event do not resolve
Hyperprolactinaemia			

Medicine Details:

Medicine Details.					
ZOLOFT (Suspected)			Reason:	Depression	
Tablet	200.0	Milligram	Daily		Oral
Batch:	Started: 27/	02/2001		Stopped:	15/06/2001
RISPERIDONE (Suspected)			Reason:		
Tablet	2.0	Milligram	Daily		Oral
Batch:	Started:	L	TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Fested Result Details	
Prolactin Prolactin level of 3000 plus.		Prolactin level of 3000 plus.			
	Radiololgy				Mri scan was performed which revealed a microadenoma.

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in' the month.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 442 of 554



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

Report Details:

Case Number: 166613 Seq: 1 Gender: F

Reported: 18/07/2001 Weight: 84.00 Hospitalisation: Age: 45

Onset Date: 04/06/2001 **DOB**: 19/01/1956

Outcome: Recovered Causality: Causality probable

Reaction Details:

	I		
Preferred Term	Severity	Report Description	Treatment
Migraine			Patient required visit to doctor, risperdal ceased.

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified psychosis

2.0 Milligram Daily

Batch: Started: 04/06/2001 **Stopped:** 25/06/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient recovered on the 27/6/2001.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 443 of 554



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

Report Details:

 Case Number:
 166866
 Seq: 1
 Gender: F

 Reported:
 24/07/2001
 Weight:

Hospitalisation: Age: 42

Onset Date: 16/05/2001 **DOB**: 20/03/1959

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	toaction Botano.			
	Preferred Term	Severity	Report Description	Treatment
	Breath odour			
	Gingivitis			

Medicine Details:

LITHIUM CARBONATE (Other drug) Reason: Obsessive compulsive neurosis

1.5 Gram Daily

Batch: Started: L TERM Stopped: CONTIN

RISPERIDONE (Suspected) Reason: Unspecified psychosis

2.0 Milligram Daily

Batch: Started: 24/01/2001 Stopped: 12/06/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Gingivitis diagnosed when teeth became loose, front tooth moved. patient will require orthodontic treatment and cosmetic dentistry.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 444 of 554



Report Details:

Case Number: 167034

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

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

Seq: 1

ospitalisation: Age: AD DOB: Onset Date: DOB: Outcome: Recovered Causality: Causality possil eaction Details: Preferred Term Severity Report Description Treatment //itamin B12 deficiency Pancytopenia Pyrexia B12 and folic acid deficiency B12 and folic acid deficiency Pancytopenia Pyrexia B15 Reason: Outcome: Recovered Report Description Treatment //itamin B12 deficiency B12 and folic acid deficiency B12 and folic acid deficiency B12 and foliate replacement of the provided Reason: Outcome: Recovered Reason: Contributed Reason: Outcome: Recovered Reason: Contributed Reason: Outcome: Recovered Reason: Contributed Reaso	Weight:				
Outcome: Recovered Saction Details: Preferred Term Severity Report Description Treatment // Itamin B12 deficiency Pancytopenia Pyrexia B12 and folic acid deficiency B12 and folic acid deficiency B12 and folic acid deficiency B12 and folic acid deficiency B12 and folic replaced Pyrexia B12 and folic acid deficiency B12 and folic replaced Pyrexia B12 and folic acid deficiency B12 and folic replaced Pyrexia B12 and folic acid deficiency B12 and folic replaced Pyrexia B12 and folic replaced Pyrexia B12 and folic acid deficiency B12 and folic replaced Pyrexia B12 and folic acid deficiency B12 and folic a					
Preferred Term Severity Report Description Treatment fitamin B12 deficiency ancytopenia yrexia B12 and folic acid deficiency ancytopenia yrexia					
Preferred Term Severity Report Description Treatment fitamin B12 deficiency Parcytopenia Pryrexia B12 and folic acid deficiency B12 and folic acid deficienc	ole				
fitamin B12 deficiency Parcytopenia Previous B12 and folic acid deficiency B12 and folate replace Previous B12 and folate Resource Previous B12 and folate Previous B12 and folate Previous B12 and folate Previous B12 and folate Pre					
ancytopenia yrexia B12 and folate replace B12 and folate replace	•				
Iedicine Details: Reason:					
Reason: O.0 Stopped: CONTIN	ement				
Batch: Started: Stopped: CONTIN Batch: Started: Stopped: CONTIN Baboratory Investigations: Date Type Range Date Tested Result Details					
RISPERDAL (Suspected) 0.0 Batch: Started: Stopped: CONTIN aboratory Investigations: Date Type Range Date Tested Result Details					
RISPERDAL (Suspected) 0.0 Batch: Started: Stopped: CONTIN aboratory Investigations: Date Type Range Date Tested Result Details					
Batch: Started: Stopped: CONTIN Batch: Started: Stopped: CONTIN Baboratory Investigations: Date Type Range Date Tested Result Details					
Batch: Started: Stopped: CONTIN Batch: Started: Stopped: CONTIN Baboratory Investigations: Date Type Range Date Tested Result Details					
RISPERDAL (Suspected) 0.0 Batch: Started: Stopped: CONTIN aboratory Investigations: Date Type Range Date Tested Result Details					
Batch: Started: Stopped: CONTIN Batch: Started: Stopped: CONTIN Baboratory Investigations: Date Type Range Date Tested Result Details					
Batch: Started: Stopped: CONTIN Stopped: CONTIN Stopped: CONT					
Batch: Started: Stopped: CONTIN Aboratory Investigations: Date Type Range Date Tested Result Details					
Aboratory Investigations: Date Type Range Date Tested Result Details					
Date Type Range Date Tested Result Details					
dditional Information:					
dditional Information:					
dditional Information:					
dditional Information:					
dditional Information:					
dultional information.					
ort Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 445					



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

Report Details:

 Case Number:
 167091
 Seq: 1
 Gender:
 M

 Reported:
 01/08/2001
 Weight:
 102.00

Hospitalisation: Age: 84

Onset Date: 25/07/2001 **DOB**: 02/02/1917

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incl	Life threatening		
Consciousness fluctuating	Life threatening		
Convulsion	Life threatening		
Hypertonia	Life threatening		Haloperidol and risperdone ceased. treated with diazepam im 5mg tds and fluid therapy.
Neuroleptic malignant syndrome	Life threatening		

Medicine Details:

Micalcinic Details.		
RISPERIDONE (Suspected)		Reason:
	1.0 Milligram	Daily
Batch:	Started:	Stopped:

Laboratory Investigations:

<u> </u>	y mroonga				
Date	Туре	Range	Date Tested	Result	Details
	Creatine				Raised cpk (1364 rr<256) and creatinine (186). after treatment cpk level decreased to 699.

Additional Information:

Patient deteriorated and died on 29/07/2001.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 446 of 554



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

Report	Details	3:
--------	---------	----

 Case Number:
 167091
 Seq: 1
 Gender: M

 Reported:
 01/08/2001
 Weight:
 102.00

Hospitalisation: Age: 84

Onset Date: 25/07/2001 **DOB**: 02/02/1917

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

todotion Botano.	dotton Botanor								
Preferred Term	Severity	Report Description	Treatment						
Renal impairment	Life threatening								

Medicine	Details:
----------	----------

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

Laboratory Investigations:

Additional Information:

Patient deteriorated and died on 29/07/2001.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 447 of 554



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

Re	port	Detail	ls:
----	------	--------	-----

Case Number: 167239 Seq: 1 Gender: F
Reported: 06/08/2001 Weight:
Hospitalisation: Age:

Onset Date: 28/06/1999 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuropathy peripheral			

Medicine Details:

Medicine Details.					
RISPERIDONE (Suspected)	Reason:				
Tablet 0.0			Oral		Oral
Batch: Started:		Stopped:			
NARDIL (Suspected)		Reason:			
Tablet	90.0	Milligram	Daily	(Oral
Batch:	Started:	L TE	ERM	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but onset was sometime in the month.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 448 of 554



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

Rep	ort	Deta	ils:
-----	-----	------	------

Case Number: 167375 Seq: 1 Gender: M
Reported: 09/08/2001 Weight:

Hospitalisation: Admitted to hospital **Age**: 53

Onset Date: 26/06/2001 **DOB**: 10/11/1947

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression Confusional state Consciousness fluctuating Delirium			Patient admitted to hospital. treated with iv haloperidol, iv diazepam, im accuphase.
Hyponatraemia			

Medicine Details:

wedicine Details:				
HALOPERIDOL (Other drug)	Reason:			
	0.0			
Batch:	Started:	Stopped:		
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia		
Tablet	6.0 Milligram	Daily Oral		
Batch:	Started: 24/06/2001	Stopped: 03/07/2001		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Sodium	137 -	04/07/2001	132MMOL/L	

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 449 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Re	port	Det	tail	s:

 Case Number:
 167591
 Seq: 1
 Gender: F

 Reported:
 16/08/2001
 Weight:

Hospitalisation: Age: 88

Onset Date: 08/08/2001 **DOB**: 15/05/1913

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

caction betails.									
Preferred Term	Severity	Report Description	Treatment						
Agranulocytosis									
Tardive dyskinesia									

Medicine Details:

Medicine Details:				
COLOXYL WITH SENNA (Other drug)		Reason:		
	0.0			
Batch:	Started:	Stopped:		
RISPERIDONE (Suspected)		Reason:		
	2.0 Milligram	Daily		
Batch:	Started:	Stopped: 10	0/08/2001 6W	

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Known chronic renal failure. (cr = 350).

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 450 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 167812 Seq: 1 Gender: F

Reported: 23/08/2001 Weight:
Hospitalisation: Age: 20

Onset Date: 28/05/2001 **DOB**: 14/10/1980

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified schizophrenia

Tablet 2.0 Milligram Daily Oral

Batch: Started: L TERM Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils	2.0 - 7.5			Neutrophil count of 1.4

Additional Information:

Relevant medical history - patient has schizophrenia, with good prognosis - has had two psychotic episodes. the patient is not taking any other medicines with the possible exception of the oral contraceptive pill. probable viral illness not long before this inital test. the onset date is not necessarily accurate but indicates the onset sometime in may 2001.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 451 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 167821
 Seq: 1
 Gender: M

 Reported:
 23/08/2001
 Weight:

Hospitalisation:Admitted to hospitalAge: 30YOnset Date:06/08/2001DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

teaction Details.				
Preferred Term	Severity	Report Description	Treatment	
Hyperreflexia				
Hypertonia				
Neuroleptic malignant syndrome			Admitted to hospital 17/07/2001.	

Medicine Details:

Medicine Details.			
RISPERIDONE (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 17/07/2001	Stopped:	06/08/2001
LITHIUM CARBONATE (Suspected)		Reason:	
Tablet	1.2 Gram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		06/08/2001	362U/L	
	Creatine		08/08/2001	417	
	Creatine		09/08/2001	348	
	Creatine		10/08/2001	292	
	Creatine		11/08/2001	191	
	Serum drug level		06/08/2001	1.0	
	Serum drug level		08/08/2001	-	

Additional Information:

Relevant medical history - bipolar disorder.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 452 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 167821
 Seq: 1
 Gender: M

 Reported:
 23/08/2001
 Weight:

Hospitalisation: Admitted to hospital Age: 30Y
Onset Date: 06/08/2001
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.			
RISPERIDONE (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 17/07/2001	Stopped:	06/08/2001
LITHIUM CARBONATE (Suspected)		Reason:	
Tablet	1.2 Gram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level		09/08/2001	-	
	Serum drug level		10/08/2001	-	
	Serum drug level		11/08/2001	-	

Additional Information:

Relevant medical history - bipolar disorder.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 453 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 168403 Seq: 1 Gender: F

Reported: 14/09/2001 Weight: 49.00 Hospitalisation: Age: 23

Onset Date: 08/08/2001 **DOB**: 23/03/1978

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			Date of recovery 11.8.01.

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

1.0 Milligram Daily

Batch: Started: 07/08/2001 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 454 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Onset Date: 28/12/2000 Outcome: Unknown eaction Details: Preferred Term Sereast cancer female Cause prolon inpatic hospit. Medicine Details: RISPERIDONE (Suspected)	Severity sed or onged	Repo		Ago DO Causalit	er: F at: 0.00 e: 52 B: 28/01/1948 ay: Causality possible Treatment Mastectomy, risperidone withdrawn
Reported: 24/09/2001 pspitalisation: Admitted to hospital Onset Date: 28/12/2000 Outcome: Unknown eaction Details: Preferred Term Serest cancer female Cause prolon inpatie hospital ledicine Details: RISPERIDONE (Suspected)	Severity sed or onged tient oitalisation		son:	Weigh Ago DO Causalit	at: 0.00 e: 52 B: 28/01/1948 ty: Causality possible Treatment Mastectomy, risperidone
Onset Date: 28/12/2000 Outcome: Unknown eaction Details: Preferred Term Sereast cancer female Great cancer female Medicine Details: RISPERIDONE (Suspected)	sed or onged tient bitalisation		son:	Ago DO Causalit	e: 52 B: 28/01/1948 cy: Causality possible Treatment Mastectomy, risperidone
Onset Date: 28/12/2000 Outcome: Unknown Paction Details: Preferred Term Breast cancer female Cause prolon inpatic hospit. Medicine Details: RISPERIDONE (Suspected)	sed or onged tient bitalisation		son:	DO	B: 28/01/1948 by: Causality possible Treatment Mastectomy, risperidone
Outcome: Unknown Paction Details: Preferred Term Ser Breast cancer female Cause prolon inpatie hospit	sed or onged tient bitalisation		son:	Causalit	ry: Causality possible Treatment Mastectomy, risperidone
Cause prolon inpatie hospit Medicine Details: RISPERIDONE (Suspected)	sed or onged tient bitalisation		son:		Treatment Mastectomy, risperidone
Preferred Term Ser Breast cancer female Cause prolon inpatie hospit Medicine Details: RISPERIDONE (Suspected)	sed or onged tient bitalisation		son:		Mastectomy, risperidone
prolon inpatie hospit. Medicine Details: RISPERIDONE (Suspected)	onged tient bitalisation	Reas			Mastectomy, risperidone withdrawn
RISPERIDONE (Suspected)		Reas		Oral	
		Reas		Oral	
RISPERIDONE (Suspected)		Reas		Oral	
				Oral	
Batch: St	Started:		Stopp		
				ed: 06/09/20	001
_aboratory Investigations:					
Date Type Range	Date Tested	Result		De	etails

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 455 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 168658 Seq: 1 Gender: F

 Reported: 24/09/2001
 Weight: 80.00

 Hospitalisation:
 Age: 35Y

Onset Date: 28/08/2001 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified psychosis

Tablet 4.0 Milligram Daily Oral

Batch: Started: 01/01/2000 Stopped: 20/09/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date is not accurate but indicates the drug was started sometime early in the year. reaction has occurred previously while on risperidone.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 456 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 169052
 Seq: 1
 Gender: F

 Reported:
 11/10/2001
 Weight:

Hospitalisation: Admitted to hospital Age: 35Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction betails.			
Preferred Term	Severity	Report Description	Treatment
Arrhythmia			Patient hospitalised. risperdal ceased.
Hypotension			
Syncope			

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified schizophrenia

Tablet 2.0 Milligram Daily Oral

Batch: Started: 04/09/2001 **Stopped:** 06/09/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Sequelae: patient fell and fractured her face.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 457 of 554



Report Details:

Case Number: 169118

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Seq: 1

Reported: 11/10/200	1		Weight:				
spitalisation: Admitted t	o hospital		Age: DOB:				
Onset Date:							
Outcome: Unknown		Causality: Causality possible					
action Details:				<u> </u>			
Preferred Term	Severity	Report D	Description	Treatment			
ection				Patient hospitalised. given bactrim.			
utropenia				bactiiii.			
edicine Details: ISPERDAL (Suspected)		Reason:					
Tablet	0.5 N	Milligram Dai	ly	Oral			
Batch:	Started:		Stopped:				
aboratory Investigat	ione:						
Date Type	Range Date Tested	d Result		Details			
.,,,,,	Trainge Date Footor	a Hoodii		2 0 0 0 0 0			
dditional Informatio	ղ:						
ort Run: 04/06/2007 11:06AM	Database: pusime02	ADRS	6004	Page 458 of 554			



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Reported: 15/10/20 spitalisation:	-01						
spitalisation:	<i>7</i> 0 I				We	eight:	
						Age : 26	
Onset Date: 26/09/20	01					DOB : 03/0	9/1975
Outcome: Recover	ed				Caus	sality: Cau	sality possible
action Details:							
Preferred Term	Sev	erity		Report De	scription		Treatment
ystonia			Acute dyst	tonia.		Given im recovery a visit to	ni cogentin. date of 26/09/2001. requi doctor.
edicine Details:	IDE (Other drug)			Reason	Dependence on un	nspecifid drugs	<u> </u>
edicine Details: IETHADONE HYDROCHLOR	IDE (Other drug)	70.0	Milligram	Reason:	Dependence on un	nspecifid drugs	S
	,	70.0	Milligram	Reason: Daily	Dependence on un	,	S
ETHADONE HYDROCHLOR Batch:	,		Milligram		·	C	CONTIN
IETHADONE HYDROCHLOR	,	ırted:	Milligram Milligram	Daily	Stopped:	C	CONTIN

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 459 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

	ails:					
Case Numb		Seq: 1				nder: F
_	ed: 15/10/2001					ght:
Hospitalisatio						Age : 26
Onset Da	te: 26/09/2001				[OOB: 29/08/1975
	e: Recovered				Causa	ality: Causality possible
Reaction De		<u> </u>				
	erred Term	Severity		Report De	scription	Treatment
Torticollis			Acute torti	icollis.		Given cogentin imi. 26/09/2001. required a visit to doctor.
Medicine D		41		D	D	and Wide days and
METHADONE	HYDROCHLORIDE (O		0.0 Milligram	Reason: Daily	Dependence on uns	pecifia arugs
Batch		Started:	_	Daily	Stopped:	CONTIN
RISPERIDONE		Otartou.		Reason:	Dependence on uns	
	(2	2.0 Milligram	Daily		proma maga
Batch	:		26/09/2001	,	Stopped: 26/0	9/2001
Laboratory	ı Investigation	S :				
Laboratory Date	Investigation		Tested Res	sult		Details

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 460 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 169325
 Seq: 1
 Gender:
 F

 Reported:
 22/10/2001
 Weight:

Hospitalisation: Admitted to hospital Age: 73Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

100011011 D 0101101			
Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Rehydrated with nasogastric feeding. patient hospitalised.

Medicine Details:

Medicine Details.				
BENZTROPINE MESYLATE (Other drug)			Reason:	
	2.0	Milligram	Daily	
Batch:	Started:			Stopped:
MIANSERIN HYDROCHLORIDE (Other drug	g)		Reason:	
	40.0	Milligram	Daily	
Batch:	Started:			Stopped:
LITHIUM CARBONATE (Other drug)			Reason:	
	750.0	Milligram	Daily	
Batch:	Started:			Stopped:
ALPRAZOLAM (Other drug)			Reason:	
	0.5	Milligram	Daily	
Batch:	Started:			Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils	2.0 - 7.5			Neutrophil - 9.6
	White blood cells	4.0 - 11.0			Wbc - 13.3

Additional Information:

History of schizoaffective disorder, depression and had a stroke in 1997.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 461 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

	se Number:	169325	Seq: 1			Gender:	F
	Reported:	22/10/2001				Weight:	
Hos	pitalisation:	Admitted to hosp	ital			Age:	73Y
	Onset Date:					DOB:	
	Outcome:	Recovered				Causality:	Causality possible
Rea	ction Detai	ls:					
Mo	dicine Deta	aile:					
	PIRIN (Other dr				Reason:		
	`	O,	150.0	Milligram	Daily		
	Batch:		Started:	ŭ	•	Stopped:	
RIS	SPERIDONE (Su	spected)			Reason:		
RIS	SPERIDONE (Su	spected)	3.0	Milligram	Reason: Daily		
RIS	BPERIDONE (Su Batch:	spected)	3.0 Started:	Milligram		Stopped:	
RIS		spected)		Milligram		Stopped:	
RIS		spected)		Milligram		Stopped:	
RIS		spected)		Milligram		Stopped:	
RIS		spected)		Milligram		Stopped:	
RIS		spected)		Milligram		Stopped:	
RIS		spected)		Milligram		Stopped:	
	Batch:			Milligram		Stopped:	
	Batch:	vestigations:		Milligram		Stopped:	
	Batch:			Milligram		Stopped:	
	Batch:			Milligram		Stopped:	
	Batch:			Milligram		Stopped:	
	Batch:			Milligram		Stopped:	
	Batch:			Milligram		Stopped:	
	Batch:			Milligram		Stopped:	
Lal	Batch:	vestigations:		Milligram		Stopped:	
Lal	Batch: Doratory In	vestigations:	Started:		Daily	Stopped:	
Lal	Batch: Doratory In	vestigations:	Started:		Daily	Stopped:	
Lal	Batch: Doratory In	vestigations:	Started:		Daily	Stopped:	
Lal	Batch: Doratory In	vestigations:	Started:		Daily	Stopped:	
Lal	Batch: Doratory In	vestigations:	Started:		Daily	Stopped:	

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 462 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 169779 Seq: 1 Gender: F

Reported: 07/11/2001 Weight: 0.00
Hospitalisation: Age: 13
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

TOUGHT DOTAILO			1
Preferred Term	Severity	Report Description	Treatment
Synostosis			Required a visit to doctor, treated with artane 2mg bd.

Medicine Details:

Medicine Details.			
TOFRANIL (Other drug)		Reason: Explosive personality disorder	
	35.0 Milligram	Daily	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Explosive personality disorder	
	2.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

This is not a neonatal report. Patient was born with problematic fusion between ulna-radias bones. At 7 months she experienced seizures. After this time, changes in behaviour & development led her to be diagnosed with 'global intellectual disability with global delay in language' (possibly a result of seizures?) - problems included: self mutilation, anger and agression. At 5 years, slight changes in gait, bone changes in foot were picked up - slight twisting of foot. This was not too bad and patient could walk without problems. Since begining Risperdal, especially in last 2 years, the foot twisting has worsened dramatically - it looks like a turned in foot when it was only subtle previously and patient has a lot more trouble walking.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 463 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 169845 Seq: 1 Gender: M

Reported: 08/11/2001 Weight:
Hospitalisation: Age: 82

Onset Date: 23/10/2001 DOB: 28/03/1919
Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Ceased risperdal.

Medicine Details:

RISPERDAL (Suspected) Reason:

Tablet 1.0 Milligram Daily Oral

Batch: Started: 16/11/2000 **Stopped:** 23/10/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine	<250 U/L	20/10/2001	569	
	Creatine	<250 U/L	26/10/2001	487	
	Creatine	<250 U/L	29/10/2001	409	
	Neutrophils	(1.5-7.5)	20/10/2001	11.2	
	Neutrophils	(1.5-7.5)	26/10/2001	7.6	
	Neutrophils	(1.5-7.5)	29/10/2001	7.6	

Additional Information:

Patient rechallenged on risperal and experienced same symptoms. patient recovered 2/11/01. see original for other drugs.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 464 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 169864
 Seq: 1
 Gender: M

 Reported:
 09/11/2001
 Weight:

Hospitalisation: Admitted to hospital Age: 43Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Torticollis			Risperdal ceased. admitted to hospital. given an injection of droperidol.

Medicine Details:

RISPERDAL (Suspected)		Reason:		
Tablet	0.0		Oral	
Batch:	Started:	L TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History - autism, developmental disability, pigeon chest, family history of motor neuron disease. risperdal was rechallenged causing the same reaction to occur.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 465 of 554



Report Details:

Case Number: 169865

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Seq: 1

Reported: 09/11/2001	- -	Weight:			
lospitalisation: Admitted to hos	spital	Age : 43Y			
Onset Date:		DOB:			
Outcome: Not yet recover	red	Causality: Causality possible			
eaction Details:	T o " T			 	
Preferred Term	Severity	Repo	ort Description	Treatment	
Neuroleptic malignant syndrome				Patient admitted to hospital. treated with cogentin, benzodiazepine and an anti-inflammatory agent.	
Medicine Details: RISPERDAL (Suspected)		Rea	son:		
Tablet	0.0	i (Ca	Ora	al	
Batch:	Started:		Stopped:	-	
Laboratory Investigations Date Type R	ange Date Tested	Result		Details	
.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	age Date : detea	. toodit		2 ottaile	
Additional Information:					
eport Run: 04/06/2007	tabase: pusime02	A	DRS004	Page 466 of 554	



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 169995
 Seq: 1
 Gender:
 F

 Reported:
 19/11/2001
 Weight:

Hospitalisation: Age: 22

Onset Date: 23/10/2001 **DOB**: 29/07/1979

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anaemia			

Medicine Details:

PHOSPHATE-SANDOZ (Other drug)		Reason:		
Tablet	0.0		Oral	
Batch:	Started: 04/10/2001	;	Stopped:	
TEMAZEPAM (Other drug)		Reason:		
Capsule	10.0 Milligram	Daily	Oral	
Batch:	Started: 04/10/2001	;	Stopped:	CONTIN
THIAMINE (Other drug)		Reason:		
Tablet	100.0 Milligram	Daily	Oral	
Batch:	Started: 04/10/2001	;	Stopped:	CONTIN
METOCLOPRAMIDE HYDROCHLORIDE	(Other drug)	Reason:		
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 04/10/2001	;	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haemoglobin		02/11/2001	86	Baseline haemoglobin level was 140g/l.
	Haemoglobin		04/11/2001	87	Baseline haemoglobin level was 140g/l.
	Haemoglobin		08/11/2001	92	Baseline haemoglobin level was 140g/l.

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 467 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Onset Date: 23/10/2001 Age: 22 DOB: 29/07/1979	Onset Date: 23/10/2001 Outcome: Unknown Causality: Causality possible action Details: PARACETAMOL (Other drug) Tablet Batch: Started: 04/10/2001 Batch: Started: 04/10/2001 Tablet 4.0 Milligram Daily Oral Reason: Paranoia Paranoia Paranoia Paranoia Paranoia Paranoia Paranoia		10/11/2001	Seq: 1			Weight:	
Onset Date: 23/10/2001 DOB: 29/07/1979 Outcome: Unknown Causality: Causality: Causality possible Jaction Details: Reason: PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral	Onset Date: 23/10/2001 DOB: 29/07/1979 Outcome: Unknown Causality: Causality possible Causality:		13/11/2001				_	22
Outcome: Unknown Causality: Causality possible caction Details: Causality: Causality possible caction Details:	Outcome: Unknown action Details: Causality: Causality possible	-	23/10/2001					
Redicine Details: Details	Action Details: Continue Details:					С		
Dedicine Details: PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral	Details: PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral						uuouy.	caacanty pools.
PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral	PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral							
PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral	PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral							
PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral	PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral							
PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral	PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral							
PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral	PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral							
PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral	PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral							
PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral	PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral							
PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral	PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral							
PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral	PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral							
PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral	PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral							
PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral	PARACETAMOL (Other drug) Reason: Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral							
Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral	Tablet 3.0 Gram Daily Oral Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral							
Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral	Batch: Started: 04/10/2001 Stopped: RISPERIDONE (Suspected) Reason: Paranoia Tablet 4.0 Milligram Daily Oral		other drug)				0.1	
RISPERIDONE (Suspected) Tablet 4.0 Milligram Daily Oral	RISPERIDONE (Suspected) Tablet 4.0 Milligram Daily Oral				Daily		Oral	
Tablet 4.0 Milligram Daily Oral	Tablet 4.0 Milligram Daily Oral			Started : 04/10/2001				
· · · · · · · · · · · · · · · · · · ·	•		spected)			Paranoia	0.1	
Batcn: Started: 22/10/2001 Stopped: 07/11/2001	Ватсп: Started: 22/10/2001 Stopped: 07/11/2001	Tablet		4.0 Milligram	Daily		Oral	
				Started: 22/10/2001		Stopped:	07/11/2001	
				Started: 22/10/2001		Stopped:	07/11/2001	
				Started: 22/10/2001		Stopped:	07/11/2001	
				Started: 22/10/2001		Stopped:	07/11/2001	
				Started : 22/10/2001		Stopped:	07/11/2001	
				Started: 22/10/2001		Stopped:	07/11/2001	
boratory Investigations:	boratory Investigations:	Batch:	vestigations			Stopped:	07/11/2001	
aboratory Investigations:	aboratory Investigations:	Batch:	vestigations			Stopped:	07/11/2001	
aboratory Investigations:	aboratory Investigations:	Batch:	vestigations			Stopped:	07/11/2001	
aboratory Investigations:	aboratory Investigations:	Batch:	vestigations			Stopped:	07/11/2001	
aboratory Investigations:	aboratory Investigations:	Batch:	vestigations			Stopped:	07/11/2001	
aboratory Investigations:	aboratory Investigations:	Batch:	vestigations			Stopped:	07/11/2001	
aboratory Investigations:	aboratory Investigations:	Batch:	vestigations			Stopped:	07/11/2001	
aboratory Investigations:	aboratory Investigations:	Batch:	vestigations			Stopped:	07/11/2001	
		Batch:				Stopped:	07/11/2001	
		Batch:				Stopped:	07/11/2001	
aboratory Investigations: dditional Information:		Batch:				Stopped:	07/11/2001	
		Batch:				Stopped:	07/11/2001	
		Batch:				Stopped:	07/11/2001	

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 468 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 170038 Seq: 1 Gender: M
Reported: 19/11/2001 Weight:
Hospitalisation: Admitted to hospital Age:

Onset Date: 01/11/2001 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion Botanoi			
Preferred Term	Severity	Report Description	Treatment
Priapism			Risperidone discontinued. admitted to hospital. date of recovery 02/11/2001.

Medicine Details:

vieuicine Delans.			
EPILIM (Other drug)		Reason:	
Tablet	2.0 Gram	Daily	Oral
Batch:	Started: 24/10/2001	Stopped:	
RANITIDINE (Other drug)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified s	chizophrenia
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 27/10/2001	Stopped:	01/11/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Relevant medical history - drug abuse, the (tetraydrocannabinol) abuse, schizoaffective disorder.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 469 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 170135 Seq: 1 Gender: F
Reported: 20/11/2001 Weight:
Hospitalisation: Admitted to hospital Age: 73Y

Onset Date: 30/06/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		38.5	
Tachycardia		Hr 120 bpm.	
Speech disorder		Mutism	
Coordination abnormal			
Faecal incontinence			
Hypertonia			
Hypokinesia			
Leukocytosis			
Neuroleptic malignant syndrome			Patient was hospitalised. tolvon, risperidone, benztropine, lithium carbonate were ceased.

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:		
	750.0 Milligram	Daily		
Batch:	Started: 31/12/1999		Stopped: 06/07/2000	
ALPRAZOLAM (Other drug)		Reason:		
	500.0 Microgram	Daily		
Batch:	Started: 31/12/1999		Stopped:	
ASPIRIN (Other drug)		Reason:		
	150.0 Milligram	Daily		
Batch:	Started: 31/12/1999		Stopped:	
TOLVON (Suspected)		Reason:		
	40.0 Milligram	Daily		
Batch:	Started: 31/12/1999		Stopped: 06/07/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Mja vol 174, 4 june 2001, page 593

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 470 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 170135
 Seq: 1
 Gender:
 F

 Reported:
 20/11/2001
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 30/06/2000
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence			

Medicine Details:

 RISPERIDONE (Suspected)
 Reason:

 3.0 Milligram
 Daily

 Batch:
 Started: 31/12/1999
 Stopped: 06/07/2001

 BENZTROPINE MESYLATE (Suspected)
 Reason:

2.0 Milligram Daily

Batch: Started: 31/12/1999 Stopped: 06/07/2000

Laboratory Investigations:

Additional Information:

Mja vol 174, 4 june 2001, page 593

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 471 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 170198 Seq: 1 Gender: F

Reported: 23/11/2001 Weight: 83.00 Hospitalisation: Age: 55Y

Onset Date: 30/05/2001 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradycardia			Propranolol ceased. admitted to cardiac ward.

Medicine Details:

CELECOXIB (Other drug)		Reason:	
	0.0	As necessary	
Batch:	Started:	Stopped:	
ALPRAZOLAM (Other drug)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	31/05/2001
SALBUTAMOL (Other drug)		Reason: Asthma	
	400.0 Microgram	Daily	
Batch:	Started:	Stopped:	CONTIN
RANITIDINE (Other drug)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

P/h of allergy to penicillin.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 472 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 170198 Seq: 1 Gender: F

Reported: 23/11/2001 Weight: 83.00 Hospitalisation: Age: 55Y

Onset Date: 30/05/2001 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

OESTROGENS CONJUGATED (Other drug)			Reason:			
	1.0	Dose Unspe	cified Daily			
Batch:	Started:			Stopped:		CONTIN
DOXEPIN HYDROCHLORIDE (Other drug)			Reason:	Migraine		
Capsule	150.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:		CONTIN
PROPRANOLOL HYDROCHLORIDE (Suspe	cted)		Reason:	Migraine		
Tablet	40.0	Milligram	Daily		Oral	
Batch:	Started: 01	01/1994		Stopped:	30/05/2001	
RISPERIDONE (Suspected)			Reason:			
Tablet	3.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:	31/05/2001	

Laboratory Investigations:

Additional Information:

P/h of allergy to penicillin.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 473 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Repoi ospitalisat Onset D	Date: 17/05/200 ome: Recovered	1	: 1			С	Gender: Weight: Age: DOB: ausality:	84Y
	referred Term	S	everity	Rep	ort Desc	ription		Treatment
Delirium Hyponatrae Orthostatic	emia hypotension						Ce ris _l	eased monoplus, diltiazer peridone.
	Details:							
FOLIC ACID Tabl	(Other drug)		0.5	Re Milligram	ason:		Oral	
Bato		9	o.s Started:	wiiiigram	Weekly	Stopped:	Orai	CONTIN
				_		оторрош.		33
METHOTRE	XATE (Other drug)			Re	ason:			
METHOTRE Tabl	-		7.5	Milligram	ason: Weekly		Oral	
Table Bat e	let ch:		7.5 Started:			Stopped:	Oral	CONTIN
Table Bate OMEPRAZO	let ch: DLE (Other drug)		Started:	Milligram Re	Weekly	Stopped:		CONTIN
Table Bate OMEPRAZO Table	ch: DLE (Other drug)	\$	Started: 40.0	Milligram	Weekly		Oral	
Tabl Bato OMEPRAZO Tabl Bato	let ch: DLE (Other drug) let ch:	\$	Started:	Milligram Re Milligram	Weekly ason: Daily	Stopped:		CONTIN
Table Bate OMEPRAZO Table Bate PREDNISON	ch: DLE (Other drug) det ch: NE (Other drug)	\$	40.0 Started:	Milligram Re Milligram	Weekly ason: Daily ason:		Oral	
Tabl Bato OMEPRAZO Tabl Bato	ch: DLE (Other drug) let ch: NE (Other drug)	5	40.0 Started:	Milligram Re Milligram	Weekly ason: Daily ason:	Stopped:		
Table DMEPRAZO Table PREDNISON Table Bate	let ch: DLE (Other drug) let ch: NE (Other drug) let ch:	; ;	40.0 Started:	Milligram Re Milligram	Weekly ason: Daily ason:		Oral	CONTIN
Table Bate OMEPRAZO Table PREDNISON Table Bate	ch: DLE (Other drug) let ch: NE (Other drug)	; ;	40.0 Started:	Re Milligram Re Dose Unspecified	Weekly ason: Daily ason:	Stopped:	Oral	CONTIN

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 474 of 554



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detai	23/11/2001 17/05/2001 Recovered	Seq: 1			C	Gender: Weight: Age: DOB: ausality:	84Y	;
Medicine Deta	aile:							
MONOPLUS NOS (Reason:	Essential beni	an hypertens	sion	
Tablet	• ,	12.5	Milligram	Daily		Oral		
Batch:		Started:	3 -	. ,	Stopped:	17/05/2001		
FOSINOPRIL (Sus	pected)			Reason:	Essential beni			
Tablet	,	20.0	Milligram	Daily		Oral		
Batch:		Started:	wiiiigiaiii	Bully	Stonned:	17/05/2001		
	OCHLORIDE (Suspect			Reason:	Essential beni			
Tablet	SOTILOTUDE (Odspect		Milligram	Daily	L33CH(lai bCH)	Oral	3011	
Batch:		Started:	wiiiigram	Dally	Stannadi	17/05/2001		
RISPERIDONE (Su	sported)	Starteu.		Reason:	Depression	17703/2001		
Tablet	specieu)	1.0	Milligram	Daily	Depression	Oral		
			wiiiigram	Dally	Ctonnadı	Olai	CONTIN	
Batch:		Started:			Stopped:		CONTIN	
Laboratory In								
Additional Inf	ormation:							

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 475 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 170304 Seq: 1 Gender: M

Reported: 27/11/2001 **Weight:** 115.00

Hospitalisation: Admitted to hospital **Age:** 43

Onset Date: 23/09/2001 DOB: 07/05/1958
Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

todotion Botanoi			
Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating		Clouding of consciousness.	
Blood creatine phosphokinase incr			
Hypertonia			Patient was hospitalised.

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

1.0 Milligram Daily

Batch: **Started**: 01/03/2000 **Stopped**: 2W

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient had similar reaction 1 year ago, also soon after starting low dose risperidone. the dose start date for risperidone is not necessarily accurate but indicates risperidone was started sometime in the month.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 476 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 170538
 Seq: 1
 Gender:
 F

 Reported:
 29/11/2001
 Weight:

Hospitalisation: Admitted to hospital Age: 47Y
Onset Date: 17/03/2001
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Patient was hospitalised. treated with cogentin.

Medicine Details:

VENTOLIN (Other drug)		Reason:	Asthma	
	5.0	Milligram Daily	/	
Batch:	Started:	L TERM	Stopped:	CONTIN
ATROVENT (Other drug)		Reason:	Asthma	
	1.0	Milligram Daily	/	
Batch:	Started:	L TERM	Stopped:	CONTIN
FLIXOTIDE (Other drug)		Reason:	Asthma	
	750.0	Microgram Daily	/	
Batch:	Started:	L TERM	Stopped:	CONTIN
SEREVENT (Other drug)		Reason:	Asthma	
Inhalation	4.0	Dose Unspecified Daily	/	Inhalation
Batch:	Started:	L TERM	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for risperdal is not necessarily accurate but indicates the drug was started sometime in the month. has had tremors previously. parkinsonian symptoms: mild tremor of the left hand, generalised hyper-reflexia, shuffling gait, decreased balance and drowsiness.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 477 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report	Details	3:
--------	---------	----

 Case Number:
 170538
 Seq: 1
 Gender: F

 Reported:
 29/11/2001
 Weight:

Hospitalisation: Admitted to hospital Age: 47Y
Onset Date: 17/03/2001
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

EPILIM (Other drug)			Reason:	Other&unspecified epilepsy	
Tablet	1.5	Gram	Daily	Oral	
Batch:	Started:		L TERM	Stopped:	CONTIN
LITHIUM CARBONATE (Other drug)			Reason:		
Tablet	250.0	Milligram	Daily	Oral	
Batch:	Started:		L TERM	Stopped:	
RISPERDAL (Suspected)			Reason:	Unspecified schizophrenia	
Tablet	4.0	Milligram	Daily	Oral	
Batch:	Started: 01/01/2000		Stopped:	CONTIN	

Laboratory Investigations:

Additional Information:

The dose start date for risperdal is not necessarily accurate but indicates the drug was started sometime in the month. has had tremors previously. parkinsonian symptoms: mild tremor of the left hand, generalised hyper-reflexia, shuffling gait, decreased balance and drowsiness.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 478 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 170971
 Seq: 1
 Gender:
 F

 Reported:
 10/12/2001
 Weight:

Hospitalisation: Age: 28

Onset Date: 06/09/2001 **DOB**: 25/08/1973

Outcome: Recovered Causality: Causality probable

Reaction Details:

touction botaile			
Preferred Term	Severity	Report Description	Treatment
Tachycardia			Patient was hospitalised. date of recovery 9.9.01. risperidone ceased.

Medicine Details:

RISPERIDONE (Suspected) Reason:

2.0 Milligram Daily

Batch: Started: 01/03/2001 **Stopped:** 07/09/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not necessarily accurate but indicates the drug was started sometime in the month.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 479 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 171082
 Seq: 1
 Gender:
 F

 Reported:
 11/12/2001
 Weight:

Hospitalisation: Age:
Onset Date: 05/09/2001
DOB:

Outcome: Recovered with sequelae Causality: Causality probable

Reaction Details:

,	teaction Details.				_
	Preferred Term	Severity	Report Description	Treatment	
	Arrhythmia				
	Dizziness			1	
	Fall				
	Orthostatic hypotension			Risperidone ceased.	

Medicine Details:

RISPERIDONE (Suspected)

Tablet

Reason: Unspecified psychosis

Daily

Oral

Batch: Started: 04/09/2001 **Stopped:** 06/09/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Sequelae: sustained fractured zygoma secondary to her fall.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 480 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 171392 Gender: U Seq: 1

Weight: 71.00 Reported: 13/12/2001 Hospitalisation: Age: 45

Onset Date: 29/10/2001 **DOB:** 04/03/1956

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia			

Medicine Details:

TEMAZEPAM (Other drug)		Reason:	Specific disorders of s	leep
	10.0 Milligram	As no	ecessary	
Batch:	Started:		Stopped:	CONTIN
FLUOXETINE HYDROCHLORIDE (O	ther drug)	Reason:	Depression	
	40.0 Milligram	Daily		
Batch:	Started:		Stopped:	CONTIN
RISPERIDONE (Suspected)		Reason:	Unspecified psychosis	

0.5 Milligram Daily

Started: 01/06/1998 Batch: Stopped: 30/11/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start date for risperidone is not necessarily accurate but indicates the drug was started sometime in the month.

ADRS004 Report Run: 04/06/2007 11:06AM Database: pusime02 Page 481 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 171619
 Seq: 1
 Gender: M

 Reported:
 02/01/2002
 Weight:
 59.00

 Hospitalisation:
 Age: 63Y

Onset Date: 23/10/2001 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anaemia			Ceased carbamazepine and risperidone.
Neutropenia			

Medicine Details:

COLOXYL WITH SENNA (Other drug)		Re	ason:	Constipation	
Tablet	2.0	Dose Unspecified	As ne	cessary O	0ral
Batch:	Started:			Stopped:	
PROPRANOLOL HYDROCHLORIDE (Other	drug)	Re	ason:	Acute myocard in	nfarc,no hypert
Tablet	80.0	Milligram	Daily	0	oral
Batch:	Started:			Stopped:	
PERINDOPRIL (Other drug)		Re	ason:	Acute myocard in	nfarc,no hypert
Tablet	2.0	Milligram	Daily	0	oral
Batch:	Started:			Stopped:	
CARBAMAZEPINE (Suspected)		Re	ason:	Paralysis agitans	;
Tablet	200.0	Milligram	Daily	0	oral
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haemoglobin	(130-180)-(2-7.5)	18/10/2001	116	
	Haemoglobin	(130-180)-(2-7.5)	23/10/2001	0.98	
	Haemoglobin	(130-180)-(2-7.5)	25/10/2001	89	
	Platelets		18/10/2001	103	
	White blood cells		18/10/2001	478 -2.37	

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 482 of 554



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

	ed		Age: DOB Causality	
edicine Details: RISPERIDONE (Suspected) Tablet Batch:	1.0 Milligram Started:	Reason: Daily	Paralysis agitans Oral Stopped:	
ASPIRIN (Suspected)		Reason:	Acute myocard infarc,no	nypert
Oral application	150.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	
ahoratory Investigations	:			
aboratory Investigations				

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 483 of 554



Case Number: 171664

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Seq: 1

Reported: 07/11/2001	ported: 07/11/2001 Weight:					
ospitalisation:		Age: 40				
Onset Date:			D	OB : 26/07/1961		
Outcome: Not yet recovered	ed		Causal	lity: Causality possible		
eaction Details:	ı	1				
Preferred Term	Severity		escription	Treatment		
onsciousness fluctuating		Decrease in consciou	is state			
confusional state						
Malaise						
leuroleptic malignant syndrome lyrexia						
ledicine Details:						
RISPERDAL (Suspected)		Reason:	Unspecified schizoph	renia		
Batch:	0.0 Started: 04/	40/0004	Stopped: 06/10/	10004		
aboratory Investigations	<u> </u>					
Date Type Ra	inge Date Test	ed Result		Details		
Additional Information:						
dullional illionnation.						
ort Run: 04/06/2007 11:06AM Dat						



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 171721 Seq: 1 Gender: M

Reported: 04/01/2002 Weight: 0.00 Hospitalisation: Age: 16

Onset Date: 28/03/2001 DOB: 02/07/1984

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Testicular disorder			

Medicine Details:

Medicine Details.					
RISPERIDONE (Suspected)			Reason:		
	3.0	Milligram	Daily	Oral	
Batch:	Started: 01/0	1/2000		Stopped:	
DEXAMPHETAMINE SULPHATE (Su	uspected)		Reason:		
Tablet	40.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
17/12/2002	Other data				In march 01, he developed a bengin 'pearl' lesion in his right testicle with small hydroceles. scrotal ultrasound 17.5.01 reveald palpable lump in right hemiscrotum, representing a calcified scrotal pearl, maximal diameter 7mm. scrotal ultrasound on 21.11.01 demontrated small bilateral hydroceles and right srotal pearl.
17/12/2002	Other data				Comparison with the previous ultrasound of 17.5.01 indicates the size of the calcified right scrotal lesion is unaltered.

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for risperidone is not accurate but indicates the drug was started sometime in the year.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 485 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 171809 Seq: 1 Gender: F

Reported: 11/01/2002 Weight: 68.00 Hospitalisation: Age: 40

Onset Date: 03/01/2002 **DOB**: 17/01/1961

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Atrioventricular block		Early heart block.	
Electrocardiogram QT prolonged			Change to small dose sertraline 50mg.

Medicine Details:

modicine Botanoi					
HALOPERIDOL (Other drug)			Reason:		
	3.7	Milligram	Daily		
Batch:	Started:			Stopped:	
BENZTROPINE MESYLATE (Other drug)			Reason:		
	0.5	Milligram	Daily		
Batch:	Started:			Stopped:	
TEMAZEPAM (Other drug)			Reason:		
	20.0	Milligram	Daily		
Batch:	Started:			Stopped:	
CITALOPRAM HYDROBROMIDE (Suspected	ed)		Reason:	Depression	
	80.0	Milligram	Daily		
Batch:	Started: 27	/11/2001		Stopped:	03/01/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start date for risperidone is not accurate but indicates the drug was started sometime in the year.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 486 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:				
Case Number: 171809 Reported: 11/01/2002 Hospitalisation: Onset Date: 03/01/2002 Outcome: Unknown Reaction Details:	Seq: 1			68.00
Medicine Details: RISPERIDONE (Suspected)		Pagani		
RISPERIDONE (Suspected)	1.5 Milligram	Reason: Daily		
Batch:	Started: 01/01/2000	Daily	Stopped:	
Laboratory Investigations:				
Additional Information: The dose start date for risperidone is r	not accurate but indicates the	drug was sta	rted sometime in the	year.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 487 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 171891 Seq: 1 Gender: M

Reported: 08/01/2002 **Weight:** 103.00

Hospitalisation: Age: 19

Onset Date: 28/06/2001 **DOB:** 31/10/1981

Outcome: Recovered Causality: Causality probable

Reaction Details:

reaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis			
Pallor			
Pharyngitis			
Vomiting			
Weight increased			Required a visit to doctor.

Medicine Details:

Medicine Details.					
THYROXINE SODIUM (Other drug)	Reason:				
	225.5 Microgram	Daily			
Batch:	Started:		Stopped:	CONTIN	
RISPERIDONE (Suspected)		Reason:	Other atyp forms scl	hizophrenia	
	500.0 Microgram	Daily			
Batch:	Started: 01/08/1999		Stopped: 28/12	2/2001	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month, the dose start date is not necessarily accurate but indicates risperidone was started sometime in the month, patient recovered 28/12/01.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 488 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:						
Case Number: 171949	Seq: 1	Gender: M				
Reported: 06/12/2001				Weight:		
Hospitalisation:				Age : 83		
Onset Date: 13/11/2001				DOB: 08/11/1918		
Outcome: Not yet recovered	ł		С	ausality: Causality possible		
eaction Details:						
Preferred Term	Severity	Report De	escription	Treatment		
Neuroleptic malignant syndrome				Haloperidol ceased.		
Medicine Details: DIAZEPAM (Other drug)		Reason:	Neuroses			
Oral application	0.0			Oral		
Batch:	Started:		Stopped:			
ATENOLOL (Other drug)		Reason:	Essential beni	ign hypertension		
Tablet	0.0			Oral		
Batch:	Started:		Stopped:			
PERHEXILINE MALEATE (Other drug)		Reason:				
Tablet	0.0			Oral		
Batch:	Started:		Stopped:			
HALDOL DECANOATE (Suspected)		Reason:				
Injection	1.0 Dose	Unspecified 4 time	es	Intravenous		
Batch:	Started: 05/11/200	1	Stopped:	09/11/2001		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 489 of 554



Case Number: 171949

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Seq: 1

Reported:	06/12/2001				Weight:		
ospitalisation:					Age : 83		
Onset Date:	13/11/2001				DOB : 08		
Outcome:	Not yet recovered			С	ausality : Ca	usality possil	ble
action Detai	ls:						
ledicine Deta	ails:						
HALOPERIDOL (St		•	Reason:				
Injection		2.0 Milligram	1 time		Intramuscular		
Batch:		Started: 05/11/2001		Stopped:	09/11/2001		
RISPERDAL (Susp	ected)		Reason:				
Tablet		1.0 Milligram	Daily		Oral		
Batch:		Started: 05/11/2001		Stopped:	12/11/2001		
aharatan, la	vootigationa						
aboratory in	vestigations:						
dd:4: 1 l-4							
dditional Inf	ormation:						

ADRS004 Page 490 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 172027
 Seq: 1
 Gender:
 F

 Reported:
 21/01/2002
 Weight:

Hospitalisation: Hospitalisation prolonged
Onset Date:

DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

touotion Dotailoi			
Preferred Term Sev		Report Description	Treatment
Convulsion		Experienced a cerebral seizure whilst in casualty.	
Hyponatraemia			
Neuroleptic malignant syndrome			

Medicine Details:

Medicine Details:					
EFEXOR (Other drug)	Reason:				
Tablet	150.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	
RISPERDAL (Suspected)			Reason:		
Oral application	3.0	Milligram	Daily	Oral	
Batch:	Started:	L	ΓERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was hospitalised with dystonia.

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 491 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details	:	
----------------	---	--

 Case Number:
 172161
 Seq: 1
 Gender:
 F

 Reported:
 24/01/2002
 Weight:
 40.00

Hospitalisation: Age: 95

Onset Date: 04/01/2002 **DOB**: 17/05/1906

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tongue oedema		Within 1-2 hours of taking risperidone.	Date of recovery 17.1.02. patient was already in hospital. risperidone ceased.
Angioedema			
Dysarthria			
Dysphagia			

Medicine Details:

FLUCLOXACILLIN SODIUM (Other drug)			Reason:	Cellul&absc otr,mult&nos sites	
	2.0	Gram	Daily		
Batch:	Started:		STERM	Stopped:	
ASPIRIN (Other drug)			Reason:	Otr&nos disord of heart rhythm	1
	150.0	Milligram	Daily		
Batch:	Started:		L TERM	Stopped:	CONTIN
DIGOXIN (Other drug)			Reason:	Otr&nos disord of heart rhythm	1
	125.0	Microgran	n Daily		
Batch:	Started:		L TERM	Stopped:	CONTIN
LASIX (Other drug)			Reason:	Congestive heart failure	
	80.0	Milligram	Daily		
Batch:	Started:		L TERM	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 492 of 554



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Case Number:	172161	Seq: 1			Gender:	F
Reported:	24/01/2002				Weight:	40.00
Hospitalisation:					Age:	95
Onset Date:	04/01/2002				DOB:	17/05/1906
Outcome:	Recovered				Causality:	Causality probable
Reaction Detai	ils:					
Madiaina Dat	alla.					
Medicine Det			Ra	ason:	Congestive heart failure	
SLOW-R (Other di	ugj	2.0	Dose Unspecified		Congestive near failure	
Batch:		Started:	L TERN		Stopped:	CONTIN
OROXINE (Other d	trua)	Otarteu.		ason:	Myxedema	CONTIN
ONOXINE (Other o	ii ug)	25.0	Microgram	Daily	Wyxcucina	
Batch:		Started:	L TERM		Stopped:	CONTIN
RISPERIDONE (Su	uspected)			ason:	оторрош.	
,	. ,	0.0				
Batch:		Started:			Stopped:	
	41 41					
Laboratory In	vestigations:					
Additional Inf	formation:					

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 493 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details

 Case Number:
 172435
 Seq: 1
 Gender: M

 Reported:
 06/02/2002
 Weight:
 68.00

Hospitalisation: Age: 17

Onset Date: 04/12/2001 **DOB**: 30/05/1984

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Dizziness		Dizziness over past few days when stands up.	
Dysphagia			Required a visit to doctor. cogentin.

Medicine Details:

FLUVOXAMINE MALEATE (Suspected) Reason: Depression

100.0 Milligram Daily

Batch: Started: 29/11/2001 Stopped:

RISPERIDONE (Suspected) Reason: Depression

0.5 Milligram Daily

Batch: Started: 29/11/2001 **Stopped:** 04/12/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 494 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Re	oa	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number:172482Seq: 1Gender: MReported:04/01/2002Weight: 77.00Hospitalisation:Admitted to hospitalAge: 83

Onset Date: 13/11/2001 DOB: 08/11/1918

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

104011011 20141101			
Preferred Term	Severity	Report Description	Treatment
Hypertension			
Neuroleptic malignant syndrome			Midazolam. patient hospitalised.
Weight decreased			

Medicine Details:

WARFARIN SODIUM (Other drug)		Reas			
	0.0				
Batch:	Started:			Stopped:	
HALOPERIDOL (Suspected)		Reas	on:		
Injection	4.0 Dose Ur	nspecified	Total		Intravenous
Batch:	Started: 05/11/2001			Stopped:	09/11/2001
GALANTAMINE HYDROBROMIDE (Susp	ected)	Reas	on:		
Tablet	24.0 Milligran	n	Daily		Oral
Batch:	Started: 08/12/2000			Stopped:	10/11/2001
RISPERIDONE (Suspected)		Reas	on:		
Tablet	1.0 Milligran	n	Daily		Oral
Batch:	Started: 05/11/2001			Stopped:	12/11/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:06AM Database: pusime02 ADRS004 Page 495 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 172505 Seq: 1 Gender: F

Reported: 06/02/2002 Weight: 65.00 Hospitalisation: Age: 25

Onset Date: 28/08/2001 **DOB**: 17/05/1976

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea			Required a visit to doctor. reduction of dose to 1.5mg has not produced reaction as yet.

Medicine Details:

ZOLOFT (Other drug)		Reason:	Depression
	50.0 Milligram	Daily	
Batch:	Started:		Stopped:
RISPERIDONE (Suspected)		Reason:	
	3.0 Milligram	Daily	
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 496 of 554



Case Number: 172611

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Seq: 1

Reported: 11/02/2002		Weight:					
ospitalisation:		Age:					
Onset Date:		DOB:					
Outcome: Unknown		Causality: Causality possible					
eaction Details:							
Preferred Term	Severity	Report Description	Treatment				
Anaemia	Required Specialist Consultation	Mild anaemia.					
eukopenia							
hrombocytopenia							
Medicine Details:							
RISPERDAL (Suspected)	0.0	Reason:					
Batch:	0.0 Started:	Stoppe					
aboratory Investigation		.1 5 1	B + 11				
Date Type	Range Date Teste	d Result	Details				
dditional Information:							
ort Run: 04/06/2007 11:07AM I	Database: pusime02	ADRS004	Page 497 of 554				



Report Run: 04/06/2007 11:07AM Database: pusime02

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Case Number: 172782		Seq:	1		Gender: ∪			
Reported: 18/02/2002		2			Weight:			
Hospitalisation:					Age:			
Onset Date) :				DOB:			
Outcome	: Unknown			Causality: Causality possible				
Reaction Deta	ails:							
	rred Term	Se	verity	Repo	rt Description	Treatment		
Agranulocytosis	3							
Medicine De			0.0	Reas	Reason:			
Batch:		C+	0.0		Stopped:			
					оторрош.			
Laboratory I	nvestigat	ions: Range	Date Tested	Result		Details		
Date	туре	Range	Date Tested	Resuit		Details		
Additional li	nformatio	ղ:						

ADRS004

Page 498 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 172980
 Seq: 1
 Gender: M

 Reported:
 20/02/2002
 Weight:

Hospitalisation: Age: 79Y

Onset Date: 19/11/2001 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Parkinsonism.	

Medicine Details:

OXYBUTYNIN HYDROCHLORIDE (Other dr	ug)		Reason:	Incontinence of	of urine
Tablet	5.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	15/10/2001
RAMIPRIL (Other drug)			Reason:	Essential beni	gn hypertension
Tablet	1.2	Milligram	Daily		Oral
Batch:	Started:			Stopped:	18/10/2001
ASPIRIN (Other drug)			Reason:	Acute,ill-def ce	erebrovascular disease w/o hyperte
Tablet	150.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	
ATENOLOL (Other drug)			Reason:	Essential beni	gn hypertension
Tablet	25.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for risperidone is not necessarily accurate but indicates the drug was started sometime in the month. patient history: advanced alzeheimers, cva 1990(I). risperidone ceased. sequelae: fractured pelvis. multifactoral gait disorder and history of falls.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 499 of 554



Case Number: 172980

Reported: 20/02/2002

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Weight:

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Seq: 1

Hospitalisation:			Age:	79Y
Onset Date: 19/11/2001			DOB:	
Outcome: Recovered			Causality:	Causality possible
Reaction Details:				
Medicine Details:				
RISPERIDONE (Suspected)		Reason:		
Tablet	1.0 Milligram	Daily	Oral	
Batch:	Started: 01/08/2000	S	stopped: 24/10/2001	
Laboratory Investigations:				
Laboratory investigations.				
Additional Information:				
The dose start date for risperidone is r	not necessarily accurate but in	dicates the dru	g was started some	etime in the month natient
history: advanced alzeheimers, cva 19	990(I). risperidone ceased. se	quelae: fractur	ed pelvis. multifact	oral gait disorder and history
of falls.				

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 500 of 554



Case Number: 173009

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Seq: 1

Reported: 21/02/20	002	Weight:				
lospitalisation:			Age: 50Y			
Onset Date:				DOB:		
Outcome: Unknow	n		Causality: Causality possible			
eaction Details:						
Preferred Term	Severity	Repo	rt Description	Treatment		
Respiratory depression	Life threatening			Reaction was life threatening. patient already in hospital.		
Medicine Details: CLONAZEPAM (Suspected)	0.0	Reas	son:			
Batch:	Started:	,	Stopped:			
RISPERIDONE (Suspected)	- Ctartour	Reason:				
(1.0) Milligram	Daily			
Batch:	Started:	· ·	Stopped:			
Laboratory Investiga	ations:					
Date Type	Range Date Te	ested Result		Details		
Additional Information	on:					
eport Run: 04/06/2007 11:07A	AM Database: pusime02	A	DRS004	Page 501 of 554		



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Case Number: 173235 Reported: 28/02/200				
Reported: 28/02/200	Seq: 1			Gender: F
-			,	Veight:
lospitalisation:				Age : 39Y
Onset Date:				DOB:
Outcome: Unknown			Ca	usality: Causality possible
eaction Details:				
Preferred Term	Severity	Repo	rt Description	Treatment
Breast engorgement		,	•	
Hyperprolactinaemia				
Tardive dyskinesia				
Therapeutic response decre	eased			
Medicine Details:	F (Other drug)	Door	on	
CITALOPRAM HYDROBROMID		Reas		Over I
Tablet		Milligram	,	Oral
Batch:	Started:	Desa	Stopped:	
RISPERIDONE (Suspected) Tablet	6.0	Reas Milligram		Oral
Batch:	Started:	wiiiiyiaiii	Daily Stopped:	Jiai
_aboratory Investigat		ad Bassit I		D-4-%
1		ed Result		Details
Date Type Prolactin	Range Date Test	l l	Prolactin 6400 iu/l while	t taking risperdal 4mg daily dose.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 502 of 554



Case Number: 173407

Reported: 06/03/2002

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight:

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Seq: 1

Hospitalisation: Admitted to hospital				Age: 73				
Onset Date: 07/02/2002				DOB : 21/05/1928				
Outcom	ne: Not yet re	ecovered			Causality: Causality possible			
action De	tails:							
Preferred Term		Severity Rep		ort Description		Treatment		
onstipation								
Dizziness							Pateint was hospitalised. treated with stemetil	
lum a malu a a a mai a							li eated with Stemetii	
yperglycaen	ша		<u> </u>					
edicine D								
CALCIUM NOS	6 (Other drug)			Rea	ason:			
			0.0					
Batch	:	S	tarted:			Stopped:		
SOLPRIN (Oth	er drug)	Reason:						
			150.0 Milli	gram	Daily			
Batch	:	S	tarted:			Stopped:		
MODURETIC (Other drug)			Rea	ason:			
Tablet		1.0 Dose Unspecified			Daily	Oral		
Batch:		Started: 01/07/2000				Stopped:		
/IOXX (Suspe	cted)			Rea	ason:			
			0.0					
Batch:		Started:			Stopped:			
_		_						
	<u>Investigat</u>		15.5.1		1			
Date	Туре	Range	Date Tested	Result			Details	
dditional	Information	n:						
ort Run: 04/06	6/2007 11:07AM	/ Database: pu	usime02		ADRS004		Page 503 of 554	



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Case Number: 173407 Reported: 06/03/2002 Hospitalisation: Admitted to hosp Onset Date: 07/02/2002 Outcome: Not yet recovered Reaction Details:			
Medicine Details:			
RISPERIDONE (Suspected) Tablet	4.0 Milligrom	Reason: Schizophrenia Daily Oral	
Batch:	4.0 Milligram Started: 30/04/1999	Daily Oral Stopped:	
Laboratory Investigations:			
Additional Information:			

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 504 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 173525 Seq: 1 Gender: F

Reported: 11/03/2002 Weight: 90.00 Hospitalisation: Age: 34

Onset Date: 28/05/2001 **DOB**: 04/10/1966

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Development of gestational diabetes on risperidone	Required a visit to doctor. insulin therapy.

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

3.0 Milligram Daily

Batch: Started: 01/01/1995 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for risperidone is not accurate but indicates risperidone was started sometime in the year.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 505 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Repo	rt D	etai	ls:
------	------	------	-----

Case Number: 173574 Seq: 1 Gender: F

Reported: 13/03/2002 Weight: 58.00 Hospitalisation: Age: 17

Onset Date: 18/12/2001 **DOB**: 06/01/1984

Outcome: Recovered Causality: Causality probable

Reaction Details:

<u>leaction betails.</u>			
Preferred Term	Severity	Report Description	Treatment
Angioedema		Swollen throat	Required a visit of a doctor.
Dyspnoea			
Tongue oedema			

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

2.0 Milligram Daily

Batch: Started: 17/12/2001 **Stopped:** 22/12/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 506 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 173827 Seq: 1 Gender: F

Reported: 19/03/2002 Weight: 55.00 Hospitalisation: Age: 29

Onset Date: 28/02/2002 DOB: 31/07/1972

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Jaw clenching.	Required a visit to doctor. decrease risperidone then cease. start olanzapine, start benztropine 1mg bd for symptoms.
Dizziness			

Medicine Details:

SODIUM VALPROATE (Other drug) Reason: Unspecified schizophrenia

1.2 Gram Daily

Batch: Started: Stopped:

RISPERIDONE (Suspected) Reason: Unspecified schizophrenia

6.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Recent dose increase from 5mg daily to 6mg daily on 27/2/2002.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 507 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Preferred Term Severity Report Description Treatmen	Case Number: 174390 Reported: 10/04/2002 Ospitalisation: Onset Date: Outcome: Recovered action Details:	Seq: 1		DC	
Batch: Started: L TERM Stopped: Batch: Started: L TERM Stopped: Stopped: Stopped: Stopped: Stopped: Started: L TERM Stopped: St		Severity	Report De	escription	Treatment
Batch: Started: L TERM Stopped: Batch: Started: L TERM Stopped: Stopped: Stopped: Stopped: Started: L TERM Stopped: Stopped: Stopped: Started: L TERM Stopped: Stop	xtrapyramidal disorder				
Batch: Started: L TERM Stopped: Batch: Started: L TERM Stopped: Stopped: Stopped: Stopped: Stopped: Started: L TERM Stopped: St					
Batch: Started: L TERM Stopped: ATENOLOL (Other drug) Reason: Essential benign hypertension 50.0 Milligram Daily Batch: Started: L TERM Stopped: RISPERIDONE (Suspected) Reason: Otr spec symp psychopathol nec 2.0 Milligram Daily Batch: Started: L TERM Stopped: 06/03/2002 Started: L TERM Stopped: Daily Batch: Started: Result Details	Medicine Details:		Poscon	Other diseases of esco	phagus
ATENOLOL (Other drug) Batch: Started: L TERM Stopped: Reason: Otr spec symp psychopathol nec 2.0 Milligram Daily Batch: Started: L TERM Stopped: 06/03/2002 Batch: Started: L TERM Stopped: 06/03/2002 Batch: Started: L TERM Daily Batch: Started: L TERM Daily Batch: Started: L TERM Details Date Type Range Date Tested Result Details	LOSEC (Other drug)	20.0 M			onagus
Batch: Started: L TERM Stopped: RISPERIDONE (Suspected) Reason: Otr spec symp psychopathol nec 2.0 Milligram Daily Batch: Started: L TERM Stopped: 06/03/2002 Batch: Started: L TERM Stopped: 06/03/2002 aboratory Investigations: Date Type Range Date Tested Result Details		Started:			
RISPERIDONE (Suspected) Reason: Otr spec symp psychopathol nec 2.0 Milligram Daily Batch: Started: L TERM Stopped: 06/03/2002 Aboratory Investigations: Date Type Range Date Tested Result Details			lilligram Daily		rtension
Batch: Started: L TERM Stopped: 06/03/2002 Aboratory Investigations: Date Type Range Date Tested Result Details	Batch:	Started:			pathol nec
.aboratory Investigations: Date Type Range Date Tested Result Details	RISPERIDONE (Suspected)				
Date Type Range Date Tested Result Details	RISPERIDONE (Suspected)	2.0 M	lilligram Daily		
Additional Information:					2002
Additional Information:	aboratory Investigation	Started:	L TERM	Stopped: 06/03/2	
Additional Information:	Batch: _aboratory Investigation	Started:	L TERM	Stopped: 06/03/2	
Additional Information:	Batch: _aboratory Investigation	Started:	L TERM	Stopped: 06/03/2	
	Batch: _aboratory Investigation	Started:	L TERM	Stopped: 06/03/2	
	Batch: -aboratory Investigation Date Type F	Started:	L TERM	Stopped: 06/03/2	
	Batch: -aboratory Investigation Date Type F	Started:	L TERM	Stopped: 06/03/2	

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 508 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Re	po	rt	De	tai	ls	:
----	----	----	----	-----	----	---

Case Number:175000Seq: 1Gender: MReported:01/05/2002Weight:Hospitalisation:Admitted to hospitalAge:

Onset Date: 16/04/2002 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancytopenia		White cells, red cells & platelets all decreased.	Patient was hospitalised. discontinued both moclobemide and risperidone.

Medicine Details:

VITAMINORUM B.P.C. (Other drug)	Reason:				
	1.0	Dose Unspecifie	d Daily		
Batch:	Started:			Stopped:	
ASCORBIC ACID (Other drug)	Reason:				
	500.0	Milligram	Daily		
Batch:	Started:			Stopped:	
PRAZOSIN HYDROCHLORIDE (Other drug)		R	eason:		
	2.0	Milligram	Daily		
Batch:	Started:			Stopped:	
NILSTAT (Other drug)		R	eason:		
	4.0	Millilitre	Daily		
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No previous history of allergy.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 509 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Reported:		Seq: 1				Gender:		
	01/05/2002				,	Weight:		
-	Admitted to hosp	oital				Age:		
Onset Date:	16/04/2002					DOB:		
Outcome:	Not yet recovere	d			Ca	ausality:	Causality pos	sible
eaction Detail	ls:							
Medicine Deta	ails:							
THIAMINE (Other d				Reason:				
		100.0	Milligram	Daily				
Batch:		Started:			Stopped:			
				_				
MOCLOBEMIDE (S	uspected)			Reason:				
MOCLOBEMIDE (S	uspected)	600.0	Milligram					
MOCLOBEMIDE (So	uspected)	600.0 Started:	Milligram	Reason: Daily	Stopped:			
			Milligram		Stopped:			
Batch:		Started:	Milligram Milligram	Daily	Stopped:			
Batch: RISPERIDONE (Sus		Started:	Milligram	Daily Reason:		19/04/2002		
Batch:		Started:	Milligram	Daily Reason:	Stopped:	19/04/2002	2	
Batch: RISPERIDONE (Sus		Started:	Milligram	Daily Reason:		19/04/2002	2	
Batch: RISPERIDONE (Sus		Started:	Milligram	Daily Reason:		19/04/2002	2	
Batch: RISPERIDONE (Sus	spected)	Started: 2.0 Started: 16/	Milligram	Daily Reason:		19/04/2002	2	
Batch: RISPERIDONE (Sus	spected)	Started: 2.0 Started: 16/	Milligram	Daily Reason:		19/04/2002	2	
Batch: RISPERIDONE (Sus	spected)	Started: 2.0 Started: 16/	Milligram	Daily Reason:		19/04/2002	2	
Batch: RISPERIDONE (Sus	spected)	Started: 2.0 Started: 16/	Milligram	Daily Reason:		19/04/2002	2	
Batch: RISPERIDONE (Sus	spected)	Started: 2.0 Started: 16/	Milligram	Daily Reason:		19/04/2002	2	
Batch: RISPERIDONE (Sus	spected)	Started: 2.0 Started: 16/	Milligram	Daily Reason:		19/04/2002	2	
Batch: RISPERIDONE (Sus	spected)	Started: 2.0 Started: 16/	Milligram	Daily Reason:		19/04/2002	2	
Batch: RISPERIDONE (Sus	spected)	Started: 2.0 Started: 16/	Milligram	Daily Reason:		19/04/2002	2	
Batch: RISPERIDONE (Sus	spected)	Started: 2.0 Started: 16/	Milligram	Daily Reason:		19/04/2002	2	
Batch: RISPERIDONE (Sus Batch: Laboratory Inv	spected)	Started: 2.0 Started: 16/	Milligram	Daily Reason:		19/04/2002		
Batch: RISPERIDONE (Sus Batch: Laboratory Inv	spected) vestigations:	Started: 2.0 Started: 16/	Milligram	Daily Reason:		19/04/2002		
Batch: RISPERIDONE (Sus Batch: Laboratory Inv	spected) vestigations:	Started: 2.0 Started: 16/	Milligram	Daily Reason:		19/04/2002	2	
Batch: RISPERIDONE (Sus	spected) vestigations:	Started: 2.0 Started: 16/	Milligram	Daily Reason:		19/04/2002		
Batch: RISPERIDONE (Sus Batch: Laboratory Inv	spected) vestigations:	Started: 2.0 Started: 16/	Milligram	Daily Reason:		19/04/2002		
Batch: RISPERIDONE (Sus Batch: Laboratory Inv	spected) vestigations:	Started: 2.0 Started: 16/	Milligram	Daily Reason:		19/04/2002		

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 510 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

	ils:				
-	r: 175257 d: 08/05/2002 i: Admitted to hos	Seq: 1			ender: F eight: Age: 50Y
Onset Date		•			DOB:
Outcome	: Unknown			Caus	sality: Causality possible
eaction Det	ails:				
Prefe	rred Term	Severity	Rep	oort Description	Treatment
Aphasia Cerebrovascula Confusional sta Coordination al Hallucination Hypertonia Neuroleptic ma	ate				Patient hospitalised. treated with dantrolene 25mg bd, bromocriptine. also required intensive nursing, including catheterisation, iv therapy and ng-tube.
Medicine De		60.1		ason: Unspecified schize	pphrenia
Batch:			Milligram	Daily	
		Started:		Stopped:	4Y
Laboratory	Investigations:		ed Result	Stopped:	
Laboratory Date				Stopped: Two weeks after risperdal	Details

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 511 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Case Number: 175257	Seq: 1	Gende	er: F
Reported: 08/05/2002		Weigh	it:
Hospitalisation: Admitted to hos	pital		e : 50Y
Onset Date:		DO	
Outcome: Unknown		Causalit	y: Causality possible
Reaction Details:			
Preferred Term	Severity	Report Description	Treatment
Pyrexia			
i yroxid	<u> </u>		
Medicine Details:			
RISPERIDONE (Suspected)		Reason: Unspecified schizophre	enia
THE EMBONE (Gaspestea)	6.0 Milligram	Daily	
Batch:	Started:	Stopped:	4Y
Dateii.	Starteu.	Gtopped.	41
Laborator La cathatta			
Laboratory Investigations:			
Additional Information:			
opert Pup : 04/06/2007 11:07AM Date	ahaaa: nuaima02	ADDS004	Dogo 540 of 554

Page 512 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 175339 Seq: 1 Gender: F

Reported: 09/05/2002 Weight: 90.00 Hospitalisation: Age: 43

Onset Date: 12/12/2001 **DOB**: 08/09/1958

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botano.			_
Preferred Term	Preferred Term Severity Report Description		Treatment
Affect lability			
Hyperproteinaemia			Required a visit to doctor. continue on meds with rpt, blood prolactin level & mri.

Medicine Details:

Medicine Details.			
EPILIM (Other drug)		Reason: Unspecified schizophrenia	
	1.5 Gram	Daily	
Batch:	Started:	Stopped:	
CLONAZEPAM (Other drug)		Reason: Unspecified schizophrenia	
	2.0 Milligram	Daily	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
	2.0 Milligram	Daily	
Batch:	Started: 01/01/2000	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start date for risperidone is not accurate but indicates the drug was started sometime in the year.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 513 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report De	otaile:						
Case Num Repor Hospitalisat Onset D	ber: 175346 rted: 09/05/200 rion: Date: 29/01/200 rme: Recovered	2		V	Gender: F Weight: 50.00 Age: 19 DOB: 20/04/1982 susality: Causality probable		
	eferred Term	Severity	Repo	ort Description	Treatment		
Galactorrho			<u>-</u>		Risperidone ceased, required		
Hyperprolac	tinaemia				a visit to doctor.		
Medicine RISPERIDON Bato	NE (Suspected)	2.0 N Started: 16/01	lilligram	son: Unspecified psy Daily Stopped: 2			
	Laboratory Investigations:						
Date	Туре	Range Date Tested	l Result		Details		
Additiona	ıl Informatio	n:					

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 514 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 175626
 Seq: 1
 Gender: M

 Reported:
 22/05/2002
 Weight:

Hospitalisation: Admitted to hospital **Age**: 52

Onset Date: 13/05/2002 **DOB:** 26/03/1950

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botanoi			
Preferred Term	Severity	Report Description	Treatment
Hepatitis			Patient hospitalised. withdrew all medications; increased hydration.

Medicine Details:

HOMEOPATHIC MEDICINE (Other drug)		Reason:
	0.0	
Batch:	Started:	Stopped:
BENZYDAMINE HYDROCHLORIDE (Oth	er drug)	Reason:
	2.0 Milli	ram As necessary
Batch:	Started:	Stopped:
ZOPICLONE (Other drug)		Reason: Specific disorders of sleep
	15.0 Milli	ram Daily
Batch:	Started:	Stopped:
SODIUM VALPROATE (Suspected)		Reason:
	1.4 Gran	n Daily
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				Bili=146, alt=821, alk phos=384. bili=27, alt=62, alk phos=94.

Additional Information:

History of heavy etoh use.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 515 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Hospitalisation: Onset Date: Outcome: Reaction Detai	22/05/2002 Admitted to hospit 13/05/2002 Unknown Is:	Seq: 1				
Medicine Deta				Danasa	Unspecified psychosis	
RISPERIDONE (Su	spectea)		2.0 Milligran	Reason: n Daily	Unspecified psychosis	
Batch:		Star	ted:	Daily	Stopped:	
Laboratory In	vestigations:					
Additional Inf History of heavy et						

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 516 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 175638 Seq: 1 Gender: M Reported: 22/05/2002 Weight:

Hospitalisation: Age: 21

Onset Date: 03/03/2002 **DOB**: 04/03/1980

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Dotano			
Preferred Term	Severity	Report Description	Treatment
Weight decreased		Lost 13kg on topiramate.	Trated with mirtazapine.
Agitation			
Depression			Treated with mirtazapine.
Psychotic disorder			

Medicine Details:

SOMAC (Other drug)	Reason: Other diseases of esophagus	
	40.0 Milligram Daily	
Batch:	Started: Stopped:	
VENTOLIN (Other drug)	Reason: Asthma	
Inhalation	4.0 Dose Unspecified Daily Inhalation	
Batch:	Started: Stopped:	
TOPIRAMATE (Suspected)	Reason: Obesity othr than endoc origin	
	200.0 Milligram Daily	
Batch:	Started: 12/11/2001 Stopped: 14/03/2002	
RISPERIDONE (Suspected)	Reason: Other diseases of esophagus	
	4.0 Milligram Daily	
Batch:	Started : 01/12/2001 Stopped :	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Still appears to have low grade psychosis started on mirtazapine depression improved. the dose start date for risperidone is not accurate but indicates the drug was started sometime in the month.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 517 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 175827 Seq: 1 Gender: F

Reported: 03/06/2002 Weight: 50.00 Hospitalisation: Age: 25

Onset Date: 20/05/2002 DOB: 28/08/1976

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Breast pain		Breast tenderness.	
Galactorrhoea			Required a visit to doctor. date of recovery 15.5.02. risperidone ceased.

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified schizophrenia

3.0 Milligram Daily

Batch: Started: 14/03/2002 Stopped: 10/04/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient hsitory of eczema.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 518 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 176460
 Seq: 1
 Gender:
 F

 Reported:
 20/06/2002
 Weight:

Hospitalisation: Age: 76

Onset Date: DOB: 27/02/1926

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Tremor			Ceased nefazodone and commenced mianerin.

Medicine Details:

OLANZAPINE (Other drug) Reason: Otr spec symp psychopathol nec

2.5 Milligram Daily

Batch: Started: 24/01/2002 Stopped: 07/02/2002

MIANSERIN HYDROCHLORIDE (Other drug) Reason: Depression

20.0 Milligram Daily

Batch: Started: 01/02/2002 Stopped: CONTIN

LITHIUM CARBONATE (Other drug) Reason: Depression

250.0 Milligram Daily

Batch: Started: 28/12/2001 Stopped: CONTIN

TEGRETOL CR (Other drug) Reason: Depression

400.0 Milligram Daily

Batch: **Started**: 13/02/2002 **Stopped**: 15/02/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking metamucil, lipitor, raloxifene. patient recovered 4/2/02.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 519 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 176460
 Seq: 1
 Gender:
 F

 Reported:
 20/06/2002
 Weight:

Hospitalisation: Age: 76

Onset Date: DOB: 27/02/1926

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

OXAZEPAM (Other drug)		Reason:	Anxiety neurosis	
	22.5 Milligram	Daily		
Batch:	Started: 07/02/2002		Stopped:	CONTIN
DIAZEPAM (Other drug)		Reason:	Anxiety neurosis	
	6.0 Milligram	Daily		
Batch:	Started:		Stopped: 07/02/2	2002
RISPERIDONE (Suspected)		Reason:	Otr spec symp psycho	pathol nec
	500.0 Milligram	1 time	е	
Batch:	Started: 23/12/2001		Stopped:	
RISPERIDONE (Suspected)		Reason:	Otr spec symp psycho	pathol nec
	1.5 Milligram	Daily		
Batch:	Started: 24/12/2001		Stopped: 27/12/2	2001

Laboratory Investigations:

Additional Information:

Patient was also taking metamucil, lipitor, raloxifene. patient recovered 4/2/02.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 520 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:					
Case Number: 176460 Sec Reported: 20/06/2002 Hospitalisation: Onset Date: Outcome: Recovered Reaction Details:	q: 1		c		
Medicine Details:					
CITALOPRAM HYDROBROMIDE (Suspected		Reason:	Depression		
	20.0 Milligram	Daily			
	Started: 25/12/2001	December		04/01/2002	
NEFAZODONE HYDROCHLORIDE (Suspecte	aa) 100.0 Milligram	Reason: Daily	Depression		
Batch:	Started: 07/01/2002	Daily	Stonned:	29/01/2002	
Laboratory Investigations:					
Additional Information: Patient was also taking metamucil, lipitor, ra	aloxifene. patient recov	ered 4/2/02			

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 521 of 554



Report Details:

Case Number: 177232

Reported: 18/07/2002

Hospitalisation: Admitted to hospital

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Age: 54Y

Weight:

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Seq: 1

Outcom	Onset Date: 30/03/2002					DOB:					
	e: Not yet red	covered	Causality: Causality possible								
action De	tails:										
Pref	erred Term	Se	everity	Rep	ort Des	cription		Treatment			
ranial nerve	disorder		C	eveloped bell's	s palsy.			Patient was hospitalised, prescribed valium and increased risperdal to 2mg.			
erpes zoster	•										
edicine D	etails:										
EPTRAN (Oth				Rea	son:						
			0.0								
Batch:	:	S	tarted:			Stopped:		CONTIN			
IPEX (Other d	rug)			Rea	son:						
			0.0								
Batch:		s	tarted:			Stopped:					
RISPERDAL (S Tablet	uspected)		4.0 M			Depression	Oral				
		c		lilligram	Daily	Stannadı	Orai	CONTIN			
Batch:		s	tarted:			Stopped:		CONTIN			
Datcii.			tarteu.			эторрец.		CONTIN			
aboratory Date	Investigati	ions: Range	Date Tested	d Result	ı		De	etails			



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:							
Case Number: 177426	Seq: 1		Gender: M				
Reported: 24/07/2002		Weight: 40.00					
Hospitalisation: Admitted to hos	pital		Age	: 12Y			
Onset Date:			DOE	3:			
Outcome: Recovered			Causality	: Causality possible			
Reaction Details:							
Preferred Term	Severity	Report Descript	ion	Treatment			
Dysarthria		Difficulty in talking					
Dyspnoea							
Dystonia							
Extrapyramidal disorder			E	Benztropine 0.02mg/kg			
Hypertonia							
Muscle twitching							
Medicine Details:							
MORPHINE SULPHATE (Suspected)		Reason:					
	0.0						
Batch:	Started:	St	opped:				
KETOROLAC (Suspected)		Reason:					
	0.0						
Batch:	Started:		opped:				
TROPISETRON HYDROCHLORIDE (S		Reason:					
	0.0						
Batch:	Started:	St	opped:				
METHYLPHENIDATE HYDROCHLORII	DE (Suspected)	Reason:					
	10.0	Milligram Daily					
Batch:	Started:	St	opped:				

Additional Information:

Laboratory Investigations:

Type

Range

Date Tested

Date

Difficulty in talking, shortness of breath and difficulty moving because of st iffness. his speech was slurred and he was unable to close his mouth. the pati ent then began experiencing a twitching in his heands, shoulders, neck and hea d, which progressed to jerking movements of his jaw and arms. j.pediatr. child health (2002) 38, 95-97.

Result

Details

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 523 of 554



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Hospitalisation: Onset Date:	24/07/2002 Admitted to hosp Recovered	Seq: 1			Gender: Weight: Age: DOB: Causality:	40.00 12Y
Medicine Deta	spected)	2.0	Milligram	Reason:	Orol	
Oral applic	ation		Milligram	Daily	Oral	
Batch:	ROCHLORIDE (Susp	Started:		Reason:	Stopped:	
SERTIME ITTE	MOCITEOMIDE (Susp		Milligram	Daily		
Batch:		Started:	wiiiigram	Dany	Stopped:	
Laboratory In	vestigations:					
Additional Inf Difficulty in talking, close his mouth. th jerking movements	shortness of breath	n and difficulty m an experiencing s. j.pediatr. child	noving becau a twitching i I health (200	use of st iffnes in his heands,)2) 38, 95-97.	s. his speech was slu shoulders, neck and l	rred and he was unable to nea d, which progressed to

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 524 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 177691 Seq: 1 Gender: F

Reported:05/08/2002Weight:105.00Hospitalisation:Admitted to hospitalAge:72Y

Onset Date: 29/06/2002 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gait disturbance		Parkinson's	Patient was hospitalised.

Medicine Details:

COLOXYL WITH SENNA (Other drug)		Reason: Constipation	
	2.0 Dose Unsp	pecified As necessary	
Batch:	Started:	Stopped:	CONTIN
PANADEINE (Other drug)		Reason:	
	0.0	As necessary	
Batch:	Started:	Stopped:	
PANADEINE FORTE (Other drug)		Reason:	
	0.0	As necessary	
Batch:	Started:	Stopped:	
LACTULOSE (Other drug)		Reason:	
	20.0 Millilitre	Daily	
Batch:	Started:	Stopped:	15/07/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 525 of 554



Report Details:

Case Number: 177691

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Seq: 1

Reported: 05	5/08/2002				Weight:	105.00
ospitalisation: Ad	dmitted to hospital				Age:	72Y
Onset Date: 29	9/06/2002				DOB:	
Outcome: Re	ecovered				Causality:	Causality probable
action Details						
ledicine Detail	s:					
THYROXINE SODIUM				Reason:		
		150.0	Microgram	Daily		
Batch:		Started:			Stopped:	CONTIN
KEFLEX (Other drug)				Reason:		
		2.0	Gram	Daily		
Batch:		Started:			Stopped: 12/07/2002	2
METFORMIN HYDRO	CHLORIDE (Other drug	1)		Reason:	Diabetes mellitus	
		1.6	Gram	Daily		
Batch:		Started:			Stopped:	CONTIN
WARFARIN SODIUM	(Other drug)			Reason:	Phleb&thrombophleb lowr	extrem
		3.0	Milligram	Daily		
Batch:		Started:			Stopped:	CONTIN
aboratory Inve	etiaatione:					
aboratory inve	stigations.					
Additional Infor	mation:					

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 526 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:			
Case Number: 177691 Reported: 05/08/2002 Hospitalisation: Admitted to hospit Onset Date: 29/06/2002 Outcome: Recovered Reaction Details:	Seq: 1	Gender: Weight: Age: DOB: Causality:	105.00 72Y
Medicine Details: RISPERIDONE (Suspected)		Reason: Schizophrenia	
Batch:	2.0 Milligram Started:	Daily Stopped: 03/07/2002	
Laboratory Investigations:			
Additional Information:			

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 527 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 177918 Seq: 1 Gender: M

Reported: 12/08/2002 Weight:
Hospitalisation: Age: 25

Onset Date: 10/06/2002 **DOB**: 05/08/1976

Outcome: Unknown Causality: Causality probable

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			Date of recovery: 23/6/02. risperidone ceased. required a visit to doctor.

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified schizophrenia

 Tablet
 2.0 Milligram
 Daily
 Oral

 Batch:
 Started: 09/06/2002
 Stopped: 16/06/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient changed to olanzapine and symptoms resolved within a week.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 528 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 177921
 Seq: 1
 Gender: M

 Reported:
 12/08/2002
 Weight: 80.00

Hospitalisation: Age:
Onset Date: 07/08/2002 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Dizziness			
Dry mouth			Sertraline ceased.

Medicine Details:

Medicine Details.				
SERTRALINE HYDROCHLORIDE (Suspect	ed)	Reason:	Depression	
Tablet	50.0 Milligram	Daily		Oral
Batch:	Started: 06/08/2002		Stopped:	09/08/2002
RISPERIDONE (Suspected)		Reason:	Unspecified ps	sychosis
Tablet	2.0 Milligram	Daily		Oral
Batch:	Started: 06/08/2002		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 529 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Preferred Term Severity Report Description Treatment	Reported: 28/08/2002 lospitalisation: Onset Date: Outcome: Not yet recovered eaction Details: Preferred Term	everity		Weig A D Causa escription	ght: Age: 35 DOB: 02/02/1967 Ality: Causality possible Treatment D. Patient required a visit to doctor, treated with steroid
Onset Date: Onset Date: Outcome: Not yet recovered Causality: Causality possible section Details: Preferred Term Severity Report Description Treatment Rash Widespread rash - crusting-photographed. Patient required a visit t doctor: treated with ster cream. Wedicine Details: RISPERIDONE (Suspected) Reason: Unspecified schizophrenia Tablet 4.0 Milligram Daily Oral Batch: Started: 08/07/2002 Stopped: 08/08/2002	ospitalisation: Onset Date: Outcome: Not yet recovered eaction Details: Preferred Term			Causa escription	Age: 35 DOB: 02/02/1967 Ality: Causality possible Treatment D. Patient required a visit to doctor, treated with steroid
Onset Date: Outcome: Not yet recovered Causality: Causality possible saction Details: Preferred Term Severity Report Description Treatment Rash Widespread rash - crusting-photographed. Patient required a visit to doctor: treated with ster cream. Wedicine Details: RISPERIDONE (Suspected) Reason: Unspecified schizophrenia Tablet 4.0 Milligram Daily Oral Batch: Started: 08/07/2002 Stopped: 06/08/2002	Onset Date: Outcome: Not yet recovered eaction Details: Preferred Term Se			Causa escription	DOB: 02/02/1967 Ality: Causality possible Treatment D. Patient required a visit to doctor. treated with steroid
Outcome: Not yet recovered seaction Details: Preferred Term Severity Report Description Treatment Rash Widespread rash - crusting-photographed. Patient required a visit to doctor, treated with ster cream. Wedicine Details: RISPERIDONE (Suspected) Reason: Unspecified schizophrenia Tablet 4.0 Milligram Daily Oral Batch: Started: 08/07/2002 Stopped: 06/08/2002	Outcome: Not yet recovered eaction Details: Preferred Term Se			Causa escription	Treatment Description: Patient required a visit to doctor, treated with steroid
Preferred Term Severity Report Description Treatment Rash Widespread rash - crusting-photographed. Patient required a visit to doctor. treated with ster cream. Wedicine Details: RISPERIDONE (Suspected) Reason: Unspecified schizophrenia Tablet 4.0 Milligram Daily Oral Batch: Started: 08/07/2002 Stopped: 06/08/2002	eaction Details: Preferred Term Se			escription	Treatment d. Patient required a visit to doctor. treated with steroid
Medicine Details: Risperidorum (Suspected) Tablet Batch: Started: 08/07/2002 Milligram Daily Oral Batch: Started: 08/07/2002 Stopped: 06/08/2002 Laboratory Investigations:	Preferred Term Se				d. Patient required a visit to doctor, treated with steroid
Medicine Details: Risperidorum (Suspected) Tablet Batch: Started: 08/07/2002 Milligram Daily Oral Batch: Started: 08/07/2002 Stopped: 06/08/2002 Laboratory Investigations:					d. Patient required a visit to doctor, treated with steroid
Medicine Details: RISPERIDONE (Suspected) Tablet 4.0 Milligram Batch: Started: 08/07/2002 Stopped: 06/08/2002 Laboratory Investigations:	Rash	\	Videspread rash - cr	usting-photographed	
Tablet 4.0 Milligram Daily Oral Batch: Started: 08/07/2002 Stopped: 06/08/2002 Laboratory Investigations:					
Reason: Unspecified schizophrenia Tablet 4.0 Milligram Daily Oral Batch: Started: 08/07/2002 Stopped: 06/08/2002 Laboratory Investigations:					
Tablet 4.0 Milligram Daily Oral Batch: Started: 08/07/2002 Stopped: 06/08/2002 Laboratory Investigations:			Reason:	Unspecified schizop	 hrenia
Laboratory Investigations:		4.0 N			
_aboratory Investigations:	Batch: S	Started: 08/07	7/2002	Stopped: 06/08	3/2002
	l aboratory Investigations:				
	Date Type Range	Date Teste	d Result		Details
	71 3				

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 530 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 178557
 Seq: 1
 Gender: M

 Reported:
 29/08/2002
 Weight:

Hospitalisation: Admitted to hospital **Age:** 20Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction betails.			
Preferred Term	Severity	Report Description	Treatment
Delusion			
Drug ineffective			
Extrapyramidal disorder			The patient was admitted into psychiatric unit of hospital, whilst in hospital patient was treated with olanzapine and amphetamine abuse ceased. risperidone was stopped.
Hallucination			

Medicine Details:

Micalcille Details.				
RISPERIDONE (Suspected)		Reason: Schizo	phrenia	
Tablet	4.0 Milligram	Daily	Oral	
Batch:	Started:	Sto	opped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History of amphetamine substance abuse.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 531 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 178719 Seq: 1 Gender: M

Reported: 04/09/2002 Weight:
Hospitalisation: Age: 29Y

Onset Date: 20/08/2002 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Ceased risperidone.	

Medicine Details:

FLUPENTHIXOL DECANOATE (Other dro	ug)	Reason: Unspecifi	ed psychosis	
Injection	20.0 Milligram	Fortnightly	Intramuscular	
Batch:	Started: 31/07/2002	Stop	ped:	
RISPERIDONE (Suspected)		Reason: Unspecifi	ed psychosis	
Tablet	6.0 Milligram	Daily	Oral	
Batch:	Started: 29/07/2002	Stop	ped: 21/08/2002	
DIAZEPAM (Suspected)		Reason: Specific of	lisorders of sleep	
Tablet	5.0 Milligram	Daily	Oral	
Batch:	Started: 29/07/2002	Stop	ped : 19/08/2002	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 532 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:			
Case Number: 178803 Reported: 09/09/20	Seq: 1	Gender Weight:	
ospitalisation:		Age	
Onset Date: 08/06/20	002	DOB	:
Outcome: Unknow	n	Causality	: Causality possible
eaction Details:			
Preferred Term	Severity	Report Description	Treatment
Eye pain Muscle twitching	Severe	Severe pain behind one eye. Twitching eye.	
Medicine Details:		Reason:	
Tablet	1.0	Milligram Daily Oral	
Batch:	Started: 08		
		sted Result Deta	ils
Laboratory Investiga Date Type	ations: Range Date Tes	sted Result Deta	ils

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 533 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Gender: F Weight: Age: 6Y DOB: ausality: Causality pos	
Treatme	ent
Treatine	ent
Oral	
Oral	
Details	
	Oral

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 534 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 179113
 Seq: 1
 Gender: M

 Reported:
 18/09/2002
 Weight:

Hospitalisation: Admitted to hospital Age: 26Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			
Dyspnoea			Admitted to hospitalised (icu).
Malaise			
Myocarditis			

Medicine Details:

Wieulcine Details.					
FLUPENTHIXOL DECANOATE (Suspected)			Reason:		
Injection	25.0	Milligram	Week	kly Intramuscu	lar
Batch:	Started:			Stopped:	
RISPERDAL (Suspected)			Reason:	Unspecified schizophrenia	
Tablet	4.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Relevant history - schizophrenia 5 years ago.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 535 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:	Re	po	rt	De	tai	ls:
-----------------	----	----	----	----	-----	-----

Case Number: 179196 Seq: 1 Gender: M

Reported: 23/09/2002 Weight:
Hospitalisation: Age: 18Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			Risperidone ceased.

Medicine Details:

RISPERDAL (Suspected) Reason:

Tablet 0.0 Oral Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine				Cpk value of greater than 2000.

Additional Information:

Long history of different antipsychotics.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 536 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 179257
 Seq: 1
 Gender: M

 Reported:
 08/10/2002
 Weight:

Hospitalisation: Age: 89Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction Details.				
Preferred Term	Severity	Report Description	Treatment	
Blood creatine phosphokinase incr				
Neuroleptic malignant syndrome			Ceased risperidone.	

Medicine Details:

Medicine Details:					
DIGOXIN (Other drug)			Reason:		
Tablet	125.0	Microgram	Daily		Oral
Batch:	Started:			Stopped:	
WARFARIN SODIUM (Other drug)			Reason:	Otr&nos disor	d of heart rhythm
Tablet	5.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	
RISPERIDONE (Suspected)			Reason:		
Tablet	3.0	Milligram	Daily		Oral
Batch:	Started: 30/0	07/2002		Stopped:	20/08/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine				Ck elevated mildly

Additional Information:

This report is a seq of 179256.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 537 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 179555
 Seq: 1
 Gender:
 F

 Reported:
 03/10/2002
 Weight:

Hospitalisation: Age: 70Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

Medicine Details:

Medicine Details.			
ZOLOFT (Suspected)		Reason: Depression	
Tablet	0.0		Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2001	Stopped:	01/01/2002

Laboratory Investigations:

Luboluto	i ji iii vootiga				
Date	Туре	Range	Date Tested	Result	Details
	Electrolytes				Over a number months (date unspecified), sodium dropped from an unspecified level to 126.

Additional Information:

The dose start and stop dates for risperidone are not accurate but indicates the drug was start and stopped somtime in the year.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 538 of 554



Report Details:

Case Number: 179613

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Seq: 1

-	02/10/200	2						Weig	ht: 88.00
Hospitalisation:					Age:				
Onset Date:					DOB:				
Outcome:	Not yet re	covered		Causality: Causality possible					
action Deta	ils:								
Preferr	ed Term	S	Severity		Repo	ort Des	cription		Treatment
alactorrhoea									Required a visit to doctor.
ticaria									
edicine Det	ails:								
ONOFEME 28 (C					Rea	son:			
			0.0						
Batch:		,	Started:				Stopped:		
DERAL (Other o	drug)				Rea	son:			
			80.0	Milligra	am	Daily			
Batch:		Started:					Stopped:		
LONIDINE HYDR	ROCHLORIDE	(Other drug)				son:			
			300.0	Milligra	am	Daily			
Batch:			Started:				Stopped:		
	uspected)					son:			
ISPERIDONE (S	,		2.0	Milligra	am	Daily		Oral	
ISPERIDONE (Si	,								
ISPERIDONE (S			Started: 01/0				Stopped:		
Tablet Batch:							Stopped:		
ISPERIDONE (So				01/199			Stopped:	D	Details

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 539 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 179738 Seq: 1 Gender: M

Reported: 08/10/2002 Weight: 74.00 Hospitalisation: Age: 22

Onset Date: 30/09/2002 DOB: 27/02/1980

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Cougentin 2mg imi. patient recovered 30/9/02.

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

Tablet 3.0 Milligram Daily Oral

Batch: Started: 24/09/2002 Stopped: 30/09/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Dose increased from 1mg to 3mg the day before reaction.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 540 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

 Case Number:
 179741
 Seq: 1
 Gender:
 M

 Reported:
 08/10/2002
 Weight:
 28.00

Hospitalisation: Age: 7

Onset Date: 26/09/2002 **DOB**: 16/05/1995

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Epistaxis		2 episodes of epistaxis.	

Medicine Details:

DEXAMPHETAMINE SULPHATE (Other drug) Reason: Behavior disorders of childhod

10.0 Milligram Daily

Batch: Started: L TERM Stopped:

RISPERIDONE (Suspected) Reason: Explosive personality disorder

Tablet 1.0 Milligram Daily Oral

Batch: Started: 01/07/2002 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Has cousin with schizophrenia on risperidone, was on a while then ceased due to nose bleeds.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 541 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Re	po	rt	De	tai	ls	:
----	----	----	----	-----	----	---

 Case Number:
 179860
 Seq: 1
 Gender:
 F

 Reported:
 16/10/2002
 Weight:
 70.00

Hospitalisation: Admitted to hospital **Age**: 80

Onset Date: 08/10/2002 **DOB**: 16/12/1921

Outcome: Recovered Causality: Causality probable

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating			Ceased risperidone. patient hospitalised. date of recovery 09/10/02.

Medicine Details:

ATENOLOL (Other drug)			Reason:	Essential benign hypertension	
	25.0 N	Milligram	Daily		
Batch:	Started:			Stopped:	
ASPIRIN (Other drug)			Reason:	Acute,ill-def cerebrovascular disease	w/o hyperte
	100.0 N	Milligram	Daily		
Batch:	Started:			Stopped:	
ATORVASTATIN (Other drug)			Reason:	Othr&unspec metabolic diseases	
	10.0 N	Milligram	Daily		
Batch:	Started:			Stopped:	
RISPERIDONE (Suspected)			Reason:		
Tablet	1.5 N	Milligram	Daily	Oral	
Batch:	Started:			Stopped: 2D)

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 542 of 554



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Preferred Term Severity Report Description Treatment /eight increased Iedicine Details:	Case Number: 180321	Seq: 1		Gend	er: F
Onset Date: Outcome: Not yet recovered	Reported: 01/11/2002			Weig	nt: 0.00
Outcome: Not yet recovered action Details: Preferred Term Severity Report Description Treatment Aleight increased Pedicine Details: Preferred Term Pedicine Details: Pedicine D	ospitalisation:			Ą	je: 13
Preferred Term Severity Report Description Treatment Preferred Term Severity Report Description Treatment	Onset Date:				
Medicine Details: TRILEPTAL (Suspected) Batch: Started: Stopped: RISPERIDONE (Suspected) Reason: Tablet Oral Batch: Started: Stopped: Tablet Started: Stopped:	Outcome: Not yet recove	ered		Causali	ty: Causality possible
Pedicine Details: TRILEPTAL (Suspected) Reason: Oral					
Reason: O.0 Oral Batch: Started: Stopped: Tablet Oral Batch: Started: Stopped: Tablet Started: Stopped: Tablet Started: Stopped: Tablet Started: Stopped: Tablet Started: Stopped: Batch: Started: Stopped: Aboratory Investigations:		Severity	Repo	ort Description	Treatment
Batch: Started: Stopped: RISPERIDONE (Suspected) Reason: Tablet Oral Batch: Started: Stopped:	Veight increased				
Reason: 0.0 Oral Batch: Started: Stopped: RISPERIDONE (Suspected) Tablet Oral Batch: Started: Stopped:					
Reason: 0.0 Oral Batch: Started: Stopped: RISPERIDONE (Suspected) Tablet Oral Batch: Started: Stopped:					
Reason: 0.0 Oral Batch: Started: Stopped: RISPERIDONE (Suspected) Tablet Oral Batch: Started: Stopped:					
Reason: 0.0 Oral Batch: Started: Stopped: Risperidone (Suspected) Tablet Oral Batch: Started: Stopped: Oral Batch: Started: Stopped:					
Reason: 0.0 Oral Batch: Started: Stopped: RISPERIDONE (Suspected) Tablet Oral Batch: Started: Stopped:					
Reason: 0.0 Oral Batch: Started: Stopped: RISPERIDONE (Suspected) Tablet Oral Batch: Started: Stopped:					
Reason: 0.0 Oral Batch: Started: Stopped: RISPERIDONE (Suspected) Tablet Oral Batch: Started: Stopped:					
Reason: 0.0 Oral Batch: Started: Stopped: RISPERIDONE (Suspected) Tablet Oral Batch: Started: Stopped:					
Batch: Started: Stopped: RISPERIDONE (Suspected) Reason: Tablet Oral Batch: Started: Stopped:					
Batch: Started: Stopped: RISPERIDONE (Suspected) Reason: Tablet Oral Batch: Started: Stopped:	TRILEPTAL (Suspected)	• •	Rea		
Tablet Oral Batch: Started: Stopped: Aboratory Investigations:	Detak				
Tablet Oral Batch: Started: Stopped: aboratory Investigations:		Started:		Stopped:	
Batch: Started: Stopped:			_		
aboratory Investigations:			Reas		
	Tablet	Otantadi	Rea	Oral	
	Tablet	Started:	Rea	Oral	
.aboratory Investigations: Date Type Range Date Tested Result Details	Tablet	Started:	Rea	Oral	
	Tablet	Started:	Rea	Oral	
	Tablet	Started:	Rea	Oral	
	Tablet	Started:	Rea	Oral	
	Tablet	Started:	Rea	Oral	
	Tablet	Started:	Rea	Oral	
	Tablet Batch :		Rea	Oral	
	Tablet Batch: aboratory Investigations	s:		Oral Stopped:	etails
	Tablet Batch: _aboratory Investigation	s:		Oral Stopped:	etails
	Tablet Batch: Laboratory Investigation	s:		Oral Stopped:	etails
	Tablet Batch: _aboratory Investigation	s:		Oral Stopped:	etails
	Tablet Batch: _aboratory Investigation	s:		Oral Stopped:	etails
	Tablet Batch: _aboratory Investigation	s:		Oral Stopped:	etails
	Tablet Batch: Laboratory Investigation	s:		Oral Stopped:	etails
Additional Information:	Tablet Batch: -aboratory Investigation: Date Type F	s:		Oral Stopped:	etails
Additional Information:	Tablet Batch: -aboratory Investigation: Date Type F	s:		Oral Stopped:	etails
Additional Information:	Tablet Batch: -aboratory Investigation: Date Type F	s:		Oral Stopped:	etails
Additional Information:	Tablet Batch: -aboratory Investigation: Date Type F	s:		Oral Stopped:	etails
Additional Information:	Tablet Batch: -aboratory Investigation: Date Type F	s:		Oral Stopped:	etails

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 543 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 180341 Seq: 1 Gender: F

Reported: 04/11/2002 Weight: 50.00 Hospitalisation: Age: 16

Onset Date: 28/09/2002 **DOB**: 10/05/1986

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia			Required a visit to doctor. patient being weaned off risperidone from 24/10/02.

Medicine Details:

RISPERIDONE (Suspected) Reason: Unspecified psychosis

Tablet 3.0 Milligram Daily Oral

Batch: Started: 01/06/2001 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start is not necessarily accurate but indicates risperidone was started sometime in the month.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 544 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number:180477Seq: 1Gender:FReported:11/11/2002Weight:55.00Hospitalisation:Admitted to hospitalAge: 76Y

Onset Date: 28/01/1999 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

i toaction Botano.			
Preferred Term	Severity	Report Description	Treatment
Anorexia			Patient hospitalised. risperdal ceased. date of recovery 03/1999.
Fatigue			
Stupor			
Thinking abnormal			
Tongue paralysis			

Medicine Details:

DIGOXIN (Other drug)	Reason:				
	1.2 N	Milligram [Daily		
Batch:	Started:	L TERM	Stopped:		
SPAN-K (Other drug)		Reaso	on:		
	120.0	Gram D	Daily		
Batch:	Started:	L TERM	Stopped:		
LASIX (Other drug)		Reaso	on:		
	40.0 N	Milligram [Daily		
Batch:	Started:	L TERM	Stopped:		
OROXINE (Other drug)		Reaso	on:		
	150.0 N	Microgram [Daily		
Batch:	Started:	L TERM	Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Description: cognitive and moter impairment/fall and consequent hip fracture. the date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for the drug resperdal is not necessarily accurate but indicates the drug was started sometime in month.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 545 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 180477 Seq: 1 Gender: F

Reported: 11/11/2002 Weight: 55.00
Hospitalisation: Admitted to hospital Age: 76Y
Onset Date: 28/01/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

ASPIRIN (Other drug)		Reason:	
	0.5 Milligram	Daily	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 15/11/1998	Stopped:	18/02/2001

Laboratory Investigations:

Additional Information:

Description: cognitive and moter impairment/fall and consequent hip fracture. the date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for the drug resperdal is not necessarily accurate but indicates the drug was started sometime in month.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 546 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 180801 Seq: 1 Gender: F

Reported: 18/12/2002 Weight: 0.00 Hospitalisation: Age: 16

Onset Date: DOB: 14/05/1986

Outcome: Recovered Causality: Causality probable

Reaction Details:

teaction Details.			
Preferred Term Severity		Report Description	Treatment
Tardive dyskinesia		Movement in the bottom lip, involuntary chewing movement and tongue movements experienced at night - psychiatrist confirmed tardive dyskinesia	Patient being weaned off Risperidone and weaned onto Quetiapine Fumarate.

Medicine Details:

RISPERDAL (Suspected) Reason: Unspecified schizophrenia

Tablet 2.0 Milligram Oral

Batch: Started: L TERM Stopped: 15/05/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient's history - Schizophrenia for 2 years. Dose of Risperidone was increased to 3mg/daily on the 16/05/02. Patient recovered 3-4 weeks from the date risperidone was ceased.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 547 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 180856 Seq: 1 Gender: F

Reported: 19/12/2002 Weight: 0.00 Hospitalisation: Age: 36

Onset Date: 09/10/2002 DOB: 09/07/1966

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Neutropenia		Patient developed neutropenia and was persistent on repeated blood tests.	

Medicine Details:

modicino Dotano.						
RISPERDAL (Suspected)			Reason:	Unspecified schizophrenia		
Tablet	2.0	Milligram	Daily	Oral		
Ratch:	Started:	ı	TERM	Stonned:	contin	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/12/2002	Neutrophils	2 - 8	09/10/2002	1.6	
19/12/2002	Neutrophils	2 - 8	11/02/2003	1.5	
19/12/2002	White blood cells	4 - 11.0	09/10/2002	3.1	
19/12/2002	White blood cells	4 - 11.0	11/02/2003	2.4	

Additional Information:

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 548 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 180880 Seq: 1 Gender: M

Reported: 19/12/2002 Weight: 90.00 Hospitalisation: Age: 75

Onset Date: 20/11/2002 **DOB:** 23/05/1927

Outcome: Recovered 22/11/2002 Causality: Causality possible

Reaction Details:

caction betails.			
Preferred Term	Severity	Report Description	Treatment
Duodenal ulcer haemorrhage	Life threatening		Over sewing of duodenal ulcer. Indomethacin dose reduced to 50mg bd.

Medicine Details:

ALLOPURINOL (Other drug)		Reason: Gout		
Tablet	100.0 Milligram		Oral	
Batch:	Started:	Stopp	ed:	CONTIN
METOPROLOL TARTRATE (Other drug)		Reason:		
Tablet	50.0 Milligram	Daily	Oral	
Batch:	Started:	Stopp	ed:	CONTIN
KETOROLAC (Suspected)		Reason: Pain		
	60.0 Milligram	1 time		
Batch:	Started: 08/11/2002	Stopp	ed:	
KETOROLAC (Suspected)		Reason: Pain		
	30.0 Milligram	1 time		
Batch:	Started: 09/11/2002	Stopp	ed:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

patient is an alcoholic.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 549 of 554



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:

Case Number: 180880 Seq: 1 Gender: M

Reported: 19/12/2002 Weight: 90.00 Hospitalisation: Age: 75

Onset Date: 20/11/2002 DOB: 23/05/1927

Outcome: Recovered 22/11/2002 Causality: Causality possible

Reaction Details:

Medicine Details:

ASPIRIN (Suspected)			Reason:	Other coagula	tion defects
	150.0	Milligram	Daily		
Batch:	Started:			Stopped:	20/11/2002
RISPERIDONE (Suspected)			Reason:		
Tablet	1.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	19/11/2002
TRAMADOL HYDROCHLORIDE (Suspected)		Reason:	Pain	
Tablet	400.0	Milligram	Daily		Oral
Batch:	Started: 07	/11/2002		Stopped:	
DIAZEPAM (Suspected)			Reason:		
Tablet	15.0	Milligram	Daily		Oral
Batch:	Started: 04	/11/2002		Stopped:	09/11/2002

Laboratory Investigations:

Additional Information:

patient is an alcoholic.

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 550 of 554



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Case Number: 18 Reported: 19 Hospitalisation: Onset Date: 20 Outcome: R	9/12/2002 0/11/2002 lecovered	Seq: 1	22/11/2002			90.00	
Medicine Detail							
INDOMETHACIN (Sus	spected)	200.0 Mil	Reaso	n: Daily			
Batch:		Started: 07/11/2		Stoppe	d:		
Laboratory Inve	estigations:						
Additional Info							

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 551 of 554



Case Number: 183078

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Seq: 1

Reported: 17/12/2002 ospitalisation:			Weig	ht: 0.00			
_		Age: 95Y					
Onset Date:		DOB:					
Outcome: Recovered		Causality: Causality possible					
action Details:							
Preferred Term	Severity	У	Report Description	Treatment			
ystonia		Patient pre inability to collapse.	esented with loss of memory, an speak, dystonia and	Reisperdal ceased.			
mnesia							
irculatory collapse							
peech disorder							
ledicine Details:			Reason				
NOPERDAL (Suspected)		Reason: 1.0 Milligram Daily Oral					
Batch:	Started	=	TERM Stopped:				
	S:	Tarrel Day					
_aboratory Investigations Date Type F	S: Range Date	Tested Res	ult E	Details			
	S: Range Date	Tested Res	ult	petails			



Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Report Details:						
Case Number: 183079	Seq: 1	Gender: M				
Reported: 17/12/2002		Weight: 0.00				
Hospitalisation:		Age: 85				
Onset Date:		DOB: Causality: Causality possible				
Outcome: Recovered			Causaii	ty: Causality possible		
Reaction Details:	Coverity	Deport De		Tractment		
Preferred Term	Severity	Report De	Treatment			
Amnesia		Patient presented with inability to speak, confi collapse.	Risperdal ceased.			
Circulatory collapse		Patient presented with inability to speak, confucollapse.	loss of memory, an usion and	Risperdal ceased.		
Confusional state		Patient presented with inability to speak, conficollapse.	loss of memory, an usion and	Risperdal ceased.		
Speech disorder		Patient presented with inability to speak, conficollapse.	Risperdal ceased.			
Medicine Details: RISPERDAL (Suspected)	1.0	Reason:	Oral			
Tablet	1.0	Milligram Daily	Oral			
Laboratory Investigation	·c'					
	Range Date Test	ed Result	D	etails		
Additional Information:						

Report Run: 04/06/2007 11:07AM Database: pusime02 ADRS004 Page 553 of 554



Case Number: 183080

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: U

Date Range: 1 Jan 1960 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: RISPERDAL,RISPERIDONE,Risperdal Consta,Risperdal Quicklet

Seq: 1

Reported: 17/12/2002				Weig	ht: 0.00		
spitalisation:			Age: 99U				
Onset Date:			DOB:				
Outcome: Recovered				Causal	ty: Causality possible		
action Details:					T		
Preferred Term	Se	verity		rt Description	Treatment		
mnesia		in	atient presented ability to speak ollapse.	l with loss of memory, an drowsiness and	Risperal ceased.		
rculatory collapse							
omnolence							
peech disorder							
edicine Details:			Dane				
RISPERDAL (Suspected) Tablet		1.0 Mi	Reas	on: Daily Oral			
Batch:	04	tarted:	S TERM	Stopped:			
aboratory Investigation							
Date Type	Range	Date Tested	Result		etails		
Date Type							
Таке Туре							
Таце Туре							
Date Type							
dditional Information:							