

Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Re	port	: Deta	ils:
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 Case Number:
 91742
 Seq: 1
 Gender:
 F

 Reported:
 23/03/1994
 Weight:

Hospitalisation: Age: 34Y
Onset Date: 17/03/1994
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

caction betails.						
Preferred Term	Severity	Report Description	Treatment			
Agitation						
Nausea						
Tremor						
Visual disturbance						

Medicine Details:

FLUANXOL (Suspected) Reason:

Injection 1.0 Dose Unspecified 1 time Intramuscular

Batch: Started: 17/03/1994 Stopped:

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
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Additional Information:

Drug was administered by "mental team" no doctor involved.

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Case Number: 92019 Reported: 05/04/1994	Coat 1				Gender:	_
116001664. UJ/UT/1334	Seq: 1				Gender: Weight:	Γ
ospitalisation:					Age:	37Y
Onset Date: 25/02/1993					DOB:	
Outcome: Unknown				C	ausality:	Causality certain
eaction Details:						•
Preferred Term	Severity	Re	eport De	scription		Treatment
jection site reaction						
rticaria					Нус	drocortisone.
ledicine Details:						
PROZAC (Other drug)		F	Reason:	Depression		
Batch:	0.0 Started:			Stopped:		
LITHIUM CARBONATE (Other drug		F	Reason:	Unspecified so	chizophrenia	
Tablet		Gram	Daily	·	Oral	
Batch:	Started:		-	Stopped:		CONTIN
STELAZINE (Other drug)		F	Reason:	Unspecified so	chizophrenia	
STELAZINE (Other drug)		Milligram	Daily		Oral	
Oral application	2.0	9				
Oral application Batch:	2.0 Started:			Stopped:		
Oral application Batch: FLUANXOL (Suspected)	Started:	F	Reason:	Unspecified so	•	
Oral application Batch: FLUANXOL (Suspected) Injection	Started:	F Milligram	Reason: 3 time	Unspecified sees	Intramuscu	lar
Oral application Batch: FLUANXOL (Suspected) Injection Batch:	Started: 20.0 Started: 25/	F Milligram		Unspecified sees	•	lar
Oral application Batch: FLUANXOL (Suspected) Injection Batch: aboratory Investigation	Started: 20.0 Started: 25/	F Milligram 02/1993		Unspecified sees	Intramuscu	lar

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 92118 Seq: 1 Gender: F
Reported: 05/04/1994 Weight:
Hospitalisation: Age: 25Y

Onset Date: DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Deep vein thrombosis			
Pulmonary embolism			

Medicine Details:

Medicine Details:			
MICROGYNON 30 (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	26/03/1994
FLUPENTHIXOL DECANOATE (Suspe	cted)	Reason: Unspecified so	chizophrenia
Injection	30.0 Milligram	Monthly	Intramuscular
Batch:	Started: 01/08/1993	Stopped:	26/03/1994
BENZTROPINE MESYLATE (Suspected	d)	Reason:	
Oral application	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	26/03/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data	Post mortem result - dvt and bilateral pulmonary e		Post mortem result - dvt and bilateral pulmonary emboli	

Additional Information:

Patient died 26/3/94. 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: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

 Case Number:
 92667
 Seq: 1
 Gender: M

 Reported:
 02/05/1994
 Weight:
 91.00

 Hospitalisation:
 Age: 25Y

Onset Date: 09/03/1994 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia			

Medicine Details:

ROXIAM (Suspected)		Reason:	Unspecified schizophrenia	
Oral application	300.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/1994		Stopped:	CONTIN
PROZAC (Suspected)		Reason:	Depression	
Capsule	60.0 Milligram	Daily	Oral	
Batch:	Started: 28/01/1994		Stopped:	CONTIN
CLONAZEPAM (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	4.5 Milligram	Daily	Oral	
Batch:	Started: 28/09/1993		Stopped:	CONTIN
CARBAMAZEPINE (Suspected)		Reason:	Unspecified schizophrenia	
Oral application	400.0 Milligram	Daily	Oral	
Batch:	Started: 09/12/1993		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Eosinophils				10/4/94 eosinophil count was noted to be 16%.

Additional Information:

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

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 92667 Seq: 1 Gender: M

 Reported:
 02/05/1994
 Weight:
 91.00

 Hospitalisation:
 Age:
 25Y

 Onset Date:
 09/03/1994
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Su	ispected)	Reason:	Unspecified schizophrenia	
Tablet	500.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/1991		Stopped:	CONTIN
BENZTROPINE MESYLATE (Suspected)		Reason:	Unspecified psychosis	
Oral application	2.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/1991		Stopped:	CONTIN
SANDOMIGRAN (Suspected)		Reason:	Migraine	
Tablet	2.0 Milligram	Daily	Oral	
Batch:	Started: 29/11/1993		Stopped:	CONTIN
FLUPENTHIXOL DECANOATE (Suspected)		Reason:	Unspecified schizophrenia	
Injection	75.0 Milligram	Daily	Intramuscular	
Batch:	Started: 01/12/1993		Stopped:	CONTIN

Laboratory Investigations:

Additional Information:

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

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL, FLUPENTHIXOL DECANOATE

Report Details:

 Case Number:
 93003
 Seq: 1
 Gender:
 F

 Reported:
 16/05/1994
 Weight:

Hospitalisation: Admitted to hospital Age: 51Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

reaction Details.	eaction betails.						
Preferred Term	Severity	Report Description	Treatment				
Injection site reaction		Injection site lump					
Anaphylactoid reaction							
Dyspnoea							
Tongue oedema							

Medicine Details:

PROCYCLIDINE HYDROCHLORIDE	(Other drug)	Reason: Paralysis agitans	
Tablet	30.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
TEMAZEPAM (Other drug)		Reason: Specific disorders of	sleep
Oral application	10.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
FLUANXOL (Suspected)		Reason: Unspecified schizoph	renia
Injection	40.0 Milligram	Monthly Intran	nuscular
Batch:	Started:	Stopped: 28/04	/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has drug hypersensitivities to almost all antibiotics, benztropine, and has been having drug reactions to almost all medications in past including psychotropics, antibiotics and analgesics. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 93120 Seq: 1 Gender: F

Reported: 23/05/1994 Weight: 69.00
Hospitalisation: Age: 35Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site inflammation		· ·	Unknown antibiotics by local doctor.

Medicine Details:

FLUANXOL (Suspected) Reason: Unspecified schizophrenia

 Injection
 40.0 Milligram
 Intramuscular

 Batch:
 Started: 22/11/1993
 Stopped: 21/12/1993

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

This reaction has occurred on both occasions the drug was administered.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

 Case Number:
 93217
 Seq: 1
 Gender:
 F

 Reported:
 30/05/1994
 Weight:

Hospitalisation: Age: 40

Onset Date: 29/03/1994 DOB: 25/10/1953
Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site reaction		Localized itch	
Urticaria		Three red wheals.	

Medicine Details:

HALDOL DECANOATE (Other drug)		Reason: Unspecified pa	sychosis
Injection	50.0 Milligram	Monthly	Intramuscular
Batch:	Started: 01/11/1993	Stopped:	29/03/1994
PROZAC (Other drug)		Reason: Depression	
Capsule	20.0 Milligram	Daily	Oral
Batch:	Started: 04/03/1994	Stopped:	22/03/1994
TEMAZEPAM (Other drug)		Reason:	
Capsule	10.0 Milligram	Daily	Oral
Batch:	Started: 04/03/1994	Stopped:	18/05/1994
FLUANXOL (Suspected)		Reason: Unspecified pa	sychosis
Injection	20.0 Milligram	1 time	Intramuscular
Batch:	Started: 29/03/1994	Stopped:	29/03/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was given 2nd dose 8/4/94 and third dose 18/5/94 with reactions occuring again but getting less severe

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 93229 Seq: 1 Gender: F

Reported: 30/05/1994 Weight:
Hospitalisation: Age: 34Y

Onset Date: 11/03/1994 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site reaction			Topical soothing preparations.

Medicine Details:

FLUANXOL (Suspected) Reason: Unspecified psychosis

Injection 20.0 Milligram Daily Intramuscular

Batch: Started: 11/03/1994 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient had same reaction when she received third injection of fluanxol depot.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL, FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 94534 Seq: 1 Gender: M
Reported: 26/07/1994 Weight:

Hospitalisation: Age: 30Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
,	Required Specialist Consultation		

Medicine Details:

MEGICITIE DELAIIS.			
ANATENSOL (Other drug)		Reason: Unspecified schizophrenia	
Oral application	5.0 Milligram	Daily Oral	
Batch:	Started:	Stopped: 28/04/1994	
FLUANXOL (Suspected)		Reason: Unspecified schizophrenia	
Injection	30.0 Milligram	Fortnightly Intramuscular	
Batch:	Started: 01/04/1994	Stopped: 28/04/1994	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL, FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 94929 Seq: 1 Gender: M

Reported: 08/08/1994 Weight: 95.00 Hospitalisation: Age: 33Y

Onset Date: 28/04/1994 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment	
Injection site inflammation		Erythematous firm and tender lump.	Flucloxacillin.	

Medicine Details:

MODECATE (Other drug)			Reason	Unspecified s	chizophrenia
Injection	50.0	Milligram	We	eekly	Intramuscular
Batch:	Started:		L TERM	Stopped:	28/04/1994
BENZTROPINE MESYLATE (Other drug)			Reason	:	
Tablet	2.0	Milligram	Da	ily	Oral
Batch:	Started:		L TERM	Stopped:	
FLUPHENAZINE NOS (Other drug)			Reason	: Unspecified p	sychosis
Oral application	150.0	Milligram	Da	ily	Oral
Batch:	Started: 01	/11/1993		Stopped:	28/05/1994
FLUPENTHIXOL DECANOATE (Suspected)			Reason	: Unspecified s	chizophrenia
Injection	80.0	Milligram	1 t	me	Intramuscular
Batch:	Started: 28	/04/1994		Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient continues to have minor local reactions to the injections of flupenthixol with small subcutaneous swelling. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Gender: M Weight: 72.00 Age: 33Y DOB: Causality: Causality certain Report Description Treatment Swelling at site ofinjection Reason: Unspecified psychosis
Age: 33Y DOB: Causality: Causality certain Report Description Treatment Swelling at site ofinjection
Causality: Causality certain Report Description Treatment Swelling at site ofinjection
Report Description Treatment Swelling at site ofinjection
Report Description Treatment Swelling at site ofinjection
Swelling at site ofinjection
Swelling at site ofinjection
Reason: Unspecified psychosis
Reason: Unspecified psychosis
filligram Daily
Stopped:
Reason:
filligram Daily
Stopped: Reason:
Reason: Intramuscular
Stopped:
d Result Details

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Det	ails:						
Case Numbe	er : 96483	Seq: 1			Gender: N	1	
Reporte	ed: 13/10/199	4			Weight:		
ospitalisatio	on:				Age: 2	9Y	
Onset Da	ite: 26/08/199	4			DOB:		
Outcom	ne: Recovere	d		С	ausality: C	Causality certain	
eaction De	etails:				-	-	
	ferred Term	Severity	y R	eport Description		Treatment	
njection site r	reaction						
ledicine D			F	Reason: Unspecified so	Unspecified schizophrenia		
Injection		2	20.0 Milligram	Fortnightly	Intramuscular	•	
Batch:			: 26/08/1994		29/09/1994		
	/ Investigat						
L aboratory Date	/ Investigat Type		Tested Result		Details		

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 96485 Seq: 1 Gender: F

Reported: 13/10/1994 Weight:
Hospitalisation: Age: 28Y

Onset Date: 16/08/1994 **DOB**:

Outcome: Recovered Causality: Causality certain

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Injection site reaction	Required Specialist Consultation		

Medicine Details:

FLUANXOL (Suspected)
Injection
200.0 Milligram
Fortnightly
Intramuscular

Started: 16/08/1994
Stopped: 19/09/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced same reaction after first and third injection of fluanxol.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:	Re	po	rt	De	tai	ls:
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Case Number: 96980 Seq: 1 Gender: F

Reported: 21/11/1994 Weight: 47.00 Hospitalisation: Age: 46Y

Onset Date: 03/11/1994 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

,	caction Details.				
	Preferred Term	Severity	Report Description	Treatment	ì
	Injection site reaction		Erythema and pain at inj site.		ı
	Urticaria			Antihistamines	ì

Medicine Details:

Medicine Details.			
PROZAC (Other drug)		Reason: Unspecified schizoph	renia
Tablet	20.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	CONTIN
FLUANXOL (Suspected)		Reason: Unspecified schizoph	renia
Injection	60.0 Milligram	Weekly Intran	nuscular
Batch:	Started: 21/10/1994	Stopped: 03/11	/1994

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL, FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 97198 Seq: 1 Gender: F

Reported: 21/11/1994 Weight: 62.00 Hospitalisation: Age: 36Y

Onset Date: 16/11/1994 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site reaction		Itchy red area	
Urticaria			

Medicine Details:

PROZAC (Other drug)		Reason: Depression	
Capsule	40.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1993	Stopped	:
TEGRETOL (Other drug)		Reason: Depression	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1994	Stopped	:
KEMADRIN (Other drug)		Reason:	
	7.5 Milligram	Daily	
Batch:	Started: 01/11/1994	Stopped	:
Batch: FLUANXOL (Suspected)			: schizophrenia
111			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred 24 hrs after injection of fluanxol. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 97664 Seq: 1 Gender: M

Reported: 12/12/1994 Weight:

Hospitalisation: Age: 60Y

Onset Date: 31/05/1994 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Skin ulcer		Ulcers on top of patients head	

Medicine Details:

FLUANXOL (Suspected) Reason: Unspecified schizophrenia

Injection 20.0 Milligram Fortnightly Intramuscular

Batch: Started: 01/01/1993 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Re	port	Detai	ls:
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Case Number: 97767 Seq: 1 Gender: F
Reported: 13/12/1994 Weight:

Hospitalisation: Age: 38Y
Onset Date: 20/10/1994
DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site reaction		Rash over site of injection, indurated.	

Medicine Details:

FLUANXOL (Suspected) Reason: Unspecified psychosis

Injection 40.0 Milligram Monthly Intramuscular

Batch: Started: 02/09/1994 Stopped: 20/10/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 97866 Seq: 1 Gender: M

Reported: 16/12/1994 **Weight:** 68.00

Hospitalisation: Age: 22Y
Onset Date: 08/09/1994
DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site reaction		Painful hard lump at injection site	

Medicine Details:

FLUANXOL (Suspected) Reason: Unspecified psychosis

Injection 60.0 Milligram Fortnightly Intramuscular

Batch: Started: 01/06/1994 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details	:	
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Case Number: 98590 Seq: 1 Gender: F

Reported: 30/01/1995 Weight: 85.00 Hospitalisation: Age: 47Y

Onset Date: 13/10/1994 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
Ī	njection site inflammation		Aceptic ulcer at injection site	

Medicine Details:

LARGACTIL (Other drug)			Reason:	Unspecified so	chizophrenia	
Oral application	300.0	Milligram	Daily		Oral	
Batch:	Started:		L TERM	Stopped:		CONTIN
ARTANE (Other drug)			Reason:			
Tablet	5.0	Milligram	Daily		Oral	
Batch:	Started:		L TERM	Stopped:		CONTIN
FLUANXOL (Suspected)			Reason:	Unspecified so	chizophrenia	
Injection	80.0	Milligram	Week	ly	Intramuscular	
Batch:	Started: 26	09/1994		Stopped:	03/11/1994	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

 Case Number:
 98697
 Seq: 1
 Gender:
 F

 Reported:
 03/02/1995
 Weight:

Hospitalisation: Age: A3
Onset Date: 10/11/1994
DOB:

Onset Date: 10/11/1994 DOB:
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction Details.	caotion Details.								
Preferred Term	Severity	Report Description	Treatment						
Acne									
Cystitis									

Medicine Details:

FLUANXOL (Suspected) Reason: Unspecified schizophrenia

Injection 80.0 Milligram Fortnightly Intravenous

Batch: Started: 01/09/1994 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

 Case Number:
 98879
 Seq: 1
 Gender:
 F

 Reported:
 09/02/1995
 Weight:

Hospitalisation: Age: 36

Onset Date: DOB: 25/11/1958

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

104011011 20141101			
Preferred Term	Severity	Report Description	Treatment
Injection site reaction			Promethazine oral, antihistamine

Medicine Details:

BENZTROPINE MESYLATE (Other drug)		Reason: P	Paralysis agitans	
Tablet	2.0 Milligram	Daily	Oral	
Batch:	Started: 10/12/1994		Stopped:	
THIORIDAZINE HYDROCHLORIDE (Other	drug)	Reason: A	Acute schizophrenia episode	
Oral application	20.0 Milligram	Daily	Oral	
Batch:	Started: 10/12/1994		Stopped:	
FLUANXOL (Suspected)		Reason: A	Acute schizophrenia episode	
Injection	40.0 Milligram	Daily	Intramuscular	
Batch:	Started: 01/12/1994		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was rechallenged with same reaction occurring.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report I	Details:
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 Case Number:
 99586
 Seq: 1
 Gender: M

 Reported:
 15/03/1995
 Weight:

Hospitalisation: Age: 47Y

Onset Date: 31/01/1995 **DOB**:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site inflammation		Redness and swelling at injection site	

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected) Reason: Unspecified schizophrenia

Injection 4.0 Dose Unspecified Weekly Intravenous

Batch: Started: 08/11/1994 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 04:59PM Database: pusime02 ADRS004 Page 23 of 105



Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Case Numb							
ospitalisatio	ed: 15/03/199	Seq 5	: 1			ender: eight: Age:	
•	ite: 07/02/199	5				DOB:	
Outcom	ne: Not yet red	covered			Cau	sality:	Causality certain
eaction De			1				
	ferred Term	Se	everity		ort Description		Treatment
njection site i	inflammation		F	Redness and sw	elling at injection site		
Medicine D	Details: BONATE (Other c	drug)		Reas	son:		
			500.0 M		Daily		
Batch			Started:	L TERM	Stopped:		
Batch	: AZINE HYDROCH		Started: r drug)	L TERM	Stopped:		
Batch CHLORPROM/	AZINE HYDROCH	ILORIDE (Othe	started: r drug) 800.0 M	L TERM Reas	Stopped: son: Daily		
Batch CHLORPROM/ Batch	AZINE HYDROCH	ILORIDE (Othe	Started: r drug)	L TERM	Stopped: Son: Daily Stopped:		
Batch CHLORPROM <i>i</i> Batch	AZINE HYDROCH	ILORIDE (Othe	Started: r drug) 800.0 M Started:	L TERM Reas filligram L TERM	Stopped: Son: Daily Stopped:		
Batch CHLORPROM <i>i</i> Batch	AZINE HYDROCH : Other drug)	HLORIDE (Othe	Started: r drug) 800.0 M Started:	L TERM Reas filligram L TERM Reas	Stopped: Son: Daily Stopped: Son:		
Batch CHLORPROMA Batch FOLIC ACID (C	AZINE HYDROCH : Other drug)	HLORIDE (Othe	Started: r drug) 800.0 M Started: 5.0 M Started:	L TERM Reas filligram L TERM Reas filligram L TERM	Stopped: Daily Stopped: Daily Stopped: Son: Daily Stopped: Son:		
Batch CHLORPROMA Batch FOLIC ACID (C Batch MULTIVITAMIN	AZINE HYDROCH : Other drug) : NS (Other drug)	ILORIDE (Othe	Started: r drug) 800.0 M Started: 5.0 M Started:	L TERM Reas filligram L TERM Reas filligram L TERM Reas lose Unspecified	Stopped: Son: Daily Stopped: Son: Daily Stopped: Son: Alternate days		
Batch CHLORPROMA Batch FOLIC ACID (C	AZINE HYDROCH : Other drug) : NS (Other drug)	ILORIDE (Othe	Started: r drug) 800.0 M Started: 5.0 M Started:	L TERM Reas filligram L TERM Reas filligram L TERM	Stopped: Daily Stopped: Daily Stopped: Son: Daily Stopped: Son:		
Batch CHLORPROMA Batch FOLIC ACID (C Batch MULTIVITAMIN Batch	AZINE HYDROCH : Other drug) : NS (Other drug)	S S S	Started: r drug) 800.0 M Started: 5.0 M Started:	L TERM Reas filligram L TERM Reas filligram L TERM Reas lose Unspecified	Stopped: Son: Daily Stopped: Son: Daily Stopped: Son: Alternate days		

Report Run: 01/06/2007 05:00PM Database: pusime02 ADRS004 Page 24 of 105



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detail	15/03/1995 07/02/1995 Not yet recovered	Seq: 1		Gender: Weight: Age: DOB: Causality:	
Medicine Deta					
	ECANOATE (Suspecte		Reason:	Introveneus	
Injection Batch:		200.0 Milligram Started: 21/12/1994	Weekly	Intravenous ped:	
Laboratory In	vestigations:				
Additional Inf	ormation:				

Report Run: 01/06/2007 05:00PM Database: pusime02 ADRS004 Page 25 of 105



Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

oort Details:						
se Number: 99591	Seq: 1		Gender			
Reported: 15/03/1995		Weight:				
pitalisation:			Age			
Onset Date: 31/01/1995			DOE			
Outcome: Not yet recovered	d		Causality	Causality: Causality certain		
ction Details: Preferred Term	Severity	Penort	Description	Treatment		
ection site inflammation	Severity	Redness and swell	·	Пеашеш		
edicine Details: ENZTROPINE MESYLATE (Other drug		Reasor Milligram Da	ı: aily			
Batch:	Started:	L TERM	Stopped:			
LUPENTHIXOL DECANOATE (Suspec		Reasor		ia		
, .			eekly			
Batch:	Started: 06/	12/1994	Stopped:			
aboratory Investigations: Date Type Ran	ge Date Tes	ted Result	Det	ails		
additional Information:						
ort Run: 01/06/2007 05:00PM Datal	base: pusime02	ADF	.S004	Page 26 of 10		



Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 101201 Seq: 1 Gender: F

Reported: 31/05/1995 Weight:
Hospitalisation: Age:
Onset Date: 24/03/1995 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash erythematous			

Medicine Details:

 FLUANXOL (Suspected)
 Reason:
 Unspecified schizophrenia

Injection 0.0 Intramuscular

Batch: Started: 01/03/1995 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.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 101386 Seq: 1 Gender: F

Reported: 08/06/1995 Weight: 65.00
Hospitalisation: Age: 34Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

100011011 D 0101101			
Preferred Term	Severity	Report Description	Treatment
Injection site pain		Extreme pain to whole of I arm & I buttock	Analgesia for pain relief> panadeine forte

Medicine Details:

CARBAMAZEPINE (Other drug)			Reason:		
Oral application	800.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	CONTIN
PROCYCLIDINE HYDROCHLORIDE (Other	er drug)		Reason:		
Tablet	10.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	CONTIN
CHLORPROMAZINE HYDROCHLORIDE	(Other drug)		Reason:		
Oral application	600.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	CONTIN
MOCLOBEMIDE (Other drug)			Reason:		
Tablet	450.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced same reaction on two occasions.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

lospitalisation: Onset Date: Outcome: eaction Deta	Recovered	Seq: 1			Gender: Weight: Age: DOB: Causality:	65.00 34Y
Medicine Det				Danasa.		
TEMAZEPAM (Oth	ier arug)	10.0	Milligram	Reason:	Oral	
Batch:		Started:	Milligram	Daily	Stopped:	CONTIN
FLUANXOL (Susp	ected)	Starteu.		Reason: l	Inspecified schizophrenia	
Injection	Jolouj	60 O	Milligram	2 times	Intramuscu	
Batch:		Started:	.viiiigraiii	2 111163	Stopped:	
_aboratory Ir	nvestigations:					

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Re	port	Det	tail	s:

 Case Number:
 101414
 Seq: 1
 Gender:
 F

 Reported:
 08/06/1995
 Weight:

Hospitalisation: Age: 26Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			
Hyperkinesia			
Hypertonia			

Medicine Details:

 FLUANXOL (Suspected)
 Reason:
 Unspecified schizophrenia

 Injection
 50.0
 Milligram
 Fortnightly
 Intramuscular

 Batch:
 Started:
 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction ocurred approx. once a fortnight.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

 Case Number:
 101462
 Seq: 1
 Gender:
 F

 Reported:
 09/06/1995
 Weight:
 60.00

Hospitalisation:
Onset Date:
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

١,	reaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Speech disorder		Inability to communicate beyond yes/no	
	Depression			
	Visual disturbance			

Medicine Details:

Medicine Details.			
FLUANXOL (Suspected)		Reason: Unspecified schizoph	nrenia
Injection	25.0 Milligram	Weekly Intrar	nuscular
Batch:	Started: 22/10/1993	Stopped: 12/12	2/1994
CHLORPROMAZINE HYDROCHLO	RIDE (Suspected)	Reason: Unspecified schizoph	nrenia
Oral application	75.0 Milligram	Daily Oral	
Batch:	Started: 01/08/1993	Stopped:	CONTIN

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Reporte ospitalisation			1		G	ender: F
ospitalisatio	d : 19/07/199	95			W	eight: 94.00
	n:					Age: 54Y
Onset Dat	te:					DOB:
Outcom	e: Not yet re	covered			Cau	sality: Causality certain
action Det	tails:					
Prefe	erred Term	Se	everity	Repo	ort Description	Treatment
jection site re	eaction		Sm	nall lumps at ir	njection site	
edicine D		HLORIDE (Other	r drug) 0.0	Reas	son:	
Batch:		Sf	tarted:		Stopped:	
NAFRANIL (O	ther drug)			Reas	son:	
			0.0			
Batch:		St	tarted:		Stopped:	
HYROXINE SO	ODIUM (Other d	rug)		Reas	son:	
			0.0			
Batch:		St	tarted:		Stopped:	
	ispected)			Reas	•	ophrenia
LUANXOL (Su			100.0 Milli	igram	Weekly	
LUANXOL (Su						
		St	tarted: 13/05/19	995	Stopped: 26	6/06/1995
LUANXOL (Su Batch:			tarted: 13/05/1	995	Stopped: 26	6/06/1995
LUANXOL (Su Batch:			tarted: 13/05/19	995 Result	Stopped: 26	5/06/1995 Details

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 103685 Seq: 1 Gender: M

Reported: 25/09/1995 Weight:

Hospitalisation: Age: 67Y
Onset Date: 13/09/1995
DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

•	todotion Details.			
	Preferred Term	Severity	Report Description	Treatment
	Face oedema			
	Urticaria			

Medicine Details:

FLUANXOL (Suspected) Reason: Paranoia

Injection 20.0 Milligram Weekly Intramuscular

Batch: Started: 26/08/1995 Stopped: 21/09/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was rechallenged on fluanxol with same reaction occurring.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL, FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 103959 Seq: 1 Gender: F

Reported: 09/10/1995

Hospitalisation:
Onset Date:

Weight: 56.00
Age: 52Y
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment					
Eosinophilia								
Pruritus								
Rash maculo-papular								

Medicine Details:

MEGICINE DETAILS.			
DOXEPIN HYDROCHLORIDE (Other drug)		Reason: Unspecified p	sychosis
Oral application	150.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1989	Stopped:	31/01/1995
FLUANXOL (Suspected)		Reason: Unspecified p	sychosis
Injection	60.0 Milligram	Weekly	Intramuscular
Batch:	Started: 01/03/1995	Stopped:	28/09/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

 Case Number:
 104397
 Seq: 1
 Gender: M

 Reported:
 02/11/1995
 Weight:

Hospitalisation: Age: 67Y
Onset Date: 30/10/1995
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Face oedema		Facial swelling	Tabs claratyne - one daily

Medicine Details:

RASTINON (Other drug) Reason: Diabetes mellitus

2.0 Dose Unspecified Daily

Batch: Started: 01/01/1983 Stopped:

ZESTRIL (Other drug) Reason: Essential benign hypertension

1.0 Dose Unspecified Daily

Batch: Started: 04/03/1995 Stopped:

FLUANXOL (Suspected) Reason: Paranoia

Injection 0.0 Intramuscular

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Facial swelling after two injections the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Report Details:

Case Number: 104528

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Seq: 1

Reported: 09/11/1995		Weight:							
lospitalisation:		Age:							
Onset Date:		DOB:							
Outcome: Unknown		Causality: Causality certain							
eaction Details:									
Preferred Term	Severity	Report D	escription	Treatment					
Injection site reaction									
Rash erythematous									
Medicine Details:									
FLUANXOL (Suspected)		Reason:							
Injection Batch:	0.0 Started:		Intraver Stopped:	nous					
Laboratory Investigatio	ons:								
Date Type	Range Date Tested	Result	De	etails					
Additional Information:									
eport Run: 01/06/2007 05:00PM	Database: pusime02	ADRS	3004	Page 36 of 105					



Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 104550 Seq: 1 Gender: M

Reported: 10/11/1995 Weight: Hospitalisation: Age:

Onset Date: 23/08/1995 **DOB**:

Outcome: Unknown Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site reaction			

Medicine Details:

FLUANXOL (Suspected) Reason: Unspecified schizophrenia

Injection 0.0 Intramuscular

Batch: Started: 01/08/1995 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

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

Case Number: 104551 Seq: 1 Gender: M

Reported: 10/11/1995 Weight:
Hospitalisation: Age:
Onset Date: 23/08/1995 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Angioedema			
Periorbital oedema			
Rash erythematous			

Medicine Details:

 FLUANXOL (Suspected)
 Reason:
 Unspecified schizophrenia

 Injection
 0.0
 Intramuscular

Batch: Started: 01/08/1995 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.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

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

Case Number: 104564 Seq: 1 Gender: U

 Reported:
 13/11/1995
 Weight:

 Hospitalisation:
 Age:

 Onset Date:
 07/09/1995
 DOB:

Outcome: Unknown Causality: Causality certain

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Injection site reaction			
Oedema			
Pruritus			

Medicine Details:

 FLUANXOL (Suspected)
 Reason:
 Unspecified schizophrenia

 Injection
 0.0
 Intramuscular

 Batch:
 Started: 01/08/1995
 Stopped:
 CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

ase Number: 104571	Seq: 1		Gend	er: M
Reported: 13/11/1995			Weigl	nt:
spitalisation:			Ag	je:
Onset Date : 07/09/1995			DC	B:
Outcome: Recovered			Causali	ty: Causality certain
ction Details:		_		
Preferred Term	Severity	Repo	ort Description	Treatment
ection site reaction		Subcutaneous It I buttock	ump 1 1/2 inch in diameter	
edicine Details:				
UANXOL (Suspected)		Rea	son: Unspecified schizophre	enia
Injection	100.0	Milligram	Fortnightly Intramu	uscular
Batch:	Started:		Stopped:	
		ed Result	D	etails
	nge Date Test	red Result	D	etails
		ed Result	D	etails
		ed Result	D	etails
		ed Result	D	etails
Date Type Ra		red Result	D	etails
aboratory Investigations: Date Type Rai		ed Result	D	etails
Date Type Ra		ed Result	D	etails
Date Type Ra		red Result	D	etails
Date Type Ra		ed Result	D	etails

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 104578 Seq: 1 Gender: F

Reported: 13/11/1995 Weight:
Hospitalisation: Age:
Onset Date: 07/09/1995 DOB:

Outcome: Unknown Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema			

Medicine Details:

 FLUANXOL (Suspected)
 Reason:
 Unspecified schizophrenia

 Injection
 0.0
 Intramuscular

Batch: Started: 01/08/1995 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run: 01/06/2007 05:00PM Database: pusime02 ADRS004 Page 41 of 105



Report Details:

Case Number: 104597

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: U

Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Seq: 1

ospitalisation:				Weigl	nt:
				Ag	je:
Onset Date: 18/08/1995				DC	B:
Outcome: Unknown				Causali	ty: Causality certain
eaction Details:					
Preferred Term	Seve	rity	Report De	escription	Treatment
jection site reaction					
edema					
ruritus					
yrexia					
lash erythematous					
ledicine Details:					
FLUANXOL (Suspected)			Reason:	Unspecified schizophre	
Injection		0.0		Intrami	
Batch:	Start	ed: 03/08/1995		Stopped: 18/08/	995
aboratory Investigation	ns:				
aboratory Investigation		ate Tested	Result	D	etails
		ate Tested	Result	D	etails
		ate Tested	Result	D	etails
aboratory Investigation Date Type		ate Tested	Result	D	etails
Date Type		ate Tested	Result	D	etails
Date Type		ate Tested	Result	D	etails
		ate Tested	Result	D	etails
Date Type		ate Tested	Result	D	etails



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Hospitalisation Onset Date Outcome Reaction Deta	: 01/12/199 : : : Unknown ails:		1		Weig A D	der: U ght: age: OB: lity: Causality possible
	red Term	Se	verity	Repo	ort Description	Treatment
Hepatic function Vomiting	abnormal					
Medicine De						
FLUANXOL (Sus	pected)		0.0	Reas	son:	
Ratch:	Batch:		0.0 Started:		Stopped:	
	CLOPIXOL DEPOT (Suspected)		arteu.	Reas	Reason:	
			0.0			
Batch:		St	Started:		Stopped:	
Laboratory I	nvestigat	ions: Range	Date Tested	Result		Details
Date	туре	Range	Date Testeu	Result		Details
Additional Ir	nformatio	n:				

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:	Rei	port	Deta	ils:
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Case Number: 105053 Seq: 1 Gender: M

Reported: 04/12/1995 Weight: 130.00 Hospitalisation: Age: 46Y

Onset Date: 10/10/1995 DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Rash		6 cm diameter on injection site	
Injection site reaction			
Pruritus			

Medicine Details:

AURORIX (Other drug)		Reason: Depre	ssion	
Tablet	150.0 Milligram	Daily	Oral	
Batch:	Started: 31/10/1994	St	opped:	
COGENTIN (Other drug)		Reason:		
Tablet	1.0 Milligram	Daily	Oral	
Batch:	Started:	St	opped:	
FLUANXOL (Suspected)		Reason:		
Injection	100.0 Milligram	Daily	Intramuscular	
Batch:	Started: 17/02/1994	St	opped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 05:00PM Database: pusime02 ADRS004 Page 44 of 105



Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:			
Case Number: 105867 Reported: 15/01/1996 Hospitalisation: Onset Date: 21/12/1995 Outcome: Recovered	Seq: 1	A(ler: F ht: 76.00 ge: 30Y DB: ity: Causality certain
eaction Details:		Causai	ity. Causanty Certain
Preferred Term	Severity	Report Description	Treatment
Injection site reaction Pruritus		Red itchy lump rose 2cm, hard.	
Medicine Details:	4 d)	Danasa Hannaifiad anyahasi	
FLUPENTHIXOL DECANOATE (Susp		Reason: Unspecified psychosis Milligram 1 time Intram	uscular
Injection Batch:	Started:	Milligram 1 time Intram Stopped:	uscular
Laboratory Investigations Date Type R	ange Date Teste	ed Result E	Petails

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL, FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 106627 Seq: 1 Gender: F

Reported: 22/02/1996 Weight: 53.00 Hospitalisation: Age: 42Y

Onset Date: 26/07/1995 **DOB**:

Outcome: Unknown Causality: Causality certain

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Anxiety			
Asthenia			
Hypotension			
Malaise			
Syncope			Prednisolone
Syncope			

Medicine Details:

Medicine Details:		
DISIPAL (Other drug)	Reason: Prophylaxis	
Tablet	100.0 Milligram Daily Oral	
Batch:	Started: 01/01/1989 Stopped: 28/10/1995	
TIMOLOL MALEATE-PILOCARPINI	(Other drug) Reason: Unspecified glaucoma	
Eye Drops	3.0 Dose Unspecified Daily Ophthalmic	
Batch:	Started: 01/01/1993 Stopped:	
FLUANXOL (Suspected)	Reason: Other atyp forms schizophrenia	
Injection	40.0 Milligram Alternating-other Intramuscular	
Batch:	Started : 01/04/1995	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction recurred on 4/8/95 after im fluanxol the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. 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: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 106628 Seq: 1 Gender: F

Reported: 22/02/1996 Weight: 53.00
Hospitalisation: Admitted to hospital Age: 42Y
Onset Date: 04/08/1995 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilic pneumonia			

Medicine Details:

	Reason: Anxiety neurosis
0.7 Milligram	Daily Oral
Started: 27/07/1995	Stopped: 28/10/1995
	Reason: Other atyp forms schizophrenia
40.0 Milligram	Alternating-other Intramuscular
Started: 01/04/1995	Stopped: 12/09/1995
	Started: 27/07/1995 40.0 Milligram

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See report no 106627 for other drugs the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

eport Details:						
ase Number: 106668	Seq: 1		Gende	er: U		
Reported: 26/02/1996	·	Weight:				
spitalisation:			Ag			
Onset Date: 10/11/1995				о. В:		
Outcome: Unknown			Causain	ty: Causality certain		
action Details:	1					
Preferred Term	Severity	Report	Description	Treatment		
ection site reaction						
edicine Details:		Reasor	: Unspecified schizophre	enia		
Injection	0.0		Intramu			
Batch:	Started:		Stopped:			
aboratory Investigations	:					
Date Type Ra	ange Date Tested	Result	De	etails		
dditional Information:	•					

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report De	etails:					
Case Num Repor Hospitalisat Onset D	ber: 107387 ted: 28/03/199	96			Gender: Weight: Age: DOB: Causality:	29Y
Reaction D	etails:					
Pro Rash	eferred Term	Severity	Report	Description		Treatment
Medicine FLUANXOL ((Suspected)	10.0	Reaso i Milligram 1	n: Unspecified	I schizophrenia Intramuscu	
Bato		Started: 27/1	2/1995	Stoppe		
FLUANXOL (Reason		l schizophrenia	
Inject Bato		50.0 Started: 03/0	•	time Stoppe	Intramuscu	ılar
Laborator	ry Investigat	ions:				
Date	Туре	Range Date Teste	ed Result		Detai	ls
Additiona	ıl Informatio	n:				

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 107738 Seq: 1 Gender: F

Reported: 04/04/1996 Weight: 55.00 Hospitalisation: Age: 38

Onset Date: DOB: 05/05/1957

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Sensation of bugs under skin.	Propranolol

Medicine Details:

wedicine Details:					
ALCOHOL (Suspected)			Reason:		
	0.0				
Batch:	Started:			Stopped:	
FLUPENTHIXOL DECANOATE (Suspected))		Reason:	Schizophrenia	1
Injection	60.0	Milligram	Weel	dy	Intramuscular
Batch:	Started:			Stopped:	
AROPAX (Suspected)			Reason:	Depression	
Tablet	20.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Senation of bugs under the skin commenced when on flupenthixol and worsened when aropax added.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL, FLUPENTHIXOL DECANOATE

Report Details:

 Case Number:
 107936
 Seq: 1
 Gender:
 F

 Reported:
 17/04/1996
 Weight:

Hospitalisation: Age: 33Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site inflammation			
Injection site pain			

Medicine Details:

 HALDOL DECANOATE (Other drug)
 Reason:

 Injection
 50.0
 Milligram
 Daily
 Intramuscular

 Batch:
 Started: 01/01/1995
 Stopped: 28/02/1996

FLUPENTHIXOL DECANOATE (Suspected) Reason:

Injection 60.0 Milligram Fortnightly Intramuscular

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Additional Information:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Reporte	er: 108126 ed: 30/04/1996	Seq: 1					_	: 72.00	
ospitalisatio							_	: 42Y	
	te: 14/03/1996						DOE		
	ne: Recovered						Causality	: Causalit	ty certain
eaction De	etalis: erred Term	Seve	rity	Por	ort De	scription		Tr	eatment
	abscess sterile	Seven	ity	110	JOIL DE	Scription		111	Calificit
Andicina D	Notaile:								
				Re	ason:	Hallucination	ns		
	uspected)		100.0 Mill		ason: Fortni		ns Intramus	cular	
FLUANXOL (Su	uspected) on		100.0 Mill ed: 12/03/1	ligram		ghtly			
	uspected) on			ligram		ghtly	Intramus		
FLUANXOL (Su Injectio Batch:	uspected) on	Start		ligram		ghtly	Intramus		

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:						
Case Number: 108426 Reported: 13/05/1996 ospitalisation: Onset Date: 15/04/1996	Seq: 1	_	:: 54.00 :: 25Y			
Outcome: Recovered		Causality	: Causality certain			
eaction Details:	I	5 15 10				
Preferred Term	Severity	Report Description	Treatment			
njection site inflammation		Localised erythematous area, 7cm diameter				
Medicine Details:						
FLUPENTHIXOL DECANOATE (Susp		Reason: Unspecified psychosis				
Injection Batch:	40.0 N Started: 12/0	40.0 Milligram 1 time Intramuscular Started: 12/04/1996 Stopped:				
Laboratory Investigations Date Type F	S: Range Date Teste	ed Result De	ails			

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report De	tai	ls:
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Case Number: 108597 Seq: 1 Gender: F

Reported: 21/05/1996 Weight:
Hospitalisation: Age: 49Y

Onset Date: 02/05/1996 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site reaction		Fibroids on buttocks	

Medicine Details:

SERENACE (Other drug)		Reason: Unspecified schize	pphrenia
	60.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
SEREPAX (Other drug)		Reason: Anxiety neurosis	
	900.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
MELLERIL (Other drug)		Reason: Unspecified schize	phrenia
	400.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
FLUANXOL (Suspected)		Reason: Unspecified schize	pphrenia
Injection	100.0 Milligram	Fortnightly Int	ramuscular
Batch:	Started: 25/04/1996	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Rep	ort	Detai	ls:
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 Case Number:
 109334
 Seq: 1
 Gender:
 F

 Reported:
 18/06/1996
 Weight:

Hospitalisation: Age: 48Y
Onset Date: 31/05/1996
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

LITHIUM CARBONATE (Suspected)		Reason:	Other malig n no spec of site
	0.0		

Batch: Started: Stopped:

FLUPENTHIXOL DECANOATE (Suspected) Reason:

0.0

Batch: Started: Stopped:

COGENTIN (Suspected) Reason:

Tablet 2.0 Milligram Daily Oral

Batch: Started: 01/01/1991 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:	Re	po	rt	De	tai	ls:
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Case Number: 110500 Seq: 1 Gender: M

Reported: 06/08/1996 Weight:
Hospitalisation: Age: 20Y

Onset Date: 14/02/1996 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

,	caction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Injection site abscess		Infected pus at injection site.	
	Injection site pain		Painful lump at injection site.	

Medicine Details:

FLUANXOL (Suspected) Reason: Unspecified psychosis

Injection 20.0 Milligram Daily Intramuscular

Batch: Started: 31/01/1996 Stopped: 14/02/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details	:	
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Case Number: 110501 Seq: 1 Gender: F

Reported: 06/08/1996 Weight:
Hospitalisation: Age: 45Y

Onset Date: 12/07/1996 DOB:
Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site inflammation		Red itchy swelling at inj site 4cm in size.	

Medicine Details:

FLUANXOL (Suspected) Reason: Schizophrenia

Injection 20.0 Milligram Daily Intramuscular

Batch: Started: 02/07/1996 Stopped: 12/07/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Re	po	rt	De	tai	ls:
	\sim		-	u	

 Case Number:
 110502
 Seq: 1
 Gender:
 F

 Reported:
 06/08/1996
 Weight:

Hospitalisation:
Onset Date: 24/07/1996
Age: 44Y
DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

•	todotion Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
	Injection site inflammation		Inflammed lump at inj site.	
	Injection site pain		Inj site was painful.	

Medicine Details:

 FLUANXOL (Suspected)
 Reason:
 Senile and presentile dementia

 Injection
 40.0 Milligram
 Daily
 Intramuscular

 Batch:
 Started: 26/06/1996
 Stopped: 24/07/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:	Rei	port	Deta	ils:
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Case Number: 110919 Seq: 1 Gender: M
Reported: 16/08/1996 Weight:
Hospitalisation: Age: A2

Onset Date: 09/08/1996 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•				1
	Preferred Term	Severity	Report Description	Treatment
	Gait disturbance		Pisa syndrome-high stepping gait	
	Coordination abnormal		Pisa syndrome-leaning backwards	

Medicine Details:

BENZTROPINE MESYLATE (Suspected)		ı	Reason:	Other&unspecif brain disease	es
	2.0 M	lilligram	Week	ly	
Batch:	Started:			Stopped:	
FLUANXOL (Suspected)		ı	Reason:	Unspecified psychosis	
	150.0 M	lilligram	Month	nly	
Batch:	Started:			Stopped:	5M

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Re	po	rt	De	tai	ls:
	~~				

Case Number:110949Seq:1Gender:FReported:19/08/1996Weight:Hospitalisation:Age:

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

Reaction Details:

Reaction Details:			
Preferred Term	Severity	Report Description	Treatment
Arthralgia			
Face oedema			
Pyrexia			

Medicine Details:

<u>Medicine Details:</u>			
FLUPENTHIXOL DECANOATE (Suspected)		Reason:	
Injection	0.0	Intramuscular	
Batch:	Started:	Stopped:	
AROPAX (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1995	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haematology				Fbc - wcc 6.3 (80% neutrophils), esr - 43.

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: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:			
Case Number: 111402	Seq : 1	Gender	
Reported: 05/09/1996		Weight	
ospitalisation:		_	: 41Y
Onset Date:		DOE	
Outcome: Recovered		Causanty	: Causality certain
eaction Details: Preferred Term	Severity	Report Description	Treatment
njection site reaction		Induration, tenderness, inflammation at inj	
Medicine Details:	spected)	Reason: Schizophrenia	
Injection	20.0 M	Milligram 2 times Intramus	cular
Batch:	Started:	Stopped:	
		·	
Laboratory Investigation	1S: Range Date Teste		ails

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report	Details:
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Case Number: 111552 Seq: 1 Gender: F

Reported: 11/09/1996 Weight: 60.00
Hospitalisation: Age: 37Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

,	Cachon Details.				_
	Preferred Term	Severity	Report Description	Treatment]
	Pruritus			Phenergan	1
	Rash				

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Suspected) Reason:

0.0

Batch: Started: Stopped:

FLUPENTHIXOL DECANOATE (Suspected) Reason: Unspecified psychosis

Injection 100.0 Milligram Daily Intramuscular

Batch: Started: 01/01/1995 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Repor	t De	tails:
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 Case Number:
 112259
 Seq: 1
 Gender: M

 Reported:
 15/10/1996
 Weight:

Hospitalisation: Age: 34Y
Onset Date: 09/10/1996 DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

104011011 D 0141101			
Preferred Term	Severity	Report Description	Treatment
Injection site reaction		Large irreg, erythematous, nontender area inj site	

Medicine Details:

FLUANXOL (Suspected) Reason: Unspecified schizophrenia

20.0 Milligram Daily

Batch: Started: 06/08/1996 **Stopped:** 09/10/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

 Case Number:
 114103
 Seq: 1
 Gender: M

 Reported:
 23/12/1996
 Weight:

Hospitalisation: Age: 42Y

Onset Date: 31/10/1996 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Tremor		Involuntary tremors	
Speech disorder		Slurring of speech	
Headache	Severe		Specialist to wean patient off medication
Hypertension			

Medicine Details:

FLUANXOL (Suspected) Reason: Depression

Injection 40.0 Milligram Alternate weeks Intramuscular

Batch: Started: 01/06/1995 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Seq: 1
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ıs:
Range Da
Database: pusimo

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:	Re	po	rt	De	tai	ls:
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Case Number: 117623 Seq: 1 Gender: F

 Reported:
 16/05/1997
 Weight:
 75.00

 Hospitalisation:
 Age:
 32Y

Onset Date: 30/04/1997 **DOB**:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
lr	jection site reaction		Local abscess, induration, tenderness (r) buttock	

Medicine Details:

 FLUANXOL (Suspected)
 Reason:
 Unspecified schizophrenia

 Injection
 40.0 Milligram
 1 time
 Intramuscular

 Batch:
 Started: 30/04/1997
 Stopped: 30/04/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number:120158Seq:1Gender:FReported:22/08/1997Weight:70.00Hospitalisation:Admitted to hospitalAge:71Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Admitted to hospital, nasogastric feeding,

Medicine Details:

ZANTAC (Other drug)	Reason:				
	3.0 Dose Unspec	cified Daily			
Batch:	Started:	St	topped:		
COLOXYL (Other drug)		Reason:			
	3.0 Dose Unspec	cified Daily			
Batch:	Started:	St	topped:		
TAZAC (Other drug)		Reason:			
	600.0 Milligram	Daily			
Batch:	Started: 23/01/1997	St	topped:		
LARGACTIL (Suspected)		Reason: Otr sp	pec symp psychopathol nec		
Injection	50.0 Milligram	1 time	Intramuscular		
Batch:	Started: 09/02/1997	St	topped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient bedbound. prior to neuroleptic administration walking independently. patient discharged to nursing home 22/07/1997. developed pneumonia and died on 9/8/1997

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:	ort Details:
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Case Number:120158Seq: 1Gender:FReported:22/08/1997Weight:70.00Hospitalisation:Admitted to hospitalAge: 71Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

FLUANXOL (Suspected)		Reason: Otr spec symp psychopathol nec
Injection	20.0 Milligram	1 time Intramuscular
Batch:	Started: 08/02/1997	Stopped:
HALDOL DECANOATE (Suspected)		Reason: Otr spec symp psychopathol nec
Injection	150.0 Milligram	1 time Intramuscular
Batch:	Started: 13/02/1997	Stopped:
AURORIX (Suspected)		Reason: Depression
Tablet	600.0 Milligram	Daily Oral
Batch:	Started: 13/02/1997	Stopped:

Laboratory Investigations:

Additional Information:

Patient bedbound. prior to neuroleptic administration walking independently. patient discharged to nursing home 22/07/1997. developed pneumonia and died on 9/8/1997

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report	Datai	10:
REDUIL	Delai	15

Case Number: 122869 Seq: 1 Gender: F

 Reported: 28/11/1997
 Weight: 80.00

 Hospitalisation:
 Age: 35Y

 Onset Date: 25/11/1997
 DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

teaction Details.				
Preferred Term	Severity	Report Description	Treatment	
Injection site abscess		Hard lump in right arm, red		

Medicine Details:

HALOPERIDOL (Other drug)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	
FLUANXOL (Suspected)		Reason: Unspecified psychosis	
Injection	10.0 Milligram	Weekly Intramuscular	
Batch:	Started: 07/11/1997	Stopped: 12/11/1997	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 125110 Seq: 1 Gender: M

Reported: 19/02/1998 Weight: 112.00 Hospitalisation: Age: 30Y

Onset Date: 07/02/1998 DOB:

Outcome: Recovered with sequelae Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site reaction		Lump the size of third of a tennis ball.	

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected) Reason:

Injection 80.0 Milligram Fortnightly Intravenous

Batch: Started: 12/11/1997 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Sequelae: sterile lump at site, palpable below skin. no history of asthma or allergies. initial reaction developed 1-2 days after depot injection.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

 Case Number:
 126759
 Seq: 1
 Gender:
 F

 Reported:
 17/04/1998
 Weight:

Hospitalisation: Age: 31

Onset Date: 04/02/1998 **DOB**: 18/07/1966

Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site reaction	January	Local reaction after injection	Pt changed to new depot and different base - sesame oil base - haldol ceased flupenthixol decanoate.
Cellulitis			

Medicine Details:

DIAZEPAM (Other drug) Reason:

2.5 Milligram As necessary

Batch: Started: 07/01/1998 Stopped:

MULTIVITAMINS (Other drug) Reason:

1.0 Dose Unspecified Daily

Batch: Started: 03/02/1998 Stopped:

FLUPENTHIXOL DECANOATE (Suspected) Reason: Unspecified psychosis

20.0 Milligram Fortnightly

Batch: Started: 19/01/1998 **Stopped:** 10/02/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt allergic to codeine and penicillin.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 126922 Seq: 1 Gender: M

Reported: 27/04/1998 Weight: 95.00 Hospitalisation: Age: 37Y

Onset Date: 11/03/1998 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site inflammation		Infammatory, red, itchy reaction at inj site.	Discontinued fluanxol and returned to modecate.

Medicine Details:

RISPERDAL (Other drug) Reason: Unspecified psychosis

6.0 Milligram Daily

Batch: Started: 10/02/1998 **Stopped:** 04/03/1998

FLUANXOL (Suspected) Reason: Unspecified psychosis

 Injection
 40.0 Milligram
 2 times
 Intramuscular

 Batch:
 Started: 17/02/1998
 Stopped: 31/03/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced reaction to fluanxol on two seperate occassions.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 127636 Seq: 1 Gender: M

Reported: 21/05/1998 Weight: 115.00 Hospitalisation: Age: 25Y

Onset Date: 26/04/1998 DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

touction botaile:			
Preferred Term	Severity	Report Description	Treatment
Cellulitis		Palpable cellulitis 100mm across, 30mm deep	
Injection site reaction			

Medicine Details:

TEMAZEPAM (Other drug) Reason: Specific disorders of sleep

Oral application 10.0 Milligram As necessary Oral

Batch: Started: 27/07/1997 Stopped: CONTIN

FLUPENTHIXOL DECANOATE (Suspected) Reason:

Injection 40.0 Milligram 1 time Intramuscular

Batch: Started: 23/04/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

First administration caused no reaction until after 2 administration. then there was a gross local reaction at 2nd inj site and a minor reaction at 1st site.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

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

Case Number: 134015 Seq: 1 Gender: F

 Reported:
 04/12/1998
 Weight:
 73.00

 Hospitalisation:
 Age:
 37Y

 Onset Date:
 20/11/1998
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Took approx 200 tablets of stelazine	Charcoal, tacrine.

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected)		Reason:	Depression		
Injection	160.0 Mil	illigram Week	ly	Intramuscular	
Batch:	Started:		Stopped:		CONTIN
PROZAC (Suspected)		Reason:	Depression		
Oral application	40.0 Mil	illigram Daily		Oral	
Batch:	Started:		Stopped:		CONTIN
COGENTIN (Suspected)		Reason:	Depression		
	1.0 Mil	illigram Daily			
Batch:	Started:		Stopped:		CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

 Case Number:
 134345
 Seq: 1
 Gender:
 F

 Reported:
 16/12/1998
 Weight:

Hospitalisation: Admitted to hospital **Age:** 50

Onset Date: 28/10/1998 **DOB**: 21/10/1948

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal tubular necrosis Renal failure acute		,	Required renal dialysis. all medication ceased except flupenthixol which was reintroduced.
Malaise Nausea			

Medicine Details:

TEMAZEPAM (Other drug)	F	Reason:	
	20.0 Milligram	1 time	
Batch:	Started: 23/10/1998	Stopped:	
DIAZERAM (Othor drug)		Passan:	

DIAZEPAM (Other drug) Reason:

2.5 Milligram 1 time

Batch: Started: 23/10/1998 Stopped:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason:

50.0 Milligram 1 time

Batch: Started: 23/10/1998 Stopped:

METFORMIN HYDROCHLORIDE (Suspected) Reason:

3.0 Gram Daily

Batch: Started: 22/10/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Renal biopsy =				29/10/98 "renal biopsy": acute tubular necrosis (toxic type) in a background of very mild diffuse diabetic glomerulosclerosis, probable iga disease (mild mesangial proliferative glomerulonephritis) and minimal parenchymal injury.
	Urine creatinine		23/10/1998	0.10	
	Urine creatinine		28/10/1998	1.04	
	Urine urea		23/10/1998	9.9	

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

ospitalisatio	r 134345	_					
ospitalisatio	1. 104040	Seq	ı: 1			Gender:	F
-	d: 16/12/199	98				Weight:	
Onset Dat	n: Admitted	to hospital				Age:	50
	e: 28/10/199					_	21/10/1948
Outcome: Recovered					Causality:	Causality possible	
Reaction Details:						•	,,
edicine De	etails: DE (Suspected))	20.0 M36:		ason:		
Datah.		,	20.0 Millio	-	Daily	Ctannadı	
Batch: CAPTOPRIL (St	uspoctod)	•	Started: 22/10/19		ason:	Stopped:	
CAPTOPRIL (SI	uspecteu)		50.0 Millig		Daily		
			JO.O IVIIIIŲ	giaiii	Daily		
Ratch:			Startod: 22/10/10	202		Stopped:	
Batch:	usnected)	;	Started: 22/10/19		ason:	Stopped:	
	uspected)	•		Re	ason:	Stopped:	
FRUSEMIDE (S	uspected)		20.0 Milliç	Re gram	ason: Daily		
FRUSEMIDE (S Batch:		;		Re gram 998		Stopped:	
FRUSEMIDE (S Batch: FLUPENTHIXOI	L DECANOATE	;	20.0 Milli(Started: 22/10/19	Re gram 998	Daily ason:		ılar
FRUSEMIDE (S	L DECANOATE	(Suspected)	20.0 Milliç	Re gram 998 Re gram	Daily	Stopped:	ular
FRUSEMIDE (So Batch: FLUPENTHIXOI Injection Batch:	L DECANOATE	(Suspected)	20.0 Millig Started: 22/10/19 10.0 Millig	Re gram 998 Re gram	Daily ason:	Stopped:	ular
FRUSEMIDE (So Batch: FLUPENTHIXOI Injection	L DECANOATE	(Suspected)	20.0 Millig Started: 22/10/19 10.0 Millig	Re gram 998 Re gram	Daily ason:	Stopped:	

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Preferred Te				Weig	ht·	
Onset Date: Outcome: Unkr action Details: Preferred Te	nown			Gender: ∪ Weight:		
Outcome: Unkr action Details: Preferred Te	nown				ge:	
eaction Details: Preferred Te	nown			D	OB:	
Preferred Te Renal failure acute				Causality: Causality possible		
Renal failure acute	rm S	everity	Repor	t Description	Treatment	
Medicine Details:						
FLUANXOL (Suspected)		0.0	Reaso	on:		
Batch:		0.0 Started:		Stopped:		
Batch.				оторреи:		
_aboratory Invest	tigations:					
Date Type	Range	Date Tested	Result	[Details	
		1				

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 135351 Seq: 1 Gender: M

Reported: 22/01/1999 **Weight:**

Hospitalisation: Age: 40Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment	
Extrapyramidal disorder		Extrapyramidal side-effects.	Flupenthixol discontinued.	

Medicine Details:

ZYPREXA (Other drug) Reason: Unspecified schizophrenia

Tablet 15.0 Milligram Daily Oral

Batch: Started: 03/11/1997 Stopped: CONTIN

FLUPENTHIXOL DECANOATE (Suspected) Reason: Unspecified schizophrenia

Injection 30.0 Milligram Daily Intramuscular

Batch: Started: Stopped: 17/11/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details		

Additional Information:

History of schizophrenia.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report	Details:
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 Case Number:
 138579
 Seq: 1
 Gender: M

 Reported:
 19/04/1999
 Weight:

 Hospitalisation:
 Age:

 Onset Date:
 01/04/1999
 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatomegaly		Enlarged liver	
Hepatic function abnormal		Liver enzyme raised	
Leukocytosis		Raised white cell count	
Cough			
Hepatic steatosis			
Splenomegaly			

Medicine Details:

ALCOHOL (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
FLUPENTHIXOL DECANOATE (Sus	spected)	Reason:	
	0.0		
Batch:	Started:	Stopped:	
TRIFLUOPERAZINE HYDROCHLOR	RIDE (Suspected)	Reason:	
	0.0		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	0.0	Daily Oral	
Batch:	Started: 17/03/1999	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		01/04/1999	72	
	AST = SGOT		01/04/1999	58	
	Bilirubin		01/04/1999	30	
	GGT = SGGT =		01/04/1999	182	
	SAP = ALP		01/04/1999	118	

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

 Case Number:
 142051
 Seq: 1
 Gender: M

 Reported:
 29/07/1999
 Weight:

Hospitalisation: Age: 18Y
Onset Date: 10/07/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination		Auditory hallucinations	
Hypertonia			Ceased neuroleptics. given hydration and treated with benztropine and clonazepam
Blood creatine phosphokinase incr Dehydration			
Neuroleptic malignant syndrome			
Pyrexia			

Medicine Details:

FLUANXOL (Suspected)		Reason: Unspecified p	sychosis
Injection	100.0 Milligram	Weekly	Intramuscular
Batch:	Started: 31/05/1999	Stopped:	
COGENTIN (Suspected)		Reason:	
Tablet	1.0 Milligram	As necessary	Oral
Batch:	Started: 30/06/1999	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified pa	sychosis
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 01/07/1999	Stopped:	12/07/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine kinase		12/07/1999	138.2	
	Creatine kinase		13/07/1999	-	
	Creatine kinase		23/07/1999	-	
	Creatine		12/07/1999	18689	
	Creatine		13/07/1999	9790	
	Creatine		23/07/1999	148	

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Ren	ort	Deta	ils:
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Case Number: 143076 Seq: 1 Gender: M
Reported: 27/08/1999 Weight:

Hospitalisation: Age: 37Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Eps due to the use of neuroleptics.	

Medicine Details:

Medicine Details.					
FLUPENTHIXOL DECANOATE (Susp	ected)	Reason:			
	0.0				
Batch:	Started: 01/05/1999		Stopped:	CONTIN	
MOCLOBEMIDE (Suspected)		Reason:			
	600.0 Milligram	Daily			
Batch:	Started: 01/01/1998		Stopped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

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	-	VI L		La	

Case Number: 144317 Seq: 1 Gender: M

Reported: 05/10/1999 Weight: 71.00 Hospitalisation: Age: 42Y

Onset Date: 18/07/1999 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysarthria		Slurred speech	

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected) Reason: Unspecified psychosis

Injection 40.0 Milligram Fortnightly Intramuscular Batch: Started: 06/07/1999 Stopped: 30/09/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report De	tails:								
Hospitalisati Onset D	ted: 11/0 on: ate:		Seq vered	: 1			c	DOB	: 74Y
Reaction D									, , , , , , , , , , , , , , , , , , ,
	eferred T	erm	S	everity	Rep	ort Desc	ription		Treatment
Urinary reter	ntion			С	hronic urinary	retention		Pe	ermanent in dwelling cathete
Medicine			spected)		Re	ason:			
Inject		(00	operator,	10.0 M		1 time		Intramuso	ular
Batc	h:			Started: 17/12	1999		Stopped:		
PAROXETINE	HYDROC	HLORIDE (Suspected			ason:			
D-4-	L -		,	20.0 M	_	Daily	04		
Batc OLANZAPINE		ed)		Started: 09/03		ason:	Stopped:		
	- (Guopooi	.ou,		20.0 M		Daily			
Batc	h:		5	Started: 21/05			Stopped:		
Laborator	y Inves Type			Date Tested	Result			Deta	sila
Date	Туре	;	Range	Date Tested	Result			Deta	IIIS
Additiona	l Inforn	nation:							

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

 Case Number:
 161072
 Seq: 1
 Gender:
 F

 Reported:
 31/01/2001
 Weight:

Hospitalisation: Age: 35

Onset Date: 23/01/2001 DOB: 27/07/1965
Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

todotion Botanoi			
Preferred Term	Severity	Report Description	Treatment
Pyrexia		Low grade temperature.	
Injection site reaction			Treated with zyrtec. required a visit to doctor.
Pain			

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected) Reason:

Injection 10.0 Milligram Daily Intramuscular

Batch: Started: 19/01/2001 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking depo provera. no previous allergies. drug injected into right and left arm.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Case Number: 168076 Seq: 1 Reported: 03/09/2001 Iospitalisation: Onset Date: 19/07/2001 Outcome: Recovered eaction Details: Preferred Term Severi Anaphylactoid reaction Medicine Details: FLUPENTHIXOL DECANOATE (Suspected) Injection Batch: Starte	rity	Reas		Gender: M Weight: Age: 51 DOB: 17/02/1950 ausality: Causality possible Treatment Resuscitation, adrenaline hydrocortisone.
Onset Date: 19/07/2001 Outcome: Recovered Paction Details: Preferred Term Severion Anaphylactoid reaction Medicine Details: FLUPENTHIXOL DECANOATE (Suspected) Injection		Reas	С	Age: 51 DOB: 17/02/1950 ausality: Causality possible Treatment Resuscitation, adrenaline
Onset Date: 19/07/2001 Outcome: Recovered Paction Details: Preferred Term Severical Section Anaphylactoid reaction Medicine Details: FLUPENTHIXOL DECANOATE (Suspected) Injection		Reas		DOB: 17/02/1950 ausality: Causality possible Treatment Resuscitation, adrenaline
Preferred Term Severing Anaphylactoid reaction Medicine Details: FLUPENTHIXOL DECANOATE (Suspected) Injection		Reas		Treatment Resuscitation, adrenaline
Preferred Term Severing Anaphylactoid reaction Medicine Details: FLUPENTHIXOL DECANOATE (Suspected) Injection		Reas	rt Description	Resuscitation, adrenaline
Medicine Details: FLUPENTHIXOL DECANOATE (Suspected) Injection		Reas	rt Description	Resuscitation, adrenaline
Medicine Details: FLUPENTHIXOL DECANOATE (Suspected) Injection	50.0 Milligr			Resuscitation, adrenaline hydrocortisone.
FLUPENTHIXOL DECANOATE (Suspected) Injection	50.0 Milligr			
FLUPENTHIXOL DECANOATE (Suspected) Injection	50.0 Milligr			
	50.0 Milligr		on: Unspecified so	chizophrenia
Batch: Starte		ram	Fortnightly	Intramuscular
	ed:	L TERM	Stopped:	
Laboratory Investigations:				
	ite Tested	Result		Details
				-

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Ren	ort	Deta	ils:
-----	-----	------	------

 Case Number:
 173317
 Seq: 1
 Gender:
 F

 Reported:
 04/03/2002
 Weight:

Reported: 04/03/2002 Weight:
Hospitalisation: Age: 33Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Foetal growth retardation			Termination of pregnancy on 21.12.01 at 20 weeks.

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected) Reason:

20.0 Milligram Fortnightly

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

This woman had a termination of pregnancy on 21/12/01 at 20 weeks gestation for severe hydrops fetalis. no recognised cause of hydrops was found.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Ren	ort	Deta	ils:
-----	-----	------	------

 Case Number:
 173901
 Seq: 1
 Gender: M

 Reported:
 25/03/2002
 Weight:
 50.00

Hospitalisation: Age: 18

Onset Date: DOB: 10/03/1984
Outcome: Unknown Causality: Causality certain

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Weight decreased		Claims to have lost 20kg in weight.	
Anorexia			
Nausea			
Vomiting			

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected) Reason: Unspecified psychosis

0.0

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reactions occur for 3-4 days after each injection. patient has had 5 injections at 2 week intervals. gradually improves somewhat over the 2 week interval.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Re	oa	rt	De	etai	ils:
----	----	----	----	------	------

 Case Number:
 175225
 Seq: 1
 Gender:
 F

 Reported:
 07/05/2002
 Weight:

Hospitalisation: Age: 27Y
Onset Date: 01/02/2002 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Neutropenia			Treated with filgrastim 300mcg daily for 8 days. clozapine, flupenthixol and chlorpromazine ceased.

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected)			Reason:		
Injection	40.0	Milligram	Fortn	ghtly	Intravenous
Batch:	Started:			Stopped:	21/01/2002
CLOZAPINE (Suspected)			Reason:	Unspecified so	hizophrenia
Tablet	100.0	Milligram	Daily		Oral
Batch:	Started: 14/0	07/1997		Stopped:	21/01/2002
CHLORPROMAZINE HYDROCHLORIDE (Su	ispected)		Reason:	Anxiety neuros	sis
Tablet	200.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	21/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		07/03/2002	0.6	
	Neutrophils		16/03/2002	11.7	
	White blood cells		07/03/2002	1.6	

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Case Number: 175643 Se Reported: 23/05/2002 Dispitalisation: Onset Date: Outcome: Not yet recovered Paction Details:	eq: 1				
action Details:			Gender: U Weight: Age: DOB: Causality: Causality possible		
Preferred Term	Severity	Rep	ort Description	Treatment	
lbuminuria					
lypoproteinaemia lephrotic syndrome				Olanzapine and flupenthixol were ceased.	
ledicine Details: OLANZAPINE (Suspected)		Rea	son:		
	30.0	Milligram	Daily		
Batch:	Started:		Stopped:		
FLUPENTHIXOL DECANOATE (Suspected)		Rea	son:		
		Milligram	Daily		
Batch:	Started:		Stopped:		
		ed Result			
Date Type Range Biochemistry	Date Teste		Albumin 25. protein in u	Details	

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Ren	ort	Deta	ils:
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 Case Number:
 179113
 Seq: 1
 Gender: M

 Reported:
 18/09/2002
 Weight:

Hospitalisation: Admitted to hospital Age: 26Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			
Dyspnoea			Admitted to hospitalised (icu).
Malaise			
Myocarditis			

Medicine Details:

Wieulcine Details.					
FLUPENTHIXOL DECANOATE (Suspected)			Reason:		
Injection	25.0	Milligram	Week	kly Intramuscu	lar
Batch:	Started:			Stopped:	
RISPERDAL (Suspected)			Reason:	Unspecified schizophrenia	
Tablet	4.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Relevant history - schizophrenia 5 years ago.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report	Details:
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Case Number: 180137 Seq: 1 Gender: F

Reported: 23/10/2002 Weight:
Hospitalisation: Age: 27

Onset Date: 09/09/2002 **DOB**: 05/09/1975

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment	
Leukopenia		Drop in white cell count to 3,2.	Ceased fluanxol depot.	

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected) Reason: Unspecified schizophrenia

Injection 40.0 Milligram Fortnightly Intramuscular

Batch: Started: 13/06/2002 Stopped: 20/09/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Case Number: 181864	Seq: 1		Gende	er: F			
Reported: 21/01/2003			Weigh	nt: 0.00			
Hospitalisation:			Ag	e : 48Y			
Onset Date: 12/01/2001			DC	B:			
Outcome: Unknown			Causali	ty: Causality possible			
Reaction Details:							
Preferred Term	Severity	Repo	ort Description	Treatment			
Akinesia		ncreased rigidity decreased ability	and akinesia to swallow involuntary togue, mild tremor of	Benztropine			
Extrapyramidal disorder Gait disturbance Hypertonia Tremor							
Medicine Details: FLUPENTHIXOL DECANOATE (SI	uspected)	Rea	son: Depression				
		Milligram	Fortnightly				
Batch:	Started:	Ü	Stopped:				
Laboratory Investigatio							
Laboratory Investigatio Date Type	Range Date Teste	d Result	De	etails			
71							
Additional Information:							
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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number:182563Seq: 1Gender:MReported:07/02/2003Weight:0.00Hospitalisation:Hospitalisation prolongedAge: 26

Onset Date: 14/08/2002 DOB: 25/11/1975

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	threatening		Given ventilated inotrope support.
Hypoventilation	threatening		Given ventilated inotrope support.
	threatening	Cardiomyopathy-life threatening and influenza symptoms a few days before presentation.	Ventilated inotrope support.

Medicine Details:

MEGICINE Details.					
RISPERIDONE (Suspected)			Reason:	Unspecified schizophrenia	
Tablet	4.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	
FLUPENTHIXOL DECANOATE (Suspecte	d)		Reason:	Unspecified schizophrenia	
Injection	20.0	Milligram	Daily		
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number:184909Seq: 1Gender:MReported:11/04/2003Weight:0.00Hospitalisation:Admitted to hospitalAge: 35

Onset Date: 14/01/2003 **DOB:** 03/04/1967

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state		At home, found confused, unable to move with rigid limbs. Diagnosed as neuroleptic malignant syndrome.	IV hydration, Bromocriptine, Benztropine.
Blood creatine phosphokinase incr Muscle rigidity Neuroleptic malignant syndrome Paralysis			

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected)		Reason:	Unspecified schizophrenia	
Injection			Intramuscular	
Batch:	Started:	S TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
11/04/2003	Creatine		14/01/2003	8,907	

Additional Information:

PHx N.M.S. from Haloperidol June 2001.

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 185101 Seq: 1 Gender: F

 Reported:
 14/04/2003
 Weight:
 0.00

 Hospitalisation:
 Age:
 28Y

 Onset Date:
 05/04/2003
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

,	caction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Leukopenia		Leucopaenia with neutropaenia.	
	Neutropenia			

Medicine Details:

Medicine Details:					
FLUVOXAMINE MALEATE (Other drug)		!	Reason:	Depression	
Tablet	100.0 M	Milligram	Daily		Oral
Batch:	Started:			Stopped:	
CHLORPROMAZINE HYDROCHLORIDE (S	Suspected)	ı	Reason:	Unspecified ps	sychosis
Tablet	100.0 M	Milligram	As ne	cessary	Oral
Batch:	Started:			Stopped:	
FLUPENTHIXOL DECANOATE (Suspected	1)	ļ	Reason:	Unspecified ps	cychosis
Injection	30.0 N	Milligram	Daily		Intramuscular
Batch:	Started: 04/04	1/2003		Stopped:	

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
	14/04/2003	Neutrophils		05/04/2003	1.76	
	14/04/2003	Neutrophils		07/04/2003	0.81	
	14/04/2003	White blood cells		05/04/2003	3.1	
Į	14/04/2003	White blood cells		07/04/2003	2.4	

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number:197516Seq: 1Gender:FReported:21/05/2004Weight:0.00Hospitalisation:Age: 58

Onset Date: 03/05/2004 DOB: 13/02/1946

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
		Generalised maculo papular rash on trunk, neck, chest, palms and feet.	Phenergan 25mg orally bd, ceased Flupenthixol and Cipramil.
	Required Visit to Doctor		

Medicine Details:

RISPERIDONE (Other drug)			Reason:	Unspecified ps	sychosis
Tablet	2.0	Milligram	Daily		Oral
Batch:	Started: 01/0	1/2004		Stopped:	
CIPRAMIL (Suspected)			Reason:	Depression	
Tablet	20.0	Milligram	Daily		Oral
Batch:	Started: 01/0	04/2004		Stopped:	05/05/2004
FLUPENTHIXOL DECANOATE (Suspected)			Reason:	Unspecified ps	sychosis
Injection	40.0	Milligram	Daily		Intramuscular
Batch:	Started: 01/0	04/2004		Stopped:	05/05/2004

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

202801	Seq	: 1		Gen	der: U		
18/11/2004				Weig	jht: 0.00		
				A	.ge: 99U		
1				D	OB:		
Unknown				Causa	lity: Causality possible		
ils:							
red Term	Se	everity	Rep	ort Description	Treatment		
1		S	Suicidal ideation	n and suicide attempt.			
			D				
			Rea				
u	•	Startod:					
DECANOATE (SI		otarteu.	Res				
SECANOATE (O	ispecteu)		Nee				
	S	Started:		Stopped:			
		In		ī	- · · ·		
Туре	Range	Date Tested	d Result		Details		
Date Type Range Date Tested Result Details Additional Information:							
	nvestigațio	tails: ected) d DECANOATE (Suspected)	tails: ected) d Started: DECANOATE (Suspected) nvestigations:	tails: ected) Started: DECANOATE (Suspected) Started:	tails: Sected) Started: Started:		

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Hospitalisati Onset D	ate: 08/01/1999 ne: Unknown				Ag DO	e: 44Y		
	eferred Term	Severity		Repo	rt Description	Treatment		
Extrapyramidal disorder		Caused or prolonged inpatient hospitalisati	syn of th	e patient expentent patient expense ex	rienced extrapyramidal ess of joints and stiffness			
Joint stiffnes	s	Caused or prolonged inpatient hospitalisati	on					
Medicine I								
PARACETAM	OL (Other drug)			Reas	son:			
Batcl	. .	Started:			Stannadı			
TEMAZEPAM		Started:		Reas	Stopped:			
I EIVIAZEFAIVI	(Other drug)			Reas	oui.			
Batcl	h:	Started:			Stopped:			
DIAZEPAM (C	Other drug)			Reas	son:			
Batcl	h·	Started:			Stopped:			
RISPERDAL (- Claritour	Reason: Unspecified schizophrenia					
	,	2	.0 Millig	Milligram Daily				
Batcl	h:	Started: 04/01/1999			Stopped:			
			Footod	Post It		otoilo		
Date	туре	Range Date	esteu	Result	Di	etalis		
Date Type 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: FLUANXOL,FLUPENTHIXOL DECANOATE

Case Number:	208755	Seq: 1		Gender:	F
Reported:	20/06/2005			Weight:	0.00
Hospitalisation:				Age:	44Y
Onset Date:	08/01/1999			DOB:	
Outcome:	Unknown			Causality:	Causality possible
Reaction Detai	ils:				
Medicine Det					
	ECANOATE (Suspecte		Reason:		
Injection		40.0 Milligram	Daily		
Batch:		Started: 06/01/1999		Stopped:	
ARTANE (Suspect	ed)		Reason:		
Tablet		12.0 Milligram	Daily	Oral	
Batch:		Started: 08/01/1999		Stopped:	
Laboratory In	vestigations:				
Additional Inf					
Clinical trial RODC	S WAVE I: RODOS	٠.			
		_			
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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report I	Details:
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 Case Number:
 211157
 Seq: 1
 Gender:
 M

 Reported:
 29/08/2005
 Weight:
 0.00

 Hospitalisation:
 Age: 61Y

Onset Date: 01/03/2005 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	Caused or prolonged inpatient hospitalisation	The patient experienced rolling of the tongue, tremor of the hands and chest pain.	
Chest pain	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TEMAZEPAM (Other drug)		Reason:	
Tablet	10.0 Milligram		Oral
Batch:	Started: 15/09/2004	Stopped:	
ISOSORBIDE DINITRATE (Other drug)		Reason:	
Tablet	60.0 Milligram		Oral
Batch:	Started: 15/09/2004	Stopped:	
DILTIAZEM HYDROCHLORIDE (Other drug)	Reason:	
Capsule	180.0 Milligram		Oral
Batch:	Started: 15/09/2004	Stopped:	
METOPROLOL TARTRATE (Other drug)		Reason:	
Tablet	50.0 Milligram		Oral
Batch:	Started: 15/09/2004	Stopped:	

Laboratory Investigations:

	Date	Type	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

		Weight: Age: DOB: Causality:	61Y
		Age: DOB:	61Y
		DOB:	
		Causality:	Causality possib
		topped:	
	Reason:	_	
Started: 15/09/2004		topped:	
	Reason:		
Started: 15/09/2004	S	topped:	
	50.0 Milligram Started: 15/09/2004 spected) 5.0 Milligram	50.0 Milligram Weekly Started: 15/09/2004 S spected) Reason: 5.0 Milligram As necessa Started: 15/09/2004 S Reason: 15.0 Milligram Daily	50.0 Milligram Weekly Started: 15/09/2004 Stopped: Spected) Reason: 5.0 Milligram As necessary Oral Started: 15/09/2004 Stopped: Reason: 15.0 Milligram Daily Oral

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 218716 Gender: M Seq: 1 Weight: 0.00 Reported: 29/05/2006

Hospitalisation: Admitted to hospital **Age:** 54

Onset Date: 27/09/2005 **DOB**: 24/08/1951 Causality: Causality possible

Outcome: Not yet recovered

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia	prolonged	Initially akathisia then marked psycho-motor retardation and parkinsonism - worsed rapidly till just seized up.	
Parkinsonism	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected) Unspecified psychosis Reason:

Injection 30.0 Milligram Fortnightly Intramuscular Batch: Started: 15/06/2005 Stopped: 15/12/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Became rapidly severly incomppasitated by the Flupenthisol and has not recovered.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Danamad. A	20655	Seq: 1		Gend	er: F		
reportea: 0	8/08/2006			Weigh	nt: 0.00		
lospitalisation:			Age: 99u				
Onset Date:			DOB:				
Outcome: F	Recovered			Causali	ty: Causality possible		
eaction Details	: :						
Preferred	Term	Severity	Report Description	on	Treatment		
Tardive dyskinesia			Tardive dyskinesia occurred initially with flupenthixol and then woresened with risperidone.		Risperdal discontinued, clozapine substituted.		
Medicine Detai							
RISPERDAL (Suspec	:ted)		Reason:				
Tablet		04 4 1 -	04-	Oral			
Batch: FLUPENTHIXOL DEG	24112475 (2	Started:	Reason:	opped:			
TEOPENTIAGE DEC	ANOATE (Suspec	ieu)	Neason.				
Batch:		Started:	Started: Stopped:				
Laboratory Inv	estigations:						
	estigations:	nge Date Tes	ted Result	Do	etails		
Laboratory Inv Date T	ype Ran	ige Date Tes	ted Result	D	etails		

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Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Report Details:

Case Number: 221849 Seq: 1 Gender: F

Reported: 25/09/2006 Weight: 90.00 Hospitalisation: Age: 37Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

-	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	njection site reaction		Developed 8 - 10 cm diameter red tender indurated injection site reactions	

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected) Reason: Unspecified psychosis

Injection 10.0 Milligram Daily Intramuscular

Batch: Started: 16/08/2006 Stopped: 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced increasing reaction with flupenthixol dose 20mg on the 23/08/06 and 30/08/06.

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Hospitalisation:

Case Number: 223782

Reported: 05/12/2006

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M Weight: 0.00

Age: 34Y

Unclear causality excluded GM medicines Only Tradenames: FLUANXOL,FLUPENTHIXOL DECANOATE

Seq: 1

Onset Date:		DOB:				
Outcome: Unknown		Causality: Causality possible				
Reaction Details:						
Preferred Term	Severity	Repo	rt Description	Treatment		
Suicidal ideation		suicidal ideation depression insomnia thinking abnorma anger	I			
Tardive dyskinesia Anger Depression Insomnia		tardive dyskinesia.		Switched to Risperidone.		
Thinking abnormal						
Medicine Details: FLUPENTHIXOL DECANOATE (S	FLUPENTHIXOL DECANOATE (Suspected) Reason:					
Batch:	Started:	L TERM	Stopped:	0		
Laboratory Investigation						
Date Type	Range Date Tes	ted Result		Details		
Additional Information:						
eport Run: 01/06/2007 05:01PM	Database: pusime02	Al	DRS004	Page 105 of 105		