

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Papart Datail			
Report Detail			
<b>Case Number:</b> 55078 <b>Reported:</b> 04/07/1988	<b>Seq</b> : 1		Gender: F Weight: 57.00
Hospitalisation:			Age: 36Y
Onset Date: 15/10/1987			DOB:
Outcome: Not yet red	covered	(	Causality: Causality possible
Reaction Detai  Preferred Term	Severity	Report Description	Treatment
Facial palsy	Severity	Report Description	rreatment
Medicine Details: TOFRANIL (Suspected)		Reason:	
, , ,	25.0 Millio		
3atch:	3tarted: 15/10/19	Stopped:	15/10/1987
Laboratory Investigati		Davit I	D. de lle
Laboratory Investigati  Date Type	Ons:  Range Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 55434 Seq: 1 Gender: F

Reported: 27/07/1988 Weight:
Hospitalisation: Age: 75Y
Onset Date: 05/06/1988 DOB:

Onset Date: 05/06/1988

Outcome: Recovered

Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Hallucination			

**Medicine Details:** 

TOFRANIL (Suspected)	Reason: Depression
	50.0 Milligram Daily
3atch:	Started: 25/05/1988 Stopped: 06/06/1988
TENORMIN (Suspected)	Reason: Essential benign hypertension
	50.0 Milligram Daily
3atch:	Started: 3topped: 17/06/1988
MINIPRESS (Suspected)	Reason: Essential benign hypertension
	0.5 Dose Unspecified Daily
3atch:	<b>Started: Stopped:</b> 17/06/1988
DYAZIDE (Suspected)	Reason: Essential benign hypertension
	1.0 Dose Unspecified Daily
3atch:	Started: 3topped: 17/06/1988

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Misclassified at Other data				Was quite well and no longer hallucinating.  Ceased tofranil 6/6/88 but hallucinations persisted - 1/52 later admitted to panch and commenced on diazepam and haloperido (dose unknown).several days later she was depressed,anxious still hallucinating so ceased all medication except diazepam. her blood pressure rose so she was restarted on tenormin 50mg daily as well diazepam and one month later



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 55526 Seq: 1 Gender: M

Reported: 11/08/1988 Weight:
Hospitalisation: Age: 68Y

Onset Date: 23/06/1988 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

-				=
	Preferred Term	Severity	Report Description	Treatment
	Hypertension			

### **Medicine Details:**

3atch:

**TENORMIN (Other drug)** Reason: Essential benign hypertension

50.0 Milligram Daily

**Started**: 23/03/1988 **Stopped**:

TOFRANIL (Suspected) Reason: Depression

125.0 Milligram Daily

**3atch**: **3tarted**: 23/06/1988 **3topped**: 25/07/1988

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result			Deta	ils	
	Other data				23/6/88	25/7/88	26/7/88	b.p. 156/96	220/125



DOB:

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report [	<b>Detai</b> l
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Case Number: 55710 Seq: 1 Gender: F

Reported: 23/08/1988 Weight: 70.00 Hospitalisation: Age: 57Y

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

Onset Date: 28/07/1988

Preferred Term	Severity	Report Description	Treatment
Libido decreased			

### **Medicine Details:**

TOFRANIL (Suspected) Reason: Depression

Tablet 75.0 Milligram Daily Oral

**3atch: 3tarted:** 26/07/1988 **3topped:** CONTIN

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail							
Case Number: 56336	Seq: 1		Gen	der: F			
Reported: 13/09/1988			Wei	ght:			
Hospitalisation:				<b>Age</b> : 55Y			
Onset Date: 16/06/1988			D	OB:			
Outcome: Recovered			Causa	lity: Causality probable			
R <u>eaction Detai</u>							
Preferred Term	Severity	Repor	Description	Treatment			
Paraesthesia							
Syncope							
Medicine Details:  IMIPRAMINE HYDROCHLORIDE (Suspected)  125.0 Milligram Daily  3atch: 3tarted: 10/06/1988 3topped: 20/06/1988							
Laboratory Investigation	ons:						
Date Type	Range Date Test	ed Result		Details			
Additional Information	:						



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail				
Case Number: 57001 Reported: 24/11/1988	<b>Seq:</b> 1		Gender Weight	
ospitalisation:				: 39Y
Onset Date: 03/11/1988			DOB	
Outcome: Recovered			Causality	: Causality probable
eaction Detai Preferred Term	Severity	Report Des	crintion	Treatment
lausea	Ocventy	report Bes	Сприоп	rreatment
omiting				
Medicine Details: TOFRANIL (Suspected) Tablet	50.0 Mil	<b>Reason:</b> Iligram Daily	Depression Oral	
3atch:	<b>Started:</b> 31/10/		Stopped: 10/11/198	8
_aboratory Investigation	<b>ONS:</b> Range Date Tested	Result	Deta	ails
Laboratory Investigation		Result	Deta	ails



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 57406 Seq: 1 Gender: F

Reported: 16/11/1988 Weight:
Hospitalisation: Age: 56Y

**Onset Date**: 31/10/1988 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Hepatitis cholestatic			
Leukopenia			

#### **Medicine Details:**

IMIPRAMINE HYDROCHLORIDE (Suspected) Reason: Depression

 Tablet
 0.0
 Oral

 3atch:
 3tarted:
 28/09/1988
 3topped:
 12/10/1988

**Laboratory Investigations:** 

Laboratory invoctigations.						
Date	Туре	Range	Date Tested	Result	Details	
	Haematology				1 leucocytic count 800, bilirubin 207 mmol, phosphatase 439, ggt 181, ast 1040, ld 402	alkaline

#### **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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Gender: F Weight: 55.0 Age: 38\ DOB: Causality: Cau		1	Seq:	58203 23/01/1989	Case Number: Reported:
Age: 38Y				23/01/1989	Reported:
DOB:					
					spitalisation:
Causality: Cau					Onset Date:
_				Recovered	
Description	Donos	erity	Sov		<u>action Detai</u> Preferre
Description	Кери	renty	Sev		
					rthostatic hypot
n:	Reas				edicine Deta
		0.0			
Stopped:		arted:	3ta		3atch:
•				ected)	TOFRANIL (Suspe
	-				3atch:
Dotaile	Pocult	Data Tastad			
Details	Result	Date Tested	Range	туре	Date
Det	Result	Date Tested	<b>ns:</b> Range	Туре	aboratory In
/1989	Stopped: Son: Depression Daily Stopped: 15/01/	Reason: Depression  gram Daily  989 Stopped: 15/01/	0.0  Arted: Stopped:  Reason: Depression  100.0 Milligram Daily  Arted: 14/01/1989 Stopped: 15/01/	3tarted: \$topped:  Reason: Depression  100.0 Milligram Daily  \$tarted: 14/01/1989 \$topped: 15/01/	ails: er drug) Reason: 0.0 3tarted: Stopped: Cted) Reason: Depression 100.0 Milligram Daily Started: 14/01/1989 Stopped: 15/01/



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Case Number: 58750 Seq: 1 Gender: F

 Reported:
 08/02/1989
 Weight:
 57.00

 Hospitalisation:
 Age:
 39Y

 Onset Date:
 07/02/1988
 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction		The second second	Promethazine inj

### **Medicine Details:**

TOFRANIL (Suspected) Reason: Depression

 Tablet
 10.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 06/02/1988
 3topped:
 08/02/1988

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 58968 Seq: 1 Gender: F

Reported: 20/02/1989 Weight:
Hospitalisation: Age: 40Y

Onset Date: 06/02/1989 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Anorexia			
Hallucination			
Insomnia			
Nausea			

**Medicine Details:** 

BUSPAR (Other drug)		Reason:	Anxiety neuro	osis	
	20.0 Milligram	Daily	,		
3atch:	<b>Started:</b> 26/12/1988		Stopped:		CONTIN
SINEQUAN (Other drug)		Reason:	Depression		
	100.0 Milligram	Daily	,		
3atch:	<b>Started:</b> 01/01/1987		Stopped:		CONTIN
TOFRANIL (Suspected)		Reason:	Depression		
	30.0 Milligram	Daily	,		
3atch:	Started: 02/02/1989		Stopped:	07/02/1989	

**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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report	Detail
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 Case Number:
 60514
 Seq:
 1
 Gender:
 M

 Reported:
 23/05/1989
 Weight:
 78.00

Hospitalisation: Age: 55Y

**Onset Date:** 21/05/1989 **DOB:** 

Outcome: Not yet recovered Causality: Causality possible

#### **Reaction Detai**

Preferred Term	Severity	Report Description	Treatment
Urinary retention			

### **Medicine Details:**

TOFRANIL (Suspected) Reason: Other disturbance of sensation

Tablet 10.0 Milligram Daily Oral

3atch: Started: 21/05/1989 Stopped:

# **Laboratory Investigations:**

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report I	Detail
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Case Number: 60708 Seq: 1 Gender: F
Reported: 29/05/1989 Weight:

Hospitalisation: Age: 25Y
Onset Date: 12/05/1989
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

todotion Botai		_	
Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			Iv diazepam stat, oral panadol for headache, dilantin 100mg o tds for few days, tofranil dose graded down and ceased.

## **Medicine Details:**

TOFRANIL (Suspected)	·	Reason:	Depression	·
Tablet	250.0 Milligram	Daily		Oral
Batch:	<b>Started:</b> 09/05/1989		Stopped:	
MELLERIL (Suspected)		Reason:	Depression	
	200.0 Milligram	Daily		
3atch:	Started: 23/04/1989		Stopped:	12/05/1989
NOCTEC (Suspected)		Reason:	Specific disor	ders of sleep
Oral application	1.0 Gram	Daily		Oral
3atch:	Started: 23/04/1989		Stopped:	12/05/1989

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

		eta	

Case Number: 60977 Seq: 1 Gender: F

Reported: 14/06/1989 Weight: 72.00 Hospitalisation: Age: 77Y

Onset Date: 22/05/1989 DOB:

Outcome: Recovered Causality: Causality possible

#### **Reaction Detai**

Preferred Term	Severity	Report Description	Treatment
Leukopenia			

## **Medicine Details:**

FOLIC ACID (Other drug)		Reason:	
	0.0		
Зatch:	Started:	Stopped:	
CYANOCOBALAMIN (Other drug)		Reason:	
	0.0		
Зatch:	Started:	Stopped:	
CHLORAL HYDRATE (Suspected)		Reason: Specific disorders of sleep	
Oral application	500.0 Milligram	As necessary Oral	
3atch:	<b>Started:</b> 23/04/1989	<b>Stopped:</b> 23/05/1989	
TEGRETOL (Suspected)		Reason: Other&unspecified epilepsy	
Tablet	400.0 Milligram	Daily Oral	
3atch:	Started:	<b>Stopped</b> : 23/05/1989	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Haematology				1 bone marrow - hypocellularity with left shift in the



Report Detail

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detai	14/06/1989 22/05/1989 Recovered	Seq:	1				Gender: Weight: Age: DOB: Causality:	72.00	
<b>Medicine Deta</b>									
IMIPRAMINE HYDE	ROCHLORIDE (Suspe	cted)			Reason:	Depression			
				Milligram	Daily				
3atch:		3ta	rted:			3topped	23/05/1989	)	
Laboratory In	vestigations:								
Additional Inf	ormation:								

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

**Report Detail** 

Case Number: 61391 Seq: 1 Gender: F

Reported: 13/07/1989

Hospitalisation:

Weight:
Age: 71Y

Onset Date: 17/05/1989 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Glossitis		Furry tongue	
Diarrhoea			

**Medicine Details:** 

ATIVAN (Other drug) Reason: Anxiety neurosis

5.0 Milligram Daily

3atch: 3tarted: 01/11/1984 3topped:

ROHYPNOL (Other drug) Reason: Anxiety neurosis

4.0 Milligram Daily

3atch: 3tarted: 01/01/1985 3topped:

IMIPRAMINE HYDROCHLORIDE (Suspected) Reason: Incontinence of urine

25.0 Milligram Daily

**3atch: 3tarted:** 17/05/1989 **3topped:** 22/05/1989

**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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 61965
 Seq:
 1
 Gender:
 M

 Reported:
 10/08/1989
 Weight:

Hospitalisation: Age: 64

**Onset Date:** 31/07/1989 **DOB:** 04/10/1924

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction			Ceased baclofen

#### **Medicine Details:**

Medicine Details.					
BACLOFEN (Suspected)		Reason:	Morb&mort du	ie otr ill-def caus	,
Tablet	20.0 Milligram	Daily		Oral	
Заtch:	Started: 29/06/1989		Stopped:	10/08/1989	
TOFRANIL (Suspected)		Reason:			
Tablet	60.0 Milligram	Daily		Oral	
3atch:	Started: 23/03/1989		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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 62766
 Seq:
 1
 Gender:
 F

 Reported:
 05/10/1989
 Weight:
 62.00

 Hospitalisation:
 Age:
 77Y

**Onset Date:** 01/10/1989 **DOB:** 

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

todotion Dotai			
Preferred Term	Severity	Report Description	Treatment
Pruritus			
Rash erythematous			Calamine lotion top prn. allergic to penicillin. antibiotic ceased
Rash maculo-papular			

**Medicine Details:** 

TOFRANIL (Suspected)		Reason:		
Tablet	75.0 Milligram	Daily	Oral	
Зatch:	<b>Started:</b> 25/09/1989	€to	pped:	
Keflin Neutral (Suspected)		Reason: Other	prophylactic procedures	
Injection	4.0 Gram	Daily	Intravenous	
3atch:	3tarted: 25/09/1989	Sto	pped: 28/09/1989	
SEPTRIN FORTE (Suspected)		Reason: Othr d	liseases of urinary tract	
Tablet	2.0 Dose Unspec	cified Daily	Oral	
3atch:	<b>Started:</b> 30/09/1989	€to	pped: 30/09/1989	
PANADOL (Suspected)		Reason:		
Oral application	6.0 Dose Unspec	cified Daily	Oral	
Зatch:	3tarted: 25/09/1989	Sto	pped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report	Detai∣
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 Case Number:
 63477
 Seq:
 1
 Gender:
 M

 Reported:
 08/09/1989
 Weight:

Hospitalisation:
Onset Date: 09/01/1989
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis			

## **Medicine Details:**

IMIPRIN (Suspected)		Reason:		
	100.0 Milligram	Daily		
3atch:	<b>Started:</b> 04/01/1989		Stopped:	
PROTAPHANE (Suspected)		Reason:		
	41.0 International	Jnit Daily		
Зatch:	Started:		Stopped:	
ACTRAPID NOVO (Suspected)		Reason:		
ACTRAPID NOVO (Suspected)	36.0 International			
ACTRAPID NOVO (Suspected)  3atch:	36.0 International		Stopped:	
			Stopped:	
3atch:		Jnit Daily	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Reported:		Seq: 1			Gender:	
•	08/09/1989				Weight:	
ospitalisation:					Age:	
Onset Date:	09/01/1989				DOB:	
Outcome:	Unknown				Causality:	Causality possible
eaction Detai						
Medicine Deta						
THIAMINE (Suspec	cted)			Reason:		
			Milligram	Daily		
3atch:		Started:			Stopped:	
URAL (Suspected)				Reason:		
		3.0	Dose Unspe	cified Daily		
			,	cilied Dally		
3atch:		Started:		coned Daily	Stopped:	
3atch:				Daily	Stopped:	
3atch:				Daily	Stopped:	
3atch:				somed Daily	Stopped:	
3atch:				somed Daily	Stopped:	
3atch:				somed Daily	itopped:	
3atch:				somed Daily	Stopped:	
	voctigations	Started:		Somed Daily	Stopped:	
	vestigations	Started:		Some Daily	itopped:	
	vestigations	Started:		Somed Daily	₹topped:	
	vestigations	Started:		acined Daily	itopped:	
	vestigations	Started:		somed Daily	itopped:	
	vestigations	Started:		Some Daily	₹topped:	
	vestigations	Started:		Some Daily	itopped:	
	vestigations	Started:		Some Daily	itopped:	
	vestigations	Started:		acined Daily	itopped:	
Laboratory In		Started:		acined Daily	itopped:	
Laboratory In		Started:		zoneu Dany	itopped:	
3atch:  Laboratory In		Started:		zonieu Dany	itopped:	
Laboratory In		Started:		zonieu Dany	itopped:	
Laboratory In		Started:		zoneu Dany	itopped:	

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**Additional Information:** 

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Reported: 20/12/1989 ospitalisation: Onset Date: 25/11/1989 Outcome: Recovered action Detai			Weight: Age: 76Y DOB: Causality: Causality certain
Preferred Term	Severity	Report Description	Treatment
Diarrhoea Vomiting			Reaction recurred when tofranil restarted on 8/12/89
Medicine Details:			
Medicine Details: TOFRANIL (Suspected)		Reason: Depression	1
TOFRANIL (Suspected) Oral application	25.0	Milligram 1 time	Oral
TOFRANIL (Suspected)	25.0 Started: 25/1	Milligram 1 time	Oral
Oral application  3atch:	Started: 25/1	Milligram 1 time	Oral
TOFRANIL (Suspected) Oral application	Started: 25/1	Milligram 1 time	Oral



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 63921
 Seq:
 1
 Gender:
 M

 Reported:
 03/01/1990
 Weight:

Hospitalisation: Age: 73Y
Onset Date: 31/08/1989
DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Genital ulceration			Sequelae. secondary infection

#### **Medicine Details:**

MEGICINE Details.				
TEGRETOL (Suspected)		Reason:	Otr&unsp forms neural	g&neurit
	0.0			
3atch:	Started: 01/08/1989		Stopped:	03W
TOFRANIL (Suspected)		Reason:	Otr&unsp forms neural	g&neurit
	0.0			
3atch:	Started: 01/08/1989		Stopped:	03W

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 63941
 Seq:
 1
 Gender:
 F

 Reported:
 04/01/1990
 Weight:

Hospitalisation: Age: 59Y
Onset Date: 14/12/1989
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

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

## **Medicine Details:**

CARAFATE (Suspected)		Reason:	Peptic ulcer nos w/o ment perf
Tablet	4.0 Gram	Daily	, Oral
3atch:	Started: 11/12/1989		Stopped: 16/12/1989
AUSTRASTAPH (Suspected)		Reason:	Pneumonia,unspecified
Injection	4.0 Gram	Daily	Intravenous
3atch:	Started: 12/12/1989		Stopped: 19/12/1989
LARGACTIL (Suspected)		Reason:	Unspecified schizophrenia
Tablet	150.0 Milligram	Daily	oral Oral
3atch:	Started:		Stopped: 12/12/1989
TOFRANIL (Suspected)		Reason:	Depression
Tablet	75.0 Milligram	Daily	oral Oral
3atch:	Started:		Stopped: 12/12/1989

**Laboratory Investigations:** 

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



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 64206
 Seq:
 1
 Gender:
 M

 Reported:
 25/01/1990
 Weight:
 79.00

 Hospitalisation:
 Age:
 76Y

**Onset Date**: 21/01/1990 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

		-	-
Preferred Term	Severity	Report Description	Treatment
Headache			
Nausea			Heparin infusion followed by
Thrombophlebitis			

**Medicine Details:** 

PANADEINE (Suspected)	Reason: Pain
	2.0 Dose Unspecified As necessary
Зatch:	Started: Stopped:
HONVAN (Suspected)	Reason: Malignant neoplasm of prostate
	360.0 Milligram Daily
Зatch:	<b>Started:</b> 04/12/1989 <b>Stopped:</b> 21/01/1990
PROGOUT (Suspected)	Reason: Gout
	300.0 Milligram Daily
Зatch:	Started: Stopped:
SUPRES (Suspected)	Reason: Essential benign hypertension
	50.0 Milligram Daily
3atch:	Started: Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

Case Number: 64206

**Reported:** 25/01/1990

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

**Weight:** 79.00

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Seq: 1

ospitalisation:				Age:	76Y
Onset Date: 21/01/1990				DOB:	Causality massible
Outcome: Not yet recovered action Detai				Causanty:	Causality possible
action Detai					
Medicine Details: TENORMIN (Suspected)			Reason:	Essential benign hypertens	ion
TENORIMIN (Suspected)	100.0	Milligram	Daily	Essential benigh hypertens	NOT
3atch:	Started:	Willigram	Daily	Stopped:	
CORTATE (Suspected)	744.404.		Reason:	торрош.	
(***)	1.5	Dose Unspec			
3atch:	Started:	·	Í	Stopped:	
TOFRANIL (Suspected)			Reason:	Pain	
	30.0	Milligram	Daily		
Batch:	Started:			Stopped:	
ROHYPNOL (Suspected)			Reason:	Pain	
	2.0	Milligram	Daily		
3atch:	Started:			Stopped:	
abaratam, Investigations					
aboratory Investigations:					
Additional Information:					
Additional Information:					
Additional Information:					
Additional Information:					

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Report Detail

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Case Number:	64206	Seq: 1				Gender:	M	
Reported:	25/01/1990					Weight:	79.00	
Hospitalisation:						Age:	76Y	
Onset Date:	21/01/1990					DOB:		
Outcome:	Not yet recovered	d			С	ausality:	Causality poss	ible
Reaction Detai	i							
Medicine Det								
FELDENE (Suspec	cted)			Reason:				
			Milligram	Daily				
3atch:		Started:		_	Stopped:			
FLORINEF (Suspe	:cted)			Reason:				
			Microgram	Daily				
3atch:		Started:			Stopped:			
Laboratory In	vestigations:							
-	_							
Additional las	farmatian.							
Additional In	formation:							
	0 00:4051 5 :	<b>.</b>		ADD0004			D 5-	
eport Run 19/07/200	J UZ:13PN Data/	base: pusime		ADRS004			Page 25	ot 279



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 64452
 Seq:
 1
 Gender:
 F

 Reported:
 20/02/1990
 Weight:
 55.00

 Hospitalisation:
 Age:
 70Y

Onset Date: 16/02/1990 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

104041011 20441			-
Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction			18/02 avil and calamine, on 20/02 add prednisolone

### **Medicine Details:**

AUGMENTIN (Suspected)		Reason:	Chronic sinusit	is
Oral application	750.0 Milligram	Daily		Oral
Зatch:	Started: 13/02/1990		Stopped:	16/02/1990
TOBISPRAY (Suspected)		Reason:	Chronic sinusit	is
Inhalation	2.0 Dose Unspec	cified Daily		Inhalation
3atch:	Started: 13/02/1990		Stopped:	CONTIN
ADALAT (Suspected)		Reason:	Essential benig	n hypertension
Oral application	40.0 Milligram	Daily		Oral
Зatch:	Started: 01/03/1988		Stopped:	CONTIN
TOFRANIL (Suspected)		Reason:	Depression	
Tablet	25.0 Milligram	Daily		Oral
3atch:	Started:		Stopped:	CONTIN

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### Additional Information:

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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

 Case Number:
 64452
 Seq:
 1
 Gender:
 F

 Reported:
 20/02/1990
 Weight:
 55.00

 Hospitalisation:
 Age:
 70Y

**Onset Date**: 16/02/1990 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

### **Medicine Details:**

Medicine Details.					
SLOW-K (Suspected)		Reas	on:	Depression	
Oral application	2	2.0 Dose Unspecified	Daily	Oral	
3atch:	Started:			Stopped:	CONTIN
NATRILIX (Suspected)		Reas	on:	Essential benign hypertension	1
Tablet	1	1.0 Dose Unspecified	Daily	Oral	
3atch:	Started:	01/03/1988		Stopped:	CONTIN

# **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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

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ИG	υu	ווע	$\mathbf{\nu}$	τιa	

Case Number: 65061 Seq: 1 Gender: F

Reported: 09/04/1990 Weight: 70.00 Hospitalisation: Age: 61Y

Onset Date: 05/03/1990 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Convulsion			Iv diazepam 10 mg

### **Medicine Details:**

ZANTAC (Other drug) Reason: Other diseases of esophagus

 Tablet
 300.0 Milligram
 Daily
 Oral

 3atch:
 3tarted: 04/03/1990
 3topped: 05/03/1990

TOFRANIL (Suspected) Reason:

0.0

3atch: Started: Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

Case Number: 66017

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Seq: 1

Reported: 12/06/1990 lospitalisation: Onset Date: Outcome: Unknown eaction Detai						eight: Age: 47 DOB: 29/0 sality: Cau	03/1943 usality poss	ible
Preferred Term	Sev	erity	Repo	rt Descr	iption		Treatment	
izziness			•					
ausea								
edicine Details:								
PROPANTHELINE BROMIDE (Su	ispected)	450.0 Mil		son:				
Batch:	Sta	150.0 Mil	ligram	Daily	Stopped:			
MIPRAMINE HYDROCHLORIDE			Reas	on:	жорреа.			
	(,	75.0 Mil		Daily				
3atch:	3ta	rted:			Stopped:			
aboratory Investigation	<b>Ons:</b> Range	Date Tested	Result			Details		
dditional Information				A D D C C C				
oort Run 19/07/200 02:14PN	Database: pu	sime	,	ADRS004			Page 29	of 279



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 66331 Seq: 1 Gender: M
Reported: 28/06/1990 Weight:
Hospitalisation: Age: 22Y

Onset Date: 22/02/1990 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Hepatitis cholestatic			

**Medicine Details:** 

FLOPEN (Suspected)			र	eason:	Other prophyla	actic procedures	
Injection		8.0	Gram	Daily		Intravenous	
Зatch:	Started:	16/0	02/1990		Stopped:	18/02/1990	
AMOXIL (Suspected)			5	eason:	Other prophyla	actic procedures	
Injection		6.0	Gram	Daily		Intravenous	
Зatch:	Started:	16/0	02/1990		Stopped:	18/02/1990	
SINEMET (Suspected)			5	eason:			
		5.0	Dose Unspecif	ied Daily			
Заtch:	Started:				Stopped:		CONTIN
RIVOTRIL (Suspected)			5	eason:			
Oral application		2.0	Milligram	Daily		Oral	
			-				

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
	Biochemistry	range	Date rested		17/2 22/2 24/2 26/2 27/2 28/2 2/3 7/3 alk (<90) 73 170 295 389 430 448 371 217 bili (<19) 12 98 143 132 46 65 46 29 ast (<43) 13 127 106 251 240 134 71 17 alt (<55) 11
	Misclassified at				91 48 49 52 67 52 24 Ggt (<50) 18 260 290 295 367 357 272 117



Report Detail

Case Number: 66331

**Reported:** 28/06/1990

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Seq: 1

28/06/1990				Weight	t:	
				Causality	: Causality possible	)
			Reason:			
ation	400.0	Milligram	Daily	Oral		
	Started:			Stopped:	CONTIN	
cted)			Reason:			
ation	20.0	Milligram	Daily	Oral		
	Started:			Stopped:	CONTIN	
vestigations:						
formation:						
formation:						
formation:						
formation:						
formation:						
formation:						
	28/06/1990 22/02/1990 Recovered  ails: ected) ation  exted) ation	ails: ected) ation 400.0 Started: ected) ation 20.0 Started:	ails: ected) ation 400.0 Milligram started: ected) ation 20.0 Milligram started:	Recovered  ails: ected) ation 400.0 Milligram Daily started: ected) ation 20.0 Milligram Daily started:	Age 22/02/1990 Recovered Causality  ails: ected) ation 400.0 Milligram Daily Oral started: stopped: cted) ation 20.0 Milligram Daily Oral started: stopped: started: stopped:	Age: 22Y 22/02/1990 Recovered Causality: Causality possible  ails: ected)



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 67149 Seq: 1 Gender: F

Reported: 20/08/1990 Weight: 75.00 Hospitalisation: Age: 84Y

Onset Date: 31/05/1990 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Dizziness			
Syncope			

## **Medicine Details:**

ANGININE (Other drug)		Reason:	
Tablet	600.0 Microgram	As necessary	Sublingual
3atch:	Started:	Stopped:	
CYTAMEN (Other drug)		Reason: Unspec vitar	nin deficien states
Injection	1.0 Milligram	Monthly	Intramuscular
Зatch:	Started: 01/02/1990	Stopped:	
PRO-BANTHINE (Other drug)		Reason: Incontinence	of urino
PRO-DANTHINE (Other drug)		Reason: Incontinence	or unite
Tablet	30.0 Milligram	Daily	Oral
` ,	30.0 Milligram Started: 01/02/1990		Oral
Tablet	· ·	Daily	Oral
Tablet  3atch:	· ·	Daily <b>3topped:</b>	Oral

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage 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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 67149 Seq: 1 Gender: F

Reported: 20/08/1990 Weight: 75.00 Hospitalisation: Age: 84Y

**Onset Date**: 31/05/1990 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

### **Medicine Details:**

OROXINE (Other drug)		Reason:	Myxedema	
Tablet	50.0 Microgram	Daily		Oral
3atch:	Started: 01/02/1990		Stopped:	CONTIN
TOFRANIL (Suspected)		Reason:	Incontinence of	of urine
Tablet	20.0 Milligram	Daily		Oral
3atch:	Started: 01/02/1990		3topped:	27/07/1990

# **Laboratory Investigations:**

#### **Additional Information:**

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

**Hospitalisation:** 

Case Number: 67595

**Reported:** 03/09/1990

Onset Date: 01/05/1990

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

DOB:

**Age:** 71Y

Weight:

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Seq: 1

Preferred Term  Oystonia Pyrexia  Fremor  Medicine Details: SINEMET (Suspected)  3atch:  IMIPRAMINE HYDROCHLORIDE (Susp	Started:	Reas Dose Unspecified	Daily Stopped: 04	Treatment  Ceased imipramine & started cogentin 3mg. changed sinemet to madopar hbs.
Medicine Details: SINEMET (Suspected)  3atch: IMIPRAMINE HYDROCHLORIDE (Susp	4.0 Started: Dected)	Reas Dose Unspecified	on: Daily Stopped: 04	Ceased imipramine & started cogentin 3mg. changed sinemet to madopar hbs.
remor  ledicine Details: SINEMET (Suspected)  3atch:	Started: pected) 20.0	Dose Unspecified	Daily Stopped: 04	cogentin 3mg. changed sinemet to madopar hbs.
ledicine Details: SINEMET (Suspected)  3atch: MIPRAMINE HYDROCHLORIDE (Susp	Started: pected) 20.0	Dose Unspecified	Daily Stopped: 04	
SINEMET (Suspected)  3atch:  MIPRAMINE HYDROCHLORIDE (Susp	Started: pected) 20.0	Dose Unspecified	Daily Stopped: 04	4/05/1990
SINEMET (Suspected)  3atch:  MIPRAMINE HYDROCHLORIDE (Susp	Started: pected) 20.0	Dose Unspecified	Daily Stopped: 04	4/05/1990
SINEMET (Suspected)  3atch: IMIPRAMINE HYDROCHLORIDE (Susp	Started: pected) 20.0	Dose Unspecified	Daily Stopped: 04	4/05/1990
SINEMET (Suspected)  3atch: IMIPRAMINE HYDROCHLORIDE (Susp	Started: pected) 20.0	Dose Unspecified	Daily Stopped: 04	4/05/1990
SINEMET (Suspected)  3atch: IMIPRAMINE HYDROCHLORIDE (Susp	Started: pected) 20.0	Dose Unspecified	Daily Stopped: 04	4/05/1990
SINEMET (Suspected)  3atch: MIPRAMINE HYDROCHLORIDE (Susp	Started: pected) 20.0	Dose Unspecified	Daily Stopped: 04	4/05/1990
MIPRAMINE HYDROCHLORIDE (Susp	Started: pected) 20.0	Reas	Stopped: 04	4/05/1990
MIPRAMINE HYDROCHLORIDE (Susp	pected)			4/05/1990
	20.0		on: Eroquoney of mic	
Зatch:				turition
satcn:		Milligram	Daily Stopped:	01W
aboratory Investigations				
aboratory Investigations:  Date Type Rar	nge Date Tes	sted Result		Details



Gender: F

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail	
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Reported: 10/10/1990 Weight: 67.00 Hospitalisation: Age: 34Y

Onset Date: 24/09/1990 DOB:

Seq: 1

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

Case Number: 67778

•	oaction Botal			
	Preferred Term	Severity	Report Description	Treatment
	Rash maculo-papular			

### **Medicine Details:**

TOFRANIL (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 05/09/1990 3topped: 24/09/1990

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 67945 Seq: 1 Gender: F

Reported: 16/10/1990 Weight: 103.00 Hospitalisation: Age: 56Y

Onset Date: 16/10/1990 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Arrhythmia			
Cough			
Extrasystoles			

### **Medicine Details:**

CAPOTEN (Suspected)		Reason:	Essential beni	gn hypertension
Oral application	100.0 Milligram	Daily		Oral
3atch:	<b>Started:</b> 01/01/1988	<b>Started</b> : 01/01/1988 <b>Stopped</b> : 16		16/10/1990
TOFRANIL (Suspected)		Reason:		
Oral application	100.0 Milligram	Daily		Oral

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 68021
 Seq:
 1
 Gender:
 F

 Reported:
 27/10/1990
 Weight:
 70.00

 Hospitalisation:
 Age:
 36Y

Onset Date: 28/08/1990 DOB:

Outcome: Unknown Causality: Causality certain

**Reaction Detai** 

todotion Dotai			
Preferred Term	Severity	Report Description	Treatment
Abdominal pain			Tofranil ceased, recommenced 3/10/90 at 25mg tds, lfts mildly raised after two weeks
Hepatitis			
Nausea			

**Medicine Details:** 

Micalcinic Details.	
OROXINE (Other drug)	Reason: Myxedema
	0.0
3atch:	Started: Stopped:
MONOTARD HM (Other drug)	Reason: Diabetes mellitus
	34.0 International Unit Daily
3atch:	Started: Stopped:
TOFRANIL (Suspected)	Reason: Anxiety neurosis
	75.0 Milligram Daily
3atch:	Started: 03/05/1990 Stopped: 30/08/1990

**Laboratory Investigations:** 

	<i>y</i>				
Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				28/08, 30/08, 03/09, 13/09, 03/10, 19/10 bili (2-25) 36 19 39 13 4 8 alk (<125) 246 225 298 147 93 78 ast (<40) 730 570 1005 108 16 175 alt (<40) 2080 1505 1710 404 34 374
	Misclassified at				Ggt (<55) 66 64 152 48 15 15



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 68158 Seq: 1 Gender: M

Reported: 02/11/1990 Weight: 75.00 Hospitalisation: Age: 52Y

**Onset Date:** 31/05/1987 **DOB:** 

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction			
Libido decreased			

#### **Medicine Details:**

<u>Medicine Details.</u>				
LITHIUM CARBONATE (Other drug)		Reason:		
	750.0 Milligram	Daily		
3atch:	Started: 01/01/1987		Stopped:	28/12/1987
IMIPRAMINE HYDROCHLORIDE (Suspe	ected)	Reason:	Depression	
Tablet	100.0 Milligram	Daily		Oral
3atch:	3tarted: 01/01/1987		Stopped:	28/07/1990

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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 68362 Seq: 1 Gender: F

 Reported:
 09/11/1990
 Weight:
 70.00

 Hospitalisation:
 Age:
 37Y

 Onset Date:
 31/01/1990
 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Weight increased			Imiprimine was ceased

#### **Medicine Details:**

Medicine Details.				
TRIFLUOPERAZINE HYDRO	CHLORIDE (Suspected)		Reason:	Schizo-affective type psychos
	25.0 Mi	illigram	Daily	
3atch:	Started:			3topped: 26/09/1990
IMIPRAMINE HYDROCHLOR	IDE (Suspected)		Reason:	Schizo-affective type psychos
	150.0 Mi	illigram	Daily	
3atch:	Started:			Stopped: 27/08/1990

**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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Re	po	rt	D	etail
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Gender: F Case Number: 68394 Seq: 1 Reported: 16/11/1990 **Weight:** 72.00

Hospitalisation: Age: 28Y

Onset Date: 08/11/1990 DOB: Causality: Causality possible

Outcome: Not yet recovered

### Reaction Detail

teaction Detai			
Preferred Term	Severity	Report Description	Treatment
Face oedema			
Rash maculo-papular			Prednisolone, aristocort cream

#### **Medicine Details:**

**IMIPRAMINE HYDROCHLORIDE (Suspected)** Reason: Depression

Tablet 100.0 Milligram Daily Oral 3atch: 3tarted: 12/10/1990 09/11/1990 Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

report Detail	Re	port	Detail
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Case Number: 68665 Seq: 1 Gender: M
Reported: 04/12/1990 Weight:
Hospitalisation: Age: 69Y

**Onset Date**: 23/01/1990 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

#### **Reaction Detai**

100000000000000000000000000000000000000			-
Preferred Term	Severity	Report Description	Treatment
Headache			Paracetamol for headache
Orthostatic hypotension			

### **Medicine Details:**

TEMAZEPAM (Suspected)		Reason:	
	10.0 Milligram	Daily	
Зatch:	Started:	Stopped:	CONTIN
TOFRANIL (Suspected)		Reason:	
	30.0 Milligram	Daily	
Заtch:	Started:	Stopped:	CONTIN
FELODIPINE (Suspected)		Reason:	
	30.0 Milligram	Daily	
3atch:	Started:	Stopped:	CONTIN
CARDIPRIN 100 (Suspected)		Reason:	
	100.0 Milligram	Daily	
3atch:	Started:	Stopped:	CONTIN

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

Case Number: 68665

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Seq: 1

Reported: 04/12/1990					Weight:		
ospitalisation:					Age:	69Y	
Onset Date: 23/01/1990					DOB:		
Outcome: Not yet recovered				C	ausality:	Causality possi	ble
eaction Detai							
Medicine Details:							
FLUCLOXACILLIN SODIUM (Suspected)			Reason:				
Injection	4.	0 Gram	Daily		Intravenous	<b>;</b>	
3atch:	Started: 1	18/01/1990	•	Stopped:	23/01/1990		
MINIPRESS (Suspected)			Reason:				
(3.3)	2.	0 Milligram	Daily				
3atch:	Started: 1		24,	Stopped:	23/01/1990		
- Julioni		10/01/1000		жоррои.	20/01/1000		
aboratory Investigations:							
aboratory investigations.							
Additional Information:							
Mantional information.							
oort Run 19/07/200 02:14PN Databas	e: pusime		ADRS004			Page 42	of 270



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 69400 Seq: 1 Gender: F

Reported: 06/02/1991 Weight: 66.00 Hospitalisation: Age: 38Y

**Onset Date**: 15/12/1990 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			

#### **Medicine Details:**

TOFRANIL (Suspected) Reason: Depression

 Tablet
 150.0
 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/11/1990
 3topped:
 17/12/1990

**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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 69520
 Seq:
 1
 Gender:
 M

 Reported:
 15/02/1991
 Weight:
 80.00

Hospitalisation: Weight: 80.00
Age: 55Y

**Onset Date**: 31/12/1990 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Dysgeusia			

# Medicine Details:

ARTANE (Suspected)		Reason:	Paralysis agitans	
	6.0 Milligram	Daily		
3atch:	<b>Started:</b> 01/01/1985		<b>Stopped:</b> 19/11/199	00
MADOPAR (Suspected)		Reason:	Paralysis agitans	
	2.0 Dose Unspe	cified Daily		
3atch:	Started: 01/11/1990		Stopped:	CONTIN
MADOPAR (Suspected)		Reason:	Paralysis agitans	
	9.0 Dose Unspe	cified Daily		
3atch:	Started: 01/11/1990		Stopped:	CONTIN
PARLODEL (Suspected)		Reason:	Paralysis agitans	
	15.0 Milligram	Daily		
3atch:	Started: 01/01/1985		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 necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 69520
 Seq:
 1
 Gender:
 M

 Reported:
 15/02/1991
 Weight:
 80.00

Hospitalisation: Age: 55Y
Onset Date: 31/12/1990
DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

#### **Medicine Details:**

MODURETIC (Suspected) Reason: Diabetes mellitus

1.0 Dose Unspecified Daily

**3atch**: **3tarted**: 02/08/1990 **3topped**: CONTIN

IMIPRAMINE HYDROCHLORIDE (Suspected) Reason: Depression

2.0 Dose Unspecified Alternate days

3atch: Started: 19/11/1990 Stopped: CONTIN

## **Laboratory Investigations:**

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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail		
Case Number: 70205	Seq: 1	Gender: F
Reported: 13/03/1991		Weight:

Hospitalisation: Age: 69Y
Onset Date: 22/08/1990
DOB:

Outcome: Death, maybe drug Causality: Causality possible

**Reaction Detai** 

todotion Dotal			
Preferred Term	Severity	Report Description	Treatment
Hypertension			
Oliguria			
Peptic ulcer perforation			
Renal failure acute			
Tachycardia			

**Medicine Details:** 

PANADEINE (Suspected)		Reason: Pain	
	2.0 Dose Unspec	ified As necessary	
3atch:	Started:	Stopped:	30/08/1990
ORUDIS SR (Suspected)		Reason: Other rheuma	atoid arthritis
Capsule	200.0 Milligram	Daily	Oral
3atch:	Started: 24/07/1990	Stopped:	21/08/1990
PROTHIADEN (Suspected)		Reason: Depression	
Oral application	50.0 Milligram	Daily	Oral
3atch:	Started:	Stopped:	21/08/1990
LACTULOSE (Suspected)		Reason: Constipation	
Oral Liquid	200.0 Millilitre	Daily	Oral
3atch:	Started:	Stopped:	21/08/1990

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Case Number:	70205	Seq: 1				Gender:	F	
Reported:	13/03/1991					Weight:		
Hospitalisation:						Age:	69Y	
Onset Date:	22/08/1990					DOB:		
Outcome:	Death, maybe dr	ug			Ca	usality:	Causality poss	ible
Reaction Detai	İ							
Medicine Deta	aile:							
	ROCHLORIDE (Susp	ected)		Reason:	Incontinence of	urine		
	` .	,	10.0 Milligram	Daily				
3atch:		Starte	ed: 02/08/1990	·		21/08/1990		
PREDNISOLONE (	Suspected)			Reason:	Other rheumato	oid arthritis		
			10.0 Milligram	Alterr	nate days			
3atch:		Starte	d: 10/08/1990		Stopped:	22/08/1990		
I aboratory In	vestigations:							
Laboratory III	ivestigations.							
Additional Inf	formation:							
onort Pun 10/07/200	0 02:14BN Datal	haca: nucim		ADDSO	24			of 070

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail				
Case Number: 70828 Reported: 18/05/ ospitalisation: Onset Date: 10/05/ Outcome: Recov	, , , , , , , , , , , , , , , , , , ,		Weig A DC	ler: M jht: 75.00 ge: 54Y DB: ity: Causality probable
eaction Detai Preferred Term	n Severity	Report Des	scription	Treatment
Constipation Coordination abnormal Dizziness Headache Tremor	Coverity	report Dec	Scription	Trodunoni
Medicine Details: TOFRANIL (Suspected)		Reason:	Otr&unsp vertebroger	n pain synd
(30000000)	25.0	Milligram Daily		
3atch:	<b>Started:</b> 02/0	5/1991	3topped: 14/05/	1991
_aboratory Investi Date Type	gations: Range Date Test	ed Result	I	Details
Additional Informa	tion:			



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 71180
 Seq:
 1
 Gender:
 F

 Reported:
 31/05/1991
 Weight:
 Weight:

Hospitalisation: Age: 43Y
Onset Date: 10/05/1991
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Neaction Detai			
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			
Pyrexia			
Rash			
Vomiting			

**Medicine Details:** 

Medicine Details.				
CATOVIT (Suspected)	Reas	on:	Debility&undu	e fatigue
Oral application	2.0 Dose Unspecified	Daily		Oral
3atch:	3tarted: 15/11/1990		Stopped:	10/05/1991
TOFRANIL (Suspected)	Reas	on:	Depression	
Tablet	50.0 Milligram	Daily		Oral
3atch:	Started: 15/11/1990		Stopped:	10/05/1991

**Laboratory Investigations:** 

<u> Luboi atoi</u>	y mivoongat								
Date	Туре	Range	Date Tested	Result		Det	ails		
	Biochemistry				10/5/91 23/5/91 ggt 304 - ast 190	133 20.	58 alp	192	83 ld



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 71277 Seq: 1 Gender: F

Reported: 14/06/1991 Weight: 65.00 Hospitalisation: Age: 68Y

Onset Date: 06/06/1991 DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Detai** 

104011011 D 0141		-	
Preferred Term	Severity	Report Description	Treatment
Cheilitis			Patient has scleroderma
Dry mouth			
Tongue ulceration			

**Medicine Details:** 

TOFRANIL (Suspected)	Reason: Depression
	50.0 Milligram Daily
3atch:	Started: 26/10/1990 Stopped:
LOSEC (Suspected)	Reason:
	20.0 Milligram Daily
Зatch:	Started: 01/09/1990 Stopped:
PLENDIL (Suspected)	Reason: Essential benign hypertension
	5.0 Milligram Daily
3atch:	Started: 21/05/1991 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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

ase Number: 71354								
	<b>Seq:</b> 1						der: F	
<b>Reported:</b> 14/06/19				Wei	=			
ospitalisation: Admitted	•						<b>Age:</b> 79Y	
Onset Date: 23/05/19					_		OB:	
Outcome: Death, m	laybe drug				C	ausa	lity: Causality possi	ble
eaction Detai	Caycomity	.	Danam	Dagari	intion		Tractment	
Preferred Term Confusional state	Severity		Repor	Descri	ption		Treatment	
							Tofranil ceased	
Dysuria Budden death							Totrariii Ceaseu	
ledicine Details:								
TOFRANIL (Suspected)			Reas	on:				
TOFRANIL (Suspected) Tablet		50.0 Millig		on: Daily		Oral		
	Started:				Stopped:	Oral		
	Started:	:	gram Reas	Daily on:	Stopped:	Oral		
Tablet 3atch: CAPOTEN (Suspected)	Started:	: 25.0 Millig	gram Reas	Daily		Oral		
Tablet  3atch:  CAPOTEN (Suspected)  3atch:	Started:	: 25.0 Millig	gram <b>Reas</b> o	Daily  on:  Daily	Stopped:	Oral		
Tablet  3atch:  CAPOTEN (Suspected)  3atch:	Started:	: 25.0 Millig :	gram Reaso gram Reaso	Daily Daily Daily Daily		Oral		
Tablet 3atch: CAPOTEN (Suspected)  3atch: LANOXIN PG (Suspected)	Started:	25.0 Millig	gram <b>Reas</b> o	Daily Daily Daily Daily	Stopped:	Oral		
Tablet 3atch:  CAPOTEN (Suspected)  3atch:  LANOXIN PG (Suspected)  3atch:	Started:	25.0 Millig	gram Reaso gram Reaso e Unspecified	Daily  Daily  Daily  Daily  Daily		Oral		
Tablet 3atch:  CAPOTEN (Suspected)  3atch:  LANOXIN PG (Suspected)	Started:	25.0 Millig	ram Reaso gram Reaso e Unspecified Reaso	Daily Daily Daily Daily Daily Daily Daily	Stopped:	Oral		
Tablet 3atch:  CAPOTEN (Suspected)  3atch:  LANOXIN PG (Suspected)  3atch:  SERENACE (Suspected)	Started:	25.0 Millig	ram Reaso gram Reaso e Unspecified Reaso	Daily  Daily  Daily  Daily  Daily	Stopped:	Oral		
Tablet 3atch: CAPOTEN (Suspected)  3atch: LANOXIN PG (Suspected)  3atch: SERENACE (Suspected)	Started: Started:	25.0 Millig	ram Reaso gram Reaso e Unspecified Reaso	Daily Daily Daily Daily Daily Daily Daily	Stopped:	Oral		
Tablet 3atch:  CAPOTEN (Suspected)  3atch:  LANOXIN PG (Suspected)  3atch:  SERENACE (Suspected)	Started: Started: Started:	25.0 Millig	ram Reaso gram Reaso e Unspecified Reaso	Daily Daily Daily Daily Daily Daily Daily	Stopped:		Details	



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 71466 Seq: 1 Gender: F

Reported: 23/04/1991 Weight: 68.00 Hospitalisation: Age: 38

**Onset Date:** 15/12/1990 **DOB:** 12/02/1952

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

todotion botal			
Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			Impramine ceased and supportive therapy given.

#### **Medicine Details:**

TRIMETHOPRIM-SULFAMETHOXAZOLE (Other drug) Reason: Otr loc skin&subcut tis infect

0.0

3atch: 3tarted: 15/12/1990 3topped: 17/12/1990

IMIPRAMINE HYDROCHLORIDE (Suspected) Reason: Depression

 Tablet
 150.0
 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/11/1990
 3topped:
 17/12/1990

**Laboratory Investigations:** 

	<u> </u>				
Date	Туре	Range	Date Tested	Result	Details
	Haematology				1 17/12/90 18/12 19/12 20/12 21/12 24/12 27/12 granulocytes: 1% 5% leucocytes: 1.0 0.9 1.0 1.1 1.3 1.7 4.9 neutrophils:

#### **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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report	Detai∣
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Case Number: 71897 Seq: 1 Gender: M

Reported: 03/07/1991 Weight: 58.00 Hospitalisation: Age: 73Y

**Onset Date**: 30/06/1991 **DOB**:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

I todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Confusional state			
Tremor			

### **Medicine Details:**

SINEMET (Other drug)			Reason:	Paralysis agitar	ns
Tablet	2.5	Dose Unspe	ecified Dai	у	Oral
3atch:	Started:	L	TERM	Stopped:	
FOLIC ACID (Other drug)			Reason:		
Tablet	5.0	Milligram	Dai	у	Oral
Зatch:	Started:	L	TERM	Stopped:	
INDERAL (Other drug)			Reason:	Essential benig	n hypertension
Tablet	40.0	Milligram	Dai	у	Oral
Зatch:	Started:	L	TERM	Stopped:	
AKINETON (Other drug)			Reason:	Paralysis agitar	ns
	2.0	Milligram	Dai	у	
Заtch:	Started:	L	TERM	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

Case Number: 71897

Reported: 03/07/1991

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

**Weight:** 58.00

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

lospitalisation: Onset Date: 30/06/1991				<b>Age</b> : 73Y <b>DOB</b> :				
Outcome: Recovered				C	ausality:	Causality prob	able	
Clion Detai								
adiaina Dataila:								
edicine Details:  MOGADON (Other drug)			Reason:	Specific disor	ders of sleep			
· ·	2.5	Milligram	Daily					
3atch:	Started:	L	TERM	Stopped:				
ACTULOSE (Other drug)	00.0	B 4******	Reason:	Constipation				
3atch:	20.0 <b>Started:</b>	Millilitre	Daily	Stopped:				
OFRANIL (Suspected)	Janteu.		Reason:	лорреи.				
, , ,	50.0	Milligram	Daily					
Batch:	Started: 29/	06/1991		Stopped:	01/07/1991			
aboratory Investigations	<b>5</b> :							
dditional Information:								
uditional information.								
ort Run 19/07/200 02:14PN Da	atabase: pusime		ADRS00	)4		Page 54	of 279	



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 71976 Seq: 1 Gender: F

Reported: 12/07/1991 Weight:
Hospitalisation: Admitted to hospital Age: 77Y

Onset Date: 31/03/1991 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Dizziness		Fell backwars into garden hitting head	

#### **Medicine Details:**

OMEPRAZOLE (Suspected)		Reason:	Other diseases of esophagus	
Capsule	20.0 Milligram	Daily	Oral	
3atch:	Started: 06/07/1989		Stopped:	
TOFRANIL (Suspected)		Reason:	Depression	
Tablet	50.0 Milligram	Daily	Oral	
3atch:	Started: 01/01/1988		Stopped:	
PRO-BANTHINE (Suspected)		Reason:	Othr diseases of urinary tract	
Tablet	45.0 Milligram	Daily	Oral	
3atch:	3tarted: 01/01/1988		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient fell backwards into garden hitting head. laceration to scalp required 8 stitches. admitted to hospital for 2 days for observation of ? head injury. no loss of consciousness, no headache. ct scan of head performed nad. discharged - full recovery. - 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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report	: Detail
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Case Number: 72107 Seq: 1 Gender: F

Reported: 12/07/1991 Weight: 51.00 Hospitalisation: Age: 39Y

Onset Date: 23/06/1991 DOB:

Outcome: Recovered Causality: Causality probable

#### **Reaction Detai**

I touction Detai		_	
Preferred Term	Severity	Report Description	Treatment
Euphoric mood		Daytime euphoria	
Hyperaesthesia		Skin sore to touch - esp legs & feet	
Hyperhidrosis		Sweating - espcially feet	
Oedema peripheral		Swollen hands and fingers	
Insomnia			

### **Medicine Details:**

XANAX (Other drug)		Reason:	Anxiety neurosi	s
Tablet	5.0 Mi	illigram Daily		Oral
3atch:	Started:	S TERM	Stopped:	
TOFRANIL (Suspected)		Reason:	Anxiety neurosi	s
Tablet	50.0 Mi	illigram Daily		Oral
Batch:	<b>Started:</b> 22/06/	1991	Stopped:	25/06/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail							
Case Number: 72	2596	Seq: 1				Gender:	F
Reported: 26	6/08/1991	•				Weight:	
Hospitalisation:						Age:	26Y
Onset Date:						DOB:	
Outcome: Re	ecovered				(	Causality:	Causality possible
Reaction Detai							
Preferred T	erm	Severi			t Description		Treatment
Drug ineffective			Recu	urrence of syn	nptoms of depressi	on	
Medicine Detail TOFRANIL (Suspecte			150.0 Mill	Reas	on: Depression Daily	Oral	
3atch:		Starte		igram	Stopped:	Olai	
Laboratory Inve	estigations:						
Date Ty			ate Tested	Result		Deta	ils
Additional Information:							



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 73628
 Seq:
 1
 Gender:
 M

 Reported:
 21/10/1991
 Weight:
 70.00

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

todotion Botai		E	
Preferred Term	Severity	Report Description	Treatment
Extrasystoles		Frequency of ventricular ectopic beats	
Tachycardia			

**Medicine Details:** 

Micalcinic Details.				
TOFRANIL (Suspected)		Reason: Depressio	1	
Tablet	100.0 Milligram	Daily	Oral	
Зatch:	Started: 29/07/1991	Stoppe	d: 09/09/1991	
PROZAC (Suspected)		Reason: Depressio	١	
Tablet	20.0 Milligram	Daily	Oral	
3atch:	<b>Started:</b> 09/09/1991	Stoppe	d: 23/09/1991	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report I	Detail
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Case Number: 75112 Seq: 1 Gender: F

Reported: 20/01/1992 Weight: 55.00 Hospitalisation: Age: 62Y

Onset Date: 14/01/1992 DOB:

Outcome: Recovered Causality: Causality probable

### Reaction Detai

teaction Detai			
Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Spasm of leg.	
Insomnia			

#### **Medicine Details:**

Micarchic Betans.						
DUCENE (Other drug)		Rea	son:			
Tablet	2.5	Milligram	As ne	ecessary	Oral	
3atch:	Started:			Stopped:		CONTIN
PANADEINE FORTE (Other drug)		Rea	son:			
	1.0 Dose Unspecified As necessary					
3atch:	Started:			Stopped:		CONTIN
TOFRANIL (Suspected)		Rea	son:	Cervicalgia		
Capsule	50.0	Milligram	Daily		Oral	
3atch:	Started: 14	/01/1992		Stopped:	16/01/1992	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 75640 Seq: 1 Gender: F

Reported: 21/02/1992 Weight:
Hospitalisation: Age: 23Y

Onset Date: 13/02/1992 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Pruritus			
Rash			

#### **Medicine Details:**

TOFRANIL (Suspected) Reason: Depression

150.0 Milligram Daily

3atch: 3tarted: 28/01/1992 3topped: 18/02/1992

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient has had no known previous allergies.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 75678 Seq: 1 Gender: F

Reported: 25/02/1992 Weight: 70.00 Hospitalisation: Age: 70Y

Onset Date: 18/02/1992 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Rash			

**Medicine Details:** 

TOFRANIL (Suspected)			
	50.0 Milligram	Daily	
3atch:	Started: 04/01/1992	Stopped:	19/02/1992
MACRODANTIN (Suspected)		Reason:	
	400.0 Milligram	Daily	
3atch:	Started: 12/12/1991	Stopped:	18/02/1992
NOROXIN (Suspected)		Reason:	
	800.0 Milligram	Daily	
3atch:	Started: 18/12/1991	Stopped:	20/12/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

See original report for other medication.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

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		.,	w		_		

 Case Number:
 75859
 Seq: 1
 Gender:
 F

 Reported:
 21/02/1992
 Weight:

Hospitalisation: Age: 80

**Onset Date:** 18/03/1991 **DOB:** 15/03/1911

Outcome: Recovered Causality: Causality possible

Reaction Detai

104011011 20141			_
Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			

## **Medicine Details:**

SENOKOT (Other drug)	Reason:				
	0.0	As necessary			
3atch:	Started:	Stopped:			
DIGOXIN (Other drug)		Reason:			
	200.0 Milligram	Daily			
3atch:	3tarted: 25/02/1991	Stopped:	CONTIN		
WARFARIN SODIUM (Other drug)		Reason:			
WARFARIN SODIOW (Other drug)		Neason.			
WARFARIN SODION (Other drug)	3.0 Milligram	Daily			
3atch:	3.0 Milligram <b>3tarted:</b> 25/02/1991		CONTIN		
, ,	· ·	Daily	CONTIN		
Batch:	· ·	Daily Stopped:	CONTIN		

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

Case Number: 75859

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Seq: 1

Hospitalisation: Onset Date:	Recovered			C		30 15/03/1911 Causality possi	ble
Medicine Deta							
VERAPAMIL HYDE	ROCHLORIDE (Suspected		Reason:				
Patch:		120.0 Milligram <b>Started:</b> 25/02/1991	Daily	Stonnad:	25/03/1001		
3atch:	ROCHLORIDE (Suspecte		Reason:	Stopped:	25/03/1991 of urine		
IMIT NAMINE III DI	CONTROLLINE (Suspecte	20.0 Milligram	Daily	incontinence	oi uiiii <del>c</del>		
3atch:		<b>Started:</b> 11/03/1991	Daily	Stopped:	01/04/1991		
Laboratory In	vestigations:						
Additional Inf	ormation:						
eport Run 19/07/200	) 02·14PN Database	e: pusime	ADRS00	)4		Page 63	of 270

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 75891
 Seq:
 1
 Gender:
 M

 Reported:
 10/03/1992
 Weight:
 91.00

 Hospitalisation:
 Age:
 67Y

 Onset Date:
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Neaction Detai	-		
Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Night sweats	
Cough			
Dizziness			
Nausea			

**Medicine Details:** 

RENITEC (Suspected)		Reason:	Essential beni	gn hypertension	
Tablet	10.0 Milligram	Daily		Oral	
3atch:	3tarted: 17/01/1992		Stopped:	03/03/1992	
CARDIZEM (Suspected)		Reason:	Chron isch he	art dis no hyper	
Tablet	120.0 Milligram	Daily		Oral	
3atch:	Started: 01/04/1991		Stopped:		CONTIN
OROXINE (Suspected)		Reason:	Myxedema		
Tablet	50.0 Microgram	Daily		Oral	
3atch:	Started: 01/08/1991		Stopped:		CONTIN
ZOCOR (Suspected)		Reason:	Othr&unspec	metabolic diseas	es
	20.0 Milligram	Daily			
	20.0 Willigram	Daily			

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### Additional Information:

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

Report Run 19/07/200 02:14PN Database: pusime ADRS004 Page 64 of 279



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 75891 Seq: 1 Gender: M
Reported: 10/03/1992 Weight: 91.00
Hospitalisation: Age: 67Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

### **Medicine Details:**

nearcine Betans.				
SOLPRIN (Suspected)		Reason:	Chron isch heart dis no	o hyper
	150.0 Milligram	Daily		
Batch:	Started: L T	TERM	Stopped:	CONTIN
TEGRETOL (Suspected)		Reason:		
Tablet	1.5 Dose Unspec	cified Daily	Oral	
Batch:	<b>Started:</b> 28/02/1992		Stopped:	CONTIN
TOFRANIL (Suspected)		Reason:		
	20.0 Milligram	Daily		
Batch:	<b>Started:</b> 28/02/1992		Stopped:	CONTIN

# **Laboratory Investigations:**

#### **Additional Information:**

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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

 Case Number:
 76036
 Seq: 1
 Gender:
 F

 Reported:
 19/03/1992
 Weight:
 59.00

 Hospitalisation:
 Age: 59Y

Onset Date: 18/03/1992 DOB:

Outcome: Not yet recovered Causality: Causality possible

#### **Reaction Detai**

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Diaphonesis	
Nausea			
Pruritus			

### **Medicine Details:**

TEGRETOL (Suspected)		Reason:		
Oral application	400.0 Milligram	Daily		Oral
3atch:	3tarted: 27/02/1992		Stopped:	18/03/1992
TOFRANIL (Suspected)		Reason:	Depression	
Tablet	175.0 Milligram	Daily		Oral
3atch:	Started: 25/02/1992		Stopped:	
RIVOTRIL (Suspected)		Reason:		
Oral application	1.0 Milligram	Daily		Oral
3atch:	Started: 25/02/1992		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Rep	00	rt	D	eta	il
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Case Number: 76095 Seq: 1 Gender: F

Reported: 14/03/1992 Weight: 77.00 Hospitalisation: Age: 42

**Onset Date**: 03/01/1992 **DOB**: 27/12/1949

Outcome: Recovered Causality: Causality probable

Reaction Detai

		_	=
Preferred Term	Severity	Report Description	Treatment
Menstrual disorder		Irregular periods.	
Hot flush			

#### **Medicine Details:**

TOFRANIL (Suspected) Reason: Depression

 Tablet
 75.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 27/12/1991
 3topped:
 20/01/1992

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 76517
 Seq: 1
 Gender: M

 Reported:
 08/04/1992
 Weight:
 89.00

 Hospitalisation:
 Age: 68Y

Onset Date: 01/04/1992 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

todotion Dotal		=	
Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Anorexia			
Nausea			
Rash morbilliform			
Vomiting			

**Medicine Details:** 

ilcalcine Details.			
EES (Suspected)		Reason: Bronchitis,und	qualified
Granules	1.6 Gram	Daily	Oral
3atch:	Started: 10/03/1992	Stopped:	01/04/1992
TEGRETOL (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
3atch:	Started: 22/02/1992	Stopped:	01/04/1992
TOFRANIL (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
3atch:	Started: 26/02/1992	Stopped:	01/04/1992

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

See original report for other drugs



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report De	tail					
Case Numb	oer: 77210	Seq: 1			Gender	: F
Report	ted: 25/05/199	2			Weight	: 62.00
Hospitalisati	on:				Age	: 29Y
Onset Da	ate: 13/05/199	2			DOB	:
Outco	me: Recovered	d	Causality: Causality probable			
Reaction D	etai					
Pref	ferred Term	Severity	Report	Description		Treatment
Pruritus						
Purpura						
Medicine I	Dotaile:					
	IOS (Other drug)		Reaso	on:		
	3,	0.0				
3atch	:	Started: 04		Stopped:		
TOFRANIL (S	suspected)		Reaso	on:		
Table	t	50.0	Milligram	Daily	Oral	
3atch	:	Started: 12	/05/1992	Stopped:	18/05/199	2
Laborator	y Investigati	ons:				
Date	Туре	Range Date Te	sted Result		Deta	ails
		-				
		•	,			
A .1 .1'4'	l Information					



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail							
Case Number: 77247	Seq: 1		Gen	der: F			
Reported: 15/05/199	-	Weight:					
Hospitalisation:		Age: 69Y					
Onset Date: 28/04/199	2	DOB:					
Outcome: Recovere	d	Causality: Causality probable					
Reaction Detai							
Preferred Term	Severity	Report Description Treatment					
Insomnia							
Tremor							
Medicine Details:  TOFRANIL (Suspected)  25.0 Milligram Daily  3atch: 3tarted: 24/04/1992 3topped: 14/05/1992							
Laboratory Investigat							
Date Type	Range Date Tes	ted Result		Details			
Additional Information	n:	·					



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 77348
 Seq:
 1
 Gender:
 F

 Reported:
 01/06/1992
 Weight:
 50.00

Hospitalisation: Age: 89Y
Onset Date: 28/05/1992
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Rash		On thigh, arms	Promethazine 25 mg tds.

# **Medicine Details:**

CLONAZEPAM (Suspected)		Reason:		
Injection	1.0 Milligram	1 time	Intravenous	
3atch:	Started: 26/05/1992	Stop	pped:	
IMIPRAMINE HYDROCHLORIDE (Suspected)		Reason: Inconti		
Tablet	10.0 Milligram	Daily	Oral	
3atch:	Started: 24/05/1992	\$to <sub>l</sub>	pped: 28/05/1992	
TRIMETHOPRIM (Suspected)				
TRIMETHOPRIM (Suspected)		Reason: Othr d	iseases of urinary trac	t
TRIMETHOPRIM (Suspected) Oral application	300.0 Milligram	Reason: Othr d	iseases of urinary trac Oral	t
` ' '	300.0 Milligram Started: 26/05/1992	Daily	j	t
Oral application	<b>Started:</b> 26/05/1992	Daily	Oral	t
Oral application  3atch:	<b>Started:</b> 26/05/1992	Daily <b>Sto</b>	Oral	t

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

Case Number: 77348

Reported: 01/06/1992

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

**Weight:** 50.00

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Hospitalisation:			Age: 89Y DOB:					
Onset Date: 28/05/1992						Caucality passi	blo	
Outcome: Not yet recovered eaction Detai					ausanty.	Causality possi	bie	
eaction Detai								
ledicine Details:								
DIGOXIN (Suspected)			Reason:	Congestive he				
Tablet		Microgram	Daily		Oral			
3atch:	Started:			Stopped:		CONTIN		
COLOXYL WITH SENNA (Suspected)			Reason:	Constipation				
Tablet		Dose Unspe	cified Daily		Oral			
3atch:	Started: 24	/05/1992		Stopped:		CONTIN		
aboratory Investigations:								
aboratory investigations.								
dditional Information:								
ort Run 19/07/200 02:14PN Databas	e: pusime		ADRS00	4		Page 72	of 279	
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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 77443 Seq: 1 Gender: F
Reported: 01/06/1992 Weight:
Hospitalisation: Age: 35Y

Onset Date: 31/05/1992 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		On trunk,upper arms and legs.	

**Medicine Details:** 

TOFRANIL (Suspected)		Reason:	Depression	
Tablet	50.0 Milligram	Daily		Oral
3atch:	Started:	L TERM	Stopped:	CONTIN
EUHYPNOS (Suspected)		Reason:		
Capsule	10.0 Milligram	Daily		Oral
3atch:	3tarted: 28/05/1992		Stopped:	
MORPHINE NOS (Suspected)		Reason:	Pain	
Injection	75.0 Milligram	Daily		Intramuscular
3atch:	3tarted: 29/05/1992		Stopped:	01/06/1992
MAXOLON (Suspected)		Reason:	Nausea and v	omiting
Injection	40.0 Milligram	Daily		Intramuscular
3atch:	3tarted: 29/05/1992		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

	77443	Seq: 1		Gender:	F	
Reported:	01/06/1992			Weight:		
spitalisation:				Age:	35Y	
Onset Date:	31/05/1992			DOB:		
Outcome:	Not yet recovere	d	C	ausality:	Causality possible	e
action Detai						
ledicine Deta						
HEPARIN SODIUM	(Suspected)		Reason:			
Injection		10.0 Thousand	Internat Daily	Subcutaneo	ous	
3atch:		3tarted: 29/05/1992	}topped:			
aboratory Inv	vestigations:					
aboratory Inv	vestigations:					
aboratory Inv	vestigations:					
aboratory Inv	vestigations:					
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aboratory Inv	vestigations:					
aboratory Inv	vestigations:					
aboratory Inv						

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Causality: Causality possible

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Re	no	rt	D	eta	i	ı
	$\sim$		_	U LU		ı

Case Number: 77574 Seq: 1 Gender: F
Reported: 02/06/1992 Weight:
Hospitalisation: Age: 69Y

Onset Date: DOB:

Outcome: Death, maybe drug

### **Reaction Detai**

todotion Botal		_	
Preferred Term	Severity	Report Description	Treatment
Adrenal insufficiency		Hypoaldosteronism	
Hyperkalaemia			
Thrombosis			

### **Medicine Details:**

FOLIC ACID (Suspected)			Reason:	Unspecifid affective psychosis	
Tablet	5.0	Milligram		Oral	
3atch:	Started:		L TERM	Stopped:	
LITHIUM CARBONATE (Suspected)			Reason:	Unspecifid affective psychosis	
Tablet	250.0	Milligram	Daily	Oral	
Заtch:	Started:		L TERM	Stopped:	
CARRAMAZERINE (Cusposted)			_		
CARBAMAZEPINE (Suspected)			Reason:	Unspecifid affective psychosis	
Oral application	400.0	Milligram	Reason: Daily	Unspecifid affective psychosis  Oral	
` ' '	400.0 <b>Started:</b>	Milligram			
Oral application	Started:	Milligram	Daily	Oral	
Oral application  3atch:	Started:	Milligram	Daily L TERM	Oral	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Histology				Widespread intimal fibroplasia, with thrombosis of superior mesenteric artery causing small bowel infarction.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 77741 Seq: 1 Gender: F

Reported: 18/06/1992 Weight:
Hospitalisation: Age: 5M

Onset Date: 31/05/1992 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Nightmare		Nightmares of snakes licking her	

#### **Medicine Details:**

TOFRANIL (Suspected)

Tablet

20.0 Milligram Daily

Oral

**3atch**: **3tarted**: 01/05/1992 **3topped**: 01W

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 77961 Seq: 1 Gender: M

Reported: 01/07/1992 Weight: 26.00 Hospitalisation: Age: 9Y

Onset Date: 01/04/1992 DOB:

Outcome: Recovered Causality: Causality certain

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Abdominal pain			

#### **Medicine Details:**

 TOFRANIL (Suspected)
 Reason:
 Incontinence of urine

 Tablet
 50.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/02/1992
 3topped:
 28/05/1992

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient rechallenged on tofranil with same reaction. 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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 78603 Seq: 1 Gender: F

**Reported:** 16/07/1992 **Weight:** 72.00

Hospitalisation: Age:
Onset Date: 09/04/1992
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		At night	
Agitation		Restlessness	
Anxiety			
Confusional state			
Coordination abnormal			
Delusion			
Hallucination			
Nightmare			

#### **Medicine Details:**

PROTHIADEN (Suspected)		Reason:	Depression	
Capsule	25.0 Milligram	Daily		Oral
3atch:	3tarted: 09/04/1992		Stopped:	14/04/1992
TOFRANIL (Suspected)		Reason:		
TOFRANIL (Suspected) Tablet	10.0 Milligram	Reason: Daily		Oral

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Tofranil commenced 14/4/92 the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Report Detail

Case Number: 79645

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Seq: 1

	eu: 20/09/198	32			V	Veight:		
	Reported: 28/09/1992 spitalisation:				Age: 90Y			
Onset Date: 21/09/1992			DOB:					
Outcon	ne: Not yet re	covered		Causality: Causality possible				
action De		<u> </u>	<del></del>			1		
Prefe	erred Term	Sev	erity/	Repor	Description	Treatment		
ash						Salicylic acid 3% cream,		
ledicine [				Reas	on:			
			0.0					
3atch:		Sta	arted:		Stopped:			
TOFRANIL (Su	uspected)			Reas	on:			
			0.0					
3atch:		Sta	arted:		Stopped:			
PANADOL (Su	uspected)		0.0	Reas	on:			
3atch:		<b>2</b> †:	arted:		Stopped:			
MOGADON (S		7.0	arteu.	Reas				
(0	,		0.0					
3atch:	:	Sta	arted:		Stopped:			
aborator	v Invoctigat	ione:						
Date	y Investigat Type	Range	Date Tested	Result		Details		



Report Detail

Case Number: 79645

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Reported: 28/09/1992					Weight:	
spitalisation:					Age:	90Y
Onset Date: 21/09/1992					DOB:	
Outcome: Not yet recovered				С	ausality:	Causality possible
action Detai						
edicine Details:						
CEFAMEZIN (Suspected)			Reason:			
Injection		4.0 Gram	Re	ducing	Intravenous	3
3atch:	Started	: 21/09/1992		Stopped:		CONTIN
JREX (Suspected)			Reason:			
		40.0 Milligram	Da	ly		
3atch:	Started	: 15/09/1992		Stopped:	24/09/1992	
Jaton.						
			Reason:	Other cellulitis	and abscess	3
		6.0 Dose Unspec			and abscess	
FLOXAPEN (Suspected)		6.0 Dose Unspec : 16/09/1992				3
FLOXAPEN (Suspected) Injection				ly	Intravenous	3
FLOXAPEN (Suspected) Injection				ly	Intravenous	3
FLOXAPEN (Suspected) Injection				ly	Intravenous	3
FLOXAPEN (Suspected) Injection  3atch:				ly	Intravenous	3
FLOXAPEN (Suspected) Injection  3atch:				ly	Intravenous	3
FLOXAPEN (Suspected) Injection  3atch:				ly	Intravenous	3
FLOXAPEN (Suspected) Injection 3atch:				ly	Intravenous	3
FLOXAPEN (Suspected) Injection 3atch:				ly	Intravenous	3
FLOXAPEN (Suspected) Injection 3atch:				ly	Intravenous	3
FLOXAPEN (Suspected) Injection				ly	Intravenous	3
FLOXAPEN (Suspected) Injection 3atch:				ly	Intravenous	3
FLOXAPEN (Suspected) Injection 3atch:				ly	Intravenous	3
FLOXAPEN (Suspected) Injection 3atch:  aboratory Investigations:				ly	Intravenous	3
Injection 3atch:  aboratory Investigations:				ly	Intravenous	3
FLOXAPEN (Suspected) Injection 3atch:				ly	Intravenous	3
FLOXAPEN (Suspected) Injection 3atch:  aboratory Investigations:				ly	Intravenous	3
Injection 3atch:  aboratory Investigations:				ly	Intravenous	3

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 80653 Seq: 1 Gender: F

Reported: 06/11/1992 Weight: 70.00 Hospitalisation: Age: 64Y

Onset Date: 15/09/1992

Outcome: Recovered

DOB:

Causality: Causality probable

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Hepatitis			
Jaundice			

#### **Medicine Details:**

Medicine Details.				
XANAX (Other drug)	Reason:			
	500.0 Microgram	Daily		
3atch:	Started:	Stopped:		
TOFRANIL (Suspected)		Reason: Depression		
Tablet	50.0 Milligram	Daily	Oral	
3atch:	Started: 01/09/1992	Stopped:	22/09/1992	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	0 - 30	23/09/1992	101	
	ALT = SGPT	0 - 30	07/10/1992	29	
	ALT = SGPT	0 - 30	27/10/1992	14	
	AST = SGOT	<40	23/09/1992	61	
	AST = SGOT	<40	07/10/1992	19	
	AST = SGOT	<40	27/10/1992	14	
	Bilirubin	<19	23/09/1992	41	

#### **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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 80653 Seq: 1 Gender: F

Reported: 06/11/1992 Weight: 70.00 Hospitalisation: Age: 64Y

**Onset Date**: 15/09/1992 **DOB**:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

### **Medicine Details:**

Medicine Details.				
XANAX (Other drug)	Reason:			
	500.0 Microgram	Daily		
3atch:	Started:	Stopped:		
TOFRANIL (Suspected)		Reason: Depression		
Tablet	50.0 Milligram	Daily	Oral	
3atch:	3tarted: 01/09/1992	Stopped:	22/09/1992	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin	<19	07/10/1992	11	
	Bilirubin	<19	27/10/1992	8	
	GGT = SGGT =	5 - 35	23/09/1992	355	
	ĜĜT = SGGT =	5 - 35	07/10/1992	108	
	GGT = SGGT =	5 - 35	27/10/1992	38	
	SAP = ALP	30 - 115	23/09/1992	910	
	SAP = ALP	30 - 115	07/10/1992	230	

#### **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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 80653 Seq: 1 Gender: F

Reported: 06/11/1992 Weight: 70.00 Hospitalisation: Age: 64Y

**Onset Date**: 15/09/1992 **DOB**:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

**Medicine Details:** 

XANAX (Other drug)	Reason:			
	500.0 Microgram	Daily		
3atch:	Started:	Stopped:		
TOFRANIL (Suspected)		Reason: Depression		
Tablet	50.0 Milligram	Daily Or	al	

**3atch**: **3tarted**: 01/09/1992 **3topped**: 22/09/1992

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP	30 - 115	27/10/1992	121	

#### **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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 80938 Seq: 1 Gender: M

Reported: 02/11/1992 Weight: 45.00 Hospitalisation: Age: 8Y

Onset Date: 11/10/1992 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Affect lability			

#### **Medicine Details:**

3atch:

VENTOLIN (Other drug)

Reason: Asthma

2.0 Dose Unspecified As necessary

Stopped:

TOFRANIL (Suspected) Reason: Incontinence of urine

Started:

Tablet 25.0 Milligram Daily Oral

3atch: 3tarted: 09/10/1992 3topped: 12/07/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Tofranil was continued until 12/07/93 at reduced dose of 25mg. after ceasing the drug, reaction abated.

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 81416 Seq: 1 Gender: F

 Reported:
 09/12/1992
 Weight:
 65.00

 Hospitalisation:
 Age:
 32Y

Onset Date: 18/11/1992 DOB:
Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Pruritus		Itching over arms and legs	

#### **Medicine Details:**

TOFRANIL (Suspected) Reason: Depression

 Tablet
 150.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/11/1992
 3topped:
 06/12/1992

**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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

**Report Detail** 

Case Number: 82178 Seq: 1 Gender: M

Reported: 27/01/1993 Weight: 83.00
Hospitalisation: Age: 38Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Systemic lupus erythematosus		Lupus like syndrome.	

#### **Medicine Details:**

CARBAMAZEPINE (Suspected) Reason: Unspecifid affective psychosis

450.0 Milligram Daily

**3atch**: **Started**: 01/01/1990 **Stopped**: 28/12/1992

IMIPRAMINE HYDROCHLORIDE (Suspected) Reason: Unspecifid affective psychosis

150.0 Milligram Daily

**3atch**: **3tarted**: 01/01/1990 **3topped**: CONTIN

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 82279
 Seq:
 1
 Gender:
 M

 Reported:
 04/02/1993
 Weight:
 66.00

 Hospitalisation:
 Age:
 81Y

Onset Date: 31/12/1992 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

todotion Botal		_	
Preferred Term	Severity	Report Description	Treatment
Gait disturbance		Inability to walk.	
Asthenia			
Coordination abnormal			Supportive care, physiotherapy
Coordination abnormal			
Neuritis			

**Medicine Details:** 

METRONIDAZOLE (Suspected)		Reason:	Other disease	s of liver
Injection	1.5 Gram	Daily		Intravenous
Зatch:	Started: 04/11/1992		Stopped:	12/11/1992
METRONIDAZOLE (Suspected)		Reason:		
Tablet	1.2 Gram	Daily		Oral
Зatch:	Started: 12/11/1992		Stopped:	03/12/1992
IMIPRAMINE HYDROCHLORIDE (Suspecte	ed)	Reason:	Incontinence of	of urine
Tablet	75.0 Milligram	Daily		Oral
Зatch:	Started: 01/11/1992		Stopped:	29/01/1993
THEOPHYLLINE (Suspected)		Reason:	Otr respiratory	systm diseases
Oral application	600.0 Milligram	Daily		Oral
Зatch:	Started:		Stopped:	29/01/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Electrographics				Nerve conduction study on 03/02/93 showed velocity emplited consistent with axonal degeneration. the motor action potential amplitude of the lateral popli teal nerve at the ankle-stimulating extensor digitorum brevis was 0.4 mv (normal>2.2 mv). the sensory action potential amolitude of the sural nerve at the ankle was 1 mv (normal > 10mv).

#### **Additional Information:**

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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Deta	ı	ı
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Case Number: 82279 Seq: 1 Gender: M

Reported: 04/02/1993 Weight: 66.00 Hospitalisation: Age: 81Y

Onset Date: 31/12/1992 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

#### **Medicine Details:**

CIMETIDINE (Suspected) Reason: Ulcer of duodenum w/o ment perf

 Tablet
 800.0
 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/11/1992
 3topped:
 29/01/1993

# **Laboratory Investigations:**

#### **Additional Information:**

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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 82441 Seq: 1 Gender: M
Reported: 15/01/1993 Weight:

Hospitalisation: Age: 91Y
Onset Date: 08/01/1993
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Inappropriate antidiuretic hormon			Fluid restriction

**Medicine Details:** 

COLOXYL WITH SENNA (Other drug)		Reason:
	2.0 Dose Unspe	pecified Daily
3atch:	Started:	Stopped:
SOLPRIN (Other drug)		Reason:
Tablet	150.0 Milligram	Daily Oral
3atch:	Started:	Stopped:
TOFRANIL (Suspected)		Reason: Incontinence of urine
Tablet	10.0 Milligram	Daily Oral
3atch:	Started: 23/12/1992	<b>Stopped:</b> 08/01/1993
ALPRIM (Suspected)		Reason: Othr diseases of urinary tract
Tablet	300.0 Milligram	Daily Oral
Batch:	Started: 06/01/1993	Stopped: 13/01/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Creatinine	0.05 - 0.11	08/12/1992	0.10	
	Creatinine	0.05 - 0.11	08/01/1993	0.08	
	Creatinine	0.05 - 0.11	09/01/1993	0.08	
	Creatinine	0.05 - 0.11	14/01/1993	0.09	
	Creatinine	0.05 - 0.11	12/01/1993	0.12	
	Creatinine	0.05 - 0.11	11/01/1993	0.09	
	Electrolytes				Osmolity (280 - 300) - 11/01/93 - 266.

### **Additional Information:**

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 82441 Seq: 1 Gender: M Reported: 15/01/1993 Weight:

Hospitalisation:
Onset Date: 08/01/1993

Age: 91Y

DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

### **Medicine Details:**

COLOXYL WITH SENNA (Other drug)	Reason:				
	2.0 Dose Unspe	ecified Daily			
Зatch:	Started:	Stopped:			
SOLPRIN (Other drug)		Reason:			
Tablet	150.0 Milligram	Daily	Oral		
3atch:	Started:	Stopped:			
TOFRANIL (Suspected)		Reason: Incontinence	of urine		
Tablet	10.0 Milligram	Daily	Oral		
Зatch:	Started: 23/12/1992	Stopped:	08/01/1993		
ALPRIM (Suspected)		Reason: Othr diseases	of urinary tract		
Tablet	300.0 Milligram	Daily	Oral		
Зatch:	Started: 06/01/1993	Stopped:	13/01/1993		

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Potassium	3.5 - 5	08/12/1992	4.9	
	Potassium	3.5 - 5	08/01/1993	4.6	
	Potassium	3.5 - 5	09/01/1993	4.4	
	Potassium	3.5 - 5	14/01/1993	4.1	
	Potassium	3.5 - 5	12/01/1993	4.4	
	Potassium	3.5 - 5	11/01/1993	4.0	
	Sodium	135-145	08/12/1992	137	



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 82441 Seq: 1 Gender: M Reported: 15/01/1993 Weight:

Hospitalisation: Age: 91Y

Onset Date: 08/01/1993 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

**Medicine Details:** 

COLOXYL WITH SENNA (Other drug)	Reason:				
	2.0 Dose Unspe	ecified Daily			
3atch:	Started:	Stopped:			
SOLPRIN (Other drug)		Reason:			
Tablet	150.0 Milligram	Daily	Oral		
3atch:	Started:	Stopped:			
TOFRANIL (Suspected)		Reason: Incontinence	of urine		
Tablet	10.0 Milligram	Daily	Oral		
3atch:	Started: 23/12/1992	Stopped:	08/01/1993		
ALPRIM (Suspected)		Reason: Othr diseases	s of urinary tract		
Tablet	300.0 Milligram	Daily	Oral		
3atch:	<b>Started:</b> 06/01/1993	Stopped:	13/01/1993		

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Sodium	135-145	08/01/1993	116	
	Sodium	135-145	09/01/1993	123	
	Sodium	135-145	11/01/1993	123	
	Sodium	135-145	12/01/1993	128	
	Sodium	135-145	14/01/1993	128	
	Urea	2.5 - 8.3	08/12/1992	7.9	
	Urea	2.5 - 8.3	08/01/1993	5.8	



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 82441 Seq: 1 Gender: M Reported: 15/01/1993 Weight:

Hospitalisation:
Onset Date: 08/01/1993

Age: 91Y

DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

### **Medicine Details:**

COLOXYL WITH SENNA (Other drug)		Reason:	
	2.0 Dose Unspe	cified Daily	
3atch:	Started:	Stopped:	
SOLPRIN (Other drug)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
3atch:	Started:	Stopped:	
TOFRANIL (Suspected)		Reason: Incontinence	of urine
Tablet	10.0 Milligram	Daily	Oral
3atch:	3tarted: 23/12/1992	Stopped:	08/01/1993
ALPRIM (Suspected)		Reason: Othr diseases	s of urinary tract
Tablet	300.0 Milligram	Daily	Oral
3atch:	<b>Started:</b> 06/01/1993	Stopped:	13/01/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Urea	2.5 - 8.3	11/01/1993	5.6	
	Urea	2.5 - 8.3	12/01/1993	8.4	
	Urea	2.5 - 8.3	14/01/1993	7.4	
	Urea	2.5 - 8.3	09/01/1993	4.8	
	Urine Sodium	30 - 300	08/01/1993	37	Osmolality urine (100-1200) - 434.
	bicarbonate	20-30	08/12/1992	33	
	bicarbonate	20-30	08/01/1993	23	

### **Additional Information:**

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 82441 Seq: 1 Gender: M
Reported: 15/01/1993 Weight:

Hospitalisation:
Onset Date: 08/01/1993
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

### **Medicine Details:**

COLOXYL WITH SENNA (Other drug)	Reason:				
	2.0 Dose Unspe	pecified Daily			
3atch:	Started:	Stopped:			
SOLPRIN (Other drug)		Reason:			
Tablet	150.0 Milligram	Daily Oral			
3atch:	Started:	Stopped:			
TOFRANIL (Suspected)		Reason: Incontinence of urine			
Tablet	10.0 Milligram	Daily Oral			
3atch:	3tarted: 23/12/1992	<b>Stopped:</b> 08/01/1993			
ALPRIM (Suspected)		Reason: Othr diseases of urinary tract			
Tablet	300.0 Milligram	Daily Oral			
3atch:	3tarted: 06/01/1993	Stopped: 13/01/1993			

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	bicarbonate	20-30	09/01/1993	29	
	bicarbonate	20-30	11/01/1993	31	
	bicarbonate	20-30	12/01/1993	29	
	bicarbonate	20-30	14/01/1993	29	



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail					
Case Number: 82763 Reported: 24/02/19		Gender: F Weight:			
ospitalisation:		<b>Age:</b> 63			
Onset Date:		<b>DOB</b> : 24/04/1929			
Outcome: Not yet r	ecovered	Causality: Causality possible			
eaction Detai Preferred Term	Severity	Report Des	scription	Treatment	
Hyperhidrosis Mouth ulceration Nightmare	Coverny	Noport Bot	yon puon	riodinoni	
Medicine Details:			<del>-</del>		
OROXINE (Other drug)	100.0 M	Reason: licrogram Daily	Thyrotoxicosis w/o	ment goiter	
3atch:	Started:	L TERM	Stopped:		
TOFRANIL (Suspected)		Reason:	son:		
	50.0 M	lilligram Daily	•		
	3tarted: 26/11	/1002	3topped: 24/0	02/1993	
3atch:		71992	710000000000000000000000000000000000000		
_aboratory Investiga				Details	



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 82809
 Seq:
 1
 Gender:
 M

 Reported:
 26/02/1993
 Weight:

Hospitalisation:
Onset Date:

DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

#### **Medicine Details:**

Medicine Details.				
DIAZEPAM (Other drug)		Reason:	Anxiety neurosis	
	10.0 Milligram	Daily		
3atch:	Started: 01/03/1992		Stopped:	CONTIN
IMIPRAMINE HYDROCHLORIDE	(Suspected)	Reason:	Depression	
	50.0 Milligram	Daily		
3atch:	<b>Started:</b> 01/06/1992		Stopped: 19/01/1993	6M

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		19/01/1993	361	
	ALT = SGPT		19/02/1993	16	
	GGT = SGGT =		19/01/1993	227	
	GGT = SGGT =		19/02/1993	53	
	SAP = ALP		19/01/1993	361	
	SAP = ALP		19/02/1993	112	

#### 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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 83590 Seq: 1 Gender: F

Reported: 21/03/1993 Weight: 82.00 Hospitalisation: Age: 71Y

Onset Date: 25/02/1993 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Hypotension			

## **Medicine Details:**

ENALAPRIL MALEATE (Suspected)			Reason:	Essential beni	gn hypertension
Tablet	5.0	Milligram	Daily		Oral
3atch:	Started:			Stopped:	25/02/1993
FRUSEMIDE (Suspected)			Reason:	Dyspnea	
Tablet	40.0	Milligram	Daily		Oral
3atch:	Started:			Stopped:	25/02/1993
TOFRANIL (Suspected)			Reason:	Depression	
TOFRANIL (Suspected) Tablet	100.0	Milligram	Reason: Daily	Depression	Oral
` ' '	100.0 <b>3tarted:</b>	Milligram		Depression Stopped:	Oral 25/02/1993
Tablet		Milligram		·	
Tablet  3atch:			Daily	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 83600 Seq: 1 Gender: F

Reported: 26/03/1993 Weight:
Hospitalisation: Age: 39Y

Onset Date: 19/03/1993 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

todotion Botal		_	_
Preferred Term	Severity	Report Description	Treatment
Depersonalisation			
Hot flush	Severe		
Visual disturbance			

#### **Medicine Details:**

TOFRANIL (Suspected) Reason:

75.0 Milligram Daily

**3atch: 3tarted:** 16/03/1993 **3topped:** 20/03/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient took 50 mg for 3 nights and then 75 mg for 1 night. reaction ceased 2 days later after ceasing the drug.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 83879 Seq: 1 Gender: F

Reported: 04/04/1993 Weight: 105.00 Hospitalisation: Age: 62Y

Onset Date: 31/01/1993 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

touchier Dotal		-	
Preferred Term	Severity	Report Description	Treatment
Pharyngitis		Inflamed throat	
Glossitis		Sore tongue	Betamethasone for psoriais
Dry mouth			
Psoriasis			

#### **Medicine Details:**

Medicine Details.				
COVERSYL (Suspected)		Reason:	Essential benign hypertension	
Tablet	4.0 Milligram	Daily	Oral	
Зatch:	Started: 17/11/1992		Stopped:	
TOFRANIL (Suspected)		Reason:	Depression	
	75.0 Milligram	Daily		
3atch:	Started: 01/01/1991		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 83894 Seq: 1 Gender: F

Reported: 06/04/1993 Weight: 60.00 Hospitalisation: Age: 37

Onset Date: 23/03/1993 DOB: 07/01/1956

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Jaundice			

#### **Medicine Details:**

TOFRANIL (Suspected) Reason: Depression

 Tablet
 150.0
 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 18/03/1993
 3topped:
 01/04/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT	< 40 U/L	01/04/1993	139	
	AST = SGOT	< 40 U/L	06/04/1993	148	
	AST = SGOT	< 40 U/L	19/04/1993	29	
	Bilirubin	< 19 UMOL/L	01/04/1993	49	
	Bilirubin	< 19 UMOL/L	06/04/1993	25	
	Bilirubin	< 19 UMOL/L	19/04/1993	21	
	GGT = SGGT =	< 45 U/L	01/04/1993	242	

# **Additional Information:**

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 83894 Seq: 1 Gender: F

Reported: 06/04/1993 Weight: 60.00 Hospitalisation: Age: 37

**Onset Date**: 23/03/1993 **DOB**: 07/01/1956

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

### **Medicine Details:**

 TOFRANIL (Suspected)
 Reason:
 Depression

 Tablet
 150.0
 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 18/03/1993
 \$topped:
 01/04/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =	< 45 U/L	06/04/1993	147	
	GGT = SGGT =	< 45 U/L	19/04/1993	71	
	SAP = ALP	30 - 120 U/L	01/04/1993	297	
	SAP = ALP	30 - 120 U/L	06/04/1993	176	
	SAP = ALP	30 - 120 U/L	19/04/1993	80	



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail							
Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Deta	84082 17/04/199 01/01/199 Recovere	93	1			DOB:	87.00 24Y
Preferre		Seve	rity	Repor	t Description		Treatment
Pruritus Rash							
Medicine Det TOFRANIL (Suspe		Star	75.0 Milli <b>ted:</b> 09/12/19		on: Depression Daily Stopped:	17/04/199	3
Laboratory In					T		
Date	Туре	Range	Date Tested	Result		Deta	ils
Additional In	formatio	n.					



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 84100 Seq: 1 Gender: M
Reported: 19/04/1993 Weight: 64.00
Hospitalisation: Age: 87Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality certain

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Vertigo			

#### **Medicine Details:**

TIMOPTOL (Other drug)		Reason: Unspecified glaucoma
Eye Drops	0.0	Ophthalmic
3atch:	Started: 01/01/1991	Stopped:
TOFRANIL (Suspected)		Reason: Incontinence of urine
Tablet	20.0 Milligram	As necessary Oral
3atch:	Started: 12/03/1993	<b>3topped</b> : 19/03/1993
RENITEC (Suspected)		Reason: Essential benign hypertension
	10.0 Milligram	Daily
3atch:	Started: 01/01/1991	Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Reaction accured twice on 2 separate occasions 1 week apart. 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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**Additional Information:** 

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

	ber: 84270 ted: 06/05/1993	Seq:	I				Gend Weig		64.00		
pitalisat									33Y		
_	ate: 19/04/1993							OB:			
Outco	me: Recovered						Causal	lity:	Causali	ity possik	le
ction D											
	ferred Term	Sev	erity	Repo	rt Desci	ription			Tre	atment	
dache											
dicine	Dotails:										
	Details:	(Sugnested)		200	2001	Anvioty nou	uragia				
PRAMINE	HYDROCHLORIDE (	(Suspected)				Anxiety neu					
PRAMINE Table	HYDROCHLORIDE ( et		150.0 Mi	lligram	son: /		Oral				
PRAMINE	HYDROCHLORIDE ( et		150.0 Mi arted: 22/01/	lligram		Anxiety neu	Oral				
PRAMINE Table	HYDROCHLORIDE ( et			lligram			Oral				
PRAMINE Table	HYDROCHLORIDE ( et			lligram			Oral				
PRAMINE Table	HYDROCHLORIDE ( et			lligram			Oral				
PRAMINE Table	HYDROCHLORIDE ( et			lligram			Oral				
PRAMINE Table	HYDROCHLORIDE ( et			lligram			Oral				
PRAMINE Table	HYDROCHLORIDE ( et			lligram			Oral				
PRAMINE Table	HYDROCHLORIDE ( et			lligram			Oral				
PRAMINE Table	HYDROCHLORIDE ( et			lligram			Oral				
PRAMINE Table	HYDROCHLORIDE ( et			lligram			Oral				
PRAMINE Table	HYDROCHLORIDE ( et			lligram			Oral				
PRAMINE Table	HYDROCHLORIDE ( et			lligram			Oral				
PRAMINE Table	HYDROCHLORIDE ( et			lligram			Oral				
PRAMINE Table	HYDROCHLORIDE ( et			lligram			Oral				
PRAMINE Table 3atch	HYDROCHLORIDE (et a:	<b>St</b> z		lligram			Oral				
PRAMINE Table 3atch	HYDROCHLORIDE ( et	<b>St</b> z		lligram			Oral				
PRAMINE Table 3atch	HYDROCHLORIDE (et n:	<b>St</b> z		lligram 1993			Oral	Detail	İs		
PRAMINE Table 3atch	HYDROCHLORIDE (et a:	ons:	arted: 22/01/	lligram 1993			Oral	Detail	ls.		
PRAMINE Table 3atch	HYDROCHLORIDE (et n:	ons:	arted: 22/01/	lligram 1993			Oral	Detail	ls.		
PRAMINE Table 3atch	HYDROCHLORIDE (et n:	ons:	arted: 22/01/	lligram 1993			Oral	Detail	ls.		



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 84426 Seq: 1 Gender: F

Reported: 11/05/1993 Weight: 63.00 Hospitalisation: Age: 48

**Onset Date**: 21/04/1993 **DOB**: 23/10/1944

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

todotion Botai		_	
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			
Jaundice			

**Medicine Details:** 

Medicine Details.					
PRO-BANTHINE (Suspected)	Reason:				
	45.0 Milligram	Daily			
3atch:	Started: 25/01/1993	Stopped:	21/04/1993		
TOFRANIL (Suspected)		Reason:			
	75.0 Milligram	Daily			
3atch:	Started: 25/01/1993	Stopped:	21/04/1993		

**Laboratory Investigations:** 

	,				
Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		21/04/1993	828	
	AST = SGOT		21/04/1993	393	
	Bilirubin		21/04/1993	30	
	GGT = SGGT =		21/04/1993	241	
	SAP = ALP		21/04/1993	276	



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report I	Detail
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 Case Number:
 84800
 Seq: 1
 Gender: M

 Reported:
 31/05/1993
 Weight: 60.00

 Hospitalisation:
 Age: 70Y

 Onset Date:
 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

reaction Detai			
Preferred Term	Severity	Report Description	Treatment
Constipation	Severe		
Urinary retention			

**Medicine Details:** 

LASIX (Other drug)		Reason:		
	120.0 Milligram	Daily		
Зatch:	Started:	Stopped	:	
SOLPRIN (Other drug)		Reason:		
Injection	300.0 Milligram	Daily	Intramuscular	
Зatch:	Started:	Stopped	:	
ZANTAC (Other drug)		Reason:		
	300.0 Milligram	Daily		
3atch:	Started:	Stopped	:	
3atch: TOFRANIL (Suspected)	Started:	Reason:	:	
	Started: 25.0 Milligram		:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

	34800	Seq: 1			Gender:	M	
Reported: 3	31/05/1993				Weight:	60.00	
ospitalisation:					Age:	70Y	
Onset Date:					DOB:		
Outcome: F	Recovered				Causality:	Causality possible	
eaction Detai							
Madiaina Data	:la:						
Medicine Detai				Reason:			
DIBENTEINE (Suspe	ecteu)	10.0	Milligram				
Zotoby			Milligram	Daily	}tonnod:		
3atch:	4 10	Started:			Stopped:		
PRO-BANTHINE (Su	ispected)			Reason:			
	ispected)		Milligram	Reason: Daily			
3atch:	ispected)	15.0 <b>Started:</b>	Milligram		Stopped:		
	uspected)		Milligram		Stopped:		
	uspected)		Milligram		Stopped:		
	ispected)		Milligram		Stopped:		
	uspected)		Milligram		3topped:		
	uspected)		Milligram		Stopped:		
	uspected)		Milligram		¥topped:		
3atch:		Started:	Milligram		Stopped:		
3atch:		Started:	Milligram		Stopped:		
3atch:		Started:	Milligram		¥topped:		
3atch:		Started:	Milligram		Stopped:		
		Started:	Milligram		Stopped:		
3atch:		Started:	Milligram		Stopped:		
3atch:		Started:	Milligram		3topped:		
3atch:		Started:	Milligram		Stopped:		
3atch:		Started:	Milligram		Stopped:		
3atch: Laboratory Inv	estigations:	Started:	Milligram		Stopped:		
3atch:	estigations:	Started:	Milligram		Stopped:		
3atch: Laboratory Inv	estigations:	Started:	Milligram		Stopped:		
3atch: Laboratory Inv	estigations:	Started:	Milligram		Stopped:		
3atch: Laboratory Inv	estigations:	Started:	Milligram		3topped:		



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Rep	oort	Det	ail
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Case Number: 84854 Seq: 1 Gender: F

Reported: 27/05/1993 Weight:
Hospitalisation: Age: 84Y

Onset Date: 08/08/1992 DOB:

Outcome: Recovered Causality: Causality possible

#### **Reaction Detai**

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			

### **Medicine Details:**

LANOXIN (Other drug)			Reason:	Congestive heart failure	
Tablet	250.0	Microgram	Daily	Oral	
3atch:	Started:			Stopped:	
LOSEC (Other drug)			Reason:	Peptic ulcer nos w/o ment pe	rf
Tablet	20.0	Milligram	Daily	Oral	
3atch:	Started:			Stopped:	
FERRO-GRADUMET (Other drug)			Reason:		
		Б 11	er a Danie		
Tablet	1.0	Dose Unspec	ified Daily	Oral	
Tablet  3atch:	1.0 Started:	Dose Unspec	ified Dally	Oral Stopped:	
		Dose Unspec	Reason:		
3atch:	Started:	Milligram		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Case Number: 8	84854	Seq: 1				Gender: F		
Reported: 2	27/05/1993					Weight:		
Hospitalisation:						<b>Age</b> : 84	1Y	
Onset Date: (	08/08/1992					DOB:		
Outcome:	Recovered				C	ausality: Ca	ausality possi	ble
Reaction Detai								
Medicine Deta				_				
TOFRANIL (Suspec	ted)			Reason:	Incontinence			
Tablet			Milligram	Daily		Oral		
3atch:		Started:			}topped:	08/08/1992		
INDERAL (Suspecte	ed)			Reason:	Chron isch he	art dis no hyper		
Tablet			Milligram	Daily		Oral		
3atch:		Started:			Stopped:	08/08/1992		
Laboratory Inv	estigations.							
_asoratory in	, congunono							
Additional Info	ormation:							
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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report	Detail
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Case Number: 85497 Seq: 1 Gender: F

Reported: 25/06/1993 Weight: 51.00 Hospitalisation: Age: 28Y

Onset Date: 21/06/1993 DOB:

Outcome: Unknown Causality: Causality possible

#### **Reaction Detai**

Preferred Term	Severity	Report Description	Treatment
Pruritus			
Rash	Severe		

#### **Medicine Details:**

Medicine Details.					
ATIVAN (Other drug)	_	Reason:			
Tablet	0.0		Oral		
Зatch:	Started:	S TERM	Stopped:	CONTIN	
TOFRANIL (Suspected)		Reason:			
Tablet	0.0		Oral		
3atch:	Started:	S TERM	Stopped:	CONTIN	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 86359 Seq: 1 Gender: F

Reported: 30/07/1993 Weight: 46.00 Hospitalisation: Age: 83Y

Onset Date: 30/05/1993 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Mouth ulceration			Mouth wash.

**Medicine Details:** 

AURORIX (Other drug)			Reason:	Depression	
Tablet	300.0	Milligram	Daily		Oral
3atch:	Started:	l	L TERM	Stopped:	
LITHICARB (Other drug)			Reason:	Depression	
Tablet	125.0	Milligram	Daily		Oral
3atch:	Started:	L	L TERM	Stopped:	
PLENDIL ER (Other drug)			Reason:	Essential ben	ign hypertension
PLENDIL ER (Other drug) Tablet	10.0	Milligram	Reason: Daily	Essential ben	ign hypertension Oral
` "	10.0 <b>Started:</b>	Ū		Essential ben	· ,,
Tablet		Ū	Daily		· ,,
Tablet  3atch:		Ū	Daily L TERM	}topped:	· ,,

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Case Number:	86359	Seq: 1			Gender:	F	
Reported:	30/07/1993				Weight:	46.00	
Hospitalisation:					Age:	83Y	
Onset Date:	30/05/1993				DOB:		
Outcome:	Recovered			С	ausality:	Causality poss	ible
Reaction Detai	İ						
Medicine Det	ails:						
TOFRANIL (Suspe	ected)		Reason:				
Tablet		25.0 Milligram	Daily		Oral		
3atch:		<b>Started:</b> 25/05/1993		Stopped:	30/05/1993		
Laboratory In	woetigatione:						
Laboratory In	ivestigations.						
<b>Additional Inf</b>	formation:						
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**Additional Information:** 

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

ase numi	oer: 86692	Seq:	1				Gender	": F
	ted: 10/08/1993	•					Weight	:: 69.00
ospitalisati				<b>A</b>			_	: 49Y
Onset D	ate: 31/01/1993						DOB	:
Outco	me: Unknown					C	ausality	: Causality possible
action D							1	
Pre	ferred Term	Seve	erity	Repor	t Descri	ption		Treatment
lash			F	Rash on face arm	s and tor	SO.	Pho	energan 25mg iv, kamethasone 4mg iv.
ruritus							uc)	Ramethasone 4mg iv.
ledicine PROLADONE				<b>Reas</b>	on:			
PROLADONE	Details:  i (Other drug) ository		2.0	<b>Reas</b> Dose Unspecified	on:		Rectal	
PROLADONE	(Other drug) ository	Sta	2.0 arted:		on:	}topped:	Rectal	
<b>PROLADONE</b> Supp	(Other drug) ository :	Sta				}topped:	Rectal	
PROLADONE Supp 3atch	(Other drug) ository : er drug)	∃ta	ırted:	Dose Unspecified		Stopped:	Rectal	
PROLADONE Supp 3atch VALIUM (Oth Table 3atch	(Other drug) ository : er drug) t		ırted:	Dose Unspecified	son:	itopped:		
PROLADONE Supp 3atch VALIUM (Oth Table	(Other drug) ository : er drug) t		4.0	Dose Unspecified  Reas  Milligram	on: Daily on:			
PROLADONE Supp 3atch VALIUM (Oth Table 3atch	c (Other drug) ository : er drug) t : Other drug)	Sta	4.0 arted:	Dose Unspecified  Reas  Milligram  Reas  Dose Unspecified	on: Daily on:	Stopped:		
PROLADONE Supp 3atch VALIUM (Oth Table 3atch ROHYPNOL (	(Other drug) ository : er drug) t : Other drug)	Sta	4.0	Dose Unspecified  Reas  Milligram  Reas  Dose Unspecified  01/1993	on: Daily on: Daily			
PROLADONE Supp 3atch VALIUM (Oth Table 3atch	(Other drug) ository : er drug) t : Other drug)	Sta	4.0 arted: 1.0 arted: 24/	Dose Unspecified  Reas  Milligram  Reas  Dose Unspecified  01/1993	on: Daily on: Daily son:	Stopped:		
PROLADONE Supp 3atch VALIUM (Oth Table 3atch ROHYPNOL ( 3atch DI-GESIC (Oth	c (Other drug) ository : er drug) t : Other drug) :	Sta Sta	4.0 arted:  1.0 arted: 24/	Name of the control o	on: Daily on: Daily son:	Stopped:		
PROLADONE Supp 3atch VALIUM (Oth Table 3atch ROHYPNOL ( 3atch DI-GESIC (Oth 3atch	c (Other drug) ository : er drug) t : Other drug) : her drug)	Sta Sta Sta	4.0 arted: 1.0 arted: 24/	Name of the control o	on: Daily on: Daily son:	Stopped:		
PROLADONE Supp 3atch VALIUM (Oth Table 3atch ROHYPNOL ( 3atch DI-GESIC (Oth 3atch	c (Other drug) ository : er drug) t : Other drug) :	Sta Sta Sta	4.0 arted:  1.0 arted: 24/	Dose Unspecified  Reas  Milligram  Reas  Dose Unspecified  01/1993  Reas  Dose Unspecified  01/1993	on: Daily on: Daily son:	Stopped:	Oral	rails



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

eport Detail					
ase Number: 86692 Reported: 10/08/1993 spitalisation: Onset Date: 31/01/1993 Outcome: Unknown action Detai	Seq: 1		c	Gender: Weight: Age: DOB: ausality:	69.00
edicine Details:					
EGRETOL (Suspected)	7	Reason:			
Tablet	300.0 Milligram	Daily		Oral	
3atch:	<b>Started:</b> 18/01/1993		Stopped:	31/01/1993	3
OFRANIL (Suspected)		Reason:			
Batch:	50.0 Milligram	Daily	\4	24/04/4000	
ACLOFEN (Suspected)	Started: 25/01/1993	Reason:	Stopped:	31/01/1993	)
Tablet	30.0 Milligram	Daily		Oral	
Batch:	3tarted: 21/01/1993	Daily	Stopped:	31/01/1993	}
boratory Investigations			лоррец	31/01/1330	<u>,                                      </u>
, ,					
, ,					
dditional Information:					

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 86926 Seq: 1 Gender: M

 Reported:
 20/08/1993
 Weight:
 88.00

 Hospitalisation:
 Age:
 64Y

 Onset Date:
 31/08/1992
 DOB:

Onset Date: 31/08/1992 DOB:
Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia			

#### **Medicine Details:**

TOFRANIL (Suspected) Reason: Depression

0.0

3atch: 3tarted: 31/01/1988

PROTHIADEN (Suspected) Reason: Depression

Capsule 250.0 Milligram Daily Oral **3atch: 3tarted:** 01/01/1988 **3topped:** 

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

		eta	

 Case Number:
 87082
 Seq:
 1
 Gender:
 F

 Reported:
 27/08/1993
 Weight:
 60.00

Hospitalisation: Age: 40Y
Onset Date: 12/08/1993
DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

100.00.00.		-	
Preferred Term	Severity	Report Description	Treatment
Aphasia		Slurred speech.	
Anticholinergic syndrome			
Mydriasis			
Visual disturbance			

**Medicine Details:** 

AURORIX (Other drug)		Reason:	Depression	
	2.0 Dose Unspe	ecified Daily		
3atch:	3tarted: 06/07/1992		Stopped:	CONTIN
OGEN (Other drug)		Reason:	Menopausal symptoms	
	1.8 Milligram	Daily		
3atch:	3tarted: 12/02/1991		Stopped:	CONTIN
ZOCOR (Other drug)		Reason:	Othr&unspec metabolic dise	eases
	20.0 Milligram	Daily		
3atch:	3tarted: 18/02/1991		Stopped:	CONTIN
VAGIFEM (Other drug)		Reason:	Vaginitis&vulvitis	
Tablet	1.0 Dose Unspe	ecified Daily	Vaginal	
3atch:	3tarted: 01/07/1993		Stopped:	CONTIN

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Hospitalisation: Onset Date:	27/08/1993 12/08/1993 Recovered	Seq:	1			Gender: Weight: Age: DOB: Causality:	60.00 40Y	ole
Madiaina Data	oilo:							
Medicine Deta				Reason:	Frequency of	micturition		
(0.000	,		75.0 Milli	Daily				
3atch:		€tar	rted: 12/08/1	2 4,	Stopped:	16/08/1993	3	
Laboratory In	vestigations:							
Additional Inf	formation:							

Report Run 19/07/200 02:14PN Database: pusime ADRS004 Page 116 of 279



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Re	port	Detail

Case Number: 87096 Seq: 1 Gender: F

Reported: 27/08/1993 Weight: 48.00 Hospitalisation: Age: 27Y

Onset Date: 09/08/1993 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

•	oaction Botal			
	Preferred Term	Severity	Report Description	Treatment
	Rash maculo-papular			

#### **Medicine Details:**

TOFRANIL (Suspected) Reason: Depression

75.0 Milligram Daily

3atch: 3tarted: 02/08/1993 3topped: 12/08/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 87550 Seq: 1 Gender: F

Reported: 09/09/1993 Weight: 56.00 Hospitalisation: Age: 88Y

Onset Date: 14/07/1993 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Leukopenia			
Thrombocytopenia			

**Medicine Details:** 

SEPTRIN FORTE (Suspected) Reason: Othr diseases of urinary tract

0.0

3atch: 3tarted: 3topped: 12/07/1993

 LASIX (Suspected)
 Reason:
 Pulmonary congestn&hypostasis

Injection 80.0 Milligram 1 time Intravenous

3atch: 3tarted: 12/07/1993 3topped:

LANOXIN PG (Suspected) Reason: Otr&nos disord of heart rhythm

Oral application 2.0 Dose Unspecified Daily Oral

3atch: 3tarted: 3topped: 15/07/1993

TOFRANIL (Suspected) Reason: Depression

Tablet 10.0 Milligram Daily Oral

3atch: 3tarted: 3topped: 12/07/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Bone marrow				Marrow biopsy showed hypocellular bone marrow with arrest of maturation at the myelocyte level.
	Platelets		11/07/1993	254	
	Platelets		16/08/1993	56	
	White blood cells		12/07/1993	17.2	
	White blood cells		16/07/1993	0.6	

#### **Additional Information:**

Patient has had no known previous allergies.

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Repo	ort D	etai
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Case Number: 87550 Seq: 1 Gender: F

Reported: 09/09/1993 Weight: 56.00 Hospitalisation: Age: 88Y

Onset Date: 14/07/1993 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

### **Medicine Details:**

NAPROXEN (Suspected)		Reason:	Osteoporosis	
Oral application	250.0 Milligram	Daily		Oral
Зatch:	Started:		Stopped:	12/07/1993
LASIX (Suspected)		Reason:	Pulmonary co	ngestn&hypostasis
LASIX (Suspected) Oral application	80.0 Milligram	Reason: Daily	Pulmonary co	ngestn&hypostasis Oral

# **Laboratory Investigations:**

#### **Additional Information:**

Patient has had no known previous allergies.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 87963 Seq: 1 Gender: F

Reported: 28/09/1993 Weight: 52.00
Hospitalisation: Age: 23Y

**Onset Date**: 09/09/1993 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

		ā.	E
Preferred Term	Severity	Report Description	Treatment
Urticaria		Over back, chest, arms and legs.	Prednisone.
Skin exfoliation		Sunburnt skin - skin peeling.	

#### **Medicine Details:**

TOFRANIL (Suspected) Reason: Depression

75.0 Milligram Daily

3atch: 3tarted: 06/09/1993 3topped: 15/09/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient has had no known previous allergies.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 88284 Seq: 1 Gender: F

Reported: 05/10/1993 Weight: 65.00 Hospitalisation: Age: 34Y

Onset Date: 30/04/1993 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

		-	
Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			

## **Medicine Details:**

TETANUS VACCINE ADSORBED (Suspect	ted)	Reason:	Mult opn wnd	s of otr&unsp loca
Injection	0.0			Intramuscular
3atch:	30/04/1993		Stopped:	30/04/1993
ROFERON-A (Suspected)		Reason:	Other disease	es of liver
Injection	9.0 Million Inte	rnation: Weel	kly	Subcutaneous
3atch:	3tarted: 08/03/1993		Stopped:	CONTIN
INDERAL (Suspected)		Reason:	Palpitation	
Tablet	160.0 Milligram	Daily	,	Oral
3atch:	Started:	TERM	Stopped:	
TOFRANIL (Suspected)		Reason:	Depression	
Tablet	125.0 Milligram	Daily	,	Oral
3atch:	Started:	TERM	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 88355 Seq: 1 Gender: F

**Reported**: 07/10/1993 **Weight**: 19.00

Hospitalisation: Age: 3

**Onset Date**: 30/04/1993 **DOB**: 06/09/1989

Outcome: Unknown Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Candidiasis			Nilstat

## **Medicine Details:**

SEPTRIN (Suspected)		Reason:	Othr diseases of urinary tract	
Oral application	3.0 Millilitre	Daily	Oral	
3atch:	<b>Started:</b> 19/03/1993		Stopped:	
TOFRANIL (Suspected)		Reason:		
	20.0 Milligram	Daily		
3atch:	Started: 16/02/1993		Stopped:	
COLOXYL (Suspected)		Reason:		
	100.0 Milligram	Daily		
3atch:	Started: 24/03/1993		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 88481 Seq: 1 Gender: F

Reported: 13/10/1993 Weight:
Hospitalisation: Age: 22Y

Onset Date: 28/10/1992 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			Desipramide commenced.

#### **Medicine Details:**

modifie Botallo.				
LITHIUM CARBONATE (Other drug)		Reason:	Schizo-affective type psychos	
Tablet	1.2 Gram	Daily	Oral	
3atch:	Started: 01/10/1992		Stopped:	
CHLORPROMAZINE HYDROCHLORIDE	(Other drug)	Reason:	Schizo-affective type psychos	
Oral application	350.0 Milligram	Daily	Oral	
3atch:	Started: 05/09/1992		Stopped:	
IMIPRAMINE HYDROCHLORIDE (Suspe	cted)	Reason:	Schizo-affective type psychos	
Tablet	75.0 Milligram	Daily	Oral	
Batch:	Started: 28/10/1992		Stopped: 28/10/1992	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Bp lying=110/75, bp standing=90/60. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 89457
 Seq:
 1
 Gender:
 F

 Reported:
 29/11/1993
 Weight:

Hospitalisation: Age: 39

**Onset Date**: 06/11/1993 **DOB**: 06/08/1954

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Confusional state			
Hyperhidrosis			
Hypertonia			
Myalgia			No response to cogentin, diazepam, and phenytoin so
Mydriasis			given'
Pupillary reflex impaired			
Pyrexia			
Respiratory disorder			
Salivary hypersecretion			

**Medicine Details:** 

MOCLOBEMIDE (Interaction)		Reason:		
	300.0 Milligram	Daily		
3atch:	Started: 01/11/1993		Stopped:	
IMIPRAMINE HYDROCHLORIDE (	Interaction)	Reason:		
	200.0 Milligram	Daily		
Batch:	Started: 01/11/1993		Stopped:	
VERAPAMIL HYDROCHLORIDE (	Other drug)	Reason:		
	0.0			
3atch:	Started:		Stopped:	
DIGOXIN (Other drug)		Reason:		
	0.0			
3atch:	Started:		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Creatine Radiololgy		07/11/1993	3,200 U/L	Serum tricyclics - 1940 mcg/l.

#### **Additional Information:**

Alcoholism. 1992 bipolar affective disorder. paroxysmal supraventricular tachycardia controlled on verapamil and digoxin. still some residual calf and thigh discomfort, flushing, shivering, amnesia.

Report Run 19/07/200 02:14PN Database: pusime ADRS004 Page 124 of 279



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

leport Detail			
Case Number: 89457	Seq: 1	G	ender: F
Reported: 29/11/1993		V	Veight:
ospitalisation:			<b>Age:</b> 39
Onset Date: 06/11/1993			<b>DOB</b> : 06/08/1954
Outcome: Recovered		Cau	usality: Causality possible
eaction Detai	<del>.</del>		
Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome			Chlorpromazine, penicillin and ceftriaxone with some
speech disorder			imarai/amaav
Stupor			
Medicine Details:			
DIAZEPAM (Other drug)		Reason:	
	7.5 Milligra		
3atch:	Started:	Stopped:	
aboratory Investigations	s:		
,gg			

#### **Additional Information:**

Alcoholism. 1992 bipolar affective disorder. paroxysmal supraventricular tachycardia controlled on verapamil and digoxin. still some residual calf and thigh discomfort, flushing, shivering, amnesia.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 89677
 Seq:
 1
 Gender:
 M

 Reported:
 07/12/1993
 Weight:
 71.00

 Hospitalisation:
 Age:
 33Y

Onset Date: 02/11/1993 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Neuropathy peripheral			Analgesia

**Medicine Details:** 

STEMETIL (Suspected)			Reason:	Nausea and v	omiting	
Suppository		0.0			Rectal	
Зatch:	Started:	02/09/1993		Stopped:		CONTIN
FLUCONAZOLE (Suspected)			Reason:	Hiv infection		
Capsule		0.0			Oral	
Зatch:	Started:	18/05/1993		Stopped:		CONTIN
4 0101 01 (ID (0			_			
ACICLOVIR (Suspected)			Reason:	Hiv infection		
Tablet		0.0	Reason:	Hiv infection	Oral	
` . ,	Started:	0.0	Reason:	Hiv infection  Stopped:	Oral	CONTIN
Tablet		0.0	Reason:		Oral	CONTIN
Tablet  3atch:	Started:	0.0		Stopped:	Oral	CONTIN

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

Case Number: 89677

**Reported:** 07/12/1993

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

**Weight:** 71.00

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Onset Date: 02/11/1993 Outcome: Not yet recovered	Age: 331  DOB:  Causality: Causality possible					
action Detai				ausanty.	. Gausality pussi	ЫG
edicine Details: DEXAMETHASONE (Suspected)		Reason:				
Tablet	8.0 Milligram	Daily		Oral		
3atch:	<b>Started:</b> 02/09/1993		Stopped:		CONTIN	
Toplot	75 O M:0:		Depression	Oral		
Tablet  3atch:	75.0 Milligram Started: 26/07/1993	Daily	Stopped:	Oral	CONTIN	
aboratory Investigations:						
dditional Information:						
ort Run 19/07/200 02:14PN Databas	e: pusime	ADRS004	1		Page 127	of 279



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report I	Detail
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 Case Number:
 89678
 Seq:
 1
 Gender:
 M

 Reported:
 07/12/1993
 Weight:
 66.00

Hospitalisation:
Onset Date: 20/11/1993

Age: 33Y

DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Dyspnoea			

## **Medicine Details:**

STEMETIL (Suspected)		Reason:	Nausea and vomiting	
Suppository	0.0		Rectal	
3atch:	Started:		Stopped:	
MS CONTIN (Suspected)		Reason:	Pain	
Tablet	0.0		Oral	
3atch:	Started:		Stopped:	CONTIN
ZOVIRAX (Suspected)		Reason:		
Tablet	0.0		Oral	
3atch:	3tarted: 26/07/1993		Stopped:	CONTIN
DEXAMETHASONE (Suspected)		Reason:		
Tablet	8.0 Milligram	Daily	<i>o</i> Oral	
3atch:	Started: 02/09/1993		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

Case Number: 89678

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Seq: 1

Reported: lospitalisation: Onset Date:	07/12/1993 20/11/1993					Weight: Age: DOB:		
Outcome:							Causality possi	ble
action Detai								
ledicine Deta				Reason:	Depression			
(0.00)	,	75.0	Milligram	Daily				
3atch:		Started:			Stopped:		CONTIN	
FLUCONAZOLE (S	suspected)			Reason:				
Capsule		100.0	Milligram	Daily		Oral		
3atch:		Started:			3topped:			
aboratory In	vestigatio	ons:						
Additional Inf	ormation	:						
oort Run 19/07/200	02:14PN	Database: pusime		ADRS00	04		Page 129	of 279



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 89732 Seq: 1 Gender: F

Reported: 08/12/1993 Weight: 55.00 Hospitalisation: Age: 24Y

Onset Date: 01/12/1993 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

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

#### **Medicine Details:**

IMIPRAMINE HYDROCHLORIDE (Suspected) Reason: Depression

25.0 Milligram Daily

3atch: 3tarted: 25/11/1993 3topped: 03/12/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Dose of imipramine was started at 25 mg daily and increased to 100 mg daily by 1.12.93



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail				
Case Number: 89876	Seq: 1		Gende	
<b>Reported:</b> 16/12/1993			_	t: 35.00
espitalisation:				e: 13Y
Onset Date:			DOE	
Outcome: Not yet recove	ered		Causality	: Causality possible
action Detai	<u> </u>		-	
Preferred Term	Severity	Report Desc	ription	Treatment
agitation				
Anxiety				
omiting				
ledicine Details: TOFRANIL (Suspected)		Reason:	Explosive personality dis	sorder
Tablet	50.0 Milli		Oral	
Batch:	Started: 24/11/19		Stopped: 12/12/19	93
<u>aboratory Investigation</u>	I <b>S:</b> Range Date Tested	Result	De	tails
		Result	De	tails



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 89877 Seq: 1 Gender: F

**Reported:** 15/12/1993 **Weight:** 19.00

Hospitalisation: Age: 3

**Onset Date**: 30/04/1993 **DOB**: 06/09/1989

Outcome: Unknown Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Candidiasis			Nilstat

## **Medicine Details:**

SEPTRIN (Suspected)	;	Reason:		
Solution	3.0 Millilitre	Daily	Oral	
3atch:	Started: 19/03/1993	Stopp	ed:	
TOFRANIL (Suspected)	;	Reason:		
Tablet	20.0 Milligram	Daily	Oral	
3atch:	Started: 16/02/1993	}top;	ed:	
COLOXYL (Suspected)	;	Reason:		
Tablet	100.0 Milligram	Daily	Oral	
3atch:	Started: 24/03/1993	Stopp	ed:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 89899
 Seq:
 1
 Gender:
 F

 Reported:
 02/12/1993
 Weight:
 64.00

 Hospitalisation:
 Age:
 82Y

**Onset Date**: 15/11/1993 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Hepatitis cholestatic			

#### **Medicine Details:**

LASIX (Other drug)		Reason: Depression	
	40.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
OROXINE (Other drug)		Reason: Depression	
	150.0 Milligram	Daily	
3atch:	Started:	Stopped:	CONTIN
TOFRANIL (Suspected)		Reason: Depression	
Injection	25.0 Milligram	Daily	Intravenous
3atch:	Started: 11/10/1993	Stopped:	19/11/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	8 - 29 U/L	07/06/1993	14	
	ALT = SGPT	8 - 29 U/L	15/11/1993	108	
	ALT = SGPT	8 - 29 U/L	07/12/1993	28	
	ALT = SGPT	8 - 29 U/L	14/01/1994	14	
	AST = SGOT	10 - 28 U/L	07/06/1993	17	
	AST = SGOT	10 - 28 U/L	15/11/1993	37	
	AST = SGOT	10 - 28 U/L	14/01/1994	19	



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 89899
 Seq:
 1
 Gender:
 F

 Reported:
 02/12/1993
 Weight:
 64.00

Hospitalisation: Age: 82Y
Onset Date: 15/11/1993
DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

## **Medicine Details:**

LASIX (Other drug)		Reason: Depression	
	40.0 Milligram	Daily	
3atch:	Started:	Stopped:	CONTIN
OROXINE (Other drug)		Reason: Depression	
	150.0 Milligram	Daily	
3atch:	Started:	Stopped:	CONTIN
TOFRANIL (Suspected)		Reason: Depression	
Injection	25.0 Milligram	Daily	Intravenous
3atch:	Started: 11/10/1993	Stopped:	19/11/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT	10 - 28 U/L	07/12/1993	22	
	GGT = SGGT =	5 - 40 U/L	07/06/1993	15	
	GGT = SGGT =	5 - 40 U/L	15/11/1993	253	
	GGT = SGGT =	5 - 40 U/L	07/12/1993	54	
	GGT = SGGT =	5 - 40 U/L	14/01/1994	20	
	SAP = ALP	30 - 95 U/L	07/06/1993	108	
	SAP = ALP	30 - 95 U/L	15/11/1993	289	



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 89899
 Seq:
 1
 Gender:
 F

 Reported:
 02/12/1993
 Weight:
 64.00

Hospitalisation: Age: 82Y
Onset Date: 15/11/1993
DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

## **Medicine Details:**

LASIX (Other drug)		Reason: Depression	
	40.0 Milligram	Daily	
3atch:	Started:	Stopped:	CONTIN
OROXINE (Other drug)		Reason: Depression	
	150.0 Milligram	Daily	
3atch:	Started:	Stopped:	CONTIN
TOFRANIL (Suspected)		Reason: Depression	
Injection	25.0 Milligram	Daily	Intravenous
3atch:	Started: 11/10/1993	Stopped:	19/11/1993

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP	30 - 95 U/L	07/12/1993	124	
	SAP = ALP	30 - 95 U/L	14/01/1994	121	



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 91063 Seq: 1 Gender: F

Reported: 14/02/1994 Weight: 56.00 Hospitalisation: Age: 44Y

Onset Date: 25/01/1994 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction		On face and shoulders	

#### **Medicine Details:**

TOFRANIL (Suspected) Reason: Depression

25.0 Milligram Daily

3atch: 3tarted: 18/01/1994 3topped: 27/01/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Tofranil commenced 25mg on 18.01.94, daily dose increased by 25mg each day, last dose 150mg was given on 27.1.94. allergic to desipramine - rash

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 91697 Seq: 1 Gender: M
Reported: 18/03/1994 Weight:

Hospitalisation: Age: 26Y
Onset Date: 16/12/1993
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

eaction Detai									
Preferred Term	Severity	Report Description	Treatment						
Otitis externa		Discharge oozing out of both ears							
Pruritus									
Rash			Promethazine and diprosone						

**Medicine Details:** 

HEPARIN SODIUM (Other drug)	Reason:	
Injection	15.0 Thousand Internat 1 time Subcutaneous	
3atch:	Started: 09/10/1993 Stopped:	
MORPHINE NOS (Other drug)	Reason: Otr&unsp vertebrogen pain synd	
Oral application	120.0 Milligram Daily Oral	
3atch:	<b>Started:</b> 07/12/1993 <b>Stopped:</b>	
PRAMIN (Other drug)	Reason: Nausea and vomiting	
Tablet	30.0 Milligram Daily Oral	
3atch:	Started: 07/12/1993 Stopped:	
FENAC (Suspected)	Reason: Otr&unsp vertebrogen pain synd	
Tablet	50.0 Milligram Daily Oral	
3atch:	<b>Started:</b> 16/12/1993 <b>Stopped:</b> 20/12/1993	

**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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

eport Detai						
Case Number:	91697	Seq: 1			Gender:	M
Reported:	18/03/1994				Weight:	
ospitalisation:					Age:	
Onset Date:				_	DOB:	
	Recovered			C	Causality:	Causality possible
eaction Detai						
Medicine Deta	ails:					
TOFRANIL (Suspe			Reason:	Otr periph ner	rve dis not au	uton
Tablet		150.0 Milligram	Daily		Oral	
3atch:		Started: 01/02/1993		Stopped:	21/12/1993	3
Laboratory In	vestigations:					
Additional Inf	ormation:					

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



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

R	٩ı	n	n	rt	D	eta	i
	<b>5</b> 1	~	_	ıL	$\boldsymbol{L}$	CLO	

 Case Number:
 92045
 Seq:
 1
 Gender:
 M

 Reported:
 05/04/1994
 Weight:

 Iospitalisation:
 Age:
 63Y

Hospitalisation: Age:
Onset Date: 23/04/1993
DOB:

Outcome: Not yet recovered Causality: Causality possible

#### **Reaction Detai**

		_	
Preferred Term	Severity	Report Description	Treatment
Hallucination		Tactile hallucination of mouth	
Delirium			

## **Medicine Details:**

SINEMET (Other drug)		Reas	on:	Paralysis agitans	
Tablet	1.0	Dose Unspecified	Daily	Oral	
3atch:	Started:			Stopped:	
MADOPAR (Other drug)		Reas	on:	Paralysis agitans	
Oral application	5.0	Milligram	Daily	Oral	
Зatch:	Started:			Stopped:	
VERAPAMIL HYDROCHLORIDE (Other dru	ıg)	Reas	on:	Essential benign hypertension	
Oral application	120.0	Milligram	Daily	Oral	
Зatch:	Started:			Stopped:	
ENALAPRIL MALEATE (Other drug)		Reas	on:	Essential benign hypertension	
Tablet	10.0	Milligram	Daily	Oral	
Зatch:	Started:			Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail			
Case Number:	92045	Seq: 1	Gender: M
Reported:	05/04/1994		Weight:

Hospitalisation: Age: 63Y
Onset Date: 23/04/1993
DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

# **Medicine Details:**

AMANTADINE HYDROCHLORIDE (Suspec	ted)		Reason:	Paralysis agita	ans
Capsule	100.0	Milligram	Daily		Oral
3atch:	Started:			Stopped:	27/04/1993
ARTANE (Suspected)			Reason:	Paralysis agita	ans
Tablet	6.0	Milligram	Daily		Oral
3atch:	Started:			Stopped:	27/04/1993
TOFRANIL (Suspected)			Reason:	Paralysis agita	ans
TOFRANIL (Suspected) Tablet	10.0	Milligram	Reason: Daily	Paralysis agita	ans Oral
, , ,	10.0 <b>Started:</b>	Milligram		Paralysis agita	
Tablet	Started:	Milligram		, ,	Oral 28/04/1993
Tablet  3atch:	Started:	Milligram Milligram	Daily	Stopped:	Oral 28/04/1993

# **Laboratory Investigations:**



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report De
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Case Number: 94385 Seq: 1 Gender: F

Reported: 13/07/1994 Weight:
Hospitalisation: Age: 89Y

Onset Date: 10/06/1994 DOB:

Outcome: Unknown Causality: Causality possible

#### **Reaction Detai**

Preferred Term	Severity	Report Description	Treatment
Urticaria			

# **Medicine Details:**

GLYCERINE (Suspected)	;	Reason: Constipation	
Suppository	3.0 Dose Unspeci	fied Weekly	Rectal
3atch:	Started: 03/06/1994	Stopped:	
VOLTAREN (Suspected)		Reason: Pain	
	50.0 Milligram	Daily	
Зatch:	Started: 09/06/1994	Stopped:	
AMOXIL (Suspected)		Reason:	
AMOXIL (Suspected) Oral application	1.5 Gram	Reason: Daily	Oral
` ' '			Oral 16/06/1994
Oral application	1.5 Gram <b>3tarted:</b> 06/06/1994	Daily	
Oral application  3atch:	1.5 Gram <b>3tarted:</b> 06/06/1994	Daily Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Case Number: 9	94385	Seq: 1				Gender:	F	
Reported:	13/07/1994					Weight:		
lospitalisation:						Age:	89Y	
Onset Date:	10/06/1994					DOB:		
Outcome: \	Unknown				(	Causality:	Causality po	ssible
eaction Detai								
Medicine Deta	ile							
PANADEINE (Suspe				Reason:	Pain			
(	,		12.0 Dose Unspe		-			
3atch:			09/06/1994	,	Stopped:			
ENDONE (Suspecte	ed)			Reason:	Pain			
			2.0 Dose Unspe	ecified Daily				
3atch:		Started:	30/05/1994		Stopped:			
Laboratory Inv	estigations:							
Additional Info	ormation:							

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 94689
 Seq:
 1
 Gender:
 F

 Reported:
 29/07/1994
 Weight:

**Hospitalisation**: Age: 70Y

**Onset Date**: 20/04/1994 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

#### **Medicine Details:**

FERRO-GRADUMET (Other drug)		Reason:	
Tablet	350.0 Milligram	Daily	Oral
3atch:	Started: 15/04/1994	Stopped:	CONTIN
MEGAFOL (Other drug)		Reason:	
Oral application	500.0 Microgram	Daily	Oral
Зatch:	Started: 18/04/1994	Stopped:	CONTIN
FLUCLOXACILLIN SODIUM (Suspected)		Reason: Otr&nos infec	&parasit diseases
Injection	2.0 Gram	Daily	Intravenous
Зatch:	Started: 08/04/1994	Stopped:	14/04/1994
STAPHYLEX (Suspected)		Reason: Unspecified s	epticemia
Oral application	1.0 Gram	Daily	Oral
3atch:	Started: 14/04/1994	Stopped:	03/05/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	5 - 45 U/L	15/05/1994	13	
	ALT = SGPT	5 - 45 U/L	16/05/1994	21	
	ALT = SGPT	5 - 45 U/L	20/07/1994	68	
	ALT = SGPT	5 - 45 U/L	25/07/1994	13	
	ALT = SGPT	5 - 45 U/L	04/07/1994	18	
	ALT = SGPT	5 - 45 U/L	27/06/1994	25	
	AST = SGOT	10 - 45 U/L	15/05/1994	46	

#### **Additional Information:**

On the day of admission the patient received four units of packed cells.

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 94689
 Seq: 1
 Gender: F

 Reported:
 29/07/1994
 Weight:

Hospitalisation:
Onset Date: 20/04/1994
DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

## **Medicine Details:**

AMOXIL (Suspected)		Reason:	Otr&nos infec	&parasit diseases
Injection	1.5 Gram	Daily		Intravenous
3atch:	3tarted: 09/04/1994		Stopped:	14/04/1994
ROCEPHIN (Suspected)		Reason:	Otr&nos infec	&parasit diseases
Injection	1.0 Gram	Daily		Intravenous
Batch:	3tarted: 07/04/1994		Stopped:	09/04/1994
DEPTRAN (Suspected)		Reason:	Unspecified pa	sychosis
Oral application	25.0 Milligram	Daily		Ovel
oral application	20.0 111111914111	Dany		Oral
3atch:	3tarted: 27/04/1994	Duny	Stopped:	27/04/1994
	· ·	Reason:	Stopped: Unspecified ps	27/04/1994
3atch:	· ·	,	- ''	27/04/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT	10 - 45 U/L	16/05/1994	41	
	AST = SGOT	10 - 45 U/L	20/06/1994	90	
	AST = SGOT	10 - 45 U/L	27/06/1994	43	
	AST = SGOT	10 - 45 U/L	04/07/1994	52	
	AST = SGOT	10 - 45 U/L	25/07/1994	53	
	Bilirubin	4 - 22 UMOL/L	15/05/1994	6	
	Bilirubin	4 - 22 UMOL/L	16/05/1994	4	

#### **Additional Information:**

On the day of admission the patient received four units of packed cells.

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 94689
 Seq: 1
 Gender: F

 Reported:
 29/07/1994
 Weight:

Hospitalisation: Age: 70Y
Onset Date: 20/04/1994
DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

# **Medicine Details:**

FERRO-GRADUMET (Other drug)		Reason:	
Tablet	350.0 Milligram	Daily	Oral
3atch:	3tarted: 15/04/1994	Stopped:	CONTIN
MEGAFOL (Other drug)		Reason:	
Oral application	500.0 Microgram	Daily	Oral
3atch:	3tarted: 18/04/1994	Stopped:	CONTIN
FLUCLOXACILLIN SODIUM (Suspected)		Reason: Otr&nos infec	&parasit diseases
Injection	2.0 Gram	Daily	Intravenous
3atch:	3tarted: 08/04/1994	Stopped:	14/04/1994
STAPHYLEX (Suspected)		Reason: Unspecified s	epticemia
Oral application	1.0 Gram	Daily	Oral
3atch:	3tarted: 14/04/1994	Stopped:	03/05/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin	4 - 22 UMOL/L	24/06/1994	3	
	Bilirubin	4 - 22 UMOL/L	25/07/1994	4	
	Bilirubin	4 - 22 UMOL/L	04/07/1994	5	
	Bilirubin	4 - 22 UMOL/L	20/06/1994	2	
	SAP = ALP	40 - 150 U/L	15/05/1994	174	
	SAP = ALP	40 - 150 U/L	16/05/1994	158	
	SAP = ALP	40 - 150 U/L	20/06/1994	277	

### **Additional Information:**

On the day of admission the patient received four units of packed cells.

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 94689
 Seq:
 1
 Gender:
 F

 Reported:
 29/07/1994
 Weight:

Hospitalisation: Age: 70Y
Onset Date: 20/04/1994
DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

## **Medicine Details:**

AMOXIL (Suspected)		Reason:	Otr&nos infec	&parasit diseases
Injection	1.5 Gram	Daily		Intravenous
3atch:	3tarted: 09/04/1994		Stopped:	14/04/1994
ROCEPHIN (Suspected)		Reason:	Otr&nos infec	&parasit diseases
Injection	1.0 Gram	Daily		Intravenous
Batch:	3tarted: 07/04/1994		Stopped:	09/04/1994
DEPTRAN (Suspected)		Reason:	Unspecified pa	sychosis
Oral application	25.0 Milligram	Daily		Ovel
oral application	20.0 111111914111	Dany		Oral
3atch:	Started: 27/04/1994	Duny	Stopped:	27/04/1994
''	· ·	Reason:	Stopped: Unspecified ps	27/04/1994
3atch:	· ·	,	- ''	27/04/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP	40 - 150 U/L	27/06/1994	242	
	SAP = ALP	40 - 150 U/L	04/07/1994	285	
	SAP = ALP	40 - 150 U/L	25/07/1994	202	

### **Additional Information:**

On the day of admission the patient received four units of packed cells.

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 95641 Seq: 1 Gender: F

Reported: 02/09/1994 Weight: 65.00 Hospitalisation: Age: 50Y

Onset Date: 15/05/1994 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

todotion Dotai			
Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Paraesthesia of mouth and face	
Constipation			
Drug withdrawal syndrome			
Dry mouth			
Vertigo			

**Medicine Details:** 

TOFRANIL (Suspected) Reason: Migraine

150.0 Milligram Daily

3atch: 3tarted: 01/12/1993 3topped: 28/05/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

**Report Detail** 

Case Number: 97594 Seq: 1 Gender: M Reported: 08/12/1994 Weight:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			

#### **Medicine Details:**

MINIPRESS (Other drug) Reason: Hyperplasia of prostate

3.0 Dose Unspecified Daily

3atch: 3tarted: 01/01/1991 3topped:

TOFRANIL (Suspected) Reason: Incontinence of urine

Tablet 1.0 Dose Unspecified Daily Oral

3atch: 3tarted: 01/11/1994 3topped: 01/12/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### Additional Information:

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



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report De	tail								
Case Numb		Seq: 1					Gende		
_	<b>ed:</b> 03/01/1995	i					Weigh		
lospitalisati							_	e: 64	
	ate: 04/10/1994					•		<b>3</b> : 08/02/1930	
	ne: Recovered					C	ausality	y: Causality p	robable
eaction De		Cayonita	.	Donort	Daa	aviation	<del></del>	Traction	
	erred Term	Severity		Report	Des	cription		Treatm	ent
Atrioventricul									
Electrocardio Hypotension	gram abnormal								
Medicine [ ACTRAPID HI	Details: M (Other drug)		10.0 Unit	Reaso	<b>n:</b> Daily	Diabetes melli	itus		
3atch:	1	3tarted:	:	L TERM		Stopped:			
PROTAPHAN	E (Other drug)			Reaso	n:	Diabetes melli	itus		
			24.0 Unit		Daily				
3atch:		Started:		L TERM		3topped:			
	HYDROCHLORIDE			Reaso		Otr&unsp forn		J&neurit	
Tablet			50.0 Millig	ram	Daily		Oral		
3atch:		3tarted:	!			Stopped:	03/10/19	994	
Laboratory Date	y Investigatio		te Tested	Result			De	etails	
Additional	Information	:							



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 99122 Seq: 1 Gender: F

Reported: 24/02/1995 Weight: 100.00 Hospitalisation: Age: 32Y

**Onset Date:** 10/02/1995 **DOB:** 

Outcome: Death, maybe drug Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Duodenal ulcer perforation			
Peritonitis			
Syncope			
Vomiting			

#### **Medicine Details:**

Micalcinic Details.					
CYANOCOBALAMIN (Suspected)		Reason:	eason:		
	20.0 Milligram	Weekly			
3atch:	Started:	Stopped:			
INDOCID (Suspected)		Reason: Pain			
Suppository	100.0 Milligram	Daily R	ectal		
3atch:	Started: 01/06/1994	Stopped:			
IMIPRAMINE HYDROCHLORIDE (Susp	ected)	Reason:			
Tablet	100.0 Milligram	Daily	Pral		
3atch:	Started: 01/01/1993	Stopped:			

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient died on the 10/2/95. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 99368 Seq: 1 Gender: M

Reported: 06/03/1995 Weight: 96.00 Hospitalisation: Age: 71Y

Onset Date: 09/12/1994 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hallucination			

# **Medicine Details:**

BETALOC (Other drug)		Reason:	Essential benign hypertension
	200.0 Milligram	Daily	
Зatch:	Started: 01/01/1993		Stopped:
DYAZIDE (Other drug)		Reason:	Essential benign hypertension
	1.0 Dose Unspe	cified Daily	
Зatch:	Started: 01/01/1992		Stopped:
ZOCOR (Other drug)		Reason:	Othr&unspec metabolic diseases
	10.0 Milligram	Daily	
3atch:	<b>Started:</b> 01/01/1991		Stopped:
			• •
ZANTAC (Other drug)		Reason:	Otr disorders stomach function
ZANTAC (Other drug)	300.0 Milligram	Reason:	

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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 99368 Seq: 1 Gender: M

Reported: 06/03/1995 Weight: 96.00 Hospitalisation: Age: 71Y

Onset Date: 09/12/1994 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

### **Medicine Details:**

ASPIRIN (Other drug)		Reason:	Acute,ill-def cerebrovascular disease w/o hyperte
	150.0 Milligram	Daily	
3atch:	Started: 01/01/1992		Stopped:
TOFRANIL (Suspected)		Reason:	
	50.0 Milligram	Daily	
Batch:	Started: 09/12/1994		Stopped: 10/12/1994

# **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. 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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

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Case Number: 99593 Seq: 1 Gender: F

Reported: 14/03/1995 Weight: 51.00 Hospitalisation: Age: 28Y

Onset Date: 18/12/1994 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Urticaria		Hive rash	Stopped drug

#### **Medicine Details:**

IMIPRAMINE HYDROCHLORIDE (Suspected) Reason: Depression

25.0 Milligram Daily

**3atch**: **3tarted**: 13/12/1994 **3topped**: 19/12/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 99663
 Seq:
 1
 Gender:
 M

 Reported:
 14/03/1995
 Weight:
 57.00

 Hospitalisation:
 Age:
 78Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

-				
	Preferred Term	Severity	Report Description	Treatment
	Leukopenia			

**Medicine Details:** 

ANGININE (Other drug)	Reason:						
	0.0						
3atch:	Started:	L TERM	Stopped:				
ASPIRIN (Other drug)		Reason:					
	0.0						
3atch:	Started:	L TERM	Stopped:				
DIGOXIN (Other drug)		Reason:	Chron isch heart dis no hyper				
	250.0	Microgram Daily					
3atch:	Started:	L TERM	Stopped:				
CAPTOPRIL (Other drug)		Reason:	Congestive heart failure				
	25.0	Milligram Daily					
Зatch:	Started:	L TERM	Stopped:				

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Lymphocytes		27/02/1995	22%	
	Monocytes		27/02/1995	40%	
	Neutrophils				25% neuts approx: 750 on 27/2/95
	White blood cells		27/02/1995	2.9	
	White blood cells		01/03/1995	3.9	
	White blood cells		03/03/1995	6.6	



Case Number: 99663

Reported: 14/03/1995

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

**Weight:** 57.00

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Seq: 1

ospitalisation:						Age:	78Y	
Onset Date:						DOB:		
Outcome: Recovered					C	ausality:	Causality prob	oable
action Detai								
Andinina Dataila.								
Medicine Details: AMIODARONE HYDROCHLORIDE (Other d	rua)		Reas	on.				
AMIODARONE ITTOROGITEORIDE (Other u		0 Milligram		Daily				
Зatch:	Started:	o wiiiigraiii	L TERM	Daily	Stopped:			
FRUSEMIDE (Other drug)	7.0		Reas	on:	жерреш.			
	80.	0 Milligram		Daily				
3atch:	Started:	g.	L TERM	,	Stopped:			
ISOSORBIDE MONONITRATE (Other drug)			Reas	on:	• • •			
		0 Milligram		Daily				
3atch:	Started:	-	L TERM		Stopped:			
IMIPRAMINE HYDROCHLORIDE (Suspecte	d)		₹eas	on:	Frequency of	micturition		
	10.	0 Milligram		Daily				
3atch:	Started: 2	21/02/1995			Stopped:	28/02/1995	5	
aboratory Investigations:								
Additional Information:								

Report Run 19/07/200 02:15PN Database: pusime ADRS004 Page 155 of 279



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 99773 Seq: 1 Gender: F

Reported: 23/03/1995 Weight:
Hospitalisation: Age: 84Y

**Onset Date**: 09/02/1994 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Detai

104011011 20141		-	=
Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		Bp 100/70.	
Dizziness			

**Medicine Details:** 

RANITIDINE (Other drug) Reason:

Tablet 300.0 Milligram Daily Oral

3atch: Started: 29/01/1994 Stopped: CONTIN

FERROUS SULPHATE (Other drug) Reason: Iron deficiency anemias

Oral application 1.0 Dose Unspecified Daily Oral

**3atch**: **3tarted**: 29/01/1994 **3topped**: CONTIN

IMIPRAMINE HYDROCHLORIDE (Suspected) Reason: Depression

Oral application 50.0 Milligram Daily Oral

**3atch**: **3tarted**: 07/02/1994 **3topped**: 09/02/1994

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient unable to tolerate 50 mg decreased back to 25 mg.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

<b>n</b> -		4	<b>n</b> -	4 - :
			חוו	TOI
	ode		UБ	ıaı

Case Number: 100133 Seq: 1 Gender: F

Reported: 10/04/1995 Weight: 54.00 Hospitalisation: Age: 30Y

Onset Date: 24/03/1995 DOB:

Outcome: Recovered Causality: Causality probable

#### **Reaction Detai**

•	todotion Dotal		_	
	Preferred Term	Severity	Report Description	Treatment
	Amnesia		Couldn't remember what people said.	
	Depersonalisation		Feeling strange	
	Nausea			

### **Medicine Details:**

TOFRANIL (Suspected) Reason: Depression
Tablet 75.0 Milligram Daily Oral

3atch: 3tarted: 23/03/1995 3topped: 26/03/1995

# **Laboratory Investigations:**

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 100413 Seq: 1 Gender: M

Reported: 26/04/1995 Weight: 85.00 Hospitalisation: Age: 63Y

Onset Date: 15/10/1994 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Jaundice			

### **Medicine Details:**

modicino 2 otano:			
TOFRANIL (Suspected)		Reason: Frequency of micturition	
	25.0 Milligram	Daily	
3atch:	3tarted: 27/09/1994	Stopped:	
PLENDIL ER (Suspected)		Reason: Essential benign hypertension	
	5.0 Milligram	Daily	
3atch:	Started: 01/10/1991	Stopped:	

**Laboratory Investigations:** 

	,					
Date	Туре	Range	Date Tested	Result	Details	
	Liver biopsy				Cholestatic hepatic damage on liver biopsy 2/12/94.	

### **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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail						
Case Number: 101208 Reported: 31/05/1995 Hospitalisation: Onset Date: 24/05/1995 Outcome: Recovered eaction Detai	Seq: 1		Wei <i>A</i> D	ider: F ight: 20.00 Age: 5Y OOB: ality: Causality probable		
Preferred Term	Severity	Report Des	 cription	Treatment		
Palpitations		'	<u> </u>			
Tachycardia						
Medicine Details:		2				
TOFRANIL (Suspected)	10.0 Millio	<b>₹eason:</b> 10.0 Milligram Daily				
3atch:	Started: 15/05/1995 Stopped: 29/05/1995					
Laboratory Investigatio  Date Type	ns: Range Date Tested	Result		Details		
Additional Information:						



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number:101357Seq:1Gender:MReported:05/06/1995Weight:78.00Hospitalisation:Admitted to hospitalAge:86Y

Onset Date: 30/03/1995 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Cachon Detai			
Preferred Term	Severity	Report Description	Treatment
Confusional state			Largactil, and restrained
Hallucination			

**Medicine Details:** 

TOFRANIL (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily Oral	
3atch:	Started:	Stopped:	
SOLPRIN (Suspected)		Reason:	
Tablet	300.0 Milligram	Daily Oral	
3atch:	Started:	Stopped:	
TENORMIN (Suspected)		Reason: Essential benign hypertension	
Tablet	50.0 Milligram	Daily Oral	
3atch:	Started:	Stopped:	
MINIPRESS (Suspected)		Reason: Essential benign hypertension	
Tablet	1.0 Milligram	Daily Oral	
Tablot		,	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 101492
 Seq:
 1
 Gender:
 M

 Reported:
 08/06/1995
 Weight:

 Hospitalisation:
 Age: 67

 Onset Date: 08/02/1995
 DOB: 28/07/1927

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Hepatitis			Monitor Ift's and ct scan.

**Medicine Details:** 

FAMOTIDINE (Other drug)		Reas	on:	Peptic ulcer n	os w/o ment perf
Tablet	40.0	Milligram	Daily		Oral
3atch:	Started:	L TERM		Stopped:	
HEPARIN SODIUM (Other drug)		Reas	on:		
Injection	10.0	Thousand Internat	Daily		Subcutaneous
Batch:	3tarted:			Stopped:	
AMOXYCILLIN SODIUM (Suspected)		Reas	on:		
Injection	0.0	Gram	3 time	S	Intravenous
3atch:	Started: 04/	/02/1995		Stopped:	10/02/1995
TOFRANIL (Suspected)		Reas	on:	Otr&unsp forn	ns neuralg&neurit
Tablet	40.0	Milligram	Daily		Oral
		J -	. ,		

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	(6-35)	06/02/1995	96	
	ALT = SGPT	(6-35)	13/02/1995	112	
	ALT = SGPT	(6-35)	21/02/1995	45	
	AST = SGOT	( 10-36 )	06/02/1995	58	
	AST = SGOT	( 10-36 )	13/02/1995	55	
	AST = SGOT	( 10-36 )	21/02/1995	22	
	Bilirubin	(5-20)	06/02/1995	9	



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 101492
 Seq:
 1
 Gender:
 M

 Reported:
 08/06/1995
 Weight:

Hospitalisation: Age: 67

**Onset Date:** 08/02/1995 **DOB:** 28/07/1927

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

## **Medicine Details:**

GENTAMICIN SULPHATE (Suspected)		Reason:	
Injection	240.0 Milligram	Daily	Intravenous
Зatch:	Started: 04/02/1995	Stopped:	10/02/1995
METRONIDAZOLE (Suspected)		Reason:	
Oral application	1.2 Gram	Daily	Oral
3atch:	Started: 04/02/1995	Stopped:	10/02/1995

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin	(5-20)	13/02/1995	7	
	Bilirubin	(5-20)	21/02/1995	6	
	GGT = SGGT =	( 0-50 )	06/02/1995	407	
	ĜĜT = SGGT =	( 0-50 )	13/02/1995	290	
	GGT = SGGT =	( 0-50 )	21/02/1995	210	
	SAP = ALP	( 36-95 )	06/02/1995	346	
	SAP = ALP	( 36-95 )	13/02/1995	216	



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 101492
 Seq:
 1
 Gender:
 M

 Reported:
 08/06/1995
 Weight:

Hospitalisation: Age: 67

**Onset Date**: 08/02/1995 **DOB**: 28/07/1927

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

# **Medicine Details:**

FAMOTIDINE (Other drug)		Reas	on:	Peptic ulcer n	os w/o ment perf
Tablet	40.0	Milligram	Daily		Oral
3atch:	Started:	L TERM		Stopped:	
HEPARIN SODIUM (Other drug)		Reas	on:		
Injection	10.0	Thousand Internat	Daily		Subcutaneous
3atch:	Started:			Stopped:	
AMOXYCILLIN SODIUM (Suspected)		Reas	on:		
Injection	0.0	Gram	3 time	es	Intravenous
3atch:	Started: 04/	02/1995		Stopped:	10/02/1995
TOFRANIL (Suspected)		Reas	on:	Otr&unsp form	ns neuralg&neurit
Tablet	40.0	Milligram	Daily		Oral
3atch:	Started: 11/	01/1995		Stopped:	08/02/1995

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP	( 36-95 )	21/02/1995	161	



Case Number: 101492

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Reported:	08/06/1995				Weight:		
Hospitalisation:					<b>Age</b> : 67	7	
Onset Date:	08/02/1995				<b>DOB</b> : 28	3/07/1927	
Outcome:	Recovered			C	ausality: C	ausality possi	ible
Reaction Detail							
<b>Medicine Det</b>	ails:						
	PHATE (Suspected)		Reason:				
Injection		240.0 Milligram	Daily		Intravenous		
3atch:		Started: 04/02/1995	•	Stopped:	10/02/1995		
METRONIDAZOLE	(Suspected)		Reason:				
Oral applic		1.2 Gram	Daily		Oral		
3atch:		Started: 04/02/1995	,	Stopped:	10/02/1995		
Laboratory In	voetigatione:						
Laboratory II	vestigations:						
Additional In	formation						
Additional in	ormation:						
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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Case Number:	101853	Seq:	1			Gender:	M	
Reported:	29/06/1995					Weight:	31.00	
Hospitalisation:						Age:		
Onset Date:	30/03/1995					DOB:		
Outcome:	Recovered					Causality:	Causality proba	able
Reaction Detai	İ					_		
Preferre		Seve	rity	Repor	t Description		Treatment	
Peripheral ischae	emia		Cold	l hands and fe	eet.			
Abdominal pain								
Dehydration								
Dizziness								
Fatigue								
Nausea								
Vomiting								
Weight decrease	ed							
TOFRANIL (Suspe	ected)	Star	1.0 Dos	Reas se Unspecified				
Salcii:		Star	tea: 26/02/1	995	stopped	i		
Laboratory Ir								
Date	Туре	Range	Date Tested	Result		Deta	ils	
Additional In	formation	:						
eport Run 19/07/20	02:15PN	Database: pus	ime	Д	DRS004		Page 165	of 279



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

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 Case Number:
 101965
 Seq:
 1
 Gender:
 F

 Reported:
 05/07/1995
 Weight:
 47.00

 Hospitalisation:
 Age:
 60Y

Onset Date: 07/02/1995 DOB:

Outcome: Not yet recovered Causality: Causality possible

## Reaction Detai

Veaction Detai	-		_
Preferred Term	Severity	Report Description	Treatment
Duodenal ulcer haemorrhage			Omeprazole 20mg bd, ranitidine 50mg iv tds.

## **Medicine Details:**

ANGININE (Suspected)	Reason:					
	0.0	As necessary				
Зatch:	Started:	Stopped:				
ASPIRIN (Suspected)		Reason:				
Oral application	150.0 Milligram	Daily Oral				
Зatch:	Started:	Stopped:				
SIMVASTATIN (Suspected)		Reason: Othr&unspec metabolic diseases				
	10.0 Milligram	Daily				
Зatch:	Started:	Stopped:				
TOFRANIL (Suspected)		Reason: Depression				
Tablet	50.0 Milligram	Daily Oral				
Зatch:	Started:	Stopped:				

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

 Case Number:
 102699
 Seq: 1
 Gender:
 F

 Reported:
 08/08/1995
 Weight:

Hospitalisation: Age: 31

Onset Date: 08/07/1995

Outcome: Recovered

DOB: 19/06/1964

Causality: Causality possible

Reaction Detai

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Coma			
Orthostatic hypotension			

## **Medicine Details:**

PANADOL (Other drug)		Reaso	n:	Other disturba	nce of sensation
	2.0	Dose Unspecified	As ne	cessary	
3atch:	Started:			Stopped:	
LASIX (Other drug)		Reaso	n:	Essential beni	gn hypertension
Tablet	120.0	Milligram	Daily		Oral
3atch:	Started:	L TERM		Stopped:	
ASPIRIN (Other drug)		Reaso	n:		
Oral application	150.0	Milligram	Daily		Oral
3atch:	Started:	L TERM		Stopped:	
COLOXYL WITH SENNA (Other drug)		Reaso	n:	Constipation	
Oral application	2.0	Dose Unspecified	Dailv		Oral
Oral application	2.0		- ,		

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

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Re	$\sim$		_	u	

 Case Number:
 102699
 Seq: 1
 Gender:
 F

 Reported:
 08/08/1995
 Weight:

Hospitalisation: Age: 31

Onset Date: 08/07/1995

Outcome: Recovered

DOB: 19/06/1964

Causality: Causality possible

**Reaction Detai** 

## **Medicine Details:**

ALDOMET (Suspected)		₹ea	son:	Essential ben	gn hypertension	
Tablet	750.0	Milligram	Daily		Oral	
3atch:	Started:	L TERM	1	Stopped:	08/07/1995	
TOFRANIL (Suspected)		Rea	son:			
Tablet	25.0	Milligram	Daily		Oral	
Зatch:	Started:	L TERN	1	Stopped:	08/07/1995	
DIAMICRON (Suspected)		Rea	son:	Diabetes mell	itus	
DIAMICRON (Suspected) Tablet	80.0	<b>Rea</b> Milligram	son: Daily	Diabetes mell	itus Oral	
` ' '	80.0 <b>Started:</b>		Daily	Diabetes mell		
Tablet		Milligram L TERM	Daily		Oral	
Tablet  3atch:		Milligram  L TERM	Daily /I	Stopped:	Oral	

# **Laboratory Investigations:**



Case Number: 102699

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

	: 08/08/1995 : : 08/07/1995 : Recovered					C		31 19/06/1964 Causality pos	sible
Medicine De				<b>.</b>		Oakson the tit			
NAPROSYN (Sus Tablet	spected)	750.0	Milligram	Reason:	aily	Osteoarthritis	Oral		
3atch:		3tarted:	_	L TERM	any	Stopped:	08/07/1995	5	
MS CONTIN (Sus	spected)	Jui tou.		Reason:		Other disturbate			
Tablet	1 /	40.0	Milligram				Oral	=	
					aliy		Olai		
3atch:		Started:		L TERM	ally	Stopped:	08/07/1995	5	
	nvestigations:	Started:			ally	Stopped:		5	

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

R	ei	n	n	rt	D	eta	i
	v	•	_		_	CLU	

Case Number: 103383 Seq: 1 Gender: M

 Reported:
 06/09/1995
 Weight:
 70.00

 Hospitalisation:
 Age:
 70Y

Onset Date: 20/08/1995 DOB:

Outcome: Recovered Causality: Causality probable

## Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Arthralgia			
Depression			
Myalgia			

#### **Medicine Details:**

ZANTAC (Other drug)						
	2	.0 Dose Unspecified	Daily			
3atch:	Started:	L TERM		Stopped:		
ANDROCUR (Other drug)		₹eas	on:			
	2	.0 Dose Unspecified	Daily			
3atch:	Started:	L TERM		Stopped:		
TOFRANIL (Suspected)		Reas	on:	Incontinence	of urine	
	3	.0 Dose Unspecified	Daily			
3atch:	Started:	15/08/1995		Stopped:	17/08/1995	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

History of allergy to penicillin.



# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Case Numl	oer:	103459	Seq:	1		G	ender: M
Report	ted:	11/09/199	95			V	Veight:
ospitalisati	on:						Age: 30Y
Onset D	ate:						DOB:
Outcome: Not yet recovered						Cau	usality: Causality possible
eaction D	etai		_	_			
Pre	ferre	d Term	Sev	erity	Report	Description	Treatment
Salactorrhoe	ea						
Synaecoma	stia						
Medicine SEREPAX (S					Reaso	on:	
				0.0			
3atch			3ta	Started:		Stopped:	
TEMAZE (Su	spect	ed)			Reaso	on:	
5.4.1				0.0			
3atch		F (0		irted:	2	}topped:	
PANADEINE	FURI	E (Suspecte	eu)	0.0	Reaso	on:	
3atch			Sta	irted:		Stopped:	
VALIUM (Sus		ed)	710	iiicu.	Reaso		
	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	· · · ,		0.0			
3atch	:		3ta	irted:		Stopped:	
		41					
aborator	y In		Range	Date Tested	Result		Details
Date		Туре	Range	Date resteu	Result		Details
Additiona	l Inf	ormatio	n:				
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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Case Number: 103459 Seq: 1 Reported: 11/09/1995 ospitalisation: Onset Date: Outcome: Not yet recovered			Gender: M Weight: Age: 30Y DOB: Causality: Causality possible			
eaction Detai						
Medicine Deta						
TOFRANIL (Suspe	cted)	0.0	Reason:			
3atch:		Started:		Stopped:		
MAXOLON (Suspe	cted)		Reason:	·		
		0.0	As nec			
3atch:		Started:		Stopped:		
.aboratory In						
	vestigations:					

Report Run 19/07/200 02:15PN Database: pusime ADRS004 Page 172 of 279



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 104264 Seq: 1 Gender: F

 Reported:
 27/10/1995
 Weight:
 55.00

 Hospitalisation:
 Age:
 38Y

 Onset Date:
 10/10/1995
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hepatitis			

**Medicine Details:** 

IMOVANE (Other drug) Reason:

0.0

3atch: 3tarted: 01/08/1995 3topped: 28/08/1995

TEMAZEPAM (Other drug) Reason:

0.0

3atch: Started: 01/08/1995 Stopped: 28/08/1995

SEREPAX (Other drug) Reason: Anxiety neurosis

30.0 Milligram Daily

3atch: 3tarted: 01/08/1995 3topped: 28/08/1995

AURORIX (Other drug) Reason: Anxiety neurosis

300.0 Milligram Daily

3atch: 3tarted: 01/08/1995 3topped: 28/08/1995

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		10/10/1995	740	
	AST = SGOT		10/10/1995	363	
	Bilirubin		10/10/1995	23	
	GGT = SGGT =		10/10/1995	176	
	LDH		10/10/1995	271	
	SAP = ALP		10/10/1995	454	

#### Additional Information:

Problems occurred as the dose of tofranil increased. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. 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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 104264 Seq: 1 Gender: F

Reported: 27/10/1995 Weight: 55.00 Hospitalisation: Age: 38Y

Onset Date: 10/10/1995 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

Medicine Details
------------------

TOFRANIL (Suspected) Reason: Anxiety neurosis

10.0 Milligram Daily

3atch: 3tarted: 01/09/1995 3topped: 15/10/1995

# **Laboratory Investigations:**

#### **Additional Information:**

Problems occurred as the dose of tofranil increased. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. 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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 104753
 Seq: 1
 Gender: M

 Reported:
 21/11/1995
 Weight:
 34.00

 Hospitalisation:
 Age: 99u

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

104011011 20141			
Preferred Term	Severity	Report Description	Treatment
Anorexia			
Weight decreased			

**Medicine Details:** 

 RITALIN (Suspected)
 Reason:

 40.0 Milligram
 Daily

 3atch: 3tarted: 01/04/1995 3topped: 18/11/1995

 TOFRANIL (Suspected)

 50.0 Milligram
 Daily

3atch: 3tarted: 01/04/1995 3topped:

**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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 105376
 Seq: 1
 Gender:
 F

 Reported:
 14/12/1995
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 27/07/1995
Age: 81Y
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Dehydration			
Hyperkalaemia			

**Medicine Details:** 

ASPIRIN (Other drug)	₹e	ason:	
Oral application	150.0 Milligram	Daily	Oral
Зatch:	Started: 15/07/1995	Stopped:	CONTIN
IMDUR (Other drug)	₹e	ason:	
Tablet	60.0 Milligram	Daily	Oral
3atch:	Started:	Stopped:	CONTIN
LASIX (Suspected)	₹e	ason:	
Oral application	40.0 Milligram	Daily	Oral
Зatch:	Started:	Stopped:	27/07/1995
SLOW-K (Suspected)	₹e	ason:	
Tablet	3.0 Dose Unspecifie	ed Daily	Oral
Зatch:	Started:	Stopped:	27/07/1995

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Potassium		27/07/1995	5.1MMOL/L	
	Potassium		30/07/1995	4.1MMOL/L	



Case Number: 105376

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Reported:	14/12/1995					Weight:		
spitalisation:	Admitted to hospita	al				Age: 8	31Y	
Onset Date:	27/07/1995					DOB:		
Outcome:	Recovered				(	Causality: (	Causality poss	ible
action Detai								
edicine Deta	ails:							
RYTHROMYCIN (	Suspected)			Reason:				
Oral applic	ation	1.5	Gram	Daily		Oral		
3atch:		Started:			3topped:	27/07/1995		
MIPRAMINE HYDI	ROCHLORIDE (Suspect	ied)		Reason:				
Tablet		50.0	Milligram	Daily		Oral		
3atch:		Started:			Stopped:	27/07/1995		
aboratory In	vestigations:							
dditional Inf	ormation:							
ort Run 19/07/200	) 02:15PN Databas	se: pusime		ADRS004			Page 177	of 279



Case Number: 105818

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

spitalisatio	ed: 12/01/1996	1	96 Weight:						
-		Age: 60Y							
Onset Da	te: 26/12/1995	)					DOE		
Outcom	ne: Recovered					C	ausalit	y: Causality possible	
action De	etai								
Prefe	erred Term	Sev	Severity Report Description					Treatment	
rine analysis	s abnormal		Dar	k urine					
epatic functi	ion abnormal								
lalaise									
edicine D				₹eas	on:				
			0.0			Stopped:			
3atch:		3t	Started:				27/12/19	995	
TOFRANIL (Su	ispected)		0.0	Reas	on:				
3atch:		24	0.0			Stopped:	27/12/19	005	
	IE HYDROCHLORI			Reas	on:	stoppeu.	21/12/13	990	
	5.1.00.1.201.1.	DE (Guopook	0.0	1000	····				
3atch:		3t	arted:			Stopped:	27/12/19	995	
AURORIX (Sus	spected)			₹eas	on:				
Tablet			450.0 Mi	lligram	Daily		Oral		
3atch:		3t	arted: 15/11/	1995		Stopped:	27/12/19	995	
oborotom	, Investigativ	ono:							
aboratory	/ Investigatio	Range	Date Tested	Result			De	etails	
Date									



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 106660
 Seq: 1
 Gender: M

 Reported:
 23/02/1996
 Weight:
 54.00

 Hospitalisation:
 Age: 73Y

**Onset Date**: 24/01/1996 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hepatitis			
Hyponatraemia			
Nausea			
Vomiting			

**Medicine Details:** 

PANADEINE FORTE (Suspected)		Reason:
	0.0	
3atch:	Started:	Stopped:
NORMISON (Suspected)		Reason:
	0.0	
3atch:	Started:	Stopped:
PARADEX (Suspected)		Reason:
	0.0	
3atch:	Started:	Stopped:
TOFRANIL (Suspected)		Reason:
	0.0	
3atch:	Started:	Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	0 - 40 U/L	31/01/1996	2607	
	AST = SGOT	0 - 40 U/L	31/01/1996	2278	
	Bilirubin	0 - 20 UMOL/L	31/01/1996	24	
	Ferritin	9.0 - 31.0 MOL/L	31/01/1996	7.5	
	GGT = SGGT =	0 - 45 U/L	31/01/1996	994	
	LDH	100 - 225 U/L	31/01/1996	1666	
	SAP = ALP	30 - 115 U/L	31/01/1996	941	

### **Additional Information:**

Very elevated lfts.



# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Case Number:	106660	Seq: 1			Gender:	M	
Reported:	23/02/1996				Weight:	54.00	
Hospitalisation:					Age:	73Y	
Onset Date:	24/01/1996				DOB:		
	Not yet recovered	t		Ca	ausality:	Causality possible	е
Reaction Detai							
Medicine Deta	ile·						
VOLTAREN (Suspe			Reason:				
, .	,	50.0 Milligram	Daily				
3atch:		Started: 20/12/1995	·	Stopped:	20/01/1996		
Laboratory Inv	estigations.						
Laboratory in	ootigutiono.						
A d d:4: a = a   l=4:							
Additional Info Very elevated lfts.	ormation:						
very elevated lits.							
_							
			ADD0004				

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 107360 Seq: 1 Gender: F

Reported: 28/03/1996 Weight:
Hospitalisation: Age: 67Y

Onset Date: 31/03/1996 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

-				=
	Preferred Term	Severity	Report Description	Treatment
	Visual disturbance			

### **Medicine Details:**

XANAX (Other drug)		Reason:	Anxiety neurosis	
Tablet	1.0 Milligram	Daily	Oral	
Зatch:	<b>Started:</b> 25/10/1995		Stopped:	
TOFRANIL (Suspected)		Reason:	Depression	
1			•	
Tablet	50.0 Milligram	Daily	Oral	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Rei	port	: Det	tail
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 Case Number:
 108630
 Seq: 1
 Gender: M

 Reported:
 22/05/1996
 Weight:

Hospitalisation:
Onset Date: 22/08/1995
Age: 85Y
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Neaction Detai		_	
Preferred Term	Severity	Report Description	Treatment
Agitation			
Confusional state			
Delirium			

## **Medicine Details:**

TEMAZEPAM (Other drug)	Reason:				
	10.0	Milligram	As ne	cessary	
3atch:	Started:			Stopped:	CONTIN
LANOXIN PG (Other drug)		₹eas	on:	Chron isch heart dis no hyper	
Tablet	2.0	Dose Unspecified	Daily	Oral	
Зatch:	Started:			Stopped:	CONTIN
LASIX (Other drug)		Reas	on:	Angina pectoris w/o hyperten	
Oral application	80.0	Milligram	Daily	Oral	
Зatch:	Started:			Stopped:	CONTIN
SLOW-K (Other drug)		Reas	on:	Congestive heart failure	
Tablet	1.0	Dose Unspecified	Daily	Oral	
3atch:	Started:			Stopped:	CONTIN

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

Patient has alzheimer's disease.



Report Detail

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Hospitalisation: Onset Date:	22/05/1996 22/08/1995 Recovered	Seq: 1		Gender: Weight: Age: DOB: Causality:	
Medicine Deta	ails:				
MORPHINE NOS (S			Reason:		
		0.0			
3atch:		Started:		Stopped:	
TOFRANIL (Suspe	cted)		Reason:		
		0.0			
3atch: MELLERIL (Suspe	otod)	Started:	Reason:	Stopped:	
WELLEKIE (Suspe	cteu)	0.0	(eason.		
3atch:		Started:		Stopped:	
Laboratory In	vestigations:				
Additional Inf Patient has alzhein					



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

		eta	

 Case Number:
 110789
 Seq: 1
 Gender: M

 Reported:
 13/08/1996
 Weight:

Hospitalisation: Age: 63

Onset Date: 25/06/1996 DOB: 23/11/1932
Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

104011011 20141		-	-
Preferred Term	Severity	Report Description	Treatment
Hypotension		Bp 55/?	One litre hartmanns solution
Bundle branch block			

## **Medicine Details:**

ZANTAC (Other drug)	Reason:				
	300.0	Milligram	Daily		
Зatch:	Started:			Stopped:	
RENITEC (Other drug)			Reason:		
	240.0	Milligram	Daily		
Зatch:	Started:			Stopped:	
TEGRETOL (Other drug)			Reason:		
	400.0	Milligram	Daily		
Зatch:	Started:			Stopped:	
STREPTOKINASE (Suspected)			Reason:	Acute myocard infarc,no hypert	
1	4.0	Daga Unana	cified 1 time		
	1.0	Dose Unspe	cined i time	;	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

Case Number: 110789

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Hospitalisation:		<b>Age</b> : 63	
Onset Date: 25/06/1996		<b>DOB</b> : 23/11/193	
Outcome: Recovered		Causality: Causality	possible
Reaction Detai			
Medicine Details:			
FELDENE (Suspected)		Reason:	
	20.0 Milligram	As necessary	
3atch:	Started:	Stopped:	
ADALAT (Suspected)		Reason:	
	20.0 Milligram	Daily	
3atch:	Started:	3topped:	
TOFRANIL (Suspected)		Reason:	
	10.0 Milligram	Daily	
3atch:	Started:	3topped:	
Laboratory Investigations:			
Laboratory Investigations:			
Laboratory Investigations:			
Laboratory Investigations:			
Laboratory Investigations:			
Laboratory Investigations:			
Laboratory Investigations:			
Laboratory Investigations:			
Additional Information:			



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number:111593Seq:1Gender:MReported:13/09/1996Weight:57.00Hospitalisation:Admitted to hospitalAge:84Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hallucination		Auditory and visual hallucinations	
Coordination abnormal		Patient experiencing falls	
Confusional state			
Urinary incontinence			

**Medicine Details:** 

ASPIRIN (Other drug)		Reason: Prophylaxis
	150.0 Milligi	ram Daily
Batch:	Started:	Stopped:
TAGAMET (Suspected)		Reason: Gastritis&duodenitis
Tablet	800.0 Milligi	ram Daily Oral
3atch:	Started:	<b>Stopped:</b> 04/09/1996
TOFRANIL (Suspected)		Reason: Incontinence of urine
Tablet	25.0 Milligi	ram Daily Oral
3atch:	Started:	<b>Stopped:</b> 06/09/1996

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 112876 Seq: 1 Gender: M

Reported: 05/11/1996 Weight: 95.00 Hospitalisation: Age: 62

**Onset Date**: 31/03/1996 **DOB**: 19/04/1933

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Sleep disorder		Flings arms during sleep	

### **Medicine Details:**

AROPAX (Suspected)	र	eason: Depression	
Tablet	20.0 Milligram	Daily	Oral
Зatch:	Started: 01/01/1993	Stopped:	
TOFRANIL (Suspected)	5	eason:	
Tablet	25.0 Milligram	Daily	Oral

**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 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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 113506
 Seq: 1
 Gender: M

 Reported:
 28/11/1996
 Weight:

Hospitalisation: Age: 61Y

**Onset Date**: 14/11/1996 **DOB**:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

teaction Betai			-
Preferred Term	Severity	Report Description	Treatment
Oedema genital		Swelling of testes	
Testicular disorder		Testes - red , hot, swollen and tender	
Drug withdrawal syndrome			
Dysuria			

# **Medicine Details:**

viedicine Details:					
TRANXENE (Other drug)			Reason:	Anxiety neurosis	
Capsule	10.0	Milligram	Daily	Oral	
3atch:	Started:			Stopped:	
PEPCIDINE (Other drug)			Reason:	Other diseases of esophagus	
	1.0	Dose Unspec	fied Daily		
3atch:	Started:			Stopped:	
IMIPRAMINE HYDROCHLORIDE (	Suspected)		Reason:		
	150.0	Milligram	Daily		
3atch:	Started:	L TI	ERM	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

History of being treated with imipramine for 8 years - reaction when coming off the imipramine



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 114458
 Seq:
 1
 Gender:
 M

 Reported:
 10/01/1997
 Weight:

Hospitalisation: Age: 61

**Onset Date**: 14/11/1996 **DOB**: 03/07/1935

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

todotion Botal		_	
Preferred Term	Severity	Report Description	Treatment
Testicular disorder		Bilaterial pain and swelling of testes.	
Dysuria		Difficulty with micturition	
Drug withdrawal syndrome			

**Medicine Details:** 

TRANXENE (Other drug)		Reason:			
	0.0				
3atch:	Started:	L TERM	Stopped:		
PEPCIDINE (Other drug)		Reason:	Other disease	es of esophagus	
	0.0				
3atch:	Started:		Stopped:		
TOFRANIL (Suspected)		Reason:	Depression		
Capsule	150.0 Milligram	n Daily		Oral	
3atch:	<b>Started:</b> 01/01/1988		Stopped:	31/01/1996	

**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.

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 115477 Seq: 1 Gender: F

Reported: 24/02/1997 Weight: 67.00 Hospitalisation: Age: 15Y

**Onset Date**: 17/02/1997 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Angioedema		Angioedema hands and forearms.	Claratyne, phenergan.

### **Medicine Details:**

CECLOR (Suspected)		Reason: Otitis medi	a w/o mastoidit nos	
Tablet	500.0 Milligram	Daily	Oral	
3atch:	Started: 15/02/1997	Stopped	i: 17/02/1997	
TOFRANIL (Suspected)		Reason:		
Tablet	20.0 Milligram	Daily	Oral	
3atch:	Started: 10/02/1997	Stopped	l:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 115566
 Seq: 1
 Gender:
 F

 Reported:
 25/02/1997
 Weight:
 52.00

 Hospitalisation:
 Age: 31Y

Onset Date: 22/02/1997 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

touction botten			
Preferred Term Severity		Report Description	Treatment
Paraesthesia		Paraesthesia hands, face, legs.	
Confusional state			
Visual disturbance			

#### **Medicine Details:**

Medicine Details.			
TOFRANIL (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
3atch:	<b>Started:</b> 20/02/1997	Stopped:	22/02/1997
TAZAC (Suspected)		Reason: Otr disorders	stomach function
Tablet	300.0 Milligram	Daily	Oral
3atch:	Started: 21/02/1997	Stopped:	22/02/1997

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 117476 Seq: 1 Gender: M Reported: 12/05/1997 Weight:

Hospitalisation: Age: 66

**Onset Date**: 07/08/1996 **DOB**: 13/08/1929

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Urinary retention			Urinary catheter inserted.

## **Medicine Details:**

DILTIAZEM HYDROCHLORIDE (Other dru	g)		Reason:	Angina pectoris w/o hyperten	
Oral application	240.0	Milligram	Daily	Oral	
3atch:	Started:		L TERM	Stopped:	
FLUVASTATIN (Other drug)			Reason:	Othr&unspec metabolic diseases	
Capsule	20.0	Milligram	Daily	Oral	
3atch:	Started:		L TERM	Stopped:	
GLYCERYL TRINITRATE (Other drug)			Reason:	Angina pectoris w/o hyperten	
GLYCERYL TRINITRATE (Other drug) Cream	15.0	Milligram	Reason: Daily	Angina pectoris w/o hyperten Transdermal	
, , , ,	15.0 Started:	3 -		· ,,	
Cream		3 -	Daily	Transdermal	
Cream  3atch:			Daily L TERM	Transdermal	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Report Detail

Case Number: 117476

Reported: 12/05/1997

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight:

oitalisation:  Onset Date: 07/08/1996  Outcome: Recovered					C		6 3/08/1929 Causality proba	able
tion Detai								
licine Details:								
HEXILINE MALEATE (Other drug)			Reaso	า:	Angina pector	is w/o hyperter	1	
Tablet	300.0	Milligram		Daily		Oral		
3atch:	Started:		L TERM		Stopped:			
NOLOL (Other drug)			Reaso		Angina pector	is w/o hyperten	1	
Tablet	50.0	Milligram	I	Daily		Oral		
3atch:	Started:		L TERM		Stopped:			
RAMINE HYDROCHLORIDE (Suspec			Reaso	1:	Depression			
Tablet		Milligram		Daily		Oral		
3atch:	Started: 20/	07/1996			Stopped:	07/08/1996		
poratory Investigations:								
litional Information:								
Run 19/07/200 02:15PN Databa	se: pusime		AD	RS00	14		Page 193	of 27



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 117850 Seq: 1 Gender: M
Reported: 26/05/1997 Weight:

Hospitalisation: Age: 56

**Onset Date**: 11/02/1997 **DOB**: 26/09/1940

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Detai

104011011 20141			-
Preferred Term	Severity	Report Description	Treatment
Pneumonia			Icu admission, ventillated.
Respiratory failure			

**Medicine Details:** 

PREDNISOLONE (Suspected)	Reason:				
	75.0	Milligram	Reduc	cing	
3atch:	Started:		L TERM	Stopped:	11/02/1997
CYCLOSPORIN-A (Suspected)			₹eason:		
Oral application	200.0	Milligram	Daily		Oral
3atch:	Started:		L TERM	Stopped:	11/02/1997
AMLODIPINE (Suspected)			Reason:	Essential ben	ign hypertension
Tablet	20.0	Milligram	Daily		Oral
3atch:	Started:		L TERM	Stopped:	
RANITIDINE (Suspected)			Reason:		
Tablet	300.0	Milligram	Daily		Oral
3atch:	Started:		L TERM	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

Organisms nocardia and pneumocystis. patient died 23/2/97. committee comment: include in annual fatality analysis

Report Run 19/07/200 02:15PN Database: pusime ADRS004 Page 194 of 279



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail							
Reported: 26/05/1997 Hospitalisation: Onset Date: 11/02/1997	<b>q</b> : 1						56 26/09/1940
Outcome: Death, maybe drug					(	Causality:	Causality possible
eaction Detai							
Medicine Details:  FOLIC ACID (Suspected)			Reaso	on:			
Tablet	5.0	Milligram		Daily		Oral	
	Started:	wiiiigram	L TERM	Dully	Stopped:	Olui	
IMIPRAMINE HYDROCHLORIDE (Suspected	<u></u>		Reaso	n:	Depression		
Tablet	100.0	Milligram		Daily		Oral	
3atch:	Started:		L TERM		Stopped:		
Laboratory Investigations:							
Additional Information: Organisms nocardia and pneumocystis. p	patient died 2	23/2/97. c	ommittee	e comi	ment: include	e in annual i	fatality analysis

Report Run 19/07/200 02:15PN Database: pusime ADRS004 Page 195 of 279



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 119032
 Seq:
 1
 Gender:
 U

 Reported:
 14/07/1997
 Weight:
 Age:
 Onset Date:
 07/06/1997
 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Confusional state		Mild nocturnal confusion	
Delirium			Suspected drugs withrawn. antibiotic therapy given

**Medicine Details:** 

WARFARIN SODIUM (Other drug)		Reason:	
	1.0 Milligram	Daily	
3atch:	Started:	Stopped:	
DIGOXIN (Other drug)		Reason:	
	250.0 Microgram	Daily	
3atch:	Started:	Stopped:	
RANITIDINE (Other drug)		Reason:	
	300.0 Milligram	Daily	
Зatch:	300.0 Milligram	Daily <b>Stopped:</b>	
3atch: SINEMET (Suspected)	· ·	•	
	· ·	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient discharged 10 days after onset of reaction. still mildly confused, this may be due to u.t.i.,recent encephalitis,parkinson's disease,drugs, or a combination.

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail						
Case Number: 1190	•				Gender:	U
Reported: 14/0	7/1997				Weight:	
Hospitalisation:					Age:	
Onset Date: 07/0	6/1997				DOB:	
Outcome: Not y	et recovered			C	Causality:	Causality possible
Reaction Detai						
<b>Medicine Details:</b>						
OXAZEPAM (Suspected)			Reason:	Disturbance of	of sleep	
	0.0					
3atch:	Started:			}topped:	12/06/1997	
IMIPRAMINE HYDROCHI	ORIDE (Suspected)		Reason:			
	25.0	Milligram	Daily			
3atch:	3tarted:			Stopped:	12/06/1997	
Laboratory Invest	igations:					

#### **Additional Information:**

Patient discharged 10 days after onset of reaction. still mildly confused, this may be due to u.t.i.,recent encephalitis,parkinson's disease,drugs, or a combination.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 119183
 Seq:
 1
 Gender:
 M

 Reported:
 18/07/1997
 Weight:
 90.00

 Hospitalisation:
 Age:
 37Y

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

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

todolion Botal			
Preferred Term	Severity	Report Description	Treatment
Dizziness			Hydrocortisone cream
Fatigue	Severe		
Headache			
Rash			
Syncope			

**Medicine Details:** 

**TEGRETOL** (Suspected) Reason: Pain Tablet 100.0 Milligram Daily Oral 3atch: 3tarted: 02/07/1997 Stopped: 02/07/1997 **TOFRANIL** (Suspected) Reason: 50.0 Milligram Daily Started: 02/07/1997 3atch: Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Allergy to trimethoprim, tetracycline, mianserin, indomethacin.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 119346 Seq: 1 Gender: F

**Reported:** 28/07/1997 **Weight:** 

Hospitalisation: Age: 70Y
Onset Date: 14/07/1997
DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Hallucination		Visual hallucinations	

#### **Medicine Details:**

TOFRANIL (Suspected) Reason: Pain

50.0 Milligram Daily

3atch: 3tarted: 13/07/1997 3topped: 15/07/1997

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Dose of tofranil was increased from 25 mg daily to 50 mg which caused the night-time hallucinations.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report D	)etail
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Case Number: 120002 Seq: 1 Gender: F
Reported: 18/08/1997 Weight:
Hospitalisation: Age: 59Y

Onset Date: 25/07/1997 DOB:

Outcome: Recovered Causality: Causality possible

## **Reaction Detai**

todotion Botai			
Preferred Term	Severity	Report Description	Treatment
Face oedema		Facial & neck oedema. could not open	
Rash		Rash face upperchest & arms to elbows.	Prednisolone
Angioedema			

## **Medicine Details:**

VERACAPS SR (Other drug)		Reason:		
	0.0			
Зatch:	Started:		Stopped:	
LIPEX (Other drug)		Reason:		
	0.0			
Batch:	Started:		Stopped:	
PREMARIN (Other drug)		Reason:		
	0.0			
Заtch:	Started:		Stopped:	
OXYBUTYNIN HYDROCHLORIDE (	Suspected)	Reason:		
	15.0 Milligram	Daily		
3atch:	Started: 14/07/1997		Stopped:	25/07/1997

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

Allergies to morphine & adhesive tapes.



Report Detail

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Case Number:	120002	Seq: 1				Gender:	F	
Reported:	18/08/1997					Weight:		
Hospitalisation:						Age:	59Y	
Onset Date:	25/07/1997					DOB:		
Outcome:					C	ausality:	Causality pos	ssible
Reaction Detai								
<b>Medicine Deta</b>								
TOFRANIL (Suspec				Reason:				
			20.0 Milligram	Daily				
3atch:		Started:	14/07/1997		Stopped:	25/07/1997	•	
Laboratory In	vestigations:							
Additional Info	ormation:							
Allergies to morphir		S.						
10/07/000	00.45DN D-4-5			A D D C C C A			D 00	

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 120440 Seq: 1 Gender: F

Reported: 01/09/1997 Weight:
Hospitalisation: Age: 16Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

todotion Dotal		<u> -</u>	_a
Preferred Term	Severity	Report Description	Treatment
Rash		Fine red rash on body (mainly neck &	Cease medication

### **Medicine Details:**

TOFRANIL (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

3atch: Started: STERM Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

No other medications or previous recation/allergies



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 121901
 Seq:
 1
 Gender:
 M

 Reported:
 28/10/1997
 Weight:
 63.00

 Hospitalisation:
 Age:
 52Y

Onset Date: 26/10/1997 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion Dotal		<u> </u>	
Preferred Term	Severity	Report Description	Treatment
Pathological fracture		Neck of femur (r) & microfractures (r)	
Osteoporosis			Needs rehabilitation and orthopedic intervention.

**Medicine Details:** 

STELAZINE (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
3atch:	Started:	Stopped:	CONTIN
ANDROCUR (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
3atch:	<b>3tarted:</b> 01/01/1992	Stopped:	13/10/1997
TOFRANIL (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
3atch:	Started:	Stopped:	CONTIN
PANADEINE FORTE (Suspected)		Reason: Pain	
Tablet	2.0 Dose Unspec	ified Daily	Oral
3atch:	3tarted: 01/01/1997	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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**Additional Information:** 

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Report De	tail				
Case Numb	<b>per</b> : 125493	Seq: 1		Gen	der: F
Report	ed: 03/03/1998			Wei	ght: 89.00
Hospitalisati					<b>\ge</b> : 66Y
	ate: 01/10/1996				OB:
	me: Recovered			Causa	lity: Causality probable
Reaction De		0	D I D.	a and a than	Tourtount
	erred Term	Severity	Report De	scription	Treatment
Headache					
l					
l					
l					
l					
1					
Madiaina	Dotoilo:				
Medicine I			Reason:	Incontinence of urine	
1011041112 (0	uopootou,	50	0.0 Milligram Dail		
3atch	:		01/10/1996		1/1997
<u> </u>				···	
	y Investigations				
Date	Type F	Range Date	Tested Result		Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 125831
 Seq: 1
 Gender: M

 Reported:
 17/03/1998
 Weight: 75.00

Hospitalisation: Age: 15Y

**Onset Date**: 03/02/1998 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Pyrexia unknown origin	
Anaemia			
Hepatic function abnormal			
Rash erythematous			

### **Medicine Details:**

TOFRANIL (Suspected)		Reason:	Behavior disor	rders of childhod
Tablet	125.0 Milligram	Daily		Oral
3atch:	3tarted: 01/05/1997		Stopped:	20/02/1998
SURMONTIL (Suspected)		Reason:	Rehavior disco	rders of childhod
COMMONTIE (Caspectea)		teason.	Deliavior disor	racis of chilarioa
Oral application	50.0 Milligram	Daily	Dellavior disor	Oral

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		03/02/1998	286	
	AST = SGOT		03/02/1998	1156	
	GGT = SGGT =		03/02/1998	155	
	Haemoglobin		03/03/1998	113	
	Haemoglobin		10/03/1998	120	

#### **Additional Information:**

Had one year rx with tofranil prior to restart may 1997, may have had some reaction at the time. not under dr care at time. allergies to penicillin the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Re	po	rt	D	eta	il
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 Case Number:
 127057
 Seq:
 1
 Gender:
 M

 Reported:
 01/05/1998
 Weight:
 24.00

 Hospitalisation:
 Age:
 5Y

Onset Date: 23/04/1998 DOB:

Outcome: Not yet recovered Causality: Causality possible

#### **Reaction Detai**

touchier Dotal									
Preferred Term	Severity	Report Description	Treatment						
Purpura		Marked purpura/ petechiae							
Epistaxis									
Thrombocytopenia									

#### **Medicine Details:**

TOFRANIL (Suspected)

25.0 Milligram Daily

3atch: 3tarted: 13/04/1998 3topped:

# **Laboratory Investigations:**

	<del></del>				
Date	Туре	Range	Date Tested	Result	Details
	Platelets		23/04/1998	7	



Report Detail

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 128745	Seq:	1		G	Gender: F	
Reported: 29/06/19				V	<b>Veight:</b> 26.00	
lospitalisation:					Age: 7Y	
Onset Date:					DOB:	
Outcome: Recover	ed				Causality: Causality probable	
eaction Detai		<del></del>				
Preferred Term	Seve	rity	Repor	t Description	Treatment	
Pruritus		Itchy	nose and leg	js .		
Medicine Details:						
TOFRANIL (Suspected)			Reas			
		10.0 Milli	gram	Daily		
3atch:	Star.	ted:		Stopped:		
Laboratory Investiga	ations:					
Date Type		Date Tested	Result		Details	
Additional Informati	001					
Additional informati	511.					
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	P				1 490 201 01210	



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report D	)etail
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Case Number: 128867 Seq: 1 Gender: M

Reported: 02/07/1998 Weight: 30.00 Hospitalisation: Age: 10Y

Onset Date: 27/06/1998 DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Somnolence		Exceptional drowsiness	
Urticaria	Generalised urticaria reaction		

#### **Medicine Details:**

TOFRANIL (Suspected) Reason:

25.0 Milligram Daily

3atch: 3tarted: 19/06/1998 3topped: 29/06/1998

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 128988 Seq: 1 Gender: F

 Reported:
 08/07/1998
 Weight:

 Hospitalisation:
 Age: 69Y

 Onset Date:
 11/05/1998
 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

- 1			_	=
	Preferred Term	Severity	Report Description	Treatment
	Hepatic function abnormal			

## **Medicine Details:**

OXYBUTYNIN HYDROCHLORIDE (Other d	rug)	Reason:	
	10.0 Milligram	Daily	
3atch:	3tarted: 11/03/1998	Stopped:	CONTIN
SIMVASTATIN (Other drug)		Reason: Othr&unspec	metabolic diseases
Tablet	10.0 Milligram	Daily	Oral
3atch:	Started:	Stopped:	CONTIN
AMLODIPINE (Other drug)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
3atch:	3tarted:	Stopped:	CONTIN
TOFRANIL (Suspected)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started: 12/03/1998	Stopped:	12/05/1998

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		09/04/1998	13	
	ALT = SGPT		11/05/1998	156	
	ALT = SGPT		15/05/1998	102	
	ALT = SGPT		12/06/1998	9	
	ALT = SGPT		27/05/1998	30	
	AST = SGOT		09/04/1998	19	
	AST = SGOT		11/05/1998	68	



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 128988 Seq: 1 Gender: F

 Reported:
 08/07/1998
 Weight:

 Hospitalisation:
 Age: 69Y

 Onset Date:
 11/05/1998
 DOB:

Onset Date: 11/05/1998 DOB:
Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

#### **Medicine Details:**

Miculcine Details.				
AMOXYCILLIN TRIHYDRATE (Suspected)		Reason:	Othr diseases of urinary tract	
Tablet	750.0 Milligram	Daily	Oral	
3atch:	Started: 11/04/1998		Stopped:	1W
WARFARIN SODIUM (Suspected)		Reason:		
Tablet	2.0 Milligram	Daily	Oral	
3atch:	Started:		Stopped:	CONTIN

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT		27/05/1998	24	
	AST = SGOT		12/06/1998	20	
	AST = SGOT		15/05/1998	51	
	GGT = SGGT =		09/04/1998	29	
	ĜĜT = SGGT =		11/05/1998	707	
	ĜĜT = SGGT =		15/05/1998	630	
	GGT = SGGT =		27/05/1998	327	



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

		eta	

Case Number: 128988 Seq: 1 Gender: F

 Reported:
 08/07/1998
 Weight:

 Hospitalisation:
 Age: 69Y

 Onset Date:
 11/05/1998
 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

## **Medicine Details:**

OXYBUTYNIN HYDROCHLORIDE (Other di	rug)	Reason:		
	10.0 Milligra	m Daily		
3atch:	Started: 11/03/1998	1	Stopped:	CONTIN
SIMVASTATIN (Other drug)		₹eason:	Othr&unspec r	netabolic diseases
Tablet	10.0 Milligra	m Daily		Oral
Заtch:	Started:		Stopped:	CONTIN
AMLODIPINE (Other drug)		₹eason:		
Tablet	5.0 Milligra	m Daily		Oral
3atch:	Started:		Stopped:	CONTIN
TOFRANIL (Suspected)		₹eason:		
	10.0 Milligra	m Daily		
Batch:	Started: 12/03/1998	1	Stopped:	12/05/1998

**Laboratory Investigations:** 

-						
	Date	Туре	Range	Date Tested	Result	Details
		GGT = SGGT =		12/06/1998	123	



Report Detail

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number:	128988	Seq: 1			Gender:	F	
Reported: (	08/07/1998				Weight:		
Hospitalisation:					Age:	69Y	
Onset Date:	11/05/1998				DOB:		
Outcome: I	Recovered			C	ausality:	Causality possi	ble
Reaction Detai							
Medicine Deta							
	HYDRATE (Suspected		Reason:	Othr diseases		act	
Tablet		750.0 Milligram	Daily		Oral		
3atch:		<b>Started:</b> 11/04/1998		Stopped:		1W	
WARFARIN SODIUM	M (Suspected)		Reason:				
Tablet		2.0 Milligram	Daily		Oral		
3atch:		Started:		Stopped:		CONTIN	
Laboratory Inv	estigations:						
•	· ·						
Additional Info	ormation:						
eport Run 19/07/200	02:15PN Databa	ase: pusime	ADRS00	)4		Page 212	of 279



Report Detail						
Roport Botan						
Case Number:	133716	Seq: 1			Gende	r: F
Reported:	25/11/1998				Weigh	t:
Hospitalisation:					Ag	e: 35Y
Onset Date:					DOI	
Outcome:	Unknown				Causalit	y: Causality possible
Reaction Detai		<del></del>				
Preferred Insomnia	l Term	Sever			Description ease in alertness	Treatment
Medicine Deta				Reaso	on: Anxiety neurosis	
Tablet	teu)	50.0 Milligram Daily Oral				
3atch:		Starte		gram	Stopped:	
I aboratory In	/estigations					
Laboratory In			Date Tested	Result	De	etails
			Date Tested	Result	De	etails



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Re	por	t D	etail
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 Case Number:
 135713
 Seq: 1
 Gender:
 F

 Reported:
 01/02/1999
 Weight:

Hospitalisation: Age: 92Y
Onset Date: 18/12/1998
DOB:

Outcome: Recovered Causality: Causality possible

## **Reaction Detai**

100011011 20101	ā	-	
Preferred Term	Severity	Report Description	Treatment
Dizziness		Light-headed resulting in fall	All medication ceased
Headache			
Palpitations			
Visual disturbance			

## **Medicine Details:**

ISORDIL (Suspected)		Reason: Chron isch heart dis no hyper
Tablet	5.0 Milligram	As necessary Sublingual
Зatch:	Started:	<b>Stopped</b> : 18/12/1998
IMDUR (Suspected)		Reason: Chron isch heart dis no hyper
Tablet	60.0 Milligram	Daily Oral
Зatch:	Started:	Stopped: 18/12/1998
TOFRANIL (Suspected)		Reason: Incontinence of urine
	10.0 Milligram	Daily
Зatch:	Started:	Stopped: 18/12/1998
ORUDIS SR (Suspected)		Reason: Other rheumatoid arthritis
	200.0 Milligram	Daily
3atch:	Started:	<b>Stopped:</b> 18/12/1998

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail							
Case Number: 135713 Reported: 01/02/1999 Hospitalisation: Onset Date: 18/12/1998	Seq: 1				Gender: Weight: Age: DOB:	92Y	
Outcome: Recovered Reaction Detai				C	ausality:	Causality possible	
Medicine Details:							
URECHOLINE (Suspected)	20.0	<b>ર</b> Milligram	eason: Daily	Incontinence o	f urine		
Batch:	Started:			Stopped:	18/12/1998	1	
Laboratory Investigations:							
Additional Information:							

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Report Detail				
Case Number: 135957	Seq: 1		Gend	er: F
Reported: 09/02/1999	•		Weig	ht:
Hospitalisation:				ge:
Onset Date:				DB:
Outcome: Recovered			Causal	ity: Causality possible
Reaction Detai				
Preferred Term	Severity	Repor	t Description	Treatment
Parosmia	F	Patient experience	ed burning,	Tofranil ceased
Medicine Details: TOFRANIL (Suspected)	50.0	Reas	·	
3atch:	Started:	Milligram	Daily Stopped:	
Laboratory Investigation	e.			
	Range Date Tes	ted Result		Details
7,52				



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 138388
 Seq: 1
 Gender:
 F

 Reported:
 13/04/1999
 Weight:

Hospitalisation: Age: 89Y
Onset Date: 19/02/1999
DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

104011011 20141			-
Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Cease imipramine.
Renal failure acute			

#### **Medicine Details:**

IMIPRAMINE HYDROCHLORIDE (Suspected) Reason:

10.0 Milligram Daily

3atch: 3tarted: 3topped: 19/02/1999

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Sodium		19/02/1999	126	
	Sodium		21/02/1999	132	
	Sodium		22/02/1999	125	
	Sodium		23/02/1999	124	
	Sodium		25/02/1999	130	

### **Additional Information:**

See original report for details of other drugs - lanoxin pg, solprin, diclocil, transiderm patch.

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 139338
 Seq: 1
 Gender:
 F

 Reported:
 10/05/1999
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 31/03/1999
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Hypotension			

**Medicine Details:** 

NORVASC (Suspected)	Re	eason:	
Tablet	5.0 Milligram	Daily	Oral
3atch:	Started: 12/03/1999	Stopped:	12/03/1999
EUHYPNOS (Suspected)	₹e	eason:	
Capsule	10.0 Milligram	Daily	Oral
3atch:	Started: 12/03/1999	Stopped:	14/03/1999
-11 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -			
DI-GESIC (Suspected)	₹€	eason:	
Tablet	1.0 Dose Unspecifie		Oral
` ' '			Oral 15/03/1999
Tablet	1.0 Dose Unspecifie  Started: 12/03/1999	ed Daily	
Tablet  3atch:	1.0 Dose Unspecifie  Started: 12/03/1999	ed Daily	

**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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 140817 Gender: U Seq: 1 Reported: 18/06/1999 Weight: Hospitalisation: Age:

Onset Date: 19/04/1999 DOB: Causality: Causality possible

Reaction Detai

Outcome: Not yet recovered

reaction Detai	=		
Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Conservative treatment - withheld drugs.

**Medicine Details:** 

**DITROPAN (Suspected)** Reason: 0.0 3tarted: 08/04/1999 19/04/1999 3atch: Stopped: **TOFRANIL** (Suspected) Reason: 0.0 Started: 08/04/1999 3atch: Stopped: 17/04/1999

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

See original report for details of other drugs: oroxine, felodipine, premarin and ralovera.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

		eta	

 Case Number:
 141426
 Seq: 1
 Gender:
 F

 Reported:
 12/07/1999
 Weight:

Hospitalisation: Age: 11Y
Onset Date: 27/06/1999
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detail

Neaction Detai			
Preferred Term	Severity	Report Description	Treatment
Abdominal pain		Abdominal discomfort	
Nightmare		Bad dreams, waking up easily	
Somnolence		Drowsiness in the day time	
Sleep disorder		Experienced restless sleep	
Dry mouth			

### **Medicine Details:**

TOFRANIL (Suspected)		Reason:	Incontinence of urine
Tablet	25.0 Milligram	Daily	Oral
3atch:	<b>Started</b> : 27/06/1999		Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 141794 Seq: 1 Gender: F

Reported: 21/07/1999 Weight: italisation: Admitted to hospital Age: 89Y

Hospitalisation: Admitted to hospital Age:
Onset Date: 12/06/1999
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Dizziness	Several falls & several fractured ribs		Tofranil ceased

#### Medicine Details:

Medicine Details.			
TOFRANIL (Suspected)	Reason:		
	25.0 Milligram	Daily	
3atch:	Started:	<b>Stopped:</b> 13/06/1999	
MOGADON (Suspected)		Reason:	
	5.0 Milligram	Daily	
3atch:	Started:	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

Please see original report for details of other drugs - mixtard, plendil er.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 142587
 Seq: 1
 Gender: M

 Reported:
 11/08/1999
 Weight:

Hospitalisation: Age: 9Y
Onset Date: 31/07/1999
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

		-	
Preferred Term	Severity	Report Description	Treatment
Affect lability	Emotional change		
Anxiety			

#### **Medicine Details:**

TOFRANIL (Suspected) Reason:

Tablet 20.0 Milligram Daily Oral

**3atch: 3tarted:** 01/07/1999 **3topped:** 

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail					
Case Number: 142684 Reported: 16/08/199 lospitalisation: Onset Date: Outcome: Unknown	<b>Seq:</b> 1		Gender: F Weight: Age: 13Y DOB: ausality: Causality possible		
eaction Detai			addanty: Gaddanty possible		
Preferred Term	Severity	Report Description	Treatment		
ncreased appetite		te large meals			
Depression		ried a lot			
Aggression	<u>'</u>	ritable	<b>1</b>		
Medicine Details:  TOFRANIL (Suspected)  Tablet	40.0	Reason: Incontinence of	urine Oral		
Satch:	io.o	· ,	Stopped:		
	ions:				
_aboratory Investigat			D:		
Laboratory Investigat  Date Type	Range Date Test	ed Result	Details		



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 143360 Seq: 1 Gender: F

Reported: 01/09/1999

Hospitalisation:
Onset Date:

Onset Date:

Weight:
Age: 43Y
DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Urticaria		Patient experienced hives.	

### **Medicine Details:**

TOFRANIL (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

3atch: Started: Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

Patient experienced hives, which started within one day and lasted for the week she took tofranil.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report D	)etail
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Case Number: 143361 Seq: 1 Gender: F
Reported: 01/09/1999 Weight:
Hospitalisation: Age:

Onset Date: DOB:

Outcome: Unknown

Causality: Cau	isality possible
----------------	------------------

#### **Reaction Detai**

todotion Dotal		_	
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Patient experienced liver malfunction.	
Alopecia			

### **Medicine Details:**

TOFRANIL (Suspected)		Reason:	
Tablet	0.0	Daily	Oral
3atch:	Started:	3top	pped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient experienced hair loss while on tofranil, which she has had a long time, the patient began tofranil five or more years ago. she is not worried about it and wears a hair piece, stated that elopecia areata had been diagnosed. she continued on tofranil but her doctor has asked her to taper off as a process of elimination.

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 143362 Seq: 1 Gender: F

Reported: 01/09/1999 Weight:
Hospitalisation: Age: 50Y

**Onset Date**: 31/05/1999 **DOB**:

Outcome: Unknown Causality: Causality possible

**Reaction Detai** 

Cuction Betai			
Preferred Term	Severity	Report Description	Treatment
Constipation			
Dry mouth			

#### **Medicine Details:**

Modified Botalio.					
TOFRANIL (Suspected)	Reason:				
Tablet	0.0	Daily	Oral		
3atch:	Started: 01/05/1999	Sto	pped:		

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 143698
 Seq: 1
 Gender:
 F

 Reported:
 13/09/1999
 Weight:

Reported: 13/09/1999

Hospitalisation:
Onset Date:

DOB:

Weight:
Age:
DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Fatigue	Still feels weary		

#### **Medicine Details:**

TOFRANIL (Suspected) Reason: Depression

Tablet 200.0 Milligram Daily Oral

3atch: Started: Stopped: CONTIN

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

The dosage of tofranil was increased to 200mg but still feels weary. the patient has been on tofranil for 9 years and says it normally takes many weeks before this "weariness and loss of strength" disappear.

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DOB:

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 144836 Seq: 1 Gender: M
Reported: 19/10/1999

Hospitalisation: Age:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

**Onset Date:** 

todotion Dotal		E	
Preferred Term	Severity	Report Description	Treatment
Dry mouth		Patient immediately experienced a dry	Prescribed a lower dose of
Cheilitis		Patient immediately experienced dry lips	

#### **Medicine Details:**

TOFRANIL (Suspected)

Tablet

25.0 Milligram

Daily

Oral

3atch:

3tarted: 01/09/1999

Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

The patient also felt a "write-off" the next day. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 144901
 Seq: 1
 Gender: F

 Reported:
 20/10/1999
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 13/09/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

104011011 20141		-	
Preferred Term	Severity	Report Description	Treatment
Dizziness		Dizzy, fall fracture r proximal femur	Tofranil ceased.
Hypotension			

**Medicine Details:** 

AROPAX (Other drug)		Reason:	Depression	
Tablet	20.0 Milligra	m Daily		Oral
3atch:	Started:	L TERM	Stopped:	
TOFRANIL (Suspected)		₹eason:		
Tablet	50.0 Milligra	m Daily		Oral
3atch:	Started: 06/09/1999	)	Stopped:	13/09/1999
CAPOTEN (Suspected)		Reason:	Essential beni	gn hypertension
Tablet	50.0 Milligra	m Daily		Oral
3atch:	Started:	L TERM	Stopped:	
3atch: ASPIRIN (Suspected)	Started:	L TERM	Stopped:	
	3tarted: 150.0 Milligra	Reason:		Oral

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 146344
 Seq: 1
 Gender: F

 Reported:
 30/11/1999
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 21/10/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

10404011 20441			
Preferred Term	Severity	Report Description	Treatment
Dehydration			Admitted to hospital
Hypotension			

**Medicine Details:** 

PHENERGAN (Suspected)			Reason:	
	0.0			
3atch:	Started:		Stoppe	ed:
VALIUM (Suspected)			Reason:	
Tablet	10.0	Milligram	As necessary	Oral
3atch:	Started:		Stoppe	ed:
PRO-BANTHINE (Suspected)			Reason:	
Tablet	60.0	Milligram	Daily	Oral
Зatch:	Started:		Stoppe	d:
TOFRANIL (Suspected)			Reason:	
Tablet	20.0	Milligram	Daily	Oral
3atch:	Started:		Stoppe	ed:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

Patient has allergies to digesic, morphine, septrin, fentanyl, codeine, iodine stemetil and maxolon.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 146870 Seq: 1 Gender: F

Reported: 13/12/1999 Weight:
Hospitalisation: Age: 21Y

Onset Date: 11/11/1999 DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Vomiting		Vomiting & can't keep any food down.	

### **Medicine Details:**

TOFRANIL (Suspected) Reason: Depression

Tablet 100.0 Milligram Daily Oral

3atch: Started: 04/11/1999 Stopped:

# **Laboratory Investigations:**

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Reactions one week after commencing tofranil. the patient was ok for the first week.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail						
Case Number: 147196 Reported: 20/12/199 Hospitalisation: Onset Date: 02/12/199		Gender: M Weight: Age: DOB:				
Outcome: Unknown			Causality	Causality possible		
eaction Detai	1 0 11		1			
Preferred Term Hot flush	Severity	Report Des	scription	Treatment		
Conjunctivitis		t flushes of face cky eyes				
Medicine Details:  TOFRANIL (Suspected)		Reason:		_		
Tablet	0.0	Reason: Daily	, Oral			
Batch:		Started: 02/12/1999 Stopped:				
Laboratory Investigat	ions: Range Date Teste	d Result	Deta	ails		
Additional Informatio	n:					



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 147537 Seq: 1 Gender: F

Reported: 24/12/1999 Weight:
Hospitalisation: Age: 47Y

Onset Date: 31/05/1999 DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Constipation		·	
Flatulence			
Weight increased			

#### **Medicine Details:**

TOFRANIL (Suspected) Reason:

Tablet 100.0 Milligram Daily Oral

3atch: 3tarted: 01/05/1999 3topped: 18/12/1999

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

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

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Report Detail

Case Number: 148166

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Reported: 17/01/20 pspitalisation:						Weigl	IL.		
		Age: 9Y							
Onset Date: 05/01/20		DOB:							
Outcome: Unknow	n		Causality: Causality possible						
action Detai						-			
Preferred Term	Sev	Severity Report Description					Treatment	•	
oathy		Withdrawn and unusual behaviour							
rug withdrawal syndrome	9								
edicine Details: OFRANIL (Suspected)			Reaso	<u> </u>					
OFRANIL (Suspected)		0.0	\6a5(	)II.					
3atch:	Sta	Started:			Stopped:				
LONIDINE HYDROCHLORIC			Reaso	on:					
	,	0.0							
3atch:	Sta	arted:			Stopped:				
Jaton.					\ _	rdore of c	hildhod		
			Reaso	on: E	Behavior diso	ideis oi c			
		100.0 Mil		on: E Daily	senavior diso	Oral			
ITALIN (Suspected)	Sta	100.0 Mil			senavior diso				
t <b>ITALIN (Suspected)</b> Tablet	Sta								
Tablet	€ta								
ITALIN (Suspected) Tablet	Sta								
ITALIN (Suspected) Tablet 3atch:									
ITALIN (Suspected) Tablet						Oral	etails		



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 150094 Seq: 1 Gender: M

Reported: 08/03/2000 Weight:

Hospitalisation: Age: 73Y
Onset Date: 24/02/2000 DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Micturition disorder		Slowed down urge to urinate.	

#### **Medicine Details:**

TOFRANIL (Suspected) Reason:

 Tablet
 25.0 Milligram
 Daily
 Oral

 3atch:
 3tarted: 24/02/2000
 3topped: 24/02/2000

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient also taking norvasc, lipex and renitec. after taking one tofranil patient noticed that his urine flow slowed during the night.

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 150445
 Seq: 1
 Gender: U

 Reported:
 16/03/2000
 Weight:

Hospitalisation: Age: 77

Onset Date: 24/02/2000 DOB: 29/08/1922
Outcome: Recovered Causality: Causality possible

Reaction Detai

Neaction Detai			
Preferred Term	Severity	Report Description	Treatment
Confusional state			Tofranil, probanthine, diazepam, panadeine forte
Somnolence			

**Medicine Details:** 

PRO-BANTHINE (Suspected)	:	Reason:
Oral application	0.0	Oral
Зatch:	Started:	Stopped: 27/02/2000
TOFRANIL (Suspected)	:	Reason:
Oral application	0.0	Oral
3atch:	Started:	<b>Stopped:</b> 27/02/2000
PANADEINE FORTE (Suspected)	;	Reason: Otr&unsp vertebrogen pain synd
Oral application	0.0	Oral
3atch:	<b>Started:</b> 02/02/2000	<b>Stopped</b> : 28/02/2000
VALIUM (Suspected)	;	Reason: Otr&unsp vertebrogen pain synd
Oral application	3.0 Dose Unspeci	cified Daily Oral
3atch:	Started: 22/02/2000	<b>Stopped:</b> 27/02/2000

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 151004
 Seq: 1
 Gender: F

 Reported:
 28/03/2000
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 01/01/2000
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Peripheral ischaemia		Cold fingers from betaloc.	
Confusional state		Confusion from probanthine.	
Hypokinesia		Decreased mobility from amantadine.	
Hallucination		Hallucinations.	Ceased amantadine, probanthine, betaloc.

**Medicine Details:** 

MS CONTIN (Suspected)		Reason:	Pain	
	20.0 Milligram	Daily		
Зatch:	3tarted: 20/12/1999		3topped: 06/01/2	000
AMANTADINE HYDROCHLORIDE	(Suspected)	Reason:	Paralysis agitans	
	200.0 Milligram	Daily		
3atch:	Started: 20/09/1999		Stopped: 08/01/2	000
IMIPRAMINE HYDROCHLORIDE (S	Suspected)	Reason:		
IMIPRAMINE HYDROCHLORIDE (S	Suspected) 45.0 Milligram	Reason: Daily		
IMIPRAMINE HYDROCHLORIDE (S	• ,		<b>3topped:</b> 10/01/2	000
,	45.0 Milligram		Stopped: 10/01/2	000
Satch:	45.0 Milligram	Daily		000

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### Additional Information:

Patient also taking omeprazole, ogen, madopar q, rocaltrol. patient allergic to benzalkonium chloride, pethidine, chloramphenicol, penicillin, benzodiazepines, some thiazides. parkinson's disease x2+ years. decreased gait past 12 months. 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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 151004
 Seq: 1
 Gender: F

 Reported:
 28/03/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 79Y

Onset Date: 01/01/2000 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

### **Medicine Details:**

Medicine Details.			
PRO-BANTHINE (Suspected)		Reason:	
	30.0 Milligram	Daily	
3atch:	Started: 01/06/1999	Stopped: 10/01/2000	
PROVERA (Suspected)		Reason: Menopausal symptoms	
	2.5 Milligram	Daily	
3atch:	Started:	Stopped: 08/01/2000	

# **Laboratory Investigations:**

#### **Additional Information:**

Patient also taking omeprazole, ogen, madopar q, rocaltrol. patient allergic to benzalkonium chloride, pethidine, chloramphenicol, penicillin, benzodiazepines, some thiazides. parkinson's disease x2+ years. decreased gait past 12 months. 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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 153211 Seq: 1 Gender: M

Reported: 29/05/2000 Weight:
Hospitalisation: Age:
Onset Date: 31/05/2000 DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Detai** 

-			=	
	Preferred Term	Severity	Report Description	Treatment
	Hepatitis			

#### **Medicine Details:**

TOFRANIL (Suspected) Reason:

Tablet 175.0 Milligram Daily Oral

**3atch: 3tarted:** 01/05/2000 **3topped:** 

# **Laboratory Investigations:**

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Reaction occurred after discontinuation of tofranil. - 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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail						
Case Number: 155	314 <b>Seq</b> :	1			Gender	: F
Reported: 24/					Weight	:
Hospitalisation:					Age	
Onset Date: 06/	07/2000				DOB	:
Outcome: Red	covered				Causality	: Causality probable
Reaction Detai					i -	
Preferred Te	erm Seve	erity	Report	Description		Treatment
Photosensitivity react	ion					
Medicine Details TOFRANIL (Suspected)			Reaso			
Tablet		75.0 Milli		Daily	Oral	
3atch:	3ta	rted: 06/07/20	000	Stopped:	09/07/200	0
Laboratory Inves						
Date Type		Date Tested	Result		Deta	ails
Additional Inforn	nation:					



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report D	<b>Detai</b> l
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Case Number: 155770 Seq: 1 Gender: M
Reported: 02/08/2000 Weight:
Hospitalisation: Age: 16Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

#### **Reaction Detai**

Preferred Term	Severity	Report Description	Treatment
Somnolence		Pronounced sedation	Ceased tofranil

### **Medicine Details:**

TOFRANIL (Suspected) Reason:

Tablet 20.0 Milligram Daily Oral

3atch: 3tarted: 3topped: 21/07/2000

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 156699
 Seq: 1
 Gender:
 F

 Reported:
 23/08/2000
 Weight:

Hospitalisation: Age: 9

**Onset Date**: 31/10/1999 **DOB**: 06/04/1990

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

todotion Dotal			<u> </u>
Preferred Term	Severity	Report Description	Treatment
Skin discolouration Insomnia		Mottled and purple looking appearance of	Tofranil dose was reduced to 10mg then ceased.
Nightmare			

### **Medicine Details:**

TOFRANIL (Suspected)		₹eason:	Incontinence	of urine
Tablet	10.0 Milligram	Daily		Oral
3atch:	Started: 01/10/1999		Stopped:	21/07/2000

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Skin reaction is most noticeable on the peripheries and most marked on the hands, not a rash, similar to appearance when skin is cold; however peripheries were not cold. - 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: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Case Number: 156876	<b>Seq:</b> 1		Gender: M	
Reported: 22/08/2000		Weight:		
lospitalisation:			<b>Age:</b> 31Y	
Onset Date: 23/06/2000			DOB:	
Outcome: Recovered			Causality: Causality possible	
eaction Detai			_	
Preferred Term	Severity	Report Description	Treatment	
Thinking abnormal		A dull head		
Rhinitis		Runny nose		
Influenza like illness				
Pyrexia			Tofranil ceased	

**Medicine Details:** 

TOFRANIL (Suspected)

Tablet

10.0 Milligram

Daily

Oral

Started: 21/06/2000

Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 157597 Seq: 1 Gender: M
Reported: 11/09/2000 Weight:
Hospitalisation: Age: A6

Onset Date: 08/08/2000 DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			Imodium.

#### **Medicine Details:**

Medicine Details.			
TOFRANIL (Suspected)		Reason:	
Tablet	0.0	Oral	
3atch:	Started:	Stopped:	
COMTAN (Suspected)		Reason: Paralysis agitans	
Tablet	200.0 Milligram	Daily Oral	
3atch:	Started: 01/01/1999	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient also taking sinemet 100/25 and selegiline. the dosage start date is not accurate but indicates that start occurred sometime during the year.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 158216
 Seq: 1
 Gender:
 F

 Reported:
 03/10/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 73

**Onset Date: DOB**: 28/10/1926

Outcome: Not yet recovered Causality: Causality possible

#### **Reaction Detai**

Preferred Term	Severity	Report Description	Treatment
Dysarthria		Difficulty speaking, slurred speech.	
Agitation		Irritability and high energy.	
Stomatitis		Sores in her mouth.	
Paraesthesia		Tingling in her feet.	
Aggression			
Confusional state			
Dry mouth			
Hallucination			
Headache			
Insomnia			

### **Medicine Details:**

TOFRANIL (Suspected)		Reason:	Incontinence of	of urine
Tablet	25.0 Milligram	Daily		Oral
3atch:	Started: 01/07/2000		Stopped:	29/08/2000

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

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



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 158216
 Seq: 1
 Gender: F

 Reported:
 03/10/2000
 Weight:

Hospitalisation: Admitted to hospital Age: 73

**Onset Date: DOB**: 28/10/1926

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

todotion Dotai			<u> </u>
Preferred Term	Severity	Report Description	Treatment
Nausea			Patient was admitted to hospital. tofranil ceased.

#### **Medicine Details:**

TOFRANIL (Suspected)

Tablet

25.0 Milligram

Daily

Oral

3atch:

3tarted: 01/07/2000

Stopped: 29/08/2000

# **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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Report Detail

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Case Number: 158602  Reported: 16/10/2000	Seq: 1		Gender: ∪ Weight: Age: DOB:			
espitalisation: Onset Date:						
Outcome: Unknown			Causality: Causality possible			
ection Detai			Oddsanty	. Cadsanty possible		
Preferred Term	Severity	Report Descri	otion	Treatment		
ponatraemia						
edicine Details: ALTREX (Suspected)	0.0	Reason:				
3atch:	Started:		Stopped:			
DFRANIL (Suspected)	-	Reason:	••			
Tablet	1.0 Do	ose Unspecified 1 time	Oral			
3atch:	Started:	·	Stopped:			
aboratory Investigation		L Bassille L	Date	2)10		
Date Type	Range Date Tested	Result	Deta	alis		
dditional Information:						
ort Run 19/07/200 02:16PN	Database: pusime	ADRS004		Page 247 of 279		



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 159437 Seq: 1 Gender: M

Reported: 20/11/2000 Weight:

Hospitalisation: Age: 66Y
Onset Date: 31/10/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detail

104011011 20141			
Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

#### **Medicine Details:**

CELEBREX (Interaction)		Reason:	
	0.0		
3atch:	Started:	Stopped:	
TOFRANIL (Interaction)		Reason: Other diseases	s of bladder

1.0 Dose Unspecified Daily

**Started:** 01/01/1993 **Stopped:** 

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Was taking tofranil for bladder dysfunction. started on celebrex - patient stated that celebrex blocked the function of tofranil. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 169789
 Seq: 1
 Gender:
 F

 Reported:
 07/11/2001
 Weight:

Hospitalisation: Age: 7

**Onset Date: DOB**: 10/10/1994

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Diplopia			Tofranil ceased.

#### **Medicine Details:**

 TOFRANIL (Suspected)
 Reason:
 Anxiety neurosis

 Tablet
 10.0
 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/10/2001
 \$topped:
 15/10/2001

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date is not necessarily accurate but indicates the drug was started sometime in the month.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Deta	il							
_	: 03/12/2001	Seq:	1		Gender: M Weight:			
ospitalisation							Age: 39	
Onset Date		avered					OB: 03/07/1962	
	: Not yet reco	overed				Causa	ality: Causality possible	
action Deta	red Term	Sev	erity/	Reno	rt Descri	ntion	Treatment	
edema periph		000	City	ПСРО	T DC3GII	ption	Treated with frusemide.	
ledicine De ALPRAZOLAM ( Tablet			4.0 Millig	<b>Reas</b>	son: Daily	Oral		
3atch:		3t	arted:	,	2,	Stopped:		
OXYCODONE H	YDROCHLORIDE	(Other drug)	)	Reas	son:	••		
Oral app			2.0 Gran	n	Daily	Oral		
3atch:		3t	arted:	Stopped:				
NEURONTIN (Su	spected)			Reas	son:			
Oral app	lication		2.4 Gran	n	Daily	Oral		
3atch:		St.	arted:			Stopped:		
TOFRANIL (Sus	pected)			Reas	son:			
Tablet			75.0 Millig	ıram	Daily	Oral		
3atch:		St:	arted:			Stopped:		
aboratory	nvestigatio	ons:						
Date	Туре	Range	Date Tested	Result			Details	
Additional li	nformation	:						



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail	
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 Case Number:
 172340
 Seq:
 1
 Gender:
 F

 Reported:
 01/02/2002
 Weight:
 70.00

 Hospitalisation:
 Age:
 77

**Onset Date**: 26/12/2001 **DOB**: 21/02/1924

Outcome: Recovered Causality: Causality probable

#### **Reaction Detai**

todotion botai			+
Preferred Term	Severity	Report Description	Treatment
Anorexia			
Arthralgia			
Hepatitis			
Hyperhidrosis			
Myalgia			Required a visit to doctor. date of recovery 30/01/02.

### **Medicine Details:**

Medicine Details.		
ASPIRIN (Other drug)		Reason: Acute,ill-def cerebrovascular disease w/o hyperte
	300.0 Milligram	Daily
3atch:	Started:	Stopped:
KARVEA (Other drug)		Reason: Essential benign hypertension
	75.0 Milligram	Daily
3atch:	Started:	Stopped:
IMIPRAMINE HYDROCHLORIDE	(Suspected)	Reason:
	10.0 Milligram	Daily
3atch:	Started: 05/12/2001	Stopped: 14/01/2002

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**



Causality: Causality probable

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 176475
 Seq:
 1
 Gender:
 M

 Reported:
 20/06/2002
 Weight:
 44.00

Hospitalisation: Age: 13

**Onset Date**: 05/06/2002 **DOB**: 01/01/1989

Reaction Detai

Outcome: Recovered

teaction Detai	-		
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Raised bilrubin and alk.phos.	
Anorexia			Withhold tofranil. required a visit to doctor.
Nausea			
Neutropenia			
Thrombocytopenia			
Vomiting			

### **Medicine Details:**

TOFRANIL (Suspected) Reason:

10.0 Milligram Daily

3atch: 3tarted: 29/04/2002 3topped: 05/06/2002

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

### **Additional Information:**

Patient recovered 11/6/02.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number:179340Seq:1Gender:MReported:23/09/2002Weight:0.00Hospitalisation:Admitted to hospitalAge:52

**Onset Date: DOB**: 14/10/1949

Outcome: Unknown Causality: Causality possible

#### **Reaction Detai**

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			
	Caused or prolonged inpatient hospitalisation		Admitted to hospital.
Tachycardia			
Thrombocytopenia	Caused or prolonged inpatient hospitalisation		Admitted to hospital.

#### **Medicine Details:**

Micarcine Details.			
VERAPAMIL HYDROCHLORIDE (0	Other drug)	Reason:	
	0.0		
3atch:	Started:	Stopped:	
TOFRANIL (Suspected)		Reason:	
	0.0		
Зatch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	500.0 Milligram	Daily Oral	
3atch:	Started: 13/05/2002	Stopped: 16/10/2002	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
23/09/2002	Platelets		05/12/2002	90	

#### **Additional Information:**

Relevent history - heart rate increase. the patient's pulse rate was high before clozaril dose was increased from 400mg to 500mg/daily. patient was a heavy smoker. ceased clozaril on 15/10/02 due to lack of efficacy and a terminal illness diagnosed.



Report Det	tail						
	iuii						
Case Numb	er: 179829	Seq:	1			Ge	nder: F
Reporte	ed: 14/10/2002					We	eight: 89.00
ospitalisatio	on:						<b>Age</b> : 58
Onset Da	te: 01/03/2002						<b>DOB</b> : 05/10/1943
	ne: Recovered						ality: Causality probable
eaction De		_	_				
Prefe	erred Term	Sev	erity	Repor	t Descriptio	า	Treatment
Arrhythmia			Irreç	gular heart bea	at.		
atigue							
lot flush							Patient required a visit to
Hyperhidrosis	3						doctor. date of recovery:
vervousness							
Palpitations							
	IMPLANT (Other dr	rug)	50.0 M:	Reas		CI-	eutanoous
Implan  3atch:		24.0	50.0 Mil urted:	ılıgram	Daily		cutaneous
TRITACE (Oth		) la	irteu.	Reas		pped:	
(••••	g/		10.0 Mil		Daily		
3atch:		3ta	ırted:		-	pped:	
ATACAND DI I	UC 40/40 E /Other de	rua)		₹eas	on:		
AIACANDIL	US 16/12.5 (Other d	. 49/					
ATACANDIL	US 16/12.5 (Other a		1.0 Do	se Unspecified	Daily		
3atch:	•		1.0 Do	se Unspecified		oped:	
	•		ırted:	Reas	Sto	pped:	
3atch: LIPITOR (Othe	er drug)	Sta	erted: 20.0 Mil	Reas	on: Daily		
3atch:	er drug)	Sta	ırted:	Reas	on: Daily	pped:	
3atch: LIPITOR (Othe 3atch:	er drug) / Investigatio	Sta	erted: 20.0 Mil	Reas	on: Daily		
3atch: LIPITOR (Othe 3atch:	er drug)	Sta	erted: 20.0 Mil	<b>Reas</b> Iligram	on: Daily		Details



Case Number: 179829

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

			С			ole
			С			ole
			С	ausality:	Causality probat	ole
	Reas	on:				
1.0						
			Stopped:			
	Reas					
30.0				Oral		
	9		Stopped:	0.0.		
, tui toui			rtoppou.			
	Started:	1.0 Dose Unspecified  Started:  Reas  30.0 Milligram	Reason: 30.0 Milligram Daily	1.0       Dose Unspecified       Daily       Stopped:         Started:       Stopped:         30.0       Milligram       Daily	1.0       Dose Unspecified       Daily         Started:       Stopped:         Reason:         30.0       Milligram       Daily       Oral	1.0       Dose Unspecified       Daily         Started:       Stopped:         Reason:         30.0       Milligram       Daily       Oral



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 180093 Seq: 1 Gender: M
Reported: 28/10/2002 Weight:

**Hospitalisation**: Admitted to hospital **Age**: 82 **Onset Date**: 09/07/2002 **DOB**: 08/02/1920

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Parkinsonism	Patient was admitted to
Hypertonia			1
Somnolence			
Tardive dyskinesia			

#### **Medicine Details:**

Medicine Details.					
IMIPRAMINE HYDROCHLORIDE (Su	spected)		Reason:		
Tablet	25.0	Milligram	Daily		Oral
3atch:	Started:	L	TERM	Stopped:	
PERICYAZINE (Suspected)			Reason:		
Tablet	2.5	Milligram	Daily		Oral
3atch:	Started:	L	TERM	Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient has signs of marked rigidity of all limbs with prominent orobuccal dyskinetic movements, normal spontaneous movements and mask-like face.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 181718 Seq: 1 Gender: F

Reported: 15/01/2003 Weight: 0.00 Hospitalisation: Age: 83

**Onset Date**: 07/06/2002 **DOB**: 15/02/1919

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

104011011 20141			
Preferred Term	referred Term Severity Report Description		Treatment
Hypotension		Hypotension and hyponatraemia	Tofranil ceased, , BP monitored-standing and supine. Patient fluid restricted.
Hyponatraemia			

**Medicine Details:** 

ASASANTIN SR (Other drug)		Reason:		
Capsule		Daily	Oral	
Зatch:	Started:		Stopped:	
RANITIDINE (Other drug)		Reason:		
Tablet	300.0 Milligra	am Daily	Oral	
Зatch:	Started:		Stopped:	
TOFRANIL (Suspected)		Reason:	Incontinence of urine	
Tablet	25.0 Milligra	am Daily	Oral	
3atch:	Started:		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
15/01/2003	Sodium				

#### **Additional Information:**

Patient was also taking Fefol, paracetamol.



# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number:	: 187142	Seq: 1		(	Gender: ∪		
Reported	20/06/200		<b>Weight</b> : 0.00				
ospitalisation: Admitted to hospital					Age: 21M		
Onset Date:	•			DOB:			
Outcome	Recovere	d		Ca	nusality: Causality possible		
action Deta			+		•		
Preferr	ed Term	Severity	Repor	t Description	Treatment		
ccidental over			Overdose/poisoni	ng	Treated with Charcoal.		
ledication erro	r						
ledicine De TOFRANIL (Susp			Reas	on.			
Tablet	cotou		Dose Unspecified		Oral		
3atch:		Started:	2000 0000000	Stopped:			
aboratory l	nvestigat	ions:					
Date	Type	Range Date T	ested Result		Details		
Additional In	formatio	n:					
oort Run 19/07/20	00 02:16PN	Database: pusime		ADRS004	Page 258 of 27		



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 189526
 Seq: 1
 Gender: M

 Reported:
 12/08/2003
 Weight: 90.00

Hospitalisation: Age: 76

**Onset Date**: 31/07/2003 **DOB**: 26/11/1926

Outcome: Unknown Causality: Causality possible

Reaction Detai

<u> </u>			<u> </u>
Preferred Term	Severity	Report Description	Treatment
Agitation	Required Visit to Doctor	Agitated b/c doesn't know what he's	
Confusional state	Required Visit to Doctor	Often confused and gets lost in the	
Hallucination		Patient gets up at night and suggests their is people in his bed.	Ceased medicine.

**Medicine Details:** 

TOFRANIL (Suspected)	र	eason:	
Tablet	30.0 Milligram	Daily	Oral
Зatch:	Started: 21/07/2003	Stopped:	09/08/2003
PRO-BANTHINE (Suspected)	र	eason:	
PRO-BANTHINE (Suspected)  Tablet	۶ 15.0 Milligram	eason: Daily	Oral

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Allergies: Aspirin - swells sup with large doses (used for osteoarthritis) approx 40 years ago.

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Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 191456 Seq: 1 Gender: F

Reported: 21/10/2003 Weight: 68.00 Hospitalisation: Admitted to hospital Age: 63

**Onset Date**: 06/09/2003 **DOB**: 03/01/1940

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Confusional state	prolonged	Acute confusional state - disorientation to time, place, person, memory impairment, delusional ideation.	ceased Tramal
Delusion	Caused or prolonged inpatient hospitalisation		
Memory impairment	Caused or prolonged inpatient hospitalisation		

### **Medicine Details:**

TRAMAL SR (Interaction)		Reason:
Tablet	400.0 Milligram	Daily Oral
Заtch:	<b>Started:</b> 02/05/2002	Stopped: 08/05/2003
TOFRANIL (Interaction)		Reason: Anxiety neurosis
Tablet	100.0 Milligram	Daily Oral
3atch:	<b>Started:</b> 18/04/2002	Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient also taking Oroxine, Orudis SR, Serepax



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 193560 Seq: 1 Gender: M

Reported: 05/01/2004 Weight: 0.00 Hospitalisation: Age: 17Y

Onset Date: 26/10/2003 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Agitation	Required Visit to Doctor	Agitation, aggressive behaviour ,irritability, violent, muscle tension and significant increased sweating.	Largactil 25mg stat. Ceased
Muscle tightness	Required Visit to Doctor	Muscle tension.	
Aggression	Required Visit to Doctor		
Hyperhidrosis	Required Visit to Doctor		
Irritability	Required Visit to Doctor		

**Medicine Details:** 

AROPAX (Other drug)		Reason:	Depression		
Tablet	60.0 Milligram	Daily		Oral	
3atch:	Started: 01/09/2003		Stopped:		contin
TOFRANIL (Suspected)		Reason:	Specific disord	ers of sleep	
Tablet	20.0 Milligram	Daily		Oral	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Punched a girl at school and was suspended from school for 1 week. History of agitation, jerking and grunting on Zoloft and Avanza. Patient was also taking Aropax and Roaccutane.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 195048 Seq: 1 Gender: M
Reported: 01/03/2004 Weight: 0.00
Hospitalisation: Age: 47

Onset Date: 05/01/2004 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome			Ceased Tramadol, started Oxycodone.
Agitation			
Cold sweat			
Heart rate increased			
Hyperhidrosis			

**Medicine Details:** 

Tablet

TRAMADOL HYDROCHLORIDE (Interaction)

Tablet

400.0 Milligram

Daily

Daily

**3atch**: **3tarted**: 23/12/2003 **3topped**: 05/01/2004

125.0 Milligram

IMIPRAMINE HYDROCHLORIDE (Interaction) Reason: Pain

3atch: Started: Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient also administered: TPN, Omeprazole, Paracetamol, Tramadol HCL, Mexiletine, Prazosin, Sorbitol.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 197974
 Seq: 1
 Gender: U

 Reported:
 08/06/2004
 Weight:
 0.00

 Hospitalisation:
 Age: 40

**Onset Date:** 09/03/2004 **DOB:** 03/04/1963

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Reflux oesophagitis	Caused or prolonged inpatient hospitalisation	mouth and chronic oesophageal thrush.	Fungilin lozenges, htdration with eating.
Dry mouth	Caused or prolonged inpatient hospitalisation		
Dysphagia	Caused or prolonged inpatient hospitalisation		

#### **Medicine Details:**

IMIPRAMINE HYDROCHLORIDE (Suspecte	ed)	Rea	son:	Toxic diffuse (	goiter
Tablet	200.0	Milligram	Daily		Oral
Зatch:	Started:	L TERM	l	Stopped:	
AMISULPRIDE (Suspected)		Rea	son:	Depression	
Tablet	800.0	Milligram	Daily		Oral
3atch:	Started:	L TERM	l	Stopped:	
THYROXINE SODIUM (Suspected)		Reas	son:		
THYROXINE SODIUM (Suspected)  Tablet	1.0	Reason Dose Unspecified			Oral
` ' '	1.0 <b>Started:</b>		Daily	Stopped:	Oral
Tablet		Dose Unspecified	Daily	Stopped: Unspecified p	
Tablet <b>3atch</b> :		Dose Unspecified L TERM	Daily		

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 197974	Seq: 1		Gen	der: ∪		
Reported: 08/06/2004				ght: 0.00		
Hospitalisation:				<b>Age</b> : 40		
Onset Date: 09/03/2004		<b>DOB</b> : 03/04/1963				
Outcome: Not yet recove	ered		Causa	llity: Causality possible		
eaction Detai				<del> </del>		
Preferred Term	Severity	Report Descr	iption	Treatment		
Oesophageal candidiasis	Caused or prolonged inpatient hospitalisation					
Medicine Details:						
OMEPRAZOLE (Suspected)		Reason:				
		Milligram Daily				
Batch:	Started:	L TERM	Stopped:			
BENZTROPINE MESYLATE (Suspe		Reason:	Oral			
Tablet  3atch:	2.0 Started:	Milligram Daily L TERM	Oral Stopped:			
Laboratory Investigation	s:					
Additional Information:						
eport Run 19/07/200 02:16PN [	Database: pusime	ADRS004		Page 264 of 279		



**DOB**: 12/02/1926

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 198539 Seq: 1 Gender: M

**Reported:** 28/06/2004 **Weight:** 102.00

Hospitalisation: Age: 78

Outcome: Recovered 24/06/2004 Causality: Causality probable

**Reaction Detai** 

Onset Date: 10/06/2004

Preferred Term	Severity	Report Description	Treatment
Tinnitus		Tinnitus - worse in left ear.	Tofranil ceased.

#### **Medicine Details:**

TOFRANIL (Suspected) Reason: Otr&unsp vertebrogen pain synd

25.0 Milligram Daily

3atch: 3tarted: 08/06/2004 3topped: 20/06/2004

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient also taking Vioxx, Somac, Zyloprim and Iscover.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report I	Detail
----------	--------

 Case Number:
 200200
 Seq:
 1
 Gender:
 M

 Reported:
 20/08/2004
 Weight:
 95.00

 Hospitalisation:
 Age:
 50

**Onset Date**: 06/04/2004 **DOB**: 24/03/1954

Outcome: Not yet recovered Causality: Causality possible

### Reaction Detai

104011011 20141		<u> </u>	
Preferred Term	Severity	Report Description	Treatment
Gait disturbance	to Doctor	Deterioration in gait and power of muscles, tremor ++ and muscle weakness since stopping Tofronil < 2 weeks ago.	
Muscular weakness	Required Visit to Doctor		
Tremor	Required Visit to Doctor		

### **Medicine Details:**

VALIUM (Other drug)		Reason:	Depression	
3atch:	Started:		Stopped:	15/04/2004
AROPAX (Other drug)		₹eason:	Depression	
3atch:	Started:		Stopped:	15/04/2004
NUDOFFN (Other deser)		_		
NUROFEN (Other drug)		Reason:		
NUKUFEN (Other drug)			ecessary	
NUROFEN (Other drug)  3atch:	Started:		ecessary  Stopped:	
	Started:		•	
3atch:	Started:	As n	Stopped:	Oral

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 202943 Seq: 1 Gender: F

Reported: 22/11/2004 Weight: 90.00 Hospitalisation: Age: 33

**Onset Date**: 15/01/2004 **DOB**: 29/06/1970

Outcome: Recovered Causality: Causality possible

Reaction Detai

104011011 20141			
Preferred Term	Severity	Report Description	Treatment
	Required Visit to Doctor	Drug level decreased.	Cassation of Xenical.

#### **Medicine Details:**

IMIPRAMINE HYDROCHLORIDE	(Interaction)		Reason:		
Tablet	250.0	Milligram	Daily	Oral	
3atch:	Started:			Stopped:	
VENICAL (Interaction)			Reason:		
XENICAL (Interaction)			teason.		
Capsule	360.0	Milligram	Daily	Oral	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Increased dose of Imipramine to reduction therapeutic blood levels.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report	Detail
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 Case Number:
 207461
 Seq: 1
 Gender:
 F

 Reported:
 27/04/2005
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 90Y
Onset Date: 04/04/2004
DOB:

Outcome: Recovered 09/04/2004 Causality: Causality probable

### Reaction Detai

ieaction Detai			
Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation	SIADH suspected.	

### **Medicine Details:**

ALENDRONATE SODIUM (Other	er drug)	Reason:	Other diseases of bone	
Зatch:	Started:		Stopped:	
CALTRATE + VITAMIN D (Othe	r drug)	Reason:	Other diseases of bone	
3atch:	Started:		Stopped:	
DIGOXIN (Other drug)		Reason:	Otr&nos disord of heart rhythm	
Зatch:	Started:		Stopped:	
DIAMICRON (Other drug)		Reason:	Diabetes mellitus	
3atch:	Started:		Stopped:	

# **Laboratory Investigations:**

Date	Туре	Range	Date Tested	Result	Details
27/04/2005	Serum osmolality		04/04/2004	280	
27/04/2005	Sodium		04/04/2004	129	
27/04/2005	Urine Sodium		04/04/2004	123	
27/04/2005	Urine osmolality		04/04/2004	525	



Case Number: 207461

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Hospitalisation:	27/04/2005 Admitted to hospital				Weight: Age:	90Y
Onset Date:	Recovered		09/04/2	2004	DOB:	Causality probable
Reaction Detai			09/04/2	2004	Gausanty.	Causanty probable
Medicine Deta				Reason:	Unspecified anemia	
3atch:		Started:			Stopped:	
ASTRIX 100 (Other	r drug)			Reason:	Transient cereb isch no hy	ypert
3atch:		Started:			Stopped:	
TOFRANIL (Suspe	cted)			Reason:	Unspecified psychosis	
Tablet			Milligram	Daily	Oral	
3atch:		Started:			Stopped:	
Laboratory In	vestigations:					
Additional Inf	ormation:					



Case Number: 211765

**Reported:** 20/09/2005

Onset Date: 25/07/2005

**Hospitalisation:** Admitted to hospital

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

**Weight:** 70.00

**Age:** 93

**DOB:** 08/07/1912

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  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  Reason:  Statch: Started: Stopped:  Stoppe	Outcome: Recovered		28/07/2005	Cau	sality: Causality possible
Caused or prolonged inpatient hospitalisation  Scle twitching  Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  RANSIDERM-NITRO (Other drug)  3atch: Started: Stopped:  STELIN 1000 (Other drug)  3atch: Started: Stopped:  STELIN 1000 (Other drug)  3atch: Started: Stopped:  Started: Stopped:  Started: Stopped:  Started: Stopped:  Started: Stopped:  Started: Stopped:  Stopped		1			
prolonged inpatient hospitalisation  Caused or prolonged inpatient hospitalisation  Edicine Details:  RANSIDERM-NITRO (Other drug)  Satch: Started: Stopped:  RUSEMIDE (Other drug)  Started: Stopped:  Started: Stopped:  STELIN 1000 (Other drug)  Satch: Started: Stopped:  Started: Stopped:  Started: Stopped:  Stopped: Stopped:  Stopped: Stopped:  Stopped: Stopped: Stopped:  Stopped: Stoppe			•	•	
prolonged inpatient hospitalisation  Bedicine Details:  RANSIDERM-NITRO (Other drug)  3atch: Started: Stopped:  RUSEMIDE (Other drug)  3atch: Started: Stopped:  STELIN 1000 (Other drug)  3atch: Started: Stopped:  STELIN 1000 (Other drug)  3atch: Started: Stopped:  Stopped: Stopped:  Stopped: Stopped	nerapy regimen changed	prolonged inpatient	Patient experience increasing Aricept	d twitching after from 5mg to 10mg.	Ceased Aricept and
3atch: Started: Stopped:  FRUSEMIDE (Other drug) Reason:  3atch: Started: Stopped:  DSTELIN 1000 (Other drug) Reason:  3atch: Started: Stopped:  Glucosamine Nos (Other drug) Reason:  3atch: Started: Stopped:  3atch: Started: Stopped:  Date Type Range Date Tested Result Details	luscle twitching	prolonged inpatient			
RANSIDERM-NITRO (Other drug)  3atch: Started: Stopped:  RUSEMIDE (Other drug)  3atch: Started: Stopped:  DSTELIN 1000 (Other drug)  3atch: Started: Stopped:  Stucosamine Nos (Other drug)  3atch: Started: Stopped:  Stucosamine Nos (Other drug)  3atch: Started: Stopped:  3atch: Started: Stopped:  Date Type Range Date Tested Result Details					
Batch: Started: Stopped:  RUSEMIDE (Other drug) Reason:  Started: Stopped:  STELIN 1000 (Other drug) Reason:  Started: Stopped:  Stopped					
RUSEMIDE (Other drug)  3atch: \$tarted: \$topped:  DSTELIN 1000 (Other drug)  3atch: \$tarted: \$topped:  Slucosamine Nos (Other drug)  3atch: \$tarted: \$topped:  Started: \$topped:  Aboratory Investigations:  Date Type Range Date Tested Result Details	RANSIDERM-NITRO (Other drug	)	Reaso	on:	
3atch: Started: Stopped:    Started: Stopped:   Stopped	Batch:	Started:		Stopped:	
Started:   Stopped:	RUSEMIDE (Other drug)		Reaso	on:	
3atch: Started: Stopped:  Glucosamine Nos (Other drug) Reason:  3atch: Started: Stopped:  aboratory Investigations:  Date Type Range Date Tested Result Details	3atch:	Started:		Stopped:	
Started:   Stopped:	OSTELIN 1000 (Other drug)		Reaso	on:	
Started:   Stopped:	3atch:	Started:		Stopped:	
aboratory Investigations:  Date Type Range Date Tested Result Details	Glucosamine Nos (Other drug)		Reaso		
	3atch:	Started:		Stopped:	
Date Type Range Date Tested Result Details	aboratory Investigatio	ns:			
dditional Information:			sted Result		Details
	Additional Information:	Range Date Te	sted Result		Details
eport Run 19/07/200 02:16PN Database: pusime ADRS004 Page 270 of	201 Dun 40/07/202 00:4001	Detabase suries		DDS004	Page 270 of 27



Case Number: 211765

**Reported:** 20/09/2005

Onset Date: 25/07/2005

**Hospitalisation:** Admitted to hospital

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

**Weight:** 70.00

**Age:** 93

**DOB**: 08/07/1912

Outcome: Recovered eaction Detai		28/07/	2005	C	causality:	Causality poss	ible
Andining Detailer							
Medicine Details: CALTRATE (Other drug)			Reason:				
3atch:	Started:			Stopped:			
ARICEPT (Suspected)			Reason:				
Tablet	10.0	Milligram	Daily		Oral		
Зatch:	3tarted:			Stopped:			
MIPRAMINE HYDROCHLORIDE (Suspect	ed)		Reason:				
Tablet		Milligram	Daily		Oral		
3atch:	Started:			Stopped:			
_aboratory Investigations:							
Additional Information:							
oort Run 19/07/200 02:16PN Databas	se: pusime		ADRS004			Page 271	of 279



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail	Re	po	rt	D	etai	il
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Case Number: 213956 Seq: 1 Gender: F

 Reported:
 02/12/2005
 Weight:
 0.00

 Hospitalisation:
 Age:
 50Y

Onset Date: 15/06/2005 DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Detai** 

•	odolion Bolai			
	Preferred Term	Severity	Report Description	Treatment
		ability	The patient developed a tremor on standing which was only affecting her legs. It generally lasted one or two minutes at a	

#### **Medicine Details:**

Medicine Details.				
PARIET (Other drug)		Reason:		
3atch:	Started:		Stopped:	
TOFRANIL (Suspected)		Reason:	Depression	
TOT KANL (Suspected)		Veason.	Depression	
	150.0 Mi	lligram Dai	ly	
3atch:	Started:	L TERM	Stopped:	Continuing.

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Patient also taking Caltrel.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

Case Number: 216078 Seq: 1 Gender: F

Reported: 22/02/2006 Weight: 55.00 Hospitalisation: Age: 86

Onset Date: 02/02/2006 DOB: 24/04/1919

Outcome: Recovered 15/02/2006 Causality: Causality possible

Reaction Detai

reaction Detai			
Preferred Term	Severity	Report Description	Treatment
Inappropriate antidiuretic hormon		The patient experienced suspected SIADH with gross hyponatraemia.	3% Saline.
Hyponatraemia	Life		

**Medicine Details:** 

TEGRETOL (Suspected) Reason: Herpes zoster

Oral

3atch: Started: 10/01/2006 Stopped: 31/01/2006

TOFRANIL (Suspected) Reason: Herpes zoster

3atch: 3tarted: 10/01/2006 3topped: 31/01/2006

DI-GESIC (Suspected) Reason: Herpes zoster

Tablet Oral

**3atch: 3tarted:** 10/01/2006 **3topped:** 31/01/2006

PULMICORT (Suspected) Reason: Emphysema

2.0 Dose Unspecified Daily

3atch: 3tarted: 3topped: 02/02/2006

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details
22/02/2006	Sodium				Na+ - 102.



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 221879
 Seq:
 1
 Gender:
 M

 Reported:
 25/09/2006
 Weight:
 0.00

 Hospitalisation:
 Age:
 88

**Onset Date**: 26/02/2006 **DOB**: 16/07/1917

Outcome: Not yet recovered Causality: Causality possible

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	Caused or prolonged inpatient hospitalisation	Donepezil dose increased from 5 mg to 10	
Orthostatic hypotension	Caused or prolonged inpatient hospitalisation	patient collapsed at thome and lost consciousness for 2-3 seconds.	
Dysarthria	Caused or prolonged inpatient hospitalisation		

### **Medicine Details:**

IMIPRAMINE HYDROCHLORIDE (Suspecte	ed)	Reason:	Depression		
	10.0 Milligram			Oral	
3atch:	Started:		Stopped:	08/03/2006	0
PRAZOSIN HYDROCHLORIDE (Suspected	)	Reason:	Incontinence of	of urine	
	2.0 Milligram			Oral	
3atch:	Started:		Stopped:		0
ARICEPT (Suspected)		Reason:	Unspecified pa	sychosis	
	5.0 Milligram	Daily		Oral	
3atch:	Started: 24/06/2005		Stopped:		0
FRUSEMIDE (Suspected)		Reason:	Edema and dr	opsy	
	80.0 Milligram	Daily		Oral	
Зatch:	Started:		Stopped:	26/02/2006	0

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report Detail

 Case Number:
 221879
 Seq:
 1
 Gender:
 M

 Reported:
 25/09/2006
 Weight:
 0.00

 Hospitalisation:
 Age:
 88

**Onset Date**: 26/02/2006 **DOB**: 16/07/1917

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		

**Medicine Details:** 

IMIPRAMINE HYDROCHLORIDE (S	Suspected)	Reason:	Depression		
	10.0 Milligram			Oral	
Зatch:	Started:		Stopped:	08/03/2006	0
PRAZOSIN HYDROCHLORIDE (Su	spected)	Reason:	Incontinence of	of urine	
	2.0 Milligram			Oral	
Зatch:	Started:		Stopped:		0
ARICEPT (Suspected)		Reason:	Unspecified ps	sychosis	
	5.0 Milligram	Daily		Oral	
3atch:	5.0 Milligram <b>Started:</b> 24/06/2005	Daily	Stopped:	Oral	0
3atch: FRUSEMIDE (Suspected)	· ·	Daily	Stopped:		0
	· ·		- ''		0

# **Laboratory Investigations:**



A							
eport Detail							
Case Number:		Seq:	1			der: F	
-	01/12/2006					ght: 0.00	
spitalisation:						<b>ge:</b> 45Y	
Onset Date:					OB:		
Outcome:				Causality: Causality poss			
action Detai							
Preferre		Seve		Report	Treatment		
lectrocardiogra	m ST segment a		P E at	atient has "experience of the commencing in the commencing in the commencing in the commencing in the commencing in the commencing in the commencing in the commencial commencia	enced ST changes on ver a number of years miparamine".		
ledicine Det				Reaso	n: Depression		
Tablet					Oral		
3atch:		Started:			Stopped:		
-aboratory Ir	nvestigations	<b>:</b> ange	Date Test	ed Result		Details	



DOB:

Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

 Case Number:
 224794
 Seq:
 1
 Gender:
 F

 Reported:
 18/01/2007
 Weight:
 0.00

 Hospitalisation:
 Age:
 99U

Outcome: Unknown Causality: Causality possible

### **Reaction Detai**

**Onset Date:** 

todotion Dotal		<u>-</u>	
Preferred Term	Severity	Report Description	Treatment
Depression  Neuralgia		Depression has worsened, Tofranil wasn't having the same effect anymore.	

#### **Medicine Details:**

MEGICINE DELANS.				
TEGRETOL (Other drug)		Reason:	Otr&unsp forms neuralg&neurit	
Tablet	300.0 Millig	gram Daily	Oral	
Зatch:	Started:		Stopped:	
TOFRANIL (Suspected)		Reason:	Depression	
Tablet	100.0 Millig	gram Daily	Oral	
3atch:	Started:		Stopped:	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Case Number: 225169 Seq: 1 Gender: F

Reported: 29/01/2007 Weight: 0.00
Hospitalisation: Required a visit to the doctor Age: 79

Onset Date: DOB: 15/11/1927

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT corrected		Dizziness, faintness, PR prolongation.	

#### **Medicine Details:**

TOFRANIL (Suspected)

Tablet

25.0 Milligram

Daily

Oral

3atch:

\$topped: 07/12/2006

**Laboratory Investigations:** 

Date	Type	Range	Date Tested	Result	Details



Date Range: 29 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: IMIPRAMINE HYDROCHLORIDE, IMIPRIN, IRAMIL, TOFRANIL

Report De
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Case Number: 230369 Seq: 1 Gender: F

Reported: 28/06/2007 Weight: 52.00 Hospitalisation: Age: 36

Onset Date: DOB: 15/12/1970

Outcome: Recovered Causality: Causality probable

**Reaction Detai** 

todotion Dotai		_	
Preferred Term	Severity	Report Description	Treatment
Restless legs syndrome		Restless legs secondary to Tofranil causing disturbed sleep.	

#### **Medicine Details:**

TOFRANIL (Suspected) Reason: Specific disorders of sleep

25.0 Milligram Daily

3atch: 3tarted: 15/06/2005 3topped: 15/05/2007

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details