

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Re	port	Det	tail	s:

Case Number: 1011111 Seq: 1 Gender: M

 Reported: 29/05/1995
 Weight: 70.00

 Hospitalisation:
 Age: 28Y

 Onset Date: 24/05/1995
 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			

Medicine Details:

TIMOLOL MALEATE EYE DROPS (Su	spected)	Reason:	
Eye Drops	0.0	Ophthalmic	
Batch:	Started: 18/05/1995	Stopped:	
ZUCLOPENTHIXOL DECANOATE (Su	ispected)	Reason: Unspecified schizophrenia	
Injection	800.0 Milligram	Weekly Intramuscular	
Batch:	Started: 08/03/1995	Stopped:	
LARGACTIL (Suspected)		Reason: Unspecified schizophrenia	
Oral application	1.2 Gram	Daily Oral	
Batch:	Started: 08/03/1995	Stopped:	
CLONAZEPAM (Suspected)		Reason: Otr spec symp psychopathol nec	
Oral application	1.0 Milligram	Daily Oral	
Batch:	Started: 10/04/1995	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Report Details:				
Case Number: 101111	Seq: 1		Gender:	M
Reported: 29/05/1995	•		Weight:	70.00
Hospitalisation:			Age:	
Onset Date: 24/05/1995			DOB:	
Outcome: Recovered				Causality possible
			Causanty.	Causality possible
Reaction Details:				
Medicine Details:				
PAROXETINE HYDROCHLORIDE (Susp	nected)	Reason:	Otr spec symp psychopath	iol nec
Tablet Tables	20.0 Milligram	Daily		ioi nee
	Started: 17/05/1995	Dally		
Batch:	Started: 17/05/1995		Stopped:	
Laboratory Investigations:				
Additional Information:				

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Report Details:

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05046	Seq:	1		Gende	
1/12/1995					
Inknown					ty: Causality possible
				Causaii	ty. Causality possible
	Se	verity	Reno	rt Description	Treatment
		Verity	Теро	Tt Description	Troument
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,					
		0.0	Reas		
	St	arted:			
Suspected)		0.0	Reas	on:	
	64			Stannadi	
	31	arteu.		Stoppeu.	
		Date Tested	Result	Di	etails
1					
I.	U.	•			
	Inknown ITerm Onormal Is: ted) estigations	Inknown I Term Seconormal Is: ted) Suspected) estigations:	Inknown Item Severity Incompanies Is: Ited) O.0 Started: Suspected) O.0 Started:	Inknown ITerm Severity Reportation Reportation Started: Suspected) Reas 0.0 Started: Started:	Inknown Causali Term Severity Report Description Onormal Started: Stopped: Suspected Reason: 0.0 Started: Stopped: Started: Stopped: Stopped: Started: Stopped: Started: Stopped: Stopped: Started: Stopped: Stopped: Started: Stopped: Stopped: Started: Stopped:

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Report Details:							
Case Number: 117	738 Seq :	1				Gender	: M
Reported: 21/0	05/1997					Weight:	105.00
Hospitalisation:						Age	: 32Y
Onset Date: 15/0)5/1997					DOB	:
Outcome: Rec	overed				Ca	ausality	: Causality possible
Reaction Details:							
Preferred Te	erm Sev	verity	Repo	rt Descripti	on		Treatment
Dyskinesia							
Laryngospasm							
Oculogyration							
Madiaira Dataila							
Medicine Details:			Reas	on:			
Injection	ANOATE (Suspected)	150.0 Milligr		Daily		Intramuso	cular
Batch:	Sta	arted: 14/05/199		-	opped:	14/05/199	
DIAZEPAM (Suspected)			Reas		- pp-our		
Oral application		10.0 Milligr		Daily		Oral	
Batch:	Sta	arted: 14/05/199		-		14/05/199	97
Laboratory Inves Date Type		Date Tested	Result			Deta	ails
Additional Inform	nation:						

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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 sch	izophrenia	
Tablet	750.0 Milligran	n Daily	(Oral	
Batch:	Started:	L TERM	Stopped:		
CLONAZEPAM (Suspected)		Reason:	Otr spec symp p	psychopathol nec	
Tablet	1.0 Milligran	n Daily	(Oral	
Batch:	Started: 21/12/1996		Stopped:	CONTIN	
SODIUM VALPROATE (Suspected)		Reason:	Other&unspecifi	ed epilepsy	
Tablet	400.0 Milligran	n Daily	(Oral	
Batch:	Started: 13/11/1996		Stopped: (05/02/1997	
BENZHEXOL HYDROCHLORIDE (Suspec	cted)	Reason:			
Tablet	10.0 Milligran	n Daily	(Oral	
Batch:	Started: 08/02/1997		Stopped: (07/05/1997	

Laboratory Investigations:

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

Additional Information:

Clopixol-acuphase taken at 50mg every 3 days.

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Report Detail	s:							
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					С	ausality:	Causality possible
Reaction Detai	ls:							
Madiaina Dat								
Medicine Deta					Reason:	Unspecified ps	vchosis	
Tablet	opeotou)		20	Milligram	Daily	Onopcomed po	Oral	
Batch:		Start		/06/1996	24,	Stopped:	04/02/1997	•
CLOPIXOL-ACUPH	IASE (Suspected)				Reason:	Unspecified ps		
Injection			50.0	Milligram	Cyclic	al	Intramuscu	lar
Batch:		Start	ed : 07/	/02/1997		Stopped:	01/03/1997	•
Laboratory In	vestigations:							

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Report Details:

 Case Number:
 119887
 Seq:
 1
 Gender:
 M

 Reported:
 14/08/1997
 Weight:

 Hospitalisation:
 Age: 27

 Onset Date: 03/07/1997
 DOB: 30/01/1970

Outcome: Recovered Causality: Causality possible

Reaction Details:

Caction Details.			•
Preferred Term	Severity	Report Description	Treatment
Dystonia Hypertension			
Neuroleptic malignant syndrome			Iv fluids, iv diazepam, wihdraw clozaril, clopixol and kemadrin. clozaril restarted at a later date.
Pyrexia			
Tachycardia			

Medicine Details:

KEMADRIN (Suspected)	eted) Reason:			
	0.0			
Batch:	Started:	Stopped:		
CLOPIXOL-ACUPHASE (Suspected)		Reason:		
Injection	150.0 Milligram	1 time	Intramuscular	
Batch:	Started: 02/07/1997	Stopped:		
CLOZARIL (Suspected)		Reason: Schizophrenia	1	
Tablet	175.0 Milligram	Daily	Oral	
Batch:	Started: 26/06/1997	Stopped:	02/07/1997	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine				Ck also rose to >6000

Additional Information:

Patient has been restarted on clozaril with no concurrent other anti-psychosis and is doing well.

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Re	po	rt	De	tai	ls:
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 Case Number:
 120660
 Seq: 1
 Gender: M

 Reported:
 10/09/1997
 Weight:

Hospitalisation: Age: 16

Onset Date: DOB: 20/01/1981

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Blood pressure dropped to 80/40	

Medicine Details:

viedicine Details:					
ZUCLOPENTHIXOL ACETATE (Susp	pected)	Reason: Unspec	ified psychosis		
Injection	100.0 Milligram	1 time	Intramus	scular	
Batch:	Started: 11/08/1997	Sto	pped:		
ZUCLOPENTHIXOL DECANOATE (S	Suspected)	Reason:			
Injection	50.0 Milligram	1 time	Intramus	scular	
Batch:	Started: 15/08/1997	Sto	pped:	CONTIN	
CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason:			
Oral application	100.0 Milligram	As necessary	Oral		
Batch:	Started: 14/07/1997	Sto	pped: 16/08/19	997	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
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Additional Information:



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Re	po	rt	De	tai	ls:
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 Case Number:
 123330
 Seq: 1
 Gender: M

 Reported:
 15/12/1997
 Weight:

Hospitalisation: Age: 41

Onset Date: 22/10/1997 **DOB**: 08/07/1956

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			lmi cogentin 2mg given and 2mg oral.

Medicine Details:

CLONAZEI	PAM (Other drug)			Reason:		
Tal	blet	2.0	Milligram	Daily		Oral
Ва	itch:	Started: 22/	/10/1997		Stopped:	23/10/1997
ZUCLOPE	NTHIXOL ACETATE (Suspected)			Reason:		

Injection 100.0 Milligram 1 time Intramuscular

Batch: Started: 22/10/1997 Stopped: 22/10/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Report Details:

Case Number: 123385 Seq: 1 Gender: M

Reported: 15/12/1997 Weight: 67.00 Hospitalisation: Age: 22

Onset Date: 08/11/1997 **DOB:** 19/10/1975

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Cogentin 2mg po.

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
Oral application	5.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped	i:
RISPERIDONE (Other drug)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 02/11/1997	Stopped	: CONTIN
BENZTROPINE MESYLATE (Other drug)		Reason:	
Oral application	2.0 Milligram	Daily	Oral
Batch:	Started: 25/10/1997	Stopped	: CONTIN
CARBAMAZEPINE (Other drug)		Reason:	
	200.0 Milligram	Daily	
Batch:	Started: 25/10/1997	Stopped	: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Report Details:

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Reported:		Seq: 1		Gender:	
	15/12/1997			Weight:	67.00
Hospitalisation:				Age:	
Onset Date:	08/11/1997				19/10/1975
Outcome:				Causality:	Causality possible
Reaction Detail	s:				
Medicine Deta	ile:				
	. ACETATE (Suspecte	d)	Reason:		
	` .	, 100.0 Milligram			
Batch:		Started: 03/10/1997		Stopped:	
	ACETATE (Suspecte		Reason:		
		100.0 Milligram	1 time		
Batch:		Started: 05/10/1997		Stopped:	
ZUCLOPENTHIXOL	ACETATE (Suspecte	d)	Reason:		
Injection		150.0 Milligram	1 time	Intramuscu	lar
Batch:		Started: 06/11/1997		Stopped:	
Laboratory Inv	vestigations:				
Laboratory Inv	vestigations:				
Laboratory Inv	vestigations:				
Laboratory Inv	vestigations:				
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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Re	po	rt	De	tai	ls:
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 Case Number:
 123780
 Seq: 1
 Gender: M

 Reported:
 06/01/1998
 Weight:

Hospitalisation: Age: 31Y
Onset Date: 30/12/1997
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Convulsion		Fitting and biting of tongue	
	Tongue oedema		Swelling of tongue nearly to suffication	

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Unspecified psychosis

 Injection
 100.0 Milligram
 1 time
 Intramuscular

 Batch:
 Started: 30/12/1997
 Stopped: 30/12/1997

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
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Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

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Report De				4					
Case Numb			Seq:	1				Gender	
Repori Iospitalisati		03/02/199	8					Weight	
-		19/01/199	ıΩ					Age DOB	
		Recovere					C		: Causality possible
eaction D			u .				•	aacanty	. Gaddanty possible
		ed Term	Se	everity	Repo	ort Des	scription		Treatment
xtrapyramic	dal di	sorder		E	xtrapyramidal o	dystonia	а		
Hypotension									
Somnolence	!								
Medicine	Deta	ails:							
ZUCLOPENT			(Suspected)		Rea	son:	Unspecified ps	sychosis	
Inject				100.0 N	lilligram	1 time		Intramuso	cular
Batc	h:		s	tarted: 19/01	/1998		Stopped:	19/01/199	98
TRIFLUOPER	RAZIN	E HYDROCH	ILORIDE (Susp	ected)	Rea	son:	Unspecified ps	sychosis	
Table	et				lilligram	Daily		Oral	
Batc	h:		S	tarted:			Stopped:	19/01/199	98
Laborator									
Date		Туре	Range	Date Tested	d Result			Deta	ails
				<u> </u>	_1				

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	Re	port	Detai	ls:
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Case Number:125312Seq: 1Gender: MReported:23/02/1998Weight:Hospitalisation:Age:

Onset Date: 22/12/1997 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Dystonia		Jaw drop, tongue rolled over, unable to speak.	Benztropine 2mg imi given and repeat again within 24 hrs with good effect.
Hypotonia		Unusual lose of tone in upper body	
Catatonia			

Medicine Details:

DIPHTHERIA AND TETANUS VACCINE ADT	(Other drug) Re	ason:		
Injection	1.0	Dose Unspecified	d 1 tim	е	Intramuscular
Batch:	Started:			Stopped:	
HALOPERIDOL (Other drug)		Re	ason:	Unspecified p	sychosis
Injection	10.0	Milligram	As ne	ecessary	Intramuscular
Batch:	Started:			Stopped:	
MIDAZOLAM (Other drug)		Re	ason:	Unspecified p	sychosis
Injection	10.0	Milligram	As ne	ecessary	Intramuscular
Batch:	Started:			Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Re	ason:	Unspecified p	sychosis
Injection	50.0	Milligram	1 tim	е	Intramuscular
Batch:	Started: 20	/12/1997		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Hospitalisation: Onset Date:	23/02/1998 22/12/1997 Recovered	Seq: 1	Gender: Weight: Age: DOB: Causality:	
Medicine Deta	ails:			
	DROCHLORIDE (Sus	pected)	Reason: Unspecified psychosis	
Tablet		50.0 Milligram	As necessary Oral	
Batch:		Started: 22/12/1997	Stopped:	
Laboratory In	vestigations:			
Additional Inf	ormation:			

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Re	port	Detai	ls:
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Case Number: 126158 Seq: 1 Gender: U

Reported: 25/03/1998 Weight:
Hospitalisation: Age:
Onset Date: 31/03/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension			

Medicine Details:

CLOPIXOL (Suspected)		Reason:		
	0.0			
Batch:	Started:	Sto	pped:	
ZOLOFT (Suspected)		Reason:		
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 necessarily accurate but indicates that onset occurred sometime during the month.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Reported	r: 127328	Seq: 1			Gender: M
	d: 13/05/1998	•			Weight:
Hospitalisation	1:				Age : 31
Onset Date	e: 25/03/1998				DOB : 16/03/1967
Outcome	: Recovered			С	ausality: Causality possible
Reaction Det	ails:				, ,
	rred Term	Severity	Report D	escription	Treatment
Tremor			Facial tremor very m	arked.	
Blepharospasn	n		Starring reaction		
Dystonia			, The state of the		Cogentin and reduced zuclopenthixol to 400 every 2 weeks. also introduced temazepam for night sedation, diazepam for tranquilisation. chlorpromazine ceased.
Medicine De	etails: (OL ACETATE (S	uspected\	Reason:		
Injection	•	•) Milligram Tota		Intramuscular
Batch:		Started: 2	•	Stopped:	mitamusculai
	ZINE HYDROCHI	ORIDE (Suspected)	Reason:		sychosis
OHEORI ROMA				necessary	3,4110010
		100.0	o willigram As i	iecessai y	
Batch:		Started:		Stopped:	25/03/1998
	Investigatio			Stopped:	25/03/1998
Laboratory Date	Investigatio		ested Result	Stopped:	25/03/1998 Details
Laboratory		ons:	ested Result	Stopped:	

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

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Report Details:

Case Number: 127445 Seq: 1 Gender: M

Reported: 15/05/1998 **Weight:** 76.00

Hospitalisation: Age: 26Y

Onset Date: 21/03/1998 **DOB**:

Outcome: Recovered Causality: Causality certain

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Depersonalisation		Disinhibited behaviour	
Confusional state		Disorganised	
Agitation			
Delirium			

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Unspecified psychosis

Injection 200.0 Milligram 1 time Intramuscular

Batch: Started: 20/03/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction recurred on 23/4/98 when given another 100mg im stat of zuclopenthixol on 22/4/98.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 128718 Seq: 1 Gender: M

Reported: 26/06/1998 **Weight:** 107.00

Hospitalisation: Age: 21Y
Onset Date: 14/06/1998
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Cuction Details.			
Preferred Term	Severity	Report Description	Treatment
Rash erythematous	Required Specialist Consultation	Rash over neck/face/scalp/torso.	Phenergan

Medicine Details:

BENZTROPINE MESYLATE (Other drug)	ı	Reason:	
	500.0 Microgram	As necessary	
Batch:	Started:	Stopped:	
DIAZEPAM (Other drug)	I	Reason:	
Oral application	10.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Other drug)	I	Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 01/10/1997	Stopped:	
LITHIUM CARBONATE (Other drug)	I	Reason:	
	2.0 Gram	Daily	
Batch:	Started: 01/10/1997	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. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 128718 Seq: 1 Gender: M

Reported: 26/06/1998 Weight: 107.00 Hospitalisation: Age: 21Y

Onset Date: 14/06/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.				
CLOPIXOL-ACUPHASE (Suspected)		Reason:		
Injection	150.0 Milligram	1 time	Intramuscular	
Batch:	Started: 14/06/1998	Stoppe	d : 14/06/1998	
MIDAZOLAM (Suspected)		Reason: Specific dis	orders of sleep	
Injection	20.0 Milligram	1 time	Intramuscular	
Batch:	Started: 14/06/1998	Stoppe	d:	

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.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details	s:					
Case Number:	129242	Seq: 1		G	Sende	er: M
Reported:	15/07/1998			V	Veigh	t:
Hospitalisation:					Ag	e:
Onset Date:	05/06/1998				DO	B:
Outcome:				Cai	usalit	y: Causality possible
R <u>eaction Detai</u>						
	ed Term	Severity	•	ort Description		Treatment
Arthralgia			Sore joints			
Dystonia			Stiff jaw			Imi cogentin 2mg stat. changed to flupenthixol for next dose due in 2weeks from 05/06/98.
Extrapyramidal d	isorder		Typical extra pyr	amidal side effects		
Medicine Deta			Rea	son:		
	or arag,	10.0	Milligram	Daily		
Batch:		Started: 29/0	_	Stopped: 1	9/05/1	998
ZUCLOPENTHIXO	L DECANOATE	(Suspected)	Rea	son:		
		100.0 I	Milligram	1 time		
Batch:		Started: 05/0	6/1998	Stopped: 0	5/06/1	998
Laboratory In	vestigatio Type	ns: Range Date Teste	ed Result		De	etails
	,,					
Additional Inf	ormation:					

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 129701
 Seq: 1
 Gender: M

 Reported:
 28/07/1998
 Weight:

Hospitalisation: Age: 23Y
Onset Date: 16/07/1998
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypothermia		34.5 degrees	

Medicine Details:

SERENACE (Other drug)		Reason: Otr sp	pec symp psychopathol nec	
Tablet	10.0 Milligram	1 time	Oral	
Batch:	Started: 13/07/1998	S	topped: 13/07/1998	
RIVOTRIL (Other drug)		Reason: Otr s	pec symp psychopathol nec	
Tablet	2.0 Milligram	1 time	Oral	
Batch:	Started: 13/07/1998	S	topped: 13/07/1998	
STELAZINE (Other drug)		Reason: Unsp	ecified psychosis	
OTELALINE (Other drug)				
Oral application	5.0 Milligram	1 time	Oral	
\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	5.0 Milligram Started: 14/07/1998	1 time	, ,	
Oral application	· ·	1 time	Oral	
Oral application Batch:	· ·	1 time	Oral topped: 14/07/1998	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:				
Case Number: 129701 Reported: 28/07/1998 Hospitalisation: Onset Date: 16/07/1998 Outcome: Recovered Reaction Details:	Seq: 1		Gender: M Weight: Age: 23Y DOB: ausality: Causality possible	
Medicine Details:				
SERENACE (Suspected)	40.0 14:11:		p psychopathol nec	
Injection Batch:	10.0 Milligram Started: 14/07/1998	1 time	Intramuscular 14/07/1998	
Laboratory Investigations:				
Additional Information:				

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DOB:

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL, CLOPIXOL DEPOT, CLOPIXOL-ACUPHASE, ZUCLOPENTHIXOL ACETATE, ZUCLOPENTHIXOL DECANOATE, ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 129815 Seq: 1 Gender: M

 Reported: 31/07/1998
 Weight: 61.00

 Hospitalisation:
 Age: 36Y

Outcome: Recovered Causality: Causality possible

Reaction Details:

Onset Date: 26/02/1998

Preferred Term	Severity	Report Description	Treatment
Priapism			Sudafed 60mg bd and drainage

Medicine Details:

HALOPERIDOL (Other drug)		Reason: Unspecified ps	sychosis
Oral application	20.0 Milligram	1 time	Oral
Batch:	Started: 15/02/1998	Stopped:	15/02/1998
ATENOLOL (Other drug)	ı	Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 01/12/1997	Stopped:	
ASPIRIN (Other drug)	ı	Reason:	
Oral application	150.0 Milligram	Daily	Oral
Batch:	Started: 01/12/1997	Stopped:	
CLOPIXOL (Suspected)	ı	Reason:	
Injection	300.0 Milligram	1 time	Intramuscular
Batch:	Started: 23/02/1998	Stopped:	23/02/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Cogentin - 2mg oral 09,11,16,22,25/06/98, diazepam - 5-20mg oral 5,8,15,16, 25/02/98, haloperidol 10mg oral 05/02/98 & 08/02/98 20mg oral 15/02/98. 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.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report	Details:
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Case Number: 129815 Seq: 1 Gender: M

Reported: 31/07/1998 Weight: 61.00 Hospitalisation: Age: 36Y

Onset Date: 26/02/1998 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

DIAZEPAM (Suspected)		Reason:	
Tablet	5.0 Milligram	1 time	Oral
Batch:	Started: 25/02/1998	Stopped:	25/02/1998
COGENTIN (Suspected)	ı	Reason:	
COGENTIN (Suspected) Tablet	2.0 Milligram	Reason: 1 time	Oral

Laboratory Investigations:

Additional Information:

Cogentin - 2mg oral 09,11,16,22,25/06/98, diazepam - 5-20mg oral 5,8,15,16, 25/02/98, haloperidol 10mg oral 05/02/98 & 08/02/98 20mg oral 15/02/98. 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.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report	Detai	ls:
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 Case Number:
 131312
 Seq: 1
 Gender: M

 Reported:
 17/09/1998
 Weight:

Hospitalisation: Age: 28

Onset Date: DOB: 31/05/1970
Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Syncope			Put to bed and elevated end of bed for 30min observation.
Hypotension		Severe bp drop	

Medicine Details:

CLONAZEPAM (Other drug)			
	2.0 Milligram	As necessary	
Batch:	Started: 12/07/1998	Stopped:	
LITHIUM CARBONATE (Other drug)		Reason:	
	1.7 Gram	Daily	
Batch:	Started:	Stopped:	CONTIN
TEGRETOL (Other drug)		Reason:	
	400.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
CLOPIXOL-ACUPHASE (Suspected)		Reason:	
	100.0 Milligram	1 time	
Batch:	Started: 12/07/1998	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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TG \ THERAPEUTIC GOODS ADMINISTRATION

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Seq: 1	Gender: M Weight: Age: 28 DOB: 31/05/1970 Causality: Causality possible
pected)	Reason:
100.0 Milligram	As necessary
Started:	Stopped:
	pected) 100.0 Milligram

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Case Number: 131317 Seq: 1 Gender: F
Reported: 17/09/1998 Weight:
Hospitalisation: Age:

Onset Date: 08/07/1998 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Dotanoi			
Preferred Term	Severity	Report Description	Treatment
Speech disorder		Limited speech, slowly resolving	
Hypertonia		Rigidity - proximal limbs	
Catatonia			Cogentin

Medicine Details:

Medicine Details.			
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason: Unspecified psychosis	
Injection	100.0 Milligram	1 time Intramuscular	
Batch:	Started: 06/07/1998	Stopped:	
DIAZEPAM (Suspected)		Reason:	
Injection	30.0 Milligram	Total Intramuscular	
Batch:	Started: 05/07/1998	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Re	po	rt	De	tai	ls:
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Gender: F Case Number: 131538 Seq: 1

Weight: 126.00 Reported: 28/09/1998 **Hospitalisation:** Age: 27Y

Onset Date: 11/09/1998 DOB:

Outcome: Recovered with sequelae Causality: Causality possible

Reaction Details:

Cachon Details.				
Preferred Term	Severity	Report Description	Treatment	
Coma			Icu supportive	1
Paralysis				

Medicine Details:			
HEROIN (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
CLOPIXOL (Suspected)		Reason: Unspecified schizophrenia	
Injection	400.0 Milligram	Weekly Intramuscular	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Sequelae: neurotic pressure sores.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Re	po	rt	De	tai	ls:
	\sim		-	u	

Case Number: 131700 Seq: 1 Gender: M

Reported: 28/09/1998 Weight:
Hospitalisation: Age: 20

Onset Date: 16/08/1998 **DOB**: 05/09/1977

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Dysarthria		Difficulty in speech.	
	Dystonia		Stiff neck,tongue starting to protrude.	Benztropine

Medicine Details:

Medicine Betans.					
OLANZAPINE (Other drug)		Reason:			
	20.0 Milligram	Daily			
Batch:	Started: 15/08/1998	\$	Stopped:	CONTIN	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:			
Injection	150.0 Milligram	1 time	Intramuso	cular	
Batch:	Started: 15/08/1998	5	Stopped:		

Laboratory Investigations:									
Date	Туре	Range	Date Tested	Result	Details				

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Re	po	rt	De	tai	ls:
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Case Number: 134563 Seq: 1 Gender: M

Reported: 21/12/1998 Weight:
Hospitalisation: Age: 38

Onset Date: 15/10/1998 **DOB**: 27/03/1960

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Legs and feet felt stiff.	Benztropine - oral

Medicine Details:

vieuicine Delans.			
RANITIDINE (Other drug)		Reason:	
	300.0 Milligram	Daily	
Batch:	Started:	Stopped	d: CONTIN
ZUCLOPENTHIXOL ACETATE (Suspected)	Reason: Otr spec sy	mp psychopathol nec
	150.0 Milligram	1 time	
Batch:	Started: 13/10/1998	Stopped	d: 13/10/1998
CHLORPROMAZINE HYDROCHLORIDE (S	uspected)	Reason: Otr spec sy	mp psychopathol nec
Oral application	600.0 Milligram	Daily	Oral
Batch:	Started: 05/10/1998	Stoppe	d: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report	Details:
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Case Number: 134564 Seq: 1 Gender: M
Reported: 21/12/1998 Weight:

Hospitalisation: Admitted to hospital **Age**: 43

Onset Date: 21/11/1998 **DOB**: 01/06/1955

Outcome: Recovered Causality: Causality possible

Reaction Details:

Duefermed Terror	0	Depart Description	Tuestassat
Preferred Term	Severity	Report Description	Treatment
Dystonia			21/11/98 benztropine(oral) then cogentin (imi)
Chest pain			
Dyspnoea			

Medicine Details:

FOLIC ACID (Other drug)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	
DILANTIN (Other drug)		Reason:	
	400.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason: Otr spec symp psychopathol n	ec
	100.0 Microgram	1 time	
Batch:	Started: 20/11/1998	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
	1.0 Milligram	Daily	
Batch:	Started: 20/11/1998	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 138240
 Seq: 1
 Gender: F

 Reported:
 06/04/1999
 Weight:

Hospitalisation: Age: 40

Onset Date: DOB: 15/11/1958
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain		·	Dosage of zuclopenthixol was reduced from 100mg forthnightly to 50mg forthnighly. zyprexa was reduced to 7.5mg daily from 10mg daily, then ceased.
Hepatic function abnormal			

Medicine Details:

Medicine Details.				
ZUCLOPENTHIXOL DECANOATE (Sus	pected)	Reason: Schizoph	renia	
Oral application	100.0 Milligram	Fortnightly	Oral	
Batch:	Started: 12/01/1999	Stopp	oed:	
ZYPREXA (Suspected)		Reason: Schizoph	renia	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 06/01/1999	Stopp	oed:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		08/01/1999	13	
	ALT = SGPT		17/02/1999	131	
	Other data				Ultrasound showed mild fatty infiltration of the liver

Additional Information:

Hsitory of marijuana, lsd and alcohol abuse until 1984. patient started on zyprexa on 5mg/day and then increased to 10mg/day which caused severe symptoms.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 138653 Seq: 1 Gender: M

Reported: 22/04/1999 Weight:
Hospitalisation: Age: 19

Onset Date: 30/11/1998 **DOB**: 12/12/1978

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction	Cogentin 2mg x2

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Unspecified schizophrenia

Injection 150.0 Milligram Daily Intramuscular

Batch: Started: 29/11/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Had zuclopenthixol 3 more times and didn't require cogentin.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 140284 Seq: 1 Gender: M

Reported: 07/06/1999 Weight:

Hospitalisation: Age: 20Y
Onset Date: 21/04/1999
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase inc	er		Clopixol ceased

Medicine Details:

CLOPIXOL (Suspected)Reason:Unspecified schizophreniaTablet20.0 MilligramDailyOral

Batch: Started: 15/04/1999 **Stopped:** 03/05/1999

Laboratory Investigations:

	<u>, </u>	• • .			
Date	Туре	Range	Date Tested	Result	Details
	Creatine		13/04/1999	18	
	Creatine		03/05/1999	1517	
	Creatine		11/05/1999	176	

Additional Information:

See original report for details of other therapy: diazepam, benztropine

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 140881
 Seq: 1
 Gender: M

 Reported:
 10/06/1999
 Weight:

Hospitalisation: Age: 30Y

Onset Date: 24/05/1999 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction betails.			
Preferred Term	Severity	Report Description	Treatment
Dyspnoea		Difficulty breathing.	
Dysphagia		Difficuly swollowing.	
Face oedema		Patient experienced swollen lips & eyelids.	
Rash		Rash on hands.	Hydrocortisone im

Medicine Details:

CLOPIXOL-ACUPHASE (Suspected) Reason:

Injection 100.0 Milligram Daily Intramuscular

Batch: Started: 24/05/1999 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient refused oral medication and clopixol arcuphase ordered as im stat on 24.5.99 and patient developed reactions.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 140897
 Seq: 1
 Gender: M

 Reported:
 28/06/1999
 Weight:
 60.00

 Hospitalisation:
 Age: 29Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Parkinsonism	

Medicine Details:

Medicine Details.					
CLOPIXOL (Suspected)	Reason:				
Injection	100.0 Milligram	1 time	Intramuscular		
Batch:	Started: 05/05/1999	Stopp	ed:		
CLOPIXOL (Suspected)		Reason:			
Injection	200.0 Milligram	1 time	Intramuscular		
Batch:	Started: 12/05/1999	Stopp	ed:		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Please see original report for details of other drugs - resperidone, thc. patient had severe parkinsonism, slowly settling. still has some rigidity.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details	:	
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Case Number: 141290 Seq: 1 Gender: M

 Reported:
 08/07/1999
 Weight:
 90.00

 Hospitalisation:
 Age:
 32Y

Onset Date: 19/05/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	caction Betails.			
	Preferred Term	Severity	Report Description	Treatment
	Neuroleptic malignant syndrome		Recent nms	Clopixol ceased
	Blood creatine phosphokinase incr			
	Confusional state			

Medicine Details:

CLOPIXOL DEPOT (Suspected) Reason:

0.0

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Symptoms of nms include rigidity, increased wcc, increased temperature, autonomic instability, increased ck.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 141434 Seq: 1 Gender: U
Reported: 12/07/1999 Weight:
Hospitalisation: Admitted to hospital Age:

Onset Date: 27/06/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Dystonia			Treated with bentropine 2mg oral with good effect.

Medicine Details:

Medicine Details.						
THIORIDAZINE HYDROCHLORIDE (Suspec	cted)		Reason:			
Tablet	100.0	Milligram	1 time		Oral	
Batch:	Started: 25/0	6/1999		Stopped:		
ZUCLOPENTHIXOL ACETATE (Suspected)			Reason:			
Injection	150.0 N	Milligram	1 time		Intramuscular	
Batch:	Started:			Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Please see original report for details of other drugs - diazepam, thioridazine

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:	Re	po	rt	De	tai	ls:
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 Case Number:
 142032
 Seq: 1
 Gender:
 F

 Reported:
 29/07/1999
 Weight:

Hospitalisation: Admitted to hospital Age: 74Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Symptoms consistent with dementia	Clopixol stopped

Medicine Details:

CLOPIXOL (Suspected) Reason:

0.0

Batch: Started: Stopped: 05/12/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drugs - aropax, diazepam, thyroxine, anginine.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 142893
 Seq: 1
 Gender: M

 Reported:
 23/08/1999
 Weight:

 Hospitalisation:
 Age: 26

 Onset Date: 18/07/1999
 DOB: 17/12/1972

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botano:						
Preferred Term Severity		Report Description	Treatment			
Dystonia			Treated with cogentin 2mg orally.			
Agitation		Motor restlessness				

Medicine Details:

ZUCLOPENTHIXOL DECANOATE (S	Suspected)	Reason:	
	200.0 Milligram	Weekly	
Batch:	Started: 12/07/1999	Stopped:	CONTIN
THIORIDAZINE HYDROCHLORIDE (Suspected)	Reason:	
	50.0 Milligram	As necessary	
Batch:	Started: 16/07/1999	Stopped:	CONTIN
DROPERIDOL (Suspected)		Reason:	
	5.0 Milligram	As necessary	
Batch:	Started: 16/07/1999	Stopped:	CONTIN
DIAZEPAM (Suspected)		Reason:	
	5.0 Milligram	As necessary	
Batch:	Started: 16/07/1999	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reduced thioridazine dose to maximum 600mg/d,

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Hospitalisation: Onset Date: Outcome: Reaction Detai	23/08/1999 18/07/1999 Not yet recovered Is:	Seq: 1		
Medicine Deta				
COGENTIN (Suspe	ected)	0.5 Milligram	Reason: As necessary	
Batch:		Started: 16/07/1999	Stopped:	CONTIN
Laboratory In	vestigations:			
Additional Inf Reduced thioridazi	ormation: ne dose to maximun	n 600mg/d,		

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Case Number:	145091 27/10/1999	Seq:	: 1			Gender: Weight:	F	
ospitalisation:						Age:	18	
Onset Date:	: 19/08/1999)				_	30/09/1980	
Outcome:	Recovered				C	ausality:	Causality prob	able
eaction Deta	ils:							
	red Term	Se	everity	Repo	rt Description		Treatme	nt
Dystonia			Ja	aw stiffness		Tre	ated with benztr	opine 2mg
Medicine Det			0.0	Reas	on:			
Batch:		s	tarted:		Stopped:			
ZUCLOPENTHIXO	OL ACETATE (S	Suspected)	100.0 Mi	Reas	on: Hallucinations Daily			
Batch:		s	tarted: 18/08/			19/08/1999)	
_aboratory li	nvestigatio Type	ONS: Range	Date Tested	Result		Detail	s.	
Date	Туре	Range	Date Testeu	Result		Detail	5	
Additional In	formation	:						
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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Re	po	rt	De	tai	ls:
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Case Number: 145929 Seq: 1 Gender: M
Reported: 16/11/1999 Weight:
Hospitalisation: Admitted to hospital Age:

Onset Date: 30/10/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Dystonia			
	Hypertonia			Cogentin 2mg orally.

Medicine Details:

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	Type	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

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:

<u> </u>	ny mivoonganono.					
Date	Туре	Range	Date Tested	Result	Details	

Additional Information:

Pt also taking sodium valproate, salbutamol, clonazepam, benztropine.



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 146907 Seq: 1 Gender: F

Reported: 13/12/1999 **Weight:**

Hospitalisation: Age: 16Y
Onset Date: 15/11/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•				1
	Preferred Term	Severity	Report Description	Treatment
	Coordination abnormal		Ataxic movements	Cogentin 2mg imi given.
	Hypertonia		Stiffness neck, mouth, face and feet.	

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Suspected) Reason:

100.0 Milligram 1 time

Batch: Started: 13/11/1999 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking trimethoprim.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 149476 Seq: 1 Gender: F

Reported: 18/02/2000 Weight:
Hospitalisation: Age: 20Y

Onset Date: 15/02/1999 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Rash on arms, face, chest and legs.	Depot injection changed.

Medicine Details:

ZUCLOPENTHIXOL DECANOATE (Suspected) Reason: Unspecified schizophrenia

Injection 50.0 Milligram 1 time Intramuscular

Batch: Started: 12/02/1999 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking zoloft, zyprexa, cogentin, thioridazine, zopliclone, coloxyl with senna.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 150948 Seq: 1 Gender: F

Reported: 28/03/2000 Weight:
Hospitalisation: Age: 18

Onset Date: 19/08/1999 **DOB**: 30/09/1980

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tetany			Benztropine 2mg.

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Hallucinations

100.0 Milligram Daily

Batch: Started: 18/08/1999 **Stopped:** 19/08/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking risperidone.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 150949 Seq: 1 Gender: M

Reported: 28/03/2000 Weight:
Hospitalisation: Age: 25

Onset Date: 28/01/2000 DOB: 10/10/1974

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	todotion Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
	Asthenia			Cogentin 2mg 28.1.00 orally 17:30.
	Somnolence		Patient became very drowsy.	

Medicine Details:

ZUCLOPENTHIXOL DECANOATE (Suspected) Reason: Unspecified psychosis

50.0 Milligram Daily

Batch: Started: 28/01/2000 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking sertraline, methadone and olanzapine.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 150995
 Seq: 1
 Gender: M

 Reported:
 28/03/2000
 Weight:

Hospitalisation: Age: 27

Onset Date: 29/01/2000 **DOB**: 26/01/1973

Outcome: Recovered Causality: Causality possible

Reaction Details:

i toaotion Botanoi			
Preferred Term	Severity	Report Description	Treatment
Arthralgia		Soreness in joints.	
Tongue oedema		Swollen in tongue.	
Hypertonia			
Myalgia			
Tetany			Patient given cogentin 2 mg.

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	Explosive per	sonality disorder	
	150.0 Milligram	1 tim	е		
Batch:	Started: 27/01/2000		Stopped:		
MIDAZOLAM (Suspected)		Reason:	Otr spec symp	p psychopathol ne	ec
	10.0 Milligram	As no	ecessary		
Batch:	Started: 27/01/2000		Stopped:		CONTIN
DIAZEPAM (Suspected)		Reason:	Otr spec symp	p psychopathol ne	ec
	10.0 Milligram	As no	ecessary		
Batch:	Started: 27/01/2000		Stopped:	28/01/2000	
SODIUM APOLATE (Suspected)		Reason:			
	800.0 Milligram	Daily	,		
Batch:	Started: 27/01/2000		Stopped:	31/01/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 151485 Seq: 1 Gender: F

Reported: 11/04/2000 Weight: 100.00 Hospitalisation: Age: 35Y

Onset Date: 27/03/2000 DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Abscess		Large aseptic hard, tender, 3-4cm(I), 10-8cm(r).	
Injection site reaction			Nsaid cream and oral ees to prevent infection.
Rash erythematous			

Medicine Details:

Medicine Details.			
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
Injection	50.0 Milligram	Daily	Intramuscular
Batch:	Started: 25/03/2000	Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
Injection	200.0 Milligram	Daily	Intramuscular
Batch:	Started: 25/03/2000	Stopped:	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Patient also taking temazepam, olanzapine, sodium valproate and benztropine. patient takes st john wort on and off, takes this at home, unprescribed. started on zuclopenthixol on 25.3.00. initially 50mg (I) buttock then 200mg (r) buttock. history of penicillin allergy.

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Case Number: 151822

Reported: 18/04/2000

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight:

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Seq: 1

- Hospitalisat	ion:					Age:	35		
Onset D	Date: 28/03/2000			DOB : 11/08/1964					
Outco	me: Not yet reco	overed		Causality: Causality certain					
eaction D	etails:								
Pr	eferred Term	Se	verity	Rep	ort Description		Treatment		
Abscess Injection site	e reaction		Se	eptic abscess	formation.	felo rev	clopenthixol ceas dene emugel appl ieved by surgical en erythromycin 2 for 5 days.	ied tds. team. and	
Medicine zuclopent	Details:	suspected)		Rea	ison:				
			200.0 Mil	lligram	Daily				
Bato	ch:	St	tarted: 26/03/2	2000	Stopped:		2D		
Laborato	ry Investigatio	ons:							
Date	Туре	Range	Date Tested	Result		Detai	ls		
Additiona	ıl Information	:		1					
eport Run: 01/	06/2007 04:28PM	Database: pu	ısime02	,	ADRS004		Page 53	of 152	



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

 Case Number:
 152147
 Seq: 1
 Gender: M

 Reported:
 26/04/2000
 Weight:

Hospitalisation: Age: 46

Onset Date: 24/03/2000 **DOB**: 07/10/1953

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Syncope		Collaped in bathroom.	
Dystonia		Involving tongue and mouth.	Benztropine 2mg orally x 3 doses.
Dizziness			
Hypotension			

Medicine Details:

Micalcinic Details.				
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:		
Injection	150.0 Milligram	Daily	Intramuscular	
Batch:	Started: 24/03/2000		Stopped:	
MIDAZOLAM (Suspected)		Reason:		
	10.0 Milligram	Daily		
Batch:	Started: 24/03/2000		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Re	po	rt	De	tai	ls:
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 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:

Micalcinic Details.				
CLOPIXOL (Suspected)		Reason:	Unspecified schizophrenia	
Injection	50.0 Milligram	Daily	Intramuscular	r
Batch:	Started: 29/02/2000		Stopped:	CONTIN
RISPERDAL (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	1.0 Milligram	Daily	Oral	
Batch:	Started: 21/02/2000		Stopped: 21/02/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 155139
 Seq: 1
 Gender:
 F

 Reported:
 20/07/2000
 Weight:

Hospitalisation: Age: 21Y
Onset Date: 10/05/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Caction Betans.			
Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Involuntary tongue movements.	
Oculogyration			Cogentin 2mg iv, commence olanzapine 10mg daily.
Torticollis			

Medicine Details:

CLOPIXOL-ACUPHASE (Suspected) Reason: Unspecified psychosis

Injection 100.0 Milligram 1 time Intramuscular

Batch: Started: 09/05/2000 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Nil previous medications, nil previous adr's.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 155174 Seq: 1 Gender: M

Reported: 20/07/2000 Weight:
Hospitalisation: Age: 37

Onset Date: 03/07/2000 DOB: 08/09/1962
Outcome: Recovered Causality: Causality certain

Reaction Details:

Droforred Torm	Coverity	Depart Description	Trootmont
Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			Zuclopenthixol stopped. cogentin 2mg given orally.

Medicine Details:

ZUCLOPENTHIXOL DECANOATE (Suspected) Reason:

200.0 Milligram Fortnightly

Batch: Started: 03/07/2000 Stopped:

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Symptom becoming increasing problem following each injection of zuclopenthi- xol. medication may be too great a dose gone from psychotic to depressed. changed to venlafaxine 3/7/00 37.5mg bd.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 155177
 Seq: 1
 Gender: M

 Reported:
 20/07/2000
 Weight:

Hospitalisation: Age: 25

Onset Date: 23/06/2000 **DOB**: 05/11/1974

Outcome: Unknown Causality: Causality possible

Reaction Details:

٠,	todotion Dotanoi			
	Preferred Term	Severity	Report Description	Treatment
	Dystonia			Benztropine 2mg imi 23/6 and again 24/6. melleril ceased
	Tongue oedema		Swollen tongue	

Medicine Details:

DIAZEPAM (Other drug)	Reason:		
ζ,	5.0 Milligram	1 time	
Batch:	Started: 22/06/2000	Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason: Unspecified neurosis	
Injection	50.0 Milligram	1 time Intramuscular	
Batch:	Started: 22/06/2000	Stopped:	
MELLERIL (Suspected)		Reason: Unspecified neurosis	
	300.0 Milligram	Daily	
Batch:	Started: 22/06/2000	Stopped: 24/06/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Only 5 doses of melleril 100mg given in conjunction with zyclopenthixol then ceased, no further dytonic reactions since then.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 155178
 Seq: 1
 Gender: U

 Reported:
 20/07/2000
 Weight:

Hospitalisation: Age: 21

Onset Date: 30/06/2000 **DOB**: 03/06/1979

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Cogentin 2mg imi given 30/6/00.

Medicine Details:

DIAZEPAM (Other drug) Reason: Anxiety neurosis

5.0 Milligram As necessary

Batch: Started: Stopped: CONTIN

ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Unspecified psychosis

Injection 50.0 Milligram 1 time Intravenous

Batch: Started: 29/06/2000 Stopped:

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified psychosis

100.0 Milligram As necessary

Batch: Started: 30/06/2000 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

2nd dose of zuclopenthixol acetate no ill effects. used speed prior to admission to hospital iv and amphetamine use for 1 year.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

i te: 11/09/20 ne: Death	,00				ge: 54 OB: 09/07/1946		
Doan.					lity: Causality possible		
etails:				Gudou	ity: Caacanty possible		
ferred Term	Se	verity	Repo	ort Description	Treatment		
า		F	ound dead at n	ight, no autopsy			
		p€	erformed.				
	L	<u> </u>			1		
N = 4 = '' =							
			Roa	son:			
canor arag,		0.0	ivea	· · · · · · · · · · · · · · · · · · ·			
:	Si	Started: Stopped:					
E MESYLATE (Other drug)	Reason:					
		0.0					
	St	Started: Stopped:					
uspected)		Reason:					
				a			
	Si	tarted:	Poo				
ispectea)		0.0	Rea	son:			
:	St			Stopped:			
				Ctoppour			
		<u> </u>					
Туре	Range	Date Tested	Result		Details		
	: fuspected) : uspected)	Other drug) : Si E MESYLATE (Other drug) : Si uspected) : Si uspected) : Si uspected)	Details: Other drug) 0.0 Started: E MESYLATE (Other drug) 0.0 Started: uspected) 0.0 Started: uspected) 0.0 Started: uspected)	Details: Other drug) Started: E MESYLATE (Other drug) Started: uspected) Started: uspected) Started: uspected) Started: uspected) Read 0.0 Started: uspected) Read 0.0 Started:	Details: Other drug) Started: Started: Stopped: EMESYLATE (Other drug) Started: Started: Stopped: Uspected) Reason: 0.0 Started: Stopped:		

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

	158074	Seq: 1				Gender:	F	
Reported:	25/09/2000					Weight:		
Hospitalisation:						Age:	54	
Onset Date:	11/09/2000						09/07/1946	
Outcome:	Death				С		Causality possible	
Reaction Detai						-	, .	
Medicine Det	ails:							
CLOZARIL (Suspe				Reason:				
Tablet		125.0	Milligram	Daily		Oral		
Batch:		Started: 20			Stopped:	11/09/2000		
EPILIM (Suspected	d)			Reason:				
		1.5	Gram	Daily				
Batch:		Started:			Stopped:			
•								
Laboratory In	vestigations:							
Laboratory In	vestigations:							
Laboratory In	vestigations:							
Laboratory In	vestigations:							
Laboratory In	vestigations:							
Laboratory In	vestigations:							
Laboratory In	vestigations:							
Laboratory In	vestigations:							
Laboratory In								

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 160450
 Seq: 1
 Gender: M

 Reported:
 08/01/2001
 Weight:
 89.00

 Hospitalisation:
 Age: 37Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

toaction Dotailor			
Preferred Term	Severity	Report Description	Treatment
Sexual dysfunction		Decreased intensity and duration of orgasm.	
Semen abnormal		Thinner consistency of ejaculate	

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Other d	rug)	Reason:	Schizophrenia	
	100.0 Milligram	As ne	ecessary	
Batch:	Started: 01/01/1985		Stopped:	
LANSOPRAZOLE (Other drug)		Reason:	Other diseases of es	sophagus
	30.0 Milligram	Daily		
Batch:	Started: 11/03/1998		Stopped:	CONTIN
FERROUS SULPHATE (Other drug)		Reason:	Unspecified anemia	
	300.0 Milligram	Daily		
Batch:	Started: 21/07/1999		Stopped:	CONTIN
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	Schizophrenia	
Injection	200.0 Milligram	Fortn	ightly Intrar	muscular
Batch:	Started: 28/09/2000		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.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

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 ps	sychosis
Injection	100.0 Milligram	1 time		Intramuscular
Batch:	Started: 22/01/2001		Stopped:	22/01/2001
CHLORPROMAZINE HYDROCHLORIDE (S	Suspected)	Reason:		
	100.0 Milligram	Daily		
Batch:	Started: 22/01/2001		Stopped:	23/01/2001
RISPERIDONE (Suspected)		Reason:		
RISPERIDONE (Suspected)	1.0 Milligram	Reason: Daily		
RISPERIDONE (Suspected) Batch:	1.0 Milligram Started: 23/01/2001		Stopped:	24/01/2001
, ,	ŭ		Stopped:	24/01/2001
Batch:	ŭ	Daily	Stopped:	24/01/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Allergic to penicillin. patient recovered 24/01/01.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 161995 Seq: 1 Gender: U
Reported: 26/02/2001 Weight:
Hospitalisation: Age:

Onset Date: 08/11/2000 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Rash on face and torso.	Cogentin. therapy ceased.
Hypertonia			

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Unspecified psychosis

Injection 1.0 Dose Unspecified 1 time Intramuscular

Batch: Started: 06/11/2000 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking bactrim ds, zidavudine, indinavir, ritonavir, abacavir, mo gadon, diazepam, risperidone, panadol.

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Case Number: 168230

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Seq: 1

	: 07/09/200	1	Weight:					
ospitalisation:						Age: 20Y		
Onset Date:	05/06/200	1		DOB:				
Outcome:	Recovered	b			ausality: Causality possible			
action Deta								
	red Term	Se	everity		ort Description	Treatment		
achycardia			5	Slight tachycard	lia			
orthostatic hypo	tension					Ck checked and ecg performed		
ledicine Det		(Other drug)		Rea	ason:			
Batch:		e	0.0 Started:		Stopped:			
LITHIUM CARBON	NATE (Other (tarteu:	Pos	son:			
LITHIUW CARDU	AVIE (Other o	ıı uy <i>)</i>	0.0	Rea	13UII.			
Batch:		s	Started:		Stopped:			
OLANZAPINE (Ot	her drug)			Rea	ison:			
•			0.0					
Batch:		s	started:		Stopped:			
DIAZEPAM (Other	r drug)			Rea	ison:			
			0.0					
Batch:		s	Started:		Stopped:			
aharatan, lu	nvestigat	ions:						
anoraiory !!		Range	Date Tested	d Result		Details		
aboratory Ir	Type	range						

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detail	07/09/2001 05/06/2001 Recovered s:	Seq: 1			Gender: Weight: Age: DOB: Causality:	20Y
Medicine Deta				Danasani		
ALCOHOL (Suspec	tea)	0.0		Reason:		
Batch:		Started:			Stopped:	
	ACETATE (Suspecte			Reason:	эторрец.	
Injection	ACETATE (Suspecte		Milligram	1 time	Intramuscu	lor
Batch:		Started:	wiiiigiaiii	Tunic	Stopped:	
Laboratory Inv	vestigations:					
Additional Info	ormation:					

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 170453
 Seq: 1
 Gender: M

 Reported:
 27/11/2001
 Weight:

Hospitalisation: Age: 70

Onset Date: DOB: 22/05/1931
Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

touotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			Sorbolene cream, steroid cream.

Medicine Details:

CLOPIXOL DEPOT (Suspected) Reason: Unspecified psychosis

 Injection
 200.0
 Milligram
 1 time
 Intravenous

 Batch:
 Started: 10/10/2001
 Stopped: 10/10/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms with first injection of clopixol, and experienced same symptoms with third injection

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 170541 Seq: 1 Gender: M

Reported: 29/11/2001 Weight:

Hospitalisation: Age: 44Y
Onset Date: 19/01/2001
DOB:

Outcome: Unknown Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		Exacerbation of akathisia.	

Medicine Details:

FLUPENTHIXOL DECANOATE (Other drug)			Reason:			
Injection	100.0	Milligram	As no	ecessary	Intramuscular	
Batch:	Started:		L TERM	Stopped:		
OLANZAPINE (Other drug)			Reason:	Unspecified s	chizophrenia	
	20.0	Milligram	Daily	,		
Batch:	Started: 22	/06/1999		Stopped:		CONTIN
RISPERDAL (Other drug)			Reason:			
	4.0	Milligram	Daily	,		
Batch:	Started:			Stopped:		
LITHIUM CARBONATE (Other drug)			Reason:			
	1.5	Gram	Daily	,		
Batch:	Started:			Stopped:		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for zuclopenthixol is not necessarily accurate but indicates the drug was started sometime in the month. 1st reaction reported on 19.1.01 - decreased dose from 200mg 2/52 to 100mg 2/52. 2nd reaction reported on 7.3.01.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detai	29/11/2001 19/01/2001 Unknown	Seq: 1		Gender: Weight: Age: DOB: Causality:	
Medicine Deta	ails:				
	L DECANOATE (Susp	pected)	Reason: Unspe	ecified schizophrenia	
		200.0 Milligram	Daily		
Batch:		Started: 01/01/1999	St	opped: 19/01/2001	
Laboratory In	vestigations:				
Additional Inf The dose start date reaction reported of	e for zuclopenthixol	is not necessarily accurate b ed dose from 200mg 2/52 to	ut indicates the d 100mg 2/52. 2n	rug was started so d reaction reported	ometime in the month. 1st d on 7.3.01.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Re	port	: Det	tails:

Case Number: 170802 Seq: 1 Gender: F

 Reported: 03/12/2001
 Weight: 65.00

 Hospitalisation:
 Age: 25Y

Onset Date: 05/11/2001 DOB:
Outcome: Not yet recovered Causality: Causality certain

Outcome: Not yet recovered Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Injection site reaction			

Medicine Details:

ZYPREXA (Other drug) Reason: Unspecified neurosis

15.0 Milligram Daily

Batch: Started: 14/08/2001 **Stopped:** 30/08/2001

CLOPIXOL (Suspected) Reason:

Injection 100.0 Milligram Daily Intramuscular

Batch: Started: 24/08/2001 Stopped: 05/11/2001

Laboratory Investigations:

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

Additional Information:



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report De	tails:						
	oer: 171204 ted: 03/12/200	Seq: 1		Gender: F Weight: 65.00			
Hospitalisati					Age: 25Y		
	ate: 05/11/200				DOB:		
	me: Not yet re	covered		Cau	sality: Causa	ality probable	
Reaction D							
-	eferred Term	Severity	Report D	Description		Treatment	
Pruritus							
Rash eryther Urticaria	matous						
Medicine			Reason:	Unspecified neuro	osis		
		15.0 N	Milligram Da	ily			
Batc	h:	Started: 14/08	3/2001	Stopped: 30	0/08/2001		
CLOPIXOL (S	Suspected)		Reason:				
Inject	ion	100.0 N	1illigram Da	ily Int	tramuscular		
Batc	h:	Started: 24/08	3/2001	Stopped: 05	5/11/2001		
	y Investigat						
Date	Туре	Range Date Tester	d Result		Details		
Additiona	l Informatio	n:	,				

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 172641
 Seq: 1
 Gender:
 F

 Reported:
 13/02/2002
 Weight:

Hospitalisation: Age: 44

Onset Date: 22/04/2001 **DOB**: 27/12/1956

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delirium			
Leukopenia			
Neutropenia			Quetiapine ceased.

Medicine Details:

PREMIA 5 (Other drug)		Reason: Menopausal symptoms	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ASPIRIN (Other drug)		Reason:	
	600.0 Milligram	Daily	
Batch:	Started:	Stopped:	
LORAZEPAM (Suspected)		Reason:	
	2.5 Milligram	As necessary	
Batch:	Started: 19/04/2001	Stopped:	
SEROQUEL (Suspected)		Reason: Unspecified schizophreni	a
	300.0 Milligram	Daily	
Batch:	Started:	Stopped:	2W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		22/04/2001	2.46	
	Neutrophils		23/04/2001	1.9	
	White blood cells		22/04/2001	4.14	
	White blood cells		23/04/2001	3.27	

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Case Number:	172641	Seq: 1			Ge	nder:	F	
Reported:	13/02/2002				We	ight:		
Hospitalisation:						Age:	44	
Onset Date:	22/04/2001					DOB:	27/12/1956	
Outcome:	Unknown				Caus	ality:	Causality possible	
Reaction Detai	ls:							
Medicine Deta	aile.							
OLANZAPINE (Sus				Reason:				\neg
(33)	,	20.0	Milligram	Daily				
Batch:		Started: 21/0		24,	Stopped:			
	L ACETATE (Suspecte		04/2001	Reason:	оторреа.			
200EOI ENTINA	L AOLIAIL (Ouspect		Milligram	Daily				
Batch:		Started:	wiiiigram	Daily	Stopped: 18/0	14/2001		
	DROCHLORIDE (Susp			Reason:	Stopped: 10/0	J 4 /200 I		_
VEITEAL AXIITE III	DROOFILORIDE (ous		Milligram	Daily				
Batch:		Started:	wiiiigram	Daily	Stopped: 20/0	14/2001		
Batcii.		Starteu.			Stopped: 20/0	J 4 /200 I		
Laboratory In	vestigations:							
•	J							
Additional Inf	ormation:							

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

case Number: 173400 Reported: 06/03/2002				
Reported: 06/03/2002	Seq: 1		Gender:	М
			Weight:	
pitalisation:			Age:	38Y
Onset Date: 01/03/2002			DOB:	
Outcome: Unknown			Causality:	Causality possible
ction Details:				
Preferred Term	Severity	Report Description	ı	Treatment
skinesia		Blinking	L	
edicine Details:				
JCLOPENTHIXOL DIHYDROCH		Reason:		
Batch:	125.0 N Started:	Ailligram Fortnightly Stop		
Doratory Investigatio Date Type	Dns: Range Date Teste	d Result	Detai	lo.



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 175310
 Seq: 1
 Gender: M

 Reported:
 10/05/2002
 Weight:

Hospitalisation: Admitted to hospital **Age**: 20

Onset Date: 12/02/2002 DOB: 07/03/1981

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			
Cough			
Dyspnoea			
Pneumonia	Life threatening		Prologation of hospitalisation.treated with perindopril 8mg. not yet recovered.
Sepsis			
Syncope			

Medicine Details:

Medicine Details.			
OLANZAPINE (Suspected)	_	Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 10/08/2001	Stopped:	05/02/2002
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason: Unspecified s	chizophrenia
Injection	50.0 Milligram	Daily	Intramuscular
Batch:	Started: 27/08/2001	Stopped:	05/02/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		11/02/2002	202	
	Electrocardiograph				Echocardiogram was performed showing global moderate to severe left and right ventricular dysfunction with mild dilatation. from this investigation a diagnosis of cardiomyopathy was made.
	Electrocardiograph				Chest x ray showed bronchopneumonia - 12/02/02
	Other data				Echocardiogram / I & r ventricular dysfunction & mild dilatation.

Additional Information:

Marajuana and amphetamine abuse.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 175310
 Seq: 1
 Gender: M

 Reported:
 10/05/2002
 Weight:

Hospitalisation: Admitted to hospital Age: 20

Onset Date: 12/02/2002 **DOB**: 07/03/1981

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

 OLANZAPINE (Suspected)
 Reason:

 Tablet
 15.0 Milligram
 Daily
 Oral

 Batch:
 Started: 10/08/2001
 Stopped: 05/02/2002

 ZUCLOPENTHIXOL ACETATE (Suspected)
 Reason: Unspecified schizophrenia

Injection 50.0 Milligram Daily Intramuscular

Batch: Started: 27/08/2001 Stopped: 05/02/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Radiololgy				X ray, bronchopneumonia
	SAP = ALP		11/02/2002	115	

Additional Information:

Marajuana and amphetamine abuse.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Reported: 29/05/2 ospitalisation: Onset Date: Outcome: Not ye eaction Details: Preferred Term Dyskinesia Medicine Details: BRICANYL (Other drug) Inhalation Batch: AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N	et recovered	Started:		ort Description son: Asthma As necessary	Causality	
Onset Date: Outcome: Not ye eaction Details: Preferred Term Oyskinesia Medicine Details: BRICANYL (Other drug) Inhalation Batch: AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N	m I	2.0 (Started:	Rea	s on : Asthma	DOB Causality	: 04/04/1972 : Causality possible
Outcome: Not ye eaction Details: Preferred Term Dyskinesia Medicine Details: BRICANYL (Other drug) Inhalation Batch: AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N	m I	2.0 (Started:	Rea	s on : Asthma	Causality	: Causality possible
Preferred Term Pyskinesia Pledicine Details: BRICANYL (Other drug) Inhalation Batch: AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N	m I	2.0 (Started:	Rea	s on : Asthma		
Preferred Term yskinesia ledicine Details: BRICANYL (Other drug) Inhalation Batch: AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N		2.0 (Started:	Rea	s on : Asthma	n l	Treatment
Medicine Details: BRICANYL (Other drug) Inhalation Batch: AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N		2.0 (Started:	Rea	s on : Asthma	n	Treatment
ledicine Details: BRICANYL (Other drug) Inhalation Batch: AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N		Started:				
BRICANYL (Other drug) Inhalation Batch: AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N		Started:				
BRICANYL (Other drug) Inhalation Batch: AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N		Started:				
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BRICANYL (Other drug) Inhalation Batch: AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N		Started:				
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BRICANYL (Other drug) Inhalation Batch: AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N		Started:				
BRICANYL (Other drug) Inhalation Batch: AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N		Started:				
BRICANYL (Other drug) Inhalation Batch: AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N		Started:				
BRICANYL (Other drug) Inhalation Batch: AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N		Started:				
BRICANYL (Other drug) Inhalation Batch: AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N		Started:				
Inhalation Batch: AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N		Started:				
Batch: AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N		Started:	Dose Unspecified	As necessary		
AMLODIPINE (Other drug) Batch: SERETIDE ACCUHALER N					Inhalation	1
Batch: SERETIDE ACCUHALER N		2.5		Stop	ped:	CONTIN
SERETIDE ACCUHALER N	NOS (Other drug	2.5	Rea	son: Essentia	al benign hyperte	nsion
SERETIDE ACCUHALER N	NOS (Other drug		Milligram	Daily		
	NOS (Other drug	Started:		Stop	ped:	CONTIN
L. L L - P				son: Asthma		
Inhalation		4.0	Dose Unspecified	Daily	Inhalation	1
Batch:		Started:		Stop	ped:	CONTIN
CLOPIXOL (Suspected)				son:		
		300.0	Milligram	Fortnightly		
Batch:		Started:		Stop	ped:	CONTIN
aboratory Investig	igations:					
Date Type		e Date Teste	ed Result		Deta	ails
	Range					

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TG \ THERAPEUTIC GOODS ADMINISTRATION

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:				
Case Number: 175725 Reported: 29/05/2002 Hospitalisation: Onset Date: Outcome: Not yet recovered Reaction Details:	Seq: 1			
Medicine Details: OLANZAPINE (Suspected)		Reason:	Schizophrenia	
(7.5 Milligrar			
Batch:	Started:		Stopped:	CONTIN
Laboratory Investigations:				
Additional Information:				

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 177194
 Seq: 1
 Gender: M

 Reported:
 15/07/2002
 Weight:

Hospitalisation: Admitted to hospital **Age**: 17

Onset Date: 30/03/2002 **DOB**: 30/12/1984

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating			Date of recovery 31.3.02. patient was hospitalised. all medications withheld.

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
	100.0 Milligram	1 time	
Batch:	Started: 29/03/2002		Stopped:
MIDAZOLAM (Suspected)		Reason:	
	5.0 Milligram	1 time	
Batch:	Started: 29/03/2002		Stopped:
CHLORPROMAZINE HYDROCHLORIDE (S	uspected)	Reason:	
CHLORPROMAZINE HYDROCHLORIDE (S	uspected) 200.0 Milligram	Reason: 1 time	
CHLORPROMAZINE HYDROCHLORIDE (S Batch:	•		Stopped:
,	200.0 Milligram		Stopped:
Batch:	200.0 Milligram	1 time	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

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$\mathbf{\nu}$	Δn	\sim 1	**	ם ו	taı	ls:
1	CN	vi	L	UG	Lai	13.

Case Number: 177472 Seq: 1 Gender: M

Reported: 26/07/2002 **Weight:** 60.00

Hospitalisation: Age:
Onset Date: 08/06/2002
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Г	teaction Details.				
	Preferred Term	Severity	Report Description	Treatment	
	Hypertonia		Muscle spasm ans neck spasm.		
	Dystonia			Required a visit to doctor. iv benztropine.	

Medicine Details:

CLOPIXOL (Suspected) Reason: Schizophrenia

Injection 100.0 Milligram Daily Intramuscular

Batch: Started: 04/06/2002 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

 Case Number:
 178047
 Seq: 1
 Gender:
 F

 Reported:
 13/08/2002
 Weight:

Hospitalisation:
Onset Date: 06/08/2002
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment	
Hypotension			Stabalisation and monitoring.	

Medicine Details:

DROPERIDOL (Other drug)		Reason: Unspeci	fied psychosis	
Injection	10.0 Milligram	1 time	Intramuscular	
Batch:	Started: 04/06/2002	Stop	pped:	
CLONAZEPAM (Other drug)		Reason: Unspeci	fied psychosis	
Injection	2.0 Milligram	1 time	Intramuscular	
Batch:	Started: 04/08/2002	Stop	pped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason: Unspeci	fied psychosis	
Injection	75.0 Milligram	1 time	Intramuscular	
Batch:	Started: 05/08/2002	Stop	pped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Re	po	rt	De	tai	ls:
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Case Number: 180538 Seq: 1 Gender: M

Reported: 13/11/2002 Weight: 65.00 Hospitalisation: Age: 21

Onset Date: 11/10/2002 DOB: 15/11/1980

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			Bed rest.

Medicine Details:

ZYPREXA (Other drug) Reason: Unspecified psychosis

15.0 Milligram Daily

Batch: Started: 03/10/2002 Stopped:

ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Unspecified psychosis

Injection 75.0 Milligram 1 time Intramuscular

Batch: Started: 11/10/2002 Stopped:

COGENTIN (Suspected) Reason: Prophylaxis

Tablet 2.0 Milligram Daily Oral

Batch: Started: 11/10/2002 **Stopped:** 15/10/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 181730 Seq: 1 Gender: F
Reported: 16/01/2003 Weight: 3.90
Hospitalisation: Age: 28D
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebral haemorrhage neonatal		Acute haemorrhage in left basal ganglia of brain.	
Infantile apnoeic attack	Required Visit to Doctor	ventilation for 1st p days of life.	Phenobarbitone for seizures; ventilation; hyperbilirubinaemia requiring phototherapy
Congenital foot malformation		Baby dysmorphic - long, thin digits and overlapping 4th toes.	
Hyperbilirubinaemia		Conjugated hyperbilirubinaemia	
Weight decrease neonatal		Feed intolerance (weight dropped by 10% until day 20)	

Medicine Details:

Medicine Details.			
CLOZARIL (Suspected)		Reason: Unspecified psychosis	
Tablet		Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	
ZUCLOPENTHIXOL DECANOATE	(Suspected)	Reason: Unspecified psychosis	
Injection		Intramuscular	
Batch:	Started:	Stopped:	
EPILIM (Suspected)		Reason:	
Tablet	1.2 Gram	Daily Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
16/01/2003	Electroencephalog				EEG - seizure from right temporal region.
16/01/2003	Other data				Acute haemorrhage determined by cerebral ultrasound and MRI scan

Additional Information:

Epilim 1200mg started in 1991 (first trimester of pregnancy), then 1500mg/day (at 20 weeks gestation age) and continues. Clozaril, zyprexa and zuclopenthixol started in 1991.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Re	po	rt	De	tai	ls:
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Case Number: 181730 Seq: 1 Gender: F
Reported: 16/01/2003 Weight: 3.90
Hospitalisation: Age: 28D
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botano:						
Preferred Term Seve		Report Description	Treatment			
Hepatosplenomegaly neonatal		Liver distrubances and hepato-splenomegaly.				
Convulsion		Seizures from day 8 onwards				
Hyperammonaemia		Transient hyperammonemia.				
Vomiting		Vomiting				
Hypoxia						

Medicine Details:

Modifilo Botalio.				
CLOZARIL (Suspected)		Reason: Unspe	ecified psychosis	
Tablet			Oral	
Batch:	Started:	St	opped:	
ZYPREXA (Suspected)		Reason:		
Batch:	Started:	St	opped:	
ZUCLOPENTHIXOL DECANOATE	(Suspected)	Reason: Unspe	ecified psychosis	
Injection			Intramuscular	
Batch:	Started:	St	opped:	
EPILIM (Suspected)		Reason:		
Tablet	1.2 Gram	Daily	Oral	
Batch:	Started:	St	opped:	

Laboratory Investigations:

Additional Information:

Epilim 1200mg started in 1991 (first trimester of pregnancy), then 1500mg/day (at 20 weeks gestation age) and continues. Clozaril, zyprexa and zuclopenthixol started in 1991.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:	Re	po	rt	De	tai	ls:
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Case Number: 183028 Seq: 1 Gender: M

 Reported: 18/02/2003
 Weight: 0.00

 Hospitalisation:
 Age: 54Y

 Onset Date: 01/11/2002
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia			Ceased Epilim and restarted Lithium.

Medicine Details:

Medicine Details.				
ZUCLOPENTHIXOL DECANOATE (S	uspected)	Reason:		
Injection	200.0 Milligram	Fortnightly	Intramuscular	
Batch:	Started:	Stoppe	d:	Contin
EPILIM (Suspected)		Reason:		
Tablet	1.0 Gram	Daily	Oral	
Batch:	Started: 06/11/2002	Stoppe	d : 12/11/2002	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Case Number: 190202

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Seq: 1

Reported: 04/09/2003	Weight: 0.00				
lospitalisation:	Age : 41				
Onset Date:			_	DB : 31/03/1962	
Outcome: Not yet recovered	d		Causali	ty: Causality possible	
eaction Details:					
Preferred Term	Severity	Report D	escription	Treatment	
Diabetes mellitus		Diabetes		Protophane insulin, Diamicr Ventolin, wt loss 15kg	
Arthritis Asthma					
Medicine Details:					
CLOPIXOL (Suspected)		Reason:	Unspecified psychosis		
	50.0	Milligram Dai			
Batch:	Started:		Stopped:		
<u> Laboratory Investigations:</u>					
Date Type Ran	ge Date Test	ed Result	D	etails	
	L				
Additional Information:					
port Run: 01/06/2007 04:28PM Datal	base: pusime02	ADRS	004	Page 86 of 152	



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 190624
 Seq: 1
 Gender:
 M

 Reported:
 18/09/2003
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 33
Onset Date: 14/09/2003
DOB: 02/08/1970

Outcome: Recovered 15/09/2003 Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Hypotension	Caused or prolonged inpatient hospitalisation	BP 104/63.	
Cyanosis		, ,	Oxygen given, Vital observations, clopixol withheld till 1709/03.

Medicine Details:

Medicine Details.		
CLOPIXOL-ACUPHASE (Suspected)		Reason: Unspecified psychosis
	150.0 Milligram	1 time
Batch:	Started: 14/09/2003	Stopped: 14/09/2003
CLOPIXOL (Suspected)		Reason: Unspecified psychosis
Tablet	20.0 Milligram	Daily Oral
Batch:	Started: 08/09/2003	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Lithium, Epilim, Diazepam.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 190854 Seq: 1 Gender: M

Reported: 24/09/2003 Weight: 81.00 Hospitalisation: Age: 28

Onset Date: 26/08/2003 **DOB**: 13/06/1975

Outcome: Unknown 26/08/2003 Causality: Causality certain

Reaction Details:

towotion bottom					
	Preferred Term	Severity	Report Description	Treatment	
		Required Visit to Doctor	Cellulitis		
	Injection site reaction				

Medicine Details:

ZUCLOPENTHIXOL DECANOATE (Suspected) Reason: Unspecified psychosis

Injection 300.0 Milligram Fortnightly Intramuscular

Batch: Started: 09/07/2003 Stopped: 26/08/2003

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Gluteal region following IMI depot Zuclopenthiacol deconate 300mg IMI 2/52 on 26/8/2003. Other drugs used: Amisulpride and Lamatrongine.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 191386
 Seq: 1
 Gender:
 F

 Reported:
 17/10/2003
 Weight:
 61.00

Hospitalisation: Age: 99U

Onset Date: DOB:

Outcome: Recovered 03/10/2003 Causality: Causality possible

Reaction Details:

10	action Details.			
	Preferred Term	Severity	Report Description	Treatment
Fe	eeling abnormal	to Doctor	After first dose of zuclopenthixol, patient "felt wierd" and became increasingly agitated.	
Αį	gitation	Required Visit to Doctor		

Medicine Details:

RISPERIDONE (Other drug) Reason: Schizophrenia

3.0 Milligram Daily

Batch: Started: 15/07/2003 Stopped: 28/09/2003

ZUCLOPENTHIXOL DIHYDROCHLORIDE (Suspected) Reason: Schizophrenia

10.0 Milligram Daily

Batch: Started: 29/09/2003 Stopped: 01/10/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Suspect drug was given with a view to depot injections later.

HEPC + pain IVI drugs. Is said to have became aggressive when treated with Interferon and Rebetol - stopped in July 2003.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 193034
 Seq: 1
 Gender:
 M

 Reported:
 10/12/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 34

Onset Date: 29/08/2003 DOB: 17/06/1969

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

rtoaction Botaile.			
Preferred Term	Severity	Report Description	Treatment
Factor VIII inhibition			Amisulpride, Cyclophosphamide, Prednisolone, Tranexamic. Clopixol ceased.
Coagulopathy Haematoma			

Medicine Details:

CLOPIXOL (Suspected)				
Injection	250.0	Milligram Dail	y Intramuscular	
Batch:	Started:	L TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Activated partial				
	Fibrinogen				
	International				
	Other data				

Additional Information:

History of excessive bleeding and acquired factor VIII inhibitor.



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Re	po	rt	De	tai	ls:
	\sim		-	u	

Case Number: 195086 Seq: 1 Gender: M

Reported: 27/02/2004 Weight: 0.00 Hospitalisation: Age: 64Y

Onset Date: 22/12/2003 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site abscess		Injection site abscesses - bilat buttocks.	

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Suspected) Reason:

Dose Unspecified

Batch: Started: S TERM Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 197479
 Seq: 1
 Gender:
 F

 Reported:
 20/05/2004
 Weight:
 0.00

 Hospitalisation:
 Age:
 99u

Onset Date: 15/01/2003 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arthritis		Arthritis, ataxia, urinary incontinence and weight increase.	Nil.
Back pain			
Coordination abnormal			
Feeling abnormal			
Gait disturbance			
Musculoskeletal stiffness			
Myalgia			
Sexual dysfunction			
Urinary incontinence			
Weight increased			

Medicine Details:

CLOPIXOL (Suspected) Reason:

Injection 50.0 Milligram Cyclical Intramuscular

Batch: Started: 15/12/2002 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Valium and Zyprexa.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 198280 Seq: 1 Gender: M

Reported: 18/06/2004 Weight: 0.00 Hospitalisation: Age: 32

Onset Date: 20/01/2004 **DOB**: 02/03/1971

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

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

Medicine Details:

Medicine Details.					
CLOPIXOL-ACUPHASE (Suspected)		Re	eason: L	Inspecified psychosis	
Injection	1.0	Dose Unspecifie	d 1 time	Intramuscular	
Batch:	Started:			Stopped:	
CLONAZEPAM (Suspected)		R	eason:		
Injection	6.0	Milligram	Total	Intramuscular	
Batch:	Started:			Stopped:	
RISPERIDONE (Suspected)		Re	eason:		
	3.0	Milligram	Daily		
Batch:	Started:			Stopped:	

Laboratory Investigations:

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

Additional Information:

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

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 198346 Seq: 1 Gender: F

Reported: 21/06/2004 Weight: 86.00 Hospitalisation: Admitted to hospital Age: 39

Onset Date: 01/07/2002 **DOB**: 17/02/1963

Outcome: Recovered 15/12/2002 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Laryngospasm	hospitalisation	Laryngeal spasm with airway loss - unable to breathe, feeling of 'closed head injury', difficulty in forming words and gait disturbances, disturbance in neurological innervation of muscle structure used in speech and breathing.	Cogentin injection. Clopixol ceased.
Dyspnoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPIXOL-ACUPHASE (Suspected) Reason: Anxiety neurosis

1.0 Dose Unspecified 1 time

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient is currently managed on Risperidal 2mg daily.

Report Run: 01/06/2007 04:29PM Database: pusime02 ADRS004 Page 94 of 152



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

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

Case Number: 198346 Seq: 1 Gender: F

Reported: 21/06/2004 Weight: 86.00 Hospitalisation: Admitted to hospital Age: 39

Onset Date: 01/07/2002 **DOB**: 17/02/1963

Outcome: Recovered 15/12/2002 Causality: Causality possible

Reaction Details:

<u>leaction betails.</u>			
Preferred Term	Severity	Report Description	Treatment
Gait disturbance	Caused or prolonged inpatient hospitalisation		
Speech disorder	Caused or prolonged inpatient hospitalisation		

	-			-	_			
N	П	ച	10	ını	e D	ומו	וכי	ıe.
IV	ш	σu	ı	111	5 L	, 51	laı	ıə.

CLOPIXOL-ACUPHASE (Suspected) Reason: Anxiety neurosis

1.0 Dose Unspecified 1 time

Batch: Started: Stopped:

Laboratory Investigations:

Additional Information:

Patient is currently managed on Risperidal 2mg daily.

Report Run: 01/06/2007 04:29PM Database: pusime02 ADRS004 Page 95 of 152



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number:199540Seq: 1Gender: MReported:30/07/2004Weight: 0.00Hospitalisation:Admitted to hospitalAge: 40Y

Onset Date: 08/04/2004 **DOB:**

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Neuroleptic malignant syndrome suspected. Confused mental state, alert but disoriented. Found in collapsed state at home.	
Blood creatine phosphokinase incr			
Circulatory collapse			
Confusional state			
Disorientation			

Medicine Details:

ZUCLOPENTHIXOL DECANOATE (Suspected) Reason:

Injection 100.0 Milligram

Batch: Started: 18/03/2004 Stopped: 01/04/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

zuclopenthixol decanoate 100mg then 50mg on 26/3/04, 50mg on 23/04/04 and 200mg per fortnight on 01/04/2004

Report Run: 01/06/2007 04:29PM Database: pusime02 ADRS004 Page 96 of 152



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 201308 Seq: 1 Gender: F

Reported: 27/09/2004 Weight: 0.00 Hospitalisation: Age: 23

Onset Date: 15/08/2004 **DOB**: 08/12/1980

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Tachycardia up to 125 bpm-lasted for approximately 1 month.	Required a visit by doctor. Treated with Atenolol 50mg total till stopped currently on 25mg/daily.

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	Manic-depression psycho,m	anic
Tablet	1.0 Gram	Daily	Oral	
Batch:	Started:		Stopped:	Continuing
CLOPIXOL DEPOT (Suspected)		Reason:	Unspecified schizophrenia	
Injection				
Batch:	Started:		Stopped: 31/07/2004	
CLOPINE (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily	Oral	
Batch:	Started: 02/07/2004		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Recovery date: 09/2004

Report Run: 01/06/2007 04:29PM Database: pusime02 ADRS004 Page 97 of 152



Case Number: 201638

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Seq: 1

y possible eatment ceased.
eatment
eatment
ceased.

Report Run: 01/06/2007 04:29PM Database: pusime02 ADRS004 Page 98 of 152



Case Number: 202698

Reported: 18/11/2004

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Weight: 0.00

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Seq: 1

spitalisation: Admitted to ho	spital	Ą	ge: 20		
Onset Date:		DB : 23/12/1983			
Outcome: Unknown			Causal	ity: Causality possible	
ection Details:		Ī		1	
Preferred Term	Severity		ort Description	Treatment	
omicidal ideation	Caused or prolonged inpatient hospitalisation	Attempted homic	cide with a bread knife.		
edicine Details:					
UCLOPENTHIXOL ACETATE (Susp	ected)	Rea	son:		
Injection					
Batch:	Started:		Stopped:		
LCOHOL (Suspected)		Rea	son:		
Oral Liquid			Oral		
Batch:	Started:		Stopped:		
RISPERIDONE (Suspected)			son:		
		Milligram	Daily		
Batch:	Started:		Stopped:		
aboratory Investigations Date Type R	Sange Date Test	ed Result	С	Details	
dditional Information:					
ort Run: 01/06/2007	atabase: pusime02		ADRS004	Page 99 of 1	



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Repo ospitalisat Onset I	Date:	Seq: 1		DOE	: 0.00 : 99U 3:
	me: Unknown			Causality	: Causality possible
eaction D	eferred Term	Severity	Reno	rt Description	Treatment
Homicidal id			Homicidal ideatio		rreatment
Medicine zuclopen [*]	THIXOL ACETATE (Suspected)	Reas	on:	
Bat		Started:		Stopped:	
	ry Investigati				
Date	Туре	Range Date Teste	d Result	Det	ails
Additiona Poor complia	al Information	ı:			
port Run: 01	/06/2007 04:29PM	Database: pusime02	Al	DRS004	Page 100 of 152



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Detail	ls:								
ospitalisation: Onset Date: Outcome:	18/11/2004 Unknown	Sec	j : 1				С	Gender: Weight: Age: DOB: ausality:	0.00 99U
eaction Deta	red Term		Severity	<u> </u>	Pana	rt Desc	ription		Treatment
Suicidal ideation			eventy	Suicidal i			лрион		Пеаннени
Medicine Det		Suspected)			Reas				
Injection				Milligram		Daily	Ctonnod		
Batch: ZOLOFT (Suspect	tod)		Started:		Reas	on:	Stopped:		
Tablet	leu)		100.0	Milligram	Neas	Daily		Oral	
Batch:			Started:	wiiiigiaiii		Daily	Stopped:	Oldi	
ZYPREXA (Suspe	cted)				Reas	on:			
Batch:			9.0 Started:	Milligram		Daily	Stopped:		
_aboratory Ir	<u>ıvestigatio</u>	ons:							
Laboratory Ir	nvestigatio	O ns: Range	Date Test	ed Re	esult			Detail	s

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

202735	Seq: 1		Gende	er: U
18/11/2004			Weigh	nt: 0.00
			Ag	e : 28
			DO	B : 19/09/1976
Unknown			Causali	ty: Causality possible
ils:				
ed Term	Severity	Rep	ort Description	Treatment
		Suicidal ideatior violence.	n, suicide attempt and	
ails:				
		Rea	son:	
,			Oral	
	Started:			
snected)		Ros		
spected)		Nea	son:	
	Started:		Stopped:	
L ACETATE (Sus				
	pected)		Stopped:	
			Stopped:	
L ACETATE (Sus	pected) Started:	Rea	Stopped: son: Stopped:	etails
L ACETATE (Sus	Started:	Rea	Stopped: son: Stopped:	etails
	18/11/2004 Unknown ils: ed Term	Unknown ils: ed Term Severity ails: cted) Started:	Unknown ils: ed Term Severity Report Suicidal ideation violence. ails: cted) Rea	Unknown Unknown Severity Report Description Suicidal ideation, suicide attempt and violence. ails: cted) Reason: Oral Started: Stopped:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Repor Hospitalisati Onset D	ate: ne: Unknowr		1		C		0.00
	ferred Term	Sev	erity	Repo	ort Description		Treatment
Aggression				tient became			
Medicine	Details:						
OLANZAPINE				Reas	son:		
Batc			arted:		Stopped:		
	HIXOL ACETATE	(Suspected)		Reas	son:		
Inject							
Batc	1:	Sta	arted:		Stopped:		
Laborator Date	y Investiga Type		Date Tested	Result		Detai	ls
Additiona	Informatio	on:					

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Hospitalisati Onset Da Outcor	ate: ne: Unknown		1				0.00
Reaction De	etails: eferred Term	Say	verity	Pan	ort Description		Treatment
Aggression	neneu renn	361		tient prone to	-		Пеаннен
Medicine I							
OLANZAPINE	(Suspected)			Reas	son:		
Detail		04.			04	.d.	
ZUCI OPENTI	1: HIXOL ACETATE		arted:	Rea	Stoppe	90:	
Injecti		(Guspecteu)		i tou			
Batcl		Sta	arted:		Stoppe	ed:	
Laborator	y Investigat	ions:					
Date	Туре		Date Tested	Result		Detai	s
Additiona	Informatio	n:					

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Weight: 0.00 Age: 27 DOB: 02/05/1977 Causality: Causality possible Scription Treatment d suicidal ideation.
DOB: 02/05/1977 Causality: Causality possible escription Treatment
Causality: Causality possible scription Treatment
scription Treatment
d suicidal ideation.
Stopped:
Oral
Stopped:
Details



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Reported: 1	02780	Seq: 1		Gende	er: U
	8/11/2004			Weigh	t: 0.00
ospitalisation:				_	e: 24
Onset Date:					B : 08/10/1980
Outcome: U				Causalit	y: Causality possible
eaction Details					
Preferred	Term	Severity		t Description	Treatment
Aggression		F	Patient became a	busive.	
Medicine Detai	İS: OCHLORIDE (Suspec	eted)	Reas	on:	
Tablet				Oral	
Batch: OLANZAPINE (Susp		Started:	Reas	Stopped:	
Batch:		Started:		Stopped:	
	ACETATE (Suspected	d)	Reas	on:	
Injection		Ctouto di		Otamanda	
Batch:		Started:		Stopped:	
_aboratory Inv Date T	estigations: ype Range	Date Tested	d Result	De	tails

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Hospitalisati Onset Da Outcor	ed: 18/11/200 on: ate: ne: Unknown		1	er: U nt: 0.00 ge: 99U DB: ty: Causality possible		
Reaction D		Cov	a with a	Done	unt Decemination	Tractment
Aggression	ferred Term	Sev	erity	ient became	ort Description	Treatment
Medicine I	Details:					
OLANZAPINE	(Suspected)			Rea	son:	
Batcl			rted:		Stopped:	
VENLAFAXIN	E HYDROCHLOR	RIDE (Suspected)		Rea	son:	
Batcl			rted:		Stopped:	
	IIXOL ACETATE	(Suspected)		Rea	son:	
Injecti		-				
Batcl	1:	Sta	rted:		Stopped:	
Laborator Date	/ Investigat Type		Date Tested	Result	D	etails
Additional	Informatio	n:				

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Hospitalisati Onset D	ate: ne: Unknown			Gender: Weight: Age: DOB: Causality:	0.00 99U
	ferred Term	Severity		ort Description	Treatment
Suicidal idea	tion		Suicidal ideation	l.	
Medicine	Details:				
RISPERDAL (Rea	son:	
Batc	1:	Started:		Stopped:	
ZUCLOPENT	IIXOL ACETATE	(Suspected)	Rea	son:	
Inject	on				
Batc	1:	Started:		Stopped:	
	y Investiga				
Date	Туре	Range Date Te	sted Result	Deta	ls
Additiona	Informatio	on:	1		

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

case Number. 202790	Seq. 1		Gende	
Reported: 18/11/2004			Weight	
spitalisation:				e: 99U
Onset Date:			DO	
Outcome: Unknown			Causality	: Causality possible
action Details:				
Preferred Term	Severity	Report Descrip	otion	Treatment
gression	Pat	ent became violent.		
edicine Details:	uspected)	Reason:		
Injection Batch:	Started:		Stopped:	
aboratory Investigation Date Type	Pns: Range Date Tested	Result	Dei	rails
Date Type	range Bate rested	resuit		idiio
additional Information:				

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Reporte		_		Gend	
	ed: 18/11/200	04			nt: 0.00
spitalisatio				_	e : 99U
Onset Da				DC	
	e: Unknown	l		Causali	ty: Causality possible
action De		T -			
	erred Term	Severity		ort Description	Treatment
kathisia			Patient develop suicide attempt.	ed akathisia and had a	
Suicide attem	nt		Saloido dilompi		
ledicine D	etails: IXOL ACETATE	(Suspected)	Rea	ason:	
Injectio	n				
Batch		Started:		Stopped:	
OLANZAPINE ((Suspected)		Rea	ason:	
Batch:	<u>: </u>	Started:		Stopped:	
LUVOX (Suspe		Started:	Rea	Stopped:	
		Started:	Rea		
LUVOX (Suspe	ected)	Started:	Rea	ason:	
LUVOX (Suspe Tablet Batch:	ected)	Started:		oral Stopped:	etails
LUVOX (Suspe Tablet Batch:	r Investiga	Started:		oral Stopped:	etails

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

			Gende	
			Weight	: 0.00
			Age	: 99U
			DOE	3:
			Causality	: Causality possible
Severity		Report Desc	ription	Treatment
	Suicidal ide	eation and sui	cide attempt.	
		Reason:		
			Oral	
Started:			Stopped:	
		Reason:		
	Milligram	Daily		
Started:			Stopped:	
	Milligram	Daily		
Started:			Stopped:	
Started: Date Test	ted Res	ult	Stopped:	ails
	Started: 15.0 Started: 200.0 Started:	Started: 15.0 Milligram Started: 200.0 Milligram Started:	Reason: Started: Reason: 15.0 Milligram Daily Started: Reason: 200.0 Milligram Daily Started:	Reason: Oral Started: Stopped: Reason: 15.0 Milligram Daily Started: Stopped: Reason: 200.0 Milligram Daily Started: Stopped: Reason: Stopped: Reason: Stopped: Reason: Stopped: Reason: Stopped:

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Case Number: 202843

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Seq: 1

Repor	ted: 19/11/200)4			Weig	ht: 0.00
Hospitalisati					_	ge: 99U
Onset D	ate:				DO	OB:
Outco	me: Unknown				Causal	ity: Causality possible
Reaction D		8				,
-	eferred Term	Se	verity		ort Description	Treatment
Homicidal id	eation		Ho sui	micidal ideation	on, violent, akathisia and	
Aggression						
Akathisia						
Suicidal idea	ition					
Medicine EFEXOR (Sur				Rea	son: Oral	
Poto	h.	C4	ortod:			
Batc ZUCL OPENT	n: HIXOL ACETATE		arted:	Rea	Stopped:	
Inject		(Juspecteu)		Rea	5UII.	
Batc		St	arted:		Stopped:	
Lahorator	v Invocticat	ione:				
Date	y Investigat Type	Range	Date Tested	Result	Γ	Details
	76.5	J				
Additiona	l Informatio	n:				
Poport Pun - 04"	06/2007 04·20DN	A Database: 200	simo02		DDS004	Dama 110 of 150

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details: Case Number: 2042							
Case Number: 2042							
	90 Sec	ן: 1			(Gender:	M
Reported: 14/01	1/2005				1	Weight:	0.00
ospitalisation: Admi	tted to hospital					Age:	41
Onset Date: 26/12	2/2004					DOB:	26/07/1963
Outcome: Deat	h		26/12/2004		Ca	usality:	Causality possible
eaction Details:							
Preferred Ter	m S	Severity	Repo	ort Descrip	otion		Treatment
Sedation			Patient was seda injection and exp injection.	ated after A pired after 1	Acuphase 18 hours o	of the	
Death							
ledicine Details:							
	Other drug)		Rea	son:			
	Other drug)	1.0		son:		Oral	
LITHIUM CARBONATE (C		1.0 (Started: 17/1	Gram		Stopped:	Oral	
LITHIUM CARBONATE (C Tablet Batch:			Gram 2/2004			Oral	
LITHIUM CARBONATE (C Tablet Batch:		Started: 17/1	Gram 2/2004			Oral	
LITHIUM CARBONATE (C Tablet Batch:		Started: 17/1	Gram 2/2004 Rea	son:		Oral	
LITHIUM CARBONATE (C Tablet Batch: THIAMINE (Other drug) Batch:		Started: 17/1 100.0	Gram 2/2004 Reas Milligram	son:	Stopped:	Oral	
Tablet Batch: THIAMINE (Other drug) Batch: Batch:	TE (Other drug)	Started: 17/1 100.0 Started: 2.0	Gram 2/2004 Reas Milligram	son:	Stopped:	Oral	
LITHIUM CARBONATE (C Tablet Batch: THIAMINE (Other drug) Batch: BENZTROPINE MESYLA	TE (Other drug)	Started: 17/1 100.0	Gram 2/2004 Reas Milligram Reas	son:	Stopped:	Oral	
LITHIUM CARBONATE (C Tablet Batch: THIAMINE (Other drug) Batch: BENZTROPINE MESYLA	TE (Other drug)	Started: 17/1 100.0 Started: 2.0 Started:	Gram 2/2004 Reas Milligram Reas Milligram	son:	Stopped:	Oral	
Tablet Batch: THIAMINE (Other drug) Batch: BENZTROPINE MESYLA Batch: CLONAZEPAM (Other drug)	TE (Other drug)	Started: 17/1 100.0 Started: 2.0 Started: 4.0	Gram 2/2004 Reas Milligram Reas	son:	Stopped:	Oral	
LITHIUM CARBONATE (C Tablet Batch: THIAMINE (Other drug) Batch: BENZTROPINE MESYLA	TE (Other drug)	Started: 17/1 100.0 Started: 2.0 Started:	Gram 2/2004 Reas Milligram Reas Milligram	son:	Stopped:	Oral	
Tablet Batch: THIAMINE (Other drug) Batch: BENZTROPINE MESYLAT Batch: CLONAZEPAM (Other drug)	TE (Other drug)	Started: 17/1 100.0 Started: 2.0 Started: 4.0	Gram 2/2004 Reas Milligram Reas Milligram	son:	Stopped:	Oral	
Batch: THIAMINE (Other drug) Batch: BENZTROPINE MESYLA Batch: CLONAZEPAM (Other drug)	TE (Other drug)	Started: 17/1 100.0 Started: 2.0 Started: 4.0	Gram 2/2004 Reas Milligram Reas Milligram Reas	son:	Stopped:	Oral Detai	ils

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Case Number: 204290

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Seq: 1

Hospitalisation: /	14/01/2005					Weight:	0.00
	Admitted to hospital					Age:	41
Onset Date: 2	26/12/2004					DOB:	26/07/1963
Outcome: [Death		26/12/2	2004	С	ausality:	Causality possible
Reaction Details	s:						
Medicine Deta	ils:						
RISPERIDONE (Other				Reason:			
		2.0	Milligram				
Batch:		Started:			Stopped:		
CLOPIXOL-ACUPHA	ASE (Suspected)			Reason:			
Injection		100.0	Milligram	3 times		Intramuscu	lar
Batch:		Started: 19	/12/2004		Stopped:	25/12/2004	
Laboratory Inv	vestigations:						
Laboratory Inv	vestigations:						
Laboratory Inv	vestigations:						
Laboratory Inv	vestigations:						
Laboratory Inv	vestigations:						
Laboratory Inv	vestigations:						
Laboratory Inv	vestigations:						
Laboratory Inv	vestigations:						
Laboratory Inv							

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Repor	ber: 205667 ted: 01/03/2005	Seq:					Gender: Weight:	
spitalisat							Age:	
Onset D							DOB:	
	me: Not yet red	covered				Ca	usality:	Causality certain
action D		<u> </u>	ı				<u> </u>	
	eferred Term	Se	everity		ort Descrip	tion		Treatment
atigue			Vei	ry tired.				
				Rea	son:			
	er drug)	s	Started:	Rea		topped:		
Medicine ARIMA (Other Bate VALPRO (Ot	er drug) :h:	s	started:			topped:		
ARIMA (Othe Bate	er drug) eh: her drug)		started: started:		son:	topped:		
ARIMA (Other Bate VALPRO (Ot	er drug) :h: her drug) :h:			Rea	son:			
ARIMA (Other Bate VALPRO (Ot Bate COGENTIN (er drug) ch: her drug) ch: Other drug)	S		Rea Rea	son: Son:			
ARIMA (Other Bate VALPRO (Ot Bate COGENTIN (er drug) :h: her drug) :h: Other drug)	S	started:	Rea Rea	son:	topped:		
ARIMA (Other Bate VALPRO (Ot Bate COGENTIN (Bate TEMAZEPAN	er drug) ch: her drug) ch: Other drug) ch:	s	Started: Started:	Rea Rea	son: Son:	topped:		
Bate VALPRO (Ot Bate COGENTIN (Bate TEMAZEPAN	er drug) ch: her drug) ch: Other drug) ch: d (Other drug)	s s	started:	Rea Rea	son: Son:	topped:		
Bate VALPRO (Ot Bate COGENTIN (Bate TEMAZEPAN	er drug) ch: her drug) ch: Other drug) ch:	s s	Started: Started:	Rea Rea	son: Son:	topped:	Deta	lc.

Has been on Clopixol for a few years. Over the last six months quite tired. 1st 3 days after injection ok and the last 3 days before

due for next injection ok. In between very tired.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Case Number:	205667	Seq: 1			Gender:	M	
Reported:	01/03/2005				Weight:	0.00	
Hospitalisation:					Age:	35Y	
Onset Date:					DOB:		
Outcome:	Not yet recovered				Causality:	Causality certain	
Reaction Detai	ls:						
Medicine Det							
CLOPIXOL (Suspe	cted)		Rea				
Injection			Dose Unspecified				
Batch:		Started:		Stoppe	d:	0	
l oborotom, lm	vootigationa						
Laboratory In	vestigations.						
Additional Inf	formation:						
		Over the last s	six months quite tire	ed. 1st 3 days aft	er injection o	ok and the last 3 days b	efore
due for next injection	on ok. In between v	ery tired.					

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Case Number:	206245	Seq:	1		Ge	nder:	M	
Reported:	23/03/200	5			We	ight:	0.00	
Hospitalisation:						Age:	99u	
Onset Date:						DOB:		
Outcome:	Not yet red	covered			Caus	ality:	Causality possible	
R <u>eaction Detai</u>								_
	ed Term	Se	verity		ort Description		Treatment	_
Depression			Th	e patient had	been treated with Clopiz	xol.		
Medicine Det								
CLOPIXOL (Suspe	ected)			Re	ason:			
Datah.		04			Otamond.			
Batch:		St	arted:		Stopped:			
<u>Laboratory In</u>	vestigati	ions:						
Date	Туре	Range	Date Tested	Result		Deta	ils	
Additional Inf	formation	1:						

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

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

Case Number: 207572 Seq: 1 Gender: M

Reported: 03/05/2005 Weight: 85.00 Hospitalisation: Age: 24

Onset Date: 10/03/2005 **DOB**: 28/10/1980

Outcome: Unknown Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Myopia	Incapacity/dis ability		

Medicine Details:

CLOPIXOL-ACUPHASE (Suspected) Reason:

Injection Dose Unspecified 3 times

Batch: Started: 10/03/2005 Stopped: 07/04/2005

CLOPIXOL DEPOT (Suspected) Reason:

Injection Dose Unspecified 3 times

Batch: Started: 10/03/2005 **Stopped:** 07/04/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
03/05/2005	Albumin				

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 207819 Seq: 1 Gender: M
Reported: 13/05/2005 Weight: 0.00
Hospitalisation: Age: 47Y

Onset Date: 19/02/1999 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

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

Medicine Details:

RANITIDINE (Other drug) Reason:

Tablet 300.0 Milligram Oral

Batch: Started: 19/02/1999 Stopped:

RISPERDAL (Suspected) Reason: Unspecified schizophrenia

Tablet 1.0 Milligram Daily Oral

Batch: **Started**: 19/02/1999 **Stopped**: 19/02/1999 0

ZUCLOPENTHIXOL ACETATE (Suspected) Reason:

Injection 200.0 Milligram Daily Intravenous

Batch: Started: Stopped: 23/02/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Clinical Trial RODOS WAVE I: RODOS

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

•	er: 207891	Seq: 1			Gend	G1. IVI	
	ed: 17/05/2005	ı			Weigh	nt: 0.00	
ospitalisatio					-	e: 69Y	
Onset Dat	te: 21/02/2004				DC		
Outcom	e: Recovered				Causali	ty: Causality possible	
eaction De							
	erred Term	Seve		•	ort Description	Treatment	
Parkinsonism		Caused prolonge inpatient hospitali	ed dys	e patient expe tonia second	erienced Parkinsonism and ary to Zuclopenthixol.	3mg IM Benztropine.	
Oystonia Cau prol inpa hos			ed				
Medicine D	etails:						
TEMAZEPAM (Rea	son:		
Batch:		Start	ed:	Stopped:			
OLANZAPINE (Other drug)			Rea	son:		
Batch:		Start	ed:	Stopped:			
CEPHALEXIN (Other drug)			Rea	son:		
Datel		O44			Ctown and		
Batch:		Start	ea:	Dr-	Stopped:		
PANCREASE (Julei arag)			Kea	SUII.		
Batch:		Started:			Stopped:		
-1	Investigation		1				
Date	Type	Range Da	ate Tested	Result	D	etails	

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Hospitalisation: Onset Date: Outcome: Reaction Detai	17/05/2005 21/02/2004 Recovered	Seq: 1				Gender: Weight: Age: DOB: ausality:	0.00 69Y	sible
Medicine Deta	ails: Magnesium trihyd	RATE (Other druc	a)	Reason:				
		(•	, ,					
Batch:		Started:			Stopped:			
CLONAZEPAM (O	ther drug)			Reason:				
Batch:		Started:			Stopped:			
ZUCLOPENTHIXO	L ACETATE (Suspect			Reason:				
Injection			Milligram	Daily		Intramuscu	ılar	
Batch:		Started:			Stopped:			
Laboratory In	vestigations:							
Additional Inf Report 207890 is t	formation: he first sequence to	this report.						

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Case Number: 208468

Reported: 03/06/2005

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Weight: 0.00

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Seq: 1

Onset Date: Outcome: Unknown Paction Details: Preferred Term Severity Report Description The patient experienced a serious attempt after three months of akath made serious, nearly lethal attempt developed deep vein thrombosis. Akathisia Deep vein thrombosis Medicine Details: ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Injection 200.0 Milligram Weekly Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: 15.0 Milligram Daily Batch: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Reason: Tablet 200.0 Milligram Daily Batch: Started: Stopped:	athisia - npts, and .
Preferred Term Severity Report Description Suicide attempt The patient experienced a serious attempt after three months of akatr made serious, nearly lethal attempt developed deep vein thrombosis. Akathisia Deep vein thrombosis Medicine Details: ZUCLOPENTHIXOL ACETATE (Suspected) Injection 200.0 Milligram Weekly Batch: Started: Stopped: OLANZAPINE (Suspected) Reason: 15.0 Milligram Daily Batch: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Tablet 200.0 Milligram Daily Reason: Reason: Reason: 15.0 Milligram Daily Reason: Reason: Reason: Tablet 200.0 Milligram Daily	Treatment Withdrawal over prolonged period. Needed Warfarin. by the control of
Preferred Term Severity Report Description uicide attempt fter three months of akath made serious, nearly lethal attempt developed deep vein thrombosis. Uicide attempt Uicide attempt Uicide attempt Uicide attempt after three months of akath made serious, nearly lethal attempt developed deep vein thrombosis. Uicide attempt after three months of akath made serious, nearly lethal attempt developed deep vein thrombosis. Uicide attempt after three months of akath made serious, nearly lethal attempt developed deep vein thrombosis. Uicide attempt after three months of akath made serious, nearly lethal attempt developed deep vein thrombosis. Uicide attempt after three months of akath made serious, nearly lethal attempt developed deep vein thrombosis. Uicide attempt after three months of akath made serious, nearly lethal attempt developed deep vein thrombosis. Uicide attempt after three months of akath made serious, nearly lethal attempt developed deep vein thrombosis. Uicide attempt after three months of akath made serious, nearly lethal attempt developed deep vein thrombosis. Uicide attempt after three months of akath made serious, nearly lethal attempt developed deep vein thrombosis. Uicide attempt after three months of akath made serious, nearly lethal attempt developed deep vein thrombosis. Uicide attempt after three months of akath made serious, nearly lethal attempt developed developed deep vein thrombosis. Uicide attempt after three months of akath made serious, nearly lethal attempt developed attempt developed developed developed developed developed attempt developed	withdrawal over prolonged period. Needed Warfarin. Withdrawal over prolonged period. Needed Warfarin. ed:
The patient experienced a serious attempt after three months of akathmade serious, nearly lethal attempt developed deep vein thrombosis. Comparison Comparis	withdrawal over prolonged period. Needed Warfarin. Withdrawal over prolonged period. Needed Warfarin. ed:
Attempt after three months of akathmade serious, nearly lethal attempt developed deep vein thrombosis. Composition Composit	ed:
Medicine Details: ZUCLOPENTHIXOL ACETATE (Suspected) Injection Batch: Started: Started: Stopped: OLANZAPINE (Suspected) Batch: Started: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Tablet 200.0 Milligram Paily Reason: Reason: Tablet Daily Reason: Daily	ed:
edicine Details: CUCLOPENTHIXOL ACETATE (Suspected) Injection 200.0 Milligram Weekly Batch: Started: Stopped: CULANZAPINE (Suspected) Reason: 15.0 Milligram Daily Batch: Started: Stopped: CULANZAPINE (Suspected) Reason: 15.0 Milligram Daily Reason: Tablet 200.0 Milligram Daily	ed:
edicine Details: CUCLOPENTHIXOL ACETATE (Suspected) Injection 200.0 Milligram Weekly Batch: Started: Stopped: CLANZAPINE (Suspected) Reason: 15.0 Milligram Daily Batch: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Reason: Tablet 200.0 Milligram Daily	ed:
Reason: Injection 200.0 Milligram Weekly Batch: Started: Stopped: DLANZAPINE (Suspected) Reason: 15.0 Milligram Daily Batch: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Reason: Tablet 200.0 Milligram Daily	ed:
Batch: Started: Stopped: DLANZAPINE (Suspected) Reason: 15.0 Milligram Daily Batch: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Reason: Tablet 200.0 Milligram Daily	ed:
DLANZAPINE (Suspected) 15.0 Milligram Daily Batch: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Tablet 200.0 Milligram Daily	ed:
Batch: Started: Stopped: **EUVOXAMINE MALEATE (Suspected) Reason: Tablet 200.0 Milligram Daily	
Batch: Started: Stopped: LUVOXAMINE MALEATE (Suspected) Reason: Tablet 200.0 Milligram Daily	
LUVOXAMINE MALEATE (Suspected) Reason: Tablet 200.0 Milligram Daily	
Tablet 200.0 Milligram Daily	Oral
,	Oral
Batch: Started: Stopped:	
	ed:
.aboratory Investigations: Date Type Range Date Tested Result	Details



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 208713
 Seq: 1
 Gender: M

 Reported:
 16/06/2005
 Weight:
 0.00

 Hospitalisation:
 Age: 29

Onset Date: 21/05/2005 **DOB:** 01/11/1975

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Swollen tongue		difficulty speaking, shakey and trouble with	Treated with Cogentin 2mg oral 02/02/05 and 1mg 02/03/05
Coordination abnormal			
Nervousness			
Speech disorder			

Medicine Details:

OMEPRAZOLE (Other drug)		Reason:	
	20.0 Milligram		
Batch:	Started: 19/05/2005	Stopped:	
CLOPIXOL-ACUPHASE (Suspected)		Reason:	
Injection	100.0 Milligram	Daily	Intramuscular
Batch:	Started: 20/05/2005	Stopped:	
QUETIAPINE (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 20/05/2005	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 21/05/2005	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL, CLOPIXOL DEPOT, CLOPIXOL-ACUPHASE, ZUCLOPENTHIXOL ACETATE, ZUCLOPENTHIXOL DECANOATE, ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 208882 Seq: 1 Gender: M

Reported: 21/06/2005 Weight: 0.00 Hospitalisation: Age: 43

Onset Date: 15/12/2004 DOB: 07/04/1961

Outcome: Death, maybe drug 15/12/2004 Causality: Causality possible

Reaction Details:

,	teaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Completed suicide		The patient committed suicide by hanging shortly after treatment with Zuclopenthixol injection.	

Medicine Details:

CLOPIXOL DEPOT (Suspected) Reason:

Injection 200.0 Milligram Monthly Intramuscular

Batch: Started: Stopped: 15/12/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Medical history include: drug addict, benzodiazepine abuse, heavy smoker and hepatitis C with impaired liver function, schizoaffective disorder, bipolar disorder, cardiovascular disease and angina. Received dialectical behaviour therapy and received care from Community Mental health Centre since Oct/2003. Former self-harming behaviour and previous suicide attempts.

Patient received injection of 200mg zuclopenthixol depot i m every month. On the day of suicide injected 200mg Clopixol depot at 11am injected in the buttock, committed suicide by hanging at 4.30 pm the same day.

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Case Number: 208953

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Seq: 1

Reported: 22/06/2005	Weight: 0.00					
lospitalisation:	Age : 21Y					
Onset Date: 19/03/2004			DC	OB:		
Outcome: Recovered			Causali	ity: Causality possible		
<u>leaction Details:</u>						
Preferred Term	Severity	Report De	escription	Treatment		
Somnolence		Patient drowsy, still ve jaw, stiffness and tired	ery very drowsy, lock d.	Given Cogentin prn and dose of Zuclopenthixol to be reduced.		
Fatigue						
Musculoskeletal stiffness						
Trismus						
Medicine Details: ZUCLOPENTHIXOL ACETATE (Suspec	ited)	Reason:				
Injection	175.0	Milligram 1 tim	е			
Batch:	Started: 18/0	Started : 18/03/2004 Stopped : 0				
Laboratory Investigations:						
Date Type Ran	nge Date Teste	ed Result		petails		
<u> </u>						
Additional Information:						
eport Run: 01/06/2007	base: pusime02	ADRS0	04	Page 125 of 152		
				- 3 - 1= 1 - 2		



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 209191 Seq: 1 Gender: F

Reported: 28/06/2005 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 69

Onset Date: 20/05/2005 DOB: 24/12/1935

Outcome: Unknown Causality: Causality possible

Reaction Details:

Droforred Term	Coverity	Donart Description	Trootmont
Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism	Caused or prolonged inpatient hospitalisation	The patient experienced pulmonary embolism and dyspnoea while on Zuclopenthixol Decanoate treatment.	Given Clexane. Zuclopenthixo Decanoate treatment ceased.
Dyspnoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MEGICINE DELANS.			
OLANZAPINE (Other drug)		Reason:	
	10.0 Milligram		
Batch:	Started:	Stopped:	
CLOPIXOL (Suspected)		Reason:	
Injection	200.0 Milligram	Daily Intra	muscular
Batch:	Started: 20/02/2005	Stopped: 20/05	5/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Zuclopenthixol decanoate treatment commenced 20/02/05, 200mg daily. Patient dates the onset of dysponea to the time that she received the injection. However, the diagnosis of pulmonary emboli was not made until some months later.

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 210453
 Seq: 1
 Gender:
 M

 Reported:
 05/08/2005
 Weight:
 0.00

Hospitalisation: Admitted to hospital **Age**: 18

Onset Date: 20/05/2005

Outcome: Recovered

20/05/2005

DOB: 05/11/1986

Causality: Causality possible

Reaction Details:

todotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
	prolonged inpatient	Patient experienced dystonic reaction 48 hours after administration of Clopixol Acuphase, patient was rigid, eyes looking up and arching of the back.	2mg Cogentin IM given.

Medicine Details:

RISPERIDONE (Other drug)		Reason:	Unspecified schizophrenia	
	3.0 Milligram			
Batch:	Started: 20/05/2005		Stopped:	0
DIAZEPAM (Other drug)		Reason:	Unspecified psychosis	
	20.0 Milligram			
Batch:	Started: 17/05/2005		Stopped : 18/05/2005	0
DIAZEPAM (Other drug)		Reason:	Unspecified psychosis	
	30.0 Milligram			
Batch:	Started: 18/05/2005		Stopped : 19/05/2005	0
RISPERIDONE (Other drug)		Reason:	Unspecified schizophrenia	
	3.0 Milligram			
Batch:	Started: 17/05/2005		Stopped: 19/05/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



Case Number: 210453

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Seq: 1

ospitalisation: Ad Onset Date: 20 Outcome: Re					Weight:	
Outcome: Re	10510005				Age:	18
	/05/2005				DOB:	05/11/1986
	covered	20/05/200	05	Ca	ausality:	Causality possible
action Details:						
ledicine Details						
RISPERIDONE (Other	drug)		Reason:	Unspecified scl	nizophrenia	
		4.0 Milligram				
Batch:		ed: 19/05/2005		Stopped:		
CHLORPROMAZINE H	YDROCHLORIDE (Other dru	ıg) F	Reason:	Unspecified sc	nizophrenia	
5				0.		
Batch:	Starte		2000001	Stopped:	ni-onbronio	
CLOPIXOL-ACUPHAS Injection	= (Suspected)		Reason: 1 time	Unspecified sc	Intramuscul	or.
Batch:	Starte	50.0 Milligram ed: 18/05/2005	i uiile	Stannadı	IIIIIaiiiuSCu	ai
Daten:	Starte	90: 16/05/2005		Stopped:		

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 212252 Gender: M Seq: 1

Reported: 05/10/2005 Weight: 80.00 Hospitalisation: **Age: 36Y**

Onset Date: 23/09/2005 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Patient experienced severe dystonic reaction when Aripiprazole therapy changed from 10mg to 15mg daily.	
Therapy regimen changed			

Medicine Details:

Batch:

LORAZEPAM (Other drug)	Reason:	Otr spec symp psychopathol nec	

6.0 Milligram **Tablet** Oral Started: 19/09/2005

MIDAZOLAM (Other drug) Reason:

Injection 10.0 Milligram Intramuscular

Started: 23/09/2005 Stopped: Batch:

ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Unspecified psychosis

Injection 150.0 Milligram 1 time Intramuscular

Started: 23/09/2005 Batch: Stopped:

Aripiprazole (Suspected) Reason: Unspecified psychosis

Tablet 15.0 Milligram Daily Oral

Batch: Started: 19/09/2005 Stopped: 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Stopped:

Additional Information:

Previous dystonic reaction to Haloperidol.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Case Number:	214240	Seq:	1			Gender:	: M	
Reported:	13/12/2005					Weight:	0.00	
lospitalisation:						Age:	31Y	
Onset Date:	26/09/2005					DOB	:	
Outcome:	Recovered			04/10/2005		Causality:	Causality poss	ible
<u>eaction Detai</u>	ls:							
Preferre	ed Term	Se	verity	Repo	ort Description	ı	Treatmer	nt
Aggression		Cause prolon inpatie hospit	ged	The patient expe	erienced aggre	ssion.		
Medicine Det				Rea	son:			
Tablet	G,		40.0 N	/lilligram		Oral		
Batch:		St	arted:	_	Stop	ped:		
OMEPRAZOLE (Ot	her drug)			Rea	son:			
			20.0 N	/lilligram				
Batch:		St	arted:		Stop	ped:		
DIAZEPAM (Other	drug)			Rea	son:			
			10.0 N	/lilligram				
Batch:		St	arted:		Stop	ped:		
AMISULPRIDE (Ot	her drug)			Rea	son:			
Batch:		St	arted:		Stop	ped:		
_aboratory In	vestigatio	ons:						
Date	Туре	Range	Date Tested	d Result		Deta	ils	
Additional Inf	ormation	:						
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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:				
Case Number: 214240 Reported: 13/12/2005 Hospitalisation: Onset Date: 26/09/2005 Outcome: Recovered Reaction Details:	Seq: 1	04/10/2005	Gender: Weight: Age: DOB: Causality:	0.00 31Y
Medicine Details:				
OLANZAPINE (Other drug)		Reason:		
Batch:	Started:		Stopped:	
CHLORPROMAZINE HYDROCHLORID	E (Other drug)	Reason:		
Batch:	Started:		Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspe			nspecified schizophrenia	
Injection		Milligram Alternate		
Batch:	Started:		Stopped:	
Laboratory Investigations:	:			
Additional Information:				

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Rep	ort	Detai	ls:
-----	-----	-------	-----

Case Number: 215167 Seq: 1 Gender: F

Reported: 23/01/2006 Weight: 68.00 Hospitalisation: Required a visit to the doctor Age: 21

Onset Date: 15/07/2005 **DOB**: 26/04/1984

Outcome: Unknown Causality: Causality probable

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		The patient developed facial movements, tongue movement and tongue and eye "tics". She was diagnosed with tardive dyskinesia.	Clopixol Depot ceased.

Medicine Details:

CLOPIXOL DEPOT (Suspected) Reason: Unspecified schizophrenia

Injection 300.0 Milligram Alternate weeks Intramuscular

Batch: Started: 15/01/2004 Stopped: 15/07/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 215962
 Seq: 1
 Gender:
 M

 Reported:
 17/02/2006
 Weight:
 0.00

Hospitalisation: Age: 36

Onset Date: 15/02/2006 DOB: 29/08/1969
Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicion Details.			
Preferred Term	Severity	Report Description	Treatment
	prolonged innatient	Tachycardia - 126 bpm (Baseline pulse 80bpm) Raised Creatine Kinase - 320 Physical Exam - Normal	Observation and biochemical monitoring. CK slowly resolving. Tachycardia resolved.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM (Other drug)		Reason:	
Tablet	500.0 Milligram	2 times	Oral
Batch:	Started: 31/01/2006	Stopped:	
CLOPIXOL-ACUPHASE (Suspected)		Reason:	
Injection			Intramuscular
Batch:	Started: 01/02/2006	Stopped:	08/02/2006
Abilify (Suspected)		Reason:	
Tablet	30.0 Milligram	1 time	Oral
Batch:	Started: 25/01/2006	Stopped:	15/02/2006

Laboratory Investigations:

	. <u>,</u>				
Date	Туре	Range	Date Tested	Result	Details
	Creatine kinase				14/02/2006 CK - 282 15/02/2006 CK - 263

Additional Information:



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

 Case Number:
 216346
 Seq: 1
 Gender: M

 Reported:
 09/03/2006
 Weight:
 0.00

 Hospitalisation:
 Age: 40

Onset Date: 16/08/2005 **DOB:** 04/08/1965

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	prolonged inpatient		Stopped neuroleptics on 16/08/05.
Blood pressure increased	Caused or prolonged inpatient hospitalisation		
Hypertonia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
Tablet	2.0 Gram	Oral	
Batch:	Started: 16/08/2005	Stopped:	
CLONAZEPAM (Other drug)		Reason: Anxiety neurosis	
Tablet	4.0 Milligram	Daily Oral	
Batch:	Started: 16/08/2005	Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason: Unspecified psychosis	
Injection	200.0 Milligram	1 time	
Batch:	Started: 11/08/2005	Stopped: 12/08/2005	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	20.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

<u> </u>	j mroonga				
Date	Туре	Range	Date Tested	Result	Details
	Creatine		19/08/2005	300	
	Serum drug level		12/08/2005	140	

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:	Re	po	rt	De	tai	ls:
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Case Number: 216884 Seq: 1 Gender: M

Reported: 03/04/2006 Weight: 80.00 Hospitalisation: Admitted to hospital Age: 24

Onset Date: 15/03/2006 **DOB:** 21/04/1981

Outcome: Recovered 16/03/2006 Causality: Causality possible

Reaction Details:

toaction Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Blood pressure decreased	Caused or prolonged inpatient hospitalisation	Fall in BP	

Medicine Details:

wedicine Details:			
CLOZAPINE (Other drug)		Reason:	
	50.0 Milligram	Daily	
Batch:	Started:	Stopped:	
CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason: Otr spec symp psychopathol nec	
	100.0 Milligram	Daily	
Batch:	Started: 15/03/2006	Stopped: 15/03/2006	
CLOPIXOL-ACUPHASE (Suspected		Reason:	
	100.0 Milligram	Daily	
Batch:	Started: 15/03/2006	Stopped: 15/03/2006	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

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

Case Number: 216974 Seq: 1 Gender: M

Reported: 04/04/2006 Weight: 61.00 Hospitalisation: Age: 39Y

Onset Date: 22/03/2006 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

100011011 D 0101101			
Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness		Found in room, neck extended forward, limbs stiff, facial grimacing.	Benztropine 2 mg IMI

Medicine Details:

OLANZAPINE (Other drug)		Reason: Unspecified pa	sychosis
	20.0 Milligram		Oral
Batch:	Started: 21/03/2006	Stopped:	
MIDAZOLAM (Suspected)		Reason:	
	10.0 Milligram	1 time	Intramuscular
Batch:	Started: 20/03/2006	Stopped:	20/03/2006
CLOPIXOL-ACUPHASE (Suspected)		Reason:	
	150.0 Milligram	Daily	
Batch:	Started: 20/03/2006	Stopped:	20/03/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report D	etails:					
Case Num	ber: 217068	Seq:	1		Gend	er: M
Repo	rted: 06/04/200)6			Weigl	ht : 0.00
Hospitalisat					~	je: 47
	Date: 30/03/200	_				DB : 15/10/1958
	ome: Not yet re	covered			Causali	ty: Causality possible
Reaction D			.,		15	- , ,
	referred Term		everity	•	ort Description	Treatment
ineuroieptic	malignant synd	rome Life threat	ening d	ieuroleptic mail ystonia, pyrexia neumonia, rapi	gnant syndrome (severe il >40.0), aspiration d AF	ICU admission, intubation to a week, cardioversion for AF, inotropes for a few days.
Atrial fibrilla	tion	Life threat	ening			
Cardiac fail	ure	Life threat	ening			
Pneumonia	aspiration	Life threat	ening			
Medicine						
LOSEC (Oth	er drug)			Rea	son:	
Bate	ch:	•	tarted: 23/03/	/2006	Stopped:	
	(Other drug)		tartea. 20/00/	Rea		
	(33 3 3 3)					
Bate	ch:	s	tarted:		Stopped:	
ISOPTIN (Ot	her drug)			Rea	son:	
Bate		S	tarted:		Stopped:	
ZOCOR (Oth	ner drug)			Rea	son:	
Bate	ch:	e	tarted:		Stopped:	
Date	<u> </u>		tartea.		оторреа.	
	ry Investigat		<u> </u>			
Date	Type	Range	Date Tested			etails
06/04/2006	Biochemistry				29/3/2006 Na 125, Cl 90, temp	0 40.3
Additiona	al Informatio	n:				
Addition		111				

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Case Number: 217068

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Seq: 1

Reported:	06/04/2006				Weight:	0.00
Hospitalisation:					Age:	47
Onset Date:	30/03/2006				DOB:	15/10/1958
Outcome:	Not yet recovered			С	ausality:	Causality possible
Reaction Detai	ils:					
Medicine Det	aile:					
COVERSYL (Other			Reason:			
Batch:		Started:		Stopped:		
STELAZINE (Othe	r drug)	oturtou.	Reason:	Otoppeu.		
Tablet	i didg)	F.O. Milligram			Oral	
		5.0 Milligram	Daily		Orai	
Batch:		Started: 01/01/1986		Stopped:		
CLOPIXOL (Suspe	ected)		Reason:			
Injection		200.0 Milligram	Fortnight	tly	Intramuscu	ılar
Batch:		Started: 01/02/2006		Stopped:	23/03/2006	3
						_
Laboratory In	vestigations:					
•	J					
A .1 .1141 1 1 1	•					
Additional In	formation:					

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Re	po	rt	De	tai	ls:
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Case Number: 217341 Seq: 1 Gender: M

Reported: 06/04/2006 Weight: 78.00 Hospitalisation: Age: 26Y

Onset Date: 01/03/2006 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Acute dystonic reaction (extradural tongue, dysarthia).	Treated with Benztropine 2mg orally.

Medicine Details:

CLOPIXOL-ACUPHASE (Suspected) Reason: Unspecified psychosis

Injection 150.0 Milligram Daily Intramuscular

Batch: Started: 27/02/2006 Stopped: 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number: 217640 Seq: 1 Gender: F

Reported: 24/04/2006 Weight: 0.00 Hospitalisation: Age: 41

Onset Date: 06/04/2006 DOB: 14/04/1964

Outcome: Recovered 18/04/2006 Causality: Causality probable

Reaction Details:

			
Preferred Term	Severity	Report Description	Treatment
Pyrexia		· · · · · · · · · · · · · · · ·	Withdrawal of all antipsychotic medications
Blood creatine phosphokinase incr			
Tachycardia			

Medicine Details:

 ZUCLOPENTHIXOL ACETATE (Suspected)
 Reason:
 Manic-depression psycho,manic

 Injection
 50.0
 Milligram
 Weekly
 Intramuscular

 Batch:
 Started: 22/03/2006
 Stopped: 03/04/2006 0
 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
24/04/2006	Creatine		06/04/2006	972	
24/04/2006	Creatine		07/04/2006	1430	
24/04/2006	Creatine		08/04/2006	2320	
24/04/2006	Creatine		09/04/2006	1970	
24/04/2006	Creatine		10/04/2006	1590	
24/04/2006	Creatine		11/04/2006	953	
24/04/2006	Creatine		13/04/2006	451	

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Case Number:						
Reported: ospitalisation:	24/04/2006	Seq:	1		Gender: Weight: Age:	0.00
Onset Date:						14/04/1964
	Recovered			18/04/2006	Causality:	Causality probable
action Detai	ils:					
Andinina Dat	-!					
ledicine Det	allS: L ACETATE (Suspe	ected)		Reason:	Manic-depression psycho	manic
Injection	E AOETATE (Ouspe	,ctcu,	50.0 Milli			
Batch:		Sta	arted: 22/03/20		Stopped: 03/04/2006	
aboratory In	nvestigations Type Ra	ange	Date Tested	Result	Detai	ls

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Case Number: 218840 Seq: 1 Gender: F

Reported: 31/05/2006 Weight: 0.00 Hospitalisation: Age: 43Y

Onset Date: 10/01/2006 DOB:

Outcome: Recovered 11/01/2006 Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Oxygen saturation decreased		On 10 Jan 2006 the patient received a dose of Clozapine 400mg. Twenty minutes later, the patient was found in his room semi-conscious, with a decreased oxygen saturation level.	Clozapine and Zuclopenthixol ceased.
Depressed level of consciousness			

Medicine Details:

Medicine Details.			
CLOZAPINE (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 10/01/2006	Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 10/01/2006	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Donort Dot							
Report Det	ails:						
Case Numb	er: 219171	Seq: 1		Gend	er: M		
Reporte	ed: 15/06/2006	6		Weig	ht: 0.00		
Hospitalisatio	on:			Ag	je : 15Y		
Onset Da	ite: 28/04/2006	ô	DOB:				
Outcom	ne: Recovered	t		Causali	ty: Causality possible		
Reaction De	tails:						
Pref	ferred Term	Severity	Repo	ort Description	Treatment		
Tremor			lying on floor, ex	o rouse, shaking, found cess saliva, EPSE, open k, tuncal dystonia, gait,	Given Benztropine imi/oral.		
Dystonia							
Extrapyramid	al disorder						
Oculogyration							
Salivary hype	rsecretion						
Somnolence							
Medicine D	ther drug)		Rea Milligram	son: Otr spec symp psycho	pathol nec		
Batch	:	Started:		Stopped:			
TEMAZEPAM	(Other drug)			son: Specific disorders of s	leep		
			Milligram				
Batch		Started:	D	Stopped:			
DIAZEPAM (O	tner arug)	E 0		son:			
		5.0	Milligram	Stopped:			
Ratch		Startod: 14/0					
Batch		Started: 14/0					
CLOPIXOL-AC	CUPHASE (Suspe	cted)	Rea	son:	ıscular		
CLOPIXOL-AC	CUPHASE (Suspection	cted)	Rea Milligram	son: 1 time Intram	uscular		
CLOPIXOL-AC Injection	CUPHASE (Suspection :	100.0 Started: 28/0	Rea Milligram	son:	uscular		
CLOPIXOL-AC Injection	CUPHASE (Suspection	100.0 Started: 28/0	Rea Milligram 04/2006	son: 1 time Intram Stopped:	uscular		

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:			
Case Number: 219171	Seq: 1	Gender:	M
Reported: 15/06/2006		Weight:	0.00
Hospitalisation:		Age:	
Onset Date: 28/04/2006		DOB:	
Outcome: Recovered			Causality possible
Reaction Details:		oudounty.	Caddanty poddibio
Reaction Details.			
Medicine Details:			
OLANZAPINE (Suspected)		Reason: Otr spec symp psychopath	nol nec
	5.0 Milligram	As necessary	
Batch:	Started: 11/04/2006	Stopped:	0
Laboratory Investigations:			
A - - :4: £4:			
Additional Information:			

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Case Number Reported					
Reported	: 220345	Seq: 1		Gend	er: M
	i : 25/07/2006			Weigl	nt: 90.00
spitalisation	: Required a vis	sit to the doctor		Ag	je: 24
Onset Date	e: 22/06/2006			DC	DB : 28/06/1981
Outcome	: Recovered		28/06/2006	Causali	ty: Causality possible
action Deta	ails:				
	rred Term	Severity	Repo	ort Description	Treatment
ash maculo-p	apular		type rash, conflu groin, over trunk face). Quite raise	ed rash maculopapular ent in areas especially and upper thighs (not on ed wheal like lesions, arms. Nausea and	Stopped Solian, treated with Phenergan.
ausea					
omiting					
LORAZEPAM (O	ther drug)	04-4-3	Reas	. , , , ,	pathol nec
Batch:		Started:		Stopped:	
EFEXOR-XR (Oth Batch:	ier drug)	Started:	Reas	son: Depression Stopped:	
Zolpidem Sando	z (Other drug)		Reas		еер
		Started:		Stopped:	
Batch:			Reas	on:	
	MESYLATE (Other o	drug)	Nea	5011.	
BENZTROPINE N	WESYLATE (Other o		Nea:		
BENZTROPINE M		Started:	Nea:	Stopped:	
BENZTROPINE M	Investigation	Started:		Stopped:	etails

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Case Number: 220345

Reported: 25/07/2006

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Weight: 90.00

Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Seq: 1

Hospitalisation: Onset Date:	Required a visit to the	e doctor			Age:	24 28/06/1981	
Onset Date: Outcome:		28/06/2	2006	Car		Causality possible	
Reaction Detai		20/00/2	.000	Cal	usanty.	Causanty possible	
Cachon Delai	10.						
Medicine Deta	ails:						
RISPERIDONE (Ot			Reason:				
Batch: SOLIAN (Suspecte	ud)	Started:	Reason:	Stopped:			
Tablet	ea)	800.0 Milligram	Daily	(Oral		
Batch:		Started: 15/06/2006	Daily	Stopped: 2			
CLOPIXOL-ACUPH	IASE (Suspected)	Startour 10/00/2000	Reason:	otoppou. 2	.2/00/2000		
	, , ,	3.0 Dose Unspec					
Batch:		Started:		Stopped:			
Laboratory In	vestigations:						
Laboratory III	vooligationo.						
Additional Inf	ormation:						

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Case Number: 2207 Reported: 15/0 Hospitalisation:							
•	•	: 1	Gender: M Weight: 0.00				
Onset Date: 02/0	8/2006				_	je: 27Y DB:	
Outcome: Rec			03/08/2006		_	ty: Causality possible	
eaction Details:	Svered		03/00/2000		Causan	ty. Causanty possible	
Preferred Te	erm S	everity	Reno	rt De	scription	Treatment	
Extrapyramidal disord		-	trapyramidal s		•	benztropine 2mg IM.	
-xiiapyraimaai aloora		sti	ffness - neck a	nd sh	uffling gait.	bonzaopino zing iwi.	
Gait disturbance							
Musculoskeletal stiffne	ess						
Medicine Details: RISPERIDONE (Other dr			Reas	son:	Unspecified psychosis		
Batch:	5	Started:			Stopped:		
BENZTROPINE MESYLA	TE (Other drug)		Reas	on:			
Batch:		Started:			Stopped:		
CHLORPROPAMIDE (Ot	her drug)		Reas	on:	Unspecified psychosis		
Batch:		Started:			Stopped:		
PANTOPRAZOLE (Other	drug)		Reas	on:	Nausea and vomiting		
Batch:	5	Started:			Stopped:		
_aboratory Inves	tigations:						
Date Type	Range	Date Tested	Result		D	etails	

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Detail	s:							
Hospitalisation: Onset Date: Outcome:	15/08/2006 02/08/2006 Recovered	Seq: 1	03/08/20	06		Gender: Weight: Age: DOB: ausality:	0.00 27Y	oossible
Reaction Detai	ls:							
Medicine Det	ails:							
PARACETAMOL (Reason:	Pain			
Batch:		Started:			Stopped:			
CLOPIXOL-ACUPI	HASE (Suspected)	Otarica.		Reason:	Unspecified ps	ychosis		
Injection		50.0 Mil		Daily	p	Intramuscu	ılar	
Batch:		Started: 01/08/2	2006		Stopped:	01/08/2006	3	
Laboratory In	vestigations:							
Additional Inf Known history sen	formation: sitivity to Antipsycho	tics. Given due to	increased	psychotic	symptoms.			

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Re	po	rt	De	tai	ls:
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 Case Number:
 221935
 Seq: 1
 Gender: M

 Reported:
 26/09/2006
 Weight:
 0.00

Hospitalisation: Age: 32

Onset Date: 26/08/2006 DOB: 17/09/1973

Outcome: Recovered 27/08/2006 Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Joint stiffness		Jaw stiffness, back stiffness, facial dystonia / fasciculation right side.	Treated with Benztropine IM 2mg.
Dystonia			
Musculoskeletal stiffness			

Medicine Details:

vieuicine Delans.			
OLANZAPINE (Other drug)		Reason:	
	10.0 Milligram		
Batch:	Started: 02/08/2006	Stopped:	
Risperdal Consta (Other drug)		Reason:	
Tablet	50.0 Milligram	Oral	
Batch:	Started: 02/08/2006	Stopped:	
CLOPIXOL-ACUPHASE (Suspected)		Reason: Otr spec symp psychopathol nec	
Injection	150.0 Milligram	1 time Intramuscular	
Batch:	Started: 23/08/2006	Stopped: 23/08/2006	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details:

Case Number:225126Seq: 1Gender:MReported:29/01/2007Weight:62.00Hospitalisation:Admitted to hospitalAge: 27Y

Onset Date: 14/09/2006 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	prolonged	paches/blisters over arms, legs and genitalia, oral mucosa lesions.	Loratadine stat, hydrocortisone cream.
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Benztrop (Other drug)	Reaso	on:
Tablet	1.0 Milligram	Oral
Batch:	Started: 07/09/2006	Stopped: 14/09/2006
NORMISON (Other drug)	Reaso	on:
	20.0 Milligram	Oral
Batch:	Started: 03/09/2006	Stopped: 15/09/2006
Valpam (Other drug)	Reaso	on:
Tablet	5.0 Milligram	Oral
Batch:	Started: 31/08/2006	Stopped: 17/09/2006
ZYPREXA (Other drug)	Reaso	on:
	10.0 Milligram	Oral
Batch:	Started: 09/09/2006	Stopped:

Laboratory Investigations:

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

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report	Details:
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Case Number:225126Seq: 1Gender: MReported:29/01/2007Weight:62.00Hospitalisation:Admitted to hospitalAge: 27Y

Onset Date: 14/09/2006 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

EPILIM (Other drug)		Reason:		
Tablet	2.2 Gram	Daily	Oral	
Batch:	Started: 11/09/2006	Stopped	: Contin	
RISPERDAL (Other drug)		Reason: Schizo-affect	tive type psychos	
	4.0 Milligram	Daily	Oral	
Batch:	Started: 02/09/2006	Stopped	1: 06/09/2006	
CLOPIXOL (Suspected)		Reason: Schizo-affect	tive type psychos	
Injection	50.0 Milligram	1 time	Intramuscular	
Batch:	Started: 07/09/2006	Stopped	:	
CLOPIXOL (Suspected)		Reason: Schizo-affect	tive type psychos	
Injection	150.0 Milligram	1 time	Intramuscular	
Batch:	Started: 08/09/2006	Stopped	:	

Laboratory Investigations:

Additional Information:



Unclear causality excluded GM medicines Only Tradenames: CLOPIXOL,CLOPIXOL DEPOT,CLOPIXOL-ACUPHASE,ZUCLOPENTHIXOL ACETATE,ZUCLOPENTHIXOL DECANOATE,ZUCLOPENTHIXOL DIHYDROCHLORIDE

Report Details: Case Number: 22 Reported: 29 ospitalisation: Ac	25126						
Reported: 29	25126						
-		Seq: 1				Gender:	M
ospitalisation: Ac	9/01/2007					Weight:	62.00
	dmitted to hospita	al				Age:	27Y
Onset Date: 14	1/09/2006					DOB:	
Outcome: No	ot yet recovered				С	ausality:	Causality possible
eaction Details:	:						
ledicine Detail	s:						
CLOPIXOL (Suspecte				Reason:	Schizo-affectiv	e type psyc	nos
Tablet		20.0	Milligram	Daily		Oral	
Batch:		Started: 06/0	09/2006		Stopped:	07/09/2006	i
CLOPIXOL (Suspecte	d)			Reason:	Schizo-affectiv	e type psyc	nos
Tablet		40.0	Milligram	Daily		Oral	
Batch:		Started: 07/0)9/2006			12/09/2006	
CLOPIXOL (Suspected	d)			Reason:	Schizo-affective		nos
Tablet			Milligram	Daily		Oral	
Batch:		Started: 12/0)9/2006		Stopped:		

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