

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 2019 Seq: 1 Gender: F

Reported: 29/05/1989 Weight: 55.00 Hospitalisation: Age: 35

**Onset Date**: 12/01/1989 **DOB**: 14/08/1953

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	,		Change to stemetil largactil 12.5mg im 12hr prn

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Nausea and vomiting

Injection 12.0 Milligram As necessary Intramuscular

Batch: Started: 12/01/1989 Stopped: 13/01/1989

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Other data				Bp 75/40

#### **Additional Information:**

see original report for other drugs. Case Sequenced to: 60691/4

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Ran	ort	Deta	ile:
Reb	OIL	Dela	IIIS.

Case Number: 2213 Seq: 1 Gender: F

Reported: 30/10/1989

Hospitalisation:
Onset Date:

Weight: 73.00
Age: 86Y
DOB:

Outcome: Not yet recovered Causality: Causality possible

#### **Reaction Details:**

Preferred Term	Severity	Report Description	Treatment
Dystonia			

#### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason:

0.0

Stopped:

LITHIUM CARBONATE (Suspected) Reason: Manic-depression psycho, manic

Started:

 Tablet
 500.0 Milligram
 Daily
 Oral

 Batch:
 Started: 12/09/1989
 Stopped: 26/09/1989

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Case Sequenced to: 63131/2

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Re	po	rt	De	tai	ls	:
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 Case Number:
 55168
 Seq: 1
 Gender: M

 Reported:
 15/07/1988
 Weight:
 63.00

 Hospitalisation:
 Age: 48Y

**Onset Date**: 15/07/1988 **DOB**:

Outcome: Recovered with sequelae Causality: Causality possible

#### **Reaction Details:**

Destand Terror	0	Demant Demantation	Taxabas and
Preferred Term	Severity	Report Description	Treatment
Coma			
Respiratory depression			Sequelae: acute let down reaction following narcan now resolved.
Tachycardia			

# **Medicine Details:**

<u>Medicine Details:</u>						
PROLADONE (Suspected)		Reason: Pain				
	3.0 Dose Unspec	ified Total				
Batch:	Started: 14/07/1988	Sto	opped:			
LARGACTIL (Suspected)		Reason:				
Suppository	100.0 Milligram	Daily	Rectal			
Batch:	Started: 14/07/1988	Sto	opped:			
TEMAZEPAM (Suspected)		Reason: Distur	pance of sleep			
Capsule	10.0 Milligram	Daily	Oral			
Batch:	Started: 11/07/1988	Ste	opped:			

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 55369
 Seq: 1
 Gender:
 F

 Reported:
 26/07/1988
 Weight:
 68.0

Reported: 26/07/1988 Weight: 68.00
Hospitalisation: Hospitalisation prolonged Age: 26Y
Onset Date: 31/07/1988 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating			
Hypertonia			
Neuroleptic malignant syndrome			Cogentin given.
Pyrexia			

#### **Medicine Details:**

HALOPERIDOL (Other drug)		Reason:		
Injection	5.0 Milligram	1 time	Intramuscular	
Batch:	Started: 05/07/1988	Sto	opped:	
MELLERIL (Other drug)		Reason:		
Oral application	125.0 Milligram	Total	Oral	
Batch:	Started: 04/07/1988	Sto	opped: 05/07/1988	
CHLORPROMAZINE HYDROCHLOR	DE (Suspected)	Reason: Psycho	osis associa w childbirth	
Oral application	300.0 Milligram	Daily	Oral	
Batch:	<b>Started:</b> 05/07/1988	Sto	opped: 09/07/1988	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

D	F	-4-	
Repo	rt L	Jeta	IIS:

Case Number: 55389 Seq: 1 Gender: M

Reported: 09/08/1988 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 19/07/1988
DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder			

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Gi dis presum psychogenic orig

25.0 Milligram 1 time

Batch: Started: 19/07/1988 Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	56115	Seq:	: 1			Gender:	M
Reported:		_				Weight:	
spitalisation:						Age:	53Y
Onset Date:	23/08/198	38				DOB:	
Outcome:	Not yet re	covered			•	Causality:	Causality possible
<u>action Deta</u>		<u> </u>				•	
	ed Term		everity	Repo	ort Description		Treatment
euroleptic mali	gnant synd	rome					
edicine Det		drug)	1.0 Gr		son: Daily		
Batch:		s	tarted:		Stopped	:	
ARGACTIL (Sus	pected)			Rea	son: Unspecified	schizophrenia	I
			700.0 Mi	lligram	Daily		
Batch:		s	tarted:		Stopped	: 22/08/1988	3
aboratory Ir				I 6 "			
Date	Туре	Range	Date Tested	Result		Detai	ls
Additional In	formatio	n:					
port Run : 01/06/20	N7 N4·13₽N	∕ Datahase n	usime02	Δ	.DRS004		Page 6 of 405

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 57495 Seq: 1 Gender: M

Reported: 21/11/1988 Weight:

Hospitalisation: Age: 23Y
Onset Date: 15/11/1988
DOB:

Outcome: Recovered Causality: Causality certain

**Reaction Details:** 

١,	teaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Urinary retention			Catheterisation. largactil ceased.
	Urinary retention			

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Unspecified psychosis

100.0 Milligram Daily

**Batch: Started:** 01/07/1988 **Stopped:** 18/11/1988

**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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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Causality: Causality possible

**Report Details:** 

Case Number: 58395 Seq: 1 Gender: F

 Reported:
 09/01/1989
 Weight:
 70.00

 Hospitalisation:
 Age:
 37Y

**Onset Date**: 03/04/1988 **DOB**:

Reaction Details:

Outcome: Unrelated death

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Dantrolene sodium.

#### **Medicine Details:**

LARGACTIL (Suspected)		Reason: Depression
Tablet	250.0 Milligram	n Daily Oral
Batch:	Started:	<b>Stopped:</b> 03/04/1988
PARNATE (Suspected)		Reason: Manic-depression psycho,manic
Tablet	40.0 Milligram	n Daily Oral
Batch:	Started:	<b>Stopped:</b> 03/04/1988
NORMISON (Suspected)		Reason:
Capsule	20.0 Milligram	n Daily Oral
Batch:	Started:	Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Other data				Urine drug screen - phenothiazines and an unidentified compound were detected.

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 59203 Seq: 1 Gender: M

**Reported:** 09/03/1989 **Weight:** 

Hospitalisation: Age: 69Y
Onset Date: 07/03/1989
DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

'	caction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Electrocardiogram abnormal			
	Orthostatic hypotension			

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Hiccough

Tablet 5.0 Dose Unspecified Daily Oral

**Batch: Started:** 06/03/1989 **Stopped:** 07/03/1989

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Electrographics				Ecg flat t's

#### **Additional Information:**

See original report for additional drugs

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# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number	er: 59785	Seq: 1					Gende	r: F	
Reporte	ed: 11/04/198	39					Weight	t:	
lospitalisatio	n:						Age	e: 44Y	
Onset Da	te: 07/04/198	39					DOE	3:	
Outcom	e: Recovere	؛d				C	ausality	y: Causality pos	sible
eaction De									
Pref	erred Term	Severi	ty	Repo	ort Des	cription		Treatme	ent
Rash							T to	horidizine instead opical calamine to	d of largactil. rash prn
Medicine D				Rea	son: l	Jnspecified so	chizophrer	nia	
Tablet		9	0.00 Mill	igram	Daily		Oral		
Batch	:	Starte	<b>d:</b> 03/04/1	989		Stopped:	09/04/19	89	
L obovotow.	. Invocting	tiono.							
Laboratory Date	Type		e Tested	Result			Det	tails	
	,,								
Additional	Informatio	n:							
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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Re	port	Detai	ls:
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 Case Number:
 59989
 Seq: 1
 Gender: F

 Reported:
 26/04/1989
 Weight:

Hospitalisation: Age: 34Y
Onset Date: 23/02/1989
DOB:

Outcome: Recovered with sequelae Causality: Causality possible

#### Reaction Details:

todotion Botanoi			
Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Paralyzed and ventilated. sequelae: disseminated intravascular coagulation

#### **Medicine Details:**

Medicine Details.				
CHLORPROMAZINE HYDROCHLORIE	DE (Suspected)	Reason:	Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily	Oral	
Batch:	Started: 07/02/1989		<b>Stopped:</b> 23/02/1989	
FLUPHENAZINE NOS (Suspected)		Reason:	Unspecified schizophrenia	
	30.0 Milligram	Daily		
Batch:	Started: 27/01/1989		<b>Stopped</b> : 23/02/1989	

**Laboratory Investigations:** 

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 60787 Seq: 1 Gender: M

Reported: 13/06/1989 Weight: 6.00 Hospitalisation: Age: 8M

**Onset Date**: 22/05/1989 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Convulsion			
Hypertonia			
Hypotension			25 mls of spps given with good
			effect. frusemide stopped.
Miosis			

#### **Medicine Details:**

Medicine Details.		
FRUSEMIDE (Other drug)		Reason: Pulmonary congestn&hypostasis
	12.0 Milligram	Daily
Batch:	Started:	Stopped:
LARGACTIL (Suspected)		Reason: Pyrexia of unknown origin
Injection	1.0 Milligram	Daily Intravenous
Batch:	Started: 22/05/1989	Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details	3
	Other data				Bp 112/80 decreased to 55/37	bp 75/50 after spps given

#### **Additional Information:**

See original report for other drugs.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details	:	
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Case Number: 61023 Seq: 1 Gender: M

Reported: 21/06/1989 Weight: 86.00 Hospitalisation: Age: 62Y

**Onset Date**: 15/06/1989 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

#### **Reaction Details:**

Preferred Term	Severity	Report Description	Treatment
Glossitis			

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Psychosis asso w phys cond nos

Oral application 800.0 Milligram Daily Oral

Batch: Started: 13/06/1989 Stopped: 19/06/1989

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Hospitalisation Onset Date Outcome	1: 19/06/198 : Admitted to 2: 06/01/198 : Recovered	to hospital					D	jht: .ge: OB:	22Y
Reaction Deta			it		Don			1	Tractmont
Priapism	rred Term	56	everity		Керс	оп De	scription	an 4m 12	Treatment piration of the corposa and injection of metaraminol g. sequelae. readmitted on 1/89 with recurrent
Urinary retentio	n								apism. same treatment with od recovery.
Medicine De									
PHENYTOIN SOI	DIUM (Other di	ug)	000.0			son:			
Batch:		S	300.0 Started:	Milligra	am	Daily	Stopped:		L TERM
PIROXICAM (Oth	ner drug)					son:			
Batch:		S	30.0 started:	Milligra	am	Daily	Stopped:		L TERM
NITRAZEPAM (O	ther drug)				Rea	son:			
			1.0	Dose l	Jnspecified	Daily			
Batch:		S	tarted:				Stopped:		L TERM
PANADEINE FOR	RTE (Other dru	ıg)				son:	Other disturbance of	sens	ation
			12.0	Dose l	Jnspecified	Daily			
Batch:		S	started:				Stopped:		
Laboratory I									
Date	Туре	Range	Date Teste	ed	Result			Detai	ls
Additional Ir	nformatio	n:	1						

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Hospitalisation: Onset Date:	19/06/1989 Admitted to hospi 06/01/1989 Recovered with s			Gender: Weight: Age: DOB: Causality:	22Y
Medicine Det		(Cuanaste I)	Dane	Otranoa sussa suss	
Injection	IE HYDROCHLORIDE	(Suspected) 100.0 Milligram	Reason: Daily	Otr spec symp psychopath Intramuscu	
Batch:		Started: 04/01/1989	Dany	Stopped:	
Laboratory In	vestigations:				
Additional Inf	formation:				

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Donorto	er: 61432	Seq:	1		Ge	ender:	M
Keporte	ed: 10/07/19	_			W	eight:	
ospitalisatio	n:					Age:	54Y
Onset Dat	te: 09/07/19	89				DOB:	
Outcom	e: Recovere	ed			Cau	sality:	Causality probable
action Det						•	
Prefe	erred Term	Se	everity	Repo	ort Description		Treatment
ruritus							
ash							
ledicine D	etails:						
THIAMINE (Oth	er drug)			Rea	son:		
			0.0				
Batch:		S	tarted:		Stopped:		
ATIVAN (Other	drug)			Rea	son:		
			0.0				
Batch:		S	tarted:		Stopped:		
LARGACTIL (S	uspected)			Rea	. ,	ychopath	ol nec
			30.0 Mill		Daily		
Batch:		S	tarted: 07/07/1	989	Stopped: 09	/07/1989	
aboratorv	Investiga	tions:					
aboratory Date	Investiga Type	tions:	Date Tested	Result		Detail	S
aboratory Date			Date Tested	Result		Detail	S

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Case Number: 62183

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

Dermatitis bullous Dysuria Pain Pruritus Rash  Medicine Details:  MYLANTA (Suspected)  Tablet Batch:  DAONIL (Suspected)	Severity  0.0  Started:	F	Report Des		DC ausali	je: 72Y
Onset Date: 20/02/1989 Outcome: Not yet recovered Deaction Details: Preferred Term  Dermatitis bullous Dysuria Pain Pruritus Rash  Medicine Details: MYLANTA (Suspected) Tablet Batch:  DAONIL (Suspected) Batch:	0.0 Started:	F			DC ausali	Burrows emulsion to the bullae, menthol, camphor cream for the itch, potassium permanganate soaks to
Preferred Term Dermatitis bullous Dysuria Pain Pruritus Rash  Medicine Details:  MYLANTA (Suspected)  Tablet Batch:  DAONIL (Suspected)  Batch:	0.0 Started:	F				Treatment  Burrows emulsion to the bullae, menthol, camphor cream for the itch, potassium permanganate soaks to
Preferred Term  Dermatitis bullous Dysuria Pain Pruritus Rash  Medicine Details:  MYLANTA (Suspected) Tablet Batch:  DAONIL (Suspected)  Batch:	0.0 Started:	F		scription		Burrows emulsion to the bullae, menthol, camphor cream for the itch, potassium permanganate soaks to
Preferred Term  Dermatitis bullous Dysuria Pain Pruritus Rash  Medicine Details:  MYLANTA (Suspected) Tablet Batch:  DAONIL (Suspected)  Batch:	0.0 Started:	F		scription		Burrows emulsion to the bullae, menthol, camphor cream for the itch, potassium permanganate soaks to
Dysuria Pain Pruritus Rash  Medicine Details:  MYLANTA (Suspected)  Tablet Batch:  DAONIL (Suspected)  Batch:	Started:		Reason:			bullae, menthol, camphor cream for the itch, potassium permanganate soaks to
Pruritus Rash  Medicine Details:  MYLANTA (Suspected)  Tablet Batch:  DAONIL (Suspected)  Batch:	Started:		Reason:			bullae, menthol, camphor cream for the itch, potassium permanganate soaks to
Pain Pruritus Rash  Medicine Details:  MYLANTA (Suspected)  Tablet Batch:  DAONIL (Suspected)  Batch:	Started:		Reason:			bullae, menthol, camphor cream for the itch, potassium permanganate soaks to
Medicine Details:  MYLANTA (Suspected)  Tablet Batch:  DAONIL (Suspected)	Started:		Reason:			bullae, menthol, camphor cream for the itch, potassium permanganate soaks to
Medicine Details:  MYLANTA (Suspected)  Tablet Batch:  DAONIL (Suspected)	Started:		Reason:			bullae, menthol, camphor cream for the itch, potassium permanganate soaks to
Tablet Batch: DAONIL (Suspected) Batch:	Started:		Reason:			
MYLANTA (Suspected)  Tablet  Batch:  DAONIL (Suspected)  Batch:	Started:		Reason:			
Tablet Batch:  DAONIL (Suspected)  Batch:	Started:		. 10000111			
Batch: DAONIL (Suspected) Batch:	Started:				Oral	
DAONIL (Suspected)  Batch:			<b>Stopped</b> : 19/02/1989			989
Batch:	2.5	Reason:				
		Milligram	Daily			
	Started:			Stopped:	19/02/1	989
• • •			Reason:			
	40.0	Milligram	Daily			
Batch:	Started:	-	,	Stopped:	19/02/1	989
LARGACTIL (Suspected)			Reason:			
	30.0	Milligram	Daily			
Batch:	Started:	•	- ,	Stopped:	19/02/1	989
				• •		
Laboratory Investigations:	D-1 = 1		ı <u>.</u>			-4-9-
Date Type Range	Date Teste	ed Result	IT		D	etails

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Case Number: 62183

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

Reported: 28/07/1989			Weigh	t:
ospitalisation:			Ag	e: 72Y
Onset Date: 20/02/1989			DO	
Outcome: Not yet recovered			Causalit	y: Causality possible
action Details:				
Andinina Dataila.				
Medicine Details: CHLORTHALIDONE (Suspected)		Reason:		
ONEON MACIDONE (Ouspected)	25.0 Milligram	Daily		
Batch:	Started:	Dany	Stopped: 19/02/19	989
SLOW-K (Suspected)	- Ctartour	Reason:	<b>Ctoppour</b> 10/02/19	
ozon it (Gasposisa)	1.0 Dose Unspe			
Batch:	Started:	Jan,	Stopped: 19/02/19	989
CEFOTAXIME SODIUM (Suspected)		Reason:		
(3.2)	4.0 Gram	Daily		
Batch:	Started: 19/02/1989	•	Stopped: 21/02/19	989
HYDROCORTISONE (Suspected)		Reason:		
	400.0 Milligram	Daily		
Batch:	Started: 19/02/1989		Stopped: 21/02/19	989
.aboratory Investigations:				
Additional Information:				
aditional information.				

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 62305 Seq: 1 Gender: F

Reported: 29/08/1989

Hospitalisation: Hospitalisation prolonged

Onset Date: 14/03/1989

Weight: 52.00

Age: 82Y

DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis cholestatic			Immunosuppressants (prednisolone)

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Otr spec symp psychopathol nec

 Tablet
 20.0 Milligram
 Daily
 Oral

 Batch:
 Started: 01/10/1988
 Stopped: 18/03/1989

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				11 liver biopsy report: section shows preserved reticulin architecture. some of the portal tracts are enlarged by an inflammatory infiltrate predominately neutrophils but also accompanied by eosinophils & mononuclear cells. rare collections of macrophages are grouped around empty spaces lying among sheets of hepatocytes, appearances consistent

#### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 62305 Seq: 1 Gender: F

**Reported:** 29/08/1989 **Weight:** 52.00 **Hospitalisation:** Hospitalisation prolonged **Age:** 82Y

Onset Date: 14/03/1989 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Otr spec symp psychopathol nec

 Tablet
 20.0 Milligram
 Daily
 Oral

 Batch:
 Started: 01/10/1988
 Stopped: 18/03/1989

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Histology				With bile granulomas. no iron or malignant cells detected. ascending cholangitis. liver function tests 10/5/89 - bili: 25, alp: 580, gmt: 686 ast: 39, alt: 34, protein: 52, albumin: 23.

#### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

Case Number: 62585 Seq: 1 Gender: M
Reported: 22/09/1989 Weight:
Hospitalisation: Age: 18Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

#### Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

#### **Medicine Details:**

PARACETAMOL (Suspected)		Reason:		
	0.0			
Batch:	Started: 27/08/1989		Stopped:	CONTIN
ISOFLURANE (Suspected)		Reason:	Other disturbance of sens	sation
	0.0			
Batch:	Started: 16/07/1989		Stopped:	
VECURONIUM BROMIDE (Suspected)		Reason:		
	0.0			
Batch:	Started: 20/07/1989		Stopped:	
FENTANYL CITRATE (Suspected)		Reason:		
	0.0			
Batch:	Started:		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				Ast ggt alp bili(conj) bili(total) 26/7/89-21/8/89: 1/9/89: 131 344 764 56 66 ast 96-785-87 4/9/89: 105 334 740 49 66 alp 171 - 494 7/9/89: 72 258 582 32 42 bili normal 19/9/89: 60 234 384 10 17

#### **Additional Information:**

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: 6	32585	Seq: 1				Gender:	M	
Reported: 2	22/09/1989					Weight:		
ospitalisation:						Age:	18Y	
Onset Date:						DOB:		
Outcome: N	Not yet recovered				С	ausality:	Causality possible	е
action Details	<b>S</b> :							
ledicine Detai		(Cuppedad)		Bassani				
Injection	HYDROCHLORIDE		Dose Unspeci	Reason:		Intramuscu	lar	
Batch:		8.0 Started: 18/		neu IUldi	Stonnadi	23/07/1989		
PANADEINE FORTE	(Suspected)	Starteu: 18/	01/1909	Reason:	Stopped:	23/0//1989	,	
FANADEINE FURTE	(Juspecieu)	3 0	Dose Unspeci					
Batch:		Started: 24/		ncu IUlai	Stopped:			
LACTULOSE (Suspe	ected)	Starteu. 24/	3.71000	Reason:	Clopped.			
	,	20.0	Millilitre	As nec	essarv			
Batch:		Started:			Stopped:			
	YDRATE (Suspected			Reason: (	Other diseases	s of luna		
	(		Gram	Daily		·		
Batch:		Started: 18/		2311,	Stopped:	25/07/1989	1	
- Duton.		Otartoa. 10/	0771000		Otoppeu.	20/01/1000		
aboratory Inv	estigations:							
Additional Info	rmation:							

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	62585	Seq: 1		Gender:	M
Reported:	22/09/1989			Weight:	
Hospitalisation:				Age:	18Y
Onset Date:				DOB:	
Outcome:	Not yet recovered	I		Causality:	Causality possible
Reaction Detai	ls:				
Medicine Deta					
NORFLOXACIN (S	uspected)		Reason:	Othr diseases of urinary tra	act
		800.0 Milligram	Daily		
Batch:		Started: 26/07/1989		Stopped:	
FLUCLOXACILLIN	SODIUM (Suspected)		Reason:	Other diseases of lung	
		4.0 Gram	Daily		
Batch:		Started: 28/07/1989		Stopped:	
PROBENECID (Sus	spected)		Reason:	Other diseases of lung	
		2.0 Gram	Daily		
Batch:		Started: 28/07/1989		Stopped:	
Laboratory In	vestigations:				
Laboratory III	vestigations.				
Additional Inf	ormation:				
			-		

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

Case Number: 62694 Seq: 1 Gender: F

Reported: 29/09/1989 Weight:
Hospitalisation: Age: 18Y

Onset Date: 29/09/1989

Outcome: Unknown

DOB:

Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Rash			

# **Medicine Details:**

BACTRIM DS (Suspected)	Reason:				
Oral application	2.0 Dose Unspecified	d Daily	Oral		
Batch:	Started: 28/09/1989	Stopp	ed: 29/09/1989		
LARGACTIL (Suspected)	Re	eason:			
Tablet	100.0 Milligram	Daily	Oral		
Batch:	Started:	Stopp	ed: 27/09/1989		
COGENTIN (Suspected)	Re	eason:			
Tablet	2.0 Milligram	Daily	Oral		
Batch:	Started:	Stopp	ed:		
VALIUM (Suspected)	Re	eason:			
Oral application	20.0 Milligram	Daily	Oral		
Batch:	Started: 28/09/1989	Stopp	ed:		

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Reported: Hospitalisation: Onset Date: Outcome: Reaction Detai	29/09/1989 29/09/1989 Unknown	Seq. 1				Weight: Age: DOB: ausality:	18Y	ossible
Medicine Deta			B	eason:				
Tablet	ectea)	800.0	Milligram	eason: Daily		Oral		
Batch:		Started:	9. 4111	Jany	Stopped:	2.31		
URAL (Suspected)			R	eason:				
Granules		3.0	Dose Unspecifie	ed Daily		Oral		
Batch:		Started: 27/	09/1989		Stopped:			
Laboratory In	vestigations:							
Additional Inf	ormation:							

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 62780 Seq: 1 Gender: F

Reported: 06/10/1989 Weight: 113.00 Hospitalisation: Age: 44Y

Onset Date: 02/10/1989 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

-				
	Preferred Term	Severity	Report Description	Treatment
	Leukopenia			
	Neutropenia			Cessation of largactil.

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Nausea and vomiting

Injection 25.0 Milligram As necessary Intramuscular

Batch: Started: 30/09/1989 Stopped: 02/10/1989

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Haematology				1 1 wbc 3000, neutrophils 0.8. invitro test demonstrated specific antibody which bound to neutrophil membrane increased immunofluorescent staining.

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 63270
 Seq: 1
 Gender: M

 Reported:
 10/10/1989
 Weight:

Hospitalisation: Age: 51

**Onset Date**: 23/09/1989 **DOB**: 01/10/1937

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

todotion Botanoi				
Preferred Term	Severity	Report Description	Treatment	ĺ
Rash			Ticarcillin stopped. calamine to rash.	]

## **Medicine Details:**

TICARCILLIN DISODIUM (Suspected)	F	Reason:	
Injection	18.0 Gram	Daily	Intravenous
Batch:	Started: 16/09/1989	Stopped:	23/09/1989
FOLIC ACID (Suspected)	F	Reason:	
Oral application	5.0 Milligram	Daily	Oral
Batch:	Started: 18/09/1989	Stopped:	CONTIN
LASIX (Suspected)		Reason:	
Oral application	80.0 Milligram	Daily	Oral
Batch:	Started: 20/09/1989	Stopped:	CONTIN
SLOW-K (Suspected)	F	Reason:	
Tablet	2.0 Dose Unspecific	ed Daily	Oral
Batch:	Started: 20/09/1989	Stopped:	22/09/1989

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

 Case Number:
 63270
 Seq: 1
 Gender: M

 Reported:
 10/10/1989
 Weight:

Hospitalisation: Age: 51

Onset Date: 23/09/1989

Outcome: Recovered

DOB: 01/10/1937

Causality: Causality possible

Reaction Details:

# **Medicine Details:**

PREDNISOLONE (Suspected)	Rea	ason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 14/09/1989	Stopped:	20/09/1989
GENTAMICIN SULPHATE (Suspected)	Rea	ason:	
Injection	240.0 Milligram	Daily	Intravenous
Batch:	Started: 16/09/1989	Stopped:	02/10/1989
SLOW-K (Suspected)	Rea	ason:	
Tablet	2.0 Dose Unspecified	Daily	Oral
Batch:	Started: 22/09/1989	Stopped:	23/09/1989
TEMAZEPAM (Suspected)	Rea	ason:	
Capsule	20.0 Milligram	Daily	Oral
Batch:	Started: 14/09/1989	Stopped:	CONTIN

# **Laboratory Investigations:**

#### **Additional Information:**

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	63270	Seq: 1		Gender:	M
Reported:	10/10/1989			Weight:	
Hospitalisation:				Age:	51
Onset Date:	23/09/1989			DOB:	01/10/1937
Outcome:	Recovered			Causality:	Causality possible
Reaction Detai	ils:				
Medicine Det			Danasa		
LARGACTIL (Susp	pected)	OF O Millianna	Reason:	Oral	
Tablet		25.0 Milligram	Daily	Oral	CONTIN
Batch:		<b>Started</b> : 14/09/1989	Danasa	Stopped:	CONTIN
OXAZEPAM (Susp	ectea)	00.0 AAUG	Reason:	0.751	
Tablet		30.0 Milligram	Daily	Oral	
Batch:	DDOCUL ODIDE (C	Started: 22/09/1989	Danasa	<b>Stopped:</b> 25/09/1989	)
	DROCHLORIDE (Sus		Reason:	lata an cana	den
Injection		2.0 Gram	Daily	Intramuscu	
Batch:		<b>Started:</b> 23/09/1989		<b>Stopped:</b> 02/10/1989	)
Laboratory In	vestigations:				
	. rootigutiono.				
<b>Additional Inf</b>	formation:				

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details:		
Case Number: 63274	Seq: 1	Gender: M

Reported: 06/11/1989 Weight:
Hospitalisation: Age: 34Y
Onset Date: 02/11/1989 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			

# **Medicine Details:**

LARGACTIL (Suspected) Reason: Unspecified schizophrenia

 Tablet
 100.0
 Milligram
 Daily
 Oral

 Batch:
 Started: 23/10/1989
 Stopped: 02/11/1989

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

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Case Number: 63636

Reported: 22/11/1989

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

**Weight:** 70.00

łospitalisation:					<b>Age:</b> 60	)	
Onset Date:					OB: 05	5/04/1929	
Outcome: Not yet recovered				Causa	ality: Ca	ausality poss	ible
eaction Details:		1					
Preferred Term	Severity	F	Report Des	cription		Treatmer	
Cataract					Meller nocte	il dose reduce	d to 50 mg
Cataract subcapsular							
Medicine Details:							
MELLERIL (Suspected)			Reason:	Unspecified psychos	sis		
	300.0	Milligram	Daily				
Batch:	Started:			Stopped:			
CHLORPROMAZINE HYDROCHLORIDE	(Suspected)		Reason:				
	500.0	Milligram	Daily				
Batch:	Started:			Stopped:			
Laboratory Investigations:							
Date Type Rang	ge Date Test	ed Resul	t T		Details		
Additional Information:							
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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 63637
 Seq: 1
 Gender: M

 Reported:
 27/11/1989
 Weight:

Hospitalisation: Age: 36

Onset Date: DOB: 25/03/1953

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

caction Details.			
Preferred Term	Severity	Report Description	Treatment
Cataract			
Cataract subcapsular			

#### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Other paranoid states

255.0 Gram Total

Batch: Started: 01/01/1982 Stopped: 31/01/1987

DIAZEPAM (Suspected) Reason:

10.0 Milligram Daily

**Batch: Started:** 01/01/1982 **Stopped:** 31/01/1987

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year. 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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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 63941
 Seq: 1
 Gender: F

 Reported:
 04/01/1990
 Weight:

Reported: 04/01/1990 Weight:
Hospitalisation: Age: 59Y

**Onset Date**: 14/12/1989 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

-					_
	Preferred Term	Severity	Report Description	Treatment	
	Hepatic function abnormal			Flopen ceased.	İ

# **Medicine Details:**

CARAFATE (Suspected)		Reason:	Peptic ulcer no	os w/o ment perf
Tablet	4.0 Gram	Daily		Oral
Batch:	Started: 11/12/1989		Stopped:	16/12/1989
AUSTRASTAPH (Suspected)		Reason:	Pneumonia,ur	specified
Injection	4.0 Gram	Daily		Intravenous
Batch:	Started: 12/12/1989		Stopped:	19/12/1989
LARGACTIL (Suspected)		Reason:	Unspecified so	chizophrenia
Tablet	150.0 Milligram	Daily		Oral
Batch:	Started:		Stopped:	12/12/1989
TOFRANIL (Suspected)		Reason:	Depression	
Tablet	75.0 Milligram	Daily		Oral
Batch:	Started:		Stopped:	12/12/1989

**Laboratory Investigations:** 

_		J J -						
L	Date	Туре	Range	Date Tested	Result	Details		
		Biochemistry				12/12 14/12 16/12 18/12 19/12 21/12 26/12 2/1/90 alp: 161 256 419 524 549 410 231 156 ggt: 380 353 433 528 624 449 236 112 ast: 27 69 37 35 42 25 19 24 bili: 9 12 11 11 9 5 8 7		

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 64040 Seq: 1 Gender: F

Reported: 18/01/1990 Weight: 18.00 Hospitalisation: Age: 06Y

**Onset Date**: 21/12/1989 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Hypotension			

#### **Medicine Details:**

TENIPOSIDE (Suspected)		Reason:	Other & unspec acute leukemia	
Injection, intravenous infusion	120.0 Milligram	Daily	Intravenous	
Batch:	Started: 21/12/1989		<b>Stopped</b> : 21/12/1989	
CYTARABINE (Suspected)		Reason:	Other & unspec acute leukemia	
Injection	220.0 Milligram	Daily	Intravenous	
Batch:	Started: 21/12/1989		<b>Stopped</b> : 21/12/1989	
LARGACTIL (Suspected)		Reason:	Nausea and vomiting	
Injection, intravenous infusion	5.0 Milligram	Daily	Intravenous	
Batch:	Started: 21/12/1989		Stopped: 21/12/1989	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Reaction occurred 5 minutes after intrathecal methotrexate had received it mtx many times before as well as oral mtx

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details:				
Case Number: 64232	Seq: 1		Gender:	F
Reported: 30/01/1990			Weight:	
lospitalisation:	<b>Age:</b> 19			
Onset Date: 28/01/1990				11/01/1971
Outcome: Recovered			Causality:	Causality probable
eaction Details:				
Preferred Term  Grand mal convulsion	Severity	Report Descrip		Treatment alium 6mg.
Medicine Details:  LARGACTIL (Suspected)		Reason:		
Injection	12.0 Mill	igram 1 time	Intramuscu	ar
_aboratory Investigations:				
<b>Laboratory Investigations:</b> Date Type Rar		Result	Detail:	S
<b>Laboratory Investigations:</b> Date Type Rar		Result	Detail:	S

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 64278 Seq: 1 Gender: F

 Reported: 11/12/1989
 Weight: 54.00

 Hospitalisation:
 Age: 28Y

 Onset Date: 04/12/1989
 DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

•	toaction Botanoi					
	Preferred Term	Severity	Report Description	Treatment		
	Pancytopenia					

## **Medicine Details:**

BENZTROPINE MESYLATE (Suspected)		Reason:		
Injection	1.0 Milligram	1 time	)	Intramuscular
Batch:	Started: 16/11/1989		Stopped:	
BUSCOPAN (Suspected)		Reason:	Abdominal pai	in
	60.0 Milligram	Total		
Batch:	Started: 14/11/1989		Stopped:	19/11/1989
PETHIDINE HYDROCHLORIDE (Suspected	)	Reason:	Abdominal pai	in
Injection	700.0 Milligram	Total		Intramuscular
Batch:	Started: 14/11/1989		Stopped:	19/11/1989
CHLORPROMAZINE HYDROCHLORIDE (Si	uspected)	Reason:	Nausea and v	omiting
Injection	275.0 Milligram	Total		Intramuscular
Batch:	Started: 14/11/1989		Stopped:	19/11/1989

**Laboratory Investigations:** 

Date		Туре	Range	Date Tested	Result	Details
		Haematology				1 wbc 0.4 x 10/l (4-11) plat 6x10/l (150-400) rbc 2.99x 10/l (3.85-5.8) esr 12mm/hr hb 7.9g/dl (12.5-16.5) inr 1.4 aptt 61 sec rat 2.2 hct 25l/l (37-47) last normal screen recorded 1/9/89. mcv 83fl (77-93)

#### **Additional Information:**

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:		Seq: 1			(	Gender:	F	
Reported:	11/12/1989				V	Veight:	54.00	
Hospitalisation:						Age:	28Y	
Onset Date:	04/12/1989					DOB:		
Outcome:	Death, maybe dr	ıg			Ca	usality:	Causality possible	
Reaction Detai	ils:							
Medicine Det	aile:							
ALODORM (Suspe				Reason:				
			5.0 Milligram	Daily				
Batch:		Started	i: 17/11/1989		Stopped:			
BACTRIM DS (Sus	spected)			Reason:				
			2.0 Dose Unspe	cified Daily				
Batch:		Started	<b>i</b> : 18/11/1989		Stopped:	19/11/1989	1	
I aboratory In	vestigations:							
Euboratory III	ivestigations.							
A 1 1141 1 1 1								
Additional In	formation:							

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: 65311 Seq: 1 Gender: F

Reported: 03/05/1990 Weight:
Hospitalisation: Age: 24Y

Onset Date: 10/09/1989

Outcome: Recovered

Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			

#### **Medicine Details:**

Micalcinic Details.						
DILANTIN (Suspected)			Reason:			
Tablet	330.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:	20/09/1989	
CHLORPROMAZINE HYDROCHLO	ORIDE (Suspected)		Reason:	Othr central ne	ervous system tb	
	50.0	Milligram	Daily			
Batch:	Started:			Stopped:	20/09/1989	
STREPTOMYCIN SULPHATE (Sus	spected)		Reason:			
	100.0	Milligram	Daily			
Batch:	Started:			Stopped:	20/09/1989	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

Report Run: 01/06/2007 04:13PM Database: pusime02 ADRS004 Page 38 of 495



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 65456 Seq: 1 Gender: F

Reported: 11/04/1990 Weight: 51.00 Hospitalisation: Age: 40Y

**Onset Date**: 09/02/1990 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Dyskinesia			

## **Medicine Details:**

LARGACTIL (Suspected)		Reason:	Malignant neoplasm of breast	
Oral application	150.0 Milligram	Total	Oral	
Batch:	Started: 09/02/1990		Stopped:	
CYCLOPHOSPHAMIDE (Suspected)		Reason:	Malignant neoplasm of breast	
Injection	750.0 Milligram	Daily	Intravenous	
Batch:	Started: 09/02/1990		Stopped:	
METHOTREXATE (Suspected)		Reason:	Malignant neoplasm of breast	
Injection	750.0 Milligram	Daily	Intravenous	
Batch:	Started: 09/02/1990		Stopped:	
FLUOROURACIL (Suspected)		Reason:	Malignant neoplasm of breast	
Injection	750.0 Milligram	Daily	Intravenous	
Batch:	Started: 09/02/1990		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Re	po	rt	De	tai	ls:
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Case Number: 65606 Seq: 1 Gender: F

Reported: 29/11/1989 Weight: 49.00 Hospitalisation: Age: 68Y

Onset Date: 28/11/1989 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Muscle twitching			

## **Medicine Details:**

MAXOLON (Other drug)		Reason:		
Oral application	30.0 Milligram	Daily	Oral	
Batch:	<b>Started:</b> 13/11/1989	S	Stopped:	CONTIN
FLUOROURACIL (Suspected)		Reason:		
Injection	1.4 Gram	Total	Intravenous	
Batch:	Started: 28/11/1989	S	Stopped:	
ADRIAMYCIN (Suspected)		Reason:		
Injection	40.0 Milligram	Daily	Intravenous	
Batch:	<b>Started:</b> 28/11/1989	S	Stopped:	
MITOMYCIN (Suspected)		Reason:		
Injection	14.0 Milligram	Daily	Intravenous	
Batch:	Started: 28/11/1989	S	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Report Run: 01/06/2007 04:13PM Database: pusime02 ADRS004 Page 40 of 495



# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	65606	Seq: 1		G	ender:	F	
Reported:	29/11/1989	•		W	eight:	49.00	
- Hospitalisation:					Age:		
Onset Date:	28/11/1989				DOB:		
Outcome:				Cau		Causality possible	
Reaction Detail					•		
Medicine Deta	ails:						
LARGACTIL (Susp			Reason:				7
Oral applica		50.0 Milligram	Daily	Oı	ral		
Batch:		Started: 28/11/1989	. ,	Stopped:			
AMOXIL (Suspecte	ed)		Reason:				-
(0.00	,	1.5 Gram	Daily				
Batch:		<b>Started:</b> 21/11/1989	,	Stopped: 29	)/11/1989	)	
				оторров			
Laboratory In	vestigations:						
Additional Inf	ormation:						
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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

DOB:

**Report Details:** 

Case Number: 66581 Seq: 1 Gender: M

Reported: 11/07/1990 Weight: 84.00 Hospitalisation: Age: 30Y

Outcome: Recovered Causality: Causality possible

Reaction Details:

Onset Date: 20/06/1990

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Barrier nursing, tobramycin iv 140mg tds.

## **Medicine Details:**

NITROUS OXIDE (Suspected)	Reaso	on:	Pain	
	0.0			
Batch:	Started: 25/05/1990		Stopped:	20/06/1990
CALCIPARINE (Suspected)	Reaso	on:	Other prophyla	actic procedures
Injection	10.0 Thousand Internat	Daily		Subcutaneous
Batch:	Started: 23/05/1990		Stopped:	20/06/1990
LARGACTIL (Suspected)	Reaso	on:	Pain	
Oral application	175.0 Milligram	Daily		Oral
Batch:	Started: 01/05/1990		Stopped:	20/06/1990
AMITRIP (Suspected)	Reaso	on:		
Oral application	125.0 Milligram	Daily		Oral
Batch:	Started: 26/04/1990		Stopped:	20/06/1990

**Laboratory Investigations:** 

<u> </u>	i ji iii tootiga				
Date	Туре	Range	Date Tested	Result	Details
	Haematology				1 1/6/90 5/6/90 13/6/90 20/6/90 23/6/90 1/7/90 neutrophils:8.89 5.63 1.92 0.04 1.22 5.11

#### **Additional Information:**

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# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: 66581	Seq: 1			Gender:	M	
Reported: 11/07/1990	•			Weight:	84.00	
Hospitalisation:				Age:		
Onset Date: 20/06/1990				DOB:		
Outcome: Recovered			С		Causality possible	
Reaction Details:				·		
Medicine Details:						
CLAFORAN (Suspected)		Reason:				
Injection	4.0 Gram	Daily		Intravenous		
Batch:	Started: 17/06/1990	,	Stopped:	20/06/1990		
GENTAMICIN SULPHATE (Suspected)		Reason:				
Injection	300.0 Milligram	Daily		Intravenous		
Batch:	Started: 17/06/1990	,	Stopped:	20/06/1990		
Laboratory Investigations:						
Laboratory invoctigations.						
Additional Information:						
Additional information.						
port Pun : 01/06/2007 04:13PM Data	phase: pusimo02	VDD6004			Dana 40 - f	40E

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# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

ty  tl) 100.0 Milligram d: 20.0 Milligram	Report De	Cause escription  Unspecified psych	nosis	ty possible reatment
d) 00.0 Milligram d:	Reason: Daily	escription  Unspecified psych	DOB: sality: Causali  Tr	
d) 00.0 Milligram d:	Reason: Daily	escription  Unspecified psych	sality: Causali	
d) 00.0 Milligram d:	Reason: Daily	escription  Unspecified psych	Tr	
d) 00.0 Milligram d:	Reason: Daily	Unspecified psych	nosis	reatment
d) 00.0 Milligram d:	Reason: Daily	Unspecified psych	nosis	reatment
00.0 Milligram	Daily			
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00.0 Milligram	Daily			
00.0 Milligram	Daily			
00.0 Milligram	Daily			
00.0 Milligram	Daily			
d:		Ora		
			al	
20.0 Milligram		Stopped:		
20.0 Milligram	Reason:	Unspecified psych	nosis	
	Daily			
d:		Stopped:		
e Tested Re	esult		Details	
e	Tested R	Tested Result	Tested Result	Tested Result Details



# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Repoi Hospitalisat Onset D Outco	<b>ne:</b> Recovered	)		Wei	nder: F ight: Age: 27 DOB: 03/10/1962 ality: Causality probable
eaction D	<b>letails:</b> eferred Term	Severity	Pen	ort Description	Treatment
Oedema pe		Seventy	ιτορι	ort Description	Heatment
Rash					
Medicine	Details:				
LARGACTIL			Rea	son:	
		100.0	Milligram	Daily	
Bato	ch:	Started: 20/	02/1990	Stopped: 23/0	2/1990
Laborato	ry Investigati	ons:			
Date	Туре	Range Date Test	ed Result		Details
Additiona	ıl Informatior	ı:			
eport Run: 01/	06/2007 04:13PM	Database: pusime02	A	ADRS004	Page 45 of 495



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 67150 Seq: 1 Gender: F

Reported: 22/08/1990 Weight:
Hospitalisation: Age: 72Y

**Onset Date**: 21/08/1990 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

t todotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Confusional state			
Convulsion			

### **Medicine Details:**

MIANSERIN HYDROCHLORIDE (Suspected	i)	Reason:	Depression	
Tablet	240.0 Milligram	Daily		Oral
Batch:	Started: 14/08/1990		Stopped:	21/08/1990
LARGACTIL (Suspected)		Reason:	Depression	
Tablet	25.0 Milligram	Daily		Oral
Batch:	Started: 01/01/1983		Stopped:	21/08/1990
BROMAZEPAM (Suspected)		Reason:	Anxiety neuros	sis
Tablet	3.0 Milligram	Daily		Oral
Batch:	Started: 01/01/1983		Stopped:	20/08/1990
ALDOMET (Suspected)		Reason:	Essential beni	gn hypertension
Tablet	250.0 Milligram	Daily		Oral
Batch:	Started: 01/01/1989		Stopped:	22/08/1990

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details:				
Case Number: 67150 Reported: 22/08/1990	Seq: 1		Gen Weig	der: F ght:
Hospitalisation:				<b>Age</b> : 72Y
Onset Date: 21/08/1990				OOB:
Outcome: Recovered			Causa	ality: Causality possible
Reaction Details:				
Medicine Details:				
VOLTAREN (Suspected)		Reason:	Unspecified arthritis	
	100.0 Milligram	Daily		
Batch:	<b>Started:</b> 01/01/1989		Stopped: 22/08	8/1990
Laboratory Investigations:				
, ,				
Additional Information:	out in all and an about the Control of		and advantage of the second	Alan alanana akami distribu sid
the dosage start date is not accurate be accurate but indicates that start occurroccurred sometime during the year. the	out indicates that start occuri red sometime during the yea e dosage start date is not ac	red sometim ar. the dosag ccurate but	ne during the year. t ge start date is not a indicates that start o	tne dosage start date is not accurate but indicates that start occurred sometime during the

Report Run: 01/06/2007 04:13PM Database: pusime02 ADRS004 Page 47 of 495



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Re	po	rt C	)eta	ils:

 Case Number:
 68215
 Seq: 1
 Gender:
 M

 Reported:
 30/10/1990
 Weight:
 80.00

 Hospitalisation:
 Age: 47Y

**Onset Date**: 06/08/1990 **DOB**:

Outcome: Recovered Causality: Causality possible

#### **Reaction Details:**

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			
Hypertension			
Pyrexia			Propranolol 40 mg tds from 03/09/90 to 05/09/90 with no effect
Salivary hypersecretion			

## **Medicine Details:**

viedicine Details:			
STELAZINE (Suspected)		Reason: Unspecified schizophrenia	
	0.0		
Batch:	Started:	Stopped:	
CHLORPROMAZINE HYDROCHLO	RIDE (Suspected)	Reason: Unspecified schizophrenia	
	100.0 Milligram	Daily	
Batch:	Started: 17/07/1990	<b>Stopped</b> : 06/08/1990	
MODECATE (Suspected)		Reason: Unspecified schizophrenia	
Injection	50.0 Milligram	Alternate weeks Intramuscular	
Batch:	Started: 09/07/1990	Stopped: 17/08/1990	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Report Run: 01/06/2007 04:13PM Database: pusime02 ADRS004 Page 48 of 495



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Re	po	rt	De	tai	ls:
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Case Number: 68499 Seq: 1 Gender: M

 Reported: 30/11/1990
 Weight: 73.00

 Hospitalisation:
 Age: 45Y

**Onset Date**: 10/11/1990 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

#### Reaction Details:

Ì	Preferred Term	Severity	Report Description	Treatment
	Oedema			

#### **Medicine Details:**

Micalcinic Details.				
CHLORPROMAZINE HYDROCHLORII	DE (Suspected)	Reason:	Unspecified psychosis	
Oral application	0.0		Oral	
Batch:	<b>Started:</b> 10/11/1990		<b>Stopped:</b> 22/11/1990	
HALOPERIDOL (Suspected)		Reason:	Unspecified psychosis	
Oral application	50.0 Milligram	Daily	Oral	
Batch:	Started: 05/11/1990		<b>Stopped:</b> 10/11/1990	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 68768 Seq: 1 Gender: M
Reported: 12/12/1990 Weight:

Hospitalisation: Age: 73Y
Onset Date: 11/12/1990
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

todotion Dotanoi			
Preferred Term	Severity	Report Description	Treatment
Rhinitis			
Tachycardia			Infusion stopped after 75 mls given, s/c adrenaline iml 1:1000

#### **Medicine Details:**

LARGACTIL (Suspected)		Reason: Otr ecz&der due otr&u	nsp cause
Injection, intravenous infusion	50.0 Milligram	1 time Intrave	nous
Batch:	Started: 11/12/1990	Stopped:	
PHENERGAN (Suspected)		Reason: Otr ecz&der due otr&u	nsp cause
Injection, intravenous infusion	50.0 Milligram	1 time Intrave	nous
Batch:	Started: 11/12/1990	Stopped:	
RINGERS SOLUTION (Suspected)		Reason: Otr ecz&der due otr&u	nsp cause
Injection, intravenous infusion	1.0 Litre	1 time Intrave	nous
Batch:	Started: 11/12/1990	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Report Run: 01/06/2007 04:13PM Database: pusime02 ADRS004 Page 50 of 495



Case Number: 69161

Reported: 17/01/1991

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

**Weight:** 75.00

eaction Details:	Outcome: Not yet recovered tion Details:  Preferred Term Severity Report Description Treatment initial pain usional state es discoloured nolence  Details:  Reason:  0.0  Batch: Started: Stopped:  GACTIL (Suspected) Reason: Hiccough Oral application 10.0 Milligram Daily Oral Batch: Started: 15/01/1991 Stopped: 16/01/1991	Outcome: Not yet recovered			
Action Details:  Preferred Term Severity Report Description Treatment odominal pain onfusional state access discoloured omnolence  Details:  ALCOHOL (Suspected)  Batch: Started: Stopped:  ARGACTIL (Suspected)  Oral application 10.0 Milligram Daily Oral	tion Details:  Preferred Term Severity Report Description Treatment  minal pain usional state es discoloured nolence  licine Details: OHOL (Suspected) Reason:  GACTIL (Suspected) Reason: Hiccough Oral application 10.0 Milligram Daily Oral Batch: Started: 15/01/1991 Stopped: 16/01/1991	_			
Preferred Term Severity Report Description Treatment odominal pain onfusional state access discoloured omnolence   edicine Details:  ALCOHOL (Suspected) Reason:  0.0  Batch: Started: Stopped:  ARGACTIL (Suspected) Reason: Hiccough Oral application 10.0 Milligram Daily Oral	Preferred Term Severity Report Description Treatment  minal pain usional state es discoloured nolence    Column Details:		∍d	Caus	ality: Causality possible
edicine Details:  ALCOHOL (Suspected)  Batch:  Started:  Started:  Reason:  ARGACTIL (Suspected)  Oral application  10.0 Milligram  Daily  Oral	minal pain usional state es discoloured nolence    Comparison				
edicine Details:  LCOHOL (Suspected)  Batch:  Started:  Stopped:  Reason:  Hiccough  Oral application  10.0 Milligram  Daily  Oral	usional state es discoloured nolence    Comparison		Severity	Report Description	Treatment
edicine Details: LCOHOL (Suspected)  Batch:  Started:  Stopped:  Reason: Hiccough Oral application  10.0 Milligram Daily Oral	es discoloured nolence    Color   Color				
edicine Details: ALCOHOL (Suspected)  Batch: Started: Stopped: ARGACTIL (Suspected)  Oral application 10.0 Milligram Daily Oral	licine Details: OHOL (Suspected)  Batch: Started: Stopped: GACTIL (Suspected) Oral application 10.0 Milligram Daily Oral Batch: Started: 15/01/1991 Stopped: 16/01/1991				
edicine Details:  ALCOHOL (Suspected)  Batch: Started: Stopped:  ARGACTIL (Suspected)  Oral application  10.0 Milligram  Daily  Oral	licine Details: OHOL (Suspected)  Batch: Started: Stopped: GACTIL (Suspected)  Oral application  Batch: Started: 15/01/1991  Stopped: 16/01/1991  Stopped: 16/01/1991				
ALCOHOL (Suspected)  0.0  Batch: Started: Stopped:  ARGACTIL (Suspected)  Oral application 10.0 Milligram Daily Oral	OHOL (Suspected)  Batch: Started: Stopped:  GACTIL (Suspected)  Oral application  Batch: Started: 15/01/1991  Stopped: 16/01/1991  Oral  Batch: Started: 15/01/1991  Oral  Oral  Daily  Oral  Stopped: 16/01/1991	omnoience			
ALCOHOL (Suspected)  0.0  Batch: Started: Stopped:  LARGACTIL (Suspected)  Oral application 10.0 Milligram Daily Oral	OHOL (Suspected)  Batch: Started: Stopped:  GACTIL (Suspected)  Oral application  Batch: Started: 15/01/1991  Stopped: 16/01/1991  Oral  Batch: Started: 15/01/1991  Oral  Oral  Daily  Oral  Stopped: 16/01/1991				
ALCOHOL (Suspected)  0.0  Batch: Started: Stopped:  LARGACTIL (Suspected)  Oral application 10.0 Milligram Daily Oral	OHOL (Suspected)  Batch: Started: Stopped:  GACTIL (Suspected)  Oral application  Batch: Started: 15/01/1991  Stopped: 16/01/1991  Oral  Batch: Started: 15/01/1991  Oral  Oral  Daily  Oral  Stopped: 16/01/1991				
ALCOHOL (Suspected)  0.0  Batch: Started: Stopped:  ARGACTIL (Suspected)  Oral application 10.0 Milligram Daily Oral	OHOL (Suspected)  Batch: Started: Stopped:  GACTIL (Suspected)  Oral application  Batch: Started: 15/01/1991  Stopped: 16/01/1991  Oral  Batch: Started: 15/01/1991  Oral  Oral  Daily  Oral  Stopped: 16/01/1991				
ALCOHOL (Suspected)  0.0  Batch: Started: Stopped:  ARGACTIL (Suspected)  Oral application  10.0 Milligram  Daily  Oral	OHOL (Suspected)  Batch: Started: Stopped:  GACTIL (Suspected)  Oral application  Batch: Started: 15/01/1991  Stopped: 16/01/1991  Oral  Batch: Started: 15/01/1991  Oral  Oral  Daily  Oral  Stopped: 16/01/1991				
Datch: Started: Stopped:  ARGACTIL (Suspected) Reason: Hiccough Oral application 10.0 Milligram Daily Oral	Batch: Started: Stopped:  GACTIL (Suspected) Reason: Hiccough Oral application 10.0 Milligram Daily Oral Batch: Started: 15/01/1991 Stopped: 16/01/1991	ledicine Details:			
Batch: Started: Stopped:  ARGACTIL (Suspected) Reason: Hiccough Oral application 10.0 Milligram Daily Oral	Batch: Started: Stopped:  GACTIL (Suspected) Reason: Hiccough  Oral application 10.0 Milligram Daily Oral  Batch: Started: 15/01/1991 Stopped: 16/01/1991	ALCOHOL (Suspected)		Reason:	
ARGACTIL (Suspected)  Oral application  10.0 Milligram  Daily  Oral	GACTIL (Suspected)  Oral application  10.0 Milligram  Daily  Oral  Batch:  Started: 15/01/1991  Stopped: 16/01/1991  Oratory Investigations:				
Oral application 10.0 Milligram Daily Oral	Oral application 10.0 Milligram Daily Oral  Batch: Started: 15/01/1991 Stopped: 16/01/1991  Oratory Investigations:		Started:		
	Batch: Started: 15/01/1991 Stopped: 16/01/1991  oratory Investigations:				
Batch: Started: 15/01/1991 Stopped: 16/01/1991	oratory Investigations:	Oral application	10.0 Mill		ıl
		Batch:	Started: 15/01/1	991 <b>Stopped</b> : 16/	01/1991
aboratory Investigations:		aboratory Investigations	:		
				Result	Details
			<b>1</b>		
			<u> </u>		
dditional Information:	itional Information:	dditional Information:	1		
dditional Information:	itional Information:	dditional Information:	1		
dditional Information:	itional Information:	dditional Information:	1		



Case Number: 69546

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

Reported: 11/02/1991			Weigh	t:
spitalisation:			Ag	e: 27Y
Onset Date: 03/02/1991			DO	
Outcome: Recovered			Causalit	y: Causality probable
action Details:	<u> </u>		1	
Preferred Term	Severity	Report D	escription	Treatment
ermatitis				
mphadenopathy				
edicine Details:				
CHLORPROMAZINE HYDROCHL		Reason:	Unspecified psychosis	
Batch:	200.0 Mil <b>Started:</b> 19/01/		/ Stopped: 04/02/1	
aboratory Investigation  Date Type		Result	De	etails
Date Type	Range Date Tested	resuit		tano
Additional Information	:			



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 70181 Seq: 1 Gender: M
Reported: 08/03/1991 Weight:
Hospitalisation: Age: 52Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndro	me		Valium

## **Medicine Details:**

MODECATE (Suspected)		Reason: Unspecified psychosis
Injection	25.0 Milligram	Daily Intramuscular
Batch:	Started: 15/02/1991	Stopped: 15/02/1991
STELAZINE (Suspected)		Reason: Unspecified psychosis
Oral application	20.0 Milligram	Daily Oral
Batch:	Started: 20/02/1991	<b>Stopped</b> : 22/02/1991
LARGACTIL (Suspected)		Reason: Unspecified psychosis
Oral application	800.0 Milligram	Daily Oral
Batch:	Started: 21/02/1991	<b>Stopped</b> : 22/02/1991
COGENTIN (Suspected)		Reason: Unspecified psychosis
Tablet	2.0 Milligram	Daily Oral
Batch:	Started: 20/02/1991	<b>Stopped</b> : 22/02/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 70292 Seq: 1 Gender: F

Reported: 03/04/1990 Weight: 65.00 Hospitalisation: Age: 21Y

**Onset Date**: 07/02/1990 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term Severity		Report Description	Treatment
Hypotension	- Continu		Observation.
Syncope			

## **Medicine Details:**

GR43175 (SUMATRIPTAN) TRIAL	(Other drug)	Reason:	Migraine	
	1.0 Dose Unspe	cified As ne	ecessary	
Batch:	<b>Started:</b> 06/11/1989		Stopped:	08/03/1990
STEMETIL (Suspected)		Reason:	Migraine	
Injection	0.0			Intravenous
Batch:	Started: 07/02/1990		Stopped:	
LARGACTIL (Suspected)		Reason:	Migraine	
Injection	400 0 Millianana	Daile		Intervance

Injection 100.0 Milligram Daily Intravenous

Batch: Started: 07/02/1990 Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 70595 Seq: 1 Gender: M

Reported: 01/05/1991 Weight: 99.00 Hospitalisation: Age: 37Y

**Onset Date**: 11/02/1991 **DOB**:

Outcome: Recovered Causality: Causality certain

Reaction Details:

•	todotion Details.				
	Preferred Term	Severity	Report Description	Treatment	
	Priapism			Surgical treatment	
	Priapism				

### **Medicine Details:**

FLUPHENAZINE DECANOATE (Other drug)		Reason:	Unspecified schizophreni	a
Injection	50.0 Milligram	Weel	kly Intramuso	cular
Batch:	Started: 10/04/1990		Stopped:	CONTIN
PROTHIADEN (Other drug)		Reason:	Depression	
Tablet	75.0 Milligram	Daily	Oral	
Batch:	Started: 24/01/1991		Stopped:	CONTIN
HYPNODORM (Other drug)		Reason:	Unspecified schizophreni	a
Tablet	2.0 Milligram	Daily	Oral	
Batch:	Started: 24/01/1991		Stopped:	CONTIN
LARGACTIL (Suspected)		Reason:	Unspecified schizophreni	a
Tablet	200.0 Milligram	Daily	Oral	
Batch:	Started: 31/01/1991		<b>Stopped:</b> 11/02/199	91

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

Case Number: 70900 Seq: 1 Gender: M

Reported: 30/04/1991 Weight: 90.00 Hospitalisation: Age: 52Y

Onset Date: 23/04/1991 DOB:

Outcome: Recovered Causality: Causality possible

#### Reaction Details:

•	todotion Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
	Ketosis			
	Pancreatitis			

## **Medicine Details:**

LORAZEPAM (Suspected)	F	Reason:		
Tablet	2.0 Milligram	1 time	Oral	
Batch:	Started: 19/04/1991		Stopped:	
METOCLOPRAMIDE HYDROCHLORIC	E (Suspected)	Reason:		
Injection	20.0 Milligram	1 time	Intravenous	
Batch:	Started: 19/04/1991		Stopped:	
COLASPASE NOS (Suspected)	F	Reason:		
Injection	45.0 Thousand Inter	nat Daily	Intravenous	
Batch:	Started: 20/04/1991		Stopped:	
LEUCOVORIN (Suspected)	- F	Reason:		
	-			
Oral application	60.0 Milligram	Daily	Oral	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

Case Number: 70900 Seq: 1 Gender: M

 Reported: 30/04/1991
 Weight: 90.00

 Hospitalisation:
 Age: 52Y

**Onset Date**: 23/04/1991 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

## **Medicine Details:**

ALLOPURINOL (Suspected)		Reason:		
Oral application	300.0 Milligram	Daily	Oral	
Batch:	Started: 19/04/1991	Sto	pped:	
AMPHOTERICIN (Suspected)		Reason:		
Lozenge	40.0 Milligram	Daily	Oral	
Batch:	Started: 19/04/1991	Sto	pped:	
LORAZEPAM (Suspected)		Reason: Nausea	and vomiting	
Tablet	8.0 Milligram	Daily	Oral	
Batch:	Started: 19/04/1991	Sto	pped:	
LARGACTIL (Suspected)		Reason: Nausea	and vomiting	
Oral application	150.0 Milligram	Daily	Oral	
Batch:	Started: 19/04/1991	Sto	pped:	

# **Laboratory Investigations:**

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Re	po	rt D	etai	ls:
----	----	------	------	-----

Case Number: 71317 Gender: M Seq: 1 Reported: 31/05/1991 Weight: Hospitalisation: Age: 54Y

Onset Date: 06/05/1991 DOB:

Outcome: Not yet recovered Causality: Causality possible

#### **Reaction Details:**

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia			Ciprofloxacin ceased.

### **Medicine Details:**

Batch:

VENTOLIN (Suspected)		Reason:	
	0.0		

Batch: Started: Stopped:

**BECOTIDE** (Suspected) Reason: Inhalation 0.0 Inhalation

Started: Stopped:

**CHLORPROMAZINE HYDROCHLORIDE (Suspected)** Reason: Nausea and vomiting

> 100.0 Milligram As necessary

Started: Stopped: METOCLOPRAMIDE HYDROCHLORIDE (Suspected) Reason: Nausea and vomiting

10.0 Milligram As necessary

Batch: Started: Stopped:

## **Laboratory Investigations:**

Date	Туре	Range	Date Tested	Result		Details
	Platelets				6/5/91 platelet count 13,	12/6/91 platelet count 20.

### **Additional Information:**

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Case Number: 71317

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

<b>Reported:</b> 31/05/1991					weight:
lospitalisation:					Age: 54Y
Onset Date: 06/05/1991					DOB:
Outcome: Not yet recovered				С	ausality: Causality possible
action Details:					
/ledicine Details:					
CIPROFLOXACIN (Suspected)			Reason:	Otr&nos infec	&parasit diseases
	1.0	Gram	Daily		
Batch:	Started: 03/	05/1991		Stopped:	10/05/1991
RANITIDINE (Suspected)			Reason:	Gastritis&duod	denitis
Tablet	300.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	10/05/1991
TEMAZEPAM (Suspected)			Reason:		
	10.0	Milligram	Daily		
Batch:	Started:			Stopped:	
MAGNESIUM ASPARTATE (Suspected)			Reason:		
Tablet	3.0	Gram	Daily		Oral
Batch:	Started:		·	Stopped:	
_aboratory Investigations:					
Additional Information:					
Additional Information:					
Additional Information:					
Additional Information:					
Additional Information:					

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	71317	Seq: 1			Gender:	М
Reported:	31/05/1991				Weight:	
Hospitalisation:					Age:	54Y
Onset Date:	06/05/1991				DOB:	
Outcome:	Not yet recovered	İ			Causality:	Causality possible
Reaction Detai	ls:					
Medicine Det						
BACLOFEN (Susp	ected)			Reason:		
Tablet			Milligram	Daily	Oral	
Batch:		Started:			Stopped:	
MENAPHTHONE S	ODIUM BISULPHITE		B 4:11:	Reason:		
<b>5</b>			Milligram	Daily	<b>0</b> .	
Batch:		Started:			Stopped:	
Laboratory In	vestigations:					
,	J					
Additional Inf	formation:					
Additional Inf	formation:					
Additional Inf	formation:					
Additional Inf	formation:					
Additional Inf	formation:					

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: 71706	Seq: 1				Gender	r: F
Reported: 05/07/1991	-				Weight	:
ospitalisation:					Age	: 90Y
Onset Date: 03/07/1991					DOE	
Outcome: Not yet recovered				С	ausality	: Causality possible
eaction Details:		r				
Preferred Term	Severity		ort Descri	ption		Treatment
Syncope		Fell down			C	argactil was not properly eased by doctor, resulted ommencement again on /7/91.
Somnolence		Heavily sedated	, drowsy, ł	nard to are	ouse	
Medicine Details:						
Medicine Details:  MOGADON (Suspected)		Rea	son:			
		Dose Unspecified			Oral	
MOGADON (Suspected)  Tablet  Batch:	1.0 <b>Started:</b> 02/	Dose Unspecified 07/1991	Daily	Stopped:	Oral	
Tablet  Batch:  LARGACTIL (Suspected)	Started: 02/	Dose Unspecified 07/1991 Rea	Daily	Stopped:		
MOGADON (Suspected)  Tablet  Batch:  LARGACTIL (Suspected)  Oral application	<b>Started:</b> 02/ 25.0	Dose Unspecified 07/1991 Rea Milligram	Daily son: Daily		Oral	04
MOGADON (Suspected)  Tablet  Batch:  LARGACTIL (Suspected)  Oral application  Batch:	Started: 02/	Dose Unspecified 07/1991 <b>Rea</b> Milligram 07/1991	Daily son: Daily	Stopped:	Oral	91
MOGADON (Suspected)  Tablet  Batch:  LARGACTIL (Suspected)  Oral application  Batch:  ECOTRIN (Suspected)	25.0 Started: 02/9	Dose Unspecified 07/1991 Rea Milligram 07/1991 Rea	Daily son: Daily son:		Oral 04/07/19	91
MOGADON (Suspected)  Tablet  Batch:  LARGACTIL (Suspected)  Oral application  Batch:	25.0 Started: 02/9	Dose Unspecified 07/1991  Rea Milligram 07/1991  Rea Dose Unspecified	Daily  son: Daily  son: Daily	Stopped:	Oral	91
MOGADON (Suspected) Tablet Batch:  LARGACTIL (Suspected) Oral application Batch:  ECOTRIN (Suspected) Tablet	25.0 Started: 02/ 1.0	Dose Unspecified 07/1991  Rea Milligram 07/1991  Rea Dose Unspecified 07/1991	Daily  son: Daily  son: Daily		Oral 04/07/19	91
MOGADON (Suspected)  Tablet  Batch:  LARGACTIL (Suspected)  Oral application  Batch:  ECOTRIN (Suspected)  Tablet  Batch:	25.0 Started: 02/ 1.0 Started: 02/	Dose Unspecified 07/1991  Rea Milligram 07/1991  Rea Dose Unspecified 07/1991	Daily  son: Daily  son: Daily	Stopped:	Oral 04/07/19	91
MOGADON (Suspected) Tablet Batch:  LARGACTIL (Suspected) Oral application Batch:  ECOTRIN (Suspected) Tablet Batch:  LANOXIN (Suspected)	25.0 Started: 02/ 1.0 Started: 02/	Dose Unspecified 07/1991  Rea Milligram 07/1991  Rea Dose Unspecified 07/1991  Rea Microgram	Daily  son: Daily  son: Daily  son: Daily	Stopped:	Oral 04/07/199 Oral	91
MOGADON (Suspected)  Tablet  Batch:  LARGACTIL (Suspected)  Oral application  Batch:  ECOTRIN (Suspected)  Tablet  Batch:  LANOXIN (Suspected)  Tablet  Batch:	25.0 Started: 02/  1.0 Started: 02/  250.0	Dose Unspecified 07/1991  Rea Milligram 07/1991  Rea Dose Unspecified 07/1991  Rea Microgram	Daily  son: Daily  son: Daily  son: Daily	Stopped:	Oral 04/07/199 Oral	91
MOGADON (Suspected)  Tablet  Batch:  LARGACTIL (Suspected)  Oral application  Batch:  ECOTRIN (Suspected)  Tablet  Batch:  LANOXIN (Suspected)  Tablet	25.0 Started: 02/  1.0 Started: 02/  250.0 Started: 02/	Dose Unspecified 07/1991  Rea Milligram 07/1991  Rea Dose Unspecified 07/1991  Rea Microgram 07/1991	Daily  son: Daily  son: Daily  son: Daily	Stopped:	Oral 04/07/199 Oral	

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# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Reported: 05/07/1991 ospitalisation: Onset Date: 03/07/1991 Outcome: Not yet recovered action Details:				aight: Age: 90Y DOB: ality: Causality possible
Iedicine Details: SLOW-K (Suspected) Tablet Batch: LASIX (Suspected) Oral application	2.0 Dose Unspect Started: 02/07/1991	Reason:	Ora Stopped:	
Batch:	Started: 02/07/1991	•	Stopped:	
aboratory Investigations:				

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 71902 Seq: 1 Gender: M
Reported: 02/07/1991 Weight:
Hospitalisation: Age: 23Y

**Onset Date**: 01/07/1991 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Puritic rash on face/cheeks/chin	
Photosensitivity reaction			
Pruritus			

#### **Medicine Details:**

LARGACTIL (Suspected)

Reason: Unspecified schizophrenia

300.0 Milligram Daily

Batch: Started: 01/01/1989 Stopped: 02/07/1991

COGENTIN (Suspected) Reason:

4.0 Milligram Daily

Batch: Started: 01/01/1989 Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Gender: F Case Number: 72357 Seq: 1 Reported: 09/08/1991 Weight:

**Hospitalisation:** Age: 67Y Onset Date: 03/04/1991 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

i toaction Botano.			
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			
Hepatomegaly			

### **Medicine Details:**

ANGININE (Suspected)		Rea	ison:		
Tablet	1.0	Dose Unspecified	As necessary	Sublingual	
Batch:	Started:		Stoppe	d:	CONTIN
SIMVASTATIN (Suspected)		Rea	ison:		
	20.0	Milligram	Daily		
Batch:	Started:		Stoppe	d: 11/04/1991	
VERAPAMIL HYDROCHLORIDE (Su	spected)	Rea	son: Essential b	enign hypertensio	n
	240.0	Milligram	Daily		
Batch:	Started:		Stoppe	d:	CONTIN
FRUSEMIDE (Suspected)		Rea	ison:		
	40.0	Milligram	Daily		

Stopped:

CONTIN

**Laboratory Investigations:** 

Batch:

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT	6-42 U/L	03/04/1991	61	
	AST = SGOT	6-42 U/L	04/04/1991	65	
	AST = SGOT	6-42 U/L	08/04/1991	75	
	AST = SGOT	6-42 U/L	06/04/1991	54	
	AST = SGOT	6-42 U/L	09/04/1991	84	
	AST = SGOT	6-42 U/L	29/04/1991	41	
	AST = SGOT	6-42 U/L	27/05/1991	49	

Started:

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 72357
 Seq: 1
 Gender:
 F

 Reported:
 09/08/1991
 Weight:

Hospitalisation:
Onset Date: 03/04/1991
Age: 67Y
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

### **Medicine Details:**

ISOSORBIDE DINITRATE (Suspected)		F	Reason:			
	30.0	Milligram	Daily			
Batch:	Started:			Stopped:	03/04/1991	
SLOW-K (Suspected)		F	Reason:			
	4.0	Dose Unspecifie	ed Daily			
Batch:	Started:			Stopped:		CONTIN
DIAZEPAM (Suspected)		F	Reason:			
	5.0	Milligram	Daily			
Batch:	Started:			Stopped:		CONTIN
CHLORPROMAZINE HYDROCHLORIDE (Se	uspected)	F	Reason:			
	100.0	Milligram	Daily			
Batch:	Started:			Stopped:	05/04/1991	

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	6-42 U/L	30/04/1991	44	
	AST = SGOT	6-42 U/L	13/04/1991	66	
	Bilirubin	20 MCMOL/L	03/04/1991	4	
	Bilirubin	20 MCMOL/L	04/04/1991	6	
	Bilirubin	20 MCMOL/L	08/04/1991	-	
	Bilirubin	20 MCMOL/L	06/04/1991	5	
	Bilirubin	20 MCMOL/L	13/04/1991	4	

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 72357 Seq: 1 Gender: F

Reported: 09/08/1991 Weight:
Hospitalisation: Age: 67Y

Onset Date: 03/04/1991 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

#### **Medicine Details:**

Medicine Details.			
TEMAZEPAM (Suspected)	F	Reason:	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
DIGOXIN (Suspected)	F	Reason:	
	250.0 Microgram	Daily	
Batch:	Started:	Stopped:	CONTIN

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin	20 MCMOL/L	30/04/1991	5	
	Bilirubin	20 MCMOL/L	27/05/1991	5	
	Bilirubin	20 MCMOL/L	29/04/1991	-	
	Bilirubin	20 MCMOL/L	09/04/1991	6	
	GGT = SGGT =	40 U/L	03/04/1991	-	
	GGT = SGGT =	40 U/L	04/04/1991	-	
	GGT = SGGT =	40 U/L	06/04/1991	75	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 72357
 Seq: 1
 Gender:
 F

 Reported:
 09/08/1991
 Weight:

Hospitalisation: Age: 67Y
Onset Date: 03/04/1991
DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

**Medicine Details:** 

ANGININE (Suspected) Reason:

Tablet 1.0 Dose Unspecified As necessary Sublingual

Batch: Started: Stopped: CONTIN

SIMVASTATIN (Suspected) Reason:

20.0 Milligram Daily

Batch: Started: Stopped: 11/04/1991

**VERAPAMIL HYDROCHLORIDE (Suspected)**Reason: Essential benign hypertension

240.0 Milligram Daily

Batch: Started: Stopped: CONTIN

FRUSEMIDE (Suspected) Reason:

40.0 Milligram Daily

Batch: Started: Stopped: CONTIN

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =	40 U/L	09/04/1991	143	
	GGT = SGGT =	40 U/L	29/04/1991	-	
	GGT = SGGT =	40 U/L	27/05/1991	128	
	GGT = SGGT =	40 U/L	30/04/1991	-	
	GGT = SGGT =	40 U/L	13/04/1991	192	
	GGT = SGGT =	40 U/L	08/04/1991	-	
	Radiololgy				Ct of the liver showed fatty infiltration but no focal lesion.

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 72357
 Seq: 1
 Gender:
 F

 Reported:
 09/08/1991
 Weight:

 Reported:
 09/08/1991
 Weight:

 Hospitalisation:
 Age:
 67Y

 Onset Date:
 03/04/1991
 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

## **Medicine Details:**

ISOSORBIDE DINITRATE (Suspected)		F	Reason:			
	30.0	Milligram	Daily			
Batch:	Started:			Stopped:	03/04/1991	
SLOW-K (Suspected)		F	Reason:			
	4.0	Dose Unspecifie	ed Daily			
Batch:	Started:			Stopped:		CONTIN
DIAZEPAM (Suspected)		F	Reason:			
	5.0	Milligram	Daily			
Batch:	Started:			Stopped:		CONTIN
CHLORPROMAZINE HYDROCHLORIDE (S	uspected)	F	Reason:			
	100.0	Milligram	Daily			
Batch:	Started:			Stopped:	05/04/1991	

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP	35-135 U/L	03/04/1991	112	
	SAP = ALP	35-135 U/L	04/04/1991	117	
	SAP = ALP	35-135 U/L	06/04/1991	102	
	SAP = ALP	35-135 U/L	08/04/1991	-	
	SAP = ALP	35-135 U/L	09/04/1991	129	
	SAP = ALP	35-135 U/L	13/04/1991	121	
	SAP = ALP	35-135 U/L	29/04/1991	-	

#### **Additional Information:**

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Case Number: 72357

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

: 09/08/199	1				Weight:	
	1					
Unknown						Causality possible
					-	, ,
			Reas	on:		
		10.0 Millio	gram	Daily		
	S	tarted:			Stopped:	CONTIN
cted)		250.0 Micr				
	s	tarted:		:	Stopped:	CONTIN
nvestiga <u>t</u>						
Туре	Range	Date Tested	Result		Deta	ils
		Date Tested 30/04/1991 27/05/1991	Result 124 140		Deta	ils
	tails:	tails: spected)	tails:  spected)  10.0 Millig Started:	tails: spected) Reas Started: cted) Reas	tails:  spected)  Started:   tails:  spected)  Reason: 10.0 Milligram Daily  Started: Stopped:  Reason: 250.0 Microgram Daily	

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 72435 Seq: 1 Gender: M
Reported: 21/08/1991 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Paraesthesia	Severe	1st degree burning on wrist/hands/face	Hamilton's sunscreen spf 15+ applied 3-4 times daily.
Dermatitis bullous		Blistering on back of hands	
Cheilitis		Cracked lips	
Pruritus			

### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Su	spected)		Reason:	Unspecified schizophren	a
Oral application	600.0	Milligram	Daily	Oral	
Batch:	Started:	L	TERM	Stopped:	
THIORIDAZINE HYDROCHLORIDE (Suspect	ted)		Reason:	Unspecified schizophren	a
Tablet	800.0	Milligram	Daily	Oral	
Batch:	Started:	L	TERM	Stopped:	
CARBAMAZEPINE (Suspected)			Reason:		
Tablet	800.0	Milligram	Daily	Oral	
Batch:	Started:	L	TERM	Stopped:	
BENZTROPINE MESYLATE (Suspected)			Reason:		
Tablet	2.0	Milligram	Daily	Oral	
Batch:	Started:	L	TERM	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient exposed to chlorpromazine approx 18 months without effects described above.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 72445
 Seq: 1
 Gender:
 F

 Reported:
 21/08/1991
 Weight:

Hospitalisation: Age:

Onset Date: 31/07/1991 DOB:

Outcome: Not yet recovered Causality: Causality possible

#### Reaction Details:

١,	caction Betails.			
	Preferred Term	Severity	Report Description	Treatment
	Paraesthesia	Severe		Hamilton's sunscreen spf 15 + applied 3-4 times daily.
	Dermatitis bullous		Blistering back of hands.	
	Cheilitis		Cracked lips	
	Dry skin		Very dry skin.	

#### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORID	E (Suspected)		Reason:	Schizophrenia	
Oral application	900.0	Milligram	Daily		Oral
Batch:	Started:	I	L TERM	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient exposed to chlorpromazine for at least the last 5 years, without reaction. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

DOB:

**Report Details:** 

Case Number: 72503 Seq: 1 Gender: F

 Reported:
 20/08/1991
 Weight:
 75.00

 Hospitalisation:
 Age:
 44Y

Outcome: Not yet recovered Causality: Causality certain

Reaction Details:

**Onset Date: 18/08/1991** 

1,	teaction Details.				
	Preferred Term	Severity	Report Description	Treatment	
	Anaphylactoid reaction			lv saline haemaccel, adrenaline, aminophylline, hydrocortisone	

### **Medicine Details:**

LARGACTIL (Suspected) Reason:

Injection 50.0 Milligram 1 time Intramuscular

Batch: Started: Stopped:

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details

#### **Additional Information:**

Has had largactil 25-50 mg im many times before without complications.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

DOB:

**Report Details:** 

Case Number: 72517 Seq: 1 Gender: F

Reported: 16/08/1991 Weight: 62.00 Hospitalisation: Age: 73Y

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Onset Date: 03/08/1991

Preferred Term	Severity	Report Description	Treatment
Jaundice		Hepatocellular jaundice	

### **Medicine Details:**

GLUCOPHAGE (Other drug)

,				
Tablet	3.0 Do	se Unspecified Daily		Oral
Batch:	Started:	L TERM	Stopped:	
PREDNISOLONE (Suspected)		Reason:		
	0.0			
Batch:	Started: 13/01/1	Started: 13/01/1991		20/07/1991

Reason:

Diabetes mellitus

LARGACTIL (Suspected) Reason:

Injection 50.0 Milligram 8 times Intramuscular

Batch: Started: Stopped:

PANADEINE FORTE (Suspected) Reason: Pain

0.0 As necessary

**Batch: Started:** 01/07/1991 **Stopped:** 20/07/1991

# **Laboratory Investigations:**

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT	6-42 U/L	07/07/1991	19	
	AST = SGOT	6-42 U/L	08/08/1991	180	
	AST = SGOT	6-42 U/L	10/08/1991	196	
	AST = SGOT	6-42 U/L	20/09/1991	67	
	AST = SGOT	6-42 U/L	12/08/1991	136	
	Bilirubin	1-20 UMOL/L	07/07/1991	8	
	Bilirubin	1-20 UMOL/L	08/08/1991	282	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 72517 Seq: 1 Gender: F

 Reported:
 16/08/1991
 Weight:
 62.00

 Hospitalisation:
 Age:
 73Y

**Onset Date**: 03/08/1991 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

### **Medicine Details:**

VOLTAREN (Suspected) Reason:

3.0 Dose Unspecified Daily

**Batch: Started:** 02/07/1991 **Stopped:** 04/08/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin	1-20 UMOL/L	10/08/1991	236	
	Bilirubin	1-20 UMOL/L	12/08/1991	185	
	Bilirubin	1-20 UMOL/L	20/09/1991	58	
	GGT = SGGT =	1-40 U/L	07/07/1991	34	
	GGT = SGGT =	1-40 U/L	08/08/1991	2726	
	GGT = SGGT =	1-40 U/L	12/08/1991	3280	
	GGT = SGGT =	1-40 U/L	20/09/1991	1822	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Gender: F Case Number: 72517 Seq: 1

Reported: 16/08/1991 Weight: 62.00 Hospitalisation: Age: 73Y

Onset Date: 03/08/1991 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

**Medicine Details:** 

**GLUCOPHAGE** (Other drug) Reason: Diabetes mellitus

Tablet 3.0 Dose Unspecified Daily Oral

Batch: Started: L TERM Stopped: PREDNISOLONE (Suspected) Reason:

0.0

Started: 13/01/1991

Batch: Stopped: 20/07/1991

LARGACTIL (Suspected) Reason:

Injection 50.0 Milligram 8 times Intramuscular

Batch: Started: Stopped:

PANADEINE FORTE (Suspected) Reason: Pain

> 0.0 As necessary

Batch: Started: 01/07/1991 Stopped: 20/07/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =	1-40 U/L	10/08/1991	2718	
	SAP = ALP	35-135 U/L	07/07/1991	103	
	SAP = ALP	35-135 U/L	08/08/1991	515	
	SAP = ALP	35-135 U/L	10/08/1991	518	
	SAP = ALP	35-135 U/L	12/08/1991	539	
	SAP = ALP	35-135 U/L	20/09/1991	433	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details:			
Report Details:  Case Number: 72517 Reported: 16/08/1991 Hospitalisation: Onset Date: 03/08/1991 Outcome: Recovered Reaction Details:	Seq: 1	Gender: Weight: Age: DOB: Causality:	62.00
Medicine Details:  VOLTAREN (Suspected)  Batch:	Reason: 3.0 Dose Unspecified Daily Started: 02/07/1991	Stopped: 04/08/1991	
Laboratory Investigations:			
Additional Information:			

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 72776
 Seq: 1
 Gender:
 F

 Reported:
 11/09/1991
 Weight:
 74.00

 Hospitalisation:
 Age: 39Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction	Severe	Sunburn, blistering hands, neck, ankle.	Betamethasone 0.05% cream.
Oedema peripheral		Swelling of hands, ankles	

# **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Su	spected)		Reason:	Other atyp for	ms schizophrenia
Oral application	1.2	Gram	Daily		Oral
Batch:	Started:		L TERM	Stopped:	11/09/1991
HALOPERIDOL (Suspected)			Reason:	Other atyp for	ms schizophrenia
Oral application	30.0	Milligram	Daily		Oral
Batch:	Started:		L TERM	Stopped:	11/09/1991
CHLORPROMAZINE HYDROCHLORIDE (Su	spected)		Reason:	Other atyp for	ms schizophrenia
Oral application	800.0	Milligram	Daily		Oral
Batch:	Started: 11	/09/1991		Stopped:	
THIORIDAZINE HYDROCHLORIDE (Suspect	ted)		Reason:		
Oral application	800.0	Milligram	Daily		Oral
Batch:	Started: 11	/09/1991		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

Patient has had long term exposure to chlorpromazine without severe reaction until now.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 72798
 Seq: 1
 Gender:
 F

 Reported:
 03/09/1991
 Weight:

Hospitalisation:
Onset Date:

Age: 39Y
DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Retinal pigmentation			

#### **Medicine Details:**

Micalcinic Details.			
LARGACTIL (Suspected)		Reason:	
Oral application	500.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1977	Stopped:	02/11/1988
MELLERIL (Suspected)		Reason:	
Oral application	600.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1978	Stopped:	02/11/1988

**Laboratory Investigations:** 

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

### **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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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 72799
 Seq: 1
 Gender:
 F

 Reported:
 03/09/1991
 Weight:

Hospitalisation: Age: 39Y
Onset Date: 15/08/1991
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cataract		Eye deterioration.	

### **Medicine Details:**

MODURETIC (Suspected)	Reason:				
Injection	100.0 Milligram	Weekly	Intramuscular		
Batch:	Started: 01/01/1978	Stopped:	24/04/1989		
LARGACTIL (Suspected)	F	Reason:			
Oral application	500.0 Milligram	Daily	Oral		
Batch:	Started: 01/01/1977	Stopped:	12/11/1988		
MELLERIL (Suspected)	F	Reason:			
Oral application	600.0 Milligram	Daily	Oral		
Batch:	<b>Started:</b> 01/01/1978	Stopped:	12/11/1988		
SERENACE (Suspected)	F	Reason:			
	60.0 Milligram	Daily			
Batch:	Started: 01/01/1989	Stopped:			

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

On 15 aug 91 further eye deterioration noted, bilateral atrophic retinal changes, corneal haze (both corneas), anterior star shaped opacity with sub- ephithelial deposits on surface of both lenses. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 72810 Seq: 1 Gender: M

 Reported:
 03/09/1991
 Weight:
 80.00

 Hospitalisation:
 Age:
 23Y

**Onset Date**: 02/09/1991 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Candidiasis			Given oral nilstat with rapid relief.

### **Medicine Details:**

STELAZINE (Other drug)		Reason: Unspecif	ied psychosis	
Oral application	30.0 Milligram	Daily	Oral	
Batch:	<b>Started:</b> 28/08/1991	Stop	ped:	CONTIN
COGENTIN (Other drug)		Reason:		
Tablet	3.0 Milligram	Daily	Oral	
Batch:	Started: 28/08/1991	Stop	ped:	CONTIN
LARGACTIL (Suspected)		Reason: Unspecif	ied psychosis	
Oral application	200.0 Milligram	Daily	Oral	
Batch:	Started: 23/08/1991	Stop	ped: 02/09/1991	

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 73136 Seq: 1 Gender: F

 Reported: 26/09/1991
 Weight: 96.00

 Hospitalisation:
 Age: 52Y

 Onset Date: 25/09/1991
 DOB:

Onset Date: 25/09/1991

Outcome: Not yet recovered

Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Urticaria		Urticaria on back/arms then everywhere	Phenergan 75mg.

### **Medicine Details:**

NORFLOXACIN (Suspected)			Reason:		
Tablet	800.0	Milligram	1 time		Oral
Batch:	Started: 25/0	09/1991		Stopped:	
CEFOTAXIME SODIUM (Suspected)			Reason:		
Injection, intravenous infusion	6.0	Gram	Daily		Intravenous
Batch:	Started: 20/0	09/1991		Stopped:	25/09/1991
THYROXINE SODIUM (Suspected)			Reason:		
	100.0	Microgram	Daily		
Batch:	Started:			Stopped:	
RIVOTRIL (Suspected)			Reason:		
	1.0	Milligram	Daily		
Batch:	Started:			Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

Previous allergies: tongue blisters with penicillin, erythromycin, and bactrim.

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**Report Details:** 

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	73136	Seq: 1			Gender:	F
Reported:	26/09/1991				Weight:	96.00
Hospitalisation:					Age:	52Y
Onset Date:	25/09/1991				DOB:	
Outcome:	Not yet recovered				Causality:	Causality possible
Reaction Detail	ls:					
Medicine Deta	ails:					
LARGACTIL (Susp				Reason:		
		100.0	Milligram	Daily		
Batch:		Started:			Stopped:	
ROHYPNOL (Suspe	ected)			Reason:		
		2.0	Milligram	Daily		
Batch:		Started:			Stopped:	
Laboratory In	vestigations:					
•	J					
Additional Inf	ormation:					
Additional Info		penicillin, eryth	ıromycin, ar	nd bactrim.		
Additional Info		penicillin, eryth	romycin, ar	nd bactrim.		
		penicillin, eryth	romycin, ar	nd bactrim.		
		penicillin, eryth	romycin, ar	nd bactrim.		

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 74024
 Seq: 1
 Gender: M

 Reported:
 03/09/1991
 Weight:

Hospitalisation:
Onset Date: 15/07/1991
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

### **Medicine Details:**

HALOPERIDOL (Suspected)		Reason:	Other paranoid	d states
Tablet	80.0 Milligram	Daily		Oral
Batch:	Started: 01/07/1991		Stopped:	15/07/1991
CHLORPROMAZINE HYDROCHLORIDE (Suspected)				
Oral application	300.0 Milligram	Daily		Oral
Batch:	Started: 15/07/1991		Stopped:	31/07/1991
MYLANTA (Suspected)		Reason:		
Oral application	30.0 Millilitre	Daily		Oral
Batch:	Started: 13/07/1991		Stopped:	02/08/1991
AMOXYCILLIN TRIHYDRATE (Suspected)		Reason:		
Oral application	1.5 Gram	Daily		Oral
Batch:	Started: 10/07/1991		Stopped:	21/07/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Potassium	3.1-4.2	23/07/1991	3.9	Serum osmolality (272-283) 23/07, 30/07, 02/08, 09/08, 19/08, 16/09 245 251 273 281 286 267
	Potassium	3.1-4.2	30/07/1991	4.4	Serum osmolality (272-283) 23/07, 30/07, 02/08, 09/08, 19/08, 16/09 245 251 273 281 286 267
	Potassium	3.1-4.2	02/08/1991	4.6	Serum osmolality (272-283) 23/07, 30/07, 02/08, 09/08, 19/08, 16/09 245 251 273 281 286 267

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 74024
 Seq: 1
 Gender: M

 Reported:
 03/09/1991
 Weight:

Hospitalisation: Age: 62Y

**Onset Date**: 15/07/1991 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

# **Medicine Details:**

HALOPERIDOL (Suspected)		Reason:	Other paranoid	d states
Tablet	80.0 Milligram	Daily		Oral
Batch:	Started: 01/07/1991		Stopped:	15/07/1991
CHLORPROMAZINE HYDROCHLORIDE (Su	spected)	Reason:		
Oral application	300.0 Milligram	Daily		Oral
Batch:	Started: 15/07/1991		Stopped:	31/07/1991
MYLANTA (Suspected)		Reason:		
Oral application	30.0 Millilitre	Daily		Oral
Batch:	Started: 13/07/1991		Stopped:	02/08/1991
AMOXYCILLIN TRIHYDRATE (Suspected)		Reason:		
Oral application	1.5 Gram	Daily		Oral
Batch:	Started: 10/07/1991		Stopped:	21/07/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Potassium	3.1-4.2	16/09/1991	4.3	Serum osmolality (272-283) 23/07, 30/07, 02/08, 09/08, 19/08, 16/09 245 251 273 281 286 267
	Potassium	3.1-4.2	19/08/1991	3.8	Serum osmolality (272-283) 23/07, 30/07, 02/08, 09/08, 19/08, 16/09 245 251 273 281 286 267
	Potassium	3.1-4.2	09/08/1991	4.3	Serum osmolality (272-283) 23/07, 30/07, 02/08, 09/08, 19/08, 16/09 245 251 273 281 286 267
	Sodium	137-145	23/07/1991	122	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 74024
 Seq: 1
 Gender: M

 Reported:
 03/09/1991
 Weight:

Hospitalisation:
Onset Date: 15/07/1991

Weight:
Age: 62Y

DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

### **Medicine Details:**

HALOPERIDOL (Suspected)		Reason:	Other paranoid	d states
Tablet	80.0 Milligram	Daily		Oral
Batch:	Started: 01/07/1991		Stopped:	15/07/1991
CHLORPROMAZINE HYDROCHLORIDE (Su	spected)	Reason:		
Oral application	300.0 Milligram	Daily		Oral
Batch:	Started: 15/07/1991		Stopped:	31/07/1991
MYLANTA (Suspected)		Reason:		
Oral application	30.0 Millilitre	Daily		Oral
Batch:	Started: 13/07/1991		Stopped:	02/08/1991
AMOXYCILLIN TRIHYDRATE (Suspected)		Reason:		
Oral application	1.5 Gram	Daily		Oral
Batch:	Started: 10/07/1991		Stopped:	21/07/1991

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	Sodium	137-145	30/07/1991	125	
	Sodium	137-145	02/08/1991	135	
	Sodium	137-145	09/08/1991	140	
	Sodium	137-145	19/08/1991	142	
	Sodium	137-145	16/09/1991	134	
	Urine Potassium	44 MMOL/L	31/07/1991		Urine osmolality (549 mmol/l) 31/07/91, 02/08/91, 09/08/91 515 660 911

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 74024
 Seq: 1
 Gender: M

 Reported:
 03/09/1991
 Weight:

Hospitalisation: Age: 62Y

Onset Date: 15/07/1991 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

# **Medicine Details:**

HALOPERIDOL (Suspected)		Reason:	Other paranoid	d states
Tablet	80.0 Milligram	Daily		Oral
Batch:	Started: 01/07/1991		Stopped:	15/07/1991
CHLORPROMAZINE HYDROCHLORIDE (Su	spected)	Reason:		
Oral application	300.0 Milligram	Daily		Oral
Batch:	Started: 15/07/1991		Stopped:	31/07/1991
MYLANTA (Suspected)		Reason:		
Oral application	30.0 Millilitre	Daily		Oral
Batch:	Started: 13/07/1991		Stopped:	02/08/1991
AMOXYCILLIN TRIHYDRATE (Suspected)		Reason:		
Oral application	1.5 Gram	Daily		Oral
Batch:	Started: 10/07/1991		Stopped:	21/07/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Urine Potassium	44 MMOL/L	09/08/1991	106	Urine osmolality (549 mmol/l) 31/07/91, 02/08/91, 09/08/91 515 660 911
	Urine Potassium	44 MMOL/L	02/08/1991	79	Urine osmolality (549 mmol/l) 31/07/91, 02/08/91, 09/08/91 515 660 911
	Urine Sodium	<5 MMOL/L	31/07/1991	95	
	Urine Sodium	<5 MMOL/L	02/08/1991	33	
	Urine Sodium	<5 MMOL/L	09/08/1991	116	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 74176
 Seq: 1
 Gender: M

 Reported:
 07/11/1991
 Weight:
 71.00

 Hospitalisation:
 Age: 26Y

**Onset Date**: 19/09/1991 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

١,	teaction betails.				
	Preferred Term	Severity	Report Description	Treatment	ı
	Blepharitis		Blepharospasm		1
	Thinking abnormal				1
	Tremor			Bentropine,	i

# **Medicine Details:**

ARACHIS OIL (Suspected)		Reason:	
Ointment	0.0		Topical
Batch:	Started: 26/08/1991	Stopped:	26/09/1991
PREDNISOLONE (Suspected)		Reason:	
Tablet	100.0 Milligram	Reducing	Oral
Batch:	Started: 24/08/1991	Stopped:	26/09/1991
CHLORPROMAZINE HYDROCHLORIDE	(Suspected)	Reason:	
Oral application	500.0 Milligram	Daily	Oral
Batch:	Started: 13/09/1991	Stopped:	
RANITIDINE (Suspected)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 28/08/1991	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: 74176	Seq: 1		Gender:	
Reported: 07/11/1991			Weight:	
Hospitalisation: Onset Date: 19/09/1991			Age: DOB:	
Outcome: Not yet recovered	1	C		Causality possible
Reaction Details:	•		auounty.	Gaddanty poddiblo
Medicine Details:				
CHLORPROMAZINE HYDROCHLORIDE	(Suspected)	Reason:		
Oral application	100.0 Milligram	Daily	Oral	
Batch:	Started: 19/09/1991	Stopped:	20/09/1991	
Laboratory Investigations:				
Laboratory investigations.				
Additional Information:				

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

spitalisation: Onset Date Outcome:	: 24/12/1991 :							
Onset Date Outcome:	1					Weig		
Outcome:							ge: 32Y	
							OB:	
41 -	Recovered					Causal	lity: Causality possible	
ction Deta							T	
	red Term	Se	everity	Repo	ort Descr	iption	Treatment	
ection site ab	scess							
edicine De		Suspected)	0.0	Rea	son:	Introv	nuacular	
Injection  Batch:		c	0.0 Started:				nuscular	
ARGACTIL (Sus	enacted)					Stopped: graine		
ARGACTIL (SUS	pecieu)		25.0 Milli		son: Mi Daily	yraine		
Batch:		ç	Started: 08/05/1991		Stopped:			
aboratory l	nvestigatio	ons:						
Date	Туре	Range	Date Tested	Result		[	Details	
	, , , , , , , , , , , , , , , , , , ,							

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 75204 Seq: 1 Gender: M
Reported: 19/11/1991 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 06/11/1991
DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Hepatitis cholestatic			

### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (S	Suspected)	Reason:		
	15.0	Milligram	Daily	/
Batch:	Started:			<b>Stopped:</b> 06/11/1991
TAGAMET (Suspected)			Reason:	
	400.0	Milligram	Daily	<i>(</i>
Batch:	Started:			<b>Stopped:</b> 06/11/1991
PREDNISONE (Suspected)			Reason:	
	10.0	Milligram	Daily	<i>(</i>
Batch:	Started:			Stopped:
POTASSIUM CHLORIDE (Suspected)			Reason:	Otr mus rheum,fibrosit&myalgia
	1.2	Gram	Daily	<i>(</i>
Batch:	Started:			Stopped:

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		05/08/1991	11	
	ALT = SGPT		06/11/1991	294	
	ALT = SGPT		11/11/1991	202	
	ALT = SGPT		02/12/1991	73	
	ALT = SGPT		27/11/1991	111	
	ALT = SGPT		18/11/1991	123	
	Bilirubin		05/08/1991	5	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 75204 Seq: 1 Gender: M

Reported: 19/11/1991 Weight:
Hospitalisation: Admitted to hospital Age: 77Y

Onset Date: 06/11/1991 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

### **Medicine Details:**

MORPHINE MIXTURE, GOVERNMENT STORES (Suspected) Reason:

20.0 Milligram Daily

Batch: Started: Stopped: 06/11/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin		02/12/1991	64	
	Bilirubin		27/11/1991	96	
	Bilirubin		06/11/1991	147	
	Bilirubin		11/11/1991	332	
	Bilirubin		18/11/1991	268	
	GGT = SGGT =		05/08/1991	24	
	GGT = SGGT =		06/11/1991	674	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 75204
 Seq: 1
 Gender: M

 Reported:
 19/11/1991
 Weight:

Hospitalisation: Admitted to hospital Age: 77Y
Onset Date: 06/11/1991
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

# **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (S	Suspected)		Reason:			
	15.0	Milligram	Daily			
Batch:	Started:			Stopped:	06/11/1991	
TAGAMET (Suspected)			Reason:			
	400.0	Milligram	Daily			
Batch:	Started:			Stopped:	06/11/1991	
PREDNISONE (Suspected)			Reason:			
	10.0	Milligram	Daily			
Batch:	Started:			Stopped:		
POTASSIUM CHLORIDE (Suspected)			Reason:	Otr mus rheur	n,fibrosit&myalgia	
	1.2	Gram	Daily			
Batch:	Started:			Stopped:		

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =		18/11/1991	384	
	GGT = SGGT =		02/12/1991	220	
	GGT = SGGT =		27/11/1991	293	
	GGT = SGGT =		11/11/1991	594	
	SAP = ALP		05/08/1991	118	
	SAP = ALP		06/11/1991	636	
	SAP = ALP		11/11/1991	732	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report D	etails	<b>S</b> :								
Hospitalisat Onset I	rted: tion: Date:	19/11/199	91 to hospita 91	Seq: 1				We I	nder: ight: Age: DOB: ality:	77Y
Reaction <b>D</b>	<b>Detai</b>	ls:								
<b>Medicine</b>	Deta	ails:								
MORPHINE	MIXTU	RE, GOVER	NMENT ST	ORES (	Suspected)	Rea	son:			
					20.0 Mill	igram	Daily			
Bate	ch:			Star	ted:			Stopped: 06/1	1/1991	
Laborato	ry In	vestigat	ions:							
Date		Туре	Range		ate Tested	Result			Detail	S
	SAP = SAP =				18/11/1991 27/11/1991	738 545				
	SAP =				02/12/1991	429				
		<u> </u>				1	l			
Additiona	al Inf	ormatio	n:							

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 75953 Seq: 1 Gender: F

Reported: 04/02/1992 Weight: 51.00 Hospitalisation: Age: 15Y

Onset Date: 22/10/1991 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Rash			

# Medicine Details:

CHLORHEXIDINE (Other drug)		Reason:		
Mouthwash	0.0		Buccal	
Batch:	Started:	Stoppe	d:	
LACTULOSE (Other drug)		Reason: Constipation	n	
Oral Liquid	20.0 Millilitre	Daily	Oral	
Batch:	Started: 18/10/1991	Stoppe	d:	CONTIN
PRIMOLUT-N (Other drug)		Reason:		
Tablet	5.0 Milligram	Daily	Oral	
Batch:	Started: 01/07/1991	Stoppe	d:	CONTIN
KETOCONAZOLE (Other drug)		Reason:		
Tablet	20.0 Milligram	Daily	Oral	
Batch:	Started: 01/08/1991	Stoppe	d:	CONTIN

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report	<b>Details:</b>
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Case Number: 75953 Seq: 1 Gender: F

 Reported:
 04/02/1992
 Weight:
 51.00

 Hospitalisation:
 Age:
 15Y

**Onset Date**: 22/10/1991 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

#### **Medicine Details:**

Medicine Details.			
LARGACTIL (Suspected)	1	Reason: Nausea and vo	miting
	25.0 Milligram	As necessary	
Batch:	Started: 20/10/1991	Stopped:	30/10/1991
RANITIDINE (Suspected)	ı	Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 22/10/1991	Stopped:	30/10/1991

# **Laboratory Investigations:**

### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Rei	nort	: De	tai	ls:

Case Number: 76850 Seq: 1 Gender: M

Reported: 01/05/1992 Weight: 85.00 Hospitalisation: Age: 26Y

**Onset Date**: 10/01/1992 **DOB**:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	Severe		

### **Medicine Details:**

LARGACTIL (Suspected) Reason: Unspecified psychosis

Oral application 200.0 Milligram Daily Oral

**Batch**: **Started**: 08/10/1990 **Stopped**: 21/01/1992

**Laboratory Investigations:** 

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

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

 Case Number:
 77008
 Seq: 1
 Gender: M

 Reported:
 08/05/1992
 Weight:

Hospitalisation: Age: 64Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

#### Reaction Details:

•	toaction Botanoi				
	Preferred Term	Severity	Report Description	Treatment	
	Hepatic function abnormal				

#### **Medicine Details:**

CHLORPROMAZINE HYDROCHL	ORIDE (Suspected)	Reason:	Otr spec symp psychopathol nec
	50.0 Milligram	As ne	necessary
Batch:	Started: 24/03/1992		<b>Stopped:</b> 30/04/1992
CHLORPROMAZINE HYDROCHL	ORIDE (Suspected)	Reason:	Otr spec symp psychopathol nec
Oral application	225.0 Milligram	Daily	y Oral
Batch:	Started: 24/03/1992		Stopped: 30/04/1992

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =				464
	SAP = ALP				628

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 78234 Seq: 1 Gender: M

**Reported**: 27/09/1991 **Weight**:

Hospitalisation: Age: 20Y
Onset Date: 12/08/1991
DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Jaundice			

### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

Oral application 25.0 Milligram As necessary Oral

Batch: Started: 16/07/1991 Stopped: 12/08/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	( 0-31 )	11/07/1991	29	
	ALT = SGPT	( 0-31 )	11/07/1991	33	
	ALT = SGPT	( 0-31 )	12/07/1991	33	
	ALT = SGPT	( 0-31 )	13/07/1991	53	
	ALT = SGPT	( 0-31 )	22/07/1991	83	
	ALT = SGPT	( 0-31 )	12/08/1991	411	
	ALT = SGPT	( 0-31 )	14/08/1991	438	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 78234
 Seq: 1
 Gender: M

 Reported:
 27/09/1991
 Weight:

Hospitalisation: Age: 20Y

Onset Date: 12/08/1991 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

Oral application 25.0 Milligram As necessary Oral

Batch: Started: 16/07/1991 Stopped: 12/08/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	( 0-31 )	16/08/1991	403	
	ALT = SGPT	( 0-31 )	18/08/1991	317	
	ALT = SGPT	( 0-31 )	24/09/1991	33	
	ALT = SGPT	( 0-31 )	26/08/1991	67	
	ALT = SGPT	( 0-31 )	19/08/1991	94	
	ALT = SGPT	( 0-31 )	16/08/1991	393	
	ALT = SGPT	( 0-31 )	15/08/1991	432	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 78234 Seq: 1 Gender: M

Reported: 27/09/1991 Weight:

Hospitalisation: Age: 20Y
Onset Date: 12/08/1991
DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

# **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

Oral application 25.0 Milligram As necessary Oral

Batch: Started: 16/07/1991 Stopped: 12/08/1991

**Laboratory Investigations:** 

	<del>, , , , , , , , , , , , , , , , , , , </del>				
Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	( 0-31 )	13/08/1991	410	
	ALT = SGPT	( 0-31 )	26/07/1991	74	
	ALT = SGPT	( 0-31 )	20/07/1991	91	
	ALT = SGPT	( 0-31 )	19/07/1991	84	
	ALT = SGPT	( 0-31 )	17/07/1991	77	
	AST = SGOT	( 0-40 )	11/07/1991		
	AST = SGOT	(0-40)	19/07/1991	218	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 78234 Seq: 1 Gender: M

Reported: 27/09/1991 Weight:

Hospitalisation: Age: 20Y
Onset Date: 12/08/1991
DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

# **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

Oral application 25.0 Milligram As necessary Oral

Batch: Started: 16/07/1991 Stopped: 12/08/1991

**Laboratory Investigations:** 

<u> </u>	<del> </del>				
Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT	( 0-40 )	22/07/1991	131	
	AST = SGOT	( 0-40 )	12/08/1991	206	
	AST = SGOT	( 0-40 )	14/08/1991	230	
	AST = SGOT	( 0-40 )	16/08/1991	221	
	AST = SGOT	( 0-40 )	26/09/1991	67	
	AST = SGOT	( 0-40 )	19/08/1991	94	
	AST = SGOT	(0-40)	15/08/1991	216	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 78234 Seq: 1 Gender: M

Reported: 27/09/1991 Weight:
Hospitalisation: Age: 20Y

Onset Date: 12/08/1991 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

# **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

Oral application 25.0 Milligram As necessary Oral

Batch: Started: 16/07/1991 Stopped: 12/08/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT	( 0-40 )	12/08/1991	211	
	AST = SGOT	( 0-40 )	26/07/1991	137	
	AST = SGOT	( 0-40 )	20/07/1991	215	
	AST = SGOT	( 0-40 )	17/07/1991	283	
	AST = SGOT	( 0-40 )	12/07/1991		
	AST = SGOT	( 0-40 )	13/07/1991		
	Bilirubin	( 0-20 )	11/07/1992	8	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 78234 Seq: 1 Gender: M

Reported: 27/09/1991 Weight:

Hospitalisation: Age: 20Y
Onset Date: 12/08/1991
DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

Oral application 25.0 Milligram As necessary Oral

Batch: Started: 16/07/1991 Stopped: 12/08/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin	( 0-20 )	11/07/1991	10	
	Bilirubin	( 0-20 )	12/07/1991	23	
	Bilirubin	(0-20)	13/07/1991	11	
	Bilirubin	(0-20)	17/07/1991	7	
	Bilirubin	(0-20)	19/07/1991	7	
	Bilirubin	(0-20)	20/07/1991	12	
	Bilirubin	( 0-20 )	22/07/1991	10	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 78234 Seq: 1 Gender: M

Reported: 27/09/1991 Weight:

Hospitalisation: Age: 20Y
Onset Date: 12/08/1991
DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

# **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

Oral application 25.0 Milligram As necessary Oral

Batch: Started: 16/07/1991 Stopped: 12/08/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin	( 0-20 )	26/07/1991	5	
	Bilirubin	( 0-20 )	12/08/1991	71	
	Bilirubin	( 0-20 )	13/08/1991	84	
	Bilirubin	( 0-20 )	14/08/1991	97	
	Bilirubin	( 0-20 )	15/08/1991	101	
	Bilirubin	( 0-20 )	16/08/1991	87	
	Bilirubin	( 0-20 )	16/08/1991	76	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 78234 Seq: 1 Gender: M

Reported: 27/09/1991 Weight:
Hospitalisation: Age: 20Y

Onset Date: 12/08/1991 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

# **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

Oral application 25.0 Milligram As necessary Oral

Batch: Started: 16/07/1991 Stopped: 12/08/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin	( 0-20 )	19/08/1991	38	
	Bilirubin	( 0-20 )	26/08/1991	16	
	GGT = SGGT =	( 0-60 )	11/07/1991	10	
	GGT = SGGT =	( 0-60 )	11/07/1991	12	
	GGT = SGGT =	( 0-60 )	13/07/1991	12	
	GGT = SGGT =	( 0-60 )	20/07/1991	29	
	GGT = SGGT =	( 0-60 )	19/07/1991	11	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 78234
 Seq: 1
 Gender: M

 Reported:
 27/09/1991
 Weight:

Hospitalisation: Age: 20Y

Onset Date: 12/08/1991 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

Oral application 25.0 Milligram As necessary Oral

Batch: Started: 16/07/1991 Stopped: 12/08/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =	( 0-60 )	17/07/1991	14	
	GGT = SGGT =	( 0-60 )	12/07/1991	9	
	GGT = SGGT =	( 0-60 )	22/07/1991	33	
	GGT = SGGT =	( 0-60 )	19/08/1991	262	
	GGT = SGGT =	( 0-60 )	18/08/1991	257	
	GGT = SGGT =	( 0-60 )	16/08/1991	277	
	GGT = SGGT =	(0-60)	16/08/1991	300	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 78234 Seq: 1 Gender: M

Reported: 27/09/1991 Weight:
Hospitalisation: Age: 20Y

Onset Date: 12/08/1991 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

Oral application 25.0 Milligram As necessary Oral

Batch: Started: 16/07/1991 Stopped: 12/08/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =	( 0-60 )	15/08/1991	332	
	GGT = SGGT =	( 0-60 )	14/08/1991	323	
	GGT = SGGT =	( 0-60 )	13/08/1991	274	
	GGT = SGGT =	( 0-60 )	12/08/1991	263	
	GGT = SGGT =	( 0-60 )	26/07/1991	31	
	GGT = SGGT =	( 0-60 )	24/09/1991	68	
	GGT = SGGT =	( 0-60 )	26/08/1991	244	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 78234
 Seq: 1
 Gender: M

 Reported:
 27/09/1991
 Weight:

Hospitalisation: Age: 20Y

Onset Date: 12/08/1991 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

Oral application 25.0 Milligram As necessary Oral

Batch: Started: 16/07/1991 Stopped: 12/08/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	LDH	( 120-250 )	11/07/1991	265	
	LDH	( 120-250 )	11/07/1991	356	
	LDH	( 120-250 )	13/07/1991	416	
	LDH	( 120-250 )	20/07/1991	500	
	LDH	( 120-250 )	19/07/1991	459	
	LDH	( 120-250 )	17/07/1991	559	
	LDH	( 120-250 )	12/07/1991	223	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 78234
 Seq: 1
 Gender: M

 Reported:
 27/09/1991
 Weight:

Hospitalisation: Age: 20Y

Onset Date: 12/08/1991 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

Oral application 25.0 Milligram As necessary Oral

Batch: Started: 16/07/1991 Stopped: 12/08/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	LDH	( 120-250 )	22/07/1991	373	
	LDH	( 120-250 )	19/08/1991	782	
	LDH	( 120-250 )	18/08/1991	166	
	LDH	( 120-250 )	16/08/1991	231	
	LDH	( 120-250 )	16/08/1991	234	
	LDH	( 120-250 )	15/08/1991	254	
	LDH	( 120-250 )	14/08/1991	266	

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 78234 Seq: 1 Gender: M

Reported: 27/09/1991 Weight:

Hospitalisation: Age: 20Y
Onset Date: 12/08/1991
DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

Oral application 25.0 Milligram As necessary Oral

Batch: Started: 16/07/1991 Stopped: 12/08/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	LDH	( 120-250 )	13/08/1991	204	
	LDH	( 120-250 )	12/08/1991	196	
	LDH	( 120-250 )	26/07/1991	366	
	LDH	( 120-250 )	24/09/1991	145	
	LDH	( 120-250 )	26/08/1991	549	
	SAP = ALP	( 35-115 )	11/07/1991	101	
	SAP = ALP	( 35-115 )	11/07/1991	97	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 78234
 Seq: 1
 Gender: M

 Reported:
 27/09/1991
 Weight:

Hospitalisation: Weight: Weight:

Onset Date: 12/08/1991 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

#### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

Oral application 25.0 Milligram As necessary Oral

Batch: Started: 16/07/1991 Stopped: 12/08/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP	( 35-115 )	12/07/1991	90	
	SAP = ALP	( 35-115 )	13/07/1991	110	
	SAP = ALP	( 35-115 )	17/07/1991	114	
	SAP = ALP	( 35-115 )	19/07/1991	96	
	SAP = ALP	( 35-115 )	20/07/1991	96	
	SAP = ALP	( 35-115 )	22/07/1991	80	
	SAP = ALP	( 35-115 )	26/07/1991	83	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 78234
 Seq: 1
 Gender: M

 Reported:
 27/09/1991
 Weight:

Hospitalisation: Age: 20Y

Onset Date: 12/08/1991 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

Oral application 25.0 Milligram As necessary Oral

Batch: Started: 16/07/1991 Stopped: 12/08/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP	( 35-115 )	12/08/1991	632	
	SAP = ALP	( 35-115 )	13/08/1991	691	
	SAP = ALP	( 35-115 )	14/08/1991	787	
	SAP = ALP	( 35-115 )	26/07/1991	817	
	SAP = ALP	( 35-115 )	16/08/1991	867	
	SAP = ALP	( 35-115 )	16/08/1991	842	
	SAP = ALP	( 35-115 )	18/08/1991	783	

## **Additional Information:**

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Case Number: 81106

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

<b>Reported:</b> 20/11/199	2	Weight:					
ospitalisation:		Age: 45Y					
Onset Date:			DO				
Outcome: Not yet re	covered	Causality: Causality possible					
action Details:							
Preferred Term	Severity	Report Des	cription	Treatment			
xtrapyramidal disorder remor		_					
ledicine Details:		Reason:					
	0.0						
Batch:	Started:		Stopped:				
ARGACTIL (Suspected)		Reason:	Unspecified psychosis				
Tablet	400.0 Mi	lligram Daily	Oral				
Batch:	Started:	L TERM	Stopped:				
aboratory Investigat	ions: Range Date Tested	Result	De	etails			
dditional Informatio	n:						
ort Run: 01/06/2007  04:14PM	Database: pusime02	ADRS004	4	Page 113 of 495			

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 81774 Seq: 1 Gender: M

Reported: 24/12/1992 Weight: 80.00 Hospitalisation: Age: 33Y

**Onset Date**: 13/07/1992 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment	
Hepatitis cholestatic				

#### **Medicine Details:**

ALCOHOL (Other drug) Reason:

6.0 Dose Unspecified Weekly

Batch: Started: Stopped:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Hiccough

 Tablet
 25.0 Milligram
 Daily
 Oral

 Batch:
 Started: 19/06/1992
 Stopped: 23/06/1992

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin	UMOL/L	22/06/1992	NORMAL	
	Bilirubin	UMOL/L	14/09/1992	858	
	Bilirubin	UMOL/L	15/12/1992	30	
	Liver biopsy				Liver biopsy confirmed cholestatic jaundice.

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 83134 Seq: 1 Gender: F

Reported: 16/02/1993 Weight: 70.00 Hospitalisation: Age: 39

**Onset Date**: 11/02/1993 **DOB**: 19/11/1953

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Dystonia			Cogentin 1mg im.

## **Medicine Details:**

CALTRATE (Other drug)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 10/02/1993	Stopped:	
DIHYDROERGOTAMINE (Suspected)		Reason:	
Injection	4.0 Milligram	Reducing	Intravenous
Batch:	Started: 10/02/1993	Stopped:	12/02/1993
STEMETIL (Suspected)		Reason:	
Injection	37.5 Milligram	Daily	Intravenous
Batch:	Started: 10/02/1993	Stopped:	12/02/1993
CHLORPROMAZINE HYDROCHLORIDE (	Buspected)	Reason:	
CHLORPROMAZINE HYDROCHLORIDE (S	Suspected) 75.0 Milligram	Reason: Daily	Oral

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details

### **Additional Information:**

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# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	83134	Seq: 1			Gender: F		
Reported:	16/02/1993	•			Weight: 70	0.00	
lospitalisation:					<b>Age:</b> 39		
Onset Date:	11/02/1993					9/11/1953	
	Recovered			С		ausality possi	ble
eaction Detai							
Medicine Det		- (Oa.a.a.ta.d)	Danasani				
	DE HYDROCHLORIDI		Reason:				
Injection		30.0 Milligram	Daily		Intravenous		
Batch:		<b>Started:</b> 10/02/1993		Stopped:	12/02/1993		
	HYDROCHLORIDE (S		Reason:				
Tablet		80.0 Milligram	Daily		Oral		
Batch:		Started: 10/02/1993		Stopped:	12/02/1993		
Laboratory In	vestigations:						
Additional Inf	formation:						
anort Pun : 01/06/200	07 04:14PM Data	hase: nusimo02	ADPSONA			Deca 440	of 40E

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 84430
 Seq: 1
 Gender: M

 Reported:
 12/05/1993
 Weight:
 62.00

 Hospitalisation:
 Age: 73Y

Onset Date: 27/04/1993 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Nouvilla Details.								
	Preferred Term	Severity	Report Description	Treatment				
	Agranulocytosis							
	Leukopenia							

#### **Medicine Details:**

TEGRETOL (Suspected)			Reason:	Explosive pers	onality disorder	
Tablet	300.0	Milligram	Daily		Oral	
Batch:	Started: 05/0	4/1993		Stopped:	28/04/1993	
LARGACTIL (Suspected)			Reason:	Explosive pers	onality disorder	
Oral application	600.0	Milligram	Daily		Oral	
Batch:	Started: 04/0	3/1993		Stopped:	04/05/1993	
DIGOXIN (Suspected)			Reason:	Otr&nos disord	d of heart rhythm	
Tablet	187.0	Microgram	Daily		Oral	
Batch:	Started:	L TE	ERM	Stopped:		CONTIN

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	White blood cells	4.0 - 11.0	05/03/1993	6.4	
	White blood cells	4.0 - 11.0	27/04/1993	1.9	
	White blood cells	4.0 - 11.0	29/04/1993	1.4	
	White blood cells	4.0 - 11.0	03/05/1993	0.9	
	White blood cells	4.0 - 11.0	06/05/1993	1.1	
	White blood cells	4.0 - 11.0	13/05/1993	2.8	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 85081 Seq: 1 Gender: F

Reported: 01/06/1993 Weight: 83.00 Hospitalisation: Age: 43Y

**Onset Date**: 04/11/1992 **DOB**:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

#### **Medicine Details:**

TEGRETOL (Other drug)		Reason:		
Tablet	900.0 Milligram	Daily	Oral	
Batch:	<b>Started:</b> 14/08/1990	Stopp	ed: 04/11/1991	
TRIPRIM (Other drug)		Reason: Othr disea	ses of urinary tract	
Tablet	300.0 Milligram	Daily	Oral	
Batch:	Started: 25/10/1991	Stopp	ed: 04/11/1991	
LARGACTIL (Suspected)		Reason: Unspecifie	d psychosis	
Tablet	600.0 Milligram	Daily	Oral	
Batch:	Started: 28/10/1991	Stopp	ed: 04/11/1991	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT	6 - 42 U/L	30/10/1991	208	
	AST = SGOT	6 - 42 U/L	04/11/1991	55	
	AST = SGOT	6 - 42 U/L	06/11/1991	58	
	AST = SGOT	6 - 42 U/L	25/11/1991	21	
	AST = SGOT	6 - 42 U/L	08/11/1991	34	
	Bilirubin	< 20 UMOL/L	30/10/1991	54	
	Bilirubin	< 20 UMOL/L	04/11/1991	21	

#### **Additional Information:**

Patient has subsequently been rechallenged with both triprim and tegretol, without any abnormal lft's being detected.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 85081 Seq: 1 Gender: F

Reported: 01/06/1993 Weight: 83.00 Hospitalisation: Age: 43Y

**Onset Date**: 04/11/1992 **DOB**:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

#### **Medicine Details:**

TEGRETOL (Other drug)		Reason:
Tablet	900.0 Milligram	Daily Oral
Batch:	<b>Started:</b> 14/08/1990	<b>Stopped:</b> 04/11/1991
TRIPRIM (Other drug)		Reason: Othr diseases of urinary tract
Tablet	300.0 Milligram	Daily Oral
Batch:	Started: 25/10/1991	<b>Stopped</b> : 04/11/1991
LARGACTIL (Suspected)		Reason: Unspecified psychosis
Tablet	600.0 Milligram	Daily Oral
Batch:	Started: 28/10/1991	<b>Stopped</b> : 04/11/1991

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	Bilirubin	< 20 UMOL/L	08/11/1991	17	
	Bilirubin	< 20 UMOL/L	25/11/1991	9	
	Bilirubin	< 20 UMOL/L	06/11/1991	18	
	SAP = ALP	35 - 135 U/L	30/10/1991	170	
	SAP = ALP	35 - 135 U/L	04/11/1991	339	
	SAP = ALP	35 - 135 U/L	06/11/1991	341	
	SAP = ALP	35 - 135 U/L	08/11/1991	254	

#### **Additional Information:**

Patient has subsequently been rechallenged with both triprim and tegretol, without any abnormal lft's being detected.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 85081 Seq: 1 Gender: F

Reported: 01/06/1993 Weight: 83.00 Hospitalisation: Age: 43Y

Onset Date: 04/11/1992

Outcome: Recovered

Causality: Causality probable

**Reaction Details:** 

#### **Medicine Details:**

TEGRETOL (Other drug)		Reason:		
Tablet	900.0 Milligram	Daily	Oral	
Batch:	<b>Started:</b> 14/08/1990	Stop	ped: 04/11/1991	
TRIPRIM (Other drug)		Reason: Othr dise	eases of urinary tract	
Tablet	300.0 Milligram	Daily	Oral	
Batch:	Started: 25/10/1991	Stop	ped: 04/11/1991	
LARGACTIL (Suspected)		Reason: Unspeci	fied psychosis	
Tablet	600.0 Milligram	Daily	Oral	
Batch:	Started: 28/10/1991	Stop	ped: 04/11/1991	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP	35 - 135 U/L	25/11/1991	120	

#### **Additional Information:**

Patient has subsequently been rechallenged with both triprim and tegretol, without any abnormal lft's being detected.

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# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	85260	Seq:	1				Gender	: F	
Reported:		-					Weight:		
ospitalisation:							_	18Y	
Onset Date:	31/08/199	)2					DOB	:	
Outcome:	Recovere	d				С	ausality	: Causality prob	able
eaction Detai	ls:								
Preferre	ed Term	Se	verity	Repo	ort Des	cription		Treatme	nt
Pruritus									
Rash erythemato	us								
Medicine Det	ails:								
CHLORPROMAZIN		HLORIDE (Suspe	cted)	Rea	son:				
Oral applic	ation		500.0 Milli	igram	Daily		Oral		
Batch:		St	arted: 05/08/1	992		Stopped:	02/09/199	2	
	41	_							
Laboratory In	Type	Range	Date Tested	Result			Deta	ils	
Bato	1,700	rango	Date Feeted	rtodate			2010		
<u> </u>		L							
Additional Inf	formatio	n·							
Additional iii	ormano	11.							
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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 85860 Seq: 1 Gender: M

 Reported: 06/07/1993
 Weight:

 Hospitalisation:
 Age: 23Y

 Onset Date: 04/05/1993
 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Dystonia	Severe		8mg im cogentin.

## **Medicine Details:**

LARGACTIL (Suspected)		Reason: Manic-depression psycho,manic	
Oral application	50.0 Milligram	1 time Oral	
Batch:	<b>Started:</b> 03/05/1993	Stopped:	
SERENACE (Suspected)		Reason: Manic-depression psycho,manic	
Injection	10.0 Milligram	1 time Intramuscular	
Batch:	Started: 03/05/1993	Stopped:	
SERENACE (Suspected)		Reason: Manic-depression psycho,manic	
Injection	5.0 Milligram	1 time Intramuscular	
Batch:	Started: 04/05/1993	Stopped:	
MELLERIL (Suspected)		Reason: Manic-depression psycho,manic	
Oral application	150.0 Milligram	Daily Oral	
Batch:	Started: 03/05/1993	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

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## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

ospitalisati Onset D	<b>ate:</b> 21/05/1993 <b>me:</b> Recovered	3	: 1			С	Gender: Weight: Age: DOB: ausality:	U Causality possible
	eferred Term	S	everity	Rep	ort Desc	ription		Treatment
onfusional	state		,	·		•		
ightmare								
ledicine								
T <b>EGRETOL</b> ( Table			200.0		son:		Oral	
Batc			200.0	Milligram L TERM	Daily	Stopped:	Orai	
	DL (Other drug)		otarteu.		son:	Stoppeu.		
	application		300.0	Milligram	Daily		Oral	
Batc		•	Started:	L TERM	-	Stopped:	Olui	
SPALGIN (					son:			
Table			8.0	Dose Unspecified	Daily		Oral	
Batc	h:	ç	Started:	•	,	Stopped:		
	IYDROCHLORIDE (	Suspected)		Rea	son:	•		
ETHIDINE H		. ,	50.0	Milligram	2 times		Intramuscu	lar
PETHIDINE H Inject	1011			_				
		\$	Started: 20/0	5/1993		Stopped:	21/05/1993	i
Inject <b>Batc</b>	h:		Started: 20/0	5/1993		Stopped:	21/05/1993	<u> </u>
Inject <b>Batc</b>			Date Teste			Stopped:	21/05/1993 Detail	

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

		Seq: 1					
Reported:	07/07/1993				Weight:		
ospitalisation:					Age:		
Onset Date:	21/05/1993				DOB:		
	Recovered			С	ausality: Ca	ausality possible	
action Detai	ils:						
Medicine Deta	aile:						
	alis. IE HYDROCHLORII	DE (Suspected)	Reason:				
Injection		50.0 Milligram	Total		Intramuscular		
Batch:		<b>Started:</b> 20/05/1993		Stonned:	21/05/1993		
		Starteu. 20/03/1993		Otoppea.			
	YDROCHLORIDE (		Reason:	оторрои.			
	YDROCHLORIDE (	Suspected)	Reason: Total	оторроц.	2.7007.7000		
	YDROCHLORIDE (						
AMITRIPTYLINE H	YDROCHLORIDE (\$	Suspected) 100.0 Milligram			21/05/1993		
AMITRIPTYLINE H	YDROCHLORIDE (S	Suspected) 100.0 Milligram					
AMITRIPTYLINE H	YDROCHLORIDE (\$	Suspected) 100.0 Milligram					
AMITRIPTYLINE H	YDROCHLORIDE (\$	Suspected) 100.0 Milligram					
AMITRIPTYLINE H	YDROCHLORIDE (	Suspected) 100.0 Milligram					
AMITRIPTYLINE H	YDROCHLORIDE (\$	Suspected) 100.0 Milligram					
AMITRIPTYLINE H	YDROCHLORIDE (S	Suspected) 100.0 Milligram					
AMITRIPTYLINE H Batch:		Suspected) 100.0 Milligram Started: 20/05/1993					
AMITRIPTYLINE H Batch:	YDROCHLORIDE (S	Suspected) 100.0 Milligram Started: 20/05/1993					
AMITRIPTYLINE H Batch:		Suspected) 100.0 Milligram Started: 20/05/1993					
AMITRIPTYLINE H Batch:		Suspected) 100.0 Milligram Started: 20/05/1993					
AMITRIPTYLINE H Batch:		Suspected) 100.0 Milligram Started: 20/05/1993					
AMITRIPTYLINE H Batch:		Suspected) 100.0 Milligram Started: 20/05/1993					
AMITRIPTYLINE H Batch:		Suspected) 100.0 Milligram Started: 20/05/1993					
AMITRIPTYLINE H Batch:		Suspected) 100.0 Milligram Started: 20/05/1993					
AMITRIPTYLINE H  Batch:	vestigations	Suspected) 100.0 Milligram Started: 20/05/1993					
AMITRIPTYLINE H  Batch:	vestigations	Suspected) 100.0 Milligram Started: 20/05/1993					
AMITRIPTYLINE H  Batch:	vestigations	Suspected) 100.0 Milligram Started: 20/05/1993					
AMITRIPTYLINE H Batch:	vestigations	Suspected) 100.0 Milligram Started: 20/05/1993					
AMITRIPTYLINE H  Batch:	vestigations	Suspected) 100.0 Milligram Started: 20/05/1993					

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Re	por	t D	etai	ils:
	Ρ-			

 Case Number:
 85999
 Seq: 1
 Gender:
 M

 Reported:
 12/07/1993
 Weight:
 54.00

 Hospitalisation:
 Age:
 52Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

## Reaction Details:

•	todotion Botans.			
	Preferred Term	Severity	Report Description	Treatment
	Delirium			
	Hypotension			
	Somnolence			

## **Medicine Details:**

HALOPERIDOL (Suspected)		Reason:	Delirium	
Injection	10.0 Milligram	1 time	9	Intramuscular
Batch:	Started: 09/06/1993		Stopped:	09/06/1993
FLUOXETINE HYDROCHLORIDE (Suspect	ed)	Reason:	Depression	
Capsule	20.0 Milligram	Daily		Oral
Batch:	Started: 19/05/1993		Stopped:	08/06/1993
TRIMIPRAMINE MALEATE (Suspected)		Reason:	Depression	
Tablet	50.0 Milligram	Daily		Oral
Batch:	Started: 04/06/1993		Stopped:	08/06/1993
HALOPERIDOL (Suspected)		Reason:	Manic-depress	sion psycho,manic
Tablet	15.0 Milligram	Daily		Oral
Batch:	Started: 07/06/1993		Stopped:	08/06/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

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## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:		Seq: 1			Gender:	
	12/07/1993				Weight:	
Hospitalisation: Onset Date:					Age: DOB:	521
Outcome:	Recovered			С		Causality possible
Reaction Detai				·	auounty.	Caddanty possible
	.01					
Medicine Deta	<b>ails:</b> E HYDROCHLORIDE	: (Cuppeted)	Decem	Dolirium		
Oral applica		400.0 Milligram	Reason: Daily	Delirium	Oral	
Batch:	20011	Started: 09/06/1993	Dany		09/06/1993	
Laboratory In	vestigations:					
A dditional laf	'a a <b>4</b> ; a					
Additional Inf	ormation:					

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 86135 Seq: 1 Gender: F

Reported: 19/07/1993 Weight:
Hospitalisation: Age: 21Y

**Onset Date**: 11/06/1993 **DOB**:

Outcome: Recovered Causality: Causality certain

Reaction Details:

•	<del></del>			
	Preferred Term	Severity	Report Description	Treatment
	Pruritus		Itchy spots.	
	Rash		On thighs, abdomen, back and arms.	

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Manic-depression psycho,manic

100.0 Milligram Daily

**Batch: Started:** 17/05/1993 **Stopped:** 11/06/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Gp accidently prescribed chlorpromazine again with same reaction occurring.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 87944
 Seq: 1
 Gender:
 F

 Reported:
 28/09/1993
 Weight:

Hospitalisation: Age: 39Y
Onset Date: 19/09/1993
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	teaction Details.				
	Preferred Term	Severity	Report Description	Treatment	l
	Face oedema				l
	Pyrexia				l
	Rash				l
	Tachycardia				

## **Medicine Details:**

RIVOTRIL (Suspected)		Reason:	
Solution	20.0 Milligram	As necessary Oral	
Batch:	Started: 17/09/1993	Stopped:	
LARGACTIL (Suspected)		Reason: Unspecified psychosis	
Oral Liquid	600.0 Milligram	Daily Oral	
Batch:	Started: 17/09/1993	<b>Stopped:</b> 18/09/1993	
MODECATE (Suspected)		Reason: Unspecified psychosis	
Injection	50.0 Milligram	Daily Intramuscular	
Batch:	Started: 16/09/1993	Stopped:	
SERENACE (Suspected)		Reason: Unspecified psychosis	
Oral Liquid	20.0 Milligram	Daily Oral	
Batch:	<b>Started:</b> 17/09/1993	Stopped:	

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient has had same reaction to chlorpromazine.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 88429 Seq: 1 Gender: F

Reported: 12/10/1993 Weight:
Hospitalisation: Age: 43Y

Onset Date: 06/07/1993 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Rhinitis			

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Headache

150.0 Milligram Daily

Batch: Started: 06/07/1993 Stopped:

DIHYDERGOT (Suspected) Reason: Headache

Injection 3.0 Milligram Daily Intravenous

Batch: Started: 06/07/1993 Stopped:

**Laboratory Investigations:** 

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

#### **Additional Information:**

Allergy reported to flagyl and ivp contrast.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 88459 Seq: 1 Gender: M
Reported: 13/10/1993 Weight:
Hospitalisation: Age: 58Y

Onset Date: 31/10/1992 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	toaction Botaile.			
	Preferred Term	Severity	Report Description	Treatment
	Haematuria			
	Renal impairment			

#### **Medicine Details:**

Wedicine Details.					
LITHIUM CARBONATE (Suspected)			Reason:		
Tablet	1.5	Gram	Daily	Oral	
Batch:	Started:		L TERM	Stopped:	CONTIN
PROPRANOLOL HYDROCHLORIDE (Su	spected)		Reason:	Abnormal involuntary mo	vement
Tablet	80.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	
STELAZINE (Suspected)			Reason:		
Tablet	5.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	
LARGACTIL (Suspected)			Reason:		
Tablet	100.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

**Laboratory Investigations:** 

	Date	Type	Range	Date Tested	Result	Details
Ī		Creatinine	(50-120)	01/10/1992	146	
		Renal biopsy =				Renal biopsy(4/12/92)=moderate interstitial fibrosis and tubular atrophy consistent with chronic lithium toxicity.

#### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Causality: Causality possible

**Report Details:** 

Case Number: 88766 Seq: 1 Gender: F
Reported: 29/10/1993 Weight:
Hospitalisation: Age: 35Y

Onset Date: DOB:

Outcome: Recovered with sequelae

#### Reaction Details:

•	todotion Botanoi			
	Preferred Term	Severity	Report Description	Treatment
	Hypotension			

## **Medicine Details:**

TAGAMET (Other drug)		Reason: Other diseases of esophagus	3
Tablet	400.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	CONTIN
LARGACTIL (Suspected)		Reason: Unspecified psychosis	
Tablet	400.0 Milligram	As necessary Oral	
Batch:	Started:	Stopped:	
DERALIN (Suspected)		Reason:	
Tablet	120.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	7D
LARGACTIL (Suspected)		Reason: Unspecified psychosis	
Tablet	1.2 Gram	Daily Oral	
Batch:	Started:	Stopped:	3D

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Sequelae: broken ankle when fell due to hypotension.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Rei	port	Detai	ls:
-----	------	-------	-----

Case Number: 88951 Seq: 1 Gender: M

Reported: 01/11/1993 Weight:
Hospitalisation: Age: 62Y

**Onset Date**: 22/10/1993 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Bp 75/33.	

### **Medicine Details:**

PARACETAMOL (Suspected) Reason:

Oral application 2.0 Dose Unspecified As necessary Oral

Batch: Started: 21/10/1993 Stopped:

CODEINE (Suspected) Reason:

Oral application 2.0 Dose Unspecified As necessary Oral

Batch: Started: 21/10/1993 Stopped:

PETHIDINE HYDROCHLORIDE (Suspected) Reason: Other specified symptoms nec

Injection 25.0 Milligram As necessary Intramuscular

Batch: Started: 22/10/1993 Stopped:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Nausea and vomiting

Oral application 12.5 Milligram Daily Oral

Batch: Started: 22/10/1993 Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

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# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: 8895 Reported: 01/17 Iospitalisation: Onset Date: 22/10 Outcome: Reco	0/1993		Gender: M Weight: Age: 6 DOB: Causality: 0	
eaction Details:				
Medicine Details:  CYTARABINE (Suspected	d)	Reason:		
Injection	, 160.0 Millio		Subcutaneou	s
Batch:	Started: 05/07/19		Stopped: 21/10/1993	
CEFTAZIDIME (Suspecte	d)	Reason:		
Injection	6.0 Grar	m Daily	Intravenous	
Batch:	Started: 21/10/19	993	Stopped:	
Laboratory Invest	igations:			
Additional Informa	ation:			
enort Pun : 01/06/2007	·14PM Database: nusime02	ADPS004		Dama 122 of 105

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Case Number: 88987

Reported: 02/11/1993

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

Weight:

Hospitalisat Onset D				Age: 35Y DOB:					
	<b>me:</b> Recovere	d		Causality: Causality possible					ible
eaction D		u				Judo	uniy. O	adduity pood	1010
	eferred Term	S	everity	R	eport De	scription		Treatmer	nt
Mouth ulcer			<b>,</b>	Throat and m		•			-
	ne phosphatase	increa							
Rash									
Medicine	Details: OL (Suspected)				Reason:	Unspecified psycho	neie		
	application		80.0	r Milligram	Daily	Orispecified psychic			
Bato		,	Started:	wiiiigram	Daily	Stopped:			
	MAZINE HYDROC			F	Reason:	Unspecified psycho	sis		
		(	0.0		Daily				
Bato	:h:	•	Started:		,	Stopped:			
Laborato	ry Investigat	ions:							
Date	Туре	Range	Date Teste	ed Result			Details		
Additiona	ıl Informatio	n:							
eport Run: 01/	06/2007 04:14PN	И Database: р	ousime02		ADRS00	)4		Page 134	of 495



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Re	poi	rt C	)eta	ils:
	PO.		otu	

Case Number: 89733 Seq: 1 Gender: M

Reported: 08/12/1993 Weight:
Hospitalisation: Age: 18Y

Onset Date: 01/12/1993 DOB:

Outcome: Recovered Causality: Causality possible

## **Reaction Details:**

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Unspecified psychosis

Oral application 400.0 Milligram Daily Oral

**Batch: Started:** 01/12/1993 **Stopped:** 02/12/1993

# **Laboratory Investigations:**

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 89976 Seq: 1 Gender: M

 Reported: 20/12/1993
 Weight: 56.00

 Hospitalisation:
 Age: 36Y

 Onset Date: 07/12/1993
 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Leukopenia			

#### **Medicine Details:**

MODECATE (Suspected)			Reason:		
Injection	75.0	Milligram	Fortni	ghtly	Intramuscular
Batch:	Started:		L TERM	Stopped:	08/11/1993
CHLORPROMAZINE HYDROCHLORIDE (Suspected)			Reason:	Unspecified so	chizophrenia
Oral application	300.0	Milligram	Daily		Oral
Batch:	Started: 03/	12/1993		Stopped:	05/12/1993
REMOXIPRIDE (Suspected)			Reason:	Unspecified so	chizophrenia
Oral application	300.0	Milligram	Daily		Oral
Batch:	Started: 03/	11/1993		Stopped:	07/12/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		07/12/1993	2.2	
	Neutrophils		09/12/1993	1.35	
	Platelets		15/11/1993	200	
	Platelets		09/12/1993	182	
	Platelets		13/12/1993	209	
	Platelets		07/12/1993	154	
	Platelets		02/12/1993	184	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 89976 Seq: 1 Gender: M

 Reported: 20/12/1993
 Weight: 56.00

 Hospitalisation:
 Age: 36Y

 Onset Date: 07/12/1993
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

#### **Medicine Details:**

MODECATE (Suspected)					
Injection	75.0 N	Milligram	Fortni	ghtly	Intramuscular
Batch:	Started:	I	TERM	Stopped:	08/11/1993
CHLORPROMAZINE HYDROCHLORIDE (Suspected)			Reason:	Unspecified so	chizophrenia
Oral application	300.0 M	Milligram	Daily		Oral
Batch:	Started: 03/12	2/1993		Stopped:	05/12/1993
REMOXIPRIDE (Suspected)			Reason:	Unspecified so	chizophrenia
Oral application	300.0 M	Milligram	Daily		Oral
Batch:	Started: 03/1	1/1993		Stopped:	07/12/1993

**Laboratory Investigations:** 

	Date	Type	Range	Date Tested	Result	Details
Ī		Platelets		20/12/1993	221	
		Platelets		05/01/1994	179	
		Platelets		01/03/1994	227	
		Platelets		14/02/1994	170	
		Platelets		31/01/1994	177	
		Platelets		24/01/1994	162	
		Platelets		19/01/1994	180	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 89976 Seq: 1 Gender: M

Reported: 20/12/1993 Weight: 56.00 Hospitalisation: Age: 36Y

**Onset Date**: 07/12/1993 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

## **Medicine Details:**

MODECATE (Suspected)					
Injection	75.0 N	Milligram	Fortni	ghtly	Intramuscular
Batch:	Started:	I	TERM	Stopped:	08/11/1993
CHLORPROMAZINE HYDROCHLORIDE (Suspected)			Reason:	Unspecified so	chizophrenia
Oral application	300.0 M	Milligram	Daily		Oral
Batch:	Started: 03/12	2/1993		Stopped:	05/12/1993
REMOXIPRIDE (Suspected)			Reason:	Unspecified so	chizophrenia
Oral application	300.0 M	Milligram	Daily		Oral
Batch:	Started: 03/1	1/1993		Stopped:	07/12/1993

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	Platelets		11/01/1994	189	
	Platelets		24/12/1993	216	
	White blood cells		15/11/1993	7.8	
	White blood cells		02/12/1993	5.4	
	White blood cells		07/12/1993	2.8	
	White blood cells		09/12/1993	2.9	
	White blood cells		13/12/1993	4.3	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 89976 Seq: 1 Gender: M

 Reported: 20/12/1993
 Weight: 56.00

 Hospitalisation:
 Age: 36Y

 Onset Date: 07/12/1993
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

#### **Medicine Details:**

MODECATE (Suspected)	ODECATE (Suspected) Reason:						
Injection	75.0	Milligram	Fortni	ghtly	Intramuscular		
Batch:	Started:		L TERM	Stopped:	08/11/1993		
CHLORPROMAZINE HYDROCHLORIDE (Suspected)			Reason:	Unspecified so	chizophrenia		
Oral application	300.0	Milligram	Daily		Oral		
Batch:	Started: 03/	12/1993		Stopped:	05/12/1993		
REMOXIPRIDE (Suspected)			Reason:	Unspecified so	chizophrenia		
Oral application	300.0	Milligram	Daily		Oral		
Batch:	Started: 03/	11/1993		Stopped:	07/12/1993		

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	White blood cells		20/12/1993	5.8	
	White blood cells		24/12/1993	5.4	
	White blood cells		05/01/1994	4.3	
	White blood cells		11/01/1994	3.8	
	White blood cells		19/01/1994	3.4	
	White blood cells		24/01/1994	5.5	
	White blood cells		31/01/1994	5.2	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

 Case Number:
 89976
 Seq: 1
 Gender:
 M

 Reported:
 20/12/1993
 Weight:
 56.00

Hospitalisation: Age: 36Y
Onset Date: 07/12/1993
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

#### **Medicine Details:**

MODECATE (Suspected)	spected) Reason:						
Injection	75.0	Milligram	Fortni	ghtly	Intramuscular		
Batch:	Started:		L TERM	Stopped:	08/11/1993		
CHLORPROMAZINE HYDROCHLORIDE (Suspected)			Reason:	Unspecified so	chizophrenia		
Oral application	300.0	Milligram	Daily		Oral		
Batch:	Started: 03/	12/1993		Stopped:	05/12/1993		
REMOXIPRIDE (Suspected)			Reason:	Unspecified so	chizophrenia		
Oral application	300.0	Milligram	Daily		Oral		
Batch:	Started: 03/	11/1993		Stopped:	07/12/1993		

**Laboratory Investigations:** 

L	Date	Туре	Range	Date Tested	Result	Details
ſ		White blood cells		14/02/1994	5.3	
		White blood cells		01/03/1994	3.93	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 90056 Seq: 1 Gender: F

 Reported: 24/12/1993
 Weight: 70.00

 Hospitalisation:
 Age: 39Y

Onset Date: 11/02/1993 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Dystonia			Benztropine.

## **Medicine Details:**

NEO-MERCAZOLE (Other drug)		Reason:	Toxic diffuse goiter	
Tablet	5.0 Milligram	Daily	Oral	
Batch:	Started: 01/08/1992		Stopped:	
CALTRATE (Other drug)		Reason:		
Tablet	600.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	
DIHYDROERGOTAMINE (Other drug)		Reason:	Migraine	
Injection	3.0 Milligram	Daily	Intravenous	
Batch:	Started: 10/02/1993		<b>Stopped:</b> 17/02/1993	
STEMETIL (Suspected)		Reason:	Nausea and vomiting	
Injection	25.0 Milligram	Daily	Intramuscular	
Batch:	Started: 11/02/1993		<b>Stopped:</b> 11/02/1993	

**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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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 90056 Seq: 1 Gender: F

Reported: 24/12/1993 Weight: 70.00 Hospitalisation: Age: 39Y

**Onset Date**: 11/02/1993 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLO	Reason:	Nausea and v	omiting	
Oral application	50.0 Milligram	Daily		Oral
Batch:	Started: 11/02/1993		Stopped:	11/02/1993
PROPRANOLOL HYDROCHLORID	E (Suspected)	Reason:	Migraine	
Tablet	80.0 Milligram	Daily		Oral
Batch:	<b>Started:</b> 10/02/1993		Stopped:	11/02/1993
MAXOLON (Suspected)		Reason:	Nausea and v	omiting
Injection	30.0 Milligram	Daily		Intramuscular
Batch:	Started: 10/02/1993		Stopped:	11/02/1993

# **Laboratory Investigations:**

#### **Additional Information:**

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

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# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Num	ber: 90455	Seq:	1			Gender:	F	
	rted: 13/01/199	_				Weight:		
lospitalisat	tion:					Age:	48Y	
Onset D	Date: 07/12/199	3				DOB:		
Outco	me: Recovere	d				Causality:	Causality certa	ain
eaction <b>D</b>	etails:							
Pr	eferred Term	Sev	erity	Rep	ort Description		Treatme	nt
Dermatitis c	ontact		De	rmatitis of ha	nds and face.	Bet	novate.	
<b>Medicine</b> CHLORPRO Bate	MAZINE HYDROCI		cted) 0.0 urted:	Rea	son: Stoppe	d:		
	ry Investigat							
Date	Type	Range	Date Tested	Result		Details	S	
Additiona	al Informatio	n:						
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Re



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 91157 Seq: 1 Gender: M

Reported: 18/02/1994 Weight: 68.00 Hospitalisation: Age: 23Y

**Onset Date**: 08/02/1994 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	todotion Botans.			
	Preferred Term	Severity	Report Description	Treatment
	Hypertonia	Severe	Muscle spasm in jaw, back, arms & legs.	Cogentin 2mg/im 2 doses.
	Dystonia			

#### **Medicine Details:**

LARGACTIL (Suspected)		Reason:	Depression	
Tablet	400.0 Milligram	Daily		Oral
Batch:	Started: 21/01/1994		Stopped:	
PROTHIADEN (Suspected)		Reason:	Depression	
Capsule	300.0 Milligram	Daily		Oral
Batch:	Started: 21/01/1994		Stopped:	
SERENACE (Suspected)		Reason:	Depression	
Tablet	5.0 Milligram	Daily		Oral
Batch:	Started: 06/02/1994		Stopped:	09/02/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 91300 Seq: 1 Gender: M

Reported: 25/02/1994 Weight:

Hospitalisation: Age: 46Y
Onset Date: 20/12/1993
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction facial muscles.	Cogentin 2mg/im.

## **Medicine Details:**

PEPCIDINE (Other drug)		Reason:	
Tablet	40.0 Milligram	Daily	Oral
Batch:	<b>Started:</b> 19/12/1993	Stopped	:
PROZAC (Other drug)		Reason:	
Capsule	20.0 Milligram	Daily	Oral
Batch:	<b>Started:</b> 19/12/1993	Stopped	:
PANADEINE FORTE (Other drug)		Reason:	
Tablet	4.0 Dose Unspeci	fied Daily	Oral
Batch:	<b>Started:</b> 19/12/1993	Stopped	:
CHLORPROMAZINE HYDROCHLORID	E (Suspected)	Reason:	
Injection	200.0 Milligram	Daily	Intramuscular
Batch:	Started: 19/12/1993	Stopped	: 20/12/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 91701 Seq: 1 Gender: M

Reported: 17/03/1994 Weight: 62.00 Hospitalisation: Age: 32Y

**Onset Date:** 14/02/1994 **DOB:** 

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Hepatitis cholestatic			

#### **Medicine Details:**

Micaicinic Details.			
PREDNEFRIN FORTE (Other drug)		Reason:	
Eye Drops	0.0		Ophthalmic
Batch:	Started: 07/02/1994	Started: 07/02/1994 Stopped:	
LARGACTIL (Suspected)		Reason:	
Oral application	200.0 Milligram	Daily	Oral
Batch:	Started: 07/02/1994	Stopped:	09/02/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	<40 U/L	01/03/1994	553	
	ALT = SGPT	<40 U/L	04/03/1994	710	
	ALT = SGPT	<40 U/L	15/03/1994	287	
	ALT = SGPT	<40 U/L	08/03/1994	341	
	AST = SGOT	<40 U/L	01/03/1994	508	
	AST = SGOT	<40 U/L	04/03/1994	202	
	AST = SGOT	<40 U/L	08/03/1994	88	

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 91701 Seq: 1 Gender: M

Reported: 17/03/1994 Weight: 62.00 Hospitalisation: Age: 32Y

**Onset Date**: 14/02/1994 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

#### **Medicine Details:**

Medicine Details.			
PREDNEFRIN FORTE (Other drug)		Reason:	
Eye Drops	0.0		Ophthalmic
Batch:	Started: 07/02/1994	Stopped:	
LARGACTIL (Suspected)		Reason:	
Oral application	200.0 Milligram	Daily	Oral
Batch:	Started: 07/02/1994	Stopped:	09/02/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT	<40 U/L	15/03/1994	109	
	Bilirubin	<17 UMOL/L	01/03/1994	120	
	Bilirubin	<17 UMOL/L	04/03/1994	172	
	Bilirubin	<17 UMOL/L	08/03/1994	155	
	Bilirubin	<17 UMOL/L	15/03/1994	92	
	GGT = SGGT =	<50 U/L	01/03/1994	265	
	GGT = SGGT =	<50 U/L	04/03/1994	233	

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 91701 Seq: 1 Gender: M

 Reported:
 17/03/1994
 Weight:
 62.00

 Hospitalisation:
 Age:
 32Y

**Onset Date**: 14/02/1994 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

#### **Medicine Details:**

Micaicinic Details.			
PREDNEFRIN FORTE (Other drug)		Reason:	
Eye Drops	0.0		Ophthalmic
Batch:	Started: 07/02/1994	Started: 07/02/1994 Stopped:	
LARGACTIL (Suspected)		Reason:	
Oral application	200.0 Milligram	Daily	Oral
Batch:	Started: 07/02/1994	Stopped:	09/02/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =	<50 U/L	15/03/1994	105	
	GGT = SGGT =	<50 U/L	08/03/1994	171	
	SAP = ALP	<120 U/L	01/03/1994	295	
	SAP = ALP	<120 U/L	04/03/1994	268	
	SAP = ALP	<120 U/L	08/03/1994	229	
	SAP = ALP	<120 U/L	15/03/1994	170	

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Re	po	rt	De	tai	ls:
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 Case Number:
 92318
 Seq: 1
 Gender: M

 Reported:
 22/04/1994
 Weight:
 70.00

 Hospitalisation:
 Age: 29Y

**Onset Date**: 27/03/1994 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

#### Reaction Details:

touotion Dotailor			
Preferred Term	Severity	Report Description	Treatment
Myocarditis			
Pyrexia			Augmentin forte, paracetamol.
Upper respiratory tract infection			

## **Medicine Details:**

AGAROL (Suspected)		Reason: Hemorrhoids	
Solution	10.0 Millilitre	2 times Oral	
Batch:	Started: 25/03/1994	Stopped:	
CLOZAPINE (Suspected)		Reason:	
	300.0 Milligram	Daily	
Batch:	Started: 21/03/1994	<b>Stopped:</b> 30/03/1994	
HALOPERIDOL (Suspected)		Reason: Unspecified psychosis	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ALPRAZOLAM (Suspected)		Reason: Unspecified psychosis	
	1.0 Milligram	Daily	
Batch:	Started: 09/01/1994	<b>Stopped:</b> 04/03/1994	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details:	rt Details:
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 Case Number:
 92318
 Seq: 1
 Gender: M

 Reported:
 22/04/1994
 Weight:
 70.00

 Hospitalisation:
 Age: 29Y

**Onset Date**: 27/03/1994 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

## **Medicine Details:**

PERICYAZINE (Suspected)		Reason:	Unspecified psychosis	
	20.0 Milligram	Daily		
Batch:	Started: 09/01/1994		<b>Stopped:</b> 02/03/1994	
CHLORPROMAZINE HYDROCHLORII	DE (Suspected)	Reason:	Unspecified psychosis	
	300.0 Milligram	Daily		
Batch:	Started: 09/01/1994		<b>Stopped:</b> 04/03/1994	
BACTRIM DS (Suspected)		Reason:	Ac upr resp inf,mult,unsp stes	
	0.0	Daily		
Batch:	Started: 17/02/1994		<b>Stopped:</b> 22/02/1994	
PROCTOSEDYL (Suspected)		Reason:	Hemorrhoids	
Ointment	2.0 Dose Unspe	cified Daily	Rectal	
Batch:	Started: 25/03/1994		Stopped:	

# **Laboratory Investigations:**

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 92419 Seq: 1 Gender: F

Reported: 26/04/1994 Weight:
Hospitalisation: Age: 45Y
Onset Date: 22/07/1993 DOB:

Onset Date: 22/07/1993

Outcome: Recovered

Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			

## **Medicine Details:**

DIAZEPAM (Other drug)	Reason: Unspecified schizophrenia	
Tablet	5.0 Milligram As necessary Oral	
Batch:	<b>Started:</b> 07/07/1993 <b>Stopped:</b>	
PARACETAMOL (Other drug)	Reason: Pyrexia of unknown origin	
Oral application	3.0 Dose Unspecified Daily Oral	
Batch:	<b>Started:</b> 07/07/1993 <b>Stopped:</b>	
SEPTRIN FORTE (Other drug)	Reason: Othr diseases of urinary tract	
Oral application	2.0 Dose Unspecified Daily Oral	
Batch:	<b>Started:</b> 07/07/1993 <b>Stopped:</b>	

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified schizophrenia

Oral application 100.0 Milligram As necessary Oral

Batch: Started: 07/07/1993 Stopped:

## **Laboratory Investigations:**

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry	< 0.06 MG/L	22/07/1993	107.00	Myoglobin
	Biochemistry	< 0.06 MG/L	22/07/1993	34.80	Myoglobin
	Biochemistry	< 0.38 MG/L	22/07/1993	3180	Urine myoglobin
	Creatine kinase	< 10U/L	22/07/1993	517	
	Creatine	25 - 200 U/L	22/07/1993	23690	
	Creatine	25 - 200 U/L	22/07/1993	139178	
	Creatine	25 - 200 U/L	23/07/1993	98778	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Re	po	rt	De	tai	ls:
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 Case Number:
 92419
 Seq: 1
 Gender:
 F

 Reported:
 26/04/1994
 Weight:

Hospitalisation: Age: 45Y
Onset Date: 22/07/1993
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

#### **Medicine Details:**

MODECATE (Suspected)		Reason: Unspeci-	fied schizophrenia	
Injection	50.0 Milligram	Fortnightly	Intramuscular	
Batch:	Started:	Stop	ped: 14/07/1993	
TRIFLUOPERAZINE HYDROCHLO	RIDE (Suspected)	Reason: Unspeci	fied schizophrenia	
Oral application	30.0 Milligram	Daily	Oral	
Batch:	Started:	Stop	ped:	
AMITRIPTYLINE HYDROCHLORID	E (Suspected)	Reason:		
Tablet	150.0 Milligram	Daily	Oral	
Batch:	Started: 21/07/1993	Stop	ped:	

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	Creatine	25 - 200 U/L	24/07/1993	42708	
	Creatine	25 - 200 U/L	25/07/1993	16831	
	Creatine	25 - 200 U/L	27/07/1993	3731	

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**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 schizophre	enia
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 schizophre	enia
Tablet	4.5 Milligram	Daily Oral	
Batch:	Started: 28/09/1993	Stopped:	CONTIN
CARBAMAZEPINE (Suspected)		Reason: Unspecified schizophre	enia
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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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 92667
 Seq: 1
 Gender: M

 Reported:
 02/05/1994
 Weight: 91.

 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	CHLORPROMAZINE HYDROCHLORIDE (Suspected)			
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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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 92972 Seq: 1 Gender: F

Reported: 13/05/1994 Weight: 50.00 Hospitalisation: Age: 87Y

Onset Date: 08/05/1994 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Oculogyration			

### **Medicine Details:**

CAPOTEN (Other drug)		Reason: Essential benign hypertension
Tablet	37.5 Milligram	Daily Oral
Batch:	Started: 05/05/1994	Stopped:
ADALAT (Other drug)		Reason: Essential benign hypertension
Tablet	40.0 Milligram	Daily Oral
Batch:	Started: 01/01/1988	Stopped:
LARGACTIL (Suspected)		Reason: Nausea and vomiting
Tablet	30.0 Milligram	Daily Oral
Batch:	Started:	<b>Stopped:</b> 08/05/1994
STEMETIL (Suspected)		Reason: Nausea and vomiting
Tablet	15.0 Milligram	Daily Oral
Batch:	Started:	<b>Stopped:</b> 08/05/1994

**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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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

	etails:				
Repor Hospitalisati Onset D Outco	<b>rate</b> : 27/04/1994 <b>me</b> : Recovered	1		Gender: Weight: Age: DOB: Causality:	75.00 35Y
eaction D	etails: eferred Term	Severity	Report Des	ecription	Treatment
Agitation Confusional Hyperreflexi	state	Seventy	Керит Бе	всприон	rreaunent
Medicine	Details:				
		LORIDE (Suspected)	Reason:	Migraine	
Inject	tion, intravenous infu	ısion 12.5 M	illigram 1 time	Intravenou	s
Bato	h:	Started: 27/04/	/1994	Stopped:	
METOCLOPE	RAMIDE HYDROCH	LORIDE (Suspected)	Reason:	Migraine	
Inject	tion, intravenous infu	usion 10.0 M	illigram 1 time	Intravenou	s
Bato	h:	Started: 27/04/	/1994	Stopped:	
<b>Laborator</b> Date	<b>'y Investigati</b> Type	Ons: Range Date Tested	Result	Detai	s
			Result	Detai	İs

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 93020 Seq: 1 Gender: F

Reported: 16/05/1994 Weight: 70.00
Hospitalisation: Age: 50Y

Onset Date: 10/05/1994 DOB:
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash			

**Medicine Details:** 

COGENTIN (Other drug)		Reason:			
	1.0 Milligram	1 time			
Batch:	Started: 08/05/1994		Stopped:		
PHENERGAN (Other drug)		Reason:			
	25.0 Milligram	Daily			
Batch:	Started: 10/05/1994		Stopped:	CONTIN	
RIVOTRIL (Suspected)		Reason:			
	4.0 Milligram	Daily			
Batch:	Started: 02/05/1994		Stopped:	CONTIN	
CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason:			
	150.0 Milligram	Daily			
Batch:	Started: 02/05/1994		<b>Stopped:</b> 10/05/	/1994	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient experienced previous dystonic reaction to haloperidol.

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	93020	Seq: 1		Gender:	F
Reported:	16/05/1994			Weight:	70.00
Hospitalisation:				Age:	50Y
Onset Date:	10/05/1994			DOB:	
Outcome:	Not yet recovered			Causality:	Causality possible
Reaction Detai	ils:				
Medicine Det	aile				
LITHIUM CARBON			Reason:		
	,	750.0 Milligram	Daily		
Batch:		Started: 04/05/1994	·	Stopped:	CONTIN
TEMAZEPAM (Sus	spected)		Reason:		
		10.0 Milligram	Daily		
Batch:		Started: 10/05/1994		Stopped:	CONTIN
					_
Laboratory In	vestigations:				
Laboratory III	ivestigations.				
Additional Inf		recetion to belonguidal			
ralient experience	u previous aystonic	reaction to haloperidol.			

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number:93024Seq:1Gender:MReported:17/05/1994Weight:85.00Hospitalisation:Admitted to hospitalAge:90Y

Onset Date: 15/03/1994 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

١,	caction Betails.			
	Preferred Term	Severity	Report Description	Treatment
	Hyperthyroidism			
	Neuroleptic malignant syndrome			
	Tachycardia			

## **Medicine Details:**

VENTOLIN (Other drug)		Reason:	Otr respiratory systm of	diseases
Inhalation	0.0		Inhalat	ion
Batch:	Started:		Stopped:	CONTIN
BECLOFORTE (Other drug)		Reason:	Otr respiratory systm of	diseases
Inhalation	0.0		Inhalat	ion
Batch:	Started:		Stopped:	CONTIN
FRUSEMIDE (Other drug)		Reason:	Congestive heart failur	re
	20.0 Milligram	Daily		
Batch:	Started:		Stopped:	CONTIN
AMILORIDE HYDROCHLORIDE (Other	r drug)	Reason:	Alkalosis	
	5.0 Milligram	Daily		
Batch:	Started:		Stopped:	CONTIN

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Creatine		15/03/1994	392	
	Creatine		18/03/1994	856	
	Other data				On admission- free t4 40.2, tsh lo.03.

#### **Additional Information:**

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Report Details:

Case Number: 93024

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

pitalisation: Admitted to hospital Onset Date: 15/03/1994 Outcome: Recovered Causality: Causality possible  Causality: Causality: Causality possible  Causa	osnitalisation:	17/05/1994					Weight:	65.00
Onset Date:         15/03/1994         DOB:           Outcome:         Recovered         Causality:         Causality possible           Cition Details:           Idicine Details:           MEPRAZOLE (Other drug)         Reason:         Other diseases of esophagus           20.0 Milligram         Daily           Batch:         Started:         Stopped:         CONTIN           NEMET (Other drug)         Reason:         Reason:         Stopped:         CONTIN           NEMET (Suspected)         Reason:         Hiccough           Tablet         75.0 Milligram         Daily         Oral           Batch:         Started:         10/03/1994         Stopped:         15/03/1994	ospitalisation. /						_	
Adicine Details:  MEPRAZOLE (Other drug)  Batch:  Started:  Started:  Started:  Stopped:  CONTIN  Reason:  3.0 Dose Unspecified Daily  Batch:  Started:  Stopped:  CONTIN  Reason:  ADDRESS Storped:  CONTIN  Reason:  ADDRESS Storped:  CONTIN  Reason:  ADDRESS Storped:  CONTIN  Reason:  Hiccough  Tablet  75.0 Milligram  Daily  Oral  Batch:  Started:  Stopped:  CONTIN  Reason:  Hiccough  Tablet  Stopped:  Stopped:  CONTIN  Reason:  ADDRESS Storped:  Stopped:  CONTIN  Reason:  Stopped:	-						_	
Adicine Details:  MEPRAZOLE (Other drug)  Batch:  Started:  Started:  Started:  Stopped:  CONTIN  Reason:  3.0 Dose Unspecified Daily  Batch:  Started:  Stopped:  CONTIN  Reason:  ADDRESS Storped:  CONTIN  Reason:  ADDRESS Storped:  CONTIN  Reason:  ADDRESS Storped:  CONTIN  Reason:  Hiccough  Tablet  75.0 Milligram  Daily  Oral  Batch:  Started:  Stopped:  CONTIN  Reason:  Hiccough  Tablet  Stopped:  Stopped:  CONTIN  Reason:  ADDRESS Storped:  Stopped:  CONTIN  Reason:  Stopped:	Outcome:	Recovered				С	ausality:	Causality possible
Reason: Other diseases of esophagus 20.0 Milligram Daily  Batch: Started: Stopped: CONTIN  REMET (Other drug)  Batch: Started: Daily  Batch: Started: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Hiccough  Tablet 75.0 Milligram Daily Oral  Batch: Started: 10/03/1994  Stopped: 15/03/1994	action Detail	s:						
Reason: Other diseases of esophagus 20.0 Milligram Daily  Batch: Started: Stopped: CONTIN  REMET (Other drug)  Batch: Started: Daily  Batch: Started: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Hiccough  Tablet 75.0 Milligram Daily Oral  Batch: Started: 10/03/1994  Stopped: 15/03/1994								
Reason: Other diseases of esophagus 20.0 Milligram Daily  Batch: Started: Stopped: CONTIN  REMET (Other drug)  Batch: Started: Daily  Batch: Started: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Hiccough  Tablet 75.0 Milligram Daily Oral  Batch: Started: 10/03/1994  Stopped: 15/03/1994								
Reason: Other diseases of esophagus 20.0 Milligram Daily  Batch: Started: Stopped: CONTIN  REMET (Other drug)  Batch: Started: Daily  Batch: Started: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Hiccough  Tablet 75.0 Milligram Daily Oral  Batch: Started: 10/03/1994  Stopped: 15/03/1994								
Reason: Other diseases of esophagus 20.0 Milligram Daily  Batch: Started: Stopped: CONTIN  REMET (Other drug)  Batch: Started: Daily  Batch: Started: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Hiccough  Tablet 75.0 Milligram Daily Oral  Batch: Started: 10/03/1994  Stopped: 15/03/1994								
Reason: Other diseases of esophagus 20.0 Milligram Daily  Batch: Started: Stopped: CONTIN  REMET (Other drug)  Batch: Started: Daily  Batch: Started: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Hiccough  Tablet 75.0 Milligram Daily Oral  Batch: Started: 10/03/1994  Stopped: 15/03/1994								
Reason: Other diseases of esophagus 20.0 Milligram Daily  Batch: Started: Stopped: CONTIN  REMET (Other drug)  Batch: Started: Daily  Batch: Started: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Hiccough  Tablet 75.0 Milligram Daily Oral  Batch: Started: 10/03/1994  Stopped: 15/03/1994								
Reason: Other diseases of esophagus 20.0 Milligram Daily  Batch: Started: Stopped: CONTIN  REMET (Other drug)  Batch: Started: Daily  Batch: Started: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Hiccough  Tablet 75.0 Milligram Daily Oral  Batch: Started: 10/03/1994  Stopped: 15/03/1994								
Reason: Other diseases of esophagus 20.0 Milligram Daily  Batch: Started: Stopped: CONTIN  REMET (Other drug)  Batch: Started: Daily  Batch: Started: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Hiccough  Tablet 75.0 Milligram Daily Oral  Batch: Started: 10/03/1994  Stopped: 15/03/1994								
Reason: Other diseases of esophagus 20.0 Milligram Daily  Batch: Started: Stopped: CONTIN  REMET (Other drug)  Batch: Started: Daily  Batch: Started: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Hiccough  Tablet 75.0 Milligram Daily Oral  Batch: Started: 10/03/1994  Stopped: 15/03/1994								
Reason: Other diseases of esophagus 20.0 Milligram Daily  Batch: Started: Stopped: CONTIN  REMET (Other drug)  Batch: Started: Daily  Batch: Started: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Hiccough  Tablet 75.0 Milligram Daily Oral  Batch: Started: 10/03/1994  Stopped: 15/03/1994								
Reason: Other diseases of esophagus 20.0 Milligram Daily  Batch: Started: Stopped: CONTIN  REMET (Other drug)  Batch: Started: Daily  Batch: Started: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Hiccough  Tablet 75.0 Milligram Daily Oral  Batch: Started: 10/03/1994  Stopped: 15/03/1994								
Reason: Other diseases of esophagus 20.0 Milligram Daily  Batch: Started: Stopped: CONTIN  REMET (Other drug)  Batch: Started: Daily  Batch: Started: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Stopped: CONTIN  REASON: Hiccough  Tablet 75.0 Milligram Daily Oral  Batch: Started: 10/03/1994  Stopped: 15/03/1994								
20.0   Milligram   Daily						011 11		
Batch:         Started:         Stopped:         CONTIN           Batch:         Started:         Stopped:         CONTIN           RGACTIL (Suspected)         Reason:         Hiccough           Tablet         75.0         Milligram         Daily         Oral           Batch:         Started:         10/03/1994         Stopped:         15/03/1994	OMEPRAZOLE (Oth	ner drug)	00.0	NATIO		Other disease	s of esopha	gus
Reason:	D-4-b-			Milligram	Daily	04		CONTINI
Batch: Started: Stopped: CONTIN  RGACTIL (Suspected) Reason: Hiccough  Tablet 75.0 Milligram Daily Oral  Batch: Started: 10/03/1994 Stopped: 15/03/1994			Started:		_	Stopped:		CONTIN
Batch: Started: Stopped: CONTIN  REASON: Hiccough  Tablet 75.0 Milligram Daily Oral  Batch: Started: 10/03/1994 Stopped: 15/03/1994	SINEMET (Other dru	ug)	0.0	5				
RGACTIL (Suspected) Tablet 75.0 Milligram Daily Oral Batch: Started: 10/03/1994 Stopped: 15/03/1994				Dose Unspe	cified Daily			
Tablet 75.0 Milligram Daily Oral  Batch: Started: 10/03/1994 Stopped: 15/03/1994			Started:		_			CONTIN
Batch: Started: 10/03/1994 Stopped: 15/03/1994					Reason:	Hiccouah		
	LARGACTIL (Suspe	ected)				3 3 3 3		
boratory Investigations:	LARGACTIL (Suspe	ected)						
	Batch:				Reason:			
	ARGACTIL (Suspe Tablet Batch:							
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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 93029 Seq: 1 Gender: M

**Reported:** 17/05/1994 **Weight:** 

Hospitalisation: Age: 49

**Onset Date**: 06/07/1993 **DOB**: 14/01/1944

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			Propranolol.

#### **Medicine Details:**

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Specific disorders of sleep

25.0 Milligram 1 time

Batch: Started: 06/07/1993 Stopped:

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Specific disorders of sleep

100.0 Milligram 1 time

Batch: Started: 05/07/1993 Stopped:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Specific disorders of sleep

75.0 Milligram Total

**Batch: Started:** 05/07/1993 **Stopped:** 06/07/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report D	etails:
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 Case Number:
 93524
 Seq: 1
 Gender: F

 Reported:
 07/06/1994
 Weight:

Hospitalisation: Age: 29Y
Onset Date: 06/03/1994
DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			

#### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORID	HLORPROMAZINE HYDROCHLORIDE (Suspected)			sychosis
Injection	150.0 Milligram	Daily		Intravenous
Batch:	Started: 21/02/1994		Stopped:	08/03/1994
FERRO-GRADUMET (Suspected)		Reason:		
Tablet	1.0 Dose Unspe	cified Daily		Oral
Batch:	Started: 23/02/1994		Stopped:	
HALOPERIDOL (Suspected)		Reason:		
	5.0 Milligram	Daily		
Batch:	Started: 24/02/1994		Stopped:	

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: 93741 Reported: 17/06/1994 ospitalisation: Onset Date: 08/07/1993 Outcome: Recovered	Seq: 1		С	Gender: Weight: Age: DOB: ausality:	19Y
Preferred Term	Severity	Report Desc	ription		Treatment
yperkinesia ypertonia				Bei	nztropine.
edicine Details: STELAZINE (Suspected)		Reason:			
Oral application	15.0 Mil			Oral	
Batch:	Started: 07/07/		Stopped:	14/07/1993	•
CHLORPROMAZINE HYDROCHLO		Reason:			
Oral application	150.0 Mil	ligram Daily		Oral	
Batch:	Started: 28/06/		Stopped:	07/07/1993	<b>,</b>
aboratory Investigatio	ns: Range Date Tested	Result		Detail	s
_aboratory Investigatio Date Type		Result		Detail	S

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 93906 Seq: 1 Gender: F

Reported: 24/06/1994 Weight:
Hospitalisation: Age: 40Y

Onset Date: 27/11/1993 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus		Itch over trunk, limbs and face	Terfenadine 120mg daily
Rash maculo-papular		Rash over trunk, limbs and face	

#### Medicine Details:

viedicine Details:			
TEMAZEPAM (Other drug)		Reason: Specific disord	ders of sleep
Oral application	10.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped:	CONTIN
CHLORPROMAZINE HYDROCHLORIDE (	Suspected)	Reason:	
Oral application	25.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped:	27/11/1993
PHENELZINE SULPHATE (Suspected)		Reason: Depression	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 22/11/1993	Stopped:	27/11/1993

**Laboratory Investigations:** 

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 94744 Seq: 1 Gender: M
Reported: 01/08/1994 Weight:
Hospitalisation: Admitted to hospital Age: 20Y

Onset Date: 08/07/1994 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Hepatitis cholestatic			

#### **Medicine Details:**

STELAZINE (Suspected)		Reason: Unspecified psychosis
	20.0 Milligram	Daily
Batch:	Started: 29/06/1994	<b>Stopped</b> : 14/07/1994
LARGACTIL (Suspected)		Reason: Unspecified psychosis
	800.0 Milligram	Daily
Batch:	Started: 29/06/1994	<b>Stopped</b> : 14/07/1994
BENZTROPINE MESYLATE (Suspected)		Reason: Hered dystonia musculor deform
	4.0 Milligram	Daily
Batch:	Started: 29/06/1994	<b>Stopped</b> : 14/07/1994

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	< 40	07/07/1994	98	
	ALT = SGPT	< 40	08/07/1994	98	
	ALT = SGPT	< 40	28/07/1994	16	
	Bilirubin	(3-20)	07/07/1994	32	
	Bilirubin	(3-20)	08/07/1994	32	
	Bilirubin	(3-20)	28/07/1994	26	
	SAP = ALP	(35-135)	07/07/1994	126	

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report	Detail	ls:
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 Case Number:
 94744
 Seq: 1
 Gender: M

 Reported:
 01/08/1994
 Weight:

Hospitalisation: Admitted to hospital Age: 20Y
Onset Date: 08/07/1994
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

### **Medicine Details:**

STELAZINE (Suspected)		Reason: Unspecified psychosis
	20.0 Milligram	Daily
Batch:	Started: 29/06/1994	<b>Stopped</b> : 14/07/1994
LARGACTIL (Suspected)		Reason: Unspecified psychosis
	800.0 Milligram	Daily
Batch:	Started: 29/06/1994	<b>Stopped</b> : 14/07/1994
BENZTROPINE MESYLATE (Suspected)		Reason: Hered dystonia musculor deform
	4.0 Milligram	Daily
Batch:	Started: 29/06/1994	<b>Stopped</b> : 14/07/1994

**Laboratory Investigations:** 

<u> </u>	J III TOOLIGA				
Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP	(35-135)	08/07/1994	126	
	SAP = ALP	(35-135)	28/07/1994	101	

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 95730
 Seq: 1
 Gender: M

 Reported:
 07/09/1994
 Weight:

**Hospitalisation**: Admitted to hospital **Age**: 39

**Onset Date**: 15/01/1994 **DOB**: 23/04/1954

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Hypotension		Bp 100/70	
Hyperhidrosis			Gentamicin and flucloxacillin.
Hyperventilation			
Myocarditis			
Pyrexia			
Rash			
Tachycardia			
Tremor			
Vomiting			

### **Medicine Details:**

CHLORPROMAZINE HYDROCHLOR	IDE (Suspected)	Reason:	
	600.0 Milligram		
Batch:	Started:	Stopped:	
MODECATE (Suspected)		Reason:	
	75.0 Milligram	Fortnightly	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	25.0 Milligram	Daily Oral	
Batch:	Started: 04/01/1994	Stopped: 11/01/1994	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily Oral	
Batch:	Started: 12/01/1994	<b>Stopped</b> : 15/01/1994	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Clozapine was restarted at 25 mgd on 7.2.94.

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detai	07/09/1994 Admitted to hospin 15/01/1994 Recovered	Seq: 1			
Medicine Deta					
HALOPERIDOL (Se	uspected)	20.0 Milligra	<b>Reason:</b> m Daily		
Batch:		Started:	20,	Stopped:	
Laboratory In	vestigations:				
Additional Inf Clozapine was rest	ormation: arted at 25 mgd on	7.2.94.			

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 95755 Seq: 1 Gender: M

Reported: 08/09/1994 Weight: 93.00 Hospitalisation: Age: 53Y

Onset Date: 30/08/1994 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

rtoaction Botano.			
Preferred Term	Severity	Report Description	Treatment
Anorexia			
Eosinophilia			
Hepatitis			

#### **Medicine Details:**

AUGMENTIN (Suspected) Reason: Bronchitis, unqualified

3.0 Dose Unspecified Daily

**Batch: Started:** 22/08/1994 **Stopped:** 27/08/1994

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason:

100.0 Milligram Daily

Batch: Started: 26/08/1994 Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	(R 12-50)	30/08/1994	447	
	ALT = SGPT	(R 12-50)	13/09/1994	46	
	Bilirubin	(R 6-24)	30/08/1994	49	
	Bilirubin	(R 6-24)	13/09/1994	15	
	Eosinophils				Eosinophilia 656.
	GGT = SGGT =	(R 5-60)	30/08/1994	480	
	GGT = SGGT =	(R 5-60)	13/09/1994	156	

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details:						
Case Number: 95755	Seq: 1	Gender: M				
Reported: 08/09/1994		Weight: 93.00				

Hospitalisation: Age: 53Y
Onset Date: 30/08/1994
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

### **Medicine Details:**

AUGMENTIN (Suspected) Reason: Bronchitis,unqualified

3.0 Dose Unspecified Daily

Batch: Started: 22/08/1994 Stopped: 27/08/1994

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason:

100.0 Milligram Daily

Batch: Started: 26/08/1994 Stopped:

**Laboratory Investigations:** 

<u> </u>	y mroonga				
Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP	(R 30_95)	30/08/1994	331	
	SAP = ALP	(R 30 95)	13/09/1994	169	

#### **Additional Information:**

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

_	r: 96077	Seq:	1		Gender: F			
	Reported: 26/09/1994				Weig	<b>Weight:</b> 93.00		
ospitalisation	<b>1</b> :				Α	ge:		
Onset Date	e:				D	OB:		
Outcome	e: Recovered				Causality: Causality possible			
action Det						_		
	erred Term	Se	verity	Repo	ort Description	Treatment		
onfusional sta	<u>ate</u>							
edicine De	etaile:							
	ROCHLORIDE (	Suspected)		Reas	son: Headache			
			25.0 Milli	igram	1 time			
Batch:		St	tarted:		Stopped:			
ARGACTIL (Su	ispected)			Reas	son: Headache			
			25.0 Milli	igram	1 time			
Batch:		St	tarted:		Stopped:			
aboratory Date	Investigation	ONS:	Date Tested	Result	[	Details		



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 96322 Seq: 1 Gender: F
Reported: 06/10/1994 Weight:
Hospitalisation: Age: 24Y

**Onset Date**: 19/09/1994 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia			

### **Medicine Details:**

HEPARIN SODIUM (Suspected)	Reaso	on: Prophylaxis	
Injection	10.0 Thousand Internal [	Daily	Subcutaneous
Batch:	Started: 05/09/1994	Stopped:	19/09/1994
DILANTIN (Suspected)	Reaso	on:	
Injection	600.0 Milligram	Daily	Intravenous
Batch:	Started: 13/09/1994	Stopped:	20/09/1994
DEXAMETHASONE (Suspected)	Reaso	on:	
Injection	4.0 Milligram	Daily	Intravenous
Batch:	Started: 16/09/1994	Stopped:	19/09/1994
RIVOTRIL (Suspected)	Reaso	on:	
	6.0 Milligram	Daily	
Batch:	<b>Started:</b> 17/09/1994	Stopped:	19/09/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Immunology				Platelet autoantibodies: platelet-bound igg - positive, platelet-bound igm - negative, serum (circulating) igg - positive, serum (circulating) igm - positive. random donor platelets - negative.
	Platelets	150 - 400	18/09/1994	138	
	Platelets	150 - 400	18/09/1994	116	
	Platelets	150 - 400	19/09/1994	104	

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 96322
 Seq: 1
 Gender:
 F

 Reported:
 06/10/1994
 Weight:

Hospitalisation: Age: 24Y
Onset Date: 19/09/1994
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

## **Medicine Details:**

MICONAZOLE NITRATE (Suspected)		Reason:	Otr&nos infec&	Aparasit diseases
Ointment	3.0 Dose Unspec	cified Daily		Topical
Batch:	Started: 13/09/1994		Stopped:	19/09/1994
MAXOLON (Suspected)		Reason:	Nausea and vo	omiting
Injection	40.0 Milligram	Daily		Intravenous
Batch:	Started: 13/09/1994		Stopped:	18/09/1994
ACICLOVIR (Suspected)		Reason:	Unspecified vii	ral encephalitis
Injection	2.2 Gram	Daily		Intravenous
Batch:	Started: 12/09/1994		Stopped:	19/09/1994
LARGACTIL (Suspected)		Reason:	Abnormal invo	luntary movement
Injection	150.0 Milligram	Daily		Intravenous
Batch:	Started: 12/09/1994		Stopped:	19/09/1994

**Laboratory Investigations:** 

	Date	Туре	Range	Date Tested	Result	Details
ĺ		Platelets	150 - 400	20/09/1994	80	
		Platelets	150 - 400	21/09/1994	82	
١		Platelets	150 - 400	22/09/1994	102	
		Platelets	150 - 400	23/09/1994	131	
١		Platelets	150 - 400	24/09/1994	221	

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 96444 Seq: 1 Gender: F

Reported: 13/10/1994 Weight: 59.00 Hospitalisation: Age: 35Y

Onset Date: 21/09/1994 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Hepatitis			

#### Medicine Details:

PROZAC (Suspected)		Reason		
Tablet	1.0 Dose	Unspecified Da	ily	Oral
Batch:	Started: 05/09/199	94	Stopped:	30/09/1994
LARGACTIL (Suspected)		Reason		
	100.0 Millig	ıram Da	ily	
Batch:	Started: 09/09/199	94	Stopped:	03/10/1994
LITHIUM CARBONATE (Suspected)		Reason	!	
	1.0 Gram	n Da	ily	
Batch:	Started:	L TERM	Stopped:	

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	0 - 40 U/L	30/09/1994	53	
	AST = SGOT	0 - 40 U/L	03/10/1994	35	
	AST = SGOT	0 - 40 U/L	05/10/1994	37	
	AST = SGOT	0 - 40 U/L	13/10/1994	28	
	Bilirubin	0 - 20 UMOL/L	30/09/1994	11	
	Bilirubin	0 - 20 UMOL/L	03/10/1994	13	
	Bilirubin	0 - 20 UMOL/L	05/10/1994	14	

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 96444 Seq: 1 Gender: F

 Reported: 13/10/1994
 Weight: 59.00

 Hospitalisation:
 Age: 35Y

**Onset Date**: 21/09/1994 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

**Medicine Details:** 

PROZAC (Suspected) Reason: Depression

Tablet 1.0 Dose Unspecified Daily Oral

Batch: Started: 05/09/1994 Stopped: 30/09/1994

LARGACTIL (Suspected) Reason:

100.0 Milligram Daily

**Batch: Started:** 09/09/1994 **Stopped:** 03/10/1994

LITHIUM CARBONATE (Suspected) Reason:

1.0 Gram Daily

Batch: Started: L TERM Stopped:

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	Bilirubin	0 - 20 UMOL/L	13/10/1994	8	
	GGT = SGGT =	0 - 50 U/L	30/09/1994	228	
	GGT = SGGT =	0 - 50 U/L	03/10/1994	178	
	GGT = SGGT =	0 - 50 U/L	05/10/1994	148	
	GGT = SGGT =	0 - 50 U/L	13/10/1994	80	
	SAP = ALP	30 - 120 U/L	30/09/1994	345	
	SAP = ALP	30 - 120 U/L	03/10/1994	270	

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report	Detail	ls:
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Gender: F Case Number: 96444 Seq: 1

Reported: 13/10/1994 Weight: 59.00 **Hospitalisation:** Age: 35Y

Onset Date: 21/09/1994 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

#### **Medicine Details:**

PROZAC (Suspected)	Reason: Depression	
Tablet	1.0 Dose Unspecified Daily Oral	

Batch: Started: 05/09/1994 Stopped: 30/09/1994

LARGACTIL (Suspected) Reason:

> 100.0 Milligram Daily

Started: 09/09/1994 **Stopped:** 03/10/1994 Batch:

LITHIUM CARBONATE (Suspected) Reason:

> 1.0 Gram Daily

Started: L TERM Batch: Stopped:

## **Laboratory Investigations:**

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP	30 - 120 U/L	05/10/1994	194	
	SAP = ALP	30 - 120 U/L	13/10/1994	99	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 96504 Seq: 1 Gender: F
Reported: 14/10/1994 Weight:

Hospitalisation: Age: 34Y
Onset Date: 27/09/1994
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Arthralgia			
Fatigue			
Hepatic function abnormal			
Lymphopenia			
Myalgia			
Pharyngitis			
Pyrexia			
Thrombocythaemia			

#### **Medicine Details:**

LITHIUM CARBONATE (Other drug)		Reason:		
	1.0 Gram	Daily		
Batch:	Started: 01/01/1993		Stopped:	CONTIN
PROZAC (Suspected)		Reason:	Depression	
Tablet	20.0 Milligram	Daily		Oral
Batch:	Started: 05/09/1994		Stopped:	30/09/1994
CHLORPROMAZINE HYDROCHLORIDE	(Suspected)	Reason:		
	50.0 Milligram	Daily		
Batch:	Started: 25/07/1994		Stopped:	30/09/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =		27/09/1994	178	
	SAP = ALP		27/09/1994	270	

#### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

 Case Number:
 96713
 Seq: 1
 Gender:
 F

 Reported:
 28/10/1994
 Weight:

Hospitalisation: Age: 24Y
Onset Date: 29/09/1994
DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Skin exfoliation			

## **Medicine Details:**

HALDOL DECANOATE (Other drug)		Reason: Unspecified schizophrenia	
Injection	100.0 Milligram	1 time Intramuscular	
Batch:	Started: 23/09/1994	Stopped:	
FOLIC ACID (Other drug)		Reason: Unspecified schizophrenia	
Oral application	5.0 Milligram	Daily Oral	
Batch:	Started:	<b>Stopped:</b> 30/09/1994	
LITHIUM CARBONATE (Other drug)		Reason: Unspecified schizophrenia	
Tablet	2.0 Gram	Daily Oral	
Batch:	Started:	Stopped:	
CHLORPROMAZINE HYDROCHLORIDE (	Suspected)	Reason: Unspecified schizophrenia	
Oral application	400.0 Milligram	Daily Oral	
Batch:	Started:	<b>Stopped:</b> 30/09/1994	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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**Additional Information:** 

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

spitalisati	ted: 10/11/1994	•	ı: 1		Gender: F Weight:				
-		4							04)/
Unset D		4						Age:	
0	ate: 21/09/1994						•	DOB:	
	me: Recovered	1					C	ausality:	Causality possible
eaction D				T	Dan	t D	-i4:		Too also and
	eferred Term	5	everity		кер	ort Desc	ription		Treatment
Agitation	_								
-lyperkinesia	<u> </u>								
Medicine I	Notaile:								
Medicine I	Details:				Rea	son:			
	WINE (Suspected)		1.0	Milligram		son: 2 times		Subcutane	ous
PHYSOSTIGN	MINE (Suspected)	•	1.0 <b>Started:</b> 21/	_			Stopped:	Subcutane 21/09/1994	
PHYSOSTIGN Injecti Batcl	MINE (Suspected) tion h:			_	1		Stopped:		
PHYSOSTIGN Injecti	MINE (Suspected) tion h: (Suspected)		Started: 21/	_	Rea	2 times	Stopped:		
PHYSOSTIGN Injecti Batcl LARGACTIL (	MINE (Suspected) ion h: (Suspected) ion		Started: 21/	09/1994 Milligram	Rea	2 times		21/09/1994	ılar
PHYSOSTIGM Injecti Batcl LARGACTIL ( Injecti Batcl	MINE (Suspected) ion h: (Suspected) ion	;	25.0 Started: 21/0	09/1994 Milligram	Rea	2 times		21/09/1994 Intramuscu	ılar
PHYSOSTIGM Injecti Batcl LARGACTIL ( Injecti Batcl	MINE (Suspected) tion h: (Suspected) tion h:	;	25.0 Started: 21/0	09/1994 Milligram	Rea	2 times son: 1 time	Stopped:	21/09/1994 Intramuscu	l Ilar

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 97234 Seq: 1 Gender: F
Reported: 21/11/1994 Weight:

Hospitalisation: Age: 41

**Onset Date**: 12/08/1994 **DOB**: 11/09/1952

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	toaction Botaile.			
	Preferred Term	Severity	Report Description	Treatment
	Dry mouth			
	Hypothyroidism			

## **Medicine Details:**

TRIFLUOPERAZINE HYDROCHLORIDE	Reason:			
	10.0 Milligram	Daily		
Batch:	Started: 12/08/1994	St	opped:	CONTIN
DIAZEPAM (Other drug)		Reason:		
	5.0 Milligram	Daily		
Batch:	Started: 12/08/1994	St	opped:	CONTIN
CHLORPROMAZINE HYDROCHLORIDE (Suspected)		Reason: Unspe	ecified schizophrenia	
Oral application	200.0 Milligram	Daily	Oral	
Batch:	Started: 21/06/1994	St	opped: 12/08/1994	
LITHIUM CARBONATE (Suspected)		Reason:		
Tablet	500.0 Milligram	Daily	Oral	
Batch:	Started: L	TERM St	opped:	CONTIN

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
Biochemistry N: 11-25; LOW <			15.08.1994 free t4 8 pmol/l.		

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 97282 Seq: 1 Gender: F
Reported: 23/11/1994 Weight:

Hospitalisation: Age: 73Y
Onset Date: 01/11/1994
DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			

## **Medicine Details:**

PETHIDINE HYDROCHLORIDE (Other drug)		Reason:	Pain	
Injection	50.0 Milligram	1 time	е	Intramuscular
Batch:	Started: 30/10/1994		Stopped:	30/10/1994
MAXOLON (Other drug)		Reason:	Nausea and vo	omiting
Injection	10.0 Milligram	1 time	е	Intramuscular
Batch:	Started: 30/10/1994		Stopped:	30/10/1994
AMPICILLIN (Other drug)		Reason:	Otr pyeloneph,	pyelit,pyelocyst
Injection	2.0 Gram	Daily		Intravenous
Batch:	Started: 30/10/1994		Stopped:	
GENTAMICIN SULPHATE (Other drug)		Reason:	Otr pyeloneph,	,pyelit,pyelocyst
Injection	240.0 Milligram	Daily		Intravenous
Batch:	Started: 30/10/1994		Stopped:	

**Laboratory Investigations:** 

Da	ate	Туре	Range	Date Tested	Result	Details
		Histology				Signs of atypical mononuclears with neutrophils showing a shift to left.
		Neutrophils		01/11/1994	0	
		White blood cells		01/11/1994	1.5	

#### **Additional Information:**

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

	97282	Seq: 1				Gender:	1	
Reported: 2	23/11/1994					Weight:		
ospitalisation:						Age:	73Y	
Onset Date: (	01/11/1994					DOB:		
Outcome: F	Recovered				С	ausality:	Causality p	orobable
eaction Details	s:							
Medicine Deta				Decre				
SOLPRIN (Other dru	<b>1</b> g)	450.0	MAIII aug = :	Reason:		Oral		
Tablet			Milligram	Daily	OA-mara	Oral		
Batch:	-4- d\	Started:		Darre	Stopped: Presenile dem			
LARGACTIL (Suspe	ctea)			Reason:	Presentle dem	entia		
	,	<b></b> ^	N 4:11:		i reseriile derii	Cittia		
5	,		Milligram	Daily				
Batch:	,	75.0 Started:	Milligram			02/11/1994		
Batch:			Milligram					
Batch:			Milligram					
Batch:	,		Milligram					
Batch:	<u>,                                      </u>		Milligram					
Batch:	,		Milligram					
Batch:	, 		Milligram					
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aboratory Inv	estigations:		Milligram					
₋aboratory Inv	estigations:		Milligram					
Batch:  -aboratory Inv	estigations:		Milligram					
aboratory Inv	estigations:		Milligram					
aboratory Inv	estigations:		Milligram					

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 97892 Seq: 1 Gender: M

Reported: 15/12/1994 Weight: 89.00 Hospitalisation: Age: 26Y

**Onset Date**: 28/11/1994 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			
Oedema			
Rash pustular			

#### **Medicine Details:**

	Reason:			
25.0 Milligram	Daily	Intramuscular		
Started: 25/11/1994	Stopped:	Stopped:		
	Reason:			
800.0 Milligram	Daily	Oral		
Started: 22/04/1994	Stopped:	28/11/1994		
	25.0 Milligram  Started: 25/11/1994  800.0 Milligram	Started: 25/11/1994 Stopped:  Reason:  800.0 Milligram Daily		

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		28/11/1994	108	
	Bilirubin		28/11/1994	6	
	GGT = SGGT =		28/11/1994	23	
	SAP = ALP		28/11/1994	107	

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details:	Re	oa	rt	De	tai	ls:
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Case Number: 98059 Seq: 1 Gender: M
Reported: 29/12/1994 Weight:

Hospitalisation: Age: 18Y
Onset Date: 23/11/1994
DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			

#### **Medicine Details:**

PERICYAZINE (Suspected) Reason: Unspecified psychosis

0.0

**Batch: Started:** 15/11/1994 **Stopped:** 28/11/1994

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified psychosis

50.0 Milligram Daily

Batch: Started: 20/11/1994 Stopped: 28/11/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 98123 Seq: 1 Gender: M
Reported: 03/01/1995 Weight:

Hospitalisation: Age: 92

**Onset Date**: 22/08/1994 **DOB**: 28/09/1901

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

TOUGHT DOLUME			
Preferred Term	Severity	Report Description	Treatment
Anorexia			
Consciousness fluctuating			
Dyspnoea			
Fatigue			
Hyperglycaemia			
Neuroleptic malignant syndrome			
Productive cough			
Pyrexia			

## **Medicine Details:**

COLOXYL WITH SENNA (Other drug)		Rea	son:	Constipation	
Tablet	2.0	Dose Unspecified	As ne	cessary	Oral
Batch:	Started:	L TERM		Stopped:	
FERRO-GRADUMET (Other drug)		Rea	son:	Unspecified an	emia
Tablet, modified release	1.0	Dose Unspecified	Daily		Oral
Batch:	Started:	L TERM		Stopped:	
ACTRAPID HM (Other drug)		Rea	son:	Diabetes mellit	us
Injection	8.0	Unit	Daily		Subcutaneous
Batch:	Started:	L TERM		Stopped:	
TEMAZEPAM (Other drug)		Rea	son:	Specific disord	ers of sleep
Capsule	10.0	Milligram	Daily		Oral
Batch:	Started:	L TERM		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient died on 25/08/94.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 98123
 Seq: 1
 Gender: M

 Reported:
 03/01/1995
 Weight:

Hospitalisation: Age: 92

**Onset Date**: 22/08/1994 **DOB**: 28/09/1901

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

**Medicine Details:** 

MS CONTIN (Other drug)		Reason: Pain	
Tablet	40.0 Milligra	n Daily	Oral
Batch:	Started:	L TERM S	Stopped:
NYSTATIN (Other drug)		Reason:	
Solution	4.0 Millilitre	Daily	Oral
Batch:	Started: 22/08/1994	S	Stopped: 24/08/1994
HALOPERIDOL (Suspected)		Reason:	
Injection	2.5 Milligra	m As necessa	ry Intramuscular
Batch:	Started: 18/08/1994	S	Stopped: 22/08/1994
CHLORPROMAZINE HYDROCHLORIDE	(Suspected)	Reason:	
Oral application	150.0 Milligra	m Daily	Oral
Batch:	Started: 18/08/1994	S	Stopped: 23/08/1994

# **Laboratory Investigations:**

#### **Additional Information:**

Patient died on 25/08/94.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 98956 Seq: 1 Gender: M
Reported: 14/02/1995 Weight:

Hospitalisation: Age: 22

**Onset Date**: 09/04/1994 **DOB**: 26/07/1971

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

## **Medicine Details:**

PHENYTOIN SODIUM (Suspected)		Reason:	
Injection	300.0 Milligram	Daily	Intravenous
Batch:	Started: 02/04/1994	Stopped:	20/04/1994
RANITIDINE (Suspected)		Reason:	
Injection	150.0 Milligram	Daily	Intravenous
Batch:	Started: 02/04/1994	Stopped:	19/04/1994
BENZYLPENICILLIN (Suspected)		Reason:	
Injection	7.2 Gram	Daily	Intravenous
Batch:	Started: 02/04/1994	Stopped:	11/04/1994
FLUCLOXACILLIN SODIUM (Suspected)		Reason:	
Injection	4.0 Gram	Daily	Intravenous
Batch:	Started: 02/04/1994	Stopped:	16/04/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	(<55)	07/04/1994	30	
	ALT = SGPT	(<55)	09/04/1994	32	
	ALT = SGPT	(<55)	11/04/1994	36	
	ALT = SGPT	(<55)	28/04/1994	52	
	ALT = SGPT	(<55)	20/04/1994	48	
	ALT = SGPT	(<55)	14/04/1994	42	
	ALT = SGPT	(<55)	09/05/1994	39	

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 98956
 Seq: 1
 Gender: M

 Reported:
 14/02/1995
 Weight:

Hospitalisation: Age: 22

Onset Date: 09/04/1994 DOB: 26/07/1971
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

#### **Medicine Details:**

Medicine Details.			
CEFOTAXIME SODIUM (Suspected)		Reason:	
Injection	3.0 Gram	Daily	Intravenous
Batch:	Started: 06/04/1994	Stopped:	11/04/1994
LARGACTIL (Suspected)		Reason: Hiccough	
Tablet	45.0 Milligram	Daily	Oral
Batch:	Started: 06/04/1994	Stopped:	09/04/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin	(<17)	07/04/1994	16	
	Bilirubin	(<17)	09/04/1994	13	
	Bilirubin	(<17)	11/04/1994	19	
	Bilirubin	(<17)	28/04/1994	11	
	Bilirubin	(<17)	09/05/1994	14	
	Bilirubin	(<17)	20/04/1994	15	
	Bilirubin	(<17)	14/04/1994	10	

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**DOB**: 26/07/1971

**Report Details:** 

 Case Number:
 98956
 Seq: 1
 Gender: M

 Reported:
 14/02/1995
 Weight:

Hospitalisation: Age: 22

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Onset Date: 09/04/1994

## **Medicine Details:**

PHENYTOIN SODIUM (Suspected)		Reason:	
Injection	300.0 Milligram	Daily	Intravenous
Batch:	Started: 02/04/1994	Stopped:	20/04/1994
RANITIDINE (Suspected)		Reason:	
Injection	150.0 Milligram	Daily	Intravenous
Batch:	Started: 02/04/1994	Stopped:	19/04/1994
BENZYLPENICILLIN (Suspected)		Reason:	
Injection	7.2 Gram	Daily	Intravenous
Batch:	Started: 02/04/1994	Stopped:	11/04/1994
FLUCLOXACILLIN SODIUM (Suspected)		Reason:	
Injection	4.0 Gram	Daily	Intravenous
Batch:	Started: 02/04/1994	Stopped:	16/04/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =	(7-43)	07/04/1994	79	
	GGT = SGGT =	(7-43)	09/04/1994	108	
	GGT = SGGT =	(7-43)	11/04/1994	216	
	GGT = SGGT =	(7-43)	20/04/1994	407	
	GGT = SGGT =	(7-43)	09/05/1994	170	
	GGT = SGGT =	(7-43)	28/04/1994	341	
	GGT = SGGT =	(7-43)	14/04/1994	412	

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 98956
 Seq: 1
 Gender: M

 Reported:
 14/02/1995
 Weight:

Hospitalisation: Age: 22

**Onset Date**: 09/04/1994 **DOB**: 26/07/1971

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

#### **Medicine Details:**

Medicine Details.			
CEFOTAXIME SODIUM (Suspected)		Reason:	
Injection	3.0 Gram	Daily	Intravenous
Batch:	Started: 06/04/1994	Stopped:	11/04/1994
LARGACTIL (Suspected)		Reason: Hiccough	
Tablet	45.0 Milligram	Daily	Oral
Batch:	Started: 06/04/1994	Stopped:	09/04/1994

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP	(30-110)	07/04/1994	78	
	SAP = ALP	(30-110)	09/04/1994	106	
	SAP = ALP	(30-110)	11/04/1994	164	
	SAP = ALP	(30-110)	14/04/1994	268	
	SAP = ALP	(30-110)	20/04/1994	261	
	SAP = ALP	(30-110)	28/04/1994	297	
	SAP = ALP	(30-110)	09/05/1994	186	

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 99632 Seq: 1 Gender: F

Reported: 16/03/1995 Weight:
Hospitalisation: Age: 66Y

Onset Date: 06/03/1995 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction		Sunburn and blisters.	Silvazine.

# **Medicine Details:**

TEGRETOL (Other drug)		Reason:	
	200.0 Milligra	m Daily	
Batch:	Started:		Stopped:
LASIX (Other drug)		Reason:	
	60.0 Milligra	m Daily	
Batch:	Started:		Stopped:
COGENTIN (Other drug)		Reason:	
	4.0 Milligra	m Daily	
Batch:	Started:		Stopped:
SLOW-K (Other drug)		Reason:	
	1.0 Dose U	nspecified Daily	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Chlorpromazine to be continued patient to use sunscreen.

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Medicine Details: CHLORPROMAZINE HYDROCHLORIDE (Suspected) 200.0 Milligram Daily Batch: Started: L.TERM Stopped: CONTIN  L. TERM Stopped: CONTIN  Additional Information:	Case Number.	99032	Seq. I			Gend	ier. r	
ospitalisation: Onset Date: 06/03/1995 Outcome: Recovered Causality: Causality possible eaction Details:  Medicine Details: CHLORPROMAZINE HYDROCHLORIDE (Suspected) 200.0 Milligram Daily Batch: Started: L.TERM Stopped: CONTIN  Additional Information:	Reported:	16/03/1995				Weig	ıht:	
Onset Date: 06/03/1995 Outcome: Recovered Causality: Causality possible caction Details:  Medicine Details:  CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Unspecifid affective psychosis 200.0 Milligram Daily Batch: Started: L TERM Stopped: CONTIN						_		
Outcome: Recovered Causality: Causality possible paction Details:  Medicine Details:  CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Unspecifid affective psychosis 200.0 Milligram Daily  Batch: Started: LTERM Stopped: CONTIN  -aboratory Investigations:		06/03/1995						
Medicine Details:  CHLORPROMAZINE HYDROCHLORIDE (Suspected)  200.0 Milligram Daily  Batch: Started: L.TERM Stopped: CONTIN  Additional Information:								e
Medicine Details: CHLORPROMAZINE HYDROCHLORIDE (Suspected) 200.0 Milligram Daily Batch: Starled: L TERM Stopped: CONTIN  Additional Information:							inty: Gadoanty poolio	
CHLORPROMAZINE HYDROCHLORIDE (Suspected)  200.0 Milligram Daily  Batch: Started: L TERM Stopped: CONTIN   aborratory Investigations:	action Botan	0.						
CHLORPROMAZINE HYDROCHLORIDE (Suspected)  200.0 Milligram Daily  Batch: Started: L TERM Stopped: CONTIN   aborratory Investigations:								
CHLORPROMAZINE HYDROCHLORIDE (Suspected)  200.0 Milligram Daily  Batch: Started: L TERM Stopped: CONTIN   Continuation:  Caboratory Investigations:								
CHLORPROMAZINE HYDROCHLORIDE (Suspected)  200.0 Milligram Daily  Batch: Started: L TERM Stopped: CONTIN								
CHLORPROMAZINE HYDROCHLORIDE (Suspected)  200.0 Milligram Daily  Batch: Started: L TERM Stopped: CONTIN   L TERM Stopped: CONTIN   Laboratory Investigations:								
CHLORPROMAZINE HYDROCHLORIDE (Suspected)  200.0 Milligram Daily  Batch: Started: L TERM Stopped: CONTIN   L TERM Stopped: CONTIN   Laboratory Investigations:								
200.0 Milligram Daily								
CHLORPROMAZINE HYDROCHLORIDE (Suspected)  200.0 Milligram Daily  Batch: Started: L TERM Stopped: CONTIN   L TERM Stopped: CONTIN   Laboratory Investigations:								
CHLORPROMAZINE HYDROCHLORIDE (Suspected)  200.0 Milligram Daily  Batch: Started: L TERM Stopped: CONTIN   L TERM Stopped: CONTIN   Laboratory Investigations:								
CHLORPROMAZINE HYDROCHLORIDE (Suspected)  200.0 Milligram Daily  Batch: Started: L TERM Stopped: CONTIN   L TERM Stopped: CONTIN   Laboratory Investigations:								
CHLORPROMAZINE HYDROCHLORIDE (Suspected)  200.0 Milligram Daily  Batch: Started: L TERM Stopped: CONTIN   L TERM Stopped: CONTIN   Laboratory Investigations:								
CHLORPROMAZINE HYDROCHLORIDE (Suspected)  200.0 Milligram Daily  Batch: Started: L TERM Stopped: CONTIN   L TERM Stopped: CONTIN   Laboratory Investigations:								
CHLORPROMAZINE HYDROCHLORIDE (Suspected)  200.0 Milligram Daily  Batch: Started: L TERM Stopped: CONTIN   L TERM Stopped: CONTIN   Laboratory Investigations:								
CHLORPROMAZINE HYDROCHLORIDE (Suspected)  200.0 Milligram Daily  Batch: Started: L TERM Stopped: CONTIN   L TERM Stopped: CONTIN   Laboratory Investigations:	Andinina Data	ila.						
Batch: Started: L TERM Stopped: CONTIN			(Supported)		Passani	Unanagifid affactive n	avahasia	
Batch: Started: L TERM Stopped: CONTIN  Laboratory Investigations:  Additional Information:	CHLORPROWAZIN	ENTUROCHLORIDE		Mailli auraura		Onspecific affective p	sychosis	
aboratory Investigations:							0.01/7/11	
Additional Information:	Batch:		Started:	L TI	ERM	Stopped:	CONTIN	
Additional Information:								
Additional Information:								
Additional Information:								
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Additional Information:								
Additional Information:								
Additional Information:								
Additional Information:	aboratory Inv	vestigations:						
	aboratory iii	rootigationo.						
		- · · · · · · · · · · · ·						
chiorpromazine to be continued patient to use sunscreen.								
	niorpromazine to	be continued patient	to use sunscre	een.				

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: 99758 Reported: 23/03/1995 ospitalisation: Onset Date: 07/02/1995 Outcome: Recovered	Seq: 1			C	Gender: Weight: Age: DOB: Causality:	72Y
eaction Details:  Preferred Term	Severity	Rei	oort Des	cription		Treatment
Agitation Confusional state Hallucination	Severe					
Madicina Datails:						
Medicine Details: CHLORPROMAZINE HYDROCHLO	ORIDE (Suspected)	Re	ason:			
		Re ) Milligram	eason:		Intramuscu	ular
CHLORPROMAZINE HYDROCHLO Injection Batch:	50.0 <b>Started:</b> 07	) Milligram		Stopped:	Intramuscu	ular
CHLORPROMAZINE HYDROCHLO Injection Batch: METOPROLOL TARTRATE (Susp	50.0 Started: 07	) Milligram 7/02/1995 Re	1 time	Stopped:		ular
CHLORPROMAZINE HYDROCHLO Injection Batch: METOPROLOL TARTRATE (Susp	50.0 Started: 07 Dected)	Milligram 7/02/1995  Re Milligram	1 time	Surgery	Intramusco	ular
CHLORPROMAZINE HYDROCHLO Injection Batch: METOPROLOL TARTRATE (Susp Tablet Batch:	50.0 Started: 07 pected) 50.0 Started: 07	) Milligram 7/02/1995 <b>Re</b> ) Milligram 7/02/1995	1 time  ason: S  1 time	Surgery Stopped:		ular
CHLORPROMAZINE HYDROCHLO Injection Batch:  METOPROLOL TARTRATE (Susp Tablet Batch:  PRAZOSIN HYDROCHLORIDE (S	50.0 Started: 07 Dected) 50.0 Started: 07 Suspected)	Milligram 7/02/1995  Re Milligram 7/02/1995  Re	1 time  ason: 5  1 time  ason: 5	Surgery	Oral	ular
CHLORPROMAZINE HYDROCHLO Injection Batch:  METOPROLOL TARTRATE (Susp Tablet Batch:  PRAZOSIN HYDROCHLORIDE (S	50.0 Started: 07 Dected) 50.0 Started: 07 Started: 07	Milligram 7/02/1995  Re 0 Milligram 7/02/1995  Re 0 Milligram	1 time  ason: S  1 time	Stopped: Surgery		ular
Injection Batch:  METOPROLOL TARTRATE (Susp Tablet Batch:  PRAZOSIN HYDROCHLORIDE (S Tablet Batch:	50.0 Started: 07 Dected) 50.0 Started: 07 Suspected)	Milligram 7/02/1995  Re 0 Milligram 7/02/1995  Re 0 Milligram 7/02/1995	1 time  ason: S  1 time  ason: S  1 time	Stopped: Stopped: Surgery Stopped:	Oral	ular
CHLORPROMAZINE HYDROCHLO Injection Batch:  METOPROLOL TARTRATE (Susp Tablet Batch:  PRAZOSIN HYDROCHLORIDE (S	50.0 Started: 07 Dected)  50.0 Started: 07 Suspected)  4.0 Started: 07	0 Milligram 7/02/1995 Re 0 Milligram 7/02/1995 Re 0 Milligram 7/02/1995	1 time  ason: S  1 time  ason: S  1 time	Stopped: Surgery	Oral	ular
CHLORPROMAZINE HYDROCHLO Injection Batch:  METOPROLOL TARTRATE (Susp Tablet Batch:  PRAZOSIN HYDROCHLORIDE (S Tablet Batch:  Tablet Batch:	50.0 Started: 07 Dected)  50.0 Started: 07 Suspected)  4.0 Started: 07	Milligram 7/02/1995  Re Milligram 7/02/1995  Re Milligram 7/02/1995  Re Milligram 7/02/1995	1 time  ason: S  1 time  ason: S  1 time	Stopped: Stopped: Surgery Stopped:	Oral	ular
CHLORPROMAZINE HYDROCHLO Injection Batch:  METOPROLOL TARTRATE (Susponder Suspension of the Company of the Comp	50.0 Started: 07 Dected)  50.0 Started: 07 Suspected)  4.0 Started: 07	Milligram 7/02/1995  Re Milligram 7/02/1995  Re Milligram 7/02/1995  Re Milligram 7/02/1995	1 time  ason: S  1 time  ason: S  1 time	Stopped: Surgery Stopped: Surgery	Oral	ular
CHLORPROMAZINE HYDROCHLO Injection Batch:  METOPROLOL TARTRATE (Susp Tablet Batch:  PRAZOSIN HYDROCHLORIDE (S Tablet Batch:  TEMAZEPAM (Suspected) Oral application	50.0 Started: 07 Dected)  50.0 Started: 07 Suspected)  4.0 Started: 07	Milligram 7/02/1995  Re 0 Milligram 7/02/1995  Re 0 Milligram 7/02/1995  Re 0 Milligram 7/02/1995	1 time  ason: S  1 time  ason: S  1 time	Stopped: Surgery Stopped: Surgery	Oral	

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	99758	Seq: 1					Gender:	F	
Reported:	23/03/1995						Weight:		
Hospitalisation:							Age:	72Y	
Onset Date:	07/02/1995						DOB:		
Outcome:	Recovered					С	ausality:	Causality possible	
Reaction Detai	ils:								
Medicine Det									
TRANSIDERM-NIT	RO (Suspected)					Surgery			
			1.0 Dose Uns	specified	1 time				
Batch:			: 07/02/1995			Stopped:			
BUPIVACAINE HY	DROCHLORIDE (Susp	ected)		Rea	son:	Surgery			
			1.0 Dose Uns	specified	1 time				
Batch:		Started	: 07/02/1995			Stopped:			
HYPNOVEL (Susp	ected)			Rea		Surgery			
			1.0 Dose Uns	specified	1 time				
Batch:		Started	: 07/02/1995			Stopped:			
HYDRALAZINE HY	DROCHLORIDE (Sus	pected)		Rea	son:	Essential beni	gn hyperten	sion	
Injection			4.0 Milligram		1 time		Intravenou	s	
Batch:		Started	: 07/02/1995			Stopped:			
	41 41								<u> </u>
Laboratory In	ivestigations:								
۸ مامانا: محمد ال4	iarmatiar-								
Additional Inf	ormation:								

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# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

| Reason:   Intramuscular   Benztropine Mesylate (Suspected)   Reason:   Injection   4.0 Milligram   1 time   Intramuscular   Batch:   Started: 07/02/1995   Stopped:   DEXAMETHASONE (Suspected)   Reason:   Injection   20.0 Milligram   1 time   Intravenous   Batch:   Started: 07/02/1995   Stopped:   Stopped:   Stopped:   Started: 07/02/1995   Stopped:   |--|
| Injection 4.0 Milligram 1 time Intramuscular  Batch: Started: 07/02/1995 Stopped:  PEXAMETHASONE (Suspected) Injection 20.0 Milligram 1 time Intravenous  Batch: Started: 07/02/1995 Stopped:  |
| Batch: Started: 07/02/1995 Stopped:  DEXAMETHASONE (Suspected) Injection 20.0 Milligram 1 time Intravenous  Batch: Started: 07/02/1995 Stopped:  |
| DEXAMETHASONE (Suspected)  Injection  20.0 Milligram  1 time Intravenous  Batch:  Started: 07/02/1995  Stopped:  |
| Injection 20.0 Milligram 1 time Intravenous  Batch: Started: 07/02/1995 Stopped:   |
|  |
|  |
|  |

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Rei	port	Detai	ls:
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Case Number: 99919 Seq: 1 Gender: F

Reported: 30/03/1995 Weight:
Hospitalisation: Age: 43Y

Onset Date: 25/03/1995 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Dystonia			Cogentin

## **Medicine Details:**

PARNATE (Other drug)		Reason:	Depression	
Tablet	30.0 Milligram	n Daily	(	Oral
Batch:	Started:	L TERM	Stopped:	
PHENERGAN (Other drug)		Reason:		
	4.0 Milligram	n Daily		
Batch:	<b>Started:</b> 15/03/1995		Stopped:	
INDERAL (Other drug)		Reason:	Migraine	
Tablet	40.0 Milligram	n Daily	(	Oral
Batch:	<b>Started:</b> 24/03/1995		Stopped:	
LARGACTIL (Suspected)		Reason:		
	50.0 Milligram	n 1 time	е	
Batch:	Started: 25/03/1995		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: 99 Reported: 30 Hospitalisation: Onset Date: 25 Outcome: R Reaction Details	0/03/1995 5/03/1995 ecovered	Seq: 1		V	Gender: Veight: Age: DOB: usality:	
Medicine Detail						
HEMINEURIN (Suspe	cted)	45 O. MUU	Reason:	,	21	
Capsule		15.0 Milligram	Daily		Oral	
Batch:		<b>Started:</b> 15/03/1995		Stopped: 2	26/03/1995	
Laboratory Inve	estigations:					
Additional Info	rmation:					

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

Case Number: 1011111 Seq: 1 Gender: M

Reported: 29/05/1995 Weight: 70.00 Hospitalisation: Age: 28Y

**Onset Date**: 24/05/1995 **DOB**:

Outcome: Recovered Causality: Causality possible

#### **Reaction Details:**

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			

# **Medicine Details:**

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

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: 101111 Reported: 29/05/1995 Hospitalisation: Onset Date: 24/05/1995 Outcome: Recovered Reaction Details:	Seq: 1		Gender: Weight: Age: DOB: Causality:	70.00
Medicine Details:  PAROXETINE HYDROCHLORIDE (Susp	acted)	Reason:	Otr spec symp psychopath	ol nec
Tablet	20.0 Milligram	Daily	Oral	of fiec
Batch:	Started: 17/05/1995	24,	Stopped:	
Laboratory Investigations:				
Additional Information:				

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 101404
 Seq: 1
 Gender:
 F

 Reported:
 08/06/1995
 Weight:

Hospitalisation: Admitted to hospital Age: 60

**Onset Date:** 10/06/1994 **DOB:** 24/07/1933

Outcome: Unknown Causality: Causality probable

**Reaction Details:** 

•	toaction Botano.			
	Preferred Term	Severity	Report Description	Treatment
	Abdominal pain			
	Hepatitis			

#### **Medicine Details:**

modicino Botano.			
LARGACTIL (Suspected)		Reason:	
Oral application	25.0 Milligram	Daily	Oral
Batch:	Started:	St	tonned:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	6-35 IU/L	09/06/1994	73	
	ALT = SGPT	6-35 IU/L	03/07/1994	450	
	ALT = SGPT	6-35 IU/L	19/07/1994	34	
	AST = SGOT	10-36 IU/L	09/06/1994	35	
	AST = SGOT	10-36 IU/L	03/07/1994	346	
	AST = SGOT	10-36 IU/L	19/07/1994	14	
	Bilirubin	5-20 UMOL/L	09/06/1994	9	

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 101404 Seq: 1 Gender: F

Reported: 08/06/1995 Weight:
Hospitalisation: Admitted to hospital Age: 60

**Onset Date**: 10/06/1994 **DOB**: 24/07/1933

Outcome: Unknown Causality: Causality probable

Reaction Details:

## **Medicine Details:**

LARGACTIL (Suspected) Reason:

Oral application 25.0 Milligram Daily Oral

Batch: Started: Stopped:

**Laboratory Investigations:** 

<u>Laborato</u>	i y iii vootiga				
Date	Туре	Range	Date Tested	Result	Details
	Bilirubin	5-20 UMOL/L	03/07/1994	8	
	Bilirubin	5-20 UMOL/L	19/07/1994	6	
	GGT = SGGT =	0-25 IU/L	09/06/1994	139	
	GGT = SGGT =	0-25 IU/L	03/07/1994	57	
	GGT = SGGT =	0-25 IU/L	19/07/1994	34	
	SAP = ALP	36-95 IU/L	09/06/1994	413	
	SAP = ALP	36-95 IU/L	03/07/1994	177	

## **Additional Information:**

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	101404	Seq:	1			Gender	F
Reported:	08/06/199	5				Weight:	
Hospitalisation:	Admitted t	o hospital				Age:	60
Onset Date:	10/06/199	4				DOB	: 24/07/1933
Outcome:	Unknown					Causality	Causality probable
Reaction Deta	ils:					•	• •
Medicine Det	ails:						
LARGACTIL (Sus				Rea	son:		
Oral applic			25.0 Millig		Daily	Oral	
Batch:		s	tarted:	•	•	Stopped:	
						•	
Laboratory Ir	waatiaati	ionor					
Date	Type	Range	Date Tested	Result		Deta	ils
	= ALP	36-95 IU/L	19/07/1994	112		200	
Additional In	formation	<b>.</b> .					
Additional in	iorinatioi	1.					

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 101462 Seq: 1 Gender: F

Reported: 09/06/1995

Hospitalisation:
Onset Date:

Weight: 60.00
Age: 33Y
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

teaction betails.			
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 schizop	hrenia
Injection	25.0 Milligram	Weekly Intra	muscular
Batch:	Started: 22/10/1993	Stopped: 12/1	2/1994
CHLORPROMAZINE HYDROCHLO	RIDE (Suspected)	Reason: Unspecified schizop	hrenia
Oral application	75.0 Milligram	Daily Oral	
Batch:	Started: 01/08/1993	Stopped:	CONTIN

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details

#### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 102085
 Seq: 1
 Gender:
 F

 Reported:
 10/07/1995
 Weight:
 74.00

 Hospitalisation:
 Age: 27

Onset Date: DOB: 14/03/1968

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Brain oedema			
Hyponatraemia			
Nausea			
Vomiting			

# **Medicine Details:**

LARGACTIL (Suspected)		Reason: Nausea and vomiting	
Injection	25.0 Milligram	As necessary Intravenous	
Batch:	Started:	Stopped:	
DROPERIDOL (Suspected)		Reason: Nausea and vomiting	
Injection	2.0 Milligram	As necessary Intravenous	
Batch:	Started:	Stopped:	
STEMETIL (Suspected)		Reason:	
Injection	12.5 Milligram	As necessary Intramuscular	
Batch:	Started:	Stopped:	
ZOFRAN (Suspected)		Reason:	
Injection	4.0 Milligram	Daily Intravenous	
Batch:	Started:	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient was not well controlled epileptic, who after surgery was hyponatraemic and vomiting, died of cerebral oedema.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Re	po	rt D	etai	ls:
----	----	------	------	-----

 Case Number:
 102085
 Seq: 1
 Gender:
 F

 Reported:
 10/07/1995
 Weight:
 74.00

 Hospitalisation:
 Age: 27

**Onset Date:** DOB: 14/03/1968

Outcome: Death, maybe drug

Causality: Causality possible

**Reaction Details:** 

#### **Medicine Details:**

DILANTIN (Suspected)		Re	eason:	Other&unspec	ified epilepsy
Tablet	300.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	
PETHIDINE HYDROCHLORIDE (Suspected)		Re	eason:		
Injection	400.0	Milligram	Daily		Intramuscular
Batch:	Started:			Stopped:	
PANADEINE FORTE (Suspected)		Re	eason:		
Tablet	12.0	Dose Unspecifie	d Daily		Oral
Batch:	Started:			Stopped:	

# **Laboratory Investigations:**

#### **Additional Information:**

Patient was not well controlled epileptic, who after surgery was hyponatraemic and vomiting, died of cerebral oedema.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

 Case Number:
 102680
 Seq: 1
 Gender: M

 Reported:
 08/08/1995
 Weight:

Hospitalisation: Admitted to hospital Age: 77Y
Onset Date: 23/07/1995
DOB:

Outcome: Not yet recovered Causality: Causality possible

#### Reaction Details:

-				
	Preferred Term	Severity	Report Description	Treatment
	Confusional state			

## **Medicine Details:**

LARGACTIL (Suspected)Reason:HiccoughTablet30.0 MilligramDailyOral

Batch: Started: 22/07/1995 Stopped: 23/07/1995

COGENTIN (Suspected) Reason: Hiccough

2.0 Milligram Daily

**Batch: Started:** 22/07/1995 **Stopped:** 23/07/1995

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 103048 Seq: 1 Gender: F

Reported: 25/08/1995 Weight:
Hospitalisation: Age: 43Y

Onset Date: 18/08/1995 DOB:

Outcome: Recovered Causality: Causality certain

**Reaction Details:** 

•	todotion Botans.			
	Preferred Term	Severity	Report Description	Treatment
	Agitation			
	Hypotension			
	Somnolence			

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Nausea and vomiting

Injection, intravenous infusion 75.0 Milligram 1 time Intravenous

Batch: Started: 18/08/1995 Stopped: 18/08/1995

**Laboratory Investigations:** 

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

#### **Additional Information:**

See original report for other drugs.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 105296 Seq: 1 Gender: F

Reported: 11/12/1995 Weight:
Hospitalisation: Age:
Onset Date: 31/12/1995 DOB:

Outcome: Unknown Causality: Causality certain

Reaction Details:

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
Abdominal pain			Treated with mylanta and zantac

## **Medicine Details:**

LARGACTIL (Suspected)

Reason:

800.0 Milligram Daily

Batch: Started: L TERM Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient has been on largactil for 10 years and recently stated on non-sugar coated largactil and claims to experience severe gastric pain within minutes of taking a dose. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Rei	port	Detai	ls:
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 Case Number:
 105493
 Seq: 1
 Gender:
 F

 Reported:
 21/12/1995
 Weight:

Hospitalisation: Age: 37Y
Onset Date: 04/12/1995
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Pruritus		On skin of hands and face	
	Rash		On skin of hands and face	

## **Medicine Details:**

FLUPHENAZINE DECANOATE (Other of	drug)	Reason:		
	25.0 Milligram	Weekly		
Batch:	Started: 25/10/1995		Stopped:	
FLUNITRAZEPAM (Other drug)		Reason:		
Tablet	4.0 Milligram	Daily		Oral
Batch:	<b>Started:</b> 14/11/1995		Stopped:	
LITHIUM CARBONATE (Other drug)		Reason:		
	750.0 Milligram	Daily		
Batch:	Started: 21/11/1995		Stopped:	
CHLORPROMAZINE HYDROCHLORID	E (Suspected)	Reason:		
	1.2 Gram	Daily		
Batch:	Started: 03/11/1995		Stopped:	05/12/1995

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 105644
 Seq: 1
 Gender: M

 Reported:
 02/01/1996
 Weight:

Hospitalisation: Admitted to hospital Age: 49Y
Onset Date: 14/11/1995
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			
Consciousness fluctuating			
Convulsion			
Hypocalcaemia			
Hyponatraemia			
Leukocytosis			
Neuroleptic malignant syndrome			Phenytoin; clonazepam, iv fluids.
Pyrexia			

#### **Medicine Details:**

Medicine Details.					
LARGACTIL (Suspected)			Reason:		
Oral application	30.0	Milligram	Daily		Oral
Batch:	Started: 01/0	07/1995		Stopped:	15/11/1995
STELAZINE (Suspected)			Reason:		
Oral application	15.0	Milligram	Daily		Oral
Batch:	Started:	L.	TERM	Stopped:	15/11/1995

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Calcium	2.13 - 2.63	14/11/1995	2.09	
	Calcium	2.13 - 2.63	15/11/1995	2.14	
	Creatine	0 - 250 U/L	14/11/1995	2878	
	Creatine	0 - 250 U/L	21/11/1995	2169	
	Creatine	0 - 250 U/L	18/11/1995	29600	
	Creatine	0 - 250 U/L	15/11/1995	61400	

#### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 105644
 Seq: 1
 Gender: M

 Reported:
 02/01/1996
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 14/11/1995
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

#### **Medicine Details:**

Medicine Details.				
LARGACTIL (Suspected)		Reason:		
Oral application	30.0 Mil	ligram Dail	у	Oral
Batch:	Started: 01/07/1	1995	Stopped:	15/11/1995
STELAZINE (Suspected)		Reason:		
Oral application	15.0 Mil	ligram Dail	у	Oral
Batch:	Started:	L TERM	Stopped:	15/11/1995

**Laboratory Investigations:** 

	. <u> </u>				
Date	Туре	Range	Date Tested	Result	Details
	Electroencephalog				Eeg - background q 6-7 h3, epileptiform dic l temporal and central
	Neutrophils	2.00 - 7.50	14/11/1995	14.46	
	Neutrophils	2.00 - 7.50	17/11/1995	6.55	
	Sodium	136 - 145	14/11/1995	118	
	Sodium	136 - 145	15/11/1995	134	
	White blood cells	4.0 - 11.0	14/11/1995	18.3	

#### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 105644
 Seq: 1
 Gender: M

 Reported:
 02/01/1996
 Weight:

Hospitalisation: Admitted to hospital

Age: 49Y

Onset Date: 14/11/1995 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

## **Medicine Details:**

Medicine Details.					
LARGACTIL (Suspected)			Reason:		
Oral application	30.0	Milligram	Daily		Oral
Batch:	Started: 01/0	07/1995		Stopped:	15/11/1995
STELAZINE (Suspected)			Reason:		
Oral application	15.0	Milligram	Daily		Oral
Batch:	Started:	L.	TERM	Stopped:	15/11/1995

**Laboratory Investigations:** 

Date	е	Туре	Range	Date Tested	Result	Details
	٧	White blood cells	4.0 - 11.0	17/11/1995	8.8	

#### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report D	Details:
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Case Number:105824Seq: 1Gender: MReported:03/01/1996Weight: 78.00Hospitalisation:Admitted to hospitalAge: 17

**Onset Date: DOB:** 16/12/1978

Outcome: Recovered Causality: Causality possible

Reaction Details:

i todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			Diazepam, flunitrazepam, bromocriptine, dantrolene.
Confusional state			
Hyperhidrosis			
Leukocytosis			
Tachycardia			
Urinary incontinence			

#### **Medicine Details:**

Medicine Details.					
LITHIUM CARBONATE (Other	drug)		Reason:		
	0.0				
Batch:	Started:			Stopped:	
CHLORPROMAZINE HYDROC	HLORIDE (Suspected)		Reason:		
	1.0	Gram	Daily		
Batch:	Started:			Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Creatine				Ck level (peak value, 2364 units/liter).

#### **Additional Information:**

Journal of clinical psychopharmacology vol 15 no 5. clozapine- induced neuroleptic malignant syndrome: review and report of new cases.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details:	Re	po	rt	De	tai	ls:
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Case Number: 105852 Seq: 1 Gender: U

Reported: 15/01/1996 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Unspecified schizophrenia

Tablet 0.0 Oral

Batch: Started: Stopped:

# **Laboratory Investigations:**

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient taking 100mg tablets

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details:	R	er	0	rt	De	tai	ls:
-----------------	---	----	---	----	----	-----	-----

Case Number: 105853 Seq: 1 Gender: U

Reported: 15/01/1996 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Unspecified schizophrenia

Tablet 0.0 Oral

Batch: Started: Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient taking 25mg tablets

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Case Number: 105901

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

Reported: 18/01/1996				We	eight:				
lospitalisation:			<b>Age</b> : 32Y						
Onset Date: 09/12/1994					DOB:				
Outcome: Recovered				Caus	sality: Causality possible				
eaction Details:									
Preferred Term	Se	verity	Repo	ort Description	Treatment				
Dry mouth									
Dyspnoea									
Palpitations									
Medicine Details:  CHLORPROMAZINE HYDROCHI	ORIDE (Suspe	ected)	Rea	son:					
ONEON ROMALINE IT BROOM	OTTIBL (Guspe	0.0	i (Cu						
Batch:	St	arted:		Stopped:					
Laboratory Investigation	one:								
Date Type	Range	Date Tested	Result		Details				
- 5.5	30		. toodit						
Additional Information	:								
eport Run: 01/06/2007 04:15PM	Database: pu	sime02	Α	DRS004	Page 216 of 495				



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

20.0 Milliged:	Re gram Re	ason:	Wei <i>J</i>	Age: 38Y DOB: ality: Causality possible  Treatment  Prednisolone, periactin, calamine lotion.
20.0 Millig ed: 400.0 Millig	Re gram Re	ason:	Causa scription	Age: 38Y DOB: ality: Causality possible  Treatment  Prednisolone, periactin, calamine lotion.
20.0 Millig ed: 400.0 Millig	Re gram Re	ason:	Causa scription  Specific disorders of	Treatment Prednisolone, periactin, calamine lotion.
20.0 Millig ed: 400.0 Millig	Re gram Re	ason:	Specific disorders of	Treatment Prednisolone, periactin, calamine lotion.
20.0 Millig ed: 400.0 Millig	Re gram Re	ason:	scription Specific disorders of	Treatment Prednisolone, periactin, calamine lotion.
20.0 Millig ed: 400.0 Millig	Re gram Re	ason:	Specific disorders of	Prednisolone, periactin, calamine lotion.
20.0 Millig ed: 400.0 Millig	Re gram Re	ason:	Specific disorders of	Prednisolone, periactin, calamine lotion.
ed: 400.0 Millig	gram Re			calamine lotion.
ed: 400.0 Millig	gram Re			
ed: 400.0 Millig	gram Re			f sleep
ed: 400.0 Millig	gram Re			fsleep
ed: 400.0 Millig	gram Re			fsleep
ed: 400.0 Millig	gram Re			
ed: 400.0 Millig	Re		,	
_			Stopped:	CONTIN
_		ason:	Other&unspecified e	pilepsy
	gram	Daily		
ed:			Stopped:	CONTIN
	Re	ason:	Essential benign hyp	pertension
2.0 Millig	gram	Daily		
ed:			Stopped:	CONTIN
_	gram	Daily		
ed:			Stopped:	CONTIN
ite Tested	Result			Details
1	160.0 Millig d:	Rea 160.0 Milligram d:	Reason: 160.0 Milligram Daily d:	Reason:  160.0 Milligram Daily  d: Stopped:

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	106132	Seq: 1		Gender: F
-	30/01/1996			Weight:
ospitalisation:				<b>Age:</b> 38Y
Onset Date:	25/01/1996			DOB:
Outcome:	Not yet recovered	d	С	ausality: Causality possible
eaction Detai	ls:			
Medicine Det	ails:			
FLUPHENAZINE D	ECANOATE (Suspec	ted)	Reason:	
Injection		25.0 Milligram	Fortnightly	Intramuscular
Batch:		Started: 19/01/1996	Stopped:	
CHLORPROMAZIN	IE HYDROCHLORIDE	(Suspected)	Reason: Anxiety neuros	sis
		20.0 Milligram	Daily	
Batch:		Started: 20/01/1996	Stopped:	28/01/1996
Laboratory In	vestigations:			
Additional Inf	formation:			
Additional Inf	formation:			
Additional Inf	formation:			
Additional Int	formation:			
Additional Inf	formation:			
Additional Inf	formation:			

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

 Case Number:
 106175
 Seq: 1
 Gender:
 F

 Reported:
 31/01/1996
 Weight:
 70.00

Hospitalisation: Age: 38Y
Onset Date: 25/01/1996
DOB:

Outcome: Not yet recovered Causality: Causality possible

#### **Reaction Details:**

•	toaction Botaile.			
	Preferred Term	Severity	Report Description	Treatment
	Pruritus			
	Rash erythematous			

## **Medicine Details:**

FLUPHENAZINE DECANOATE (Other drug)		Reason: Anxiety neurosis	
Injection	25.0 Milligram	Fortnightly Intramuscular	
Batch:	<b>Started:</b> 19/01/1996	Stopped:	
TERIL (Other drug)		Reason: Other&unspecified epilepsy	
Tablet	400.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
TEMAZEPAM (Other drug)		Reason: Specific disorders of sleep	
Oral application	20.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
COVERSYL (Other drug)		Reason: Essential benign hypertension	
Tablet	2.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Onset Date: 25/01/1996 Outcome: Not yet recovered eaction Details:    Medicine Details:	Case Number:	106175	Seq: 1				Gender:		
Onset Date: 25/01/1996 Outcome: Not yet recovered causality: Causality possible caction Details:    Medicine Details:		31/01/1996					_		
Outcome: Not yet recovered leaction Details:  Medicine Details:  VERACAPS SR (Other drug) Capsule 160.0 Milligram Daily Oral Batch: Started: Started: Stopped: Stopped: LARGACTIL (Suspected) Batch: Started: 20/01/1996 Stopped: 28/01/1996  LARGACTIL (Suspected) Started: 20/01/1996 Stopped: Land Land Land Land Land Land Land Land	lospitalisation:								
Medicine Details:  VERACAPS SR (Other drug) Capsule 160.0 Milligram Daily Oral Batch: Started: Stopped:  LARGACTIL (Suspected) Batch: Started: 20/01/1996 Stopped: 28/01/1996  Laboratory Investigations:	Onset Date:	25/01/1996							
Medicine Details:  VERACAPS SR (Other drug) Capsule 160.0 Milligram Daily Oral Batch: Started: Stopped:  LARGACTIL (Suspected) Batch: Started: 20/01/1996 Stopped: 28/01/1996  Laboratory Investigations:			ı			С	ausality:	Causality poss	ible
VERACAPS SR (Other drug) Capsule 160.0 Milligram Daily Oral Batch: Started: Stopped:  LARGACTIL (Suspected) Batch: Started: 20/01/1996 Stopped: 28/01/1996  Laboratory Investigations:	eaction Detail	s:							
VERACAPS SR (Other drug) Capsule 160.0 Milligram Daily Oral Batch: Started: Stopped:  LARGACTIL (Suspected) Batch: Started: 20/01/1996 Stopped: 28/01/1996  Laboratory Investigations:									
VERACAPS SR (Other drug) Capsule Batch: Started:  Cansule Batch: Started:  Cansule Batch:  Started:  Cansule Batch:  Started:  Cansule Batch:  Started:  Cansule Batch:  Started:  Cansule Batch:  Started:  Cansule Batch:  Started:  Cansule Batch:  Cansule Batch:  Cansule Batch:  Cansule Batch:  Cansule Batch:  Cansule Batch:  Started:  Cansule Batch:									
VERACAPS SR (Other drug) Capsule 160.0 Milligram Daily Oral Batch: Started: Stopped:  LARGACTIL (Suspected) Batch: Started: 20/01/1996 Stopped: 28/01/1996  Laboratory Investigations:									
VERACAPS SR (Other drug) Capsule 160.0 Milligram Daily Oral Batch: Started: Stopped:  LARGACTIL (Suspected) Batch: Started: 20/01/1996 Stopped: 28/01/1996  Laboratory Investigations:									
VERACAPS SR (Other drug) Capsule Batch: Started: Canage									
VERACAPS SR (Other drug) Capsule Batch: Started: Canage									
VERACAPS SR (Other drug) Capsule Batch: Started: Canage									
VERACAPS SR (Other drug) Capsule Batch: Started: Canage									
VERACAPS SR (Other drug) Capsule Batch: Started: Canage									
Capsule 160.0 Milligram Daily Oral  Batch: Started: Stopped:   Reason: 600.0 Milligram Daily  Batch: Started: 20/01/1996 Stopped: 28/01/1996  Laboratory Investigations:									
VERACAPS SR (Other drug) Capsule Batch: Started:  Cansule Batch: Started:  Cansule Batch:  Started:  Cansule Batch:  Started:  Cansule Batch:  Started:  Cansule Batch:  Started:  Cansule Batch:  Started:  Cansule Batch:  Started:  Cansule Batch:  Cansule Batch:  Cansule Batch:  Cansule Batch:  Cansule Batch:  Cansule Batch:  Started:  Cansule Batch:									
VERACAPS SR (Other drug) Capsule Batch: Started:  Cansule Batch: Started:  Cansule Batch:  Started:  Cansule Batch:  Started:  Cansule Batch:  Started:  Cansule Batch:  Started:  Cansule Batch:  Started:  Cansule Batch:  Started:  Cansule Batch:  Cansule Batch:  Cansule Batch:  Cansule Batch:  Cansule Batch:  Cansule Batch:  Started:  Cansule Batch:									
Capsule Batch: Started: Stopped:    Reason:	<b>Medicine Deta</b>	ils:							
Batch: Started: Stopped:  LARGACTIL (Suspected)  Reason: 600.0 Milligram Daily Batch: Started: 20/01/1996 Stopped: 28/01/1996  Laboratory Investigations:	VERACAPS SR (Ot	her drug)			Reason:	Essential beni	gn hyperten	sion	
LARGACTIL (Suspected)  600.0 Milligram Daily  Batch: Started: 20/01/1996 Stopped: 28/01/1996  Laboratory Investigations:	Capsule		160.0	Milligram	Daily		Oral		
Batch: Started: 20/01/1996 Stopped: 28/01/1996  Laboratory Investigations:	Batch:		Started:			Stopped:			
Batch: Started: 20/01/1996 Stopped: 28/01/1996  Laboratory Investigations:	LARGACTIL (Suspe	ected)			Reason:				
Laboratory Investigations:			600.0	Milligram	Daily				
	Batch:		Started: 20/	/01/1996		Stopped:	28/01/1996	5	
Laboratory Investigations:  Additional Information:									
	Laboratory Inv	vestigations:							
Additional Information:									
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Additional information.	Additional Info	ormation:							
	Additional lill	omation.							

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 106241
 Seq: 1
 Gender:
 F

 Reported:
 02/02/1996
 Weight:

Hospitalisation:Admitted to hospitalAge: 64YOnset Date:02/03/1995DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			
Hepatitis cholestatic			Sphinectastomy
Nausea			

#### **Medicine Details:**

CARDIPRIN 100 (Other drug)	Reason:				
Tablet	1.0	Dose Unspecified	Daily		Oral
Batch:	Started:	L TERM		Stopped:	
PROVERA (Other drug)	Reason:				
Tablet	5.0	Milligram	Daily		Oral
Batch:	Started:	L TERM		Stopped:	
ESTIGYN (Other drug)		Rea	son:		
Tablet	20.0	Microgram	Daily		Oral
Batch:	Started:	L TERM		Stopped:	
LARGACTIL (Suspected)	Reason:				
Tablet	25.0	Milligram	Daily		Oral
Batch:	<b>Started:</b> 25/01/1995			Stopped:	02/03/1995

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	4-35U/L	26/03/1995	49	
	ALT = SGPT	4-35U/L	17/11/1995	37	
	Bilirubin	5-20 UMOL/L	26/03/1995	315	
	Bilirubin	5-20 UMOL/L	17/11/1995	10	
	Computerised				Ct abdo: pelvis - slightly dilated ducts

#### **Additional Information:**

Patient's alcohol intake seldom, sequelae: continued mild liver disfunction the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 106241
 Seq: 1
 Gender:
 F

 Reported:
 02/02/1996
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 02/03/1995
Age: 64Y
DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

#### **Medicine Details:**

Medicine Details.					
RENITEC (Suspected)			Reason:		
Tablet	5.0	Milligram	Daily		Oral
Batch:	Started:	LT	ERM	Stopped:	28/03/1994
ASCORBIC ACID (Suspected)			Reason:		
Oral application	500.0	Milligram	Daily		Oral
Batch:	Started:	LT	ERM	Stopped:	

**Laboratory Investigations:** 

	Date	Туре	Range	Date Tested	Result	Details
		Liver biopsy				21/11/95 - liver biopsy showing mild parenchymal changes with scattered bile plugging consistent with reaction to drugs intake.
		SAP = ALP	18-116 U/L	26/03/1995	509	
Į		SAP = ALP	18-116 U/L	17/11/1995	206	

#### **Additional Information:**

Patient's alcohol intake seldom, sequelae: continued mild liver disfunction the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

	106319	Seq:	1		Gender: F			
Reported:	07/02/1996	;			Weig	ht:		
ospitalisation:					Α	ge:		
Onset Date:					D	OB:		
Outcome:	Not yet rec	overed			Causal	ity: Causality possible		
action Deta			1					
	ed Term	Sev	erity	Repoi	t Description	Treatment		
epatic function	abnormal							
ledicine Det AROPAX (Suspec				Reas	on:			
			0.0					
Batch:			rted:		Stopped:			
THE OPPOSITE THE			4 10					
CHLUKPKUMAZII	NE HYDROCHL	ORIDE (Suspe		Reas	on:			
Batch:	NE HYDROCHI		0.0 urted:	Reas	on: Stopped: 05/09	1995		
	NE HYDROCHI		0.0	Reas		1995		
Batch:		Sta	0.0	Reas		1995		
		Sta	0.0	Reas	<b>Stopped:</b> 05/09	71995 Details		

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 106395
 Seq: 1
 Gender:
 F

 Reported:
 12/02/1996
 Weight:
 60.00

Hospitalisation: Admitted to hospital Age: 27
Onset Date: 09/11/1995
DOB: 27/10/1968

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Anorexia			
Nausea			
Pyrexia			
Red blood cell sedimentation rate i			
Vomiting			

#### **Medicine Details:**

CLOZARIL (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral	
Batch:	Started: 25/10/1995		Stopped:	CONTIN
SODIUM VALPROATE (Suspected)		Reason:		
	2.0 Gram	Daily		
Batch:	Started:		Stopped:	
CLONAZEPAM (Suspected)		Reason:	Otr spec symp psychopathol	nec
	1.0 Milligram	Daily		
Batch:	Started:		Stopped:	
CHLORPROMAZINE HYDROCHLORIDE	(Suspected)	Reason:	Unspecified psychosis	
	400.0 Milligram	Daily		
Batch:	Started: 20/10/1995		Stopped: 05/11/1995	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Erythrocyte	<21	29/11/1995	61	
	Erythrocyte	<21	06/12/1995	43	
	Erythrocyte	<21	03/01/1996	18	

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 106617 Seq: 1 Gender: F

Reported: 23/02/1996 Weight: 55.00 Hospitalisation: Age: 25Y

Onset Date: 13/02/1996 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

•	todotion Dotails.			
	Preferred Term	Severity	Report Description	Treatment
	Encephalopathy			
	Psychotic disorder			

#### Medicine Details:

BENZTROPINE MESYLATE (Suspected)				
	2.0 Milligram	Daily		
Batch:	Started: 13/02/1996		Stopped:	
AROPAX (Suspected)		Reason:	Depression	
	40.0 Milligram	Daily		
Batch:	Started: 01/09/1995		Stopped:	
CHLORPROMAZINE HYDROCHLORIDE (S	Suspected)	Reason:	Unspecified psychosis	
	400.0 Milligram	Daily		
Batch:	Started: 01/12/1995		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Brain syndrome developed within hours of taking benztropin the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 106997
 Seq: 1
 Gender: M

 Reported:
 11/03/1996
 Weight:
 90.00

 Hospitalisation:
 Age: 22Y

Onset Date: 31/03/1996 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

toaction Botano.			
Preferred Term	Severity	Report Description	Treatment
Acne			
Rash pustular			

#### **Medicine Details:**

BENZTROPINE MESYLATE (Other drug)		Reason:	
	0.0	As necessary	
Batch:	Started: 22/02/1996	Stopped:	
MIDAZOLAM (Other drug)		Reason:	
	0.0	As necessary	
Batch:	Started: 12/02/1996	Stopped:	
DROPERIDOL (Other drug)		Reason:	
	0.0	As necessary	
Batch:	Started: 12/02/1996	Stopped:	
FLUPENTHIXOL DECANOATE (Other drug	)	Reason: Unspecified psychosis	
	60.0 Milligram	Fortnightly	
Batch:	Started:	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Re	ро	rt	De	tai	s:
----	----	----	----	-----	----

 Case Number:
 106997
 Seq: 1
 Gender: M

 Reported:
 11/03/1996
 Weight:
 90.00

 Hospitalisation:
 Age: 22Y

**Onset Date**: 31/03/1996 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

## **Medicine Details:**

RANITIDINE (Other drug)				
	300.0 Milligram	Daily		
Batch:	Started: 29/02/1996		Stopped:	
LACTULOSE (Other drug)		Reason:	Constipation	
	20.0 Millilitre	Daily		
Batch:	<b>Started:</b> 10/02/1996		Stopped:	
CHLORPROMAZINE HYDROCHLO	RIDE (Suspected)	Reason:	Unspecified psychosis	
Oral application	650.0 Milligram	Daily	Oral	
Batch:	Started: 07/02/1996		<b>Stopped:</b> 06/03/1996	

# **Laboratory Investigations:**

#### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 107836
 Seq: 1
 Gender:
 F

 Reported:
 12/04/1996
 Weight:

Hospitalisation: Age: 49Y
Onset Date: 31/12/1995
DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Dizziness			

#### Medicine Details:

MEGICINE DELANS.				
LARGACTIL (Suspected)		Reason:	Unspecifid affective psych	osis
Oral application	50.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/1976		Stopped:	CONTIN
LITHICARB (Suspected)		Reason:	Unspecifid affective psych	osis
Tablet	750.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/1976		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. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number:107892Seq: 1Gender:FReported:15/04/1996Weight:65.00Hospitalisation:Admitted to hospitalAge: 81

**Onset Date**: 20/01/1996 **DOB**: 10/04/1914

Outcome: Recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Confusional state			
Dizziness			
Hypokalaemia			
Hyponatraemia			
Inappropriate antidiuretic hormone			lv kcl and fluid restriction
Somnolence			

#### **Medicine Details:**

BENZTROPINE MESYLATE (Other drug)			Reason:	Other atyp for	ms schizophrenia
Tablet	1.0	Milligram	Daily		Oral
Batch:	Started:	l	_ TERM	Stopped:	
ENALAPRIL MALEATE (Other drug)			Reason:	Essential beni	gn hypertension
Oral application	20.0	Milligram	Daily		Oral
Batch:	Started:	l	_ TERM	Stopped:	
CHLORPROMAZINE HYDROCHLORIDE (Su	spected)		Reason:	Other atyp for	ms schizophrenia
Oral application	30.0	Milligram	Daily		Oral
Batch:	Started:	l	_ TERM	Stopped:	22/01/1996
NATRILIX (Suspected)			Reason:	Essential beni	gn hypertension
Tablet	1.0	Dose Unsp	ecified Daily		Oral
Batch:	Started:	l	TERM	Stopped:	22/01/1996

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Potassium	3.5-5.0	23/01/1996	2.8	
	Potassium	3.5-5.0	29/01/1996	4.0	
	Serum osmolality	275 - 295	23/01/1996	226	
	Serum osmolality	275 - 295	29/01/1996	-	
	Sodium	135-145	23/01/1996	105	
	Sodium	135-145	29/01/1996	128	

#### **Additional Information:**

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Report Details:

Case Number: 107911

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

Reported: 15/04/19	96			Weig	ht:		
lospitalisation:			Age: 23Y				
Onset Date:				DC	OB:		
Outcome: Recovere	ed			Causali	ity: Causality probable		
eaction Details:							
Preferred Term	Se	everity	Repo	rt Description	Treatment		
Pharyngitis							
Medicine Details:							
CHLORPROMAZINE HYDROC	HLORIDE (Susp	ected)	Reas	son:			
		300.0 Milli	gram	Daily			
Batch:	s	tarted: 07/11/1	995	Stopped: 15/11/	1995		
Laboratory Investiga	tione:						
Date Type	Range	Date Tested	Result	D	etails		
7,1	- 3						
Additional Informatio	on:						
port Run: 01/06/2007 04:15P	M Database։ pւ	usime02	А	DRS004	Page 230 of 495		



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

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

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

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

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

#### **Medicine Details:**

Medicine Details.				
CHLORPROMAZINE HYDROCHLOR	IDE (Suspected)	Reason:		
	300.0 Milligram	Daily		
Batch:	<b>Started:</b> 07/11/1995		<b>Stopped:</b> 15/11/1995	
RISPERIDONE (Suspected)		Reason:		
	4.0 Milligram	Daily		
Batch:	Started:		Stopped:	

**Laboratory Investigations:** 

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

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Do							
	etails:						
Case Num	ber: 107912	Seq:	1			Gender:	M
Repo	rted: 15/04/199	6				Weight:	
lospitalisat	ion:					Age:	
Onset D	Date: 16/11/199	5				DOB:	
Outco	me: Not yet re	covered				Causality:	Causality possible
eaction <b>D</b>	etails:						
Medicine	Dotaile:						
	MAZINE HYDROCH	HLORIDE (Suspe	cted)	Reas	on:		
			300.0 Milli		Daily		
Bate	ch:	Sta	arted: 07/11/19		-	d: 15/11/1995	5
RISPERIDO	NE (Suspected)			Reas			
			4.0 Milli	gram	Daily		
Bate	ch:	Sta	arted:		Stoppe	d:	
aborato	ry Investigat	ione					
	ry Investigat		Date Tested	Result		Detai	s
L <b>aborato</b> Date	Туре	<b>ions:</b> Range	Date Tested 20/11/1995	Result 0.55		Detai	Is
						Detai	İs
	Type Eosinophils Erythrocyte		20/11/1995	0.55		Detai	ls
	Type Eosinophils		20/11/1995 18/11/1995	0.55 29		Detai	Is
	Type Eosinophils Erythrocyte		20/11/1995 18/11/1995 17/11/1995	0.55 29 341		Detai	is
	Type Eosinophils Erythrocyte		20/11/1995 18/11/1995 17/11/1995	0.55 29 341		Detai	ls
	Type Eosinophils Erythrocyte		20/11/1995 18/11/1995 17/11/1995	0.55 29 341		Detai	İs
Date	Type Eosinophils Erythrocyte	Range	20/11/1995 18/11/1995 17/11/1995	0.55 29 341		Detai	ls
Date	Type Eosinophils Erythrocyte GGT = SGGT = GGT = SGGT =	Range	20/11/1995 18/11/1995 17/11/1995	0.55 29 341		Detai	is
Date	Type Eosinophils Erythrocyte GGT = SGGT = GGT = SGGT =	Range	20/11/1995 18/11/1995 17/11/1995	0.55 29 341		Detai	is
Date	Type Eosinophils Erythrocyte GGT = SGGT = GGT = SGGT =	Range	20/11/1995 18/11/1995 17/11/1995	0.55 29 341		Detai	ls

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 107915 Seq: 1 Gender: M
Reported: 15/04/1996 Weight:
Hospitalisation: Age: 18Y

Onset Date: 16/11/1995 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Prefereu Terrii	Seventy	Report Description	Пеаннени
Blood creatine phosphokinase incr			
Eosinophilia			
Hepatic function abnormal			
Orthostatic hypotension			
Pyrexia			
Rash			
Tachycardia			

## **Medicine Details:**

<u>Medicine Details:</u>				
FLUPHENAZINE DECANOATE	(Suspected)	Reason:		
	0.0			
Batch:	Started:		Stopped:	
CHLORPROMAZINE HYDROCI	HLORIDE (Suspected)	Reason:		
	200.0 Milligram	Daily		
Batch:	Started: 06/11/1995		Stopped:	

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		17/11/1995	315	
	ALT = SGPT		18/11/1995	178	
	AST = SGOT		17/11/1995	135	
	AST = SGOT		18/11/1995	38	
	Creatine		17/11/1995	122	
	Eosinophils		22/11/1995	0.77	
	GGT = SGGT =		17/11/1995	156	

### **Additional Information:**

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Report Details:

Report Run: 01/06/2007 04:15PM Database: pusime02

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Num	<b>ber:</b> 1079	915	Seq:	1			Gender:	M
Repo	rted: 15/0	4/1996					Weight:	
Hospitalisat							Age:	18Y
Onset D	<b>Date:</b> 16/1	1/1995					DOB:	
Outco	me: Unk	nown					Causality:	Causality possible
Reaction <b>D</b>	Details:							
Madialas	Dataila							
Medicine		IOATE (Suspec	etod)		D,	eason:		
FLOFFIENAZ	LINE DECAN	IOATE (Suspec	ieuj	0.0	N	ason.		
Bate	ch·		9	tarted:			Stopped:	
		DROCHLORIDE			R	eason:	оторрец.	
		J. (00112014121	- (Guop	200.0 Milli		Daily		
Bate	ch·		S	tarted: 06/11/1		Daily	Stopped:	
	-			tartour oor in it			otoppou.	
		tigations:		D-4. T	l 5 "	1	<b>-</b>	
Date	Type GGT = SGG		ige	Date Tested	Result		Detai	S
	GG1 = SGG	01 =		18/11/1995	127			
Additiona	al Inform	nation:						
Additiona	al Inform	nation:						
Additiona	al Inform	nation:						
Additiona	al Inform	nation:						
Additiona	al Inform	nation:						

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Report Details:

**Hospitalisation:** 

**Onset Date:** 

Case Number: 108494

Reported: 15/05/1996

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

**Age:** 30

**DOB:** 25/09/1965

Weight:

action Details: Preferred Term					sality: Causality possible
	Sev	verity	Report D	escription	Treatment
emor		Pa	rkinsonian		
orticollis		Sp	asmodic torticollis		
eadache					Rest, panadol prn, soft collar, stat dose valium 5mg, stat dose indocid 100mg; bentropine (2 doses of 2mg given 12 hours apart) along with diazepam.
yperkinesia ain					
ledicine Details: CHLORPROMAZINE HYDROC	HLORIDE (Suspe	cted) 200.0 Mill	Reason:	necessary	chopathol nec
Batch:	Sta	arted:		Stopped:	3D
AROPAX (Suspected)			Reason:		
		60.0 Mill	igram Dai	-	
Batch:	316	arted:		Stopped:	12M
aboratory Investigat		Date Tested	Result		Details
aboratory Investigat  Date Type		Date Tested	Result		Details
	Range	Date Tested	Result		Details



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 108956 Seq: 1 Gender: F

Reported: 04/06/1996 Weight:
Hospitalisation: Age: 45Y

**Onset Date**: 27/02/1996 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

	Preferred Term	Severity	Report Description	Treatment
F	Rash maculo-papular		Rash on face chest and abdomen.	Promethazine.

## **Medicine Details:**

RIVOTRIL (Other drug)		Reason: Otr spec symp psy	chopathol nec
Oral application	4.0 Milligram	Daily Ora	al
Batch:	Started: 01/12/1995	Stopped:	CONTIN
NITOMAN (Other drug)		Reason:	
Tablet	50.0 Milligram	Daily Ora	al
Batch:	Started:	Stopped:	CONTIN
COGENTIN (Other drug)		Reason:	
Oral application	1.0 Milligram	Daily Ora	al
Batch:	Started:	Stopped:	CONTIN
PRAMIN (Other drug)		Reason: Other diseases of	esophagus
Tablet	30.0 Milligram	Daily Ora	al
Batch:	Started: 14/12/1995	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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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Rei	port	Detai	ls:
-----	------	-------	-----

 Case Number:
 108956
 Seq: 1
 Gender:
 F

 Reported:
 04/06/1996
 Weight:

Hospitalisation: Age: 45Y
Onset Date: 27/02/1996
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

## **Medicine Details:**

Micalcinic Details.					
ACTILAX (Other drug)		Reason:	Constipation		
Oral Liquid	20.0 Millilitre	Daily		Oral	
Batch:	Started:		Stopped:		CONTIN
LARGACTIL (Suspected)		Reason:	Otr spec symp	psychopathol ne	ec
Oral application	200.0 Milligram	Daily		Oral	
Batch:	Started: 22/02/1996		Stopped:	29/02/1996	

## **Laboratory Investigations:**

#### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details:	
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 Case Number:
 108975
 Seq: 1
 Gender: M

 Reported:
 04/06/1996
 Weight:

Hospitalisation: Age: 49Y
Onset Date: 25/05/1996 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Cold sweat			
Dizziness			
Hypotension			Haemaccel iv.
Pallor			
Somnolence			

#### **Medicine Details:**

Medicine Details.				
ADALAT OROS (Other drug)		Reason: Essentia	al benign hypertension	
Tablet	60.0 Milligram	Daily	Oral	
Batch:	Started: 23/05/1996	Stop	oped:	
PRINIVIL (Other drug)		Reason: Essentia	al benign hypertension	
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started: 23/05/1996	Stop	oped:	
LARGACTIL (Suspected)		Reason: Hiccoug	jh	
Injection	25.0 Milligram	1 time	Intravenous	
Batch:	Started: 25/05/1996	Stor	oped: 25/05/1996	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 109363 Seq: 1 Gender: F

Reported: 19/06/1996 Weight:
Hospitalisation: Age: 93Y

**Onset Date**: 01/02/1996 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity Report Description		Treatment
Jaundice			

## **Medicine Details:**

LASIX (Other drug)		Rea	son:	Congestive heart failure	
Oral application	80.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	
LANOXIN PG (Other drug)		Rea	son:	Congestive heart failure	
Tablet	2.0	Dose Unspecified	Daily	Oral	
Batch:	Started:			Stopped:	
ASPIRIN (Other drug)		Rea	son:	Chron isch heart dis no hyper	
	0.5	Dose Unspecified	Daily		
Batch:	Started:			Stopped:	
MONOTARD HM (Other drug)		Rea	son:	Diabetes mellitus	
Injection	44.0	Linit	Daily	Subcutaneous	
Injection	44.0	Offic	Daily	Subcularieous	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	(5-30)	05/02/1996	560	
	ALT = SGPT	(5-30)	12/02/1996	84	
	AST = SGOT	(10-30)	05/02/1996	234	
	AST = SGOT	(10-30)	12/02/1996	18	
	Bilirubin	(<20)	05/02/1996	75	
	Bilirubin	(<20)	12/02/1996	15	
	GGT = SGGT =	(< 30)	05/02/1996	252	

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Rep	ort	Deta	ils:
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 Case Number:
 109363
 Seq: 1
 Gender:
 F

 Reported:
 19/06/1996
 Weight:

Hospitalisation:
Onset Date: 01/02/1996
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

## **Medicine Details:**

EUHYPNOS (Other drug)		Reason: Specific disorders of sleep	
Capsule	10.0 Milligram	Daily Oral	
Batch:	Started: 29/12/1995	Stopped:	
LARGACTIL (Suspected)		Reason: Unspecified psychosis	
Tablet	25.0 Milligram	As necessary Oral	
Batch:	Started: 01/02/1996	<b>Stopped</b> : 05/02/1996	
MELLERIL (Suspected)		Reason: Unspecified psychosis	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 23/01/1996	<b>Stopped</b> : 01/02/1996	

**Laboratory Investigations:** 

	Date	Type	Range	Date Tested	Result	Details
ĺ		GGT = SGGT =	(< 30)	12/02/1996	149	
		SAP = ALP	(30-90)	05/02/1996	348	
		SAP = ALP	(30-90)	12/02/1996	255	

### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 110066
 Seq: 1
 Gender: M

 Reported:
 19/07/1996
 Weight:
 90.00

 Hospitalisation:
 Age: 26Y

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

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

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

#### **Medicine Details:**

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

**Laboratory Investigations:** 

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

#### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details:					
Case Number: 110089	Seq: 1			Gei	nder: F
Reported: 19/07/1996					ight:
Hospitalisation:					<b>Age</b> : 80Y
Onset Date:				I	DOB:
Outcome: Not yet recove	ered			Caus	ality: Causality possible
Reaction Details:					
Preferred Term	Severity	Rep	ort De	scription	Treatment
Pruritus					
Rash					Kenalone, celestone, calamine lotion
Medicine Details:  TRYPTANOL (Other drug)			ason:	Anxiety neurosis	
Tablet	25.0	Milligram	Daily	Oral	
Batch:	Started:	L TERN	l	Stopped:	
LARGACTIL (Suspected)		Re	ason:	Anxiety neurosis	
Oral application	50.0	Milligram	Daily	Oral	
Batch:	Started:	L TERM	l	Stopped:	
Laboratory Investigation  Date Type	I <b>S:</b> Range Date Tes	sted Result			Details
	•		•		•

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 110304 Seq: 1 Gender: F

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

Onset Date: 10/07/1996 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	caction betails:								
	Preferred Term	Severity	Report Description	Treatment					
	Dystonia								
	Oculogyration			Cogentin iv stat.					

#### **Medicine Details:**

TEMAZE (Other drug)		Reason:	Specific disorders of sle	ер
	20.0 Milligram	Daily	•	
Batch:	Started: 12/06/1996		Stopped:	CONTIN
LARGACTIL (Suspected)		Reason:	Otr spec symp psychopa	athol nec
	100.0 Milligram	As no	ecessary	
Batch:	Started: 04/07/1996		Stopped:	CONTIN
RISPERDAL (Suspected)		Reason:	Unspecified psychosis	
	2.0 Milligram	Daily	•	
Batch:	Started: 19/06/1996		Stopped:	CONTIN

**Laboratory Investigations:** 

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 110316 Seq: 1 Gender: F

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

Onset Date: 25/06/1996 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Dystonia		Dystonic reaction	
	Oculogyration			

## **Medicine Details:**

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

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

See original report for other drugs

Report Run: 01/06/2007 04:15PM Database: pusime02 ADRS004 Page 244 of 495



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details:					
Case Number: 110316	Seq: 1		Gend	ler: F	
Reported: 29/07/1996	·		Weig	ht:	
Hospitalisation:			A	<b>ge:</b> 49Y	
Onset Date: 25/06/1996			DO	OB:	
Outcome: Recovered			Causal	ity: Causality possible	
Reaction Details:					
Medicine Details:					
RIVOTRIL (Suspected)		Reason:	Otr spec symp psycho	opathol nec	
	500.0 Microgram	As ne	ecessary		
Batch:	Started: 20/06/1996		Stopped: 26/06/		
RISPERDAL (Suspected)	0.0 14:11:	Reason:	Unspecified schizophi	renia	
Tablet	2.0 Milligram	Daily	Oral	CONTIN	
Batch:	<b>Started:</b> 19/06/1996		Stopped:	CONTIN	
Laborator La cattacta					
Laboratory Investigations:					
Additional Information: See original report for other drugs					
See original report for other drugs					

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 111275 Seq: 1 Gender: M

**Reported:** 30/08/1996 **Weight:** 

Hospitalisation: Age: 23Y
Onset Date: 09/10/1995
DOB:

Outcome: Recovered Causality: Causality certain

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Rash		Raised rash over nose and cheeks	

#### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified psychosis

200.0 Milligram Daily

**Batch: Started:** 23/08/1995 **Stopped:** 18/10/1995

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### Additional Information:

Raised rash over nose and cheeks, super-imposed with fungal infection and cold sores. the rash did not resolve until chlorpromazine was ceased. the patient was inadvertently rechallenged with chlorpromazine as a prn medication in june 1996 - the rash re-developed and resolved when chlorpromazine was ceased.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 111474 Seq: 1 Gender: M
Reported: 06/09/1996 Weight:

Hospitalisation: Age: 14

 spitalisation:
 Age: 14

 Onset Date: 26/06/1996
 DOB: 12/09/1981

Outcome: Death, maybe drug Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Hepatic failure			
Jaundice			

## **Medicine Details:**

AMPHOTERICIN (Suspected) Reason:

0.0

Batch: Started: 16/06/1996 Stopped:

G COLONY STIMULATING FACTOR NOS (Suspected) Reason: Agranulocytosis

0.0

Batch: Started: 21/06/1996 Stopped:

PENTAMIDINE ISETHIONATE (Suspected) Reason:

0.0

Batch: Started: Stopped:

CODEINE (Suspected) Reason:

30.0 Milligram As necessary

Batch: Started: 13/06/1996 Stopped:

#### **Laboratory Investigations:**

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT		02/07/1996	59	
	AST = SGOT		03/07/1996	46	
	AST = SGOT		08/07/1996	22	
	Bilirubin	MMOL/L	26/06/1996		Bil subsequently hovered between 400 and 660 mmol/l until the time of death.
	Bilirubin	MMOL/L	01/07/1996		Bil subsequently hovered between 400 and 660 mmol/l until the time of death.

#### **Additional Information:**

Patient history: hodgkin's disease, chemotherapy. patient died 26/7/96.

Report Run: 01/06/2007 04:15PM Database: pusime02 ADRS004 Page 247 of 495



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 111474
 Seq: 1
 Gender: M

 Reported:
 06/09/1996
 Weight:

Hospitalisation: Age: 14

**Onset Date**: 26/06/1996 **DOB**: 12/09/1981

Outcome: Death, maybe drug Causality: Causality possible

**Reaction Details:** 

## **Medicine Details:**

FLUCLOXACILLIN SODIUM (Suspected)		Reason:		
	4.0 Gram	Daily		
Batch:	Started: 13/06/1996		Stopped:	
CEFTAZIDIME (Suspected)		Reason:		
	3.4 Gram	Daily		
Batch:	Started: 09/06/1996		Stopped:	
CHLORPROMAZINE HYDROCHLORIDE (S	uspected)	Reason:		
	50.0 Milligram	Daily		
Batch:	Started: 12/06/1996		Stopped:	21/06/1996
PERIACTIN (Suspected)		Reason:		
	12.0 Milligram	Daily		
Batch:	Started: 13/06/1996		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin	MMOL/L	02/07/1996		Bil subsequently hovered between 400 and 660 mmol/l until the time of death.
	Bilirubin	MMOL/L	03/07/1996		Bil subsequently hovered between 400 and 660 mmol/l until the time of death.
	Bilirubin	MMOL/L	08/07/1996		Bil subsequently hovered between 400 and 660 mmol/l until the time of death.
	GGT = SGGT =		02/07/1996	81	

#### **Additional Information:**

Patient history: hodgkin's disease, chemotherapy. patient died 26/7/96.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 111474
 Seq: 1
 Gender: M

 Reported:
 06/09/1996
 Weight:

Hospitalisation: Age: 14

**Onset Date**: 26/06/1996 **DOB**: 12/09/1981

Outcome: Death, maybe drug Causality: Causality possible

**Reaction Details:** 

**Medicine Details:** 

AMPHOTERICIN (Suspected) Reason:

0.0

Batch: Started: 16/06/1996 Stopped:

G COLONY STIMULATING FACTOR NOS (Suspected) Reason: Agranulocytosis

0.0

Batch: Started: 21/06/1996 Stopped:

PENTAMIDINE ISETHIONATE (Suspected) Reason:

0.0

Batch: Started: Stopped:

CODEINE (Suspected) Reason:

30.0 Milligram As necessary

Batch: Started: 13/06/1996 Stopped:

**Laboratory Investigations:** 

	Date	Туре	Range	Date Tested	Result	Details		
Ī		GGT = SGGT =		03/07/1996	86			
		GGT = SGGT =		08/07/1996	93			
		Liver biopsy				Liver biopsy: microscopic description- the liver shows mild portal fibrosis. liver cells show prominent haemosiderosis and ballooning around the centrilobular veins. marked canalicular cholestasis is seen. inflammatory infiltration is inconspicuous.		

## **Additional Information:**

Patient history: hodgkin's disease, chemotherapy. patient died 26/7/96.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 111474
 Seq: 1
 Gender: M

 Reported:
 06/09/1996
 Weight:

Hospitalisation: Age: 14

**Onset Date**: 26/06/1996 **DOB**: 12/09/1981

Outcome: Death, maybe drug Causality: Causality possible

**Reaction Details:** 

**Medicine Details:** 

FLUCLOXACILLIN SODIUM (Suspected)		Reason:		
	4.0 Gram	Daily		
Batch:	Started: 13/06/1996		Stopped:	
CEFTAZIDIME (Suspected)		Reason:		
	3.4 Gram	Daily		
Batch:	Started: 09/06/1996		Stopped:	
CHLORPROMAZINE HYDROCHLORIDE (S	uspected)	Reason:		
ONEON NOMALINE IN BROOMEDINGE (O	uspecteu)	iveason.		
oneon nomaline management (o	50.0 Milligram	Daily		
Batch:	•		Stopped:	21/06/1996
	50.0 Milligram		Stopped:	21/06/1996
Batch:	50.0 Milligram	Daily	Stopped:	21/06/1996

## **Laboratory Investigations:**

#### **Additional Information:**

Patient history: hodgkin's disease, chemotherapy. patient died 26/7/96.

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number	: 111836	Seq:	1			Gender:	U	
Reported	96			Weight:				
ospitalisation	: Hospitalis	sation prolong	ed		Age: AD			
Onset Date	:					DOB:		
Outcome	covered		Causality: Causality certain			in		
eaction Deta								
	red Term	Se	everity	Repo	ort Description		Treatmen	ıt
Cellulitis								
njection site rea	action							
Medicine De				Rea	son:			
Injection	,		0.0			Intramuscu	ular	
Batch:		s	tarted: 07/09/1	996	Stopped	d:		
_aboratory I	nvestiga	tions:						
Date	Туре	Range	Date Tested	Result		Detai	ils	
Additional Ir	nformatio	n:						
port Run : 01/06/2	007 04·15PI	M Datahase ni	ısime02	Δ	.DRS004		Page 251	of 405

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Gender: F Case Number: 111953 Seq: 1

Reported: 01/10/1996 Weight: 60.00 Hospitalisation: Age: 23Y DOB:

Onset Date: 08/09/1996

Outcome: Unknown Causality: Causality certain

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Injection site inflammation		Cellulitis at injection site	

#### **Medicine Details:**

ESTIGYN (Other drug)	Reason:				
	1.0 Dose Unspecified Daily				
Batch:	Started: 01/07/1996	Stopped:	CONTIN		
MICROLUT (Other drug)	Reason:				
	1.0 Dose Unspecified I	Daily			
Batch:	Started: 01/07/1996	Stopped:	CONTIN		
PROTHIADEN (Other drug)	Reason:				
	75.0 Milligram	Daily			
Batch:	Started: 01/06/1996	Stopped:	CONTIN		
ERGODRYL (Other drug)	Reason:				
	1.0 Dose Unspecified I	Daily			
Batch:	CONTIN				

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details:			
Case Number: 111953	Seq: 1		Gender: F
Reported: 01/10/1996	•		Weight: 60.00
Hospitalisation:			<b>Age</b> : 23Y
Onset Date: 08/09/1996			DOB:
Outcome: Unknown			Causality: Causality certain
Reaction Details:			•
Medicine Details:  LARGACTIL (Suspected)  Injection	0.0	Reason:	Intramuscular
Batch:	0.0 <b>Started:</b> 07/09/1996	Stop	
Laboratory Investigation	ıs:		
Laboratory Investigation  Additional Information:	IS:		

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accurate but indicates that start occurred sometime during the month.



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 112700
 Seq: 1
 Gender:
 F

 Reported:
 31/10/1996
 Weight:

Hospitalisation: Age: 50Y
Onset Date: 21/10/1996
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Dysphagia		Patient couldn't swallow her breakfast	
Palpitations		Patient felt her "heart began to race"	Chlorpromazine ceased
Throat tightness		Throat felt dry, tight, paralysed, constricted	
Coordination abnormal		Uncoordinated and stumbling	
Neutropenia			

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected)
50.0 Milligr

Batch: Started: 21/10/1996 Stopped:

DOXORUBICIN HYDROCHLORIDE (Suspected) Reason:

1.0 Dose Unspecified 2 times

**Batch**: **Started**: 18/09/1996 **Stopped**: 08/10/1996

CYCLOPHOSPHAMIDE (Suspected)

Reason:

1.0 Dose Unspecified 2 times

**Batch: Started:** 18/09/1996 **Stopped:** 08/10/1996

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		22/10/1996	0.38	
	White blood cells		22/10/1996	2.1	

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 113167 Seq: 1 Gender: M
Reported: 14/11/1996 Weight:
Hospitalisation: Age: 48Y

Onset Date: 08/11/1996 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Injection site reaction		Red veins, "tracking"	Largactil infusion discontinued after 2 hours and boluses continued with normal saline flushing before and after each bolus.

## **Medicine Details:**

LARGACTIL (Suspected)		Reason:	Explosive personality disorder
Injection, intravenous infusion	0.0		Intravenous
Batch:	Started: 08/11/1996		<b>Stopped:</b> 09/11/1996
SALINE (Suspected)		Reason:	
	0.0		
Batch:	Started: 08/11/1996		<b>Stopped:</b> 09/11/1996
AMINOPHYLLINE (Suspected)		Reason:	Otr respiratory systm diseases
Injection, intravenous infusion	0.0		Intravenous
Batch:	Started: 08/11/1996		<b>Stopped:</b> 10/11/1996
GLUCOSE (Suspected)		Reason:	
	0.0		
Batch:	Started:		Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Iv largactil and aminophylline "piggy backed" onto peripheral iv; precipitation +++ in line. largactil 500mg in 50ml normal saline at 2ml/hr. aminophylline 1000mg in 100mls in glucose 5% at 3ml/hr.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 113205
 Seq: 1
 Gender: M

 Reported:
 18/11/1996
 Weight:

Hospitalisation: Age: 55Y
Onset Date: 07/08/1996
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

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

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (S	Suspected)		Reason:	
Oral application	100.0	Milligram	As necessary	Oral
Batch:	Started:		Stoppe	d:
LITHIUM CARBONATE (Suspected)			Reason:	
Tablet	1.2	Gram	Daily	Oral
Batch:	Started:		Stoppe	d: 07/08/1996
RISPERIDONE (Suspected)			Reason:	
Tablet	6.0	Milligram	Daily	Oral
Batch:	Started: 01	/06/1995	Stoppe	d: 07/08/1996
THIOPENTONE SODIUM (Suspected)			Reason:	
	200.0	Milligram	Daily	
Batch:	Started:		Stoppe	d:

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	Creatine		08/08/1996	3004	
	Creatine		12/08/1996	1746	
	White blood cells		08/08/1996	15.1	

#### **Additional Information:**

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

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## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detai	18/11/1996 07/08/1996 Recovered	Seq: 1			Gender: Weight: Age: DOB: Causality:	55Y
Medicine Deta		4- d\		D		
SUXAMETHONIUN	I CHLORIDE (Suspec		Milligram	Reason: Daily		
Batch:		Started:	g	24,	Stopped:	
Laboratory In	vestigations:					
Additional Inf the dosage start da		y accurate but ind	dicates that	start occurred	sometime during the	month.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

R	ep	ort	De	tai	ls:
---	----	-----	----	-----	-----

 Case Number:
 114117
 Seq: 1
 Gender: M

 Reported:
 23/12/1996
 Weight:
 82.00

 Hospitalisation:
 Age: 37

**Onset Date**: 07/11/1996 **DOB**: 07/07/1959

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Left ventricular failure		Left ventricular failure	
Blood creatine phosphokinase incr			
Cardiomegaly			
Dizziness			
Dyspnoea			
Electrocardiogram abnormal			
Influenza like illness			
Myocarditis			Cease clozapine/chlorpromazine; pharmacological management of left ventricular failure; bedrest and oxygen.

#### **Medicine Details:**

CEFACLOR MONOHYDRATE (Other drug)		Reason:		
Oral application	750.0 Milligram	Daily	Oral	
Batch:	Started:	Sto	pped:	
CLOZARIL (Suspected)		Reason: Unspec	ified schizophrenia	
	150.0 Milligram	Daily		
Batch:	Started: 22/10/1996	Sto	pped: 05/11/1996	
CHLORPROMAZINE HYDROCHLORIDE (Su	ispected)	Reason: Unspec	ified schizophrenia	
Oral application	400.0 Milligram	Daily	Oral	
Batch:	Started: 23/09/1996	Sto	pped: 05/11/1996	

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	Chest X-ray				Chest xray: 5/11/96 normal; 7/11/96 florid pulmonary oedema
	Creatine				Cpk: elevation in total ck x 10 fold from 4-6/11/96; total ck >1100
	Other data				Left v size at upper limit of normal with lvef of 50%.

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details:					
Case Number: 114117	Seq: 1			Gender:	М
<b>Reported:</b> 23/12/1996				Neight:	
Hospitalisation:			·	Age:	
Onset Date: 07/11/1996				_	07/07/1959
			0-	_	
Outcome: Recovered			Ca	usality:	Causality possible
Reaction Details:				<u> </u>	
Preferred Term	Severity	Report De	scription		Treatment
Palpitations					
Pulmonary oedema					
Pyrexia					
Tachycardia					
Medicine Details:					
CEFACLOR MONOHYDRATE (Other dr	ua)	Reason:			
Oral application	750.0 Milligram	Daily		Oral	
Batch:	Started:	Dally	Stopped:	Orai	
	Starteu.	Bassani		izanbrania	
CLOZARIL (Suspected)	450.0 14:11:	Reason:	Unspecified sch	izopnrenia	
	150.0 Milligram	Daily			
Batch:	Started: 22/10/1996		Stopped:		
CHLORPROMAZINE HYDROCHLORIDE		Reason:	Unspecified sch		
Oral application	400.0 Milligram	Daily		Oral	
Batch:	Started: 23/09/1996		Stopped:	05/11/1996	
Laboratory Investigations:					
Additional Information:					

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 114703 Seq: 1 Gender: F
Reported: 23/01/1997 Weight:
Hospitalisation: Age: 52Y

Onset Date: 04/01/1997 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			
Catatonia			Dantrolene, bromocriptine
Drug ineffective			
Hyperglycaemia			
Pyrexia			

#### **Medicine Details:**

ilculcine Details.					
CARTIA (Suspected)			Reason:		
Tablet	100.0	Milligram	Daily	Oral	
Batch:	Started:	L	TERM	Stopped:	
PREMARIN (Suspected)			Reason:	Menopausal symptoms	
Tablet	625.0	Microgram	Daily	Oral	
Batch:	Started:	L	TERM	Stopped:	
COVERSYL (Suspected)			Reason:	Essential benign hypertension	
Tablet	4.0	Milligram	Daily	Oral	
Batch:	Started: 01/0	01/1996		Stopped:	
STELAZINE (Suspected)			Reason:		
	8.0	Milligram	Daily		
Batch:	Started:	L	TERM	Stopped:	

#### **Laboratory Investigations:**

Date	Туре	Range	Date Tested	Result	Details
	Creatine		04/01/1997	5136	
	Creatine		04/01/1997	8947	
	Creatine		05/01/1997	10356	
	Creatine		06/01/1997	7074	
	Creatine		07/01/1997	3663	
	Creatine		08/01/1997	1198	

#### **Additional Information:**

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

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## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	114703	Seq: 1			Gende	er: F	
Reported:	23/01/1997				Weigh	nt:	
Hospitalisation:					Ag	<b>e</b> : 52Y	
Onset Date:	04/01/1997				DO	B:	
Outcome:	Not yet recovered				Causalit	ty: Causality possible	
Reaction Detai	ls:						
Medicine Deta	aile:						
	IE HYDROCHLORIDE	(Suspected)		Reason:			
Injection			Milligram	Daily	Intramu	scular	
Batch:		Started: 03/	01/1997		<b>Stopped:</b> 04/01/1	997	
Laboratory In	voetinatione:						
Laboratory III	vestigations.						
A alaliti a al l f	:4!						
Additional Inf	ormation: ate is not accurate b	it indicates that	etart occurr	ad sometime o	luring the year		
the dosage start de	ale is not accurate bi	at infulcates triat	start occurre	o sometime (	idinig tile year.		

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Onset Date: 07/02/1997 Outcome: Recovered Causality: Causality probable cotion Details:  Preferred Term Severity Report Description Treatment thostatic hypotension  Preferred Term Severity Report Description Treatment thostatic hypotension  Preferred Term Severity Report Description Treatment thostatic hypotension  Preferred Term Severity Report Description Treatment thostatic hypotension  Preferred Term Severity Report Description Treatment thostatic hypotension  Preferred Term Severity Report Description Treatment thostatic hypotension  Preferred Term Severity Reason:  75.0 Milligram Daily Stopped:  Preferred Term Severity Reason:  75.0 Milligram Daily Stopped:  Preferred Term Severity Preatment Treatment	aca Niiml								
spitalisation: Age: 54Y Onset Date: 07/02/1997 DOB: Outcome: Recovered Causality: Causality probable action Details:  Preferred Term Severity Report Description Treatment of thostatic hypotension Reason:  Preferred Term Severity Report Description Treatment of thostatic hypotension Reason:  Preferred Term Severity Report Description Treatment of thostatic hypotension Reason:  Preferred Term Severity Report Description Treatment of thostatic hypotension Daily  Batch: Started: Stopped:  Preferred Term Severity Report Description Treatment of thostatic hypotension Daily Stopped:  Preferred Term Severity Reason: Pain Daily Oral Batch: Started: Of 100.0 Milligram Daily Oral Stopped: O7/02/1997 Stopped: O7/02/1997				<b>j:</b> 1					F
Onset Date: 07/02/1997 Outcome: Recovered Causality: Causality probable action Details:  Preferred Term Severity Report Description Treatment rithostatic hypotension    Page	_		7					_	
Outcome: Recovered Causality: Causality probable action Details:  Preferred Term Severity Report Description Treatment arthostatic hypotension    Iedicine Details:	-		_					_	
Preferred Term Severity Report Description Treatment  Preferred Term Severity Report Description Treatment  Preferred Term Severity Report Description Treatment  Preferred Term Severity Report Description Treatment  Preferred Term Severity Report Description Treatment  Preferred Term Severity Report Description Treatment  Preferred Term Severity Reason:  Prefer							_		
Preferred Term Severity Report Description Treatment orthostatic hypotension    Indicine Details:			a .				С	ausality:	Causality probable
Medicine Details:  DOXEPIN HYDROCHLORIDE (Other drug)  Batch: Started: Stopped:  SODIUM VALPROATE (Other drug)  Batch: Started: Stopped:  CHLORPROMAZINE HYDROCHLORIDE (Suspected) Oral application Batch: Started: Of/02/1997  Stopped: Stopped: Stopped: Oral  Pain Oral Batch: Started: Of/02/1997  Stopped: O7/02/1997				ovority	Dani	ort Doc	porintion	- I	Trootmant
Medicine Details:  DOXEPIN HYDROCHLORIDE (Other drug) 75.0 Milligram Daily  Batch: Started: Stopped:  SODIUM VALPROATE (Other drug)  Batch: Started: Stopped:  CHLORPROMAZINE HYDROCHLORIDE (Suspected) Oral application 100.0 Milligram Daily  Batch: Started: Stopped:  CHLORPROMAZINE HYDROCHLORIDE (Suspected) Oral application 100.0 Milligram Daily Oral  Batch: Started: 06/02/1997 Stopped: 07/02/1997			5	eventy	керс	אנו טפּּ	scription		rreatment
Batch: Started: Stopped:  SODIUM VALPROATE (Other drug)  Batch: Started: Stopped:  SODIUM VALPROATE (Other drug)  Batch: Started: Stopped:  CHLORPROMAZINE HYDROCHLORIDE (Suspected) Oral application  Batch: Started: O6/02/1997  Stopped: O7/02/1997  Stopped: O7/02/1997									
Batch: Started: Stopped:  Batch: Started: Stopped:  SODIUM VALPROATE (Other drug)  Batch: Started: Stopped:  400.0 Milligram Daily  Batch: Started: Stopped:  CHLORPROMAZINE HYDROCHLORIDE (Suspected) Oral application 100.0 Milligram Daily Oral  Batch: Started: Of/02/1997 Stopped: 07/02/1997									
Batch: Started: Stopped:  SODIUM VALPROATE (Other drug)  Batch: Started: Stopped:  SODIUM VALPROATE (Other drug)  Batch: Started: Stopped:  CHLORPROMAZINE HYDROCHLORIDE (Suspected) Oral application  Batch: Started: O6/02/1997  Stopped: O7/02/1997  Stopped: O7/02/1997									
DOXEPIN HYDROCHLORIDE (Other drug)  75.0 Milligram  Daily  Batch:  Stopped:  SODIUM VALPROATE (Other drug)  Batch:  Started:  Stopped:  Batch:  Started:  Stopped:  CHLORPROMAZINE HYDROCHLORIDE (Suspected) Oral application  100.0 Milligram Daily  Reason:  Reason:  Pain  Oral application  Started: 06/02/1997  Stopped: 07/02/1997									
Batch: Started: Stopped:  SODIUM VALPROATE (Other drug) Reason:  400.0 Milligram Daily  Batch: Started: Stopped:  CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Pain  Oral application 100.0 Milligram Daily Oral  Batch: Started: 06/02/1997 Stopped: 07/02/1997			Other drug)		Rea	son:			
Batch: Started: Stopped:  SODIUM VALPROATE (Other drug) Reason:  400.0 Milligram Daily  Batch: Started: Stopped:  CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Pain  Oral application 100.0 Milligram Daily Oral  Batch: Started: 06/02/1997 Stopped: 07/02/1997		(	u. ug/	75.0 Mil					
SODIUM VALPROATE (Other drug)  400.0 Milligram Daily  Batch: Started: Stopped:  CHLORPROMAZINE HYDROCHLORIDE (Suspected)  Oral application 100.0 Milligram Daily Oral  Batch: Started: 06/02/1997 Stopped: 07/02/1997  Aboratory Investigations:	Batc	h:	;		<b>5</b> -		Stopped:		
Batch: Started: Stopped:  CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Pain  Oral application 100.0 Milligram Daily Oral  Batch: Started: 06/02/1997 Stopped: 07/02/1997  Aboratory Investigations:	SODIUM VAL	PROATE (Other d	rug)		Rea	son:			
CHLORPROMAZINE HYDROCHLORIDE (Suspected) Oral application 100.0 Milligram Daily Oral Batch: Started: 06/02/1997 Stopped: 07/02/1997  Aboratory Investigations:				400.0 Mil	lligram	Daily			
Oral application 100.0 Milligram Daily Oral  Batch: Started: 06/02/1997 Stopped: 07/02/1997  Aboratory Investigations:	Batc								
Batch: Started: 06/02/1997 Stopped: 07/02/1997  aboratory Investigations:		4 4 7 W I F I W / D D O O I I	ILORIDE (Sus	pected)		son:	Pain		
aboratory Investigations:	CHLORPROM		` '			_			
	CHLORPRON Oral a	application			_	Daily			_
Date Type Range Date Tested Result Details	CHLORPROM Oral a	application			_	Daily	Stonnad:		7
	CHLORPROM Oral a Batc	application h: y Investigati	ions:	<b>Started:</b> 06/02/	1997	Daily	Stopped:	07/02/1997	
	CHLORPROM Oral a Batc	application h: y Investigati	ions:	<b>Started:</b> 06/02/	1997	Daily	Stopped:	07/02/1997	
	CHLORPROM Oral a Batc	application h: y Investigati	ions:	<b>Started:</b> 06/02/	1997	Daily	Stopped:	07/02/1997	
	CHLORPROM Oral a Batc	application h: y Investigati	ions:	<b>Started:</b> 06/02/	1997	Daily	Stopped:	07/02/1997	
	CHLORPROM Oral a Batc	application h: y Investigati	ions:	<b>Started:</b> 06/02/	1997	Daily	Stopped:	07/02/1997	
	CHLORPROM Oral a Batc	application h: y Investigati	ions:	<b>Started:</b> 06/02/	1997	Daily	Stopped:	07/02/1997	
	Oral a Batc  Batc  Date	application  th:  Ty Investigati  Type	ions: Range	<b>Started:</b> 06/02/	1997	Daily	Stopped:	07/02/1997	
Additional Information:	Oral a Batc  Batc  Date	application  th:  Ty Investigati  Type	ions: Range	<b>Started:</b> 06/02/	1997	Daily	Stopped:	07/02/1997	
Additional Information:	Oral a Batc  Batc  Date	application  th:  Ty Investigati  Type	ions: Range	<b>Started:</b> 06/02/	1997	Daily	Stopped:	07/02/1997	
Additional Information:	Oral a Batc  Batc  Date	application  th:  Ty Investigati  Type	ions: Range	<b>Started:</b> 06/02/	1997	Daily	Stopped:	07/02/1997	
Additional Information:	Oral a Batc  Batc  Date	application  th:  Ty Investigati  Type	ions: Range	<b>Started:</b> 06/02/	1997	Daily	Stopped:	07/02/1997	

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Case Number: 115355

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

<b>Reported:</b> 14/02/1997	1					weignt:		
ospitalisation:						Age:		
Onset Date: 29/11/1996	3					DOB:	17/01/1946	
Outcome: Unknown					C	ausality:	Causality poss	ible
action Details:	-							
Preferred Term	Se	verity	Repo	rt Descr	ription		Treatmer	nt
gitation								
remor								
edicine Details:			Reas	on:				
Injection		50.0 Millig		1 time		Intramuscu	lar	
Batch:	C+	arted:	jiaiii	i tillie	Stopped:	intramuscu	iai	
aboratory Investigati								
Date Type	Range	Date Tested	Result			Detail	S	
additional Information	1:							
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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

ase Number: 115592 Reported: 26/02/1997	Seq: 1		Gende Weigh	
spitalisation:			=	e: 46Y
Onset Date: 25/01/1997			DÖ	
Outcome: Recovered			Causalit	y: Causality probable
action Details:				
Preferred Term	Severity	Report	Description	Treatment
ushing	Severe			
edicine Details:				
HLORPROMAZINE HYDROCHLORIDE		Reasor		ер
Oral application  Batch:	10.0 M Started:	illigram D	aily Oral Stopped:	
<b>aboratory Investigations:</b> Date Type Rang	ne Date Tested	Regult	De	tails
t <b>ory Investigations:</b> Type Rang	ge Date Tested	Result	De	tails

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 116048 Seq: 1 Gender: F

Reported: 14/03/1997 Weight:
Hospitalisation: Age: 73Y

**Onset Date**: 08/01/1997 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome			Cyproheptadine.

## **Medicine Details:**

VENLAFAXINE HYDROCHLORIDE	(Suspected)	Reason:	Depression	
Tablet	150.0 Milligram	Daily		Oral
Batch:	Started: 23/12/1996		Stopped:	02/01/1997
VENLAFAXINE HYDROCHLORIDE	(Suspected)	Reason:	Depression	
Tablet	75.0 Milligram	Daily		Oral
Batch:	Started: 02/01/1997		Stopped:	08/01/1997
CHLORPROMAZINE HYDROCHLO	RIDE (Suspected)	Reason:	Pain	
Oral application	50.0 Milligram	Daily		Oral
Batch:	Started: 02/01/1997		Stopped:	08/01/1997

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Rep	ort	Deta	ails:
-----	-----	------	-------

Case Number: 117517 Seq: 1 Gender: F

Reported: 12/05/1997 Weight: 73.00 Hospitalisation: Age: 28Y

**Onset Date**: 23/03/1997 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Hydration

#### **Medicine Details:**

Mcdicine Details.				
FLUPHENAZINE DECANOATE (Susp	ected)	Reason:		
Injection	25.0 Milligram	Daily	Intramuscular	
Batch:	Started: 19/03/1997		Stopped:	
CHLORPROMAZINE HYDROCHLORII	DE (Suspected)	Reason:		
	400.0 Milligram	Daily		
Batch:	Started:		Stopped:	
LITHICARB (Suspected)		Reason:		
	1.0 Gram	Daily		
Batch:	Started: 22/03/1997		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 118860
 Seq: 1
 Gender: M

 Reported:
 07/07/1997
 Weight:

Hospitalisation: Age: 16Y
Onset Date: 13/06/1997
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

- <del>100.00.00.00.00.00.00.00.00.00.00.00.00.</del>					
Preferred Term	Severity	Treatment			
Pruritus					
Rash	Rash over arms and trunk				
Rash erythematous					

## **Medicine Details:**

DROLEPTAN (Other drug)			Reason:	Otr spec symp	psychopathol n	ec
Injection	5.0	Milligram	1 time	)	Intramuscular	
Batch:	Started: 13/	06/1997		Stopped:		
RESPOLIN (Other drug)			Reason:	Asthma		
Inhalation	4.0	Dose Unspec	ified Daily		Inhalation	
Batch:	Started:			Stopped:		CONTIN
LITHICARB (Suspected)			Reason:	Unspecified ps	sychosis	
Tablet	1.0	Gram	Daily		Oral	
Batch:	Started: 05/	06/1997		Stopped:	13/06/1997	
BECLOFORTE (Suspected)			Reason:	Asthma		
Inhalation	1.0	Milligram	Daily		Inhalation	
Batch:	Started:			Stopped:		CONTIN

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

Patient allergic to penicillin.

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# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	118860	Seq: 1		Ge	ender:	M	
	07/07/1997	•			eight:		
ospitalisation:					Age:	16Y	
Onset Date:	13/06/1997				DOB:		
Outcome:	Not yet recovered	I		Caus	sality:	Causality possib	ole
action Detai	ils:						
ledicine Det	ails:						
LARGACTIL (Susp	pected)		Reason:	Unspecified psych	osis		
		325.0 Milligram	Daily				
Batch:		Started: 05/06/1997		Stopped:		CONTIN	
COGENTIN (Suspe	ected)		Reason:				
Tablet		2.0 Milligram	Daily	Or	al		
Batch:		Started: 11/06/1997		Stopped:		CONTIN	
aboratory In	vestigations:						
	gaara						
dditional Inf	formation:						
atient allergic to p							
<del></del>							
ort Run: 01/06/200	07 04:15PM Datab	ase: pusime02	ADRS00	04		Page 268	of 495



## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Hospitalisati Onset D	ted: on: ate: me:	0 2 N	1/08/199 0/06/199 lot yet re	97	<b>Sec</b>	<b>ą:</b> 1				C	Gender: Weight: Age: DOB:	63.00 62Y
			Term		S	Severity		Repo	ort De	scription		Treatment
Dysarthria Dysphagia Dysphonia Throat tightn												
Medicine AROPAX (Su								Po-	2001	Doproceion		
AROPAX (Su	spec	tec	1)			20.0	Millia		son: Daily	Depression		
Batc	h:					Started: 13/0	_		Daily	Stopped:		CONTIN
ENALAPRIL		ΞA	TE (Suspe	ected)				Rea	son:			
				·		2.5	Millig	ıram	Daily			
Batc	h:					Started:				Stopped:		
AMOXYCILLI	N SO	DI	UM (Susp	ected)				Rea	son:			
						1.5	Gram	n	Daily			
Batc						Started: 16/0	06/199			Stopped:	23/06/1997	7
TEMAZEPAM	(Sus	spe	ected)					Rea				
D-4-						20.0			Daily	04		
Batc	n:					Started: 20/0	J6/19S	97		Stopped:		
Laborator	y Ir	١V	estiga	tions	:							
Date			уре		nge	Date Test	ed	Result			Detai	ls
Additiona	l In	fo	rmatio	on:								

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## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Hospitalisation: Onset Date: Outcome: Reaction Detai	01/08/1997 20/06/1997 Not yet recovered <b>Is:</b>	Seq: 1		Gender: Weight: Age: DOB: Causality:	63.00 62Y
Medicine Deta		(O )	D		
CHLORPROMAZIN	IE HYDROCHLORIDE	50.0 Milligram	Reason: Daily		
Batch:		Started: 18/06/1997	Daily	<b>Stopped:</b> 19/06/1997	7
Laboratory In	vestigations:				
Additional Inf	ormation:				

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 120028
 Seq: 1
 Gender: M

 Reported:
 18/08/1997
 Weight:

Hospitalisation: Age: 34Y
Onset Date: 13/11/1996 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Hepatitis			All medications ceased. restarted on lower dose carbamazepine
Nausea			
Vomiting			

#### **Medicine Details:**

LARGACTIL (Suspected)		Reason: Unspecifid affective psychosis	
	350.0 Milligram	Daily	
Batch:	Started:	Stopped:	
TEGRETOL (Suspected)		Reason:	
	1.0 Gram	Daily	
Batch:	Started:	Stopped:	
PROZAC (Suspected)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started:	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		13/11/1996	1572	
	ALT = SGPT		20/11/1996	562	
	AST = SGOT		13/11/1996	728	
	AST = SGOT		20/11/1996	110	
	Bilirubin		13/11/1996	63	
	Bilirubin		20/11/1996	27	
	GGT = SGGT =		13/11/1996	696	

## **Additional Information:**

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Case Number: 120028

Seq: 1

## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

pitalisat	lian.						Weight:
	lion:						Age: 34Y
Onset D	Date: 13/11/19	96					DOB:
Outco	me: Recovere	ed					Causality: Causality possible
ction D	Details:						
ممائمالمما	Detelle						
	Details: (Suspected)				Poo	son:	Unspecifid affective psychosis
LARGACTIL	(Suspecteu)		250.0	Million			Onspectific affective psychosis
D-4-	-1		350.0	wiiiigi	am	Daily	Otania da
Bato			Started:				Stopped:
regretol (	(Suspected)					son:	
			1.0	Gram		D-:1	
			1.0	Orani		Daily	
Bato			Started:	Oram		Dally	Stopped:
				Orani		son:	Stopped:
			Started:	Milligra	Rea		Stopped:
	uspected)		Started:		Rea	son:	Stopped:
PROZAC (Su	uspected)		Started: 20.0		Rea	son:	
PROZAC (Su	uspected)		Started: 20.0		Rea	son:	
PROZAC (Su	uspected)		Started: 20.0		Rea	son:	
PROZAC (Su	uspected)		Started: 20.0		Rea	son:	
PROZAC (Su Bato	uspected) ch:	tions:	Started: 20.0		Rea	son:	
PROZAC (Su Bato	uspected)	tions:	Started: 20.0	Milligra	Rea	son:	
Bato  Bato  Bato  Date	ry Investiga		20.0 Started:	Milligra	<b>Rea</b> am	son:	Stopped:
Bato  Bato  Bato  Date	uspected) ch: ry Investiga		20.0 Started:  Date Tes	Milligrated 96	<b>Rea</b> am Result	son:	Stopped:

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**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	ecified Daily		
Batch:	Started:	Stopped:		
COLOXYL (Other drug)		Reason:		
	3.0 Dose Unspec	ecified Daily		
Batch:	Started:	Stopped:		
TAZAC (Other drug)		Reason:		
	600.0 Milligram	Daily		
Batch:	Started: 23/01/1997	Stopped:		
LARGACTIL (Suspected)		Reason: Otr spec symp psychopathol nec		
Injection	50.0 Milligram	1 time Intramuscular		
Batch:	Started: 09/02/1997	Stopped:		

**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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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 120158 Seq: 1 Gender: F

Reported: 22/08/1997 Weight: 70.00
Hospitalisation: Admitted to hospital Age: 71Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

#### **Medicine Details:**

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

## **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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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 120660 Seq: 1 Gender: M

Reported: 10/09/1997 Weight:
Hospitalisation: Age: 16

Onset Date: DOB: 20/01/1981

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

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

#### **Medicine Details:**

ZUCLOPENTHIXOL ACETATE (Suspected)	)	Reason: Unspecified pa	sychosis
Injection	100.0 Milligram	1 time	Intramuscular
Batch:	Started: 11/08/1997	Stopped:	
ZUCLOPENTHIXOL DECANOATE (Suspec	ted)	Reason:	
Injection	50.0 Milligram	1 time	Intramuscular
Batch:	Started: 15/08/1997	Stopped:	CONTIN
CHLORPROMAZINE HYDROCHLORIDE (S	uspected)	Reason:	
Oral application	100.0 Milligram	As necessary	Oral
Batch:	Started: 14/07/1997	Stopped:	16/08/1997

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 121620 Seq: 1 Gender: F

Reported: 16/10/1997 Weight: 70.00 Hospitalisation: Age: 50Y

Onset Date: 31/08/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Profound generalized muscle stiffness	

#### **Medicine Details:**

EFEXOR (Suspected) Reason: Depression

150.0 Milligram Daily

**Batch: Started:** 01/07/1997 **Stopped:** 28/09/1997

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Specific disorders of sleep

 Oral application
 50.0
 Milligram
 Daily
 Oral

 Batch:
 Started: 01/08/1997
 Stopped: 28/09/1997

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### Additional Information:

Similar reaction previously to prozac, but not to aropax or zoloft. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 122981 Seq: 1 Gender: F

 Reported:
 03/12/1997
 Weight:
 77.00

 Hospitalisation:
 Age:
 39Y

**Onset Date**: 15/11/1997 **DOB**:

Outcome: Not yet recovered Causality: Causality certain

**Reaction Details:** 

,	caction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Confusional state		Confusion and sedation.	
	Injection site reaction		Tearing pain in right thigh.	

## **Medicine Details:**

LARGACTIL (Suspected) Reason:

Injection 75.0 Milligram 1 time Intramuscular

Batch: Started: Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Sequelae: patient has remained immobile for 1 week with ongoing pain on weight bearing in the right thigh.

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Case Number: 123050

Seq: 1

## THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

ospitalisation: Onset Date: 24/10/199						weignt:	
Onest Date: 24/10/100						Age:	76Y
Oilset Date: 24/10/198	97					DOB:	
Outcome: Not yet re	ecovered				С	ausality:	Causality possible
action Details:						-	- •
Preferred Term	Severit	y	Repo	rt Descr	iption		Treatment
yncope		Falls	<u> </u>				
onfusional state							
xtrapyramidal disorder							
aecal incontinence							
rinary incontinence							
ledicine Details:							
DIGOXIN (Other drug)			Reas	on:			
	25	50.0 Microgra	am	Daily			
Batch:	Started	:	L TERM		Stopped:		
FOLIC ACID (Other drug)			Reas	on:			
		5.0 Milligran	n	Daily			
Batch:	Started	:	L TERM		Stopped:		
HALOPERIDOL (Suspected)			Reas	on:			
		1.5 Milligran	n	Daily			
Batch:	Started	:	L TERM		Stopped:	24/10/1997	
ARGACTIL (Suspected)			Reas	on:			
Oral application	2	25.0 Milligran	n	Daily		Oral	
Batch:	Started	:	L TERM		Stopped:	24/10/1997	
	ione:						
ahoratory Investigat	IVIIO.						
aboratory Investigat		Tested	Result			Details	5

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## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Onset Date: 24/10/1997 Outcome: Not yet recovered Causality: Causality possible Reaction Details:    Medicine Details:	Case Number:	123050	Seq: 1			Gender:	F
Hospitalisation: Age: 76Y DOB: Onset Date: 24/10/1997 DOB: Outcome: Not yet recovered Causality: Causality possible deaction Details:    Medicine Details:	Reported:	03/12/1997				Weight:	
Onset Date: 24/10/1997 Outcome: Not yet recovered Causality: Causality possible Reaction Details:  Medicine Details:  VALIUM (Suspected)  Batch:  ALDOMET (Suspected)  Reason:  1.5 Gram Daily Batch: Started: L TERM Stopped:  ALDOMET (Suspected)  Reason:  1.5 Gram Daily Batch: Started: L TERM Stopped:  L TERM Stopped:  L TERM Stopped:  L TERM Stopped:							76Y
Outcome: Not yet recovered teaction Details:  Medicine Details:  VALIUM (Suspected)  T.5 Milligram Daily Batch: Started: L TERM Stopped:  ALDOMET (Suspected)  Reason:  1.5 Gram Deily Batch: Started: L TERM Stopped:  L TERM Stopped:  L TERM Stopped:  L TERM Stopped:		24/10/1997					
Medicine Details:  VALIUM (Suspected)  7.5 Milligram  Daily  Batch:  Started: L.TERM Stopped:  ALDOMET (Suspected)  1.5 Gram Daily  Batch: Started: L.TERM Stopped:  L.TERM Stopped:  L.TERM Stopped:  L.TERM Stopped:							
Medicine Details:  VALIUM (Suspected)  7.5 Milligram Daily Batch: Started: LTERM Stopped:  ALDOMET (Suspected)  Reason:  1.5 Gram Daily Batch: Started: LTERM Stopped:  LTERM Stopped:  LTERM Stopped:						•	• •
VALIUM (Suspected) 7.5 Milligram Daily Batch: Started: L TERM Stopped:  ALDOMET (Suspected) Reason: 1.5 Gram Daily Batch: Started: L TERM Stopped:  L TERM Stopped:							
VALIUM (Suspected)  7.5 Milligram Daily  Batch: Started: L TERM Stopped:  ALDOMET (Suspected)  Reason:  1.5 Gram Daily  Batch: Started: L TERM Stopped:  L TERM Stopped:							
VALIUM (Suspected)  7.5 Milligram Daily  Batch: Started: L TERM Stopped:  ALDOMET (Suspected)  Reason:  1.5 Gram Daily  Batch: Started: L TERM Stopped:  L TERM Stopped:							
VALIUM (Suspected)  7.5 Milligram Daily  Batch: Started: L TERM Stopped:  ALDOMET (Suspected)  Reason:  1.5 Gram Daily  Batch: Started: L TERM Stopped:  L TERM Stopped:							
VALIUM (Suspected)  7.5 Milligram Daily  Batch: Started: L TERM Stopped:  ALDOMET (Suspected)  Reason:  1.5 Gram Daily  Batch: Started: L TERM Stopped:  L TERM Stopped:							
VALIUM (Suspected)  7.5 Milligram Daily  Batch: Started: L TERM Stopped:  ALDOMET (Suspected)  Reason:  1.5 Gram Daily  Batch: Started: L TERM Stopped:  L TERM Stopped:							
VALIUM (Suspected) 7.5 Milligram Daily Batch: Started: L TERM Stopped:  ALDOMET (Suspected) Reason: 1.5 Gram Daily Batch: Started: L TERM Stopped:  L TERM Stopped:							
VALIUM (Suspected)  7.5 Milligram Daily  Batch: Started: L TERM Stopped:  ALDOMET (Suspected)  Reason:  1.5 Gram Daily  Batch: Started: L TERM Stopped:  L TERM Stopped:							
VALIUM (Suspected)  7.5 Milligram Daily  Batch: Started: L TERM Stopped:  ALDOMET (Suspected)  Reason:  1.5 Gram Daily  Batch: Started: L TERM Stopped:  L TERM Stopped:							
VALIUM (Suspected)  7.5 Milligram Daily  Batch: Started: L TERM Stopped:  ALDOMET (Suspected)  1.5 Gram Daily							
VALIUM (Suspected)  7.5 Milligram Daily  Batch: Started: L TERM Stopped:  ALDOMET (Suspected)  Reason:  1.5 Gram Daily  Batch: Started: L TERM Stopped:  L TERM Stopped:							
VALIUM (Suspected)  7.5 Milligram Daily  Batch: Started: L TERM Stopped:  ALDOMET (Suspected)  Reason:  1.5 Gram Daily  Batch: Started: L TERM Stopped:  L TERM Stopped:							
VALIUM (Suspected)  7.5 Milligram Daily  Batch: Started: L TERM Stopped:  ALDOMET (Suspected)  Reason:  1.5 Gram Daily  Batch: Started: L TERM Stopped:  L TERM Stopped:	Medicine Det:	aile:					
Batch: Started: L TERM Stopped:  ALDOMET (Suspected) Reason:  1.5 Gram Daily  Batch: Started: L TERM Stopped:  L TERM Stopped:  L TERM Stopped:  L TERM Stopped:					Reason:		
Batch: Started: L TERM Stopped:  ALDOMET (Suspected) Reason:  1.5 Gram Daily  Batch: Started: L TERM Stopped:  L TERM Stopped:  L TERM Stopped:	` .	,	7.5	Milligram			
ALDOMET (Suspected)  1.5 Gram Daily  Batch: Started: L TERM Stopped:  Laboratory Investigations:	Batch:					Stopped:	
Batch: Started: L TERM Stopped:  Laboratory Investigations:		cted)				•	
Batch: Started: LTERM Stopped:  Laboratory Investigations:	` .	,	1.5	Gram			
Laboratory Investigations:	Batch:					Stopped:	
	<u>I</u>						
	Laboratory In	vestigations:					
Additional Information:	_	_					
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Additional Information:							
	Additional Inf	ormation:					

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 123311 Seq: 1 Gender: F

Reported: 11/12/1997 Weight: 37.00 Hospitalisation: Age: 29Y

**Onset Date**: 07/12/1997 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Jaundice			

#### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected)

Suppository

200.0 Milligram

Daily

Reason: Nausea and vomiting

Rectal

Stopped: 07/12/1997

Stopped: 07/12/1997

**Laboratory Investigations:** 

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

#### **Additional Information:**

Patient allergic to penicillin.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 124270 Seq: 1 Gender: F
Reported: 20/01/1998 Weight:
Hospitalisation: Age: 32Y

Onset Date: 14/01/1998 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Blepharitis		Eye flickering	
Hemiparesis		Left side weakness.	
Hypoaesthesia		Numb I side of face, neck. I hand and tongue.	Benztropine iv 2mg.
Dysarthria		Speech difficulties.	
Oculogyration			
Somnolence			

#### **Medicine Details:**

KEFLEX (Other drug)	I	Reason:		
	0.0			
Batch:	Started: 13/01/1998		Stopped:	
PANADEINE (Other drug)		Reason:		
	2.0 Dose Unspecif	ied As nece	essary	
Batch:	Started: 12/01/1998		Stopped:	13/01/1998
TEMAZE (Other drug)		Reason:		
	10.0 Milligram	Daily		
Batch:	Started: 12/01/1998		Stopped:	13/01/1998
PANADEINE FORTE (Other drug)		Reason:		
	8.0 Dose Unspecif	ied Daily		
Batch:	Started: 13/01/1998		Stopped:	13/01/1998

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Multiple allergies to: metoclopramide, cyclizine, betadine, sulphas, penicillin. patient is paraplegic 24 weeks pregnant.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 124270
 Seq: 1
 Gender:
 F

 Reported:
 20/01/1998
 Weight:

Hospitalisation:
Onset Date: 14/01/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

## **Medicine Details:**

ASPIRIN (Other drug)		Reason:	
	300.0 Milligram	Daily	
Batch:	<b>Started:</b> 13/01/1998	Stopped:	13/01/1998
NORMACOL (Other drug)		Reason:	
	0.0	Alternate days	
Batch:	<b>Started:</b> 12/01/1998	Stopped:	13/01/1998
BISALAX (Other drug)		Reason:	
Suppository	0.0	Alternate days	Rectal
Batch:	<b>Started:</b> 13/01/1998	Stopped:	13/01/1998
LARGACTIL (Suspected)		Reason: Nausea and v	omiting
	25.0 Milligram	Daily	
Batch:	<b>Started:</b> 14/11/1997	Stopped:	14/11/1997

# **Laboratory Investigations:**

#### **Additional Information:**

Multiple allergies to: metoclopramide, cyclizine, betadine, sulphas, penicillin. patient is paraplegic 24 weeks pregnant.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Reported: 22								
-		Seq: 1					Gender:	F
	2/01/1998						Weight:	70)/
ospitalisation:	2/42/4007						Age:	
Onset Date: 19 Outcome: Re						C	DOB:	Causality possible
eaction Details						C.	ausaiily:	Causanty possible
Preferred		Severity		F	Report Desc	ription		Treatment
Jrinary retention	101111	Coverity			able to urinat		Ce	ased melleril.
Polydipsia								
Medicine Detail NORVASC (Other dru				. Avur	Reason:			
Batch:		Started:		Milligram	Daily	Stannadı		CONTIN
SOLPRIN (Other drug	1)	Started:			Reason:	Stopped:		CONTIN
and (outlot drug	,,	150	0.C	Milligram	Daily			
Batch:		Started:		ū	,	Stopped:		CONTIN
	HYDROCHLORID	E (Suspected)			Reason: C	tr spec symp	nsychonath	nol nec
CHLORPROMAZINE I							payonopan	
CHLORPROMAZINE Injection		50	7.O.C	Milligram	1 time		Intramuscu	
Injection <b>Batch:</b>		50 Started:		2/1997	1 time	Stopped:		
Batch: MELLERIL (Suspecte	d)	Started:	18/12	2/1997	1 time	Stopped:	Intramuscu	
Injection Batch: MELLERIL (Suspecte Tablet	d)	Started:	18/12	2/1997	1 time		Intramuscu Oral	ılar
Injection Batch: MELLERIL (Suspecte Tablet Batch:		Started: 20 Started:	18/12	2/1997	1 time		Intramuscu	ılar
Injection Batch: MELLERIL (Suspecte Tablet	estigations:	Started: 20 Started:	18/12 D.O M	2/1997 Milligram	1 time  Reason:  Daily		Intramuscu Oral	ılar

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 124527 Seq: 1 Gender: M
Reported: 29/01/1998 Weight:

Hospitalisation: Hospitalisation prolonged Age: 22

**Onset Date:** 18/12/1997 **DOB:** 21/12/1974

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Rash morbilliform		Rash spreading to entire body.	

#### Medicine Details:

CLONAZEPAM (Suspected)		Reason:	
Tablet	1.0 Milligram	As necessary	Oral
Batch:	Started:	Stoppe	ed:
LITHICARB (Suspected)		Reason: Unspecifid	affective psychosis
Tablet	1.2 Gram	Daily	Oral
Batch:	Started: 06/12/1997	Stoppe	ed:
CHLORPROMAZINE HYDROCHLOR	IDE (Suspected)	Reason:	
	150.0 Milligram	Daily	
Batch:	Started:	Stoppe	ed:

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details

#### **Additional Information:**

Reaction- acute onset of febrile illness associated with morbiliform rash starting on anterior chest wall, but spreading to the entire body. resolved after 4 days with residual elevated plaque-like rash on bilateral anterior tibial surfaces.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 124906
 Seq: 1
 Gender: M

 Reported:
 12/02/1998
 Weight:
 120.00

 Hospitalisation:
 Age: 74Y

**Onset Date**: 09/02/1998 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

redotton Betans.							
Preferred Term	Severity	Report Description	Treatment				
Dyspnoea			Patient required intubation, inotropic support and iv hydrocortisone in icu				
Hypotension							
Tachycardia							

## **Medicine Details:**

PARACETAMOL (Other drug)	R	eason:	
Oral application	1.0 Gram	As necessary	Oral
Batch:	Started: 05/02/1998	Stopped	:
RANITIDINE (Other drug)	R	eason:	
Oral application	300.0 Milligram	Daily	Oral
Batch:	Started: 05/02/1998	Stopped	:
ASPIRIN (Other drug)	R	eason:	
Oral application	100.0 Milligram	Daily	Oral
Batch:	Started: 05/02/1998	Stopped	:
HEPARIN SODIUM (Other drug)	R	eason:	
Injection	10.0 Thousand Interr	nat Daily	Subcutaneous
Batch:	Started: 05/02/1998	Stopped	:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient post cabg. nine-year history of ihd. uncomplicated operation and early recovery. no known allergies. pmh - prostatism. medications on admission: gtn patch, atenolol, isordil, pressin.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Repor	t Detail	s:
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Case Number: 124906 Seq: 1 Gender: M

Reported: 12/02/1998 Weight: 120.00 Hospitalisation: Age: 74Y

Onset Date: 09/02/1998 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

## **Medicine Details:**

Medicine Details.				
INDOMETHACIN (Other drug)		Reason:		
Suppository	200.0 Milligram	Daily	Rectal	
Batch:	<b>Started:</b> 05/02/1998	Stopp	oed:	
CHLORPROMAZINE HYDROCHLORIE	DE (Suspected)	Reason: Reactive	confusion	
Oral application	10.0 Millilitre	1 time	Oral	
Batch:	Started: 09/02/1998	Stopp	<b>Ded:</b> 09/02/1998	

## **Laboratory Investigations:**

#### **Additional Information:**

Patient post cabg. nine-year history of ihd. uncomplicated operation and early recovery. no known allergies. pmh - prostatism. medications on admission: gtn patch, atenolol, isordil, pressin.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 126750
 Seq: 1
 Gender: M

 Reported:
 17/04/1998
 Weight: 61.00

**Hospitalisation:** Admitted to hospital **Age:** 73

**Onset Date**: 01/03/1998 **DOB**: 10/06/1924

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Syncope		Collapse	

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Unspecified psychosis

2.0 Dose Unspecified Daily

**Batch: Started:** 01/01/1994 **Stopped:** 02/03/1998

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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

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## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	127328	Seq:	1				Gende	er: M
Reported	: 13/05/199	98					Weigh	it:
Hospitalisation:							Ag	<b>e:</b> 31
Onset Date		98					_	<b>B</b> : 16/03/1967
	Recovere					С		ty: Causality possible
Reaction Deta		<b>~</b>				•	auou	y. Gaddanty possible
	red Term	Se	everity	Repo	ort Desci	ription		Treatment
Tremor				acial tremor ve				
Blepharospasm					-	<b></b>		
Dystonia							Cogentin and reduced zuclopenthixol to 400 every 2 weeks. also introduced temazepam for night sedation, diazepam for tranquilisation. chlorpromazine ceased.	
Medicine De		(Suspected)		Rea	son:			
Injection			400.0 Milligram		Total Intram		Intramu	scular
Batch: S		tarted: 23/03/	1998	Stopped:				
CHLORPROMAZI	NE HYDROCI	HLORIDE (Suspe	ected)	Rea	son: Ur	nspecified ps	sychosis	
			100.0 Mi	illigram	As neces	sary		
Batch: Sta		tarted:	Stopped: 25/03/			25/03/1	998	
Laboratory I			Dots Tosted	Davit				
Date	Туре	Range	Date Tested	Result			De	etails
Additional In	formatio	n:						

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 127838 Seq: 1 Gender: F
Reported: 27/05/1998 Weight:
Hospitalisation: Admitted to hospital Age: 56Y

Onset Date: 13/04/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Gastrointestinal haemorrhage		Gastrointestinal tract bleed	Admitted to icu - transfusion
Anaemia			
Haematemesis			
Prothrombin level decreased			

**Medicine Details:** 

COUMADIN (Interaction)		Reason:		
	5.0 Milligram	Daily		
Batch:	Started: 01/01/1990		Stopped:	
LUVOX (Interaction)		Reason:	Depression	
	100.0 Milligram	Daily		
Batch:	Started: 16/03/1998		Stopped:	13/04/1998
LARGACTIL (Interaction)		Reason:	Depression	
	50.0 Milligram	Daily		
Batch:	Started: 16/03/1998		Stopped:	13/04/1998
LASIX (Other drug)		Reason:		
	40.0 Milligram	Daily		
Batch:	Started: L	. TERM	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Haemoglobin				Haemoglobin 2.6
	International				Inr on admision > 20

#### **Additional Information:**

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

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**Report Details:** 

## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	127838	Seq: 1				Gender:	F
Reported:	27/05/1998					Weight:	
Hospitalisation:	Admitted to hospit	tal				Age:	56Y
Onset Date:	13/04/1998					DOB:	
Outcome:	Recovered					Causality:	Causality possible
Reaction Detai	ls:						
Medicine Deta	aile:						
SPAN-K (Other dru				Reaso	n:		
(**************************************	3,	1.2	Gram		aily		
Batch:		Started:		L TERM	,	Stopped:	
LANOXIN (Other di	rug)			Reaso	n:		
		187.0	Microgra	m D	aily		
Batch:		Started:		L TERM		Stopped:	
Laboratory In	voetigatione:						
Laboratory III	vestigations.						
Additional Inf							
tne dosage start da	ite is not accurate bu	ut indicates tha	t start occ	curred some	etime d	during the year.	

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: 128100 Seq: 1 Gender: F

Reported: 05/06/1998 Weight: 58.00 Hospitalisation: Age: 77Y

Onset Date: 01/05/1998 DOB:

Outcome: Recovered Causality: Causality possible

#### **Reaction Details:**

•	todotion Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
	Confusional state			
	Hallucination			

## **Medicine Details:**

SINEMET (Other drug)		Reason:	Paralysis agitans	
	3.0	Dose Unspecified Dail	у	
Batch:	Started:	L TERM	Stopped:	
ZANTAC (Other drug)		Reason:	Ulcer of duodenum w/o ment perf	
	300.0	Milligram Dail	у	
Batch:	Started:	L TERM	Stopped:	
ASTRIX 100 (Other drug)		Reason:		
	100.0	Milligram Dail	у	
Batch:	Started:	L TERM	Stopped:	
NOTEN (Other drug)		Reason:	Essential benign hypertension	
	50.0	Milligram Dail	у	
Batch:	Started:	L TERM	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Report Details:

## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: 128100 Reported: 05/06/1998 Hospitalisation: Onset Date: 01/05/1998 Outcome: Recovered Reaction Details:	Seq: 1			C	Gender: Weight: Age: DOB: ausality:	58.00 77Y
Medicine Details:						
LUMIN (Other drug)			Reason:	Depression		
		Milligram	Daily			
Batch:	Started:		L TERM	Stopped:		
COGENTIN (Suspected)	0.0	N 4:11:	Reason:			
Betali		Milligram	Daily	Otamond.	04/05/4000	
Batch: STELAZINE (Suspected)	Started: 30/	04/1998	Reason:	Unspecified ps	04/05/1998	
STELAZINE (Suspected)	1.0	Milligram	Daily	Unspecified ps	sychosis	
Batch:	Started:		L TERM	Stonned:	04/05/1998	
LARGACTIL (Suspected)	Otarica.		Reason:	Unspecified ps		
_ interversiz (edoposica)	100.0	Milligram	Daily	C. opcomou po	,, 000.0	
Batch:	Started:		L TERM	Stopped:	04/05/1998	
Laboratory Investigations:						
Additional Information:						

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 128593 Seq: 1 Gender: M

Reported: 22/06/1998 Weight: 73.00 Hospitalisation: Age: 43Y

**Onset Date**: 11/06/1998 **DOB**:

Outcome: Recovered Causality: Causality certain

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Injection site abscess			Treated with flucloxacillin

#### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason:

Injection 300.0 Milligram Total Intramuscular

Batch: Started: Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient given 2 injections of chlorpromazine. one 100mg in arm and second 200mg in hip. developed injection abscess.

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**Report Details:** 

**Additional Information:** 

## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

of/1998  /et recovered  rm So	everity			DO	int: ge: 68Y OB: ity: Causality possib	ale.
	everity			DO	OB:	ماد
	everity					ماد
	everity			Causai	ity. Causality possit	
rm S	everity					ЛС
3	CVCIILV	Ren	ort Descr	intion	Treatment	
		ιτορι	<u> </u>	iption	Treatment	
n						
··						
Suspected)		Rea	son:			
	0.0					
5	Started:			Stopped:		
		Rea	ison:			
	0.0					
5	Started:			Stopped:		
		Rea	ison:			
	5.0 Milli	igram	Daily	Oral		
5				Stopped:	CONTIN	
	T= . =		T			
Range	Date Tested	Result			Details	
Kange	Date Tested	Result			retails	
)	Suspected) S	Suspected)  0.0  Started:  0.0  Started:  5.0 Mill  Started:	Suspected)  0.0  Started:  0.0  Started:  Rea  5.0 Milligram  Started:	Suspected)  Reason:  0.0  Started:  0.0  Started:  Reason:  5.0 Milligram Daily  Started:	Suspected)  Reason:  0.0  Started:  Reason:  0.0  Started:  Stopped:  Reason:  5.0 Milligram Daily Oral Started:  Stopped:	Suspected) Reason:  0.0 Started: Stopped:  0.0 Started: Stopped:  Reason: 5.0 Milligram Daily Oral Started: Stopped: CONTIN

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Within five days after beginning zyprexa patient experienced symptoms medications were continued and patient is still experiencing symptoms. patient is also on an antihypertensive (unspecified) drug.



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 129271
 Seq: 1
 Gender:
 F

 Reported:
 17/07/1998
 Weight:

Hospitalisation: Age: 44Y

Onset Date: 13/05/1998 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Skin discolouration	Required Specialist Consultation	Hyperpigmentation mainly face	

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE	E (Suspected)	Reason: Nausea a	and vomiting	
Injection	12.5 Milligram	As necessary	Intravenous	
Batch:	Started:	Stop	oed:	
METOCLOPRAMIDE HYDROCHLORIDE	E (Suspected)	Reason: Nausea a	and vomiting	
	10.0 Milligram	As necessary		
Batch:	Started: 11/05/1998	Stop	oed:	
AMPHOTERICIN (Suspected)		Reason:		
Injection	26.0 Milligram	Daily	Intravenous	
Batch:	Started:	Stop	ped: CONTIN	1
PROMETHAZINE HYDROCHLORIDE (S	uspected)	Reason:		
Injection	12.5 Milligram	Daily	Intravenous	
Batch:	Started: 11/05/1998	Stop	ped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Amphotericin commenced feb 98 for 2 weeks, then ceased. recommenced 20/3/98 at 40mg iv/d, decreased to 30mg due to declining renal function and low. now currently on 26mg iv/d. allergies: allopurinol, metals, canned food.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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UG	vu	Iι	Ut	; La	иэ.

 Case Number:
 129271
 Seq: 1
 Gender:
 F

 Reported:
 17/07/1998
 Weight:

Hospitalisation: Age: 44Y
Onset Date: 13/05/1998 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

## **Medicine Details:**

Medicine Details.						
CYTARABINE (Suspected)	Reason:					
	150.0 Milligram	Daily				
Batch:	Started: 11/05/1998	Stopped:	16/05/1998			
IDARUBICIN (Suspected)		Reason:				
Injection	18.0 Milligram	Daily	Intravenous			
Batch:	Started: 11/05/1998	Stopped:	12/05/1998			

## **Laboratory Investigations:**

#### **Additional Information:**

Amphotericin commenced feb 98 for 2 weeks, then ceased. recommenced 20/3/98 at 40mg iv/d, decreased to 30mg due to declining renal function and low. now currently on 26mg iv/d. allergies: allopurinol, metals, canned food.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 130740 Seq: 1 Gender: F

 Reported:
 02/09/1998
 Weight:

 Hospitalisation:
 Age:
 63Y

 Onset Date:
 23/08/1998
 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

caction Details.			
Preferred Term	Severity	Report Description	Treatment
Myalgia		Aching pain in legs	
Paraesthesia			

#### **Medicine Details:**

Medicine Details.							
LARGACTIL (Suspected)	Reason:						
	100.0 Milligram	Daily					
Batch:	Started: 01/08/1998	Stopped:	CONTIN				
PROTHIADEN (Suspected)	F	Reason:					
	150.0 Milligram	Daily					
Batch:	Started: 01/08/1998	Stopped:	CONTIN				

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

R	е	p	0	r	t	D	e	ta	il	S	:

 Case Number:
 131861
 Seq: 1
 Gender:
 F

 Reported:
 08/10/1998
 Weight:

Hospitalisation: Age: 64Y
Onset Date: 05/07/1998 DOB:

Outcome: Not yet recovered Causality: Causality possible

#### **Reaction Details:**

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal		Talking faster than she is thinking	

#### **Medicine Details:**

Medicine Details.			
LARGACTIL (Suspected)			
	100.0 Milligram	Daily	
Batch:	Started: 05/07/1998	Stopped:	CONTIN
PROTHIADEN (Suspected)		Reason:	
	150.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
TEMAZEPAM (Suspected)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 132006
 Seq: 1
 Gender: M

 Reported:
 15/10/1998
 Weight:

Hospitalisation: Age: 69

**Onset Date**: 31/08/1998 **DOB**: 06/04/1929

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

caction Details.				
Preferred Term	Severity	Report Description	Treatment	l
Blood creatine phosphokinase incr				
Neuroleptic malignant syndrome			Chlorpromazine caesed	

## **Medicine Details:**

ASPIRIN (Other drug)		Reason:	Chron isch heart dis n	o hyper	
	150.0 Milligram	Daily			
Batch:	Started:		Stopped:	CONTIN	
IMDUR (Other drug)		Reason:	Chron isch heart dis n	o hyper	
	120.0 Milligram	Daily			
Batch:	Started:		Stopped:	CONTIN	
MIANSERIN HYDROCHLORIDE (	Other drug)	Reason:	Unspecified psychosis	3	
	60.0 Milligram	Daily			
Batch:	Started:		Stopped:	CONTIN	
CHLORPROMAZINE HYDROCHL	ORIDE (Suspected)	Reason:	Otr spec symp psycho	pathol nec	
	150.0 Milligram	Daily			
Batch:	Started:		Stopped: 02/09/	1998	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Creatine				Ck peaked 1338 01/09/98

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 132117 Seq: 1 Gender: F
Reported: 19/10/1998 Weight:
Hospitalisation: Age: 38Y

**Onset Date**: 06/10/1998 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Elevated temperature 40 degrees	
Headache			
Hepatitis			

## **Medicine Details:**

NEO-CYTAMEN (Other drug)		Reason: Other vitamin b defici	ency
Injection	1.0 Milligram	Weekly Intrave	enous
Batch:	Started: 02/10/1998	Stopped:	CONTIN
FEFOL (Other drug)		Reason: Unspecified anemia	
Capsule	350.0 Milligram	Daily Oral	
Batch:	Started: 27/09/1998	Stopped:	CONTIN
TEMAZE (Other drug)		Reason: Otr spec symp psycho	opathol nec
Capsule	20.0 Milligram	Daily Oral	
Batch:	Started: 02/10/1998	Stopped:	CONTIN
LITHICARB (Other drug)		Reason: Unspecifid affective p	sychosis
Tablet	1.2 Gram	Daily Oral	
Batch:	Started:	Stopped:	CONTIN

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		06/10/1998	725	
	ALT = SGPT		07/10/1998	600	
	ALT = SGPT		14/10/1998	173	
	ALT = SGPT		08/10/1998	398	
	Bilirubin		06/10/1998	11	
	Bilirubin		07/10/1998	25	
	Bilirubin		08/10/1998	19	

#### **Additional Information:**

Pt currently has a urinary tract infection

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 132117
 Seq: 1
 Gender:
 F

 Reported:
 19/10/1998
 Weight:

Hospitalisation:
Onset Date: 06/10/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

#### **Medicine Details:**

Medicine Details.		
LARGACTIL (Suspected)		Reason: Otr spec symp psychopathol nec
	100.0 Milligram	As necessary
Batch:	Started: 26/09/1998	<b>Stopped:</b> 06/10/1998
RISPERDAL (Suspected)		Reason: Manic-depression psycho,manic
Tablet	2.0 Milligram	Daily Oral
Batch:	Started: 26/09/1998	<b>Stopped:</b> 07/10/1998

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin		14/10/1998	11	
	GGT = SGGT =		06/10/1998	51	
	GGT = SGGT =		07/10/1998	76	
	GGT = SGGT =		14/10/1998	59	
	GGT = SGGT =		08/10/1998	84	
	SAP = ALP		06/10/1998	125	
	SAP = ALP		07/10/1998	143	

#### **Additional Information:**

Pt currently has a urinary tract infection

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 132117
 Seq: 1
 Gender:
 F

 Reported:
 19/10/1998
 Weight:

Hospitalisation:
Onset Date: 06/10/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

## **Medicine Details:**

NEO-CYTAMEN (Other drug)		Reason: Other vitamin b defic	iency
Injection	1.0 Milligram	Weekly Intrav	venous
Batch:	Started: 02/10/1998	Stopped:	CONTIN
FEFOL (Other drug)		Reason: Unspecified anemia	
Capsule	350.0 Milligram	Daily Oral	
Batch:	Started: 27/09/1998	Stopped:	CONTIN
TEMAZE (Other drug)		Reason: Otr spec symp psych	nopathol nec
Capsule	20.0 Milligram	Daily Oral	
Batch:	Started: 02/10/1998	Stopped:	CONTIN
LITHICARB (Other drug)		Reason: Unspecifid affective	osychosis
Tablet	1.2 Gram	Daily Oral	
Batch:	Started:	Stopped:	CONTIN

**Laboratory Investigations:** 

	Date	Туре	Range	Date Tested	Result	Details
ĺ		SAP = ALP		08/10/1998	143	
ı		SAP = ALP		14/10/1998	118	

#### **Additional Information:**

Pt currently has a urinary tract infection

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Detail	s:							
Case Number: Reported: Hospitalisation: Onset Date:	19/10/1998	Seq: 1					Gender: Weight: Age: DOB:	38Y
Outcome:	Not yet recovered	I				С	ausality:	Causality possible
Reaction Detai							•	, ,
Medicine Det	ails:							
LARGACTIL (Susp					Reason:	Otr spec symp	psychopath	ol nec
			100.0	Milligram	As ne	cessary		
Batch:		Star	ted: 26/	09/1998			06/10/1998	
RISPERDAL (Susp	ected)				Reason:	Manic-depress		manic
Tablet		_		Milligram	Daily		Oral	
Batch:		Star	ted: 26/	09/1998		Stopped:	07/10/1998	
Laboratory In	vestigations:							

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Report Details:

Hospitalisation:

Case Number: 133375

Reported: 17/11/1998

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

**Age:** 48

Weight:

Onset Da	ate: 01/10/199	8			<b>DOB</b> : 04/02/1950				
Outcor	<b>ne:</b> Not yet re	covered		Causality: Causality probable					
action De	etails:								
Pre	ferred Term	S	everity	Rep	ort Des	cription	Treatment		
ine analysi	is abnormal			Dark urine					
eadache									
undice									
usea							Largactil and epilim ceased. cholestyramine given for itcl		
uritus							cholestyramine given for ito		
rexia									
omiting									
edicine [ ANADOL (O				Rea	ıson:				
Tablet	-		10.0 D	ose Unspecified		Or	al		
Batch		5	Started:			Stopped:			
ITHICARB (C				Rea	son:				
•	O,		1.0	Gram	Daily				
Batch	h:	Ş	Started:		•	Stopped:	CONTIN		
PILIM (Other	r drug)			Rea	son:				
			3.0	Gram	Daily				
Batch	h:	Started:			Stopped:		2M		
ARGACTIL (	Suspected)			Rea	son:				
			300.0 N	1illigram	Daily				
Batch	h:	5	Started:			Stopped:	2M		
horator	y Investigat	ione:							
Date	Туре	Range	Date Tested	d Result			Details		
			Date Tester	d Result			Details		
itional	l Informatio	n:							
ort Run : 01/0	06/2007 04:15PM	I Database: r	ousime02		ADRS004		Page 304 of 495		



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 133655 Seq: 1 Gender: F
Reported: 24/11/1998 Weight:
Hospitalisation: Age: 46Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

Medicifor Details.			
Preferred Term	Severity	Report Description	Treatment
Hepatitis		Elev. liver enzymes, cholestatis, no jaundice.	
Abdominal pain			
Nausea			
Pruritus			

## **Medicine Details:**

modium Dotaile.				
CLONAZEPAM (Other drug)		Reason:		
	0.0			
Batch:	Started:		Stopped:	
PANADEINE (Other drug)		Reason:		
	0.0			
Batch:	Started:		Stopped:	
OMEPRAZOLE (Other drug)		Reason:		
	0.0			
Batch:	Started:		Stopped:	
PROCHLORPERAZINE MALEATE (C	Other drug)	Reason:		
	0.0			
Batch:	Started:		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	<51 U/L	16/11/1998	31	
	ALT = SGPT	<51 U/L	13/11/1998	56	
	ALT = SGPT	<51 U/L	09/11/1998	137	
	ALT = SGPT	<51 U/L	08/11/1998	141	
	ALT = SGPT	<51 U/L	11/11/1998	94	
	AST = SGOT	<40 U/L	16/11/1998	23	
	AST = SGOT	<40 U/L	13/11/1998	34	

#### **Additional Information:**

Hepatitis settled spontaneously.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 133655
 Seq: 1
 Gender: F

 Reported:
 24/11/1998
 Weight:

Hospitalisation:
Onset Date:

DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

#### **Medicine Details:**

Medicine Details.					
NEFAZODONE HYDROCHLO	RIDE (Suspected)		Reason:		
	200.0	Milligram	Daily		
Batch:	Started:			Stopped:	05/11/1998
CHLORPROMAZINE HYDRO	CHLORIDE (Suspected)		Reason:		
	200.0	Milligram	Daily		
Batch:	Started:			Stopped:	03/11/1998

**Laboratory Investigations:** 

Date	е Туре	Range	Date Tested	Result	Details
	AST = SGOT	<40 U/L	11/11/1998	51	
	AST = SGOT	<40 U/L	08/11/1998	144	
	AST = SGOT	<40 U/L	09/11/1998	95	
	Bilirubin	<25 UMOL/L	16/11/1998	8	
	Bilirubin	<25 UMOL/L	13/11/1998	8	
	Bilirubin	<25 UMOL/L	11/11/1998	14	
	Bilirubin	<25 UMOL/L	08/11/1998	9	

#### **Additional Information:**

Hepatitis settled spontaneously.

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Repo Hospitalisa Onset	<b>Date:</b> ome: Unknow		. 1			Gender: Weight: Age: DOB: Causality:	46Y
Medicine	Details:						
	AM (Other drug)			Rea	son:		
			0.0				
Bat	tch:	s	tarted:			Stopped:	
PANADEIN	E (Other drug)			Rea	son:		
			0.0				
Rat	tch:	9	tarted:			Stopped:	
	DLE (Other drug)		tarteu.	Poo	son:	Stoppeu.	
OWIEFRAZO	DLE (Other drug)		0.0	Rea	SOII.		
_			0.0				
	tch:		tarted:			Stopped:	
PROCHLOF	RPERAZINE MALI	EATE (Other drug	)	Rea	son:		
			0.0				
Ba	tch:	S	tarted:			Stopped:	
Laborata	ory Investiga	otiono					
Date	Type	Range	Date Tested	Result		Deta	ils
	Bilirubin	<25 UMOL/L	09/11/1998	10			
	GGT = SGGT =	<50 U/L	16/11/1998	119			
	GGT = SGGT =	<50 U/L	13/11/1998	142			
	GGT = SGGT =	<50 U/L	09/11/1998	240			
	GGT = SGGT =	<50 U/L	08/11/1998	299			
	GGT = SGGT =	<50 U/L	11/11/1998	189			
	SAP = ALP	30 - 120 U/L	16/11/1998	123			
	<b>al Informati</b> ttled spontaneou						

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 133655 Seq: 1 Gender: F

Reported: 24/11/1998 Weight:
Hospitalisation: Age: 46Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

#### **Medicine Details:**

vicultific Details.					
NEFAZODONE HYDROCHLOR	IDE (Suspected)		Reason:		
	200.0	Milligram	Daily		
Batch:	Started:			Stopped:	05/11/1998
CHLORPROMAZINE HYDROCI	HLORIDE (Suspected)		Reason:		
	200.0	Milligram	Daily		
Batch:	Started:			Stopped:	03/11/1998

**Laboratory Investigations:** 

L	Date	Type	Range	Date Tested	Result	Details
ſ		SAP = ALP	30 - 120 U/L	13/11/1998	124	
		SAP = ALP	30 - 120 U/L	11/11/1998	144	
		SAP = ALP	30 - 120 U/L	09/11/1998	163	
l		SAP = ALP	30 - 120 U/L	08/11/1998	219	

#### **Additional Information:**

Hepatitis settled spontaneously.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**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)		Reason:	
	20.0 Milligram	1 time	
Batch:	Started: 23/10/1998		Stopped:
DIAZEPAM (Other drug)		Reason:	
	2.5 Milligram	1 time	
Batch:	Started: 23/10/1998		Stopped:
CHLORPROMAZINE HYDROCHLO	RIDE (Suspected)	Reason:	
	50.0 Milligram	1 time	
Batch:	<b>Started:</b> 23/10/1998		Stopped:
METFORMIN HYDROCHLORIDE (S	uspected)	Reason:	
	3.0 Gram	Daily	
Batch:	Started: 22/10/1998		Stopped:

**Laboratory Investigations:** 

ĺ	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.
ı		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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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Repor espitalisat Onset D	ber: 134345 rted: 16/12/ rion: Admitte Date: 28/10/ me: Recove	998 ed to hospi 998	Seq:	1			c			
action D								<b>,</b>		
		eq)			Re	ason.				
	Details: MIDE (Suspect	ed)		20.0 Mil		eason:				
ledicine GLIBENCLAI Batc	MIDE (Suspect	ed)	Sta	20.0 Mil arted: 22/10/	ligram	eason: Daily	Stopped:			
GLIBENCLAI Bato	MIDE (Suspect	ed)	Sta		ligram 1998		Stopped:			
GLIBENCLAI Bate CAPTOPRIL	MIDE (Suspect ch: (Suspected)	ed)		50.0 Mil	ligram 1998 <b>Re</b> ligram	Daily				
GLIBENCLAI Bato CAPTOPRIL Bato	MIDE (Suspect ch: (Suspected) ch:	ed)		arted: 22/10/	ligram 1998 Re ligram 1998	Daily eason: Daily	Stopped:			
GLIBENCLAI Bato CAPTOPRIL Bato	MIDE (Suspect ch: (Suspected)	ed)		50.0 Mil	ligram 1998 Re ligram 1998	Daily  Pason: Daily  Pason:				
Bate CAPTOPRIL Bate FRUSEMIDE	MIDE (Suspect ch: (Suspected) ch: (Suspected)	ed)	Sta	50.0 Mil arted: 22/10/ 20.0 Mil	ligram 1998 Re ligram 1998 Re ligram	Daily eason: Daily	Stopped:			
Bate CAPTOPRIL  Bate FRUSEMIDE  Bate	MIDE (Suspect ch: (Suspected) ch: (Suspected)		Sta Sta	50.0 Mil	ligram 1998 Re ligram 1998 Re ligram	Daily  Pason: Daily  Pason:				
Bate CAPTOPRIL  Bate FRUSEMIDE  Bate	MIDE (Suspect ch: (Suspected) ch: (Suspected) ch:		Sta Sta	50.0 Mil arted: 22/10/ 20.0 Mil	ligram 1998 Re ligram 1998 Re ligram 1998	Daily  Pason: Daily  Pason: Daily	Stopped:	Intramusco	ular	
Bate CAPTOPRIL Bate FRUSEMIDE Bate FLUPENTHIX	MIDE (Suspect ch: (Suspected) ch: (Suspected) ch: (Suspected) ch: KOL DECANOA		Sta Sta ted)	50.0 Mil arted: 22/10/- 20.0 Mil arted: 22/10/-	ligram 1998 Re ligram 1998 Re ligram 1998 Re	Daily  Pason: Daily  Pason: Daily  Pason:	Stopped:	Intramusco	ular	
Bato CAPTOPRIL  Bato FRUSEMIDE  Bato FLUPENTHIX  Inject	MIDE (Suspect ch: (Suspected) ch: (Suspected) ch: KOL DECANOA tion ch:	TE (Suspect	Sta Sta ted)	50.0 Mil arted: 22/10/2 20.0 Mil arted: 22/10/2 10.0 Mil	ligram 1998 Re ligram 1998 Re ligram 1998 Re	Daily  pason: Daily  pason: Daily  pason:	Stopped:	Intramusco	ular	
Bato CAPTOPRIL  Bato FRUSEMIDE  Bato FLUPENTHIX  Inject Bato	MIDE (Suspect ch: (Suspected) ch: (Suspected) ch: (Suspected) ch: KOL DECANOA	TE (Suspect	Sta Sta ted)	50.0 Mil arted: 22/10/2 20.0 Mil arted: 22/10/2 10.0 Mil	ligram 1998 Re ligram 1998 Re ligram 1998 Re	Daily  pason: Daily  pason: Daily  pason:	Stopped:	Intramusco		

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Rei	port	Detai	ls:
-----	------	-------	-----

Case Number: 134563 Seq: 1 Gender: M

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

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

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

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

#### Medicine Details:

viedicine Details:					
RANITIDINE (Other drug)		Reason:			
	300.0 Milligram	Daily			
Batch:	Started:	Sto	pped:	CONTIN	
ZUCLOPENTHIXOL ACETATE (Sus	pected)	Reason: Otr spe	c symp psychop	athol nec	
	150.0 Milligram	1 time			
Batch:	Started: 13/10/1998	Sto	pped: 13/10/19	998	
CHLORPROMAZINE HYDROCHLOR	IDE (Suspected)	Reason: Otr spe	c symp psychop	athol nec	
Oral application	600.0 Milligram	Daily	Oral		
Batch:	Started: 05/10/1998	Sto	pped:	CONTIN	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 134879 Seq: 1 Gender: U

Reported: 04/01/1999 Weight: 53.00 Hospitalisation: Age: 19

Onset Date: 22/07/1997

Outcome: Recovered

DOB: 22/10/1977

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Heart rate increased to 214 from 100.	Ceased largactil.

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Facial paralysis

 Injection
 25.0 Milligram
 1 time
 Intravenous

 Batch:
 Started: 22/07/1997
 Stopped: 22/07/1997

**Laboratory Investigations:** 

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

#### **Additional Information:**

See original report for other drugs.

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Report Details:

Case Number: 135345

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

Reported: 22/01/19	999		Weight:				
ospitalisation:			<b>Age</b> : 34				
Onset Date:					<b>DOB</b> : 28/01/1964		
Outcome: Not yet	recovered		Causality: Causality possible				
eaction Details:					1		
Preferred Term	S	Severity	Repo	t Description	Treatment		
Orug ineffective							
Medicine Details:							
BENZTROPINE MESYLATE ( Tablet	Other drug)	2.0 Milliç	Reas				
Batch:	,	اااااار Started:	gram	As necessary Ora Stopped:	CONTIN		
CHLORPROMAZINE HYDRO			Reas		CONTIN		
CHECKF ROMAZINE HIDRO	OTTEORIDE (Sus	0.0	Neas	on.			
Batch:	!	Started:		Stopped:			
Laboratory Investiga	ations:						
Date Type	Range	Date Tested	Result		Details		
Additional Informati	on:						
eport Run: 01/06/2007 04:15	PM Database: p	ousime02	AI	PRS004	Page 313	of 495	



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 136469 Seq: 1 Gender: F

Reported: 22/02/1999 Weight:
Hospitalisation: Age: 33Y

**Onset Date**: 16/02/1999 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

teaction betails.			
Preferred Term	Severity	Report Description	Treatment
Depersonalisation		Feeling whoosy & spaced out.	
Agitation		Motor restlessness.	Dose was reduced to 10mg bd and the patient experienced no adverse effects at this dose.

#### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Hyperemes gravidar w/o neurits

Oral application 50.0 Milligram Daily Oral

**Batch: Started:** 16/02/1999 **Stopped:** 16/02/1999

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient was 12 weeks pregnant.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

	ber: 138518	Seq: 1		Gende	
	rted: 19/04/1999			Weigh	
spitalisa				Age	
Onset [	Date: 10/02/1999			DO	B:
	me: Recovered			Causalit	y: Causality possible
action <u>C</u>		<u> </u>			
	eferred Term	Severity		ort Description	Treatment
ash			Rash after 8 day	s of vancomycin.	
	<b>D</b> 4 11				
	Details:	(Suspected)	Rea	son:	
	Details:	(Suspected)		son:	
	IN HYDROCHLORIDE			son: Stopped:	
ANCOMYC Bat	IN HYDROCHLORIDE	0 <b>Started</b> :	0		
'ANCOMYC Bat	IN HYDROCHLORIDE	0 <b>Started</b> :	0 Rea	Stopped:	
Bate Bate BENTAMICI Bate	IN HYDROCHLORIDE ch: N SULPHATE (Suspec ch:	Started:	0 Rea	Stopped:	
/ANCOMYC Bat BENTAMICI Bat	IN HYDROCHLORIDE ch: N SULPHATE (Suspec	Started:  oted)  Started:	0 Rea	Stopped:	
ANCOMYC Bat BENTAMICI Bat IEVIRAPINI	IN HYDROCHLORIDE ch: N SULPHATE (Suspec ch: E (Suspected)	Started:  0 Started:  0 Started:	0 Rea	Stopped: Stopped: Stopped:	
Bate BENTAMICI Bate BEVIRAPINI Bate	IN HYDROCHLORIDE ch: N SULPHATE (Suspec ch: E (Suspected) ch:	Started:  oted)  Started:	0 <b>Rea</b> 0 <b>Rea</b> 0	Stopped: Stopped: Stopped: Stopped:	
/ANCOMYC Bat GENTAMICI Bat IEVIRAPINI Bat	IN HYDROCHLORIDE ch: N SULPHATE (Suspec ch: E (Suspected) ch:	Started:  O Started:  O Started:  O Started:	0 <b>Rea</b> 0 <b>Rea</b> 0 <b>Rea</b>	Stopped: Stopped: Stopped:	
Bate BENTAMICI Bate NEVIRAPINI Bate STC (Suspec	in HYDROCHLORIDE ch: N SULPHATE (Suspec ch: E (Suspected) ch: cted)	Started:  O Started:  O Started:  O Started:	0 <b>Rea</b> 0 <b>Rea</b> 0 <b>Rea</b>	Stopped: Stopped: Stopped: Stopped: Stopped:	
/ANCOMYC Bat GENTAMICI Bat IEVIRAPINI Bat	in HYDROCHLORIDE ch: N SULPHATE (Suspec ch: E (Suspected) ch: cted)	Started:  O Started:  O Started:  O Started:	0 <b>Rea</b> 0 <b>Rea</b> 0 <b>Rea</b>	Stopped: Stopped: Stopped: Stopped:	
Bate BEVIRAPINI Bate TC (Suspect	in HYDROCHLORIDE ch: N SULPHATE (Suspec ch: E (Suspected) ch: cted)	Started:  O Started:  O Started:  O Started:	0 <b>Rea</b> 0 <b>Rea</b> 0 <b>Rea</b>	Stopped: Stopped: Stopped: Stopped: Stopped:	
Bate SENTAMICI Bate NEVIRAPINI Bate STC (Suspect	in HYDROCHLORIDE ch: N SULPHATE (Suspecth: E (Suspected) ch: cted)	Started:  O Started:  O Started:  O Started:	0	Stopped: Stopped: Stopped: Stopped: Stopped: Stopped:	etails

## **Additional Information:**

See original report for other drug details - omeprazole, flumirazine, frusamide & quinine.

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Report Details:

## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:		Seq: 1	Gender:	F
	19/04/1999		Weight:	
Hospitalisation:			Age:	
Onset Date:			DOB:	
	Recovered		Causality:	Causality possible
Reaction Detai	IS:			
Madiaina Date	nilo.			
Medicine Deta	alis. IE HYDROCHLORIDE	(Suspected)	Reason:	
		0.0		
Batch:		Started:	Stopped:	
AMITRIPTYLINE H	YDROCHLORIDE (Su	spected)	Reason:	
		0.0		
Batch:		Started:	Stopped:	
Laboratory In	vestigations:			
Additional Inf	ormation:	ls - omeprazole, flumirazine,	frucamido 8 quinino	
Gee Original report	ioi otilei ulug uetai	is - omeprazoie, numnazme,	nusamue a quimile.	

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 138917
 Seq: 1
 Gender:
 F

 Reported:
 30/04/1999
 Weight:

Hospitalisation: Admitted to hospital Age: 29Y

Onset Date: 29/03/1999

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			Given diazepam as no response to benztropine.

#### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Migraine

Injection 0.0 Intravenous

Batch: Started: Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

See original report for other drg: fluvoxamine (luvox)

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Gender: F Case Number: 139670 Seq: 1

Weight: Reported: 18/05/1999 **Hospitalisation:** Age: 31Y

**Onset Date: 18/03/1999** DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term Severity		Report Description	Treatment
Syncope		Collapse with fall and broke nose	
Convulsion		Myoclonic jerks	
Urinary incontinence			

Medicine Details:			
LARGACTIL (Interaction)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
CLOZARIL (Interaction)		Reason: Unspecified schizophrenia	
Tablet	500.0 Milligram	Daily Oral	
Batch:	Started: 03/12/1998	Stopped:	

**Laboratory Investigations:** 

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

#### **Additional Information:**

See original report for other drugs: warfarin and venlafaxine.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 140242 Seq: 1 Gender: F

Reported: 03/06/1999 Weight:

Hospitalisation: Admitted to hospital Age: 39Y
Onset Date: 27/05/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u>teaction Details.</u>	action betails.							
Preferred Term Severity		Report Description	Treatment					
Apnoea								
Hypotension			Iv fluids					
Hypothermia								
Somnolence								

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Migraine

Injection 12.5 Milligram 1 time Intravenous

Batch: Started: Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

See original report for other drug: aropax.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 140404
 Seq: 1
 Gender:
 F

 Reported:
 10/06/1999
 Weight:

Hospitalisation: Admitted to hospital Age: 27Y
Onset Date: 11/05/1999
DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Depression		Became very depressed about extreme weight gain.	
Cushing's syndrome		Patient developed cushingoid syndrome on face.	
Purpura		Pink/purple striae on axillae & lower abdomen.	
Hypertension			
Obesity			

#### **Medicine Details:**

OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily Oral	
Batch:	<b>Started:</b> 01/01/1999	<b>Stopped:</b> 07/05/1999	
LARGACTIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	150.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1999	<b>Stopped:</b> 07/05/1999	
LUVOX (Suspected)		Reason: Unspecified schizophrenia	
Tablet	100.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1999	<b>Stopped:</b> 07/05/1999	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				Fasting cortisol 370 (125-695)nmol/l.

#### **Additional Information:**

See original report for other drug details - coversyl. stopped all psychotropic tablets 4 days prior to admission. patient came in with significant paracetamol overdose. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 140828 Seq: 1 Gender: M

Reported: 24/06/1999 Weight: 92.00 Hospitalisation: Age: 40Y

**Onset Date**: 03/02/1999 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

	Preferred Term	Severity	Report Description	Treatment
Hepatitis cholestatic Severe		Severe cholestatic hepatic reaction		

#### **Medicine Details:**

Medicine Details.				
ZOLOFT (Suspected)		Reason:	Depression	
Tablet	0.0			Oral
Batch:	<b>Started:</b> 19/01/1999		Stopped:	25/01/1999
CHLORPROMAZINE HYDROCHLORII	DE (Suspected)	Reason:	Depression	
Oral application	30.0 Milligram	Daily		Oral
Batch:	Started: 25/01/1999		Stopped:	05/02/1999

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT				Peak 229u/l
	Bilirubin				Peak of 627 umol/l
	SAP = ALP				Peak 78u/l

#### **Additional Information:**

Tests returned to normal 17/6/99.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 141467 Seq: 1 Gender: M

**Reported:** 13/07/1999 **Weight:** 82.00

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia			

#### Medicine Details:

FLUPHENAZINE HYDROCHLORIDE	(Suspected)	Reason:			
	0.0				
Batch:	Started:	L TERM	Stopped:	28/07/1994	
CHLORPROMAZINE HYDROCHLOR	IDE (Suspected)	Reason:			
	0.0				
Batch:	Started:	L TERM	Stopped:	28/07/1994	
RISPERIDONE (Suspected)		Reason:			
	6.0 Mill	igram Daily			
Batch:	Started: 01/02/1	994	Stopped:	08/07/1994	

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details

#### **Additional Information:**

See original report for other drug details - metoprolol. had previous tardive dyskinesia 1993-1994 which seemed to resolve after change to clozapine, then reappeared. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 142007
 Seq: 1
 Gender: M

 Reported:
 28/07/1999
 Weight:

Hospitalisation: Age: 24Y

Onset Date: 07/07/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

touction Details.			
Preferred Term	Severity	Report Description	Treatment
Angioedema			
Dyspnoea			Treated with adrenaline, promethazine, hydrocortisone.
Face oedema			
Tongue oedema			

## **Medicine Details:**

LARGACTIL (Suspected) Reason:

Tablet 150.0 Milligram Total Oral

Batch: Started: 06/07/1999 Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient took 2 x largactil tablets at night for about 5 days. took 8 x largactil 6/7/99 then experienced symptoms.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 142549
 Seq: 1
 Gender: M

 Reported:
 11/08/1999
 Weight:

Hospitalisation: Age:

Onset Date: 05/08/1999

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

١,	teaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Tardive dyskinesia		Slight tardive dyspkinesia	
	Dysarthria		Thick speech	
	Dry mouth			

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Hiccough

Tablet 25.0 Milligram Daily Oral

Batch: Started: Stopped: 05/08/1999

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

See original report for other drugs: noten, solprin, liptior, imdur.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 142992 Seq: 1 Gender: M

Reported: 26/08/1999 Weight:

Hospitalisation: Age: 54Y
Onset Date: 13/07/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Rash			Ceased largactil and serzone. given phenergan 25mg daily.

#### **Medicine Details:**

Medicine Details.		
LARGACTIL (Suspected)	Reason:	Depression
Tablet	100.0 Milligram Daily	y Oral
Batch:	Started: 07/07/1999	<b>Stopped:</b> 14/07/1999
SERZONE (Suspected)	Reason:	Depression
Tablet	100.0 Milligram Daily	y Oral
Batch:	Started: 07/07/1999	Stopped: 14/07/1999

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details

### **Additional Information:**

See original report for details of other drug: plendil er. previous exposure to serzone did not cause a reaction.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Repo	ort D	etai	ls:
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 Case Number:
 144203
 Seq: 1
 Gender: F

 Reported:
 29/09/1999
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 24/08/1999
DOB:

Outcome: Unknown Causality: Causality possible

## **Reaction Details:**

Preferred Term	Severity	Report Description	Treatment	
Suicide attempt			Physical observations qid.	

### **Medicine Details:**

iedicine Details.			
HALOPERIDOL (Suspected)		Reason:	
	0.0		
Batch:	<b>Started:</b> 24/08/1999	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily Oral	
Batch:	<b>Started:</b> 08/09/1998	<b>Stopped:</b> 11/08/1999	
LARGACTIL (Suspected)		Reason:	
	25.0 Milligram	Daily	
Batch:	Started:	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details:			
Case Number: 144606	Seq: 1	Gender:	F
Reported: 12/10/1999		Weight:	
Hospitalisation:		Age:	
Onset Date: 31/07/1998			29/12/1934
Outcome: Unknown		Causality:	Causality possible
Reaction Details:			
Preferred Term	Severity	Report Description	Treatment
Weight increased			
Medicine Details:			
TEMAZEPAM (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	

Laboratory Investigations:

RENITEC (Other drug)

Batch:

Batch:

LARGACTIL (Suspected)

Tablet

Batch:

**DUCENE** (Other drug)

Euboratory invostigations:					
Date	Туре	Range	Date Tested	Result	Details

0.0

0.0

Started: 01/07/1998

100.0 Milligram

Started:

Started:

Reason:

Reason:

Reason:

Daily

Stopped:

Stopped:

Stopped:

Oral

CONTIN

Depression

## **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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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 145297 Seq: 1 Gender: M

Reported: 02/11/1999 Weight: 63.00 Hospitalisation: Age: 49

**Onset Date**: 14/02/1999 **DOB**: 12/10/1949

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Deafness		Difficulty hearing people speak, fullness of ears.	Gentamicin ceased.

#### Medicine Details:

Medicine Details.				
GENTAMICIN SULPHATE (Suspected)		Reason:	Prophylaxis	
Injection	900.0 Milligram	Total		Intravenous
Batch:	Started: 13/02/1999		Stopped:	15/02/1999
CHLORPROMAZINE HYDROCHLORIDE (S	uspected)	Reason:	Hiccough	
Oral application	0.0	As ne	cessary	Oral
Batch:	Started: 13/02/1999		Stopped:	15/02/1999

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Serum drug level		15/02/1999	0.2	Gentamicin levels at 5am and 12pm, dose given at 6am.
	Serum drug level		15/02/1999	3.3	Gentamicin levels at 5am and 12pm, dose given at 6am.

## **Additional Information:**

Patient previously exposed to frusemide, past exposure to gentamicin unknown. see orignal report for other drug details: aciclovir, diflucan, neupogen, pramin, losec, maxipime, cocaine mouthwash, gastro-stop, hydrocortisone, phenergan, pethidine, & lasix.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 145805
 Seq: 1
 Gender:
 F

 Reported:
 11/11/1999
 Weight:

Hospitalisation: Age: 30

**Onset Date**: 05/11/1999 **DOB**: 19/02/1969

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Congenital foot malformation			Planning surgery to remove three toes and possibly a metatarsal bone at one year of age.
Neonatal disorder		Permanent deformity	

### **Medicine Details:**

ZOLOFT (Suspected) Reason: Depression

0.0

Batch: Started: 01/01/1997 Stopped: 28/04/1999

ZACTIN (Suspected) Reason:

0.0

Batch: Started: 01/04/1999 Stopped: 28/07/1999

LARGACTIL (Suspected) Reason:

0.0

Batch: Started: Stopped:

MELLERIL (Suspected) Reason: Depression

Tablet 3.0 Dose Unspecified Daily Oral

**Batch: Started:** 01/01/1997 **Stopped:** 28/04/1999

## **Laboratory Investigations:**

Date	Туре	Range	Date Tested	Result	Details
	Other data				Hypertrophic foot from his mid foot distally with an extra toe diagnosed as localised giantism.

#### Additional Information:

In 1997 mother started taking zoloft and 6 mths later started taking melleril. then she became pregnant. she was taking zoloft, melleril, zactin and largactil during pregnancy, also smoking 20-30 cigarettes per day, no alcohol. she is heb b vacc., syphilis neg. and rubella immunised. on 5/11/99 she had her 4th baby boy, born by spontaneous vaginal delivery at full term. he was noted as having a congenital abnormality of his left foot. he had a hypertrophic foot from his mid foot distally with an extra toe. his first two toes and his little toe and the medial side of his foot are normal. he has been seen by an orthopaedic surgeon and diagnosed with localised giantism. surgery is planned, otherwise the baby is doing well, he is bottle fed and gaining weight normally, he is due to

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: 146025					
ase Mullibel. 140020	Seq: 1			Gender:	F
Reported: 19/11/1999				Weight:	
spitalisation: Admitted to hos	spital			Age:	AD
Onset Date:				DOB:	
Outcome: Not yet recovered	ed			Causality:	Causality possible
action Details:					
Preferred Term	Severity	Repo	rt Description		Treatment
uscle twitching		Baby expereince	d twitching in leg		
onvulsion neonatal					
rug withdrawal syndrome neona	ata				
ervousness					
edicine Details:					
		Reas	on:		
ledicine Details: SERTRALINE HYDROCHLORIDE (Sus	spected)	Reas			
SERTRALINE HYDROCHLORIDE (Sus Batch:	0.0 Started:	Reas	on: Stopped:	:	
SERTRALINE HYDROCHLORIDE (Sus	0.0 Started: DE (Suspected)	Reas Reas	Stopped	:	
SERTRALINE HYDROCHLORIDE (Sus Batch: CHLORPROMAZINE HYDROCHLORID	0.0 Started: DE (Suspected) 0.0		Stopped:		
Batch:  Batch:  Batch:  Batch:  Batch:  Batch:	0.0 Started: DE (Suspected)	Reas	Stopped:		
SERTRALINE HYDROCHLORIDE (Sus Batch: CHLORPROMAZINE HYDROCHLORID	0.0 Started: DE (Suspected) 0.0 Started:		Stopped:		
Batch: CHLORPROMAZINE HYDROCHLORIDE (Sustained) Batch: Batch: METHYLDOPA (Suspected)	0.0 Started:  DE (Suspected) 0.0 Started:	Reas	Stopped: Stopped:	:	
Batch:  Batch:  Batch:  Batch:  Batch:  Batch:  METHYLDOPA (Suspected)  Batch:	0.0 Started: DE (Suspected) 0.0 Started:	Reas	Stopped: Stopped: Stopped:	:	
Batch: CHLORPROMAZINE HYDROCHLORIDE Batch:  Batch: METHYLDOPA (Suspected)  Batch: YPREXA (Suspected)	0.0 Started:  DE (Suspected) 0.0 Started:  0.0 Started:	Reas Reas Reas	Stopped: Stopped: Stopped: Stopped:	:	t transfer
Batch:  Batch:  Batch:  Batch:  Batch:  Batch:  METHYLDOPA (Suspected)  Batch:	0.0 Started:  DE (Suspected) 0.0 Started:  0.0 Started:	Reas Reas	Stopped: Stopped: Stopped: Stopped: Daily	: Breast milk	s transfer
Batch: Batch: Batch: Batch: Batch: Batch: Batch: METHYLDOPA (Suspected) Batch: CYPREXA (Suspected) Oral application Batch:	0.0 Started:  0.0 Started:  0.0 Started:  10.0 Started:	Reas Reas Reas	Stopped: Stopped: Stopped: Stopped:	: Breast milk	s transfer
Batch:  Batch:  Batch:  Batch:  Batch:  Batch:  METHYLDOPA (Suspected)  Batch:  CYPREXA (Suspected)  Oral application  Batch:  Batch:  Charactery Investigations	0.0 Started:  0.0 Started:  0.0 Started:  10.0 Started:	Reas Reas Milligram	Stopped: Stopped: Stopped: Stopped: Daily	: Breast milk	

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 147085 Seq: 1 Gender: M

Reported: 17/12/1999 Weight: 77.00 Hospitalisation: Age: 34

**Onset Date**: 31/03/1999 **DOB**: 05/12/1964

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation			
Blood creatine phosphokinase incr	1		
Confusional state			
Hepatic function abnormal			
Hypertonia			
Leukocytosis			
Neuroleptic malignant syndrome	Life threatening		

#### **Medicine Details:**

Medicine Details.			
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	25.0 Milligram	Daily	
Batch:	<b>Started:</b> 01/01/1998	<b>Stopped:</b> 28/03/1999	
LARGACTIL (Suspected)		Reason:	
	400.0 Milligram	Daily	
Batch:	Started:	Stopped:	

**Laboratory Investigations:** 

	Date	Туре	Range	Date Tested	Result	Details
ĺ		Creatine				Ck increased to 4900.

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 149273 Seq: 1 Gender: M

**Reported:** 18/02/2000 **Weight:** 90.00

Hospitalisation: Age: 47Y
Onset Date: 10/02/2000 DOB:

Outcome: Recovered Causality: Causality certain

**Reaction Details:** 

caction betails.							
Preferred Term	Severity	Report Description	Treatment				
Tachycardia		138 bpm.					
Hypertension		215/100.					
Electrocardiogram abnormal		Ecg sighs settled over next 30-60 mins.					
Electrocardiogram abnormal		St segment depression.					

### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Migraine

Injection, intravenous infusion 20.0 Milligram Daily Intravenous

Batch: Started: Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

Ecg - sunus rhythum (had slowed to 98) st segment depression. chlorpromazine given slowly over 10 minutes, approx 1 minutes in infusion reactions occured.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 149488 Seq: 1 Gender: F

Reported: 21/02/2000 Weight: 61.00 Hospitalisation: Age: 23Y

Onset Date: 28/01/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Hepatic function abnormal		Elevated alt (alanine transferase).	Ceased chlorpromazine. used zuclopenthixol tab. started clozapine 12/2/2000 and zuclopenthixol withdrawn.

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason:		
Oral application	50.0 Milligram	As nece	essary	Oral
Batch:	Started: 25/01/2000		Stopped:	02/02/2000
CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason: (	Otr spec symp	psychopathol nec
Oral application	225.0 Milligram	Daily		Oral
Batch:	Started: 25/01/2000		Stopped:	02/02/2000
OLANZAPINE (Suspected)		Reason: [	Depression	
Tablet	15.0 Milligram	Daily		Oral
Batch:	Started: 12/01/2000		Stopped:	04/02/2000

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		21/12/1999	23	
	ALT = SGPT		28/12/1999	28	
	ALT = SGPT		28/01/2000	108	
	ALT = SGPT		01/02/2000	164	
	ALT = SGPT		04/02/2000	188	
	ALT = SGPT		08/02/2000	81	
	ALT = SGPT		09/02/2000	62	

## **Additional Information:**

Patient also taking moclobemide, clonazepam, propranolol and benztropine.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 149488 Seq: 1 Gender: F

Reported: 21/02/2000 Weight: 61.00 Hospitalisation: Age: 23Y

**Onset Date**: 28/01/2000 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason:		
Oral application	50.0 Milligram	As neces	ssary	Oral
Batch:	Started: 25/01/2000		Stopped:	02/02/2000
CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason: O	tr spec symp	psychopathol nec
Oral application	225.0 Milligram	Daily		Oral
Batch:	Started: 25/01/2000		Stopped:	02/02/2000
OLANZAPINE (Suspected)		Reason: D	epression	
Tablet	15.0 Milligram	Daily		Oral
Batch:	Started: 12/01/2000		Stopped:	04/02/2000

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		11/02/2000	55	
	Bilirubin				Bilirubin always normal.
	GGT = SGGT =		21/12/1999	12	
	GGT = SGGT =		01/02/2000	23	
	GGT = SGGT =		04/02/2000	26	
	GGT = SGGT =		08/02/2000	25	
	GGT = SGGT =		11/02/2000	21	

## **Additional Information:**

Patient also taking moclobemide, clonazepam, propranolol and benztropine.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 149488 Seq: 1 Gender: F

Reported: 21/02/2000 Weight: 61.00 Hospitalisation: Age: 23Y

Onset Date: 28/01/2000 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason:		
Oral application	50.0 Milligram	As necessary	Oral	
Batch:	Started: 25/01/2000	Stopped	: 02/02/2000	
CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason: Otr spec sym	np psychopathol nec	
Oral application	225.0 Milligram	Daily	Oral	
Batch:	Started: 25/01/2000	Stopped	: 02/02/2000	
OLANZAPINE (Suspected)		Reason: Depression		
Tablet	15.0 Milligram	Daily	Oral	
Batch:	<b>Started:</b> 12/01/2000	Stopped	: 04/02/2000	

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =		09/02/2000	23	
	GGT = SGGT =		28/01/2000	18	
	GGT = SGGT =		28/12/1999	16	
	SAP = ALP		21/12/1999	83	
	SAP = ALP		28/12/1999	95	
	SAP = ALP		28/01/2000	108	
	SAP = ALP		01/02/2000	108	

## **Additional Information:**

Patient also taking moclobemide, clonazepam, propranolol and benztropine.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 149488 Seq: 1 Gender: F

Reported: 21/02/2000 Weight: 61.00 Hospitalisation: Age: 23Y

Onset Date: 28/01/2000 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason:			
Oral application	50.0 Milligram	As necessary	Oral		
Batch:	Started: 25/01/2000	Stopped:	02/02/2000		
CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason: Otr spec sym	p psychopathol nec		
Oral application	225.0 Milligram	Daily	Oral		
Batch:	Started: 25/01/2000	Stopped:	02/02/2000		
OLANZAPINE (Suspected)		Reason: Depression			
Tablet	15.0 Milligram	Daily	Oral		
Batch:	<b>Started:</b> 12/01/2000	Stopped:	04/02/2000		

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP		04/02/2000	112	
	SAP = ALP		08/02/2000	101	
	SAP = ALP		09/02/2000	96	
	SAP = ALP		11/02/2000	103	

## **Additional Information:**

Patient also taking moclobemide, clonazepam, propranolol and benztropine.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 149609 Seq: 1 Gender: M

Reported: 24/02/2000 Weight:
Hospitalisation: Age: 43

**Onset Date**: 31/08/1999 **DOB**: 03/05/1956

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Vomiting			

## **Medicine Details:**

LARGACTIL (Suspected) Reason:

Oral Liquid 2.5 Millilitre 1 time Oral

Batch: Started: Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

Patient experienced symptoms ten minutes after taking largactil syrup. patient was also taking cogentin and modecate. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 149689 Seq: 1 Gender: M

Reported: 28/02/2000 Weight:
Hospitalisation: Age: 43

**Onset Date**: 31/08/1999 **DOB**: 03/05/1956

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Vomiting			

## **Medicine Details:**

LARGACTIL (Suspected) Reason:

Oral Liquid 2.5 Millilitre 1 time Oral

Batch: Started: Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

Patient was also taking cogentin, modecate, disprin. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 150547 Seq: 1 Gender: F
Reported: 21/03/2000 Weight:
Hospitalisation: Admitted to hospital Age: 24Y

Onset Date: 31/03/2000 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

reaction Details.	action betails.							
Preferred Term	Severity	Report Description	Treatment					
Agranulocytosis			Zyprexa, fluoxetine,diazepam,sodium valproate and chlorpromazine ceased.					
Neutropenia								

## **Medicine Details:**

FLUOXETINE HYDROCHLORIDE (Other dru	g)		Reason:	
Capsule	20.0	Milligram	Daily	Oral
Batch:	Started:			Stopped:
ZYPREXA (Suspected)			Reason:	
Tablet	5.0	Milligram	Daily	Oral
Batch:	Started:			Stopped:
DIAZEPAM (Suspected)			Reason:	
	10.0	Milligram	Daily	
Batch:	Started:			Stopped:
SODIUM VALPROATE (Suspected)			Reason:	
	800.0	Milligram	Daily	
Batch:	Started:			Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils				Neutrphils / 0.49 x 1000000 cells/ml / mar-200/ below, resulted in 49000000 cell/l.

## **Additional Information:**

The patient has no haematological history and has an eating disorder. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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**Report Details:** 

Case Number: 150547

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

Reported:	21/03/2000				Weight:	
Hospitalisation:	Admitted to hospital				Age:	24Y
Onset Date:	31/03/2000				DOB:	
Outcome:	Recovered				Causality:	Causality possible
Reaction Detai	ls:					
<b>Medicine Det</b>	ails:					
CHLORPROMAZIN	IE HYDROCHLORIDE (Su	spected)		Reason:		
		10.0	Milligram	Daily		
Batch:		Started:			Stopped:	
Laboratory In	voctigations					
Laboratory In	ivestigations.					
Additional Inf						
The patient has no	haematological history	and has an	eating disord	ler the date	of onset is not neces	sarily accurate but indicates
mai onsei occurre	a sometime during the n	nonul.				

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 151642
 Seq: 1
 Gender: M

 Reported:
 14/04/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 25Y
Onset Date: 19/04/1999
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

١,	teaction betails.				
	Preferred Term	Severity	Report Description	Treatment	
	Face oedema		Lower lip swelling		
	Tongue oedema		Swollen tongue	Hydrocortisone, phenergan.	
	Dyspnoea				Ì

## **Medicine Details:**

LARGACTIL (Suspected)

Reason:

25.0 Milligram Daily

Batch: Started: 19/04/1999 Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

Patient was also taking methadone, luvox, panadeine forte. reaction developed after 2nd dose of largactil.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

Case Number: 152154 Gender: M Seq: 1 Weight: Reported: 26/04/2000

Hospitalisation: Admitted to hospital **Age:** 37

Onset Date: 19/04/2000 **DOB:** 31/10/1962

Outcome: Recovered Causality: Causality possible

## **Reaction Details:**

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			

## **Medicine Details:**

OLANZAPINE (Other drug)		Reason:			
	0.0				
Batch:	Started:			Stopped:	
RISPERIDONE (Suspected)			Reason:		
	0.0				
Batch:	Started:			Stopped:	
CHLORPROMAZINE HYDROCHLORIDE (Suspected)			Reason:		
	0.0				
Batch:	Started:			Stopped:	
CLOZARIL (Suspected)			Reason:	Unspecified schizophrenia	
Tablet	500.0	Milligram	Daily	Oral	

Stopped:

CONTIN

Laboratory Investigations:

Batch:

<u>Lubol atol</u>	abolatory 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.

Started: 01/01/1997

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report De	tails:				
Case Numb	er: 152363	Seq: 1		Gend	ler: F
	<b>ed</b> : 04/05/200	•		Weig	ht:
Hospitalisation				_	ge: A3
Onset Da					OB:
	<b>ne:</b> Unknown				ity: Causality possible
Reaction De				Guasai	ny. Caasanty possible
	ferred Term	Severity	Report D	Description	Treatment
Deafness			learing impairment.	•	
Medicine [	Details:				
AVAPRO (Sus			Reason:		
		0.0			
Batch	n:	<b>Started:</b> 01/01	/1999	Stopped:	
CHLORPROM	AZINE HYDROCI	HLORIDE (Suspected)	Reason:		
		0.0			
Batch	n:	Started:		Stopped:	
SERTRALINE	HYDROCHLORI	DE (Suspected)	Reason:		
		0.0			
Batch	1:	Started:		Stopped:	
Labaratan	. Invoction	iono			
Date	y Investigat Type	Range Date Tested	d Result	Г	Details
Date	Турс	range Date restet	T Result		octans .
					J
Additional	Informatio	n:			
		ccurate but indicates that s	tart occurred somet	ime during the vear.	
2 2 2 3 2 3 2 3 3 3					

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 152397
 Seq: 1
 Gender:
 F

 Reported:
 05/05/2000
 Weight:

Hospitalisation: Age: 60

**Onset Date: DOB:** 26/12/1939

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botalio.								
Preferred Term	Severity	Report Description	Treatment					
Thinking abnormal		Dullness in the head						
Disturbance in attention		Lack of alertness and lack of concentration.						
Confusional state								
Dizziness								

### **Medicine Details:**

Medicine Details.					
VENTOLIN (Other drug)			Reason:		
	0.0				
Batch:	Started:			Stopped:	
LARGACTIL (Suspected)			Reason:	Anxiety neurosis	
Tablet	50.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

Symptoms starts when patient gets out of bed continues for a few hours.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 153802
 Seq: 1
 Gender: F

 Reported:
 15/06/2000
 Weight:

Hospitalisation: Age: 69

Onset Date: DOB: 26/12/1930

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

caction betails.				
Preferred Term	Severity	Report Description	Treatment	l
Disturbance in attention		Impairment of concentration expecially for driving		
Dizziness			Mcer? - for dullness in head.	l

## **Medicine Details:**

LARGACTIL (Suspected)Reason:Nausea and vomitingTablet50.0 MilligramDailyOral

Batch: Started: 01/03/2000 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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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 155233 Seq: 1 Gender: F

Reported: 20/07/2000 Weight:
Hospitalisation: Age: 48Y

**Onset Date**: 07/12/1999 **DOB**:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

٠,	todotion Dotanoi			
	Preferred Term	Severity	Report Description	Treatment
	Hypotension		Bp standing 95/65	
	Syncope			Largactil ceased. diazepam dose increased.

## **Medicine Details:**

LARGACTIL (Suspected)Reason:HallucinationsOral application200.0 MilligramDailyOralBatch:Started: 07/12/1999Stopped: 09/12/1999

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

Patient also taking medroxyprogesterone, oestrogens, diazepam, lithium carbona te. p/h of allergies to risperidone - dystonia, haloperidol - urinary retention.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 155455
 Seq: 1
 Gender: M

 Reported:
 26/07/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 28Y
Onset Date: 28/01/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

104011011 20141101			
Preferred Term	Severity	Report Description	Treatment
Tachycardia		110 bpm.	
Hypotension		90/75 mmhg.	Clozaril ceased.
Nausea			
Pallor			

### **Medicine Details:**

viedicine Details:				
CHLORPROMAZINE HYDROCHLOR	IDE (Interaction)	Reason:		
	500.0 Milligram	Daily		
Batch:	Started:	St	opped:	
CLONAZEPAM (Interaction)		Reason:		
	3.0 Milligram	Daily		
Batch:	Started:	St	opped:	
CLOZARIL (Interaction)		Reason: Unspe	ecified schizophrenia	
Tablet	425.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/1997	St	opped: 02/03/2000	

**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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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 159339 Seq: 1 Gender: F

Reported: 16/11/2000 Weight:
Hospitalisation: Age: 24Y

Onset Date: 28/06/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			Chlorpromazine ceased. treated with loratadine 10mg daily.

### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

25.0 Milligram As necessary

Batch: Started: Stopped: 28/06/2000

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

Patient also taking sodium valproate, budesonide, vitamin b complex and olanzapine. patient has had chlorpromazine prn previously with no problem. rxn possibly due to patient being in sun without wearing sunblock.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 160045 Seq: 1 Gender: F

 Reported: 15/12/2000
 Weight: 80.00

 Hospitalisation:
 Age: 45Y

 Onset Date: 13/11/2000
 DOB:

Outcome: Recovered with sequelae Causality: Causality possible

**Reaction Details:** 

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Glaucoma		Bilateral acute angle closure glaucoma.	Acute treatment, bilateral iridotomy, timolol, iv mannitol, topical apraclonidine hcl, latanoprost and pilocarpine.
Mydriasis		Fixed and dilated pupil	
Eye pain		Retro-orbital pain	
Visual disturbance		Visual acuity reduced	
Nausea			
Vomiting			

## **Medicine Details:**

VENLAFAXINE HYDROCHLORIDE (Suspected) Reason: Depression

75.0 Milligram Daily

**Batch: Started:** 09/11/2000 **Stopped:** 17/11/2000

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified psychosis

150.0 Milligram Daily

**Batch: Started:** 06/11/2000 **Stopped:** 23/11/2000

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Other data				On admission, intraocular pressures were 16 mmhg in the right and 50 mmhg in the left eye, and gonioscopy revealed closed angles (grade 1-2).

### **Additional Information:**

Sequelae: decreased visual accuity. nil prior history of glaucoma. previous trials of ssri's, nil problems. patient also taking sodium valproate and lithium slow release.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 160299
 Seq: 1
 Gender:
 F

 Reported:
 28/12/2000
 Weight:

Hospitalisation: Age: 44

**Onset Date**: 16/12/2000 **DOB**: 18/02/1956

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

todotion Botans.			
Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction	Severe	Severe photosensitive rash.	Required a visit to doctor.
Urticaria			

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Unspecified schizophrenia

0.0

Batch: Started: Stopped: 18/12/2000

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

Rash developed on being discharged from hospital and walking home in sun. rash only present on sun exposed parts.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 160854 Seq: 1 Gender: M

Reported: 22/01/2001 Weight: 72.00 Hospitalisation: Age: 32Y

Onset Date: 09/01/2001 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			Phenergan 25mg tds and prednisolone 50mg/day. date of recovery: 17/1/2001.
Pruritus			
Pyrexia			

**Medicine Details:** 

TEGRETOL (Suspected)		Reason:		
	400.0 Milligram	Daily		
Batch:	Started: 01/11/2000		Stopped:	09/01/2001
ZOLOFT (Suspected)		Reason:		
	200.0 Milligram	Daily		
Batch:	Started:		Stopped:	09/01/2001
LARGACTIL (Suspected)		Reason:		
	25.0 Milligram	Daily		
Batch:	Started:		Stopped:	09/01/2001
ORUVAIL SR (Suspected)		Reason:		
	200.0 Milligram	Daily		

**Laboratory Investigations:** 

Batch:

Date	Type	Range	Date Tested	Result	Details

Stopped: 09/01/2001

## **Additional Information:**

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

Started:

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Hospitalisation: Onset Date:	22/01/2001 09/01/2001 Recovered	Seq: 1		Gender: Weight: Age: DOB: Causality:	72.00
Medicine Deta			Reason:		
2010N (Guspecter	ω,	30.0 Mil			
Batch:		Started:	· ·	Stopped:	
Laboratory In	vestigations:				
Additional Inf the dosage start da		y accurate but indic	ates that start occurred	sometime during the	month.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 161118
 Seq: 1
 Gender:
 F

 Reported:
 01/02/2001
 Weight:

Hospitalisation: Age: 23

**Onset Date**: 24/01/2001 **DOB**: 25/05/1977

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Dystonia	Life threatening	Severe dystonia reaction	Given cogentin im.
Oculogyration			

## **Medicine Details:**

CLOPIXOL-ACUPHASE (Suspected)		Reason:	Unspecified ps	ychosis
Injection	100.0 Milligram	1 time	)	Intramuscular
Batch:	Started: 22/01/2001		Stopped:	22/01/2001
CHLORPROMAZINE HYDROCHLORIDE (	Suspected)	Reason:		
	100.0 Milligram	Daily		
Batch:	Started: 22/01/2001		Stopped:	23/01/2001
RISPERIDONE (Suspected)		Reason:		
	1.0 Milligram	Daily		
	1.0 Willingram	24,		
Batch:	Started: 23/01/2001	24,	Stopped:	24/01/2001
Batch: DIAZEPAM (Suspected)	· ·	Reason:	Stopped:	24/01/2001
	· ·		Stopped:	24/01/2001

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

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

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 161536 Seq: 1 Gender: F

Reported: 14/02/2001 Weight: 90.00 Hospitalisation: Age: 21Y

Onset Date: 09/08/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

100.00.00.00.00.00.			
Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Mainly on face & trunk.	Chlorpromazine recommenced on 9.8.00 and finally ceased on 24.8.00. date of recovery 25.8.00.

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason:

225.0 Milligram Daily

Batch: Started: 28/07/2000 Stopped: 06/08/2000

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Skin biopsy				Skin biopsy done.

### **Additional Information:**

Patient also taking heparin, lasix, chlovescent, hydrocortisone, veuronium, actrapid, morphine, midazolam, fluconazole, maxepa, nilstat, losec, sorbilax and microlax.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 161539 Seq: 1 Gender: F

**Reported:** 14/02/2001 **Weight:** 80.00

Hospitalisation: Age:
Onset Date: 07/02/2001
DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

eaction Details.								
Preferred Term	Severity	Report Description	Treatment					
Cellulitis								
Injection site reaction			Treated with antibiotics. required a visit to doctor.					

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Headache

50.0 Milligram Daily

Batch: Started: 07/02/2001 Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

Drug not expired but colour changed from clear to light yellow.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 161845 Seq: 1 Gender: M

Reported: 23/02/2001 Weight:

Hospitalisation: Age: 23Y
Onset Date: 03/02/2001
DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Ceased chlorpromazine.

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Other disturbance of sensation

75.0 Milligram Daily

**Batch: Started:** 01/02/2001 **Stopped:** 03/02/2001

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Sodium		03/02/2001	135	Prior to chlorpromazine (na +) was 145.

## **Additional Information:**

Patient was also taking flucloxacillin, gentamicin, alepam, ventolin, atrovent

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Report Details:

Case Number: 162245

Reported: 05/03/2001

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

Weight:

Onset Date:				Age: 21Y			
	DOB:						
Outcome: Recovered					Causality: Causality possible		
action Details:		.,		- · · ·	<u> </u>	<del></del>	
Preferred Term	Sev	erity	•	Description		Treatment	
araesthesia		На	Illucinations of ins	ects on skin.			
nxiety izziness							
rug withdrawal syndrome							
yperhidrosis							
somnia							
edicine Details:	OPIDE (Suspen	otod)	Reason				
ALORPROMAZINE HTDROCHL	-OKIDE (Suspec	50.0 Mill					
Batch:	Sta	rted:	igiaiii Da	Stopped:			
/ENLAFAXINE HYDROCHLORID		rteu.	Reason				
	_ (,	300.0 Mill					
			o .				
Batch:	Sta	rted:		Stopped:			
Batch: NITRAZEPAM (Suspected)	Sta	rted:	Reason				
	Sta	rted: 10.0 Mill		: ily			
				:			
NITRAZEPAM (Suspected)	Sta	10.0 Mill		: ily	Details		

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 162735
 Seq: 1
 Gender: M

 Reported:
 15/03/2001
 Weight:

Hospitalisation: Age: 34

**Onset Date**: 06/01/2001 **DOB**: 17/02/1966

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction		Rash over face and exposed parts of the limbs	Phenergan, rikoderm lotion, strict sun protection, hamilton wash, signacort cream, elocon oin.
Face oedema			
Rash erythematous			
Seborrhoea			

### **Medicine Details:**

modicino Botanoi			
LARGACTIL (Suspected)		Reason: Unspecified ps	ychosis
Tablet	100.0 Milligram	As necessary	Oral
Batch:	Started: 27/10/2000	Stopped:	03/01/2001
QUILONUM SR (Suspected)		Reason:	
	1.3 Gram	Daily	
Batch:	Started: 05/01/2001	Stopped:	12/01/2001

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details

## **Additional Information:**

Patient also taking flupenthixol, sodium valproate, clonazepam.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details:			
Case Number: 163769 Reported: 17/04/200 Hospitalisation: Onset Date: 28/02/200 Outcome: Unknown	01		Gender: U Weight: Age: 17 DOB: 25/01/1984 Causality: Causality possible
Reaction Details:  Preferred Term	Severity	Report Descriptio	n Treatment
Pallor Oculogyration Somnolence Hypertonia Coordination abnormal Coma Vomiting	Ap Ey Sle Sti	peared pale. es rolling back. ept immediately. ff arms. esteady gait.	Given benztropine 2mg/ orally.
Medicine Details:  CHLORPROMAZINE HYDROCI  Batch:	HLORIDE (Suspected) 100.0 Mill Started:		ped:
Laboratory Investigat			
Date Type	Range Date Tested	Result	Details
	l		

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Repo lospitalisat Onset D	Date:		1		We	ender: U eight: Age: DOB:
	me: Recovere	d			Caus	sality: Causality possible
eaction <b>D</b>	eferred Term	Se	verity	Reno	ort Description	Treatment
Coordinatio			. Only	Пор	Dooonphon	Hodunon
<b>Medicine</b> LARGACTIL Bate	(Suspected)	Si	0.0 tarted:	Rea	son: Unspecified schize Stopped:	ophrenia
<b>Laborato</b> Date	<b>ry Investigat</b> Type	<b>ions:</b> Range	Date Tested	Result		Details
Additiona	al Informatio	n:				
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Re



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 164822
 Seq: 1
 Gender: M

 Reported:
 24/05/2001
 Weight:

Hospitalisation: Age: 31

**Onset Date**: 03/05/2001 **DOB**: 01/08/1969

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

Neaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Urinary retention			Chlorpromazine and benztropine withdrawn, changed to risperidone.

#### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified psychosis

100.0 Milligram As necessary

**Batch**: **Started**: 01/05/2001 **Stopped**: 03/05/2001

BENZTROPINE MESYLATE (Suspected) Reason: Unspecified psychosis

1.0 Milligram As necessary

Batch: Started: 02/05/2001 Stopped: 03/05/2001

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient recovered 3/5/01.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Rei	po	rt	De	tai	ls:
-----	----	----	----	-----	-----

 Case Number:
 164948
 Seq: 1
 Gender: M

 Reported:
 28/05/2001
 Weight:

Hospitalisation: Age: 60

**Onset Date**: 18/05/2001 **DOB**: 08/12/1940

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Priapism			Cavernosal drainage and aramine.

# **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Depression

2.0 Dose Unspecified Daily

**Batch: Started:** 17/05/2001 **Stopped:** 18/05/2001

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 165923 Seq: 1 Gender: F
Reported: 28/05/2001 Weight:
Hospitalisation: Age: AD

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

104011011 20141101			
Preferred Term	Severity	Report Description	Treatment
Neonatal disorder			
Pulmonary hypertension			Required a visit to doctor.

## **Medicine Details:**

Medicine Details.			
EPILIM (Suspected)		Reason:	Other&unspecified epilepsy
	2.0 Gr	ram Daily	
Batch:	Started:		Stopped:
LARGACTIL (Suspected)		Reason:	Other&unspecified epilepsy
	200.0 Mi	lilligram Daily	
Batch:	Started:		Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Other data				Baby born with narrowing of pulmonary arteries.

## **Additional Information:**

Mother is an epileptic, on epilim and largactil throughout the pregnancy.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 166869
 Seq: 1
 Gender: M

 Reported:
 25/07/2001
 Weight:

**Hospitalisation:** Admitted to hospital **Age:** 26

**Onset Date**: 16/07/2001 **DOB**: 12/06/1975

Outcome: Recovered Causality: Causality possible

Reaction Details:

	I _		
Preferred Term	Severity	Report Description	Treatment
Leukopenia			Chlorpromazine discontinued.
Neutropenia			

# **Medicine Details:**

ZYPREXA (Suspected) Reason: Unspecified psychosis

30.0 Milligram Daily

Batch: Started: Stopped:

LARGACTIL (Suspected) Reason: Unspecified psychosis

400.0 Milligram Daily

Batch: Started: Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

Patient recovered on the 24/7/2001.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 167015
 Seq: 1
 Gender: M

 Reported:
 30/07/2001
 Weight:

Hospitalisation: Age: 50Y
Onset Date: 28/12/1999 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Dysuria		Difficulty in passing urine.	
Visual disturbance		Vision disturbance	
Dizziness			
Haematuria			
Hypothermia			
Pharyngitis			
Thirst			

## **Medicine Details:**

LARGACTIL (Suspected) Reason:

0.0

**Batch: Started:** 01/01/1999 **Stopped:** 28/12/1999

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

The onset date plus the dates of administration for largactil are not accurate but indicate that onset and largactil administration was sometime in 1999.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

ase Number: 168128	Soa: 1		_	
B ( ) 0=/00/0000	Seq: 1			der: M
Reported: 05/09/2001				ght: 90.00
ospitalisation:				ge: 55
Onset Date: 26/08/2001				<b>OB</b> : 21/08/1946
Outcome: Recovered			Causa	lity: Causality possible
eaction Details:  Preferred Term	Severity	Penort C	escription	Treatment
Somnolence	Seventy	Groginess	escription	Heatment
Hallucination		Groginess		
lightmare				
		Reason:		
	2.0	Reason:  Dose Unspecified As a	necessary	
	2.0 Started:		necessary Stopped:	CONTIN
Medicine Details: VENTOLIN (Other drug)  Batch: PANADEINE FORTE (Other drug	Started:	Dose Unspecified As a		CONTIN
VENTOLIN (Other drug)  Batch:	Started:	Dose Unspecified As I	Stopped:	CONTIN
VENTOLIN (Other drug)  Batch:  PANADEINE FORTE (Other drug  Batch:	Started:	Dose Unspecified As a L TERM  Reason:  Dose Unspecified As a 108/2001	Stopped: necessary Stopped: 29/08	/2001
VENTOLIN (Other drug)  Batch:  PANADEINE FORTE (Other drug  Batch:  LANOXIN (Other drug)	Started: 2.0 Started: 26/0	Dose Unspecified As a L TERM  Reason:  Dose Unspecified As a 108/2001  Reason:	Stopped: necessary Stopped: 29/08 Otr&nos disord of hea	/2001
VENTOLIN (Other drug)  Batch:  PANADEINE FORTE (Other drug)  Batch:  LANOXIN (Other drug)  Tablet	Started:  2.0 Started: 26/0 375.0	Dose Unspecified As In L TERM  Reason: Dose Unspecified As In 198/2001  Reason: Microgram Dail	Stopped: necessary Stopped: 29/08 Otr&nos disord of here y Oral	/2001 art rhythm
VENTOLIN (Other drug)  Batch:  PANADEINE FORTE (Other drug)  Batch:  LANOXIN (Other drug)  Tablet  Batch:	Started: 2.0 Started: 26/0	Dose Unspecified As a L TERM  Reason:  Dose Unspecified As a 108/2001  Reason:  Microgram Dail L TERM	Stopped: necessary Stopped: 29/08 Otr&nos disord of hea	/2001
VENTOLIN (Other drug)  Batch:  PANADEINE FORTE (Other drug)  Batch:  LANOXIN (Other drug)  Tablet	Started:  2.0 Started: 26/0 375.0 Started:	Dose Unspecified As In L TERM  Reason: Dose Unspecified As In 108/2001  Reason: Microgram Dain L TERM  Reason:	Stopped: necessary Stopped: 29/08 Otr&nos disord of hea y Oral Stopped:	/2001 art rhythm
VENTOLIN (Other drug)  Batch:  PANADEINE FORTE (Other drug)  Batch:  LANOXIN (Other drug)  Tablet  Batch:  RANI 2 (Other drug)	Started:  2.0 Started: 26/0 375.0 Started:	Dose Unspecified As In L TERM  Reason: Dose Unspecified As In 1987  Reason: Microgram Dain L TERM  Reason: Dose Unspecified Dain	Stopped: necessary Stopped: 29/08 Otr&nos disord of her y Oral Stopped:	/2001 art rhythm CONTIN
Batch:  PANADEINE FORTE (Other drug  Batch:  LANOXIN (Other drug)  Tablet  Batch:  RANI 2 (Other drug)  Batch:	Started:  2.0 Started: 26/0 375.0 Started:  1.0 Started:	Dose Unspecified As In L TERM  Reason: Dose Unspecified As In 108/2001  Reason: Microgram Dain L TERM  Reason:	Stopped: necessary Stopped: 29/08 Otr&nos disord of hea y Oral Stopped:	/2001 art rhythm
Batch: PANADEINE FORTE (Other drug  Batch:  LANOXIN (Other drug)  Tablet  Batch:  RANI 2 (Other drug)	Started:  2.0 Started: 26/0 375.0 Started:  1.0 Started:	Dose Unspecified As I L TERM  Reason: Dose Unspecified As I 08/2001  Reason: Microgram Dail L TERM  Reason: Dose Unspecified Dail L TERM	Stopped: necessary Stopped: 29/08 Otr&nos disord of her y Oral Stopped:  y Stopped:	/2001 art rhythm CONTIN

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Details:		
Case Number: 168128	Seq: 1	Gender: M

Reported: 05/09/2001 Weight: 90.00 Hospitalisation: Age: 55

Onset Date: 26/08/2001 DOB: 21/08/1946
Outcome: Recovered Causality: Causality possible

Reaction Details:

# **Medicine Details:**

AURORIX (Other drug)			Reason:	Depression	
Tablet	900.0	Microgram	Daily	Oral	
Batch:	Started:	L	. TERM	Stopped:	CONTIN
ASTRIX 100 (Other drug)			Reason:	Otr&nos disord of hear	t rhythm
Tablet	100.0	Milligram	Daily	Oral	
Batch:	Started:	L	. TERM	Stopped:	CONTIN
FLIXOTIDE (Other drug)			Reason:		
	500.0	Milligram	Daily		
Batch:	Started:	L	. TERM	Stopped:	CONTIN
LARGACTIL (Suspected)			Reason:		
	200.0	Milligram	1 time	)	
Batch:	Started:			Stopped:	

# **Laboratory Investigations:**

# **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Rei	nort	: De	tai	ls:

Case Number: 168639 Seq: 1 Gender: F

Reported: 21/09/2001 Weight: 70.00 Hospitalisation: Age: 51

**Onset Date:** 10/08/2001 **DOB:** 08/01/1950

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Aphthous stomatitis			Date of recovery 17/09/01

# **Medicine Details:**

PARACETAMOL (Suspected)		Reason: Unspecified arthritis	Unspecified arthritis		
	0.0				
Batch:	Started:	Stopped:			
CALTRATE (Suspected)		Reason:			
	600.0 Milligram	Daily			
Batch:	Started:	Stopped:			
LOSEC (Suspected)		Reason: Other diseases of esophagus			
	40.0 Milligram	Daily			
Batch:	Started:	Stopped:			
NORMISON (Suspected)		Reason: Specific disorders of sleep			
	10.0 Milligram	Daily			
Batch:	Started:	Stopped:			

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details

## **Additional Information:**

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**Report Details:** 

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Reported: 21/09 ospitalisation: Onset Date: 10/09 Outcome: Reco	8/2001		\	<b>Veight:</b> 70.00 <b>Age:</b> 51
Onset Date: 10/08 Outcome: Reco				<b>Age:</b> 51
Outcome: Reco				
	overed			<b>DOB</b> : 08/01/1950
eaction Details:			Ca	usality: Causality possible
ledicine Details:				
TEVETEN (Suspected)		Reas	_	
Oral application		Milligram	•	Oral
Batch:	Started:		Stopped:	
_ARGACTIL (Suspected)		Reas	son:	
	25.0	Milligram	Daily	
Batch:	Started:		Stopped:	
PREPULSID (Suspected)		Reas		of esophagus
	30.0	Milligram	Daily	
Batch:	Started:		Stopped:	

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 168853
 Seq: 1
 Gender: M

 Reported:
 03/10/2001
 Weight:

Hospitalisation: Age: 59

**Onset Date**: 23/08/2001 **DOB**: 06/04/1942

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

١,	todotion Botans.			
	Preferred Term	Severity	Report Description	Treatment
	Agitation		Became more agitated.	
	Rash			
	Tongue oedema			

## **Medicine Details:**

HEPARIN SODIUM (Other drug)

Reason: Phleb&thrombophleb lowr extrem

Injection 0.0 Subcutaneous

Batch: Started: 17/08/2001 Stopped:

PARACETAMOL (Other drug) Reason: Pain

1.0 Gram As necessary

Batch: Started: 17/08/2001 Stopped:

TRAMADOL HYDROCHLORIDE (Other drug) Reason: Pain

50.0 Milligram As necessary

Batch: Started: 17/08/2001 Stopped:

SALBUTAMOL (Other drug) Reason:

5.0 Milligram As necessary

Batch: Started: 17/08/2001 Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

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Report Details:

Case Number: 168853

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

Age: 59   DOB: 06/04/1942   Causality: Causality probable   Causality: Causality probable   Causality: Causality probable   Causality: Causality probable   Causality: Causality probable   Causality: Causality probable   Causality: Causality probable   Causality: Causality probable   Causality: Causality probable   Causality: Causality probable   Causality: Causality probable   Causality: Causality: Causality probable   Causality: Caus			Weight:
Outcome: Recovered  Acaction Details:    Causality: Causality probable   Causality   Causa			<b>Age</b> : 59
ASPIRIN (Other drug)  Batch: Started: 17/08/2001  Batch: Started: 17/08/2001  Batch: Started: Started: Stopped:  METOPROLOL TARTRATE (Other drug)  Neason: Pain in chest Stopped:  Stopped:			<b>DOB</b> : 06/04/1942
Reason:   Stopped:			Causality: Causality probable
ASPIRIN (Other drug)  Batch: Started: Stopped:  DILTIAZEM HYDROCHLORIDE (Other drug)  Batch: Started: 17/08/2001  Batch: Started: 17/08/2001  AMIODARONE HYDROCHLORIDE (Other drug)  Tablet 400.0 Milligram Daily  Batch: Started: 22/08/2001  Batch: Started: 22/08/2001  METOPROLOL TARTRATE (Other drug)  100.0 Milligram Daily  Reason: Otr&nos disord of heart rhythm  Stopped:  Reason: Otr&nos disord of heart rhythm  Daily  Daily  Oral  Stopped:			
ASPIRIN (Other drug)  Batch: Started: Stopped:  DILTIAZEM HYDROCHLORIDE (Other drug)  Batch: Started: 17/08/2001  Batch: Started: 17/08/2001  AMIODARONE HYDROCHLORIDE (Other drug)  Tablet 400.0 Milligram Daily  Batch: Started: 22/08/2001  Batch: Started: 22/08/2001  METOPROLOL TARTRATE (Other drug)  100.0 Milligram Daily  Reason: Otr&nos disord of heart rhythm  Stopped:  METOPROLOL TARTRATE (Other drug)  100.0 Milligram Daily  Daily  Daily  Oral  Stopped:			
ASPIRIN (Other drug)  Batch:  Started:  DILTIAZEM HYDROCHLORIDE (Other drug)  Batch:  Started:  90.0 Milligram  Daily  Batch:  Stopped:  Pain in chest  Daily  Stopped:  Stopped:  AMIODARONE HYDROCHLORIDE (Other drug)  Tablet  400.0 Milligram  Daily  Oral  Stopped:  METOPROLOL TARTRATE (Other drug)  100.0 Milligram  Daily  Reason:  Otr&nos disord of heart rhythm  Stopped:  Stopped:  Stopped:  Stopped:  Otr&nos disord of heart rhythm  Daily  Oral  Daily  Otr&nos disord of heart rhythm  Daily  Daily  Otr&nos disord of heart rhythm  Daily			
ASPIRIN (Other drug)  Batch:  Started:  DILTIAZEM HYDROCHLORIDE (Other drug)  Batch:  Started:  90.0 Milligram  Daily  Batch:  Stopped:  Pain in chest  Daily  Stopped:  Stopped:  AMIODARONE HYDROCHLORIDE (Other drug)  Tablet  400.0 Milligram  Daily  Oral  Stopped:  METOPROLOL TARTRATE (Other drug)  100.0 Milligram  Daily  Reason:  Otr&nos disord of heart rhythm  Stopped:  Stopped:  Stopped:  Stopped:  Otr&nos disord of heart rhythm  Daily  Oral  Daily  Otr&nos disord of heart rhythm  Daily  Daily  Otr&nos disord of heart rhythm  Daily			
ASPIRIN (Other drug)  Batch:  Started:  DILTIAZEM HYDROCHLORIDE (Other drug)  Batch:  Started:  90.0 Milligram  Daily  Batch:  Stopped:  Pain in chest  Daily  Stopped:  Stopped:  AMIODARONE HYDROCHLORIDE (Other drug)  Tablet  400.0 Milligram  Daily  Otr&nos disord of heart rhythm  Tablet  Started: 22/08/2001  Stopped:  METOPROLOL TARTRATE (Other drug)  100.0 Milligram  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily			
ASPIRIN (Other drug)  Batch:  Started:  DILTIAZEM HYDROCHLORIDE (Other drug)  Batch:  Started:  90.0 Milligram  Daily  Batch:  Stopped:  Pain in chest  Daily  Stopped:  Stopped:  AMIODARONE HYDROCHLORIDE (Other drug)  Tablet  400.0 Milligram  Daily  Otr&nos disord of heart rhythm  Tablet  Started: 22/08/2001  Stopped:  METOPROLOL TARTRATE (Other drug)  100.0 Milligram  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily			
ASPIRIN (Other drug)  Batch:  Started:  DILTIAZEM HYDROCHLORIDE (Other drug)  Batch:  Started:  90.0 Milligram  Daily  Batch:  Stopped:  Pain in chest  Daily  Stopped:  Stopped:  AMIODARONE HYDROCHLORIDE (Other drug)  Tablet  400.0 Milligram  Daily  Otr&nos disord of heart rhythm  Tablet  Started: 22/08/2001  Stopped:  METOPROLOL TARTRATE (Other drug)  100.0 Milligram  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily			
ASPIRIN (Other drug)  Batch:  Started:  DILTIAZEM HYDROCHLORIDE (Other drug)  Batch:  Started:  90.0 Milligram  Daily  Batch:  Stopped:  Pain in chest  Daily  Stopped:  Stopped:  AMIODARONE HYDROCHLORIDE (Other drug)  Tablet  400.0 Milligram  Daily  Otr&nos disord of heart rhythm  Tablet  Started: 22/08/2001  Stopped:  METOPROLOL TARTRATE (Other drug)  100.0 Milligram  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily			
ASPIRIN (Other drug)  Batch:  Started:  DILTIAZEM HYDROCHLORIDE (Other drug)  Batch:  Started:  90.0 Milligram  Daily  Batch:  Stopped:  Pain in chest  Daily  Stopped:  Stopped:  AMIODARONE HYDROCHLORIDE (Other drug)  Tablet  400.0 Milligram  Daily  Otr&nos disord of heart rhythm  Tablet  Started: 22/08/2001  Stopped:  METOPROLOL TARTRATE (Other drug)  100.0 Milligram  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily			
ASPIRIN (Other drug)  Batch:  Started:  DILTIAZEM HYDROCHLORIDE (Other drug)  Batch:  Started:  90.0 Milligram  Daily  Batch:  Stopped:  Pain in chest  Daily  Stopped:  Stopped:  AMIODARONE HYDROCHLORIDE (Other drug)  Tablet  400.0 Milligram  Daily  Otr&nos disord of heart rhythm  Tablet  Started: 22/08/2001  Stopped:  METOPROLOL TARTRATE (Other drug)  100.0 Milligram  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily			
ASPIRIN (Other drug)  Batch:  Started:  DILTIAZEM HYDROCHLORIDE (Other drug)  Batch:  Started:  90.0 Milligram  Daily  Batch:  Stopped:  Pain in chest  Daily  Stopped:  Stopped:  AMIODARONE HYDROCHLORIDE (Other drug)  Tablet  400.0 Milligram  Daily  Otr&nos disord of heart rhythm  Tablet  Started: 22/08/2001  Stopped:  METOPROLOL TARTRATE (Other drug)  100.0 Milligram  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily			
ASPIRIN (Other drug)  Batch:  Started:  DILTIAZEM HYDROCHLORIDE (Other drug)  Batch:  Started:  90.0 Milligram  Daily  Batch:  Stopped:  Pain in chest  Daily  Stopped:  Stopped:  AMIODARONE HYDROCHLORIDE (Other drug)  Tablet  400.0 Milligram  Daily  Otr&nos disord of heart rhythm  Tablet  Started: 22/08/2001  Stopped:  METOPROLOL TARTRATE (Other drug)  100.0 Milligram  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily			
ASPIRIN (Other drug)  Batch:  Started:  DILTIAZEM HYDROCHLORIDE (Other drug)  Batch:  Started:  90.0 Milligram  Daily  Batch:  Stopped:  Pain in chest  Daily  Stopped:  Stopped:  AMIODARONE HYDROCHLORIDE (Other drug)  Tablet  400.0 Milligram  Daily  Otr&nos disord of heart rhythm  Tablet  Started: 22/08/2001  Stopped:  METOPROLOL TARTRATE (Other drug)  100.0 Milligram  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily  Otr&nos disord of heart rhythm  Daily			
Batch: Started: Stopped:  DILTIAZEM HYDROCHLORIDE (Other drug) Reason: Pain in chest  90.0 Milligram Daily  Batch: Started: 17/08/2001 Stopped:  AMIODARONE HYDROCHLORIDE (Other drug) Reason: Otr&nos disord of heart rhythm  Tablet 400.0 Milligram Daily Oral  Batch: Started: 22/08/2001 Stopped:  METOPROLOL TARTRATE (Other drug) Reason: Otr&nos disord of heart rhythm  100.0 Milligram Daily Oral  Stopped:		Bassani	
Batch: Started: Stopped:  DILTIAZEM HYDROCHLORIDE (Other drug)  Batch: Started: 17/08/2001  Batch: Started: 17/08/2001  AMIODARONE HYDROCHLORIDE (Other drug)  Tablet 400.0 Milligram Daily  Batch: Started: 22/08/2001  Batch: Started: 22/08/2001  METOPROLOL TARTRATE (Other drug)  100.0 Milligram Daily  Otr&nos disord of heart rhythm  Stopped:  METOPROLOL TARTRATE (Other drug)  Daily  Daily  Otr&nos disord of heart rhythm  Daily  Daily	150.0 Milligram		
Batch: Started: 17/08/2001 Stopped:  AMIODARONE HYDROCHLORIDE (Other drug)  Batch: 400.0 Milligram  Batch: Started: 22/08/2001  Batch: Started: 22/08/2001  Stopped:  Oral  Stopped:  Oral  Stopped:  Oral  Stopped:  METOPROLOL TARTRATE (Other drug)  Daily  Otr&nos disord of heart rhythm  Oral  Stopped:  Meason: Otr&nos disord of heart rhythm  Daily  Daily  Daily  Otr&nos disord of heart rhythm  Daily		Daily	Stonnad
Batch: Started: 17/08/2001 Stopped:  AMIODARONE HYDROCHLORIDE (Other drug) Reason: Otr&nos disord of heart rhythm  Tablet 400.0 Milligram Daily Oral  Batch: Started: 22/08/2001 Stopped:  METOPROLOL TARTRATE (Other drug) Reason: Otr&nos disord of heart rhythm  100.0 Milligram Daily Daily	otal teu.	Roseon:	
Batch: Started: 17/08/2001 Stopped:  AMIODARONE HYDROCHLORIDE (Other drug) Reason: Otr&nos disord of heart rhythm  Tablet 400.0 Milligram Daily Oral  Batch: Started: 22/08/2001 Stopped:  METOPROLOL TARTRATE (Other drug) Reason: Otr&nos disord of heart rhythm  100.0 Milligram Daily	90.0 Milliaram		i aiii iii Gilest
AMIODARONE HYDROCHLORIDE (Other drug)  Tablet  400.0 Milligram  Daily  Oral  Stopped:  METOPROLOL TARTRATE (Other drug)  100.0 Milligram  Daily  Otr&nos disord of heart rhythm  Stopped:  Otr&nos disord of heart rhythm  Daily		Daily	Stonnad
Tablet 400.0 Milligram Daily Oral  Batch: Started: 22/08/2001 Stopped:  METOPROLOL TARTRATE (Other drug) Reason: Otr&nos disord of heart rhythm  100.0 Milligram Daily		Rosson:	
Batch: Started: 22/08/2001 Stopped:  METOPROLOL TARTRATE (Other drug) Reason: Otr&nos disord of heart rhythm  100.0 Milligram Daily			
METOPROLOL TARTRATE (Other drug)  Reason: Otr&nos disord of heart rhythm  100.0 Milligram Daily		Daily	
100.0 Milligram Daily	Ctartea: EE/00/E001	Reason:	
	100.0 Milligram		On all the district of the dis
Daton. Otariea. 22/00/2001 Otoppea.		Daily	Stonned:
	Started: 22/00/2001		Stopped.
additional Information:			
aboratory Investigations:		90.0 Milligram  Started: 17/08/2001  19)  400.0 Milligram  Started: 22/08/2001	150.0 Milligram Daily  Started:  90.0 Milligram Daily  Started: 17/08/2001  19) Reason: 400.0 Milligram Daily  Started: 22/08/2001  Reason: 100.0 Milligram Daily

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Hospitalisation: Onset Date:	03/10/2001 23/08/2001 Recovered	<b>Seq:</b> 1		,			able
Medicine Deta							
DIAZEPAM (Other	drug)	40.0 Milligram	Reason: Daily	Otr spec symp	psychopatho	ol nec	
Batch:		Started: 22/08/2001	Dally	Stopped:			
LARGACTIL (Susp	ected)		Reason:	Otr spec symp	psychopath	ol nec	
Injection		25.0 Milligram	Daily		Intramuscul		
Batch:		<b>Started:</b> 22/08/2001		Stopped:	23/08/2001		
Laboratory In	vestigations:						
Additional Inf	formation:						
anort Pun · 04/06/200	07 04:16PM Datah	pase, unsimo03	ADPSOC	M		Desc 272	of 405

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: 170647 Reported: 30/11/2001 Dispitalisation: Onset Date: 18/06/2001 Outcome: Recovered Paction Details:	Seq: 1		Wei <i>J</i> C	der: U ght: Age: 13Y OOB: Ality: Causality possible
Preferred Term	Severity	Report De	escription	Treatment
Dyskinesia Hypertonia Agitation	C	Odd movements of m Fightening of other m	outh and head.	lv benztropine. date of recovery: 18/6/2001.
edicine Details:		Reason:	Nausea and vomiting	9
Oral application	0.0		Oral	
	<b>.</b>			
Batch:	Started:	Pagani	Stopped:	~
CHLORPROMAZINE HYDROCHLO	ORIDE (Suspected)	Reason:	Nausea and vomiting	9
		Reason:		g
CHLORPROMAZINE HYDROCHLO Oral application Batch:  _aboratory Investigatio	ORIDE (Suspected) 0.0 Started:		Nausea and vomiting	
CHLORPROMAZINE HYDROCHLO	ORIDE (Suspected) 0.0 Started:		Nausea and vomiting	g Details
CHLORPROMAZINE HYDROCHLO Oral application Batch:  Laboratory Investigatio	ORIDE (Suspected) 0.0 Started:		Nausea and vomiting	

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

Case Number:170652Seq: 1Gender: MReported:30/11/2001Weight: 24.00Hospitalisation:Admitted to hospitalAge: 7

Onset Date: 02/10/2001 DOB: 27/04/1994

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Tongue oedema	Required Specialist Consultation	Mildly swollen tongue.	
Rash Face oedema			Required a visit to doctor. patient was hospitalised for observation. prednisolone, phenergan oral. date of recovery: 8/10/2001.

## **Medicine Details:**

LARGACTIL (Suspected) Reason: Behavior disorders of childhod

 Solution
 2.0 Millilitre
 Daily
 Oral

 Batch:
 Started: 30/09/2001
 Stopped: 02/10/2001

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 170824 Seq: 1 Gender: F

Reported: 03/12/2001 Weight: 53.00 Hospitalisation: Age: 15

**Onset Date**: 14/05/2001 **DOB**: 20/04/1986

Outcome: Unknown Causality: Causality possible

Reaction Details:

100.00.00.00.00.			
Preferred Term	Severity	Report Description	Treatment
Breast enlargement		Increased breast size	
Galactorrhoea			Dose reduction of chlorpromazine.

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified psychosis

Capsule 10.0 Milligram As necessary Oral

Batch: Started: 14/03/2001 Stopped:

**Laboratory Investigations:** 

	Date	Туре	Range	Date Tested	Result	Details
Г		Prolactin	(66-490)	14/05/2001	413	

#### **Additional Information:**

Previously experienced galactorrhoea with bericyazine.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

Case Number: 172475 Seq: 1 Gender: U

Reported: 07/02/2002 Weight: 78.00 Hospitalisation: Age: 33

**Onset Date:** 13/01/2002 **DOB:** 30/01/1968

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema	Severe		Required a visit to doctor, treated with avanza 30mg.

# **Medicine Details:**

LARGACTIL (Suspected) Reason:

100.0 Milligram Daily

Batch: Started: 19/12/2001 Stopped: 20/12/2001

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 172531 Seq: 1 Gender: M

Reported: 08/02/2002 Weight: 80.00 Hospitalisation: Age: 45

**Onset Date**: 22/07/2001 **DOB**: 23/09/1955

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			Date of recovery oct 01.

## **Medicine Details:**

LARGACTIL (Suspected) Reason:

100.0 Milligram Daily

Batch: Started: 21/07/2001 Stopped: 23/07/2001

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Reported later past akathisia to typical antipsychotics.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 173036
 Seq: 1
 Gender: M

 Reported:
 22/02/2002
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 43

Onset Date: 28/01/2002 DOB: 20/10/1958

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

recorded Botanol								
	Preferred Term	Severity	Report Description	Treatment				
	Thrombocytopenia							

## **Medicine Details:**

SODIUM VALPROATE (Other drug)		Reason:	Other&unspecified epilepsy
	2.0 Gram	Daily	

2.0 Gram Dai

Batch: Started: L TERM Stopped:

AVANZA (Suspected) Reason: Depression

30.0 Milligram Daily

**Batch**: **Started**: 22/01/2002 **Stopped**: 31/01/2002

CLONAZEPAM (Suspected) Reason: Anxiety neurosis

3.0 Milligram Daily

Batch: Started: 17/01/2001 Stopped:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Anxiety neurosis

100.0 Milligram Daily

**Batch: Started:** 17/01/2002 **Stopped:** 31/01/2002

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
17/12/2002	Platelets		01/05/2006	84	

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number:173089Seq: 1Gender: MReported:25/02/2002Weight: 75.00Hospitalisation:Admitted to hospitalAge: 42

**Onset Date:** 17/02/2002 **DOB:** 24/08/1959

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope	Life threatening		Patient admitted to icu for airway protection and haemofiltration. given bromocriptine 5mg tds. zyprexa, largactil, anafranil and xanax ceased. transferred to renal ward for continuing dialysis and management of renal function.
Blood creatine phosphokinase incr	Severe Life threatening	Severe rigidity.	

## **Medicine Details:**

XANAX (Suspected)		Reason: Obsessive compulsive neurosis
	0.5 Milligram	As necessary
Batch:	Started:	<b>Stopped:</b> 18/02/2002
ZYPREXA (Suspected)		Reason: Obsessive compulsive neurosis
	25.0 Milligram	Daily
Batch:	Started:	<b>Stopped:</b> 18/02/2002
LARGACTIL (Suspected)		Reason: Obsessive compulsive neurosis
	25.0 Milligram	Daily
Batch:	Started:	<b>Stopped:</b> 18/02/2002
ANAFRANIL (Suspected)		Reason: Obsessive compulsive neurosis
	25.0 Milligram	Daily
Batch:	Started:	Stopped: 18/02/2002

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Creatine		17/02/2002	130536	

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number:173089Seq: 1Gender: MReported:25/02/2002Weight: 75.00Hospitalisation:Admitted to hospitalAge: 42

**Onset Date**: 17/02/2002 **DOB**: 24/08/1959

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life threatening		
Neuropathy peripheral	Life threatening		
Renal impairment	Life threatening		
Rhabdomyolysis	Life threatening		
Tremor			

# **Medicine Details:**

XANAX (Suspected)		Reason: Obsessive compulsive neurosis
	0.5 Milligram	As necessary
Batch:	Started:	<b>Stopped:</b> 18/02/2002
ZYPREXA (Suspected)		Reason: Obsessive compulsive neurosis
	25.0 Milligram	Daily
Batch:	Started:	<b>Stopped:</b> 18/02/2002
LARGACTIL (Suspected)		Reason: Obsessive compulsive neurosis
	25.0 Milligram	Daily
Batch:	Started:	<b>Stopped:</b> 18/02/2002
ANAFRANIL (Suspected)		Reason: Obsessive compulsive neurosis
	25.0 Milligram	Daily
Batch:	Started:	<b>Stopped:</b> 18/02/2002

# **Laboratory Investigations:**

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 174125 Seq: 1 Gender: M

Reported: 02/04/2002 Weight: 110.00 Hospitalisation: Age: 23Y

Onset Date: 23/11/2001 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Hepatitis		Drug-induced hepatitis.	

# **Medicine Details:**

CLOZAPINE (Other drug)		Reason:	Unspecified sc	hizophrenia
Tablet	400.0 Milligram	Daily		Oral
Batch:	Started: 06/11/2001		Stopped:	
SODIUM VALPROATE (Suspected)		Reason:	Unspecifid affe	ective psychosis
Oral application	2.4 Gram	Daily		Oral
Batch:	Started: 17/09/2001		Stopped:	19/12/2001
CHLORPROMAZINE HYDROCHLORIDE	(Suspected)	Reason:	Other disturbat	nce of sensation
Oral application	800.0 Milligram	Daily		Oral
Batch:	Started: 17/09/2001		Stopped:	18/12/2001
AMITRIPTYLINE HYDROCHLORIDE (Su	spected)	Reason:	Salivary secret	tion disturbance
Tablet	25.0 Milligram	Daily		Oral
Batch:	Started: 15/11/2001		Stopped:	17/12/2001

Laboratory Investigations:

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

## **Additional Information:**

Nil allergies of relevance.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

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:

<u> </u>			1
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	ightly	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	spected)		Reason:	Anxiety neuros	sis
Tablet	200.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	21/01/2002

**Laboratory Investigations:** 

L	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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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 176160 Seq: 1 Gender: M
Reported: 11/06/2002 Weight:

Hospitalisation: Age: 27

Onset Date: 05/02/2002 DOB: 26/06/1974

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Neaction Betails.	caction betails.								
Preferred Term	Severity	Report Description	Treatment						
Leukopenia									
Neutropenia			Date of recovery 7.2.02. chlorpromazine ceased.						

#### Medicine Details:

DIAZEPAM (Other drug)		Reason:				
	5.0 Milligram	As necessary				
Batch:	Started: 01/02/2002	Stopped:	CONTIN			
CHLORPROMAZINE HYDROCHLO	RIDE (Suspected)	Reason:				
	100.0 Milligram	As necessary				
Batch:	Started: 01/02/2002	Stopped: 05/02/2	002			
CLOZAPINE (Suspected)		Reason: Unspecified schizophre	nia			
	12.5 Milligram	Daily				
Batch:	Started: 30/01/2002	Stopped: 04/03/2	002			

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		05/02/2002	1.82	
	White blood cells		05/02/2002	4.7	

## **Additional Information:**

Increasing clozapine dose from 12.5mg on 30.1.02 to 350mg on 7.2.02. non-compliant with clozapine when discharged from hospital.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Re	po	rt	De	tai	ls:
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Case Number: 177194 Seq: 1 Gender: M
Reported: 15/07/2002 Weight:

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

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

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

## **Medicine Details:**

ZUCLOPENTHIXOL ACETATE (Suspected)	)	Reason:	
	100.0 Milligram	1 time	
Batch:	Started: 29/03/2002		Stopped:
MIDAZOLAM (Suspected)		Reason:	
	5.0 Milligram	1 time	
Batch:	Started: 29/03/2002		Stopped:
CHLORPROMAZINE HYDROCHLORIDE (S	uspected)	Reason:	
	200.0 Milligram	1 time	
Batch:	Started: 29/03/2002		Stopped:
BENZTROPINE MESYLATE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 30/03/2002		Stopped:

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 178558 Seq: 1 Gender: M

Reported: 30/08/2002 Weight: 108.00 Hospitalisation: Age: 50Y

Onset Date: 13/08/2002 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Try ceasing first mirtazapine and then olanzopine.

# Medicine Details:

CHLORPROMAZINE HYDROCHLORID	DE (Suspected)	Reason: Depression	
Tablet	50.0 Milligram	As necessary	Oral
Batch:	Started: 01/08/2002	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 01/04/2002	Stopped:	03/08/2002
MIRTAZAPINE (Suspected)		Reason: Depression	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 01/08/2002	Stopped:	
LORAZEPAM (Suspected)		Reason: Depression	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started: 01/08/2002	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils				Neutrophil count 1.46.

## **Additional Information:**

The dose start dates are not necessarily accurate but indicates mirtazapine, lorazepam, chlorpramazine, olanzopine were started sometime in the month.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 179124
 Seq: 1
 Gender:
 F

 Reported:
 19/09/2002
 Weight:

**Hospitalisation**: Admitted to hospital **Age**: 37

Onset Date: 26/08/2002 DOB: 16/10/1964

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatocellular damage	Life threatening		Ceased zyprexa and largactil. patient was hospitalised.

#### Medicine Details:

Medicine Details.			
LARGACTIL (Suspected)		Reason: Unspecified schizophi	enia
Tablet	100.0 Milligram	1 time Oral	
Batch:	Started: 23/08/2002	Stopped: 23/08/	2002
ZYPREXA (Suspected)		Reason: Unspecified schizophi	enia
Tablet	5.0 Milligram	Daily Oral	
Batch:	Started: 25/08/2002	Stopped: 27/08/	2002

**Laboratory Investigations:** 

	. <u>,</u>				
Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		25/08/2002	48	
	ALT = SGPT		26/08/2002	490	
	ALT = SGPT		01/09/2002	496	
	ALT = SGPT		28/08/2002	704	
	AST = SGOT		25/08/2002	45	
	AST = SGOT		26/08/2002	289	
	AST = SGOT		28/08/2002	143	

## **Additional Information:**

Previous hepatotoxicity with chlorpromazine.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 179124
 Seq: 1
 Gender:
 F

 Reported:
 19/09/2002
 Weight:

Hospitalisation: Admitted to hospital Age: 37

Onset Date: 26/08/2002 DOB: 16/10/1964

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

#### **Medicine Details:**

Medicine Details.			
LARGACTIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	100.0 Milligram	1 time Oral	
Batch:	Started: 23/08/2002	<b>Stopped:</b> 23/08/2002	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	5.0 Milligram	Daily Oral	
Batch:	Started: 25/08/2002	Stopped: 27/08/2002	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT		01/09/2002	67	
	GGT = SGGT =		25/08/2002	38	
	GGT = SGGT =		26/08/2002	154	
	GGT = SGGT =		28/08/2002	264	
	GGT = SGGT =		01/09/2002	226	

## **Additional Information:**

Previous hepatotoxicity with chlorpromazine.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 179399
 Seq: 1
 Gender: M

 Reported:
 25/09/2002
 Weight:

Hospitalisation: Age: 32

**Onset Date: DOB:** 15/10/1969

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction			Chlorpromazine ceased.

#### **Medicine Details:**

Medicine Details.				
DIAZEPAM (Other drug)				
	10.0 Milligram	As neo	cessary	
Batch:	Started: 06/08/2002		Stopped:	CONTIN
SODIUM VALPROATE (Other drug)		Reason:		
	2.0 Gram	Daily		
Batch:	Started: 06/08/2002		Stopped:	
CHLORPROMAZINE HYDROCHLORIDE	(Suspected)	Reason:	Other disturbance of s	ensation
	400.0 Milligram	Total		
Batch:	Started: 12/08/2002		<b>Stopped:</b> 16/08/2	2002

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Photosensitive rash on his hands-swollen hands, following exposure to sun- light. patient has had previous exposure to drug and apparently experienced similar reaction in past but not documented as adr because "common" adverse effect. has received drug with noted adverse effects since then.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**DOB:** 04/07/1968

**Report Details:** 

 Case Number:
 180775
 Seq: 1
 Gender: M

 Reported:
 18/12/2002
 Weight:
 85.00

Hospitalisation: Age: 34

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Onset Date: 12/11/2002

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia		Steroid refractory autoimmune thrombocytopenia.	

# **Medicine Details:**

LARGACTIL (Suspected)	Reason: Hiccough						
	1.0 Dose Unspecified 1 time						
Batch:	Started: 01/11/2002	Stoppe	ed: 01/11/2002				
COLOXYL (Suspected)	F	Reason:					
	1.0 Dose Unspecifi	ed As necessary					
Batch:	<b>Started</b> : 04/11/2002 <b>Stopped</b> : 12/11/2002						
DILANTIN (Suspected)	F	Reason: Convulsion	ns				
Capsule	300.0 Milligram	Daily	Oral				
Batch:	<b>Started</b> : 29/10/2002 <b>Stopped</b> : 12/11/2002						
ZANTAC (Suspected)	Reason:						
Tablet	300.0 Milligram Daily Oral						
Batch:	Started: 29/10/2002 Stopped: CONTIN						

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
18/12/2002	Platelets		12/11/2002	35	
18/12/2002	Platelets		29/10/2002	237	

#### **Additional Information:**

Previous exposure as a child (febrile convulsions until 9 years of age).

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**Report Details:** 

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	180775	Seq: 1			Gender:	M
Reported:	18/12/2002				Weight:	85.00
Hospitalisation:					Age:	34
Onset Date:	12/11/2002				DOB:	04/07/1968
Outcome:	Not yet recovere	d			Causality:	Causality possible
Reaction Deta	ils:					
Medicine Det				Reason:		
DEXAMETHASON Tablet	= (Suspected)	16.0	Milligram		Oral	
		Started: 29/		Daily		CONTIN
Batch:		Started: 29/	10/2002		Stopped:	CONTIN
Laboratory Ir	vestigations:					
Additional In	formation					
	e as a child (febrile o	convulsions until	0 years of a	ne)		
rievious exposure	as a criliu (lebrile i	CONVUISIONS UNIII	9 years or a	ge).		

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 181964 Seq: 1 Gender: M

Reported:23/01/2003Weight:0.00Hospitalisation:Required a visit to the doctorAge:99U

**Onset Date:** 20/10/2002 **DOB:** 

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
		<b>. .</b>	oral steroids and antihistamines
Blister	Required Visit to Doctor		

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Rash

100.0 Milligram Daily

Batch: Started: 19/10/2002 Stopped: 21/10/2002

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient also taking olanzepine, lithium, microgynon, temazepam and spiractin.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 182560 Seq: 1 Gender: M

Reported: 07/02/2003 Weight: 0.00 Hospitalisation: Age: 94

**Onset Date**: 24/08/2002 **DOB**: 18/10/1907

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Caused or prolonged inpatient hospitalisation	BP 70/20, HR = 57 and hyponatraemia	
Syncope	Caused or prolonged inpatient hospitalisation	Syncopal episode, funny feelings, increased confusion	Atropine, IV fluids, warmed, transfusion
Renal impairment	prolonged	Syncopal episode, funny feelings, increased confusion, BP 70/20, HR = 57 and hyponatraemia	Atropine, IV fluids, warmed, transfusion

## **Medicine Details:**

GLYCERYL TRINITRATE (Suspected)		Reason:
Batch:	Started:	<b>Stopped</b> : 25/08/2002
BISACODYL (Suspected)		Reason:
	5.0 Milligram	As necessary
Batch:	Started:	Stopped: 25/08/2002
TEMAZEPAM (Suspected)		Reason:
	10.0 Milligram	Daily
Batch:	Started:	<b>Stopped:</b> 25/08/2002
FRUSEMIDE (Suspected)		Reason: Left ventricular failure
	80.0 Milligram	Daily
Batch:	Started:	<b>Stopped:</b> 25/08/2002

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
07/02/2003	Creatinine				
07/02/2003	Haemoglobin				
07/02/2003	Sodium				

## **Additional Information:**

Patient also taking aspirin, pilocarpine.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 182560 Seq: 1 Gender: M

Reported: 07/02/2003 Weight: 0.00 Hospitalisation: Age: 94

**Onset Date**: 24/08/2002 **DOB**: 18/10/1907

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anaemia	Caused or prolonged inpatient hospitalisation		
Bradycardia	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

#### **Medicine Details:**

LISINOPRIL (Suspected)			Reason:	Left ventricular failure
	20.0	Milligram	Daily	

Batch: Started: Stopped: 25/08/2002

DIGOXIN (Suspected) Reason: Otr&nos disord of heart rhythm

125.0 Microgram Daily

Batch: Started: Stopped: 25/08/2002

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason:

50.0 Milligram Daily

Batch: Started: Stopped: 25/08/2002

TIMOLOL MALEATE (Suspected) Reason: Unspecified glaucoma

Eye Drops 2.0 Dose Unspecified Daily

Batch: Started: Stopped: 25/08/2002

# **Laboratory Investigations:**

#### **Additional Information:**

Patient also taking aspirin, pilocarpine.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 182560 Seq: 1 Gender: M

Reported: 07/02/2003 Weight: 0.00 Hospitalisation: Age: 94

**Onset Date**: 24/08/2002 **DOB**: 18/10/1907

Outcome: Recovered Causality: Causality possible

Reaction Details:

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

# **Medicine Details:**

GLYCERYL TRINITRATE (Suspected)		Reason:
Batch:	Started:	<b>Stopped:</b> 25/08/2002
BISACODYL (Suspected)		Reason:
	5.0 Milligram	As necessary
Batch:	Started:	<b>Stopped:</b> 25/08/2002
TEMAZEPAM (Suspected)		Reason:
	10.0 Milligram	Daily
Batch:	Started:	<b>Stopped:</b> 25/08/2002
FRUSEMIDE (Suspected)		Reason: Left ventricular failure
	80.0 Milligram	Daily
Batch:	Started:	<b>Stopped:</b> 25/08/2002

# **Laboratory Investigations:**

## **Additional Information:**

Patient also taking aspirin, pilocarpine.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 182560 Seq: 1 Gender: M

Reported: 07/02/2003 Weight: 0.00 Hospitalisation: Age: 94

**Onset Date**: 24/08/2002 **DOB**: 18/10/1907

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

**Medicine Details:** 

LISINOPRIL (Suspected) Reason: Left ventricular failure

20.0 Milligram Daily

Batch: Started: Stopped: 25/08/2002

**DIGOXIN (Suspected)** Reason: Otr&nos disord of heart rhythm

125.0 Microgram Daily

Batch: Started: Stopped: 25/08/2002

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason:

50.0 Milligram Daily

Batch: Started: Stopped: 25/08/2002

TIMOLOL MALEATE (Suspected) Reason: Unspecified glaucoma

Eye Drops 2.0 Dose Unspecified Daily

Batch: Started: Stopped: 25/08/2002

# **Laboratory Investigations:**

#### **Additional Information:**

Patient also taking aspirin, pilocarpine.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 182575
 Seq: 1
 Gender: M

 Reported:
 10/02/2003
 Weight:
 0.00

Hospitalisation: Weight: 0.00

**Onset Date**: 24/09/2002 **DOB**: 25/07/1934

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Abnormal lever function tests	

# **Medicine Details:**

PRAVASTATIN SODIUM (Suspected)		Reason:	Othr&unspec	netabolic diseases
Tablet	20.0 Milligram	Daily		Oral
Batch:	Started: 14/09/2002		Stopped:	14/10/2002
CHLORPROMAZINE HYDROCHLORIDE (S	uspected)	Reason:		
Tablet	25.0 Milligram	Daily		Oral
Batch:	Started: 18/09/2002		Stopped:	15/10/2002
ASASANTIN SR (Suspected)		Reason:	Prophylaxis	
Capsule	2.0 Dose Unspec	ified Daily		Oral
Batch:	Started: 14/09/2002		Stopped:	23/09/2002
DIPYRIDAMOLE (Suspected)		Reason:		
Oral application	400.0 Milligram	Daily		Oral
Batch:	Started: 24/09/2002		Stopped:	08/10/2002

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
10/02/2003	ALT = SGPT	< 50	24/09/2002	7	
10/02/2003	ALT = SGPT	< 50	25/09/2002	8	
10/02/2003	ALT = SGPT	< 50	21/10/2002	169	
10/02/2003	ALT = SGPT	< 50	06/11/2002	44	
10/02/2003	ALT = SGPT	< 50	14/10/2002	270	
10/02/2003	AST = SGOT	< 40	24/09/2002	16	
10/02/2003	AST = SGOT	< 40	25/09/2002	22	

## **Additional Information:**

Patient also taking panadol, coloxyl with senna, motilium, glycerin, aspirin, plavix, losec, maxolon.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 182575 Seq: 1 Gender: M

Reported: 10/02/2003 Weight: 0.00 Hospitalisation: Age: 68

**Onset Date**: 24/09/2002 **DOB**: 25/07/1934

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

**Medicine Details:** 

MOVICOL (Suspected) Reason: Constipation

1.0 Dose Unspecified Daily

Batch: Started: 24/09/2002 Stopped: 11/10/2002

SALBUTAMOL (Suspected) Reason:

Inhalation 20.0 Milligram Daily

**Batch**: **Started**: 24/09/2002 **Stopped**: 29/10/2002

TIMENTIN (Suspected) Reason: Otr&nos infec&parasit diseases

 Injection
 12.4 Gram
 Daily
 Intravenous

 Batch:
 Started: 24/09/2002
 Stopped: 01/10/2002

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
10/02/2003	AST = SGOT	< 40	14/10/2002	191	
10/02/2003	AST = SGOT	< 40	21/10/2002	116	
10/02/2003	AST = SGOT	< 40	06/11/2002	35	
	GGT = SGGT =	< 50	24/09/2002	79	
10/02/2003	GGT = SGGT =	< 50	06/11/2002	211	
10/02/2003	GGT = SGGT =	< 50	21/10/2002	726	
	GGT = SGGT =	< 50	25/09/2002	79	

#### **Additional Information:**

Patient also taking panadol, coloxyl with senna, motilium, glycerin, aspirin, plavix, losec, maxolon.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 182575 Seq: 1 Gender: M

Reported: 10/02/2003 Weight: 0.00 Hospitalisation: Age: 68

Onset Date: 24/09/2002 DOB: 25/07/1934

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

# **Medicine Details:**

PRAVASTATIN SODIUM (Suspected)		Reason:	Othr&unspec r	metabolic diseases
Tablet	20.0 Milligram	Daily		Oral
Batch:	Started: 14/09/2002		Stopped:	14/10/2002
CHLORPROMAZINE HYDROCHLORIDE (S	uspected)	Reason:		
Tablet	25.0 Milligram	Daily		Oral
Batch:	Started: 18/09/2002		Stopped:	15/10/2002
ASASANTIN SR (Suspected)		Reason:	Prophylaxis	
Capsule	2.0 Dose Unspec	ified Daily		Oral
Batch:	Started: 14/09/2002		Stopped:	23/09/2002
DIPYRIDAMOLE (Suspected)		Reason:		
Oral application	400.0 Milligram	Daily		Oral
Batch:	Started: 24/09/2002		Stopped:	08/10/2002

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
10/02/2003	GGT = SGGT =	< 50	14/10/2002	509	
10/02/2003	LDH	110 - 250	24/09/2002	155	
10/02/2003	LDH	110 - 250	25/09/2002	447	
10/02/2003	LDH	110 - 250	14/10/2002	221	
10/02/2003	LDH	110 - 250	21/10/2002	176	
10/02/2003	LDH	110 - 250	06/11/2002	148	
10/02/2003	SAP = ALP	40 - 110	24/09/2002	131	

### **Additional Information:**

Patient also taking panadol, coloxyl with senna, motilium, glycerin, aspirin, plavix, losec, maxolon.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 182575 Seq: 1 Gender: M

Reported: 10/02/2003 Weight: 0.00 Hospitalisation: Age: 68

Onset Date: 24/09/2002 DOB: 25/07/1934

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

### **Medicine Details:**

MOVICOL (Suspected)

Reason: Constipation

1.0 Dose Unspecified Daily

Batch: Started: 24/09/2002 Stopped: 11/10/2002

SALBUTAMOL (Suspected) Reason:

Inhalation 20.0 Milligram Daily

Batch: Started: 24/09/2002 Stopped: 29/10/2002

TIMENTIN (Suspected) Reason: Otr&nos infec&parasit diseases

 Injection
 12.4 Gram
 Daily
 Intravenous

 Batch:
 Started: 24/09/2002
 Stopped: 01/10/2002

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
10/02/2003	SAP = ALP	40 - 110	25/09/2002	139	
10/02/2003	SAP = ALP	40 - 110	14/10/2002	614	
10/02/2003	SAP = ALP	40 - 110	21/10/2002	1130	
10/02/2003	SAP = ALP	40 - 110	06/11/2002	519	

#### **Additional Information:**

Patient also taking panadol, coloxyl with senna, motilium, glycerin, aspirin, plavix, losec, maxolon.

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Report Details:

Case Number: 182797

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

Reported: 12/02/2003			Weig	<b>ht:</b> 0.00
espitalisation:				<b>ge</b> : 99U
Onset Date:				OB:
Outcome: Unknown			ity: Causality possible	
action Details:		<del></del>		
Preferred Term	Severity		ort Description	Treatment
stemic lupus erythematosus	;	Systemis lupus e	erythematosus	
ledicine Details:  ZOLOFT (Suspected)		Reas	son:	
Tablet		Dose Unspecified	Oral	
Batch:	Started:		Stopped:	
TEGRETOL (Suspected)		Reas	son:	
Oral application		Dose Unspecified	Oral	
Batch:	Started:		Stopped:	
ARGACTIL (Suspected)		Reas	son:	
		Dose Unspecified		
Batch:	Started:		Stopped:	
.aboratory Investigatio	<b>ns:</b> Range Date Tes	sted Result		Details
Additional Information:				
oort Run: 01/06/2007 04:16PM	Database: pusime02	Α	DRS004	Page 400 of 495

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 182876 Seq: 1 Gender: M

Reported: 14/02/2003 Weight: 0.00 Hospitalisation: Age: 31

**Onset Date**: 09/02/2003 **DOB**: 19/07/1971

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botanoi			
Preferred Term	Severity	Report Description	Treatment
Visual acuity reduced		Reduced visual acuity, nerve fibre (axonal oedema) and choroidal lesions - almost consistent with macular infarction.	

# **Medicine Details:**

LARGACTIL (Suspected)		Reason:	
Batch:	Started:	Stopped:	
DIAZEPAM (Suspected)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started:	Stopped:	
CAMPRAL (Suspected)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started:	Stopped:	
MAXOLON (Suspected)		Reason:	
Oral application	40.0 Milligram	Daily	
Batch:	Started:	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

Methanol to be excluded.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number:183751Seq: 1Gender:MReported:06/03/2003Weight:0.00Hospitalisation:Admitted to hospitalAge: 77

**Onset Date**: 25/02/2003 **DOB**: 01/02/1926

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Severe neutropenia, agranulocytosis and pyrexia.	Neupogen for 4 days
Agranulocytosis	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

#### **Medicine Details:**

Medicine Details.			
CHLORPROMAZINE HYDROCHL	ORIDE (Suspected)	Reason:	
Batch:	Started:	Stopped:	
GLIVEC (Suspected)		Reason: Neoplasm stomach nature nos	
Capsule	400.0 Milligram	Daily Oral	
Batch:	Started: 03/02/2003	<b>Stopped</b> : 25/03/2003	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Bone marrow Neutrophils				

### **Additional Information:**

Patient recovered from agranulocytosis, but died soon after from progressive gastrointestinal stomal cancer.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report	Detail	s:
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 Case Number:
 184183
 Seq: 1
 Gender:
 F

 Reported:
 19/03/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 69Y

Onset Date: 01/07/2002 DOB:

Outcome: Not yet recovered Causality: Causality possible

### **Reaction Details:**

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Fall			Dose of Chlorpromazine and Pericyazine was halved and Benztropine.
Orthostatic hypotension			
Tardive dyskinesia			

## **Medicine Details:**

SALBUTAMOL (Other drug)	TAMOL (Other drug) Reason:					
	4.0	Dose Unspec	ified Daily			
Batch:	Started:			Stopped:		Contin
VENLAFAXINE HYDROCHLORIDE (Other	drug)		Reason:			
Capsule	75.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:		Contin
PERICYAZINE (Suspected)			Reason:			
Tablet	10.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:	01/07/2002	
CHLORPROMAZINE HYDROCHLORIDE (S	Suspected)		Reason:	Schizo-affective	e type psychos	
Tablet	200.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:	01/07/2002	

Laboratory Investigations:

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

## **Additional Information:**

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**Report Details:** 

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

	184183	Seq: 1				Gender:	•
Reported:	19/03/2003					Weight:	0.00
lospitalisation:						Age:	69Y
Onset Date:	01/07/2002					DOB:	
Outcome:	Not yet recovered	b			С	ausality:	Causality possible
eaction Detai	ls:						
<b>Medicine Deta</b>	ails:						
	SYLATE (Suspected	)		Reason:			
Tablet		2.0	Milligram	Daily		Oral	
Batch:		Started:			Stopped:	01/07/2002	
MORPHINE AND A	SPIRIN MIXTURE (St	uspected)		Reason:			
		8.0	Milligram	Daily			
Batch:		8.0 Started:	Milligram	Daily	Stopped:	01/07/2002	
Batch:			Milligram	Daily	Stopped:	01/07/2002	
Batch:			Milligram	Daily	Stopped:	01/07/2002	
Batch:			Milligram	Daily	Stopped:	01/07/2002	
Batch:			Milligram	Daily	Stopped:	01/07/2002	
Batch:			Milligram	Daily	Stopped:	01/07/2002	
Batch:			Milligram	Daily	Stopped:	01/07/2002	
			Milligram	Daily	Stopped:	01/07/2002	
	vestigations:		Milligram	Daily	Stopped:	01/07/2002	
	vestigations:		Milligram	Daily	Stopped:	01/07/2002	
	vestigations:		Milligram	Daily	Stopped:	01/07/2002	
	vestigations:		Milligram	Daily	Stopped:	01/07/2002	
	vestigations:		Milligram	Daily	Stopped:	01/07/2002	
	vestigations:		Milligram	Daily	Stopped:	01/07/2002	
	vestigations:		Milligram	Daily	Stopped:	01/07/2002	
	vestigations:		Milligram	Daily	Stopped:	01/07/2002	
Laboratory In			Milligram	Daily	Stopped:	01/07/2002	
Laboratory In			Milligram	Daily	Stopped:	01/07/2002	
Laboratory In			Milligram	Daily	Stopped:	01/07/2002	
Batch:  Laboratory In  Additional Inf			Milligram	Daily	Stopped:	01/07/2002	
Laboratory In			Milligram	Daily	Stopped:	01/07/2002	

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**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:

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

#### Medicine Details:

FLUVOXAMINE MALEATE (Other drug)		Reason: Depression	
Tablet	100.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
CHLORPROMAZINE HYDROCHLORIDE (S	uspected)	Reason: Unspecified psychosis	
Tablet	100.0 Milligram	As necessary Oral	
Batch:	Started:	Stopped:	
FLUPENTHIXOL DECANOATE (Suspected)		Reason: Unspecified psychosis	
Injection	30.0 Milligram	Daily Intramuscular	
Batch:	Started: 04/04/2003	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	
14/04/2003	White blood cells		07/04/2003	2.4	

## **Additional Information:**

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Report Details:

Case Number: 185134

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

Reported: 17/04/2003			Weigh	t: 80.00
lospitalisation: Admitted to	hospital			<b>e</b> : 30
Onset Date: 09/04/2003			DO	<b>B</b> : 17/10/1972
Outcome: Not yet reco	overed		Causali	y: Causality possible
eaction Details:				
Preferred Term	Severity	Repor	t Description	Treatment
Dystonia		Dystonic reaction	and obtunded.	
Depressed level of conscious	ness			
Medicine Details:  LARGACTIL (Suspected)		Reaso	on:	
o (ouopouou)		Dose Unspecified	<del></del>	
Batch:	Started:	•	Stopped:	
Laboratory Investigatio	nne:			
Date Type	Range Date Tes	sted Result	De	etails
.,,,,,,	3 32 23.3 190	1333.11		
Additional Information	•			
eport Run: 01/06/2007 04:16PM	Database: pusime02	AD	RS004	Page 406 of 495



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 185379 Seq: 1 Gender: M

Reported: 28/04/2003 Weight: 120.00 Hospitalisation: Admitted to hospital Age: 33

**Onset Date:** 17/04/2003 **DOB:** 18/02/1970

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Dotanoi			
Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Pins and needles in both hands and both soles of feet, swollen left forearm and painful palms and soles.	
Oedema peripheral	Required Visit to Doctor		
Pain	Required Visit to Doctor		

### **Medicine Details:**

ZYPREXA (Other drug)		Reason: Unspecified psychosis
	20.0 Milligram	Daily
Batch:	Started:	Stopped:
RISPERDAL (Other drug)		Reason: Unspecified psychosis
	10.0 Milligram	Daily
Batch:	Started:	Stopped:
CHLORPROMAZINE HYDROCHLO	RIDE (Suspected)	Reason: Unspecified psychosis
	40.0 Milligram	Daily
Batch:	Started:	<b>Stopped:</b> 20/03/2003

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Re	ро	rt	De	tai	ls:
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Case Number:186394Seq: 1Gender:MReported:30/05/2003Weight:0.00Hospitalisation:Admitted to hospitalAge: 29

Onset Date: 15/04/2003 DOB: 07/05/1973

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Cardiac complaints, syncope	
Electrocardiogram QT prolonged		Cardiac complaints, syncope	
Syncope		Cardiac complaints, syncope	

## **Medicine Details:**

METOPROLOL TARTRATE (Other dr	ug)	Reason:	
Batch:	Started:	Stopped:	
AMISULPRIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CHLORPROMAZINE HYDROCHLORI	DF (Suspected)	Reason:	
	DE (Gaspectea)	reason.	
	DE (Guopostou)	reason.	
Batch:	Started:	Stopped:	
	,		
Batch:	,	Stopped:	

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details

#### **Additional Information:**

Reporter stated that a beta-blocker was "maybe" related to the increasing QT interval. Medical history of alcohol abuse.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 186485
 Seq: 1
 Gender:
 M

 Reported:
 02/06/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 27Y

Onset Date: 20/03/2003 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		Ceased Seroquel and Chlorpromazine, no further Droperidol given.

### **Medicine Details:**

SEROQUEL (Suspected)		Reason:		
Tablet			Oral	
Batch:	Started:	Sto	pped: 21/03/2003	
DROPERIDOL (Suspected)		Reason: Otr spe	c symp psychopathol nec	
Injection	10.0 Milligram	1 time	Intramuscular	
Batch:	Started:	Sto	pped:	
CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason: Otr spe	c symp psychopathol nec	
Tablet	100.0 Milligram	Daily	Oral	
Batch:	Started: 18/03/2003	Sto	pped: 21/03/2003	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
02/06/2003	Creatinine				
02/06/2003	Neutrophils	(2-7.5)	03/04/2003	1.24	
02/06/2003	Neutrophils	(2-7.5)	28/03/2003	1.09	
02/06/2003	Neutrophils	(2-7.5)	20/03/2003	1.61	
02/06/2003	White blood cells		20/03/2003	3.5	
02/06/2003	White blood cells		28/03/2003	2.8	
02/06/2003	White blood cells		03/04/2003	2.7	

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 187649
 Seq: 1
 Gender:
 F

 Reported:
 31/01/2002
 Weight:
 0.00

 Hospitalisation:
 Age: 57

 Onset Date: 18/12/2003
 DOB: 28/07/1946

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Eczema		lupus erythematosus, epistaxis and eczematous rash.	
Epistaxis		lupus erythematosus, epistaxis and eczematous rash.	
Systemic lupus erythematosus		lupus erythematosus, epistaxis and eczematous rash.	Imovane commenced.

### **Medicine Details:**

wedicine Details:				
MERSYNDOL (Other drug)		Rea	son: Migraine	
Tablet		Dose Unspecified	As necessary	Oral
Batch:		Stopped:		
AMITRIPTYLINE HYDROCHLORIDE	(Other drug)	Rea	son:	
Tablet	25.0	Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:	
CHLORPROMAZINE HYDROCHLOR	Rea	son:		
Tablet	100.0	Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:	18/12/2002

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	Activated partial		18/12/2002	53	
31/01/2002	International		18/12/2002	1.2	
	Other data				

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Started: Suspected)	Rea	_	Weig A D Causa n posed to	nder: M ght: 0.00 Age: 36 DOB: 09/02/1967 ality: Causality possible  Treatment Changed for Monoplus to fosinopril alone, treated with steroid creams and moisturisers.	
Started: Suspected)	Rea	on the areas execk, and hands	n posed to	Treatment  Changed for Monoplus to fosinopril alone, treated with steroid creams and	
Started: Suspected)	Rea	on the areas execk, and hands	posed to	Changed for Monoplus to fosinopril alone, treated with steroid creams and	
Started: Suspected)	Rea	on the areas execk, and hands	posed to	Changed for Monoplus to fosinopril alone, treated with steroid creams and	
Started: Suspected)	unlight face, ne	eck, and hands		fosinopril alone, treated with steroid creams and	
Suspected)	Rea	Stop	pped:		
Suspected)	Rea	Stop	pped:		
Suspected)	Rea	Stop	pped:		
Suspected)		_	ped:		
		son:			
222 2 -			Reason:		
200.0 N	lilligram	Total			
Started: 22/05	5/2003 <b>Stopped</b> :				
	Rea	son: Unspeci	fied schizoph	hrenia	
225.0 Milligram		Daily	Oral		
Started: 13/05/2003		Stop	ped:	Contin	
e Date Testec	d Result			Details	
e	Started: 22/05 225.0 M Started: 13/05	225.0 Milligram  Started: 13/05/2003	Started: 22/05/2003  Reason: Unspeci 225.0 Milligram Daily  Started: 13/05/2003  Stop	Started: 22/05/2003  Reason: Unspecified schizop 225.0 Milligram Daily Oral Started: 13/05/2003  Stopped:	

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 189563 Seq: 1 Gender: M

Reported: 15/08/2003 Weight: 70.00 Hospitalisation: Age: 32

**Onset Date:** 11/08/2003 **DOB:** 27/07/1971

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	toaction Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
	Extrapyramidal disorder		Found by carer with arching back and stiffening.	Cogentin.
	Blood creatine phosphokinase incr			

## **Medicine Details:**

LARGACTIL (Suspected) Reason:

Tablet 25.0 Milligram Daily Oral

Batch: Started: Stopped: 11/08/2003

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient also taking Oxazepam and Quinine.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 190213 Seq: 1 Gender: F

Reported: 04/09/2003 Weight: 58.00 Hospitalisation: Age: 17

**Onset Date:** 30/08/2003 **DOB:** 20/06/1986

Outcome: Recovered 31/08/2003 Causality: Causality possible

**Reaction Details:** 

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Headache	to Doctor	Severe headache (? atypical migraine), blanching mascular rash proximal to IV site.	Cessation of Chlorpromazine.
Rash macular	Required Visit to Doctor		

## **Medicine Details:**

Ritalin LA (Other drug)		Reason:	
Capsule	1.0 Dose Unspecifi	ed Daily	Oral
Batch:	Started:	Stopped:	
MAXOLON (Suspected)		Reason:	
Tablet	10.0 Milligram	3 times	Oral
Batch:	Started: 30/08/2003	Stopped:	31/08/2003
ASPIRIN (Suspected)		Reason:	
Tablet	600.0 Milligram	1 time	Oral
Batch:	Started: 30/08/2003	Stopped:	
PANADEINE FORTE (Suspected)		Reason:	
Tablet	2.0 Dose Unspecific	ed 1 time	Oral
Batch:	Started: 30/08/2003	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

Nil previous known ADRs.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Rei	port	Detai	ls:
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Case Number: 190213 Seq: 1 Gender: F

Reported: 04/09/2003 Weight: 58.00 Hospitalisation: Age: 17

**Onset Date**: 30/08/2003 **DOB**: 20/06/1986

Outcome: Recovered 31/08/2003 Causality: Causality possible

Reaction Details:

# **Medicine Details:**

AMITRIPTYLINE HYDROCHLORIDE	(Suspected)	Reason:		
Tablet	50.0 Milligram	1 time		Oral
Batch:	Started: 30/08/2003		Stopped:	
DIHYDERGOT (Suspected)		Reason:		
	3.0 Dose Unspecif	ied Daily		
Batch:	Started: 30/08/2003		Stopped:	31/08/2003
LARGACTIL (Suspected)		Reason:		
Injection	12.5 Milligram	Daily		Intravenous
Batch:	Started: 30/08/2003		Stopped:	30/08/2003

# **Laboratory Investigations:**

## **Additional Information:**

Nil previous known ADRs.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 190756 Seq: 1 Gender: F

 Reported: 23/09/2003
 Weight: 0.00

 Hospitalisation:
 Age: 77Y

 Onset Date: 09/09/2003
 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	toaction Botanoi			
	Preferred Term	Severity	Report Description	Treatment
	Jaundice cholestatic		Increased LFT's, jaundice becoming cholestatic	
	Liver function test abnormal			

# **Medicine Details:**

CHLORPROMAZINE HYDROCHLORID	E (Suspected)	Reason:		
	50.0 Milligram	Daily		
Batch:	Started: 21/08/2003	Stopp	ed: 09/09/2003	
TRIMETHOPRIM (Suspected)		Reason: Othr disea	ases of urinary tract	
Tablet	300.0 Milligram	Daily	Oral	
Batch:	Started: 24/08/2003	Stopp	ed: 29/08/2003	
PRAVACHOL (Suspected)		Reason:		
Tablet	40.0 Milligram	Daily	Oral	
Batch:	Started: 04/03/2003	Stopp	ed: 09/09/2003	
ASASANTIN SR (Suspected)		Reason:		
Capsule		Daily	Oral	
Batch:	Started: 27/08/2003	Stopp	ed: 09/09/2003	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

History:Penirdapril, Argio oedema. Othe drugs used: Coloxyl and senna, Serbiteil, Oxycodiene, Auapro, Atenolol.

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**Report Details:** 

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Onset Date:    Outcome: Recovered eaction Details:    Preferred Term Seven depatitis Caused of prolonge inpatient hospitalis  Medicine Details:	or Hepatitis nos d	Weight: 0.00 Age: 99U DOB: Causality: Causality possible  cription Treatment
Outcome: Recovered  eaction Details: Preferred Term Sevel Hepatitis Caused of prolonge inpatient hospitalis  Medicine Details:	or Hepatitis nos d	DOB: Causality: Causality possible
Onset Date:    Outcome: Recovered eaction Details:    Preferred Term Seven Hepatitis Caused of prolonge inpatient hospitalis  Medicine Details:	or Hepatitis nos d	DOB: Causality: Causality possible
Outcome: Recovered Paction Details: Preferred Term Seven Hepatitis Caused of prolonge inpatient hospitalis  Medicine Details:	or Hepatitis nos d	Causality: Causality possible
Preferred Term Seven Hepatitis Caused of prolonge inpatient hospitalis  Medicine Details:	or Hepatitis nos d	
Preferred Term Sever Hepatitis Caused of prolonge inpatient hospitalis  Medicine Details:	or Hepatitis nos d	cription Treatment
Repatitis Caused oprolonge inpatient hospitalis  Medicine Details:	or Hepatitis nos d	
RISPERDAL (Suspected)	Reason:	
Batch: Starte		Stopped:
CHLORPROMAZINE HYDROCHLORIDE (Suspecte	ed) Reason:	
Batch: Starte	ed:	Stopped:
_aboratory Investigations:	sto Toolool Dooult	Deteile
Date Type Range Da	ate Tested Result	Details

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 192136
 Seq: 1
 Gender:
 F

 Reported:
 12/11/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 20

Onset Date: 19/10/2003 DOB: 07/04/1983

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Nausea	Required Specialist Consultation	Nausea, followed a few days later by raised liver function tests and jaundice (pale stools, dark urine, yellow sclera).	Cessation of sodium valproate (Epilim) and metoclopramide (Pramin) for nausea.
Jaundice	Required Specialist Consultation		
Liver function test abnormal	Required Specialist Consultation		

## **Medicine Details:**

NILSTAT (Other drug)	F	Reason:		
Solution	1.0 Millilitre	1.0 Millilitre 4 times Or		
Batch:	Started: 12/10/2003	Stopped:	11/11/2003	
ZYPREXA (Other drug)	F	Reason:		
Tablet	10.0 Milligram	1 time	Oral	
Batch:	Started: 14/10/2003	<b>Started:</b> 14/10/2003 <b>Stopped:</b>		
EPILIM (Suspected)	F	Reason:		
Tablet	700.0 Milligram	1 time	Oral	
Batch:	Started: 16/10/2003	Stopped:	05/11/2003	
EPILIM (Suspected)	F	Reason:		
Tablet	1000.0 Milligram	1 time	Oral	
Batch:	Started: 16/10/2003	Stopped:	05/11/2003	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
12/11/2003	Albumin				

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

 Case Number:
 192136
 Seq: 1
 Gender:
 F

 Reported:
 12/11/2003
 Weight:
 0.00

Hospitalisation: Age: 20

Onset Date: 19/10/2003 DOB: 07/04/1983
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

# **Medicine Details:**

SERENACE (Suspected)			
Injection	10.0 Milligram	As necessary	Intramuscular
Batch:	Started: 09/10/2003	Stopped:	11/11/2003
LARGACTIL (Suspected)		Reason:	
Tablet	150.0 Milligram	As necessary	Oral
Batch:	Started: 09/10/2003	Stopped:	11/11/2003
HYPNOVEL (Suspected)		Reason:	
Injection	7.5 Milligram	As necessary	Intramuscular
Batch:	<b>Started:</b> 09/10/2003	Stopped:	11/11/2003
ANTENEX (Suspected)		Reason:	
Tablet	10.0 Milligram	As necessary	Oral
Batch:	Started: 12/10/2003	Stopped:	11/11/2003

# **Laboratory Investigations:**

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Det	taile				
	lans.				
Case Numb	er: 193937	Seq: 1		Ger	nder: F
Report	ed: 16/01/200	4		Wei	ight: 0.00
ospitalisatio	on: Admitted t	o hospital		<b>Age:</b> 19	
Onset Da	ate: 10/12/200	3		[	DOB:
Outcon	ne: Not yet red	covered		Causa	ality: Causality possible
eaction De	etails:				
	ferred Term	Severi	ty Repo	ort Description	Treatment
Extrapyramid	lal disorder	Caused o prolonged inpatient hospitalisa	stiffness, tongue hands.	disorder, akathisa, jaw e protrusion and stiff	Ceased Abtlify, given benztropine 1mg/day.
Madicina F	<b>D</b> otaile:				
<b>Medicine E</b> Abilify (Suspe			Rea	son:	
	ected)	Starte		son: Stopped:	
Abilify (Suspe	ected) n:	Starte	d:		
Batch	ected) n: Suspected)	Starte	d: Rea	Stopped:	
Abilify (Suspe Batch LARGACTIL (S	ected) n: Suspected)		d: Rea	Stopped:	
Abilify (Suspe Batch LARGACTIL (S	ected) n: Suspected)		d: Rea	Stopped:	
Abilify (Suspe Batch LARGACTIL (\$	ected) n: Suspected)		d: Rea	Stopped:	
Abilify (Suspe Batch LARGACTIL (S Batch	ected) n: Suspected) n:	Starte	d: Rea	Stopped:	
Abilify (Suspe Batch LARGACTIL (S Batch	ected) n: Suspected)	Started	d: Rea	Stopped:	Details

### **Additional Information:**

Patient was also taking tegretol and Largactil.

Medical history was significant for pervasive developmental disorder, petit mal epilepsy, and allergy to ethosuxomide and sodium valproate. The patient was undergoing a course of electroconvulsive therapy at the time of this report.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 194719 Seq: 1 Gender: F

Reported: 18/02/2004 Weight: 0.00 Hospitalisation: Age: 56Y

Onset Date: 13/09/2003 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Acaction Details.			
Preferred Term	Severity	Report Description	Treatment
Confusional state		Acute psychotic symptoms, disoriented, erythema, sebberoic dermatitis.	Ceased chlorpomazine, given 1% hydrocortisone and clotrimazole cream.
Disorientation			
Erythema			
Seborrhoeic dermatitis			

### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified psychosis

30.0 Millilitre Daily

**Batch: Started:** 10/09/2003 **Stopped:** 15/09/2003

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

Patient was also taking haloperidol, Benztropine, Lithium Carbonate, Sodium Valproate, Lamotrigine.

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Report Details:

Case Number: 198181

Reported: 16/06/2004

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

Weight: 0.00

Hospitalisation:				<b>Age</b> : 49Y					
Onset Da	ate: 15/03/200	4	DOB:						
	ne: Not yet re	covered		Causality: Causality possible					
action De				_			ı		
	ferred Term	Se	everity		eport Des			Treatmer	
nxiety				Increasing ai	nxiety and	flushed face.	Regul given	ar doses withl PRN	neld, only
ushing									
	<b>.</b>								
edicine [	Oetails: (Other drug)				Reason:				
)	(Guior arag)								
Batch	n:	S	tarted:			Stopped:			
HLORPROM	AZINE HYDROCH	ILORIDE (Susp	ected)		Reason:	Anxiety neurosis	5		
Tablet	t		150.0	Milligram	Daily	(	Oral		
Batch	n:	S	tarted:			Stopped:			
ahorator	y Investigat	ione:							
Date	Type	Range	Date Test	ed Result			Details		
24.0	. )   0	90	24.0 . 001				20100		
dditional	Information	ղ։							
ort Run: 01/0	6/2007 04:17PN	Database: p	usime02		ADRS004	1		Page 421	of 495



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 198190 Seq: 1 Gender: M

Reported: 16/06/2004 Weight: 0.00 Hospitalisation: Age: 42

Onset Date: 13/03/2004 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Priapism		Priapism and agitation.	Nebulised 5mg salbutamol with no effect (twice). Transfered to A & E. Withdraw blood and fluid from penile area to resolve the situation. Injected adrenaline 1:10,000 diluted 1 in 10ml. Urologist injected aramine to subside.
Agitation			

**Medicine Details:** 

DROPERIDOL (Suspected)			Reason:
Injection	10.0 Milli	gram	Daily

Batch: Started: 13/03/2004 Stopped:

QUETIAPINE (Suspected)Reason:Tablet300.0MilligramDailyOral

Batch: Started: Stopped:

 CHLORPROMAZINE HYDROCHLORIDE (Suspected)
 Reason: Otr spec symp psychopathol nec

 Tablet
 200.0 Milligram
 Daily
 Oral

Batch: Started: 13/03/2004 Stopped:

DIAZEPAM (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral Batch: Started: 13/03/2004 Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Large amounts of alcohol injested previous night (18 schooners). Priapism resolved but was exacerbated by chlorpromazine.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Repoi	t Do	tai	le ·
Keboi	T De	tai.	IS:

Case Number: 198452 Seq: 1 Gender: M

Reported: 24/06/2004 Weight: 75.00 Hospitalisation: Age: 17

Onset Date: 14/08/2003 DOB: 30/03/1986

Outcome: Recovered 16/09/2003 Causality: Causality possible

Reaction Details:

Neaction Details.							
	Preferred Term	Severity	Report Description	Treatment			
	Liver function test abnormal			Chlorpromazine ceased, Thyroxine 50 ug commenced.			
	Blood thyroid stimulating hormone						

### **Medicine Details:**

CHLORPROMAZINE HYDROCHL	ORIDE (Suspected)	Reason:	
Potob.	Ctowto d.	Chammadi	
Batch:	Started:	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
24/06/2004	ALT = SGPT	(0-20)	14/08/2003	286	
24/06/2004	Thyroid	(0.6-3.5)	29/08/2003	5.1	
	Thyroxine		29/08/2003	Normal	
24/06/2004	Tri-iodo thyronine		29/08/2003	Normal	

### **Additional Information:**

Patient was also taking Lithium, Sodium Valproate, Olanzepine.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report	Details:
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 Case Number:
 199751
 Seq: 1
 Gender:
 F

 Reported:
 06/08/2004
 Weight:
 0.00

Hospitalisation: Age: 78

Onset Date: 09/03/2004 DOB: 05/08/1925

Outcome: Recovered Causality: Causality possible

Reaction Details:

touction Dotailor			
Preferred Term	Severity	Report Description	Treatment
Paradoxical drug reaction			Midazolam given 2 x 0.5mg + midazolam 1mg and Prochlorperazine 10mg/tds as prn given for vertigo.
Confusional state Restlessness			Midazolam given 2 x 0.5mg + Midazolam 1mg.

# **Medicine Details:**

ATENOLOL (Other drug)			Reason:	
Tablet	50.0	Milligram	Daily	,
Batch:	Started:	L	TERM	Stopped:
PROMETHAZINE HYDROCHLORID	E (Suspected)		Reason:	Vertigo
Injection	25.0	Milligram	1 tim	е
Batch:	Started:			Stopped:
CHLORPROMAZINE HYDROCHLO	RIDE (Suspected)		Reason:	Vertigo

Injection 25.0 Milligram 1 time

Batch: Started: Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** Gender: M Case Number: 200599 Seq: 1 Reported: 07/09/2004 Weight: 0.00 Hospitalisation: **Age:** 26 Onset Date: 27/08/2004 DOB: 21/03/1978 Outcome: Recovered with sequelae Causality: Causality possible Reaction Details: Preferred Term Severity Report Description Treatment Grand mal convulsion Caused or Patient was found with tonic-clonic Haloperidol was immediately prolonged seizures on the floor, biting through his top ceased, following that, lip (mucosal surface only) and hitting the Sertraline was ceased. He was inpatient left side of his forehead on a skirting commenced on Diazepam hospitalisation board. 5mg and had his nightly Clozaril dose withheld. Clozaril continued as per usual the following day. **Medicine Details: SERTRALINE HYDROCHLORIDE (Suspected)** Reason: **Tablet** Oral Batch: Stopped: **CHLORPROMAZINE HYDROCHLORIDE (Suspected)** Reason: Started: Stopped: Batch: **HALOPERIDOL** (Suspected) Reason: As necessary Batch: Started: Stopped: 27/08/2004 **CLOZARIL** (Suspected) Reason: Tablet 25.0 Milligram Daily Oral Batch: Started: 19/08/2004 Stopped: Continuing **Laboratory Investigations:** Date Type Date Tested Result Details Range **Additional Information:** 

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Gender: F Case Number: 201542 Seq: 1

Weight: 0.00 Reported: 08/10/2004 Hospitalisation: **Age:** 57

Onset Date: 21/09/2004 **DOB:** 16/10/1946

Outcome: Death, maybe drug 21/09/2004 Causality: Causality possible

Reaction Details:

•	toaction Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
	Drug ineffective		The drug was ineffective - the patient committed suicide by jumping.	
	Completed suicide			

### **Medicine Details:**

ALPRAZOLAM (Other drug)		Reason:	
	2.0 Gram		
Batch:	Started:	Stopped:	

STILNOX (Other drug) Reason:

10.0 Milligram

Started: Stopped: Batch:

AVANZA (Other drug) Reason:

60.0 Milligram

Batch: Started: Stopped:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason:

1.0 Dose Unspecified 1 time

Batch: Started: 20/09/2004 Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

# **Additional Information:**

She was taking ongoing Avanza, Zanax and Stilnox. Report 201541 is the first sequence to this report.

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Hospitalisation: Onset Date:	08/10/2004 21/09/2004 Death, maybe dru	Seq: 1	21/09/2004			0.00	e
Medicine Deta ZYPREXA (Suspec Batch:		15.0 Mi <b>Started:</b> 20/09/		on: Daily Stoppe	d:	0	
Laboratory In	vestigations:						
Laboratory in	vesugations.						
Additional Inf She was taking on Report 201541 is to	formation: going Avanza, Zana ne first sequence to	x and Stilnox. this report.					

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 202058 Seq: 1 Gender: M

**Reported:** 27/10/2004 **Weight:** 105.00

Hospitalisation: Age: 31

**Onset Date**: 13/10/2004 **DOB**: 11/08/1973

Outcome: Recovered 04/10/2004 Causality: Causality certain

**Reaction Details:** 

veaction Details.			
Preferred Term	Severity	Report Description	Treatment
Torticollis	inpatient	Buccolingual crisis associated with torticollic crisis (neck with no arm involvement)	
Dysarthria		Aslo dysarthria or mutism associated with difficulty in maintaining an airway.	
Extrapyramidal disorder		Patient experienced an extrapyramidal effect from Chlorpromazine.	Treated with Prednisone and Telfast. Drug temporarily ceased.

#### **Medicine Details:**

AUGMENTIN DUO FORTE (Other drug)	Reason:			
Tablet	1.0	Dose Unspecified	Total	Oral
Batch:	Started:		Stopped:	
TRAMAL SR (Other drug)		Rea	son:	
Tablet	200.0	Milligram	As necessary	Oral
Batch:	Started:	L TERM	Stopped:	
DIAZEPAM (Other drug)		Rea	son:	
	5.0	Milligram	As necessary	
Batch:	Started:	L TERM	Stopped:	
ENDEP (Other drug)		Rea	son:	
Tablet	25.0	Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### Additional Information:

Suspected drug is cert/rechallenge. Problem occurred with increased dose of Chlorpromazine from 100mg to 200mg on 11/10/04 went to hospital 13/10/04 ceased drug 13/10/04 - symptoms subsided took 200mg 14/10/04 at 1.30pm at 2.15 - 2.30pm severe extrapyramidal symptoms.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 202058 Seq: 1 Gender: M

**Reported:** 27/10/2004 **Weight:** 105.00

Hospitalisation: Age: 31

**Onset Date:** 13/10/2004 **DOB:** 11/08/1973

Outcome: Recovered 04/10/2004 Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	Caused or prolonged inpatient hospitalisation		

#### **Medicine Details:**

Medicine Details.						
RISPERIDONE (Other drug)			Reason:			
Tablet	2.0	Milligram	Daily	Oral		
Batch:	Started:	L	TERM	Stopped:		
LARGACTIL (Suspected)			Reason:	Unspecified neurosis		
	200.0	Milligram	Daily			
Batch:	Started: 11/	10/2004		Stopped: 14/10/2004	0	

# **Laboratory Investigations:**

#### Additional Information:

Suspected drug is cert/rechallenge. Problem occurred with increased dose of Chlorpromazine from 100mg to 200mg on 11/10/04 went to hospital 13/10/04 ceased drug 13/10/04 - symptoms subsided took 200mg 14/10/04 at 1.30pm at 2.15 - 2.30pm severe extrapyramidal symptoms.

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: 202808	Seq: 1		Gender	r: U
Reported: 18/11/2004	·		Weight	: 0.00
ospitalisation:			Age	: 99U
Onset Date:			DOE	3:
Outcome: Unknown			Causality	: Causality possible
action Details:				
Preferred Term	Severity	Report D	Description	Treatment
uicidal ideation		Suicidal ideation and	I suicide attempt.	
uicide attempt		]		
ledicine Details:				
SEROQUEL (Suspected)		Reason:		
Tablet	Ctoutoul.		Oral	0
Batch:	Started:	Passani	Stopped:	0
_ARGACTIL (Suspected)		Reason:		
Batch:	Started:		Stopped:	
Daten.	Starteu.		эторреи.	
aboratory Investigation		ed Result	Det	oilo
Date Type	Range Date Test	eu Resuit	Det	alls
I				
dditional Information:				
eport Pun : 01/06/2007	Oatahasa: nusima02	ADDS	2004	Dogg 420

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number:204127Seq: 1Gender: MReported:12/01/2005Weight:82.00Hospitalisation:Admitted to hospitalAge: 71

Onset Date: 12/09/2004 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Encephalopathy	Severe		ICU admission. Methylene blue 50mg IV q4h then commenced with 90mg IV stat. Patient given Aciclovir, Vancomycin and Ceftriaxone.
Confusional state	Severe		

## **Medicine Details:**

ALLOPURINOL (Other drug)		Reason:	Other prophyla	actic procedures
	300.0 Milligram			Oral
Batch:	Started: 10/09/2004		Stopped:	13/09/2004
PROCHLORPERAZINE MALEATE (O	ther drug)	Reason:	Nausea and vomiting	
Injection	12.0 Milligram			
Batch:	Started: 10/09/2004		Stopped:	13/09/2004
MORPHINE NOS (Other drug)		Reason:	Pain	
Injection	2.0 Milligram			Subcutaneous
Batch:	Started: 12/09/2004		Stopped:	13/09/2004
LORAZEPAM (Other drug)		Reason:	Specific disord	ders of sleep
Tablet	1.0 Milligram			Oral
Batch:	Started: 03/09/2004		Stopped:	13/09/2004

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Re	po	rt	De	tai	ls:
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Case Number:204127Seq: 1Gender: MReported:12/01/2005Weight: 82.00Hospitalisation:Admitted to hospitalAge: 71

Onset Date: 12/09/2004 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

# **Medicine Details:**

PARACETAMOL (Other drug)		Reason:	Pain	
	4.0 Gram			Oral
Batch:	Started: 03/09/2004		Stopped:	13/09/2004
LACTULOSE (Other drug)		Reason:	Constipation	
Oral Liquid	40.0 Millilitre			
Batch:	Started: 06/09/2004		Stopped:	13/09/2004
COLOXYL WITH SENNA (Other drug)		Reason:	Constipation	
Tablet	4.0 Dose Unspe	ecified		Oral
Batch:	Started: 06/09/2004		Stopped:	13/09/2004
FAMCICLOVIR (Other drug)		Reason:	Herpes zoster	
Tablet	750.0 Milligram			Oral
Batch:	Started: 06/09/2004		Stopped:	

# **Laboratory Investigations:**

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

Case Number:204127Seq: 1Gender: MReported:12/01/2005Weight: 82.00Hospitalisation:Admitted to hospitalAge: 71

Onset Date: 12/09/2004 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

## **Medicine Details:**

HEPARIN SODIUM (Other drug)	Reason:	Phleb&thrombophleb lowr extrem
Injection	10.0 Thousand Internal	Subcutaneous
Batch:	Started: 06/09/2004	<b>Stopped:</b> 13/09/2004
MOVICOL (Other drug)	Reason:	Constipation
Solution, powder for	1.0 Dose Unspecified	
Batch:	Started: 10/09/2004	<b>Stopped:</b> 13/09/2004
RITUXIMAB (Other drug)	Reason:	
Injection	750.0 Milligram	Intravenous
Batch:	Started: 11/09/2004	<b>Stopped:</b> 11/09/2004
ETOPOSIDE (Other drug)	Reason:	
Injection	200.0 Milligram	Intravenous
Batch:	Started: 11/09/2004	<b>Stopped:</b> 13/09/2004

# **Laboratory Investigations:**

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Repo	ort D	etail	s:
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Case Number:204127Seq: 1Gender: MReported:12/01/2005Weight: 82.00Hospitalisation:Admitted to hospitalAge: 71

Onset Date: 12/09/2004 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

## **Medicine Details:**

OXYCONTIN (Other drug)		Reason: Pair	n		
Tablet	40.0 US opacity ι	unit me		Oral	
Batch:	Started: 07/09/2004	;	Stopped:	13/09/2004	
CHLORPROMAZINE HYDROCHLOR	RIDE (Suspected)	Reason:			
	12.0 Milligram	As necess	ary		
Batch:	Started: 12/09/2004		Stopped:	12/09/2004	
CARBOPLATIN (Suspected)		Reason:			
Injection	430.0 Milligram	Daily		Intravenous	
Batch:	Started: 12/09/2004	;	Stopped:	12/09/2004	0
IFOSFAMIDE (Suspected)		Reason:			
Injection, powder for	8.0 Gram	Daily		Intravenous Ir	nfusion
Batch:	Started: 12/09/2004		Stopped:	12/09/2004	0

## **Laboratory Investigations:**

#### **Additional Information:**

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## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detai	12/01/2005 Admitted to hosp 12/09/2004 Recovered	Seq: 1		Gender: Weight: Age: DOB: Causality:	82.00 71	
Medicine Deta						
MESNA (Suspected	d)	0.0 0	Reason:	Interven	_	
Injection  Batch:		8.0 Gram <b>Started:</b> 12/09/2004	Daily	Intravenou ed: 12/09/2004		
Laboratory In	vestigations:					
Additional Inf	ormation:					

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 204713 Seq: 1 Gender: M

Reported: 31/01/2005 Weight: 0.00 Hospitalisation: Age: 56

Onset Date: 18/04/2004 DOB:

Outcome: Recovered 26/06/2004 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Mild neutropenia.	Required medical attention.

## **Medicine Details:**

METOPROLOL TARTRATE (Other drug)		Reas	on:	Essential benign hypertension
	50.0	Milligram		
Batch:	Started:			Stopped:
ASASANTIN SR (Other drug)		Reas	on:	
	2.0	Dose Unspecified		
Batch:	Started:			Stopped:
CIPRAMIL (Other drug)		Reas	on:	Depression
	20.0	Milligram		
Batch:	Started:			<b>Stopped:</b> 16/04/2004
ZOCOR (Other drug)		Reas	on:	Othr&unspec metabolic diseases
	40.0	Milligram		

**Laboratory Investigations:** 

Batch:

Date	Туре	Range	Date Tested	Result	Details
31/01/2005	Neutrophils	2.0-8.0	18/04/2004	1.84	

Stopped:

Started:

#### **Additional Information:**

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## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number: 204713	Seq: 1			Gender:	M
Reported: 31/01/2005				Weight:	0.00
Hospitalisation:				Age:	56
Onset Date: 18/04/2004				DOB:	
Outcome: Recovered		26/06/2	2004	Causality:	Causality possible
Reaction Details:					
Medicine Details:			Danasas	Unanacifical cabinantanacia	
LARGACTIL (Suspected) Tablet	100.0	Milliaram	Reason:	Unspecified schizophrenia	
Batch:	Started: 15	Milligram	Daily	Oral <b>Stopped</b> :	
Batch:	Started: 15/	03/2004		Stopped:	
<b>Laboratory Investigations:</b>					
Additional Information:					
Additional Information:					
Additional Information:					
Additional Information:					
Additional Information:					

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number:204979Seq: 1Gender:FReported:05/02/2005Weight:0.00Hospitalisation:Required a visit to the doctorAge: 28

Onset Date: 18/04/2004 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		breath, dry cough and wheeze.	Salbutamol for SOB, Propranolol dose decreased for hypotension.
Cough	Required Visit to Doctor		
Dyspnoea	Required Visit to Doctor		
Wheezing	Required Visit to Doctor		

### **Medicine Details:**

PANADEINE (Other drug) Reason: Migraine

2.0 Dose Unspecified Oral

Batch: Started: 14/04/2004 Stopped:

METOCLOPRAMIDE HYDROCHLORIDE (Other drug) Reason: Nausea and vomiting

10.0 Milligram

Batch: Started: 14/04/2004 Stopped:

PARACETAMOL (Other drug) Reason: Migraine

2.0 Dose Unspecified As necessary Oral

Batch: Started: 14/04/2004 Stopped: contin

PETHIDINE HYDROCHLORIDE (Suspected) Reason: Migraine

 Injection
 150.0
 Milligram
 Daily
 Intravenous

 Batch:
 Started: 14/04/2004
 Stopped: 18/04/2004

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
05/02/2005	Other data				BP 80/50

#### **Additional Information:**

No history of asthma. 17 weeks pregnant.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Detail	s:					
Case Number:	204979	Seq: 1			Gender:	F
Reported:	05/02/2005	•			Weight:	0.00
Hospitalisation:	Required a visit to	the doctor			Age:	28
Onset Date:	18/04/2004				DOB:	
Outcome:	Recovered			С	ausality:	Causality possible
Reaction Detai	ils:				_	
<b>Medicine Det</b>	ails:					
PROPRANOLOL H	HYDROCHLORIDE (Su	spected)	Reason:	Migraine		
Tablet		40.0 Milligram	Daily		Oral	
Batch:		Started: 16/04/2004		Stopped:	19/04/2004	ļ
CHLORPROMAZIN	NE HYDROCHLORIDE	(Suspected)	Reason:	Hiccough		
Injection		38.0 Milligram	Daily		Intravenou	S
Batch:		Started: 17/04/2004		Stopped:	19/04/2004	ļ.
Laboratory In	vestigations:					

#### **Additional Information:**

No history of asthma. 17 weeks pregnant.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 205347 Seq: 1 Gender: F

Reported: 17/02/2005 Weight: 0.00 Hospitalisation: Age: 45

**Onset Date**: 19/04/2004 **DOB**:

Outcome: Recovered 19/04/2004 Causality: Causality possible

Reaction Details:

100011011 D 0101101			
Preferred Term	Severity	Report Description	Treatment
Depressed level of consciousness			Required medical attention. Treated with Flumazenil.

## **Medicine Details:**

SALBUTAMOL (Other drug)		Rea	son:	Asthma	
Inhalation	4.0	Dose Unspecified	Daily		Inhalation
Batch:	Started:			Stopped:	
IPRATROPIUM BROMIDE (Other drug)		Rea	son:	Asthma	
Inhalation	4.0	Dose Unspecified	Daily		Inhalation
Batch:	Started:			Stopped:	
NILSTAT (Other drug)		Rea	son:	Moniliasis	
	2.0	Millilitre	Daily		
Batch:	Started: 05/	/04/2004		Stopped:	21/04/2004
HEPARIN SODIUM (Other drug)		Rea	son:	Phleb&thromb	ophleb lowr extrem
Injection	10.0	Thousand Internat	Daily		Subcutaneous
Batch:	Started: 05/	/04/2004		Stopped:	21/04/2004

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Case Number: 205347

Reported: 17/02/2005

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

Weight: 0.00

spitalisation:				Age: 4	5	
Onset Date: 19/04/2004				DOB:		
Outcome: Recovered	19/04/	2004	C	ausality: C	Causality poss	ible
ction Details:						
edicine Details:						
ILORPROMAZINE HYDROCHLORID	E (Suspected)	Reason:	Unspecified ps	sychosis		
Tablet	150.0 Milligram	Daily		Oral		
Batch:	Started: 15/04/2004	,	Stopped:	20/04/2004		
AZEPAM (Suspected)		Reason:	Unspecified ps			
Tablet	15.0 Milligram	Daily		Oral		
Batch:	Started: 15/04/2004	·	Stopped:	19/04/2004		
OZAPINE (Suspected)		Reason:	Unspecified ps			
Tablet	12.0 Milligram	Daily		Oral		
Batch:	Started: 18/04/2004	·	Stopped:	19/04/2004		
boratory Investigations:						
Iditional Information:						
ditional information:						
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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report	: Details:
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Case Number:207428Seq: 1Gender:FReported:27/04/2005Weight:0.00Hospitalisation:Treated in outpatient department only.Age: 32Y

Onset Date: 25/03/2004 DOB:

Outcome: Recovered with sequelae 25/03/2004 Causality: Causality probable

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Circulatory collapse		Collapse secondary to viral illness and additive hypotensive effect - systonic BP = 85, HR = 134.	Change Chlorpromazine to Olanzapine.
Hypotension			
Tachycardia			

#### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Depression

12.5 Milligram Daily Oral

Batch: Started: 22/03/2004 Stopped: 25/03/2004

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 208142 Seq: 1 Gender: F

Reported: 24/05/2005 Weight: 70.00 Hospitalisation: Age: 38

Onset Date: 05/05/2005 DOB: 20/02/1967

Outcome: Recovered 07/05/2005 Causality: Causality possible

Reaction Details:

todottott Botanoi		-	
Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	prolonged inpatient	Sertraline and Tramadol triggered a seizure (tonic clonic). Two other fits last 3 weeks since started on Tramadol 3 weeks ago. Symptoms of suspected serotonin syndrome - neurologic physiologic as well as seizures.	Stop all medications.
Convulsion	Caused or prolonged inpatient hospitalisation		

#### **Medicine Details:**

SERTRALINE HYDROCHLORIDE (Interactio	n)		Reason:		
Tablet	100.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	
TRAMADOL HYDROCHLORIDE (Interaction	)		Reason:	Osteoarthritis	
Tablet	150.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	
LARGACTIL (Interaction)			Reason:		
	100.0	Milligram	Daily		
Batch:	Started:			Stopped:	
LITHIUM CARBONATE (Other drug)			Reason:		
Tablet	1.0	Gram	Daily		Oral
Batch:	Started:			Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

The patient had a MVA five years ago with head injuries.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

Case Number: 208142 Seq: 1 Gender: F

Reported: 24/05/2005 Weight: 70.00 Hospitalisation: Age: 38

Onset Date: 05/05/2005 DOB: 20/02/1967

Outcome: Recovered 07/05/2005 Causality: Causality possible

Reaction Details:

Made Botano.			
Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation		

ıvu		Deta	mo.

Seretide 250/50 Accuhaler (Other drug) Reason:

Inhalation 4.0 Dose Unspecified Daily Inhalation

Batch: Started: Stopped:

# **Laboratory Investigations:**

#### **Additional Information:**

The patient had a MVA five years ago with head injuries.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 208760 Seq: 1 Gender: M

Reported: 20/06/2005 Weight: 0.00 Hospitalisation: Age: 99u

Onset Date: 24/12/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Caction Botano			
Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation	The patient experienced a stiff neck and hypersalivation.	
Salivary hypersecretion	Caused or prolonged inpatient hospitalisation		

#### **Medicine Details:**

PAROXETINE HYDROCHLORIDE (Oth	er drug)	Reason:		
	20.0 Milligram		Oral	
Batch:	Started: 22/12/1998	Stoppe	ed:	
RISPERDAL (Suspected)		Reason: Unspecified	d schizophrenia	
	2.0 Milligram	Daily	Oral	
Batch:	Started:	Stoppe	ed:	
CHLORPROMAZINE HYDROCHLORIC	E (Suspected)	Reason:		
	200.0 Milligram	Daily	Oral	
Batch:	Started: 21/12/1998	Stoppe	ed:	
DIAZEPAM (Suspected)		Reason:		
	10.0 Milligram	Daily	Oral	
Batch:	Started: 21/12/1998	Stoppe	ed:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Clinical trial RODOS WAVE I: RODOS.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 209423 Seq: 1 Gender: M
Reported: 04/07/2005 Weight: 0.00
Hospitalisation: Age: 59

**Onset Date:** 13/05/2005 **DOB:** 04/04/1946

Outcome: Death, maybe drug 20/06/2005 Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Renal failure acute			Clopine ceased on 19 June 2004.
Pneumonia		The patient died, possibly of a chest infection.	Clopine ceased on 19 June 2004.
Hyperkalaemia	Death		

## **Medicine Details:**

ASPIRIN (Suspected)		Reason:			
			Oral		
Batch:	Started:		Stopped:	0	
CHLORPROMAZINE HYDROC	HLORIDE (Suspected)	Reason:	Unspecified schizophre	enia	
			Oral		
Batch:	Started:		Stopped:	0	
EPROSARTAN MESYLATE (S	suspected)	Reason:	Essential benign hype	rtension	
			Oral		
Batch:	Started:		Stopped:	0	
SODIUM VALPROATE (Suspe	ected)	Reason:	Other&unspecified epi	lepsy	
			Oral		
Batch:	Started:		Stopped:	0	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
04/07/2005	Creatinine	50-110	06/04/2005	200	
04/07/2005	Creatinine	50-110	16/06/2005	235	
04/07/2005	Potassium	3.5-5.6	06/04/2005	5.9	
04/07/2005	Potassium	3.5-5.6	16/06/2005	5.9	
04/07/2005	Urea	2.1-9.0	06/04/2005	11.0	
04/07/2005	Urea	2.1-9.0	16/06/2005	16.5	

#### **Additional Information:**

History: schizophrenia, epilepsy, chronic renal failure.

Report Run: 01/06/2007 04:17PM Database: pusime02 ADRS004 Page 446 of 495



Case Number: 209423

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

Reported:	04/07/2005			Weight:	0.00	
lospitalisation:				Age:	59	
Onset Date:	13/05/2005				: 04/04/1946	
Outcome:	Death, maybe drug	20/06/200	5	Causality:	Causality possible	
eaction Detai	ls:					
Medicine Det						
CLOPINE (Suspec	ted)		eason:	01		
Tablet		350.0 Milligram	Daily	Oral		
Batch:		Started: 07/06/2004		<b>Stopped:</b> 19/06/200	4	
Laboratory In	vestigations:					
<b>Additional Int</b> History: schizophr	formation: enia, epilepsy, chronic r	enal failure.				
	04.47DM 5 1 1		4 D D O O C :			

Report Run: 01/06/2007 04:17PM Database: pusime02 ADRS004 Page 447 of 495



Case Number: 210560

Reported: 10/08/2005

Seq: 1

## THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

Weight: 0.00

Preferred Term Severity Report Description  Oxic epidermal necrolysis Incapacity/dis ability  Patient developed toxic epidermal necrolysis.  Incapacity/dis ability  Patient developed toxic epidermal necrolysis.  Incapacity/dis ability  Patient developed toxic epidermal necrolysis.  Incapacity/dis ability  Patient developed toxic epidermal necrolysis.  Incapacity/dis ability  Patient developed toxic epidermal necrolysis.  Incapacity/dis ability  Patient developed toxic epidermal necrolysis.  Incapacity/dis ability  Patient developed toxic epidermal necrolysis.  Incapacity/dis ability  Patient developed toxic epidermal necrolysis.  Incapacity/dis ability  Patient developed toxic epidermal necrolysis.  Incapacity/dis ability  Patient developed toxic epidermal necrolysis.  Incapacity/dis ability  Patient developed toxic epidermal necrolysis.  Incapacity/dis ability  Patient developed toxic epidermal necrolysis.  Incapacity/dis ability  Patient developed toxic epidermal necrolysis.  Incapacity/dis ability  Patient developed toxic epidermal necrolysis.  Incapacity/dis ability  Patient developed toxic epidermal necrolysis.  Incapacity/dis ability  Patient developed toxic epidermal necrolysis.  Incapacity/dis ability	Report Description Report Description Treatment  Ceased Lamictal, Quetiapine, Chlorpromazine HCL, Lithium salt, Sodium Valproate, Biperiden. Treatment with Risperdone was started.  Reason: Oral Stopped: Reason: Oral Stopped: Reason: Oral Oral Oral	Causality: Causality probable  stion Details:  Preferred Term Severity Report Description Treatment c epidermal necrolysis Incapacity/dis ability Report Description Incapacity/dis ability Report Des	Oneot Dato:					I	
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Edicine Details:  AMICTAL (Suspected) Batch: Started: Batch: Started: Batch: Started: Started: Started: Starped:  Batch: Started: Started: Starped:  Batch: Started: Started: Starped:  Batch: Started: Starped:  Cease Chlorp Salt, St. Bliperic Risper  Chlorp Salt, St. Bliperic Risper  Chlorp Salt, St. Bliperic Risper  Chlorp Salt, St. Bliperic Risper  Chlorp Salt, St. Bliperic Risper  Cral  Batch: Started: Stopped:  Case Chlorp Salt, St. Bliperic Risper  Cral  Stopped:  Coral  Stopped:  Cease Chlorp Salt, St. Bliperic Risper  Cral  Stopped:  Cease Chlorp Salt, St. Bliperic Risper  Chlorp Salt, St. Bliperic Risper  Cral  Stopped:  Cease Chlorp Salt, St. Bliperic Risper  Cral  Coral  Stopped:  ITHIUM CARBONATE (Suspected)  Tablet Batch: Started: Started: Stopped:  Cral	Reason:  Ceased Lamictal, Quetiapine Chlorpromazine HCL, Lithium salt, Sodium Valproate, Biperiden. Treatment with Risperdone was started.  Reason:  Oral  Stopped:  Reason:  Oral  Stopped:  Reason:  Oral  Stopped:  Reason:  Oral  Oral  Oral  Oral  Oral  Oral  Oral  Oral  Oral  Oral	c epidermal necrolysis  Incapacity/dis ability  Patient developed toxic epidermal Clotroproazie HCL, Lithiun Chloryonazie	action Detail	s:					
edicine Details:  AMICTAL (Suspected)  Batch:  Started:  Started:  Stopped:  CHIORPROMAZINE HYDROCHLORIDE (Suspected)  Batch:  Started:  Started:  Stopped:  CHIORPROMAZINE HYDROCHLORIDE (Suspected)  Reason:  Reason:  Stopped:  CHIORPROMAZINE Started:  Stopped:  CHIORPROMAZINE Started:  Stopped:  CHIORPROMAZINE Started:  Stopped:  CHIORPROMAZINE Started:  Stopped:  CHIORPROMAZINE Started:  CHIORPROMAZINE Started:  CHIORPROMAZINE Started:  CHIORPROMAZINE Stopped:  CHIO	Chlorpromazine HCL, Lithium salt, Sodium Valproate, Biperiden. Treatment with Risperdone was started.  Reason: Unspecifid affective psychosis Oral Stopped: Reason: Oral Stopped: Reason: Oral Stopped: Reason: Oral Oral Oral Oral	dicine Details:  MICTAL (Suspected) Tablet Batch: Started: Stopped:  Batch: Started: Stopped:  COral Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  COral Batch: Started: Stopped:  COral Batch: Started: Stopped:  COral Batch: Started: Stopped:  COral Batch: Started: Stopped:  COral Batch: Started: Stopped:  COral Batch: Started: Stopped:  COral Batch: Started: Stopped:  COral Batch: Started: Stopped:  COral Batch: Started: Stopped:  COral Batch: Started: Stopped:  COral Batch: Tablet Started: Stopped:  COral Batch: Tablet Started: Stopped:  COral Batch: Tablet Started: Stopped:  COral Batch: Tablet Started: Stopped:  COral Batch: Tablet Started: Stopped:  COral Batch: Tablet Started: Stopped:  COral Batch: Doral Batch: Doral Batch: Started: Stopped:  COral Batch: Doral Batch: Biperione. Batch: Biperione. Batch: Biperione. Batch: Biperione. Batch: Biperione. Batch: Biperione. Batch: Biperione. Batch: Biperione. Batch: Biperione. Batch: Biperione. Batch: Batch: Biperione. Batch: Biperione. Batch: Batch: Batch: Biperione. Batch: B	Preferre	d Term	Se	everity	Report D	escription	Treatment
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Batch: Started: Stopped:  HLORPROMAZINE HYDROCHLORIDE (Suspected) Reason:  Batch: Started: Stopped:  THIUM CARBONATE (Suspected) Reason:  Tablet Oral  Batch: Started: Stopped:	Stopped:  Reason:  Stopped:  Oral	Batch: Started: Stopped:  LORPROMAZINE HYDROCHLORIDE (Suspected) Reason:  Batch: Started: Stopped:  HIUM CARBONATE (Suspected) Reason:  Tablet Oral  Batch: Started: Stopped:  Poratory Investigations:  Date Type Range Date Tested Result Details		, cottou,			110000111		
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shavatam, Invastigations.		Date Type Range Date Tested Result Details	Batch: ITHIUM CARBONA Tablet				Reason:	Oral	
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dditional Information:			Batch: ITHIUM CARBONA Tablet Batch:  Aboratory Inv Date	ATE (Suspected)  Vestigation  Type	s <b>s</b> :	started:		Oral	
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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Detail	s:					
Case Number:	210560 10/08/2005 Unknown	Seq: 1		,	Gender: Weight: Age: DOB: usality:	0.00 17Y
Medicine Det	ails:					
SODIUM VALPRO			Reason:		Oral	
Batch:		Started:		Stopped:	Orai	
BIPERIDEN HYDR	OCHLORIDE (Suspec	ted)	Reason:			
Tablet					Oral	
Batch:		Started:		Stopped:		
Laboratory In	vestigations:					
Additional In	formation:					

Report Run: 01/06/2007 04:17PM Database: pusime02 ADRS004 Page 449 of 495



Case Number: 210643

Reported: 12/08/2005

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: U

Weight: 0.00

Onset Date: 15/05/2003 Outcome: Recovered				P	. <b>ge</b> : 99U
				D	OB:
41 D-4-11-				Causa	lity: Causality probable
action Details:					
Preferred Term	S	everity	Rep	ort Description	Treatment
izziness		P s	'atient develope edation, nightn	ed dizziness, hypotension nares and lethargy.	Chlopromazine ceased.
ypotension					
ethargy					
ightmare					
edation					
ledicine Details: FLUVOXAMINE MALEATE (Other d	drug)		Pas	ison:	
-LUVOXAMINE MALEATE (Other d	irug)	200.0 M		15011.	
Batch:	¢	Started:	illigram	Stopped:	
FRISEQUENS (Other drug)		marteu.	Res	ison:	
Moregorius (Other drug)		10 D	ose Unspecified	3011.	
Batch:	ş	Started:	osc onspecifica	Stopped:	
ZOPICLONE (Other drug)			Rea	ison:	
		7.5 M	1illigram		
Batch:	5	Started:		Stopped:	
CHLORPROMAZINE HYDROCHLO	RIDE (Susp	pected)	Rea	ison:	
Tablet		30.0 M	lilligram	Daily Oral	
Batch:	5	Started: 14/05	/2003	<b>Stopped:</b> 15/05	/2003 0
aboratory Investigatior	16.				
Date Type	Range	Date Tested	Result		Details



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 212602 Seq: 1 Gender: F

Reported: 17/10/2005 Weight: 0.00 Hospitalisation: Age: 39Y

Onset Date: 12/07/2005 DOB:

Outcome: Recovered 12/07/2005 Causality: Causality probable

**Reaction Details:** 

Medicilon Details.			
Preferred Term	Severity	Report Description	Treatment
Syncope			Given 500 ml Normal Saline. Patient was pre-treated with 500 ml Normal Saline as well.
Unresponsive to stimuli			

#### **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Migraine

Injection 12.5 Milligram 3 times Intravenous Infusion

Batch: Started: 12/07/2005 Stopped: 12/07/2005

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Noted in pre-procedure checklist that patient documented as having "hypotension at times".

Report Run: 01/06/2007 04:17PM Database: pusime02 ADRS004 Page 451 of 495



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 212695 Seq: 1 Gender: M

Reported: 19/10/2005 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 37

Onset Date: 25/09/2005 DOB: 20/10/1967

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash papular		Pateint developed papular rash over face and upper torso (not itchy).	Reaction gradually settled by withdrawal of Largactil

### **Medicine Details:**

Tablet 50.0 Milligram 1 time Oral

Batch: Started: 25/09/2005 Stopped:

MORPHINE SULPHATE (Suspected) Reason: Pain

Injection 2.5 Milligram Daily Intravenous

Batch: Started: 25/09/2005 Stopped:

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details

#### **Additional Information:**

Report 212693 is the first sequence to this report.

Report Run: 01/06/2007 04:17PM Database: pusime02 ADRS004 Page 452 of 495



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 214017
 Seq: 1
 Gender:
 M

 Reported:
 05/12/2005
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 60
Onset Date: 14/08/2005
DOB: 25/09/1944

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse	Caused or prolonged inpatient hospitalisation	(in chair), was grey in colour, had altered	Treated with IV fluids (Hartman's) and Potassium supplements. Ceased Chlorpromazine.
Convulsion	Caused or prolonged inpatient hospitalisation		

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ıv						-14	

OLANZAPINE (Other drug)		Reason:
Batch:	Started:	Stopped:
MIRTAZAPINE (Other drug)		Reason:
Batch:	Started:	Stopped:
DIAZEPAM (Other drug)		Reason:
Batch:	Started:	Stopped:
Zolpidem Sandoz (Other drug)		Reason:
Batch:	Started:	Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
05/12/2005	Calcium		17/08/2005	2.00	
05/12/2005	Creatinine		17/08/2005	89	
05/12/2005	Magnesium		17/08/2005	0.63	
05/12/2005	Potassium		17/08/2005	2.9	
05/12/2005	Sodium		17/08/2005	120	
05/12/2005	bicarbonate		17/08/2005	17	

#### **Additional Information:**

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Case Number: 214017

Reported: 05/12/2005

Hospitalisation: Admitted to hospital

Seq: 1

## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

Weight: 0.00

**Age:** 60

Onset Date: 14/08/2005		<b>DOB</b> : 25/09/1944					
Outcome: Recovered		Causality: Causality possible					
action Details:							
Preferred Term	Severity	Report Description	Treatment				
łypokalaemia	Caused or prolonged inpatient hospitalisation						
Hyponatraemia	Caused or prolonged inpatient hospitalisation						
lypotension	Caused or prolonged inpatient hospitalisation						
Medicine Details:							
CHLORPROMAZINE HYDROCHLO		Reason:					
	50.0 Milligram	As necessary					
Batch:	Started:	Stopped:					
VENLAFAXINE HYDROCHLORIDE		Reason:					
	225.0 Milligram	Daily					
Batch:	Started:	Stopped:					
Laboratory Investigatio	ns:						
Additional Information:							
oort Run: 01/06/2007 04:17PM	Database: pusime02	ADRS004	Page 454 of 495				



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 214512 Seq: 1 Gender: F

Reported: 03/01/2006 Weight: 50.00 Hospitalisation: Admitted to hospital Age: 31

**Onset Date**: 15/12/2005 **DOB**: 10/10/1974

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea	Caused or prolonged inpatient hospitalisation	Patient experienced shortness of breath, throat tight and tongue swelling.	Salbutamol, Hydrocortisone, Ranitidine, Adrenaline.
Swollen tongue	Caused or prolonged inpatient hospitalisation		
Throat tightness	Caused or prolonged inpatient hospitalisation		

### **Medicine Details:**

ASPALGIN (Other drug) Reason: Headache

2.0 Dose Unspecified

**Batch: Started:** 15/12/2005 **Stopped:** 15/12/2005

METOCLOPRAMIDE HYDROCHLORIDE (Other drug) Reason: Nausea and vomiting

10.0 Milligram

Batch: Started: 15/12/2005 Stopped: 15/12/2005

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Headache

 Injection
 25.0 Milligram
 1 time
 Intravenous

 Batch:
 Started: 15/12/2005
 Stopped: 15/12/2005

Laboratory Investigations:

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

#### **Additional Information:**

Report Run: 01/06/2007 04:17PM Database: pusime02 ADRS004 Page 455 of 495



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 214546
 Seq: 1
 Gender:
 M

 Reported:
 04/01/2006
 Weight:
 0.00

Hospitalisation: Age: 41

Onset Date: DOB: 16/05/1964
Outcome: Unknown Causality: Causality possible

Reaction Details:

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
Akathisia		The patient experienced akathisia with suicidal and homicidal overtones.	
Homicidal ideation			
Suicidal ideation			

#### **Medicine Details:**

CHLORPROMAZINE HYDROCHLO	RIDE (Suspected)		Reason:		
	150.0	Milligram	Daily		
Batch:	Started:			Stopped:	
VALIUM (Suspected)			Reason:		
	5.0	Milligram	Daily		
Batch:	Started:			Stopped:	
RISPERIDONE (Suspected)			Reason:		
	5.0	Milligram	Daily		
Batch:	Started:			Stopped:	

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details

#### **Additional Information:**

Report 214544 is the first sequence to this report and report 214545 is the second sequence.

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## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Reported: 12/01/2006	Age: 41 Onset Date: Onset Date: Outcome: Not yet recovered Outcome: Not yet		1. 214090	Seq.	•			Gend	
Onset Date: Outcome: Not yet recovered action Details: Preferred Term Severity Report Description Treatment kin discolouration Patient developed a purple-brown skin pigmentation.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Reason: Specific disorders of sleep  Batch: Started: Stopped: 0  Valpam (Other drug) Reason: Otr spec symp psychopathol nec  Batch: Started: Stopped:  SOMAC (Other drug) Reason: Other diseases of esophagus  Batch: Started: Stopped:  STEMETIL (Other drug) Reason: Nausea and vomitting  Batch: Started: Stopped:  STEMETIL (Other drug) Reason: Nausea and vomitting  Batch: Started: Stopped:	Onset Date: Outcome: Not yet recovered	-						_	
Outcome: Not yet recovered action Details:  Preferred Term Severity Report Description Treatment Ain discolouration Patient developed a purple-brown skin pigmentation.  Patient developed a purple-brown skin Peplace Chlorpromazine vollanzapine.  Pedicine Details:  Pedicine Description Skin properties to propert	Outcome: Not yet recovered action Details:  Preferred Term			visit to the d	octor				~
Preferred Term Severity Report Description Treatment  Patient developed a purple-brown skin pigmentation.  Patient developed a purple-brown skin pigmentation.  Patient developed a purple-brown skin pigmentation.  Replace Chlorpromazine volanzapine.	Preferred Term Severity Report Description Treatment in discolouration Patient developed a purple-brown skin plane and the programment of the programment of the presence of t	Onset Date	e:					D	<b>OB</b> : 19/03/1964
Preferred Term Severity Report Description Treatment  Apatient developed a purple-brown skin pigmentation.  Patient developed a purple-brown skin pigmentation.  Replace Chlorpromazine volanzapine.  Replace Chlorer discountered volanzapine.  Replace Chlorer discountered volanzapine.  Replace Chlorer discountered volanzapine.  Replace Chlorer discountered volanzapine.  Replace Chlorer discountered volanzapine.  Replace Chlorer discountered volanzapine.  Replace Chlorer discountered volanza	Preferred Term Severity Report Description Treatment in discolouration Patient developed a purple-brown skin Replace Chlorpromazine will Clanzapine.  Patient developed a purple-brown skin Clanzapine.  Patient developed a purple-brown skin Clanzapine.  Replace Chlorpromazine will Clanzapine.  Replace Chlorpromazine will Clanzapine.  Replace Chlorpromazine will Clanzapine.  Replace Chlorpromazine will Clanzapine.  Replace Chlorpromazine will Clanzapine.  Replace Chlorpromazine will Clanzapine.  Replace Chlorpromazine will Clanzapine.  Replace Chlorpromazine will Clanzapine.  Replace Chlorpromazine will Clanzapine.  Replace Chlorpromazine will clanzapine.  Replace Chlorpromazine will clanzapine.  Replace Chlorpromazine will clanzapine.  Reason: Specific disorders of sleep  Reason: Other druep:  Reason: Other patient clanzapine.  Stopped:  Stopped:  Reason: Other druep Clanzapine.  Reason: Nausea and vomiting  Reason: Stopped:  Reason: Stopped:  Reason: Stopped:  Reason: Other druep Clanzapine.  Reason: Nausea and vomiting  Reason: Details  Details	Outcome	: Not yet rec	overed:				Causal	ity: Causality possible
Patient developed a purple-brown skin pigmentation.  Patient developed a purple-brown skin pigmentation.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.  Replace Chlorpromazine volanzapine.	edicine Details: EMAZEPAM (Other drug)  Batch: Started: Stopped: OMAC (Other drug)  Batch: Started: Started: Stopped: OMAC (Other drug)  Batch: Started: Stopped: OMAC (Other drug)  Batch: Started: Stopped: OMAC (Other drug)  Reason: Other diseases of esophagus  Batch: Started: Stopped: Stopped:  Stopped: Sto								1
edicine Details:  EMAZEPAM (Other drug)  Batch:  Started:  Stopped:  Otr spec symp psychopathol nec  Batch:  Started:  Stopped:  OMAC (Other drug)  Reason:  Other diseases of esophagus  Batch:  Started:  Stopped:  Stopped:  OMAC (Other drug)  Reason:  Other diseases of esophagus  Batch:  Started:  Stopped:	edicine Details:  EMAZEPAM (Other drug)  Batch: Started: Stopped: 0  Alpam (Other drug)  Reason: Otr spec symp psychopathol nec  Batch: Started: Stopped:  FOMAC (Other drug)  Reason: Other diseases of esophagus  Batch: Started: Stopped:  FOMAC (Other drug)  Reason: Nausea and vomiting  Batch: Started: Stopped:  Batch: Started: S			Se					
Pedicine Details:  TEMAZEPAM (Other drug)  Batch:  Started:  Stopped:  Otr spec symp psychopathol nec  Batch:  Started:  Stopped:  SOMAC (Other drug)  Batch:  Started:  Stopped:  STEMETIL (Other drug)  Batch:  Started:  Stopped:	edicine Details:  TEMAZEPAM (Other drug)  Batch: Started: Stopped: 0  Alpam (Other drug)  Reason: Otr spec symp psychopathol nec  Batch: Started: Stopped:  SOMAC (Other drug)  Reason: Other diseases of esophagus  Batch: Started: Stopped:  STEMETIL (Other drug)  Reason: Nausea and vomiting  Batch: Started: Stopped:  STEMETIL (Other drug)  Batch: Started: Stopped:  Aboratory Investigations:  Date Type Range Date Tested Result Details	kin discoloura	ation		Pat	ient develope	d a p	urple-brown skin	Replace Chlorpromazine with
Batch: Started: Stopped: 0  Batch: Started: Stopped: 0  Calpam (Other drug) Reason: Otr spec symp psychopathol nec  Batch: Started: Stopped:  BoMAC (Other drug) Reason: Other diseases of esophagus  Batch: Started: Stopped:  CTEMETIL (Other drug) Reason: Nausea and vomiting  Batch: Started: Stopped:	Batch: Started: Stopped: 0  Alpam (Other drug) Reason: Otr spec symp psychopathol nec  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:								
Reason: Otr spec symp psychopathol nec  Batch: Started: Stopped:  BoMAC (Other drug) Reason: Other diseases of esophagus  Batch: Started: Stopped:  STEMETIL (Other drug) Reason: Nausea and vomiting  Batch: Started: Stopped:	Batch: Started: Stopped:  SOMAC (Other drug) Reason: Other diseases of esophagus  Batch: Started: Stopped:  STEMETIL (Other drug) Reason: Nausea and vomiting  Batch: Started: Stopped:  Started: Stopped:  Stopped:  Started: Stopped:  Date Type Range Date Tested Result Details					Rea	son:	Specific disorders of s	sleep
Batch: Started: Stopped:  GOMAC (Other drug) Reason: Other diseases of esophagus  Batch: Started: Stopped:  GTEMETIL (Other drug) Reason: Nausea and vomiting  Batch: Started: Stopped:	Batch: Started: Stopped:  Batch: Started: Stopped:  STEMETIL (Other drug) Reason: Nausea and vomiting  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:	Batch:		St	arted:			Stopped:	0
Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped: Stopped:  Batch: Started: Stopped:	Batch: Started: Stopped:  STEMETIL (Other drug) Reason: Nausea and vomiting  Batch: Started: Stopped:  Batch: Started: Stopped:  Baboratory Investigations:  Date Type Range Date Tested Result Details	/alpam (Other o	drug)			Rea	son:	Otr spec symp psycho	opathol nec
Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:	Batch: Started: Stopped:  STEMETIL (Other drug) Reason: Nausea and vomiting  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Date Type Range Date Tested Result Details								
Batch: Started: Stopped:  Reason: Nausea and vomiting  Batch: Started: Stopped:  aboratory Investigations:	Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Batch: Started: Stopped:  Baboratory Investigations:  Date Type Range Date Tested Result Details	Batch:		St	arted:			Stopped:	
Reason: Nausea and vomiting  Batch: Started: Stopped:  aboratory Investigations:	Batch: Started: Stopped:  Aboratory Investigations:  Date Type Range Date Tested Result Details	OMAC (Other	drug)			Rea	son:	Other diseases of esc	phagus
Reason: Nausea and vomiting  Batch: Started: Stopped:  aboratory Investigations:	Batch: Started: Stopped:  aboratory Investigations:  Date Type Range Date Tested Result Details								
Batch: Started: Stopped:	Batch: Started: Stopped:  Aboratory Investigations:  Date Type Range Date Tested Result Details			St	arted:			Stopped:	
aboratory Investigations:	Date Type Range Date Tested Result Details	TEMETIL (Oth	er drug)			Rea	son:	Nausea and vomiting	
aboratory Investigations:	Date Type Range Date Tested Result Details	Potob		64	anto di			Stonnadi	
	Date Type Range Date Tested Result Details			<u></u>	arteu:			Stopped:	
	Date Type Range Date Tested Result Details	Batcii.							
	dditional Information:		Investigati	ons:					
	dditional Information:	aboratory			Date Tested	Result		[	Details
		aboratory			Date Tested	Result		[	Details
Additional Information:		Date	Туре	Range	Date Tested	Result		[	Details
dditional Information:		aboratory Date	Туре	Range	Date Tested	Result		[	Details

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## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Reported: 12/01/2006 Weight: 50.00 ospitalisation: Required a visit to the doctor Age: 41 Onset Date: DOB: 19/03/1964 Causality: Causality possible eaction Details:  Medicine Details:  LARGACTIL (Suspected) Reason: Specific disorders of sleep Tablet 200.0 Milligram Daily Oral Batch: Started: 15/01/2005 Stopped: 13/07/2005	Case Number:		Seq: 1		Gender: Weight:	
Onset Date: Outcome: Not yet recovered Causality: Causality possible action Details:  Iedicine Details:  LARGACTIL (Suspected) Tablet 200.0 Milligram Daily Oral Batch: Started: 15/01/2005 Stopped: 13/07/2005	-		o the doctor			
Outcome: Not yet recovered	-	required a viole t	5 the dootor			
Action Details:    Idedicine Details:   LARGACTIL (Suspected)   Reason: Specific disorders of sleep   Tablet   200.0 Milligram   Daily   Oral   Batch: Started: 15//01/2005   Stopped: 13/07/2005		Not vet recovered	d			
Reason: Specific disorders of sleep   Tablet			•		Guasanty.	Oddodnity possible
ARGACTIL (Suspected) Tablet 200.0 Milligram Daily Oral Batch: Started: 15/01/2005 Stopped: 13/07/2005						
ARGACTIL (Suspected) Tablet 200.0 Milligram Daily Oral Batch: Started: 15/01/2005 Stopped: 13/07/2005						
LARGACTIL (Suspected) Tablet 200.0 Milligram Daily Oral Batch: Started: 15/01/2005 Stopped: 13/07/2005						
ARGACTIL (Suspected) Tablet 200.0 Milligram Daily Oral Batch: Started: 15/01/2005 Stopped: 13/07/2005						
ARGACTIL (Suspected) Tablet 200.0 Milligram Daily Oral Batch: Started: 15/01/2005 Stopped: 13/07/2005						
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LARGACTIL (Suspected) Tablet 200.0 Milligram Daily Oral Batch: Started: 15/01/2005 Stopped: 13/07/2005						
LARGACTIL (Suspected) Tablet 200.0 Milligram Daily Oral Batch: Started: 15/01/2005 Stopped: 13/07/2005						
LARGACTIL (Suspected) Tablet 200.0 Milligram Daily Oral Batch: Started: 15/01/2005 Stopped: 13/07/2005	ledicine Deta	ails:				
Batch: Started: 15/01/2005 Stopped: 13/07/2005  aboratory Investigations:				Reason:	Specific disorders of sleep	)
aboratory Investigations:	Tablet		200.0 Milligram	Daily	Oral	
	Batch:		Started: 15/01/2005		Stopped: 13/07/200	5
	ahayatam, la	veetiestiese				
dditional Information:	aboratory in	vestigations:				
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Additional Information:						
	dditional Inf	ormation:				

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**Hospitalisation:** 

**Onset Date:** 

Case Number: 215354

Reported: 30/01/2006

Seq: 1

## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

Weight: 0.00

**Age:** 33

**DOB:** 02/11/1972

Outcome: Unknown			Caus	ality: Causality possible
eaction Details:				
Preferred Term	Severity	Report	Description	Treatment
ersonality change	Caused or prolonged inpatient hospitalisation	suicide, akathisia, h 'manic', had jittery l concentrate, could	depression, attempted ne was unstable, egs, could not not sleep, but slept or no desire for sex, felt	1
gitation	Caused or prolonged inpatient hospitalisation			
ledicine Details:				
AROPAX (Suspected)		Reason	1:	
			Oral	
Batch:	Started:		Stopped:	
LARGACTIL (Suspected)		Reason	n: Depression	
Batch:	Started:		Stopped:	
NEULACTIL (Suspected)		Reason	n:	
Tablet			Oral	
Batch:	Started:		Stopped:	
_aboratory Investigation	Range Date Test	ed Result		Details
Additional Information:				
oort Run: 01/06/2007  04:17PM  [	Database: pusime02	ADR	RS004	Page 459 of 495



Case Number: 215354

Reported: 30/01/2006

Seq: 1

## THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

Weight: 0.00

Hospitalisation:			Age	e: 33
Onset Date:			_	<b>B</b> : 02/11/1972
Outcome: Unknown		С	ausalit	y: Causality possible
Reaction Details:				
Preferred Term	Severity	Report Description		Treatment
Akathisia	Caused or prolonged inpatient hospitalisation			
Depression	Caused or prolonged inpatient hospitalisation			
Libido decreased	Caused or prolonged inpatient hospitalisation			
Medicine Details:				_
AROPAX (Suspected)		Reason:		
			Oral	
Batch:	Started:	Stopped:		
LARGACTIL (Suspected)		Reason: Depression		
Batch:	Started:	Stopped:		
NEULACTIL (Suspected)		Reason:		
Tablet			Oral	
Batch:	Started:	Stopped:		
Laboratory Investigation	าร:			
Additional Information:				
Coport Pup : 01/06/2007	Database: nusime 22	ADDS004		Dags 400 of 405

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Case Number: 215354

Reported: 30/01/2006

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

Weight: 0.00

lospitalisation:			Age:	
Onset Date:				: 02/11/1972
Outcome: Unknown		C	ausality	: Causality possible
eaction Details:				
Preferred Term	Severity	Report Description		Treatment
Mania	Caused or prolonged inpatient hospitalisation			
Suicide attempt	Caused or prolonged inpatient hospitalisation			
Andining Detailer				
Medicine Details:		Dagage		
AROPAX (Suspected)		Reason:	Oral	
Potoh.	Ctartad.	Stannadi	Orai	
Batch:	Started:	Stopped:		
LARGACTIL (Suspected)		Reason: Depression		
Batch:	Started:	Stopped:		
NEULACTIL (Suspected)		Reason:		
Tablet			Oral	
Batch:	Started:	Stopped:		
Laboratory Investigatio	าร:			
Additional Information:				
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Case Number: 215715

Seq: 1

## THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

Reported: 10/02/2006				Weigh	<b>t:</b> 0.00
ospitalisation:				_	e: 12
Onset Date: 09/04/2005				_	<b>B</b> : 10/09/1992
Outcome: Unknown			1	Causalit	y: Causality possible
eaction Details:					
Preferred Term	Severity	Re	eport Description		Treatment
omiting		The patient de flexing, vomititie.	eveloped left leg and ing, sweating, twitching	hip ng and	Chlorpromazine HCL ceased and monitor recovery.
yperhidrosis luscle twitching					
ledicine Details:					
OMEPRAZOLE (Other drug)			Reason:		
		) Milligram	_		
Batch:	Started:	_	Stopped	:	
CHLORPROMAZINE HYDROCHLORI	DE (Suspected)	F	Reason:		
	00.6	B 4:11:	Б. 11	<u> </u>	
Batch:	20.0 Started:	) Milligram	Daily <b>Stopped</b>	Oral :	
Batch:		) Milligram	-		
Batch:		) Milligram	-		
Batch:		) Milligram	-		
aboratory Investigations	Started:		-	:	
_aboratory Investigations	Started:		-	:	etails
.aboratory Investigations	Started:		-	:	etails
.aboratory Investigations	Started:		-	:	etails
aboratory Investigations	Started:		-	:	etails
aboratory Investigations  Date Type R	Started:		-	:	etails
aboratory Investigations  Date Type R	Started:		-	:	etails
aboratory Investigations  Date Type R	Started:		-	:	etails
.aboratory Investigations	Started:		-	:	etails

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## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

-				Gend	
ospitalisati	ted: 10/02/2006				nt: 8.60
-				_	e: 1
	ate: 24/08/2005				<b>B</b> : 24/03/2004
	<b>ne:</b> Not yet reco	vered		Causali	ty: Causality certain
eaction D		<del></del>			
	eferred Term	Severity		ort Description	Treatment
remor			The patient beca	ame very jittery, shaky and ch dose of Largactil.	Largactil ceased.
ritability			imable poor eac	or doco or Eurguotii.	
Medicine I	Details: CTONE (Other drug)		Rea	ason:	
Batcl	h:	Started:		Stopped:	
FRUSEMIDE	(Other drug)		Rea	ison:	
Batcl	h:	Started:		Stopped:	
CHLORAL HY	DRATE (Other drug	<u>.                                      </u>	Rea	ason:	
Batcl		Started:		Stopped:	
	ther drug)		Rea	ison:	
CLEXANE (O					
		Started:		Stopped:	
CLEXANE (O	h:			Stopped:	
CLEXANE (O			ested Result		etails

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## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Hospitalisation: Onset Date: Outcome: Reaction Detai	10/02/2006  24/08/2005  Not yet recovered  Is:	Seq: 1		,		8.60
Medicine Deta	<b>BİİS:</b> DCHLORIDE (Other dı	ana)	Reason:			
MORPHINE HTDR	OCHLORIDE (Other di	ug)	Reason.			
Batch:		Started:		Stopped:		
PARACETAMOL (	Other drug)		Reason:			
Batch:		Started:		Stopped:		
LARGACTIL (Susp	ected)		Reason:			
Batch:		16.0 Milligram <b>Started:</b> 22/08/2005	Daily	Stopped:	Nasogastri	
Laboratory In	vestigations:					
Additional Inf Suspect drug certa						

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Case Number: 215768

Reported: 13/02/2006

Seq: 1

## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

Weight: 5.70

Onset Date: 31/10/2 Outcome: Not yet eaction Details:  Preferred Term					
action Details:					<b>DB</b> : 13/01/2005
	recovered			Causali	ty: Causality possible
Preferred Term					
1 10101104 10111	ı S	Severity		ort Description	Treatment
Dystonia		T  -  "	The patient expe His eyes were w rolled back into	erienced possible dystonia. ide open, but eyeballs head" (upwards).	Stat dose Diazepam NGT 0.5mg.
culogyration					
edicine Details:					
ALDACTONE (Other drug)			Rea	son:	
Batch:	!	Started:		Stopped:	
ANDOCAL NOS (Other dru	ng)		Rea	son:	
Batch:	!	Started:		Stopped:	
ASIX (Other drug)			Rea	son:	
Batch:	:	Started:		Stopped:	
ANCOMYCIN HYDROCHLO	ORIDE (Other drug	g)	Rea	son:	
Batch:	:	Started:		Stopped:	
aboratory Investig	ations:				
Date Type	Range	Date Tested	d Result	D	etails



## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Hospitalisation: Onset Date:	13/02/2006 31/10/2005 Not yet recovered	Seq: 1			5.70
Medicine Deta	ails:				
	PHATE (Other drug)		Reason:		
Batch:		Started:		Stopped:	
CAPTOPRIL (Othe	r drug)		Reason:		
Batch:		Started:		Stopped:	
RANITIDINE (Othe	r drug)		Reason:		
Batch:		Started:		Stopped:	
POTASSIUM CHLO	ORIDE (Other drug)		Reason:		
Batch:		Started:		Stopped:	
Laboratory In	vestigations:				
Additional Inf	ormation:				

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## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Hospitalisation: Onset Date:	13/02/2006 31/10/2005 Not yet recovered	Seq: 1				5.70	
	MINE HYDROCHLORI	DE (Other drug)	Reason:				
				_			
Batch:	NATE (Other descri	Started:	Danas	Stopped:			4
CALCIUM GLUCO	NATE (Other drug)		Reason:				
Batch:		Started:		Stopped:			
CHLORPROMAZIN	IE HYDROCHLORIDE		Reason:				
5.44		3.0 Milligram	1 time	040	Nasogastri		
Batch:		<b>Started:</b> 30/10/2005		Stoppea:	30/10/2005		
Laboratory In	vestigations:						
Additional Inf	formation:						

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 215948
 Seq: 1
 Gender:
 M

 Reported:
 16/02/2006
 Weight:
 0.00

**Hospitalisation**: Admitted to hospital **Age**: 65

**Onset Date**: 14/10/2004 **DOB**: 09/07/1939

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Patient developed myocarditis, fever, hypotension, tachycardia, decreased oxygen saturation, increased troponin, increased LFT's, urine positive for myoglobin. ECHO global LV dysfunction.	Treated with Prednisone, Tritace, Carvedilol, Aldactone, Warfarin, Digoxin and reduced Risperidone gradually to 1.5mg/daily and Frusemide.
Ejection fraction decreased	Caused or prolonged inpatient hospitalisation		

## **Medicine Details:**

CLOZAPINE (Suspected)		Reason:	Unspecified so	chizophrenia	
Tablet	25.0 Milligram	Daily		Oral	
Batch:	Started: 29/09/2004		Stopped:	30/09/2004	
CHLORPROMAZINE HYDROCHLORIDE	(Suspected)	Reason:			
Tablet	50.0 Milligram	Daily		Oral	
Batch:	Started: 10/09/2004		Stopped:	26/09/2004	0
RISPERIDONE (Suspected)		Reason:	Unspecified so	chizophrenia	
Tablet	2.0 Milligram	Daily		Oral	
Batch:	Started: 10/09/2004		Stopped:	27/09/2004	0
Batch: CLOZAPINE (Suspected)	<b>Started:</b> 10/09/2004	Reason:	Stopped:	27/09/2004	0
	<b>Started:</b> 10/09/2004 12.5 Milligram	Reason: Daily	Stopped:	27/09/2004 Oral	0

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
16/02/2006	Echocardiogram				Echo: global LV dysfunction. EF about 25%.
16/02/2006	Electrocardiograph				ECG: nil conduction deficitis.
16/02/2006	Troponin				Troponin - 0.38.

#### **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Re	por	t De	tails:	:
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Case Number:215948Seq: 1Gender: MReported:16/02/2006Weight: 0.00Hospitalisation:Admitted to hospitalAge: 65

Onset Date: 14/10/2004 DOB: 09/07/1939

Outcome: Not yet recovered Causality: Causality possible

#### Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal	Caused or prolonged inpatient hospitalisation		
Hypotension	Caused or prolonged inpatient hospitalisation		
Myoglobinuria	Caused or prolonged inpatient hospitalisation		

#### **Medicine Details:**

RISPERIDONE (Suspected)		Reason:			
Tablet	4.0 Milligram	Daily		Oral	
Batch:	Started: 27/09/2004		Stopped:	06/10/2004	0
RISPERIDONE (Suspected)	ı	Reason:			
Tablet	3.0 Milligram	Daily		Oral	
Batch:	Started: 10/09/2004		Stopped:	29/09/2004	0
CLOZAPINE (Suspected)	ı	Reason:			
Tablet	50.0 Milligram	Daily		Oral	
Batch:	Started: 01/10/2004		Stopped:	04/10/2004	

# **Laboratory Investigations:**

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number:215948Seq: 1Gender:MReported:16/02/2006Weight:0.00Hospitalisation:Admitted to hospitalAge: 65

Onset Date: 14/10/2004 DOB: 09/07/1939

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oxygen saturation decreased	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Renal impairment	Caused or prolonged inpatient hospitalisation		

# **Medicine Details:**

CLOZAPINE (Suspected)		Reason:	Unspecified so	chizophrenia	
Tablet	25.0 Milligram	Daily		Oral	
Batch:	Started: 29/09/2004		Stopped:	30/09/2004	
CHLORPROMAZINE HYDROCHLORID	E (Suspected)	Reason:			
Tablet	50.0 Milligram	Daily		Oral	
Batch:	Started: 10/09/2004		Stopped:	26/09/2004	0
RISPERIDONE (Suspected)		Reason:	Unspecified so	chizophrenia	
Tablet	2.0 Milligram	Daily		Oral	
Batch:	Started: 10/09/2004		Stopped:	27/09/2004	0
CLOZAPINE (Suspected)		Reason:			
CLOZAPINE (Suspected) Tablet	12.5 Milligram	Reason: Daily		Oral	

# **Laboratory Investigations:**

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

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

Case Number:215948Seq: 1Gender:MReported:16/02/2006Weight:0.00Hospitalisation:Admitted to hospitalAge: 65

**Onset Date**: 14/10/2004 **DOB**: 09/07/1939

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		

#### **Medicine Details:**

RISPERIDONE (Suspected)		Reason:			
Tablet	4.0 Milligram	Daily		Oral	
Batch:	Started: 27/09/2004		Stopped:	06/10/2004	0
RISPERIDONE (Suspected)	ı	Reason:			
Tablet	3.0 Milligram	Daily		Oral	
Batch:	Started: 10/09/2004		Stopped:	29/09/2004	0
CLOZAPINE (Suspected)	ı	Reason:			
Tablet	50.0 Milligram	Daily		Oral	
Batch:	Started: 01/10/2004		Stopped:	04/10/2004	

# **Laboratory Investigations:**

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 216800 Seq: 1 Gender: M

 Reported:
 30/03/2006
 Weight:
 65.00

 Hospitalisation:
 Age:
 39Y

 Onset Date:
 14/02/2006
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Rhabdomyolysis		Patient complained of myalgias which did not resolve over next 10 day.	Ceased Chlorpromazine and Mirtazapine.

#### **Medicine Details:**

Medicine Details.					
CHLORPROMAZINE HYDROCHLORIDE (S	Suspected)	Reason:	Specific disord	lers of sleep	
Tablet	100.0 Milligram	Daily		Oral	
Batch:	Started: 25/01/2006		Stopped:	24/02/2006	0
MIRTAZAPINE (Suspected)		Reason:	Depression		
Tablet	30.0 Milligram	Daily		Oral	
Batch:	Started: 13/01/2006		Stopped:	24/02/2006	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
29/03/2006	Creatine		23/02/2006	10300	

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 216884
 Seq: 1
 Gender: M

 Reported:
 03/04/2006
 Weight:
 80.00

Hospitalisation: Admitted to hospital Age: 24

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

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

**Reaction Details:** 

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

#### **Medicine Details:**

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

**Laboratory Investigations:** 

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

## **Additional Information:**

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F Case Number: 217086 Seq: 1 Reported: 06/04/2006 Weight: 0.00 Hospitalisation: Admitted to hospital **Age:** 33 Onset Date: 01/01/2002 DOB: 24/05/1968 Outcome: Unknown Causality: Causality possible Reaction Details: Preferred Term Severity Report Description Treatment Patient felt indifferent and felt frustrated. Feeling abnormal Caused or Ceased medication. Returned prolonged Slept all day/night, anxious, did not sleep, to hospital for medication adjustment. Patient now on confused inpatient Abilify, Seroquel and Lithium. hospitalisation Caused or Anxiety prolonged inpatient hospitalisation Confusional state Caused or prolonged inpatient hospitalisation **Medicine Details:** LITHIUM CARBONATE (Suspected) Reason: Unspecified schizophrenia **Tablet** Oral Batch: Started: L TERM Stopped: **VALIUM (Suspected)** Reason: Anxiety neurosis Started: Batch: Stopped: RISPERDAL (Suspected) Reason: Unspecified schizophrenia Batch: Started: Stopped: HALOPERIDOL (Suspected) Reason: Batch: Started: Stopped: **Laboratory Investigations:** Date Type Date Tested Result Details Range **Additional Information:** 

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Case Number: 217086

Reported: 06/04/2006 **Hospitalisation:** Admitted to hospital

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

Weight: 0.00

**Age:** 33

<b>Onset Date:</b> 01/01/2002								
Outcome: Unknown		Causality: Causality possible						
action Details:								
Preferred Term	Severity	Report Description	Treatment					
rustration	Caused or							
	prolonged inpatient							
	hospitalisation							
nsomnia	Caused or							
	prolonged							
	inpatient hospitalisation							
omnolence	Caused or							
omiolence	prolonged							
	prolonged inpatient							
	hospitalisation							
Indiaina Dataila.								
ledicine Details: PROZAC (Suspected)		Reason:						
Batch:	Started:	Stoppe	d:					
LARGACTIL (Suspected)		Reason:						
Batch:	Started:	Stoppe	4.					
aboratory Investigation	าร:							
dditional Information:								
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Case Number: 218093

Reported: 05/05/2006

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

Weight: 0.00

Hospitalisati	on: Admitted	to hospital				Age: 28Y			
Onset Da	ate: 01/12/200	)5		DOB:					
Outcor	me: Unknown			Causality: Causality possible					
eaction D									
	eferred Term	i	everity	Rep	ort Description	Treatment			
Photosensitiv	vity reaction	Cause prolor inpatie hospit	nged	Reddened skin ( sunlight.	over areas exposed to	Chlorpronmazine ceased.			
Medicine I				Rea	son:				
OLANZAI INL	- (Other drug)			1100	3011.				
Batcl	h:	Si	tarted:		Stopped:				
DIAZEPAM (C	Other drug)			Rea	son:				
Batcl		St	tarted:	•••					
CEPHALEXIN	I (Other drug)			Rea	son:				
Batcl	h:	Sʻ	tarted:		Stopped:				
	.E (Other drug)		turtou.	Rea	son:				
	. 0,								
Batcl	h:	Si	tarted:		Stopped:				
Labaratar		······································							
Date	y Investigat Type	Range	Date Teste	d Result		Details			
Duto	1,400	rango	Date Foote	a Hoodii					
Additiona	I Informatio	n:							
eport Run:01/0	)6/2007 04:17PN	M Database: ри	usime02	ļ	ADRS004	Page 476 of 495			



# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

-	05/05/2006 Admitted to hospit 01/12/2005 Unknown	Seq: 1			DOB:	0.00 28Y	ssible
Medicine Deta	ails:						
ZOPICLONE (Other			Reasor	n:			
Batch:		Started:		Stopped:			
PANADEINE (Other	er drug)		Reasor	n:			
Batch:		Started:		Stopped:			
ZUCLOPENTHIXO	L ACETATE (Other dru	ra)	Reasor	1:			
Batch:		Started:		Stopped:			
BENZTROPINE ME	ESYLATE (Other drug)		Reasor	1:			
Batch:		Started:		Stopped:			
Laboratory In	vestigations:						
Additional Inf	formation:						

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:		Seq: 1			ender:		
Reported:				W	eight:		
	Admitted to hospita	al			Age:	28Y	
Onset Date:					DOB:	0 111 111	
Outcome:				Cau	sality:	Causality possible	
action Detail	s:						
Medicine Deta		• • •					
CHLORPROMAZIN	E HYDROCHLORIDE (		Reason:				
<b>5</b> / 1		300.0 Milligram	Daily	Oi			
Batch:		Started: 14/11/2005		Stopped: 01	/12/2005		
aboratory In	vestigations:						
Additional laf	- www o 4 i o vo v						
Additional Info	ormation:						
					_		

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 218790
 Seq:
 1
 Gender:
 F

 Reported:
 30/05/2006
 Weight:
 0.0

Reported: 30/05/2006 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 79

**Onset Date**: 15/11/2005 **DOB**: 23/10/1926

Outcome: Unknown Causality: Causality probable

Reaction Details:

•	todotion Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
	Rhabdomyolysis		Patient experienced a fall at home, unable to get up for 12 hours.	
	Fall			

#### **Medicine Details:**

Modifile Botalie.					
ASPIRIN (Other drug)		Reason:			
Batch:	Started:		Stopped:		
TEMAZEPAM (Other drug)		Reason:	Specific disorders of sle	еер	
Batch:	Started:		Stopped:	0	
CITALOPRAM HYDROBROMIDI	E (Other drug)	Reason:	Anxiety neurosis		
Batch:	Started:		Stopped:	0	
CYANOCOBALAMIN (Other dru	ıg)	Reason:			
Batch:	Started:		Stopped:		

# **Laboratory Investigations:**

Date	Type	Range	Date Tested	Result	Details
30/05/2006	Creatine		22/11/2005	705	
30/05/2006	Creatine		21/11/2005	1073	
30/05/2006	Creatine		19/11/2005	5748	
30/05/2006	Creatine		18/11/2005	11969	
30/05/2006	Creatine		20/11/2005	2590	
30/05/2006	Creatine		17/11/2005	21491	
30/05/2006	Creatine		16/11/2005	46154	

# **Additional Information:**

Statins - myopathy.

Report 218791 is the second sequence to this report.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 218790 Seq: 1 Gender: F

Reported: 30/05/2006 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 79

**Onset Date:** 15/11/2005 **DOB:** 23/10/1926

Outcome: Unknown Causality: Causality probable

**Reaction Details:** 

## **Medicine Details:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected)

Tablet

1.5 Gram
Daily
Oral

Batch: Started: Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
30/05/2006	Creatine		15/11/2005	39378	
30/05/2006	Creatine		16/11/2005	36244	
30/05/2006	Creatinine		17/11/2005	0.18	
30/05/2006	Creatinine		16/11/2005	0.19	
30/05/2006	Creatinine		16/11/2005	0.20	
30/05/2006	Troponin		18/11/2005	0.07	Troponin I.
30/05/2006	Troponin		17/11/2005	0.15	Troponin I.

# **Additional Information:**

Statins - myopathy.

Report 218791 is the second sequence to this report.

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report D	etails	s:						
Case Num	nber:	218790	Se	<b>q</b> : 1			Gender:	F
Repo	rted:	30/05/200	)6				Weight:	0.00
Hospitalisa	tion:	Admitted	to hospital				Age:	79
Onset I	Date:	15/11/200	)5				_	23/10/1926
Outco	ome:	Unknown					Causality:	Causality probable
Reaction E	Detai	ls:					_	• .
Medicine	Deta	ails:						
ASPIRIN (Of	ther dr	ug)			Re	ason:		
Bat	ch:			Started:			Stopped:	
TEMAZEPA	M (Oth	er drug)			Re	ason:	Specific disorders of sleep	
Bat	ch:			Started:			Stopped:	0
CITALOPRA	M HYC	ROBROMIC	E (Other drug	g)	Re	ason:	Anxiety neurosis	
Bat	ch:			Started:			Stopped:	0
CYANOCOE	BALAM	IN (Other dr	ug)		Re	ason:		
Bat	ch:			Started:			Stopped:	
Laborato	ry In							
Date		Туре	Range	Date Tested	Result		Detai	ls
30/05/2006	Tropor			16/11/2005	0.13	Tropon		
30/05/2006	Tropor	nin		15/11/2005	0.07	Tropon	in I.	

## **Additional Information:**

Statins - myopathy.
Report 218791 is the second sequence to this report.

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Case Number:	218790	Seq: 1			Gender:	F
Reported:	30/05/2006				Weight:	0.00
Hospitalisation:	Admitted to hosp	ital			Age:	79
Onset Date:	15/11/2005				DOB:	23/10/1926
Outcome:	Unknown				Causality:	Causality probable
Reaction Detai	ils:					
<b>Medicine Det</b>	ails:					
	NE HYDROCHLORIDE	(Suspected)		Reason:	Anxiety neurosis	
Tablet		1.5	Gram	Daily	Oral	
Batch:		Started:			Stopped:	
Laboratory In	vestigations:					
,	J					
<b>Additional Inf</b>	formation:					
Statins - myopathy	/. the second sequenc	o to this seese!				
Report 218/91 is t	ne second sequenc	e to this report.				

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Case Number: 220053

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: F

dmitted to hospital 5/05/2006 DOB: 16/11/1936 Causality: Causality possible in the prolonged inpatient hospitalisation in the prolonged inpatient hospitalisation in the prolonged inpatient hospitalisation in Started: Stopped:    Started: Stopped: Started: Started: Stopped: Started: Stopped: Started: Stopped: Started: Started: Started: Started: Started: Started: Started: Started: Started: Started: Started:
Term Severity Report Description Treatment  Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Started: Stopped:  Started: Stopped:  Started: Stopped:  Started: Stopped:  Started: Stopped:
Term Severity Report Description Treatment  Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Reason:  Started: Stopped:  Started: Stopped:  Started: Stopped:
Term Severity Report Description Treatment  Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Reducing dose Chlorpromazine then ceased. Laxatives.  Chorpromazine then ceased. Chlorpromazine then ceased. Laxatives.  Chorpromazine then ceased. Chlorpromazine then ceased. Laxatives.  Chorpromazine then ceased. Chlorpromazine then ceased. Laxatives.  Chorpromazine then ceased. Chlorpromazine then ceased. Chlorpromazine then ceased. Laxatives.  Chorpromazine then ceased. Chlorpromazine then ceased. Stopped inpatient pseudoobstructions.  Started: Stopped:  Started: Stopped:
Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Reducing dose Chlorpromazine then ceased. Laxatives.  Chlorpromazine then ceased. Laxatives.  Chlorpromazine then ceased. Laxatives.  Chlorpromazine then ceased. Laxatives.  Chlorpromazine then ceased. Laxatives.  Started: Stopped:  Started: Stopped:  Stopped:  Stopped:  Started: Stopped:
prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation    Started: Stopped:   Started: Stopped:   Stopped:   Started: Stopped:   Stopped:   Started: Stopped:   Started: Stopped:   Started: Stopped:   Started: Stopped:   Started: Stopped:   Started: Stopped:   Started: Stopped:   Started: Stopped:   Started: Stopped:   Started: Stopped:   Started: Stopped:   Stopped:   Started: Stopped:   Started: Stopped:   Stopped:   Started: Stopped:   Stopped:   Stopped:   Started: Stopped:   St
prolonged inpatient hospitalisation    Started: Stopped:   Stopped:   Started: Stopped:   Started: Stopped:   Started: Stopped:   Started: Stopped:   Started: Stopped:   Started: Stopped:   Started: Stopped:   Started: Stopped:   Started: Stopped:   Started: Stopped:   Stopped:   Started: Stopped:   Stopped:   Started: Stopped:   Stopped:
Started: Stopped:  Started: Stopped:  Inaler (Other drug) Reason:  Started: Stopped:  Stopped:  Started: Stopped:
Started: Stopped:  Ihaler (Other drug) Reason:  Started: Stopped:  Stopped:  Started: Stopped:
Started: Stopped:  Started: Stopped:  Started: Stopped:
Started: Stopped: SING SOLUTION (Other drug) Reason: Started: Stopped:
SING SOLUTION (Other drug) Reason: Started: Stopped:
Started: Stopped:
ther drug) Reason:
Started: Stopped:
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estigations:
ype Range Date Tested Result Details

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Hospitalisation: Onset Date:	14/07/2006 Admitted to hospit 15/05/2006 Not yet recovered Is:				50.00
SANDOCAL NOS			Reason:		
Batch:		Started:		Stopped:	
ALENDRONATE S	ODIUM (Other drug)		Reason:		
Batch:		Started:		Stopped:	
CHLORPROMAZIN	IE HYDROCHLORIDE		Reason:		
Batch:		100.0 Milligram  Started:	Daily	<b>Stopped:</b> 15/05/2006	3
Laboratory In	vestigations:				
Additional Inf	ormation:				

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

R	er	n	rt	D	eta	il	S	•

Case Number: 221610 Seq: 1 Gender: M

Reported: 13/09/2006 Weight: 70.00 Hospitalisation: Age: 29

**Onset Date**: 12/07/2006 **DOB**: 26/02/1977

Outcome: Recovered 14/07/2006 Causality: Causality probable

# Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Agitation		Agitation, insomnia and tachycardia.	
Insomnia			
Tachycardia			

# **Medicine Details:**

ALPRAZOLAM (Other drug)	Reason:	Anxiety neurosis
Tablet	4.0 Microgram	Oral
Batch:	Started: 20/07/2005	Stopped:
LARGACTIL (Suspected)	Reason:	

 Tablet
 10.0
 Milligram
 Daily
 Oral

 Batch:
 Started: 12/07/2006
 Stopped: 13/07/2006

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number:222310Seq: 1Gender:MReported:10/10/2006Weight:0.00Hospitalisation:Admitted to hospitalAge: 67

**Onset Date**: 17/09/2006 **DOB**: 26/11/1938

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia	Life threatening	Leucopenia, neutropenia, lymphopenia, thrombocytopenia, febrile neutropenia.	
Febrile neutropenia	Life threatening		
Lymphopenia	Life threatening		
Neutropenia	Life threatening		
Thrombocytopenia	Life threatening		

#### **Medicine Details:**

IBUPROFEN (Other drug)	Reaso	n: Pain
	А	s necessary Oral
Batch:	Started:	<b>Stopped:</b> 17/09/2006
CELESTONE (Other drug)	Reaso	n: Otr ecz&der due otr&unsp cause
Cream	3.0 Dose Unspecified D	aily Topical
Batch:	Started:	<b>Stopped:</b> 17/09/2006
LARGACTIL (Suspected)	Reaso	n: Behavior disorders of childhod
Tablet	100.0 Milligram D	aily Oral
Batch:	Started:	<b>Stopped:</b> 19/09/2006

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

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Case Number: 223102

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Gender: M

Repor	ted: 14/11/2006	5			We	eight: 8.60			
łospitalisat				Age: 1					
-	ate: 22/08/2006	<b>;</b>				<b>DOB</b> : 03/08/2005			
Outco	me: Unknown				Caus	sality: Causality possible			
eaction D	etails:								
	eferred Term	Se	verity	Repo	ort Description	Treatment			
Dystonia			Oc	cculogyric dys	onia.	Bentropine 2 x 100mcg IV dose given.			
NA - ali - i -	Dataile								
Medicine	<u>Details:</u> MAZINE HYDROCHI	ORIDE (Sueno	acted)	Pos	son:				
SHLOKPKU	MAZINE HTURUUHI	LONIDE (Suspe	scieuj	Rea	50II.				
Bato	h:	St	arted: 18/08/2	2006	Stopped: 21/	08/2006			
l aborator	y Investigati	one.							
Date	Type	Range	Date Tested	Result		Details			
						_			
Additions	I Information								
Audiliolia	า กาเบากาลเเบก								
eport Run: 01/	06/2007 04:17PM	Database: pu	ısime02	A	DRS004	Page 487 of 495			



Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

 Case Number:
 223787
 Seq: 1
 Gender: M

 Reported:
 05/12/2006
 Weight:
 101.00

Hospitalisation: Age: 43

**Onset Date:** DOB: 25/04/1963

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botanoi			
Preferred Term	Severity	Report Description	Treatment
Hepatic enzyme increased	threatening		Risperidone, quetiapine and chlorpromazine ceased.

## **Medicine Details:**

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia
	25.0 Milligram	1 time
Batch:	Started: 17/10/2006	<b>Stopped:</b> 20/10/2006
CHLORPROMAZINE HYDROCHLORIDE	E (Suspected)	Reason: Otr spec symp psychopathol nec
	100.0 Milligram	As necessary
Batch:	Started: 10/10/2006	<b>Stopped:</b> 20/10/2006 0
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia
Tablet	2.0 Milligram	Daily Oral
Batch:	Started: 11/10/2006	<b>Stopped:</b> 20/10/2006
QUETIAPINE (Suspected)		Reason: Unspecified schizophrenia
Tablet	200.0 Milligram	Daily Oral
Batch:	Started:	<b>Stopped:</b> 20/10/2006

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
05/12/2006	ALT = SGPT		20/10/2006	ALTx30	
05/12/2006	GGT = SGGT =		20/10/2006	GGT x 30	
05/12/2006	SAP = ALP		20/10/2006	Alk Phos x 4	

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number: 223834 Seq: 1 Gender: M

Reported: 06/12/2006 Weight: 0.00 Hospitalisation: Age: 50Y

**Onset Date**: 01/10/2006 **DOB**:

**Outcome:** Recovered 12/10/2006 **Causality:** Causality possible

Reaction Details:

iteaction Details.			
Preferred Term	Severity	Report Description	Treatment
Jaundice		Jaundice, abnormal LFT's	Ceased chlorpromazine
Liver function test abnormal			

## **Medicine Details:**

METOCLOPRAMIDE HYDROCHLORIDE (Other drug)		Reason:		
Batch:	Started:	Stopped:		
PHYTOMENADIONE (Other drug)		Reason:		
Batch:	Started:	Stopped:		
TIMENTIN (Other drug)		Reason: Unspecified septicemia		
Batch:	Started:	Stopped:		
FRUSEMIDE (Other drug)		Reason:		
Batch:	Started:	Stopped:		

# **Laboratory Investigations:**

Date	Туре	Range	Date Tested	Result	Details
06/12/2006	ALT = SGPT		30/09/2006	20	
06/12/2006	ALT = SGPT		01/10/2006	16	
06/12/2006	ALT = SGPT		02/10/2006	20	
06/12/2006	ALT = SGPT		05/10/2006	20	
06/12/2006	Albumin		30/09/2006	15	
06/12/2006	Albumin		01/10/2006	14	
06/12/2006	Albumin		02/10/2006	15	

## **Additional Information:**

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06/12/2006

SAP = ALP

**Additional Information:** 

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** Gender: M Case Number: 223834 Seq: 1 Reported: 06/12/2006 Weight: 0.00 Hospitalisation: Age: 50Y Onset Date: 01/10/2006 DOB: Outcome: Recovered 12/10/2006 Causality: Causality possible Reaction Details: **Medicine Details:** PANTOPRAZOLE (Other drug) Reason: Batch: Started: Stopped: ACICLOVIR (Other drug) Reason: Stopped: Batch: Started: **CHLORPROMAZINE HYDROCHLORIDE (Suspected)** Reason: Otr spec symp psychopathol nec 150.0 Milligram Daily Nasogastric Started: 29/09/2006 Batch: Stopped: 02/10/2006 HYDROCORTISONE (Suspected) Reason: Unspecified septicemia Injection 200.0 Milligram Daily Intravenous Batch: Started: 29/09/2006 Stopped: 02/10/2006 **Laboratory Investigations:** Type Date Tested Result Details Date Range 06/12/2006 Albumin 05/10/2006 17 Bilirubin 06/12/2006 30/09/2006 22 06/12/2006 Bilirubin 01/10/2006 57 Bilirubin 06/12/2006 05/10/2006 33 06/12/2006 Bilirubin 02/10/2006 124 SAP = ALP 06/12/2006 30/09/2006 66

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01/10/2006



# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report Hospitalisati Onset Da	<b>ate:</b> 01/10/200 <b>ne:</b> Recovered	6		12/10/2006		Gender: Weight: Age: DOB: Causality:	0.00 50Y
Medicine I	Details:						
METOCLOPR	AMIDE HYDROCH	LORIDE (Other	r drug)	Rea	son:		
Batcl			tarted:			Stopped:	
PHYTOMENA	DIONE (Other dru	ıg)		Rea	son:		
Batcl	<b>.</b> .	6	tarted:			Stopped:	
TIMENTIN (Ot		3	iarieu.	Reason: Unspecified septicemia			
TIMENTIN (O	iner drug)			Noa	3011.	Onspecified septicernia	
Batcl	h:	S	tarted:			Stopped:	
FRUSEMIDE (				Rea	son:		
Batcl	h:	S	tarted:			Stopped:	
l abarata	u lovesticet	ions:					
Date	y Investigat Type	Range	Date Tested	Result		Detai	ls
	SAP = ALP	rango	02/10/2006	78		Dotai	
06/12/2006	SAP = ALP		05/10/2006	85			
Additional	l Informatioi	n:					

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

06/40/0000	-				Gender:	IVI
06/12/2006				,	Weight:	0.00
					Age:	
01/10/2006					DOB:	
		12/10/2	2006	Ca	usality:	Causality possible
15:						
aile:						
			Reason:			
3,						
	Started:			Stopped:		
drug)			Reason:			
E IIVBB00::: 05:::	Started:		<b>.</b>			-1
E HYDROCHLORII		Millioner				
			Daily			
F (Suspected)	Started: 29/0	3/4UUD	Reason:			,
= (Ouspecieu)	200 n I	Milligram				s
			Dany			
		• •				
vestigations	:					
ormation:						
ormation:						
ormation:						
ormation:						
	Recovered  Is:  ails: (Other drug)  IE HYDROCHLORII  IE (Suspected)	Recovered  Is:  ails: (Other drug)  Started: drug)  Started: 150.0   Started: 29/0  E (Suspected)  200.0	Recovered 12/10// Is:  ails: (Other drug)  Started: drug)  Started: IE HYDROCHLORIDE (Suspected)  150.0 Milligram Started: 29/09/2006  IE (Suspected)  200.0 Milligram Started: 29/09/2006	Recovered 12/10/2006  Is:    Add   Started   Started	Recovered 12/10/2006 Calls:    Sails:	Recovered   12/10/2006   Causality:

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Rep	ort	Deta	ils:
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Case Number: 225639 Seq: 1 Gender: F

Reported: 09/02/2007 Weight: 0.00 Hospitalisation: Age: 42

**Onset Date**: 04/02/2007 **DOB**: 16/10/1964

Outcome: Unknown Causality: Causality probable

Reaction Details:

touction Dotailor			
Preferred Term	Severity	Report Description	Treatment
Sinus congestion		developed nasal stuffiness about 30 minutes after an injection of Largactil.	

## **Medicine Details:**

LARGACTIL (Suspected) Reason:

 Injection
 12.5
 Milligram
 Intravenous

 Batch:
 Started: 04/02/2007
 Stopped: 04/02/2007

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

**Report Details:** 

Case Number:226561Seq: 1Gender:FReported:13/03/2007Weight:0.00Hospitalisation:Admitted to hospitalAge: 59Y

Onset Date: 01/01/2007 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

teaction Detaile.			
Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		Chlorpromazine ceased.

#### **Medicine Details:**

TRITACE (Other drug)			Reason:	Essential beni	gn hypertension
Tablet	1.3	Milligram	Daily		Oral
Batch:	Started:		L TERM	Stopped:	10/01/2007
LIPITOR (Suspected)			Reason:	Othr&unspec	metabolic diseases
Tablet	20.0	Milligram	Daily		Oral
Batch:	Started:		L TERM	Stopped:	10/01/2007
LARGACTIL (Suspected)			Reason:	Depression	
Tablet	25.0	Milligram	Daily		Oral
Batch:	Started: 15/	12/2006		Stopped:	08/01/2007

**Laboratory Investigations:** 

 	<u> </u>					
Date	Туре	Range	Date Tested	Result	Details	
13/03/2007	ALT = SGPT				688	
13/03/2007	Bilirubin				268,	
	GGT = SGGT =				1386	
	Other data				Hep A, B and C - neg.	
13/03/2007	SAP = ALP				903	

## **Additional Information:**

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Date Range: 15 Jul 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: CHLORPROMAZINE HYDROCHLORIDE,LARGACTIL,PROMACID,PROTRAN

Report D	Details:
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Case Number:228036Seq: 1Gender: MReported:27/04/2007Weight: 0.00Hospitalisation:Admitted to hospitalAge: 59Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

#### **Reaction Details:**

caction Botano				
Preferred Term	Severity	Report Description	Treatment	
Suicide attempt	prolonged	Patient ingested 200 x 10mg Largactil tablets and 750mls whiskey in apparent suicide attempt		

## **Medicine Details:**

LARGACTIL (Suspected)			
Tablet	2.0 Gram	Total Ora	ral
Batch:	Started:	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

## **Additional Information:**

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