

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number:69070Seq:1Gender:FReported:10/01/1991Weight:84.00Hospitalisation:Admitted to hospitalAge:70Y

Onset Date: 20/08/1990 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion botal		_	
Preferred Term	Severity	Report Description	Treatment
Cerebrovascular disorder			Sequlelae: expressive dysphagia, r facial paresis,

Medicine Details:

OMEPRAZOLE (Suspected)		Reason: Other	diseases of esophagus	
	40.0 Milligram	Daily		
3atch:	Started: 14/03/1988	€to	pped: 26/04/1988	
OMEPRAZOLE (Suspected)		Reason: Other	diseases of esophagus	
	20.0 Milligram	Daily		
3atch:	Started: 27/04/1988	Sto	pped: 28/10/1990	
LITHIUM CARBONATE (Suspected)		Reason:		
LITHIUM CARBONATE (Suspected)	500.0 Milligram	Reason: Daily		
LITHIUM CARBONATE (Suspected) 3atch:	500.0 Milligram	Daily	pped:	
	3 -	Daily	pped: iseases of thyroid gland	
3atch:	3 -	Daily	•	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Case Number:69070Seq:1Gender:FReported:10/01/1991Weight:84.00Hospitalisation:Admitted to hospitalAge:70Y

Onset Date: 20/08/1990 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

Medicine Details.			
CLOMIPRAMINE HYDROCHLORIDE (Susp	pected)	Reason:	Depression
	100.0 Milligram	Daily	
3atch:	Started:		Stopped:
METOPROLOL TARTRATE (Suspected)		Reason:	Essential benign hypertension
	200.0 Milligram	Daily	
3atch:	Started:		Stopped: 20/08/1990

Laboratory Investigations:

Additional Information:

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

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report De	tail							
Case Numb	er: 69223	Seq: 1		Gen	der: F			
	ed: 22/01/199		Weight: 49.00					
ospitalisati		1						
-		0			Age: 30Y			
	ate: 22/11/199		DOB:					
	me: Recovered	d	Causality: Causality possible					
eaction De		 			<u> </u>			
	ferred Term	Severity	Report Des	cription	Treatment			
Pruritus								
Purpura								
Rash					Oral phenergan			
Madiaina I	Dataila.							
Medicine I		RIDE (Suspected)	Reason:	Depression				
	application							
		175.0						
3atch:	:	\$tarted: 13/			2/1990			
	y Investigat	Started: 13/	11/1990					
		Started: 13/	11/1990		2/1990 Details			
Laboratory	y Investigat	Started: 13/	11/1990					



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

 Case Number:
 69260
 Seq:
 1
 Gender:
 M

 Reported:
 23/01/1991
 Weight:
 89.0

Reported: 23/01/1991 Weight: 89.00 Hospitalisation: Age: 67Y

Onset Date: 25/11/1990 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			
Hepatic function abnormal			

Medicine Details:

LASIX (Other drug)		Reason:	Congestive he	art failure	
Oral application	40.0 Milligram	Daily		Oral	
Batch:	3tarted: 01/01/1988		Stopped:		CONTIN
POTASSIUM CHLORIDE (Other drug)		Reason:			
	1.2 Gram	Daily			
3atch:	3tarted: 01/01/1988		Stopped:		CONTIN
FELDENE (Suspected)		Reason:	Osteoarthritis		
	10.0 Milligram	Daily			
3atch:	Started: 01/06/1989		Stopped:	06/01/1991	
ANAFRANIL (Suspected)		Reason:	Depression		
	175.0 Milligram	Daily			
Зatch:	3tarted: 25/11/1990		Stopped:	06/01/1991	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		24/10/1990	-	
	ALT = SGPT		02/01/1991	510	
	ALT = SGPT		05/01/1991	-	
	ALT = SGPT		07/01/1991	427	
	ALT = SGPT		03/01/1991	511	
	ALT = SGPT		09/01/1991	-	
	ALT = SGPT		13/01/1991	-	

Additional Information:

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

Case Number: 69260 Seq: 1 Gender: M

Reported: 23/01/1991 Weight: 89.00 Hospitalisation: Age: 67Y

Onset Date: 25/11/1990 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

LASIX (Other drug)		Reason:	Congestive he	eart failure	
Oral application	40.0 Milligram	Daily		Oral	
3atch:	Started: 01/01/1988		Stopped:		CONTIN
POTASSIUM CHLORIDE (Other drug)		Reason:			
	1.2 Gram	Daily			
3atch:	3tarted: 01/01/1988		Stopped:		CONTIN
FELDENE (Suspected)		Reason:	Osteoarthritis		
	10.0 Milligram	Daily			
3atch:	3tarted: 01/06/1989		Stopped:	06/01/1991	
ANAFRANIL (Suspected)		Reason:	Depression		
	175.0 Milligram	Daily			
3atch:	3tarted: 25/11/1990		Stopped:	06/01/1991	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		17/01/1991	159	
	ALT = SGPT		23/01/1991	159	
	ALT = SGPT		21/01/1991	123	
	ALT = SGPT		15/01/1991	184	
	ALT = SGPT		11/01/1991	370	
	AST = SGOT		24/10/1990	18	
	AST = SGOT		02/01/1991	240	

Additional Information:

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 69260 Seq: 1 Gender: M

Reported: 23/01/1991 Weight: 89.00 Hospitalisation: Age: 67Y

Onset Date: 25/11/1990 **DOB:**

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

LASIX (Other drug)		Reason:	Congestive he	eart failure
Oral application	40.0 Milligram	Daily		Oral
3atch:	3tarted: 01/01/1988		Stopped:	CONTIN
POTASSIUM CHLORIDE (Other drug)		Reason:		
	1.2 Gram	Daily		
3atch:	3tarted: 01/01/1988		Stopped:	CONTIN
FELDENE (Suspected)		Reason:	Osteoarthritis	
	10.0 Milligram	Daily		
3atch:	3tarted: 01/06/1989		Stopped:	06/01/1991
ANAFRANIL (Suspected)		Reason:	Depression	
	175.0 Milligram	Daily		
3atch:	3tarted: 25/11/1990		Stopped:	06/01/1991

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT		03/01/1991	228	
	AST = SGOT		05/01/1991	-	
	AST = SGOT		13/01/1991	-	
	AST = SGOT		17/01/1991	63	
	AST = SGOT		23/01/1991	55	
	AST = SGOT		21/01/1991	55	
	AST = SGOT		15/01/1991	65	

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Report Detail

Case Number: 69260 Seq: 1 Gender: M

Reported: 23/01/1991 Weight: 89.00 Hospitalisation: Age: 67Y

Onset Date: 25/11/1990 **DOB:**

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

LASIX (Other drug)		Reason:	Congestive he	eart failure	
Oral application	40.0 Milligram	Daily		Oral	
3atch:	Started: 01/01/1988		Stopped:		CONTIN
POTASSIUM CHLORIDE (Other drug)		Reason:			
	1.2 Gram	Daily			
3atch:	Started: 01/01/1988		Stopped:		CONTIN
FELDENE (Suspected)		Reason:	Osteoarthritis		
	10.0 Milligram	Daily			
3atch:	Started: 01/06/1989		Stopped:	06/01/1991	
ANAFRANIL (Suspected)		Reason:	Depression		
	175.0 Milligram	Daily			
Зatch:	Started: 25/11/1990		Stopped:	06/01/1991	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT		11/01/1991	117	
	AST = SGOT		09/01/1991	-	
	AST = SGOT		07/01/1991	159	
	Bone marrow				Normal cellularity & erythropoiesis, markedly decreased granulopoiesis with a left shift. majority of cells are blasts & promyelocytes, with very few mature myeloid cells. profound granulocytic hypoplasia consistent with drug induced change.

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Report Detail

Case Number: 69260 Seq: 1 Gender: M

Reported: 23/01/1991 Weight: 89.00 Hospitalisation: Age: 67Y

Onset Date: 25/11/1990 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

LASIX (Other drug)		Reason:	Congestive he	eart failure	
Oral application	40.0 Milligram	Daily		Oral	
3atch:	Started: 01/01/1988		Stopped:		CONTIN
POTASSIUM CHLORIDE (Other drug)		Reason:			
	1.2 Gram	Daily			
3atch:	Started: 01/01/1988		Stopped:		CONTIN
FELDENE (Suspected)		Reason:	Osteoarthritis		
	10.0 Milligram	Daily			
3atch:	Started: 01/06/1989		Stopped:	06/01/1991	
ANAFRANIL (Suspected)		Reason:	Depression		
	175.0 Milligram	Daily			
Зatch:	Started: 25/11/1990		Stopped:	06/01/1991	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haemoglobin		24/10/1990	13.9	
	Haemoglobin		02/01/1991	11.1	
	Haemoglobin		03/01/1991	11.1	
	Haemoglobin		05/01/1991	12.1	
	Haemoglobin		07/01/1991	10.1	
	Haemoglobin		09/01/1991	10.2	
	Haemoglobin		11/01/1991	10.4	

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Report Detail

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Reported: 23/01/1991 Weight: 89.00 Hospitalisation: Age: 67Y

Onset Date: 25/11/1990 **DOB:**

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

LASIX (Other drug)		Reason:	Congestive he	eart failure	
Oral application	40.0 Milligram	Daily		Oral	
3atch:	3tarted: 01/01/1988		Stopped:		CONTIN
POTASSIUM CHLORIDE (Other drug)		Reason:			
	1.2 Gram	Daily			
3atch:	3tarted: 01/01/1988		Stopped:		CONTIN
FELDENE (Suspected)		Reason:	Osteoarthritis		
	10.0 Milligram	Daily			
3atch:	3tarted: 01/06/1989		Stopped:	06/01/1991	
ANAFRANIL (Suspected)		Reason:	Depression		
	175.0 Milligram	Daily			
3atch:	3tarted: 25/11/1990		Stopped:	06/01/1991	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haemoglobin		13/01/1991	12.2	
	Haemoglobin		15/01/1991	11.1	
	Haemoglobin		17/01/1991	11.6	
	Haemoglobin		21/01/1991	11.9	
	Haemoglobin		23/01/1991	12.0	
	Lymphocytes		24/10/1990	-	
	Lymphocytes		02/01/1991	58%	

Additional Information:

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Report Detail

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Reported: 23/01/1991 Weight: 89.00 Hospitalisation: Age: 67Y

Onset Date: 25/11/1990 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

LASIX (Other drug)		Reason:	Congestive he	art failure	
Oral application	40.0 Milligram	Daily		Oral	
Batch:	3tarted: 01/01/1988		Stopped:		CONTIN
POTASSIUM CHLORIDE (Other drug)		Reason:			
	1.2 Gram	Daily			
3atch:	3tarted: 01/01/1988		Stopped:		CONTIN
FELDENE (Suspected)		Reason:	Osteoarthritis		
	10.0 Milligram	Daily			
3atch:	Started: 01/06/1989		Stopped:	06/01/1991	
ANAFRANIL (Suspected)		Reason:	Depression		
	175.0 Milligram	Daily			
Зatch:	3tarted: 25/11/1990		Stopped:	06/01/1991	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Lymphocytes		05/01/1991	65	
	Lymphocytes		09/01/1991	80	
	Lymphocytes		13/01/1991	69	
	Lymphocytes		23/01/1991	35	
	Lymphocytes		21/01/1991	42	
	Lymphocytes		17/01/1991	52	
	Lymphocytes		15/01/1991	58	

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Report Detail

Case Number: 69260 Seq: 1 Gender: M

Reported: 23/01/1991 Weight: 89.00 Hospitalisation: Age: 67Y

Onset Date: 25/11/1990 **DOB:**

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

LASIX (Other drug)		Reason:	Congestive he	eart failure	
Oral application	40.0 Milligram	Daily		Oral	
3atch:	Started: 01/01/1988		Stopped:		CONTIN
POTASSIUM CHLORIDE (Other drug)		Reason:			
	1.2 Gram	Daily			
3atch:	Started: 01/01/1988		Stopped:		CONTIN
FELDENE (Suspected)		Reason:	Osteoarthritis		
	10.0 Milligram	Daily			
3atch:	Started: 01/06/1989		Stopped:	06/01/1991	
ANAFRANIL (Suspected)		Reason:	Depression		
	175.0 Milligram	Daily			
3atch:	3tarted: 25/11/1990		Stopped:	06/01/1991	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Lymphocytes		11/01/1991	75	
	Lymphocytes		07/01/1991	88	
	Lymphocytes		03/01/1991	56	
	Monocytes		24/10/1990	-	
	Monocytes		23/01/1991	10	
	Monocytes		21/01/1991	11	
	Monocytes		17/01/1991	13	

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Report Detail

Case Number: 69260 Seq: 1 Gender: M

Reported: 23/01/1991 Weight: 89.00 Hospitalisation: Age: 67Y

Onset Date: 25/11/1990 **DOB:**

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

LASIX (Other drug)		Reason:	Congestive he	eart failure	
Oral application	40.0 Milligram	Daily		Oral	
3atch:	Started: 01/01/1988		Stopped:		CONTIN
POTASSIUM CHLORIDE (Other drug)		Reason:			
	1.2 Gram	Daily			
3atch:	3tarted: 01/01/1988		Stopped:		CONTIN
FELDENE (Suspected)		Reason:	Osteoarthritis		
	10.0 Milligram	Daily			
3atch:	Started: 01/06/1989		Stopped:	06/01/1991	
ANAFRANIL (Suspected)		Reason:	Depression		
	175.0 Milligram	Daily			
Зatch:	3tarted: 25/11/1990		Stopped:	06/01/1991	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Monocytes		15/01/1991	17	
	Monocytes		13/01/1991	24	
	Monocytes		11/01/1991	24	
	Monocytes		09/01/1991	8	
	Monocytes		07/01/1991	12	
	Monocytes		02/01/1991	6%	
	Monocytes		05/01/1991	16	

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Report Detail

Case Number: 69260 Seq: 1 Gender: M

Reported: 23/01/1991 Weight: 89.00 Hospitalisation: Age: 67Y

Onset Date: 25/11/1990 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

LASIX (Other drug)		Reason:	Congestive he	eart failure	
Oral application	40.0 Milligram	Daily		Oral	
3atch:	Started: 01/01/1988		Stopped:		CONTIN
POTASSIUM CHLORIDE (Other drug)		Reason:			
	1.2 Gram	Daily			
3atch:	Started: 01/01/1988		Stopped:		CONTIN
FELDENE (Suspected)		Reason:	Osteoarthritis		
	10.0 Milligram	Daily			
3atch:	Started: 01/06/1989		Stopped:	06/01/1991	
ANAFRANIL (Suspected)		Reason:	Depression		
	175.0 Milligram	Daily			
3atch:	3tarted: 25/11/1990		Stopped:	06/01/1991	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Monocytes		03/01/1991	7	
	Neutrophils		24/10/1990	33%	
	Neutrophils		02/01/1991	34	
	Neutrophils		05/01/1991	15	
	Neutrophils		09/01/1991	1.36	
	Neutrophils		13/01/1991	5.5	
	Neutrophils		23/01/1991	53	

Additional Information:

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Report Detail

Case Number: 69260 Seq: 1 Gender: M

Reported: 23/01/1991 Weight: 89.00 Hospitalisation: Age: 67Y

Onset Date: 25/11/1990 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

LASIX (Other drug)		Reason:	Congestive he	eart failure	
Oral application	40.0 Milligram	Daily		Oral	
Batch:	3tarted: 01/01/1988		Stopped:		CONTIN
POTASSIUM CHLORIDE (Other drug)		Reason:			
	1.2 Gram	Daily			
3atch:	3tarted: 01/01/1988		Stopped:		CONTIN
FELDENE (Suspected)		Reason:	Osteoarthritis		
	10.0 Milligram	Daily			
3atch:	Started: 01/06/1989		Stopped:	06/01/1991	
ANAFRANIL (Suspected)		Reason:	Depression		
	175.0 Milligram	Daily			
3atch:	Started: 25/11/1990		Stopped:	06/01/1991	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		21/01/1991	45	
	Neutrophils		17/01/1991	33	
	Neutrophils		15/01/1991	23	
	Neutrophils		11/01/1991	0.93	
	Neutrophils		07/01/1991	5.7	
	Neutrophils		03/01/1991	34	
	White blood cells		24/10/1991	4.9	

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

Case Number: 69260 Seq: 1 Gender: M

Reported: 23/01/1991 Weight: 89.00 Hospitalisation: Age: 67Y

Onset Date: 25/11/1990 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

LASIX (Other drug)		Reason:	Congestive he	eart failure	
Oral application	40.0 Milligram	Daily		Oral	
3atch:	Started: 01/01/1988		Stopped:		CONTIN
POTASSIUM CHLORIDE (Other drug)		Reason:			
	1.2 Gram	Daily			
Batch:	Started: 01/01/1988		Stopped:		CONTIN
FELDENE (Suspected)		Reason:	Osteoarthritis		
	10.0 Milligram	Daily			
Batch:	Started: 01/06/1989		Stopped:	06/01/1991	
ANAFRANIL (Suspected)		Reason:	Depression		
	175.0 Milligram	Daily			
Batch:	3tarted: 25/11/1990		Stopped:	06/01/1991	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells		02/01/1991	2.4	
	White blood cells		03/01/1991	1.7	
	White blood cells		05/01/1991	2.1	
	White blood cells		07/01/1991	1.0	
	White blood cells		09/01/1991	1.0	
	White blood cells		11/01/1991	2.6	
	White blood cells		13/01/1991	1.6	

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

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

Case Number: 69260 Seq: 1 Gender: M

Reported: 23/01/1991 Weight: 89.00 Hospitalisation: Age: 67Y

Onset Date: 25/11/1990 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

LASIX (Other drug)		Reason:	Congestive he	eart failure	
Oral application	40.0 Milligram	Daily		Oral	
3atch:	Started: 01/01/1988		Stopped:		CONTIN
POTASSIUM CHLORIDE (Other drug)		Reason:			
	1.2 Gram	Daily			
3atch:	3tarted: 01/01/1988		Stopped:		CONTIN
FELDENE (Suspected)		Reason:	Osteoarthritis		
	10.0 Milligram	Daily			
3atch:	3tarted: 01/06/1989		Stopped:	06/01/1991	
ANAFRANIL (Suspected)		Reason:	Depression		
	175.0 Milligram	Daily			
3atch:	3tarted: 25/11/1990		Stopped:	06/01/1991	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells		15/01/1991	2.0	
	White blood cells		17/01/1991	3.0	
	White blood cells		21/01/1991	3.8	
	White blood cells		23/01/1991	4.6	

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

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Case Number: 69829

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Seq: 1

_	ted: 05/03/1991		Weight:					
lospitalisat			Age : 48Y					
Onset D				DOB:				
	me: Recovered				usality : Ca	Causality probable		
eaction D		- 1	İ			-		
Pre	ferred Term	Sev	erity/	Repo	rt Description		Treatment	
Ejaculation f								
Hyperhidros	is							
Pruritus								
Rash								
Medicine CLOMIPRAM	Details:	RIDE (Suspect	ed)	ç _e a	son: Depression			
OLOMII IVAM	IINE III BROOFILOI	IIDE (Guspect	50.0 Mil		Daily			
3atch	n:	3t	arted: 01/02/1			14/02/1991		
_aborator Date	y Investigati Type	ONS: Range	Date Tested	Result	<u> </u>	Details		
Date	Турс	range	Date Tested	result		Details		
Additiona	I Information	:						
oort Run 20/0	07/200 09:54AN	Database: p	usime		ADRS004		Page 17	of 164



Case Number: 69941

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Seq: 1

Reported: 13/03/1991 Ospitalisation: Onset Date: 28/02/1991 Outcome: Recovered		Weight: 70.00 Age: 30Y DOB: Causality: Causality possib				
Preferred Term	Severity	Report Description	Treatment			
accommodation disorder						
onfusional state						
izziness						
ry mouth						
ledicine Details:						
ANAFRANIL (Suspected)		Reason:				
3atch:	0.0 Started:	Stopped:				
.aboratory Investigation	e.					
	Range Date Tested	Result	Details			
	J I					
Additional Information:						
ort Run 20/07/200 09:54AN D	atabase: pusime	ADRS004	Page 18 of 164			



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Case Number: 70001	Seq: 1		Gei	nder: F
Reported: 18/03/199			We	eight: 60.00
Hospitalisation:				Age: 54Y
Onset Date: 15/03/199	1		Ī	DOB:
Outcome: Recovered	i		Caus	ality: Causality probable
Reaction Detai				
Preferred Term	Severity	Repor	t Description	Treatment
Anorexia				
Arthralgia				
Headache				
Paraesthesia				
Tachycardia				
Medicine Details: ANAFRANIL (Suspected)		Reas	on: Depression	
ANAI NAME (Suspecteu)	,	1.0 Dose Unspecified		
3atch:		15/03/1991		03/1991
Laboratory Investigati				
Date Type	Range Date	Tested Result		Details
Additional Information	1:			
eport Run 20/07/200 09:54AN	Database: pusime	A	DRS004	Page 19 of 164



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report D)etail
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 Case Number:
 70116
 Seq:
 1
 Gender:
 F

 Reported:
 25/03/1991
 Weight:
 72.00

Hospitalisation: Age: 30Y

Onset Date: 22/03/1991 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Pruritus			
Rash maculo-papular			Astemizole 10mg daily

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Suspected) Reason: Depression

 Tablet
 125.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 21/02/1991
 3topped:
 23/03/1991

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail				
Case Number: 70227	Seq: 1		Ger	nder: F
Reported: 03/04/199			We	ight: 52.00
Hospitalisation:				Age : 20Y
Onset Date:				OOB:
Outcome: Recovere	ed		Caus	ality: Causality certain
R <u>eaction Detai</u>				<u> </u>
Preferred Term	Severity	Report	Description	Treatment
Anorexia				
Nausea				
Medicine Details: ANAFRANIL (Suspected)		Reaso		
Tablet		Dose Unspecified	Daily Ora	
3atch:	Started: 25	/03/1991	Stopped : 25/0	03/1991
Laboratory Investigat				
Date Type	Range Date Te	sted Result		Details
Additional Informatio	n:			



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Reported: 28/05/1991 Weight: 65.00 spitalisation: Age: 34Y Onset Date: DOB: Outcome: Recovered Causality: Causality probable action Detai Preferred Term Severity Report Description Treatment araesthesia Redicine Details: Redicine Details: Reason: Depression Tablet 75.0 Milligram 1 time Oral 3 atch: Started: Stopped:	Case Numbe Reporte espitalisatio					
Reported: 28/05/1991	Reporte ospitalisatio	or: 71051				
spitalisation: Age: 34Y Onset Date: DOB: Outcome: Recovered Causality: Causality probable action Detai Preferred Term Severity Report Description Treatment araesthesia edicine Details: INAFRANIL (Suspected) table: Too Milligram 1 time Oral 3 atch: 3 tarted: 3 topped:	spitalisatio	CI. / 1031	Seq: 1		Gen	der: F
spitalisation: Age: 34Y Onset Date: DOB: Outcome: Recovered Causality: Causality probable action Detai Preferred Term Severity Report Description Treatment araesthesia edicine Details: INAFRANIL (Suspected) table T5.0 Milligram 1 time Oral 3 atch: 3 tarted: 3 topped:	spitalisatio	ed: 28/05/1991			Wei	ght: 65.00
Onset Date: Outcome: Recovered Causality: Causality probable action Detail Preferred Term Severity Report Description Treatment araesthesia edicine Details: NAFRANIL (Suspected) Reson: Depression Tablet 75.0 Milligram 1 time Oral 3 atch: Started: Stopped:	-					
Outcome: Recovered action Detail Preferred Term Severity Report Description Treatment araesthesia Causality: Causality probable Causality Caus						
Preferred Term Severity Report Description Treatment araesthesia Iedicine Details: ANAFRANIL (Suspected) Reason: Depression Tablet 75.0 Milligram 1 time Oral 3atch: Started: Starte						
Preferred Term Severity Report Description Treatment araesthesia Iedicine Details: ANAFRANIL (Suspected) Reason: Depression Tablet 75.0 Milligram 1 time Oral Started: Stopped: Stopped:						y
Redicine Details: ANAFRANIL (Suspected) Reason: Depression Tablet 75.0 Milligram 1 time Oral 3atch: Started: Stopped: Stopped: Aboratory Investigations:			Severity	Report Descri	ption	Treatment
ANAFRANIL (Suspected) Tablet 75.0 Milligram 1 time Oral 3atch: Started: Stopped: aboratory Investigations:	araesthesia					
ANAFRANIL (Suspected) Tablet 75.0 Milligram 1 time Oral 3atch: Started: Stopped: aboratory Investigations:						
ANAFRANIL (Suspected) Tablet 75.0 Milligram 1 time Oral 3atch: Started: Stopped: aboratory Investigations:						
ANAFRANIL (Suspected) Tablet 75.0 Milligram 1 time Oral 3atch: Started: Stopped:						
ANAFRANIL (Suspected) Tablet 75.0 Milligram 1 time Oral 3atch: Started: Stopped:						
ANAFRANIL (Suspected) Tablet 75.0 Milligram 1 time Oral 3atch: Started: Stopped:						
ANAFRANIL (Suspected) Tablet 75.0 Milligram 1 time Oral 3atch: Started: Stopped: aboratory Investigations:						
Tablet 75.0 Milligram 1 time Oral 3atch: 3tarted: 3topped: aboratory Investigations:						
ANAFRANIL (Suspected) Tablet 75.0 Milligram 1 time Oral 3atch: Started: Stopped: aboratory Investigations:						
ANAFRANIL (Suspected) Tablet 75.0 Milligram 1 time Oral 3atch: Started: Stopped:						
ANAFRANIL (Suspected) Tablet 75.0 Milligram 1 time Oral 3atch: Started: Stopped:						
Tablet 75.0 Milligram 1 time Oral 3atch: Started: Stopped: aboratory Investigations:						
aboratory Investigations:						
aboratory Investigations:				Ailligram 1 time		
	3atch:		Started:		Stopped:	
				d Result		Details
				ed Result		Details
				ed Result		Details
				ed Result		Details
				ed Result		Details
				ed Result		Details
				ed Result		Details
additional Information:	Date	Туре		ed Result		Details
additional Information:	Date	Туре		ed Result		Details
Additional Information:	Date	Туре		ed Result		Details
dditional Information:	Date	Туре		ed Result		Details
dditional Information:	Date	Туре		ed Result		Details

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report I	Detail
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Case Number: 71052 Seq: 1 Gender: F

Reported: 28/05/1991 Weight: 50.00 Hospitalisation: Age: 36Y

Onset Date: 22/04/1991 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Paraesthesia			

Medicine Details:

ANAFRANIL (Suspected) Reason: Depression

50.0 Milligram 1 time

3atch: **3tarted**: 22/04/1991 **3topped**:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail				
Case Number: 71332 Reported: 17/06/1991 ospitalisation:	Seq: 1		Ag	ht: 82.00 je: 70Y
Onset Date: 08/06/1991 Outcome: Recovered			DO Causalit	B: ty: Causality probable
eaction Detai			D : "	
Preferred Term	Severity	Report	Description	Treatment
Orthostatic hypotension Syncope				
ledicine Details:				
ANAFRANIL (Suspected)		Reaso	·	
Зatch:	50.0 ! 3tarted: 23/0	Milligram	Daily Stopped: 06/06/1	004
_aboratory Investigatio	Range Date Teste	ed Result		retails
Additional Information:				
Auditional information:				



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 71710 Seq: 1 Gender: F

Reported: 06/07/1991 Weight: 60.00 Hospitalisation: Age: 30Y

Onset Date: 05/07/1991 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Syncope		Vasovagal reaction	
Hyperhidrosis			
Nausea			

Medicine Details:

HISMANAL (Suspected)		Reason:	Hay fever	
Oral application	10.0 Milligram	Daily	Oral	
3atch:	3tarted: 03/07/1991		Stopped:	CONTIN
ANAFRANIL (Suspected)		Reason:	Obsessive compulsive neur	osis
Tablet	25.0 Milligram	Daily	Oral	
I abict	25.0 Willigram	Daily	Olai	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Also had consumed 2 x whisky's prior to taking medications



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 71989
 Seq:
 1
 Gender:
 M

 Reported:
 26/07/1991
 Weight:
 89.00

 Hospitalisation:
 Age:
 34Y

Onset Date: 11/06/1991 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Leaction Detai			
Preferred Term	Severity	Report Description	Treatment
Deafness		Blocked ears.	
Ejaculation failure		Delayed ejaculation	
Hyperhidrosis		Profuse sweating	
Tongue oedema		Tongue swelled to twice normal size	
Dizziness			
Glossitis			
Nausea			

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	Anxiety neuro	osis
Tablet	750.0 Milligram	Daily		Oral
3atch:	3tarted: 16/01/1991		Stopped:	
MINOMYCIN (Other drug)		Reason:	Acne variolifo	rmis
Tablet	200.0 Milligram	Daily		Oral
Зatch:	3tarted: 06/06/1991		Stopped:	
ANAFRANIL (Suspected)		Reason:	Depression	
Tablet	50.0 Milligram	Daily		Oral
3atch:	3tarted: 11/06/1991		Stopped:	25/06/1991

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

Case Number: 72046 Seq: 1 Gender: F

Reported: 30/06/1991 Weight: 57.00 Hospitalisation: Age: 39Y

Onset Date: 31/01/1991 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Oedema		Oedema of face and hands	
Dyspnoea		Paroxysmal nocturnal dyspnoea	
Cardiomyopathy			
Hyperhidrosis			
Left ventricular failure			Captopril & frusemide, commenced on mianserin
Tachycardia			

Medicine Details:

SEREPAX (Other drug)		Reason:		
Tablet	60.0 Milligram	Daily	Oral	
Зatch:	Started:	Stop	pped:	
MICROLUT (Other drug)		Reason:		
Tablet	1.0 Dose Unspec	cified Daily	Oral	
Зatch:	Started:	Stop	pped:	
ANAFRANIL (Suspected)		Reason: Depres	sion	
Tablet	250.0 Milligram	Daily	Oral	
3atch:	Started: 01/11/1990	}top	pped: 22/03/1991	
INDERAL (Suspected)		Reason: Excess	sive sweating	
Tablet	80.0 Milligram	Daily	Oral	
3atch:	Started: 01/01/1991	}top	pped: 28/03/1991	

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

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 73066 Seq: 1 Gender: M

Reported: 23/09/1991 Weight: 65.00 Hospitalisation: Age: 48Y

Onset Date: 05/08/1991 **DOB**:

Outcome: Recovered Causality: Causality certain

Reaction Detai

Preferred Term Severit		Report Description	Treatment		
Malaise		Flu like feeling			
Visual disturbance		Visual distortion - rippling effect			
Nausea					
Urinary retention	Required Specialist Consultation				

Medicine Details:

ANAFRANIL (Suspected) Reason:

50.0 Milligram Daily

3atch: 3tarted: 05/08/1991 3topped: 09/08/1991

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Symptoms occured on each occasion with anafranil



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 73171
 Seq:
 1
 Gender:
 F

 Reported:
 28/09/1991
 Weight:
 80.00

 Hospitalisation:
 Age:
 41Y

Onset Date: 13/09/1991 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion Dotal		<u> -</u>	_
Preferred Term Severity		Report Description	Treatment
Tremor		Fine tremor of hands	
Hyperhidrosis		Profuse sweating of neck and head.	
Rash		Redness of head and neck.	

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Susp	ected)	Reason:	Depression	
	75.0 Millig	gram Daily		
3atch:	3tarted: 13/09/19	91	Stopped:	CONTIN
NATRILIX (Suspected)		Reason:		
	1.0 Dos	e Unspecified Daily		
Зatch:	Started:		Stopped:	
INDERAL (Suspected)		Reason:		
	120.0 Millig	gram Daily		
Заtch:	Started:		Stopped:	
XANAX (Suspected)		Reason:		
	0.5 Millig	gram Daily		
3atch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Dose of clomipramine commenced at 150 mg and was decreased to 75 mg



Case Number: 73484

Reported: 18/10/1991

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 55.00

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Seq: 1

Hospitalisati			Age : 35Y						
	ate: 23/08/199		DOB:						
	me: Recovered	d				Causality: Ca	ausality proba	able	
Reaction D	etaı ferred Term	Sov	ority.	Donor	t Description	1	Treatment		
Tremor	ienea reim	Seve		•	Description		пеаннени		
Anxiety			Shak	ang.					
Hyperhidrosi	ie								
Nausea									
Vomiting									
Medicine									
ANAFRANIL			50.0 14:00	Reas					
Table 3atch		240	50.0 Milli rted: 23/08/1	-	1 time	Oral			
	y Investigat								
Date	Туре	Range	Date Tested	Result		Details			
Additiona	l Informatio	1:							
eport Run 20/0	07/200 09:54AN	Database: pu	sime	А	DRS004		Page 30	of 164	



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Case Number: 73485	Seq: 1		G	ender: M
Reported: 18/10/1991	•			Veight: 85.00
lospitalisation:				Age : 29
Onset Date: 29/08/1991				DOB : 30/05/1962
Outcome: Recovered			Cau	sality: Causality probable
eaction Detai				
Preferred Term	Severity	Repo	ort Description	Treatment
Tremor		Shaking.		
Anxiety				
Hyperhidrosis				
Nausea				
Vomiting				
Medicine Details: ANAFRANIL (Suspected)		200	Dorrossion	
Tablet	50 (Rea) Milligram	son: Depression 1 time O	ral
Batch:	Started: 29		itopped:	iai
Laboratory Investigation				
Date Type	Range Date Te	ested Result		Details
Additional Information:	•			
eport Run 20/07/200 09:54AN	Database: pusime		ADRS004	Page 31 of 164



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail		
Case Number: 73811	Seq: 1	Gender: F
Reported: 29/10/1991		Weight: 44.00
Hospitalisation:		Age: 61Y

Onset Date: 19/10/1991 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Dystonia			

Medicine Details:

ANAFRANIL (Suspected) Reason: Depression

1.0 Dose Unspecified Daily

3atch: 3tarted: 18/10/1991 3topped: 19/10/1991

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report De	tail						
lospitalisation Onset Da Outcor	ed: 24/01/199 on: Admitted tate: me: Recovered	to hospital	1		C	Gender: Weight: Age: DOB: Causality:	36Y
eaction De	etaı ferred Term	Seve	rity	Renor	Description		Treatment
Constipation		Severe	inty	Пороп	Bedeription		Trediment
Medicine I	Details:						
	INE HYDROCHLO	RIDE (Suspected)	Reas	on: Depression		
3atch:	:	€tari	0.0 ted:		Stopped:		
SENOKOT (St	uspected)			Reas			
Tablet	t		20.0 Dos	e Unspecified	Daily	Oral	
3atch:	:	€tart	ted:	L TERM	Stopped:		
_aboratory	y Investigat		Date Tested	Result		Deta	ils



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail				
Case Number: 75190	Seq: 1		Ger	nder: F
Reported: 24/01/19	92		We	ight:
ospitalisation:				Age: 22Y
Onset Date:			Γ	OOB:
Outcome: Recovered	ed		Caus	ality: Causality possible
eaction Detai				<u>†</u>
Preferred Term	Severity	Report I	Description	Treatment
Constipation	Severe			
/ledicine Details:				
CLOMIPRAMINE HYDROCHLO	ORIDE (Suspected)	Reasor	n: Depression	
	0.0			
3atch:	Started:		Stopped:	
SENOKOT (Suspected)		Reasor		
Tablet	20.0	Dose Unspecified [
3atch:	Started:		Stopped:	06M
_aboratory Investiga	tions:			
Date Type	Range Date Tes	ted Result		Details



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 75426 Seq: 1 Gender: M

Reported: 12/12/1991 Weight: 85.00
Hospitalisation: Age: 26Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Mania			

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Suspected) Reason: Depression

0.0

3atch: 3tarted: 01/10/1991 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.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 75718 Seq: 1 Gender: F

Reported: 25/02/1992 Weight: 70.00 Hospitalisation: Age: 28Y

Onset Date: 12/02/1992 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			

Medicine Details:

PRIADEL (Other drug)			Reason:	Unspecifid affective psycho	sis
Tablet	800	0.0 Milligram	Daily	Oral	
3atch:	Started:		L TERM	Stopped:	CONTIN
STELAZINE (Other drug)			Reason:	Unspecifid affective psycho	sis
Oral application	5	5.0 Milligram	Daily	Oral	
3atch:	Started:	01/02/1991		Stopped:	CONTIN
ANAFRANIL (Suspected)			Reason:		
Tablet	C	0.0		Oral	
3atch:	Started:	10/02/1992		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction happen on three separate occassions. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Case Number: 76010 Seq: 1 Gender: F Reported: 16/03/1992 Weight: Age: 29Y Onset Date: 02/03/1992 DOB: Outcome: Recovered Causality: Causality proba eaction Detail Preferred Term Severity Report Description Treatment Anxiety Nausea Vomiting Medicine Details: ANAFRANIL (Suspected) Reason: Depression Tablet 25.0 Milligram Daily Oral 3atch: Started: 02/03/1992 Stopped: 04/03/1992					
Onset Date: 02/03/1992 DOB: Ontcome: Recovered Causality: Causality probabation: Preferred Term Severity Report Description Treatment Anxiety Natusea Anomiting Medicine Details: ANAFRANIL (Suspected) Tablet 25.0 Milligram Daily Oral Batch: Started: 02/03/1992 Stopped: 04/03/1992 Anaboratory Investigations:	Reported. 10/03/1992	Seq: 1			
Onset Date: 02/03/1992 Outcome: Recovered Recovered Causality: Causality probabaction Detail Preferred Term Severity Report Description Treatment Anxiety Nausea //omiting Medicine Details: ANAFRANIL (Suspected) Reason: Depression Tablet 25.0 Milligram Daily Oral 3atch: 3tarted: 02/03/1992 3topped: 04/03/1992				•	_
Outcome: Recovered Preferred Term Severity Report Description Treatment Anxiety Nausea //omiting Medicine Details: ANAFRANIL (Suspected) Patch: 3tarted: 02/03/1992 Stopped: 04/03/1992 Anafranic Started: 02/03/1992 Stopped: 04/03/1992 Aboratory Investigations:					
Preferred Term Severity Report Description Treatment Anxiety Nausea Anxiety Nause				Cai	
Preferred Term Severity Report Description Treatment Anxiety Nausea //omiting Medicine Details: ANAFRANIL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: 3tarted: 02/03/1992 3topped: 04/03/1992 aboratory Investigations:					,
Medicine Details: ANAFRANIL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: 3tarted: 02/03/1992 3topped: 04/03/1992		Severity	Report De	escription	Treatment
Medicine Details: ANAFRANIL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: 3tarted: 02/03/1992 3topped: 04/03/1992	nxiety				
Medicine Details: ANAFRANIL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: 3tarted: 02/03/1992 3topped: 04/03/1992	lausea				
ANAFRANIL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: 02/03/1992 Stopped: 04/03/1992 aboratory Investigations:	omiting/				
ANAFRANIL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: 3tarted: 02/03/1992 3topped: 04/03/1992 Aboratory Investigations:					
Tablet 25.0 Milligram Daily Oral 3atch: 3tarted: 02/03/1992 3topped: 04/03/1992 aboratory Investigations:			Reason:	Depression	
aboratory Investigations:		25.0 Mil	ligram Da		Oral
aboratory Investigations:	3atch:	Started: 02/03/1	1992	Stopped: 0	4/03/1992
Date Type Range Date Tested Result Details					
77	Date Type	Range Date Tested	Result		Details
Additional Information:	Additional Information:				



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

Case Number: 76114 Seq: 1 Gender: F

Reported: 21/03/1992 Weight: 60.00 Hospitalisation: Age: 30Y

Onset Date: 10/02/1992 **DOB:**

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Tachycardia			

Medicine Details:

RIVOTRIL (Other drug) Reason: Anxiety neurosis

1.0 Milligram Daily

3atch: Started: 01/08/1991 Stopped: CONTIN

ANAFRANIL (Suspected) Reason: Transient situational disturb

25.0 Milligram Daily

3atch: 3tarted: 06/02/1992 3topped: 11/02/1992

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: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 76138
 Seq: 1
 Gender: M

 Reported:
 18/03/1992
 Weight:

Hospitalisation: Age: 32Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Nervousness			

Medicine Details:

Medicine Details:			
MODECATE (Other drug)	\$	leason:	
	0.0		
3atch:	Started:	Stopped:	
ANAFRANIL (Suspected)	2	leason:	
Tablet	150.0 Milligram	Daily	Oral
3atch:	Started: 01/06/1991	Stopped:	28/02/1992

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



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

Case Number: 76139 Seq: 1 Gender: M

Reported: 18/03/1992 Weight:
Hospitalisation: Age: 36Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agitation			

Medicine Details:

ANAFRANIL (Suspected) Reason:

 Tablet
 50.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/11/1991
 3topped:
 28/02/1992

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

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail							
Case Number: 77 Reported: 18 Hospitalisation: Onset Date: 15 Outcome: Re	3/05/1992 5/04/1992	Seq:	1		C	Gender: Weight: Age: DOB: Causality:	88.00 43Y
Preferred T	erm	Seve	erity	Repor	Description		Treatment
Hepatitis Hot flush	<u></u>			T (Opon	Весоприст		
Medicine Details: ANAFRANIL (Suspected) Tablet 75.0 Milligram Daily Oral 3atch: \$tarted: 31/03/1992 \$topped: 01/05/1992							
Laboratory Inve							
Date Ty	ре	Range	Date Tested	Result		Deta	ils
Additional Infor	mation:						



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 77392 Seq: 1 Gender: M

Reported: 03/06/1992 Weight: 78.00 Hospitalisation: Age: 51Y

Onset Date: 28/05/1992 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis Severe			Antibiotic cover.

Medicine Details:

Medicine Betans.						
DIAZEPAM (Other drug)	Reason:					
	5.0 Milligram	As necessary				
3atch:	Started:	Stopped:				
PROTHIADEN (Suspected)		Reason:				
	0.0					
3atch:	Started: 01/12/1991	Stopped:				
ANAFRANIL (Suspected)		Reason: Depression				
	100.0 Milligram	Daily				
3atch:	Started: 06/04/1992	Stopped:	28/05/1992			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	5-44 U/L	28/05/1992	44	
	Bilirubin	0-20 UMOL/L	28/05/1992	30	
	GGT = SGGT =	0-60 U/L	28/05/1992	62	
	Lymphocytes	1.5-4.0	28/05/1992	0.5	
	Lymphocytes	1.5-4.0	29/05/1992	-	
	Lymphocytes	1.5-4.0	31/05/1992	-	
	Lymphocytes	1.5-4.0	01/06/1992	1.4	

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: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 77392 Seq: 1 Gender: M

Reported: 03/06/1992 Weight: 78.00 Hospitalisation: Age: 51Y

Onset Date: 28/05/1992 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

Modifile Botalie:								
DIAZEPAM (Other drug)	Reason:							
	5.0 Milligram	As necessary						
Зatch:	Started:	Stopped:						
PROTHIADEN (Suspected)		Reason:						
	0.0							
Зatch:	Started: 01/12/1991	Stopped:						
ANAFRANIL (Suspected)		Reason: Depression						
	100.0 Milligram	Daily						
Зatch:	Started: 06/04/1992	Stopped:	28/05/1992					

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Lymphocytes	1.5-4.0	30/05/1992	0.7	
	Lymphocytes	1.5-4.0	04/06/1992	3.2	
	Monocytes	0.2-0.8	28/05/1992	0.0	
	Monocytes	0.2-0.8	31/05/1992	-	
	Monocytes	0.2-0.8	04/06/1992	0.4	
	Monocytes	0.2-0.8	01/06/1992	0.1	
	Monocytes	0.2-0.8	30/05/1992	-	

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: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

Case Number: 77392 Gender: M Seq: 1

Reported: 03/06/1992 Weight: 78.00 Hospitalisation: Age: 51Y

Onset Date: 28/05/1992 DOB: Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

DIAZEPAM (Other drug) Reason: 5.0 Milligram As necessary Started: 3atch: Stopped: **PROTHIADEN (Suspected)** Reason: 0.0 3tarted: 01/12/1991 3atch: Stopped:

Depression **ANAFRANIL** (Suspected) Reason:

> 100.0 Milligram Daily

3tarted: 06/04/1992 28/05/1992 3atch: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Monocytes	0.2-0.8	29/05/1992	-	
	Neutrophils	2.0-7.5	28/05/1992	0.1	
	Neutrophils	2.0-7.5	29/05/1992	-	
	Neutrophils	2.0-7.5	30/05/1992	0.0	
	Neutrophils	2.0-7.5	04/06/1992	2.0	
	Neutrophils	2.0-7.5	01/06/1992	0.1	
	Neutrophils	2.0-7.5	31/05/1992	-	

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: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 77392 Seq: 1 Gender: M

 Reported:
 03/06/1992
 Weight:
 78.00

 Hospitalisation:
 Age:
 51Y

Onset Date: 28/05/1992 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

DIAZEPAM (Other drug)			
	5.0 Milligram	As necessary	
3atch:	Started:	Stopped:	
PROTHIADEN (Suspected)		Reason:	
	0.0		
3atch:	Started: 01/12/1991	Stopped:	
ANAFRANIL (Suspected)		Reason: Depression	
	100.0 Milligram	Daily	
3atch:	Started: 06/04/1992	Stopped:	28/05/1992

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP	39-117	28/05/1992	101	
	White blood cells	4.0-11.0	28/05/1992	0.8	
	White blood cells	4.0-11.0	29/05/1992	0.8	
	White blood cells	4.0-11.0	30/05/1992	0.8	
	White blood cells	4.0-11.0	31/05/1992	1.0	
	White blood cells	4.0-11.0	01/06/1992	1.8	
	White blood cells	4.0-11.0	04/06/1992	7.6	

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: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 77536 Seq: 1 Gender: F

Reported: 06/06/1992 Weight: 51.00 Hospitalisation: Age: 78Y

Onset Date: 20/05/1992 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Detai

	-	-	
Preferred Term	Severity	Report Description	Treatment
Abdominal pain	Severe		
Vomiting			

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Suspected) Reason:

 Tablet
 25.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 20/05/1992
 3topped:
 20/05/1992

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction occured on two occasions when attempting to implement a small dose (25mg) of clomipramine.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 77660
 Seq:
 1
 Gender:
 F

 Reported:
 16/06/1992
 Weight:
 53.00

 Hospitalisation:
 Admitted to hospital
 Age:
 30Y

 Onset Date:
 16/06/1992
 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Neaction Detai			
Preferred Term	Severity	Report Description	Treatment
Tachycardia		Pulse 142	
Pyrexia		Temperature 38.2	
Agitation			
Dry mouth			
Hyperhidrosis			
Syncope			
Visual disturbance			
Vomiting			

Medicine Details:

ATIVAN (Other drug)			Reas	on:	Depression		
Tablet		3.0	Dose Unspecified	Daily		Oral	
3atch:	Started:	16/	06/1990		Stopped:		CONTIN
NORMISON (Other drug)			Reas	on:			
Capsule		1.0	Dose Unspecified	Daily		Oral	
3atch:	Started:	16/	06/1992		Stopped:		CONTIN
NARDIL (Suspected)			Reas	on:	Depression		
NARDIL (Suspected) Tablet		2.0	Reas Dose Unspecified		Depression	Oral	
	Started:				Depression Stopped:	Oral 16/06/1992	
Tablet	Started:		Dose Unspecified	Daily	·		
Tablet 3atch:	Started:	16/	Dose Unspecified 06/1990	Daily	Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report I	Detail
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 Case Number:
 77697
 Seq:
 1
 Gender:
 M

 Reported:
 18/06/1992
 Weight:
 70.00

 Hospitalisation:
 Age:
 42Y

Onset Date: 18/05/1992 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure		Retarded ejaculation	

Medicine Details:

ANAFRANIL (Suspected) Reason: Depression

 Tablet
 25.0 Milligram
 Daily
 Oral

 3atch:
 3tarted: 16/04/1992
 3topped: 18/06/1992

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 79512 Seq: 1 Gender: M

Reported: 18/09/1992 Weight: 62.00 Hospitalisation: Age: 40Y

Onset Date: 04/09/1992 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Nausea	Severe		
Vomiting			

Medicine Details:

ANAFRANIL (Suspected) Reason: Depression

 Tablet
 25.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 02/09/1992
 3topped:
 07/09/1992

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was rechallenged on anafranil several times with same reaction



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 80104 Seq: 1 Gender: F

Reported: 29/09/1992 Weight: 74.00 Hospitalisation: Age: 46Y

Onset Date: 09/09/1992 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Dizziness			
Nausea			

Medicine Details:

ANAFRANIL (Suspected) Reason: Irritable colon

25.0 Milligram Daily

3atch: 3tarted: 09/09/1992 3topped: 10/09/1992

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction recurred when 2nd dose of anafranil tried.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 81360 Seq: 1 Gender: F

Reported: 07/12/1992 Weight: 61.00 Hospitalisation: Age: 69Y

Onset Date: 30/11/1992 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Mania			

Medicine Details: ANAFRANIL (Suspected)

	100.0 Milligram	Daily	·			
3atch:	Started: 01/10/1992		Stopped:	05/11/1992		
PROTHIADEN (Suspected)		Reason:	Depression			
	150.0 Milligram	Daily				
3atch:	3tarted: 08/11/1992		3topped:		CONTIN	

Reason:

Depression

OXAZEPAM (Suspected) Reason: Specific disorders of sleep

60.0 Milligram Daily

3atch: Started: L TERM Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Acute hypomania secondary to concurrent tca and electoconvulsive treatment.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail				
Case Number: 82243	Seq: 1		Ger	nder: F
Reported: 27/01/1993			We	ight:
Hospitalisation:				Age: 47Y
Onset Date: 21/01/1993				OOB:
Outcome: Recovered			Causa	ality: Causality probable
eaction Detai				·
Preferred Term	Severity	Report	Description	Treatment
Diarrhoea				
Flushing				Ceased drug.
Hyperhidrosis				
Nausea				
Vomiting				
Medicine Details: ANAFRANIL (Suspected)		Reaso	n: Depression	-
(Gaopotta)	25.0 Mil		Daily	
3atch:	Started: 21/01/			1/1993
Laboratory Investigation				
Data Tuna	Range Date Tested	Result		Details
Date Type		I .		



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 85853
 Seq: 1
 Gender: U

 Reported:
 05/07/1993
 Weight:

Hospitalisation: Age:
Onset Date: 30/06/1993
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

reaction Detai			
Preferred Term	Severity	Report Description	Treatment
Hallucination			
Tachycardia			
Tremor			

Medicine Details:

VALIUM (Other drug)	Reas	on:	Anxiety neurosis	
Tablet	3.7 Milligram	Daily	Oral	
3atch:	Started: L TERM		Stopped:	
NORMISON (Other drug)	Reas	on:	Anxiety neurosis	
	1.0 Dose Unspecified	Daily		
3atch:	Started: 01/01/1992		Stopped:	
ESTRADERM (Other drug)	Reas	on:		
	50.0 Microgram	Daily		
Зatch:	Started: 01/01/1992		Stopped:	
ANAFRANIL (Suspected)	Reas	on:		
	0.0			
Зatch:	Started: 10/06/1993		Stopped:	1W

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 85943 Seq: 1 Gender: F

Reported: 09/07/1993 Weight: 60.00 Hospitalisation: Age: 48Y

Onset Date: 20/02/1993 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hair texture abnormal		Hair straighter.	
Alopecia			

Medicine Details:

ANAFRANIL (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 01/11/1992 3topped: 28/02/1993

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 86794 Seq: 1 Gender: M

Reported: 13/08/1993 Weight: 76.00 Hospitalisation: Age: 46Y

Onset Date: 03/08/1993 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Headache			

Medicine Details:

XANAX (Other drug) Reason: Anxiety neurosis

500.0 Microgram As necessary

3atch: 3tarted: 11/06/1993 3topped:

ANAFRANIL (Suspected) Reason: Depression

75.0 Milligram Daily

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has had no known previous allergies.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number:87132Seq:1Gender:FReported:24/08/1993Weight:65.00Hospitalisation:Treated in outpatient department only.Age:31Y

Onset Date: 14/08/1993 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Preferred Term Severity Report Description		Treatment					
Atrial fibrillation			Propanolol 1mg iv.					
Nausea								
Tachycardia								
Vomiting								

Medicine Details:

ANAFRANIL (Suspected)			Reason:	Depression	
Tablet	50.0 M	lilligram	Daily		Oral
3atch:	Started:			Stopped:	

Laboratory Investigations:

					
Date	Туре	Range	Date Tested	Result	Details
	Electrographics				Atrial fibrillation rate 200/min.

Additional Information:

Previously treated with anaphranil 150mg daily, 12 months ago - reactions of sweating, dry mouth and sinus tachycardia.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Repo	ort D	etai
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 Case Number:
 87629
 Seq:
 1
 Gender:
 F

 Reported:
 13/09/1993
 Weight:
 80.00

Hospitalisation: Age: 39Y

Onset Date: 06/09/1993 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Anxiety	Severe		

Medicine Details:

LEXOTAN (Suspected)	Reason:				
	2.0	Dose Unspecified	As necess	sary	
3atch:	Started:	L TERM		Stopped:	
ANAFRANIL (Suspected)		Reas	on:		
	50.0	Milligram	Daily		
3atch:	3tarted: 05	/09/1993		Stopped:	06/09/1993
	Reason:				
SURMONTIL (Suspected)		₹eas	on:		
SURMONTIL (Suspected)	50.0	Reas Milligram	on: Daily		
SURMONTIL (Suspected) 3atch:	50.0 3tarted:		Daily	}topped:	
		Milligram	Daily	Stopped:	
3atch:		Milligram L TERM	Daily	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Case Number: 87629 Reported: 13/09/1993 Hospitalisation: Onset Date: 06/09/1993 Outcome: Not yet recovered Reaction Detai	Seq: 1		Gender: Weight: Age: DOB: Causality:	80.00
Medicine Details:				
RENITEC (Suspected)	10.0 Million	Reason:		
3atch:	10.0 Milligra	am Daily L TERM	Stopped:	
Laboratory Investigations:				
Additional Information:				

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

 Case Number:
 89373
 Seq: 1
 Gender: M

 Reported:
 24/11/1993
 Weight: 111.00

Hospitalisation: Age: 54Y
Onset Date: 31/10/1993
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction			
Peyronie's disease			

Medicine Details:

LIPEX (Suspected)		Reason:	Othr&unspec metabolic of	diseases
Tablet	10.0 Milligram	Daily	Oral	
3atch:	Started: 01/08/1992		Stopped:	CONTIN
ANAFRANIL (Suspected)		Reason:	Phobic neurosis	
Tablet	250.0 Milligram	Daily	Oral	
3atch:	3tarted: 01/12/1990		Stopped:	CONTIN
RIVOTRIL (Suspected)		Reason:	Phobic neurosis	
Tablet	4.0 Milligram	Daily	Oral	
3atch:	Started: 01/04/1992		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. 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: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

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\mathbf{r}	ㄷ	u	u	'I L	ப	eta	

 Case Number:
 91169
 Seq:
 1
 Gender:
 F

 Reported:
 21/02/1994
 Weight:
 83.00

 Hospitalisation:
 Age:
 60Y

Hospitalisation: Age: Onset Date: 09/02/1994 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Severe		
Flushing	Severe		
Insomnia	Severe		
Nystagmus	Severe		
Urticaria			
Vomiting	Severe		

Medicine Details:

ESTRADERM (Other drug)			Reason:	Menopausal symptoms	
Cream	50.0	Milligram	Week	dy Transdermal	
3atch:	Started:		L TERM	Stopped:	
SEREPAX (Other drug)			Reason:	Anxiety neurosis	
	30.0	Milligram	Daily		
3atch:	Started:		L TERM	Stopped:	
PROVERA (Other drug)			Reason:	Menopausal symptoms	
Tablet	10.0	Milligram	Daily	Oral	
3atch:	Started:		L TERM	Stopped:	
ANAFRANIL (Suspected)			Reason:	Anxiety neurosis	
	25.0	Milligram	1 time	е	
3atch:	Started: 09	/02/1994		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Report Detail

Hospitalisation:

Reaction Detai

Convulsion

Dystonia Hyponatraemia

Case Number: 91483

Reported: 09/03/1994

Onset Date: 20/02/1994

Preferred Term

Additional Information:

Outcome: Recovered

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Report Description

Gender: M

DOB:

Weight: 22.00

Age: 12Y

Causality: Causality probable

Treatment

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Seq: 1

Severity

Severe

PULMICORT (Other drug)			₹6	ason:		
			400.	0 Microgram	Daily		
3atch:		3	tarted:	L TEF	RM	Stopped:	
RICANYL (O	ther drug)			₹6	ason:		
Inhala	tion		4.	0 Dose Unspecific	ed Daily		Inhalation
3atch:		3	tarted:	L TEF	RM	Stopped:	
NAFRANIL (Suspected)			36	ason:	Depression	
Tablet			50.	0 Milligram	Daily		Oral
3atch:		3	tarted: 1	8/02/1994		Stopped:	20/02/1994
nborator	/ Investigat	ions:					
	Туре	Range	Date T	ested Result			Details

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

 Case Number:
 91699
 Seq:
 1
 Gender:
 F

 Reported:
 16/03/1994
 Weight:
 63.00

Hospitalisation: Age: 56Y
Onset Date: 16/01/1994
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Arthralgia Mouth ulceration Myalgia Purpura Thrombocytopenia			Prednisone 50mg daily and iv gammaglobulin 0.4gm/kg/day for 3 days

Medicine Details:

Micaronic Details.					
MULTIVITAMINS (Other drug)	Reason:				
	1.0 Do	ose Unspecified Daily			
Зatch:	Started:		Stopped:		
ANAFRANIL (Suspected)		Reason:	Depression		
Tablet	50.0 Mi	illigram Daily		Oral	
Зatch:	3tarted: 16/12/	/1993	Stopped:	14/01/1994	
NATURE'S OWN CALCIUM & MAGNESI	UM (Suspected)	Reason:	Pain in limb		
Tablet	1.0 Do	ose Unspecified Daily		Oral	
Batch:	Started: 01/11/	/1993	Stopped:	17/01/1994	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Platelets	150-450	17/01/1994	3	
	Platelets	150-450	18/01/1994	1	
	Platelets	150-450	21/01/1994	1	
	Platelets	150-450	24/01/1994	25	
	Platelets	150-450	27/01/1994	219	
	Platelets	150-450	07/03/1994	245	

Additional Information:

Drug induced thrombocytopenia due to chloroquine 6 1/2 years ago. has not been exposed on this occasion (including tonic water and lemon squeeze. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report l	Detail
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Case Number: 92783 Seq: 1 Gender: F

Reported: 05/05/1994 Weight: 85.00 Hospitalisation: Age: 33Y

Onset Date: 14/05/1993 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Caction Detai			
Preferred Term	Severity	Report Description	Treatment
Fatigue			
Hepatic function abnormal			
Malaise			
Nausea			

Medicine Details:

MEGICINE DELANS.			
KEFLEX (Other drug)		Reason:	
Oral application	100.0 Milligram	Daily	Oral
3atch:	Started:	Stopped:	
ANAFRANIL (Suspected)		Reason:	
	1.0 Dose Unspec	ified Daily	
3atch:	Started: 07/05/1993	Stopped:	14/05/1993

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		14/05/1993	175	
	AST = SGOT		14/05/1993	177	
	GGT = SGGT =		14/05/1993	81	



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Repo	ort D	etai
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Case Number: 93904 Seq: 1 Gender: F

Reported: 24/06/1994 Weight:
Hospitalisation: Age: 68Y

Onset Date: 24/08/1993 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Detai

todotion Dotal			
Preferred Term	Severity	Report Description	Treatment
Yawning			

Medicine Details:

TEGRETOL (Other drug)			Reason:			
Oral application	200.0	Milligram	Daily		Oral	
3atch:	Started:			Stopped:		CONTIN
OXAZEPAM (Other drug)			Reason:			
Tablet	45.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:		CONTIN
TEMAZEPAM (Other drug)			Reason:			
TEMAZEPAM (Other drug)	20.0	Milligram	Reason: Daily			
TEMAZEPAM (Other drug) 3atch:	20.0 Started:	Milligram		}topped:		CONTIN
, ,	Started:	Milligram		Stopped:		CONTIN
3atch:	Started: pected)	Milligram Milligram	Daily	Stopped:	Intravenous	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

Case Number: 96010 Seq: 1 Gender: F

Reported: 22/09/1994 Weight: 60.00 Hospitalisation: Age: 38Y

Onset Date: 31/12/1991 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Involuntary movement of right jaw	

Medicine Details:

ANAFRANIL (Suspected) Reason: Depression

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

Case Number: 96340 Seq: 1 Gender: F

Reported: 07/10/1994 Weight: 62.00
Hospitalisation: Age: 62Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis			

Medicine Details:

SIMVASTATIN (Suspected)		Reason:	Othr&unspec	metabolic diseases
Tablet	10.0 Milligram	Daily		Oral
3atch:	Started: 01/01/1992		Stopped:	28/10/1994
OESTROGENS NOS (Suspected)		Reason:		
	625.0 Microgram	Daily		
3atch:	Started: 01/01/1981		Stopped:	28/10/1994
CLOMIPRAMINE HYDROCHLORIDE (S	Suspected)	Reason:		
	25.0 Milligram	Daily		
3atch:	3tarted: 01/01/1987		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 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. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report	: Detail
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 Case Number:
 96624
 Seq:
 1
 Gender:
 F

 Reported:
 19/10/1994
 Weight:

Hospitalisation: Age: AD

Onset Date: 02/10/1994 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Detai

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Acidosis			Intubation, ventilation
Neonatal respiratory distress syn			

Medicine Details:

<u>Medicine Details:</u>			
FENTANYL CITRATE (Suspected)		Reason:	
	0.0		
3atch:	Started:	Stopped:	
CLOMIPRAMINE HYDROCHLORID	E (Suspected)	Reason: Depression	
	150.0 Milligram	Daily	
3atch:	Started:	Stopped:	9M

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Profound respiratory acidosis with retained foetal lung fluid. need for intubation and ventilation. rapid return to normal carbon dioxide exchange. infant was then agitated and jittery and took some days to return to normal behaviour. levels were not collected. sequelae: unsettled behaviour, feeding, hypertonic transit problems. mother taking clomipramine in a single nocturnal dose during whole pregnancy.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 97120 Seq: 1 Gender: M

Reported: 16/11/1994 Weight: 38.00 Hospitalisation: Age: 14Y

Onset Date: 09/11/1994 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

TOWARD DOTAL			
Preferred Term	Severity	Report Description	Treatment
Hallucination		Hearing voices	
Thinking abnormal		No coherent thought procedures	
Psychotic disorder			

Medicine Details:

ANAFRANIL (Suspected) Reason: Otr spec symp psychopathol nec

100.0 Milligram Daily

3atch: 3tarted: 20/10/1994 3topped: 11/11/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Similar reaction to tofranil



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

 Case Number:
 97242
 Seq:
 1
 Gender:
 M

 Reported:
 21/11/1994
 Weight:

Hospitalisation: Age: 12

Onset Date: 03/10/1994 **DOB**: 28/07/1982

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Purpura		Rash on neck and shoulders	

Medicine Details:

ANAFRANIL (Suspected) Reason:

 Tablet
 75.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 05/09/1994
 3topped:
 03/10/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 97243 Seq: 1 Gender: F
Reported: 21/11/1994 Weight:

Hospitalisation: Admitted to hospital Age: 57
Onset Date: DOB: 23/07/1937

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Purpura		Multiple bruises and petechial spots.	Predisone, iv gamma globlin.
Arthralgia			
Myalgia			

Medicine Details:

Modicino Botano.			
VITAMIN NOS (Other drug)	3	eason:	
Tablet	0.0		Oral
Зatch:	Started:	Stopped:	
PREMARIN (Other drug)	2	eason:	
	300.0 Microgram	Daily	
Зatch:	Started:	Stopped:	
ANAFRANIL (Suspected)	2	eason:	
Tablet	50.0 Milligram	Daily	Oral
3atch:	Started: 16/12/1993	Stopped:	17/10/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haemoglobin	(119-165)	17/01/1994	136	
	Haemoglobin	(119-165)	19/01/1994	115	
	Haemoglobin	(119-165)	20/01/1994	121	
	Haemoglobin	(119-165)	27/01/1994	121	
	Haemoglobin	(119-165)	24/01/1994	135	
	Platelets	(150-450)	17/01/1994	3	
	Platelets	(150-450)	19/01/1994	2	



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail				
Case Number:	97243	Seq:	1	Gender: F
Reported:	21/11/1994			Weight:

Hospitalisation: Admitted to hospital Age: 57

Onset Date: DOB: 23/07/1937

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

VITAMIN NOS (Other drug)	4	leason:	
Tablet	0.0		Oral
3atch:	Started:	Stopped:	
PREMARIN (Other drug)	Reason:		
	300.0 Microgram	Daily	
3atch:	Started:	Stopped:	
ANAFRANIL (Suspected)	4	leason:	
Tablet	50.0 Milligram	Daily	Oral
3atch:	Started: 16/12/1993	Stopped:	17/10/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Platelets	(150-450)	20/01/1994	2	
	Platelets	(150-450)	24/01/1994	25	
	Platelets	(150-450)	27/01/1994	219	



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 97284 Seq: 1 Gender: F
Reported: 23/11/1994 Weight:
Hospitalisation: Age: 41Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Fixed eruption			

Medicine Details:

ANAFRANIL (Suspected) Reason: Depression

1.0 Dose Unspecified Daily

3atch: Started: Stopped:

Laboratory Investigations:

	j mir o o mjamorno.				
Date	Туре	Range	Date Tested	Result	Details
	Skin biopsy				Biopsy showed texture of fixed drug eruption.

Additional Information:

Rash returned after using anafranil again.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 97570 Seq: 1 Gender: M

Reported: 07/12/1994 Weight: 54.00 Hospitalisation: Age: 16Y

Onset Date: 27/10/1994 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hallucination		Auditory hallucinations	

Medicine Details:

Micarchic Details.			
ANAFRANIL (Other drug)	;	Reason:	
Tablet	25.0 Milligram	Daily	Oral
3atch:	Started: 10/06/1994	Stopped:	
ANAFRANIL (Suspected)	;	Reason:	
Tablet	100.0 Milligram	Daily	Oral
3atch:	Started: 06/07/1994	Stopped:	13/07/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient developed auditory hallucinations within one week of increasing dose of anafranil from 25mg to 100mg nocte.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

Case Number:97896Seq:1Gender:MReported:16/12/1994Weight:88.00Hospitalisation:Admitted to hospitalAge:59Y

Onset Date: 08/12/1994 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detail

104011011 20141		<u>-</u>	
Preferred Term	Severity	Report Description	Treatment
Syncope		Sudden loss of consciousness w/o warning	
Orthostatic hypotension			

Medicine Details:

XANAX (Other drug)	Reason:	
	1.0 Milligram Da	aily
3atch:	Started: 01/05/1994	Stopped:
AVOMINE (Other drug)	₹eason:	
	1.0 Dose Unspecified Da	aily
Заtch:	Started:	Stopped:
BETALOC (Other drug)	Reason:	
	200.0 Milligram Da	aily
3atch:	Started: 01/01/1993	Stopped:
ANAFRANIL (Suspected)	Reason:	
	125.0 Milligram D	aily
Зatch:	Started: 01/01/1993	Stopped: 09/12/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Case Number:97896Seq:1Gender:MReported:16/12/1994Weight:88.00Hospitalisation:Admitted to hospitalAge:59YOnset Date:08/12/1994DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details

ACCUPRIL (Suspected) Reason:

20.0 Milligram Daily

3atch: 3tarted: 01/01/1993 **3topped:** 09/12/1994

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 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: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

	per: 97902	Seq: 1			Gender: F	
-	ed: 16/12/1994				Weight: 53.00	
ospitalisati Opset Da	on: ate: 08/12/1994				Age : 73Y DOB :	
	ne: Not yet reco			C	ausality: Causality possib	<u>م</u> ا
eaction De	=	overed			dusanty. Causanty possib	ic
	erred Term	Severity	Report Des	cription	Treatment	
lepatic funct	tion abnormal		·	·		
/lalaise						
/Iyalgia						
yrexia						
ledicine I			Reason:			
		25.0	Milligram Daily			
3atch:		Started: 17/		Stopped:	20/11/1994	
ANAFRANIL (Suspected)		Reason:			
Zatak			Milligram Daily			
3atch:	:	50.0 Started: 21/		Stopped:		
	y Investigatic	Started: 21/	11/1994		Details	
_aborator	y Investigatio	Started: 21/	11/1994		Details	



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 98581
 Seq:
 1
 Gender:
 M

 Reported:
 30/01/1995
 Weight:
 58.00

 Hospitalisation:
 Age:
 72Y

Onset Date: 06/01/1995 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Haematuria			
Thrombocytopenia			

Medicine Details:

SENOKOT (Other drug) Reason: Constipation

1.0 Dose Unspecified Daily

3atch: Started: Stopped: CONTIN

ANAFRANIL (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: **3tarted**: 31/12/1994 **3topped**: 06/01/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Platelets	(50-45)	29/10/1994	168	
	Platelets	(50-45)	06/01/1995	57	
	Platelets	(50-45)	06/01/1995	69	
	Platelets	(50-45)	09/01/1995	76	
	Platelets	(50-45)	11/01/1995	88	
	Platelets	(50-45)	17/01/1995	109	
	Platelets	(50-45)	24/01/1994	125	

Additional Information:



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 100388 Seq: 1 Gender: M

Reported: 24/04/1995 Weight: 85.00 Hospitalisation: Age: 28Y

Onset Date: 28/02/1995 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hypertonia			

Medicine Details:

ANAFRANIL (Suspected) Reason: Pain

 Tablet
 25.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 27/02/1995
 3topped:
 28/02/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient rechallenged on anafranil resulting in same reaction. see original report for other drugs.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

se Number: 100983	_	4			_		_
	Seq:	1				ender:	F
Reported: 19/05/1995					V	Veight:	00
pitalisation: Onset Date:						Age:	29 20/05/1965
Outcome: Recovered					Car		
					Cat	isanty:	Causality possible
action Detai Preferred Term	Seve	rity	Renor	t Descrip	tion		Treatment
epatitis	0000	illy	ТСРОГ	СОСОПР	tion		rreatment
edicine Details: THIUM CARBONATE (Other drug	I)		Reas	on:			
Tablet		1.2 Grar	m	Daily	C	ral	
3atch:		ted:			Stopped:		
LOMIPRAMINE HYDROCHLORID	E (Suspected		₹eas				
Tablet		325.0 Millio	gram	Daile	_		
				Daily		ral	
3atch:	Star	ted: 17/03/19			Stopped:	ral	
						Deta	ils



Report Detail

Case Number: 101005

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Seq: 1

Reported: 22/05/199 Hospitalisation: Onset Date: Outcome: Recovered			Weight: 75.00 Age: 53Y DOB: Causality: Causality possible				
Reaction Detai Preferred Term	Sev	verity	Report F	Description	Treatment		
Abdominal pain	361	/GIILY	Report L	Description	Heatment		
Vomiting							
Medicine Details:							
CLOMIPRAMINE HYDROCHLO	ORIDE (Suspect		Reason	:			
3atch:	.	0.0 arted:		Stopped:			
Laboratory Investigat	t ions: Range	Date Tested	Result		Details		
Additional Informatio	n:						
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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 101176
 Seq: 1
 Gender:
 F

 Reported:
 29/05/1995
 Weight:

Hospitalisation: Age: 35Y

Onset Date: 17/05/1995 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Detai

touotion Dotai			-
Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Felt like something under skin	
Urticaria		Urticaria in arms and legs	
Drug withdrawal syndrome			
Eructation			
Nausea			

Medicine Details:

ANAFRANIL (Suspected) Reason: Depression

1.0 Dose Unspecified Daily

3atch: **3tarted**: 01/08/1994 **3topped**:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient restarted on anafranil (2 night) refered to doctor for slow withdrawal the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

 Case Number:
 103572
 Seq: 1
 Gender: M

 Reported:
 15/09/1995
 Weight:
 19.00

 Hospitalisation:
 Age: 6Y

Onset Date: 21/06/1995 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

104011011 20141			=
Preferred Term	Severity	Report Description	Treatment
Bruxism			

Medicine Details:

ANAFRANIL (Suspected) Reason: Explosive personality disorder

50.0 Milligram Daily

3atch: 3tarted: 20/06/1995 3topped: 10/08/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

Case Number: 104081 Seq: 1 Gender: F

Reported: 17/10/1995 Weight: 76.00 Hospitalisation: Age: 47Y

Onset Date: 04/10/1995 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Dizziness			
Nausea			

Medicine Details:

PRIMOLUT-N (Other drug) Reason: Menopausal symptoms

2.5 Milligram Daily

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

PREMARIN (Other drug) Reason: Menopausal symptoms

625.0 Microgram Daily

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

ANAFRANIL (Suspected) Reason: Depression

Tablet 1.0 Dose Unspecified Daily Oral

3atch: 3tarted: 03/10/1995 **3topped:** 05/10/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 104446
 Seq: 1
 Gender:
 F

 Reported:
 06/11/1995
 Weight:
 50.00

 Hospitalisation:
 Age: 39Y

Onset Date: 26/10/1995 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Fatigue		, ,	
Headache			
Nausea	Severe		

Medicine Details:

ANAFRANIL (Suspected) Reason: Depression

 Tablet
 25.0 Milligram
 1 time
 Oral

 3atch:
 3tarted:
 26/10/1995
 3topped:
 26/10/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has ornithine-transcarbamylase deficiency (otc).



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Case Number	r : 104706	Seq: 1					Gender: F		
Reported	d: 20/11/199	5					Weight: 55	5.00	
lospitalisatior	ո։						Age : 54		
Onset Date	e: 15/09/199	5					DOB:		
Outcome	e: Recovered	d				C	ausality: Ca	ausality poss	ible
eaction Det	ai						-		
	red Term	Sever	ity	Repor	t Descr	iption		Treatment	
Agitation									
Dizziness									
Ory mouth									
Dysgeusia									
Dystonia									
Nausea									
Paraesthesia									
Гremor									
Medicine De AROPAX (Susp				Reas	on: [Depression			
Tablet			20.0 Milli	gram	Daily		Oral		
3atch:		Starte	ed: 15/09/19	995		Stopped:	15/09/1995		
CLOMIPRAMINE	HYDROCHLO	RIDE (Suspected)		Reas	on:				
Tablet			50.0 Milli	gram	Daily		Oral		
3atch:		Starte	ed:			Stopped:	13/09/1995		
_aboratory									
Date	Туре	Range [Date Tested	Result			Details		
Additional I	nformatior	1 :							
oort Run 20/07/2	200 09:55AN	Database: pusir	me	A	.DRS004			Page 85	of 164



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail				
Case Number: 105081	Seq: 1		Ger	nder: U
Reported: 04/12/199			We	ight:
Hospitalisation:				Age:
Onset Date: 03/11/199	95		[OOB:
Outcome: Recovere	d		Caus	ality: Causality probable
Reaction Detai				
Preferred Term	Severity	Report	Description	Treatment
Hepatic function abnormal				
Medicine Details: ANAFRANIL (Suspected)		Reaso	on: Depression	
Tablet	75.0	Milligram	Daily Oral	
3atch:	3tarted: 05/1			0/1995
Laboratory Investigat	ions:			
Date Type	Range Date Test	ed Result		Details
Additional Information	n:			

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 105459
 Seq: 1
 Gender:
 F

 Reported:
 19/12/1995
 Weight:

Hospitalisation: Age: 43Y

Onset Date: 30/11/1995 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Detai

touotion Dotai			
Preferred Term	Severity	Report Description	Treatment
Confusional state			
Coordination abnormal			
Hyperreflexia			
Hypertonia			
Somnolence			

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Suspected) Reason:

300.0 Milligram Daily

3atch: 3tarted: 01/02/1992 3topped: 30/11/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

When patient rechallenged on clomipramine reaction occurred again. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

 Case Number:
 106510
 Seq: 1
 Gender: M

 Reported:
 19/02/1996
 Weight:

Hospitalisation: Age: 40Y
Onset Date: 31/10/1995
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Sus	pected)	Reason:		
	50.0 Milligram	Daily		
3atch:	3tarted: 01/01/1991		Stopped:	16/02/1996
ATENOLOL (Suspected)		₹eason:		
	50.0 Milligram	Daily		
3atch:	3tarted: 01/01/1993		Stopped:	
FELODIPINE (Suspected)		Reason:		
FELODIPINE (Suspected)	10.0 Milligram	Reason: Daily		
FELODIPINE (Suspected) 3atch:	10.0 Milligram Started: 01/01/1992		Stopped:	
, , ,	· ·		Stopped:	
Batch:	· ·	Daily	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. 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: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 106923
 Seq: 1
 Gender:
 F

 Reported:
 06/03/1996
 Weight:

Hospitalisation: Age: 32

Onset Date: 11/10/1995 **DOB**: 04/02/1963

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia			

Medicine Details:

Micalonic Details.					
CLOMIPRAMINE HYDROCHLORIDE	E (Suspected)		Reason:		
	200.0	Milligram	Daily		
3atch:	Started:			Stopped:	
THIORIDAZINE HYDROCHLORIDE (Suspected)			Reason:		
	100.0	Milligram	Daily		
3atch:	Started:			Stopped:	
CLONAZEPAM (Suspected)			Reason:		
	2.0	Gram	Daily		
3atch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Prolactin	(70-320)	11/10/1995	1681	
	Prolactin	(70-320)	23/11/1995	1989	
	Prolactin	(70-320)	14/12/1995	1027	

Additional Information:



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 108056
 Seq: 1
 Gender:
 F

 Reported:
 26/04/1996
 Weight:
 64.00

 Hospitalisation:
 Age: 44Y

Onset Date: 12/04/1996 DOB:

Outcome: Not yet recovered Causality: Causality certain

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Proximal muscular spasm	Iv valium
Somnolence			
Tremor			

Medicine Details:

PLACIL (Suspected) Reason:

25.0 Milligram Daily

3atch: 3tarted: 12/04/1996 3topped: 12/04/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Rechallenge: reaction recurred when medication administered a second time on 19 april 1996



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Case Number: 109489 Reported: 25/06/1996 Hospitalisation: Onset Date: 21/06/1996 Outcome: Unknown			Ag DO	nt: 65.00 e: 69Y
eaction Detai Preferred Term	Severity	Report Des	scription	Treatment
Nausea	Governity	, topon Dot	, on paren	rrodunone
Medicine Details:				
ANAFRANIL (Suspected)		Reason:		
(,	25.0 Milli		ie	
3atch:	Started:		Stopped:	
_aboratory Investigatio	ons:			
Date Type	Range Date Tested	Result	D	etails
Additional Information	:			
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Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Case Number: 110845 Reported: 15/08/199 Hospitalisation: Onset Date: 07/08/199 Outcome: Unknown Reaction Detai				c	Gender: M Weight: 70.00 Age: 42Y DOB: ausality: Causality possible
Preferred Term	Severit	у	Report	Description	Treatment
Cough			•	·	
Dry mouth					
Dyspnoea					
Tremor					Reassurance; patient self medicated with murelax and one dose of atrovent neb.
Medicine Details: ANAFRANIL (Suspected) Tablet		25.0 Milli	Reaso gram	on: Depression 1 time	Oral
3atch:	Starte	d: 07/08/19		Stopped:	07/08/1996
Laboratory Investigat	ions:				
Date Type		ate Tested	Result		Details
.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,					
Additional Information	n:				

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

 Case Number:
 111517
 Seq:
 1
 Gender:
 F

 Reported:
 10/09/1996
 Weight:
 65.00

 Hospitalisation:
 Age:
 25Y

Onset Date: 27/08/1996 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment			
Mania		Hypomania				
Palpitations						

Medicine Details:

ANAFRANIL (Interaction) Reason: Depression

150.0 Milligram Daily

3atch: **3tarted**: 01/05/1996 **3topped**: 27/08/1996

CODRAL DAYTIME/NIGHTIME TABLETS (Interaction) Reason: Ac upr resp inf,mult,unsp stes

2.0 Dose Unspecified Daily

3atch: 3tarted: 3topped: 27/08/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail						
Case Number: 1124 Reported: 23/1 Hospitalisation: Onset Date: Outcome: Unkr	0/1996	1			Age DOB	t: 70.00 e: 20Y
eaction Detai	1					
Preferred Ter		erity	Repor	Description		Treatment
Drug withdrawal convu	ulsions					
Medicine Details:			2000	<u> </u>		_
ALPRAZOLAM (Other dr	ug)	1.0 Milli	Reason Toram	on: Daily		
3atch:	St	arted:	grani	Stopped	i:	
ANAFRANIL (Suspected			Reas			
Tablet		150.0 Milli	gram	Daily	Oral	
3atch:	St.	arted:		Stopped	d:	1Y
Laboratory Invest	t igations: Range	Date Tested	Result		De	tails
I		I				



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number:112629Seq:1Gender:FReported:29/10/1996Weight:51.00Hospitalisation:Admitted to hospitalAge:27Y

Onset Date: 04/10/1996 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Constipation			Enemas, admission to hospital, colofac liquid per oral
Abdominal pain			

Medicine Details:

AROPAX (Suspected)		Reason:	
	20.0 Milligram	Daily	
3atch:	Started:	Stopped:	4W
XANAX (Suspected)		Reason: Anxiety neurosis	
	3.0 Milligram	Daily	
3atch:	Started: 01/08/1995	Stopped:	CONTIN
ANAFRANIL (Suspected)		Reason: Anxiety neurosis	
	50.0 Milligram	Daily	
3atch:	Started: 23/08/1996	Stopped:	CONTIN
PREPULSID FORTE (Suspected)		Reason:	
	40.0 Milligram	Daily	
3atch:	Started: 30/05/1996	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 112708 Seq: 1 Gender: M

Reported: 31/10/1996 Weight: 82.00 Hospitalisation: Age: 20Y

Onset Date: 13/10/1996 **DOB:**

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizures	

Medicine Details:

MEGICINE DETAILS.			
XANAX (Suspected)		Reason: Anxiety neurosis	
Tablet	1.0 Milligram	Daily Ora	I
Заtch:	Started: 01/10/1995	Stopped:	
ANAFRANIL (Suspected)		Reason: Depression	
Tablet	150.0 Milligram	Daily Ora	I
3atch:	Started: 01/10/1995	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Re	por	t D	etail
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 Case Number:
 115990
 Seq:
 1
 Gender:
 F

 Reported:
 12/03/1997
 Weight:
 58.00

Hospitalisation: Age: 40

Onset Date: 18/02/1997 **DOB**: 15/08/1956

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Somnolence			
Urticaria			

Medicine Details:

SODIUM VALPROATE (Suspected)		Reason:	Other&unspecified epilepsy	
Oral application	500.0 Milligram	Daily	Oral	
3atch:	Started: 18/02/1997		Stopped:	
CLOZAPINE (Suspected)		Reason:		
	350.0 Milligram	Daily		
3atch:	Started:		Stopped:	
CLONAZEPAM (Suspected)		Reason:		
CLONAZEPAM (Suspected)	1.0 Milligram	Reason: Daily		
CLONAZEPAM (Suspected) 3atch:	1.0 Milligram		Տtopped:	
	Started:			
3atch:	Started:	Daily	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Case Number:	115990	Seq: 1			Gender:	F	
Reported:	12/03/1997				Weight:	58.00	
Hospitalisation:					Age:	40	
Onset Date:	18/02/1997				DOB:	15/08/1956	
Outcome:	Unknown				Causality:	Causality possib	le
Reaction Detai							
Medicine Deta	ails:						
ACTRAPID HM (Su			Reas	on:			
		14.0	International Unit	Daily			
Зatch:		3tarted:			Stopped:		
ULTRATARD HM (Suspected)		Reas				
		22.0	International Unit	Daily			
3atch:		Started:			Stopped:		
Laboratory In	vestigations:						
_	_						
Additional Inf	ormation:						
	J						
opert Pup 20/07/200) 00:55AN Data	hasa: nusima	,	VDB6004		Daga 00 - 4	

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 124625
 Seq: 1
 Gender: F

 Reported:
 02/02/1998
 Weight:

Hospitalisation: Age: 32Y

Onset Date: 31/12/1998 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Weight increased			Switched to zoloft

Medicine Details:

ANAFRANIL (Suspected)		Reason:				
Tablet	0.0	Daily	Oral			
Batch:	Started:	Stop	pped:			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number:125146Seq:1Gender:FReported:13/02/1998Weight:Hospitalisation:Admitted to hospitalAge:24Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Tremor	Severe	Legs shaking violently and chattering of	
Convulsion		Myoclonic jerking	
Agitation			
Coordination abnormal			
Flushing			
Insomnia			
Serotonin syndrome			
Urinary retention			
Vomiting			

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Interaction)			Reason:		
	50.0	Milligram	1 time		
3atch:	Started:			Stopped:	
FLUNITRAZEPAM (Interaction)			Reason:		
	2.0	Milligram	1 time		
3atch:	Started:			Stopped:	
MOCLOBEMIDE (Interaction)			Reason:		
	750.0	Milligram	Daily		
3atch:	Started:			Stopped:	17D

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

International clinical psychopharmacology 1997, 12, 339-342, v12.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 126259
 Seq: 1
 Gender:
 F

 Reported:
 27/03/1998
 Weight:

Hospitalisation: Age: 29

Onset Date: 02/03/1998 DOB: 18/06/1968

Outcome: Recovered Causality: Causality possible

Reaction Detai

todotion botal		E	
Preferred Term	Severity	Report Description	Treatment
Rash erythematous			Anafranil ceased and given phenergan

Medicine Details:

ANAFRANIL (Suspected) Reason: Depression

 Tablet
 150.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 22/02/1998
 3topped:
 05/03/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Suspected allergy to penicillin



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 129906
 Seq: 1
 Gender: M

 Reported:
 05/08/1998
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 13/07/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		Many falls causing humerus.	Ceased anafranil.

Medicine Details:

PEPCIDINE (Other drug)		Reas	on:			
Tablet	1.0	Dose Unspecified	Daily		Oral	
3atch:	Started:			Stopped:		
ALCOHOL (Suspected)		Reas	on:			
	0.0					
3atch:	Started:			Stopped:		
ANAFRANIL (Suspected)		Reas	on:			
	2.0	Dose Unspecified	Daily			
Batch:	Started:			Stopped:	14/07/1998	
ALODORM (Suspected)		Reas	on:			
Tablet	1.0	Dose Unspecified	Daily		Oral	
3atch:	Started:			Stopped:	16/07/1998	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Sequelae: # humerus



Report Detail

Case Number: 129906

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Seq: 1

Reported: 05/08/1998 Hospitalisation: Admitted to hospital Onset Date: 13/07/1998 Outcome: Not yet recovered Reaction Detai		(Weight: Age: 74Y DOB: Causality: Causality po	ssible
Medicine Details: MS CONTIN (Suspected)	30.0 Milligram	Reason:		
3atch:	Started:	Stopped:	16/07/1998	
Laboratory Investigations:				
Additional Information: Sequelae: # humerus				
eport Run 20/07/200 09:55Al Database	e: pusime	ADRS004	Dago 10	3 of 16/

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

Case Number: 130848 Seq: 1 Gender: F

Reported: 07/09/1998 Weight:
Hospitalisation: Age: 45Y

Onset Date: 31/07/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Convulsion		Myoclonus of the jaw	
Convuision		inyocionus of the jaw	Zyprexia ceased and anafranil reduced to 7 tablets a day and then ceased.
Drug level increased			

Medicine Details:

ZYPREXA (Suspected)		Reason:	Depression	
Tablet	10.0 Milligram	Daily		Oral
3atch:	Started: 01/06/1998		Stopped:	28/08/1998
ANAFRANIL (Suspected)		Reason:	Depression	
ANAFRANIL (Suspected) Tablet	300.0 Milligram	Reason: Daily	•	Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Serum drug level				The blood levels of clompramine were 980ng/ml which was well above the usual therapeutic range of 200-300ng/ml.

Additional Information:

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

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

Case Number: 131944 Seq: 1 Gender: F

Reported: 12/10/1998 Weight:
Hospitalisation: Age: 48Y

Onset Date: 31/12/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hypotension		Blood pressure drop	

Medicine Details:

Medicine Details:						
CLOMIPRAMINE HYDROCHLORIDE (Suspected)			Reason:			
0.0						
Зatch:	Started:			Stopped:		
ZOLOFT (Suspected)			Reason:	Depression		
Tablet	50.0	Milligram	Daily		Oral	
Зatch:	Started:			Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient suffered a fall six months ago. fall was suspected to be due to a blood pressure drop believed caused by co-administration of zoloft and clomipramine. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

Case Number: 133195 Seq: 1 Gender: M

Reported: 13/11/1998 Weight: 70.00 Hospitalisation: Age: 38Y

Onset Date: 29/09/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Clomipramine weaned

Medicine Details:

Medicine Details.				
DIAZEPAM (Other drug)		Reason:	Obsessive compulsive neurosis	,
Oral application	20.0 Milligram	Daily	Oral	
3atch:	Started: 01/11/1997		Stopped:	
CLOMIPRAMINE HYDROCHLORID	DE (Suspected)	Reason:	Obsessive compulsive neurosis	;
Tablet	300.0 Milligram	Daily	Oral	
3atch:	Started: 01/11/1997		Stopped: 28/11/1998	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		29/09/1998	173	
	GGT = SGGT =		29/09/1998	194	
	SAP = ALP		29/09/1998	138	

Additional Information:

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

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

 Case Number:
 133384
 Seq:
 1
 Gender:
 M

 Reported:
 17/11/1998
 Weight:
 70.00

 Hospitalisation:
 Age:
 38Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Ceased anafranil

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Suspected) Reason: Obsessive compulsive neurosis

 Tablet
 300.0 Milligram
 Daily
 Oral

 3atch:
 Started:
 01/11/1997
 Stopped:
 28/11/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry	. tunge	24.0 . 00.04		Alk 138, ggt 194, alt 173.

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: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Reported: 11/01/1999 ospitalisation: Onset Date: Outcome: Recovered eaction Detai				Weight: Age: 18Y DOB: Causality: Causality possible			
	erred Term	Severity	Report Des	scription	Treatment		
gitation		,	'	•			
Convulsion							
ypertonia							
ypotension							
luscle twitch							
Serotonin sy	_				12mg cyproheptadine.		
Speech disor					0 - 7 - 1 - 2 - 3 -		
		Started:		Stopped:	3M		
3atch:	DE (Interaction)		Reason:	···			
		0.0	Reason:				
	DE (Interaction)		Reason:	Stopped:			
3atch:	DE (Interaction)	0.0 Started:			Details		
MOCLOBEMII 3atch:	DE (Interaction)	0.0 Started:			Details		

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 135723 Seq: 1 Gender: F

Reported: 01/02/1999 Weight:
Hospitalisation: Age: 46Y

Onset Date: 18/01/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Tongue oedema		Swelling of tongue and mouth.	Ceased anafranil.

Medicine Details:

RIVOTRIL (Other drug)

Reason: Hearing disturb excpt deafness

1.0 Milligram Daily

3atch: Started: 03/09/1998 Stopped: 18/01/1999

ANAFRANIL (Suspected) Reason:

 Tablet
 25.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 18/01/1999
 3topped:
 23/01/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Symptoms occurred 5 days after beginning anafranil.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

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Case Number:136486Seq:1Gender:MReported:22/02/1999Weight:Hospitalisation:Admitted to hospitalAge:27Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detail

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Tremor			Clomipramine ceased. 40mg paroxetine was administered daily, and a behavioral approach was adopted. dexamphetamine 5mg three times daily was prescribed without benefit.

Medicine Details:

Modifile Botalie:					
CLOMIPRAMINE HYDROCHLO	ORIDE (Suspected)		Reason:		
	200.0	Milligram	Daily		
3atch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

There was perceptible improvement on 150mg clomipramine at night but he remained slow in daily tasks such as showering, dressing & eating. he improved further when the dose was increased to 200mg at night. repetitive movements were reduced and the time taken for motor tasks was less. he could not tolerate higher doses because of tremor. the patient has a history of depression & stereotypies.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 136889
 Seq: 1
 Gender: M

 Reported:
 02/03/1999
 Weight:
 72.00

 Hospitalisation:
 Age: 77Y

Onset Date: 25/02/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

todotion Dotal		=	
Preferred Term	Severity	Report Description	Treatment
Coordination abnormal			
Dizziness			
Hyperhidrosis			
Nausea			
Tremor			

Medicine Details:

modifile Botalie.					
VENTOLIN (Other drug)	Reason: Otr respiratory systm diseases				
Inhalation	1.0 Dose Unspecified As necessary Inhalation				
3atch:	Started: L TERM Stopped:				
BECLOFORTE (Other drug)	Reason: Otr respiratory systm diseases				
Inhalation	4.0 Dose Unspecified Daily Inhalation				
3atch:	Started: 01/02/1992 Stopped:				
ANAFRANIL (Suspected)	Reason: Obsessive compulsive neurosis				
Tablet	75.0 Milligram Total Oral				
Зatch:	Started : 25/02/1999 Stopped : 26/02/1999				

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No true allergies, but a history of peculiar reactions to medication. ceclor - abdominal pain. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Outcome: Unknown			Gender: F Weight: Age: DOB: Causality: Causality possible
action Detai Preferred Term	Severity	Report Description	Treatment
alactorrhoea	Seventy	Report Description	rreatment
edicine Details: NAFRANIL (Suspected)		Reason:	
Tablet 3atch:	0.0 Started:	Daily ≩toppe	Oral
boratory Investigations Date Type R	: ange Date Teste	d Result	Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Case Number: 137952	Seq: 1	Gender: M		
Reported: 30/03/1999 ospitalisation:		Weight: Age: 70Y		
Onset Date:			Age: 701 DOB:	
Outcome: Unknown		Ca	nusality: Causality possible	
action Detai			ideanity. Cadeanity pecololic	
Preferred Term	Severity	Report Description	Treatment	
/sphagia		·		
naryngitis				
edicine Details:		Reason: Unspecified ps		
Tablet	0.0	·	Oral	
3atch:	Started:	Stopped:		
aboratory Investigation	ns: Range Date Tested	Result	Details	
Additional Information:				
ort Run 20/07/200 09:55AN	Database: pusime	ADRS004	Page 113 of 164	



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 137968
 Seq:
 1
 Gender:
 M

 Reported:
 30/03/1999
 Weight:
 94.00

Hospitalisation: Age: 19Y

Onset Date: 12/03/1999 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agitation		Panic secondary to symptoms	
Headache	Severe	Sensation of head rush then severe	Penicillin 8mg prn (up to 32mg/day) for 4 days then 16mg/day for 2-3 days + codeine phosphate imi when pethidine failed imi.
Hypertonia			TATINITICA TERRATA IIIII
Hyperventilation			
Paraesthesia			

Medicine Details:

ANAFRANIL (Suspected)	Reason:				
	50.0 Milligram	1 time			
3atch:	Started: 11/03/1999	Stopped:	12/03/1999		
AROPAX (Suspected)		Reason:			
Tablet	20.0 Milligram	As necessary	Oral		
Batch:	Started: 25/02/1999	Stopped:	04/03/1999		
LUMIN (Suspected)		Reason: Specific disor	ders of sleep		
Tablet	40.0 Milligram	Daily	Oral		
3atch:	Started: 06/11/1998	}topped:	12/03/1999		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reactions not reversed by rebreathing. suspected drugs given for severe ptsd. see original report for details of other drugs - neulactil, mogadon, normison.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 138277 Seq: 1 Gender: U
Reported: 01/04/1999 Weight:
Hospitalisation: Age:

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Nightmare			

Medicine Details:

ANAFRANIL (Suspected) Reason: Obsessive compulsive neurosis

Tablet 150.0 Milligram Daily Oral

3atch: Started: Stopped: 4M

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Nightmares occurred 4 months after clozapine was started.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 139251 Seq: 1 Gender: F
Reported: 06/05/1999 Weight: 55.00
Hospitalisation: Age: A4

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

100000000000000000000000000000000000000		-	
Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Milk in breasts	
Breast engorgement			

Medicine Details:

ANAFRANIL (Suspected) Reason: Depression

125.0 Milligram Daily

3atch: **3tarted**: 12/11/1998 **3topped**: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Anafranil at this dose is successful. patient prefers to continue anafranil cease parlodel and suffer the side effects.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 139657 Seq: 1 Gender: F

Reported: 18/05/1999 Weight:
Hospitalisation: Age: 40Y

Onset Date: 31/12/1999 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			Parlodel

Medicine Details:

ANAFRANIL (Suspected) Reason:

Tablet 25.0 Milligram Daily Oral

3atch: 3tarted: 04/11/1998 **3topped:**

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 140313 Seq: 1 Gender: M
Reported: 07/06/1999 Weight:
Hospitalisation: Age: 17Y

Onset Date: 13/05/1999 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Confusional state			
Muscle twitching			

Medicine Details:

ANAFRANIL (Suspected)

Tablet

75.0 Milligram
Daily
Oral

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking ritalin. patient experienced symptoms when dose of anafranil was inceased to 75mg from 50mg daily.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail				
Case Number: 141722 Reported: 19/07/19 lospitalisation:	•		Gender: Weight: Age:	34Y
Onset Date:			DOB:	
Outcome: Unknow	/n		Causality:	Causality possible
eaction Detai Preferred Term	Severity	Report Desc	rintion	Treatment
Alopecia	Seventy	Report Desc	приоп	Heatment
Medicine Details: ANAFRANIL (Suspected) Tablet	75.0	Reason: Milligram Daily	Obsessive compulsive ne	urosis
3atch:	3tarted: 27/0		Stopped:	CONTIN
		od Rosult	Dota	ilo
Laboratory Investiga Date Type	ations: Range Date Teste	ed Result	Deta	ils



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 142633
 Seq: 1
 Gender:
 F

 Reported:
 13/08/1999
 Weight:

Hospitalisation: Age: 19Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Sensory disturbance		Electric shock sensation down arms and	

Medicine Details:

ANAFRANIL (Suspected)

Tablet

50.0 Milligram

Daily

Oral

3atch:

\$tarted: 01/01/1994

CONTIN

DEXAMETHASONE (Suspected)

Reason:

Cataplexy&narcolepsy brain dis

CONTIN

15.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

 Case Number:
 144121
 Seq: 1
 Gender:
 F

 Reported:
 01/09/1999
 Weight:

Hospitalisation: Age: 34Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion Botal	-	_	
Preferred Term	Severity	Report Description	Treatment
Alopecia	Required Specialist Consultation	Alopecia 2w after starting anafranil.	

Medicine Details:

ANAFRANIL (Suspected) Reason:

Tablet 100.0 Milligram Daily Oral

3atch: **3tarted**: 01/05/1999 **3topped**: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

After ceasing zoloft, hair stabilized but 2 weeks after starting anafranil it started again - mild, generalised, not generally obvious but hairdresser noticed as well as the patient. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 144841 Seq: 1 Gender: M

Reported: 19/10/1999 **Weight:**

Hospitalisation: Age: 15Y
Onset Date: 31/10/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

todotion Dotal			
Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Maculopapular rash on abdomen, feet and	Anafranil was discontinued but then readministered.

Medicine Details:

Medicine Details.			
CLONAZEPAM (Other drug)		Reason:	
	0.5 Milligram	As necessary	
Зatch:	Started:	Stopped:	
ANAFRANIL (Suspected)		Reason:	
Tablet	75.0 Milligram	Daily Oral	
3atch:	Started: 01/07/1999	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Anafranil given for obsessive compulsive disorder. patient has no known allergies. - 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: 146625

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Seq: 1

espitalisation: Onset Date:		Weight:				
Ouser pare:		Age: DOB:				
Outcome: Unknown	1	Causality: Causality possible				
eaction Detai	ı		Gaus	anty. Causality possible		
Preferred Term	Severity	Repor	t Description	Treatment		
norexia			·			
nsomnia						
Medicine Details: PANADOL (Other drug)		Reas	ion:			
. , (0.0		····			
3atch:	Started:		Stopped:			
MULTIVITAMINS (Other drug)		Reas	on:			
	0.0					
3atch:	Started:		Stopped:			
	25.0					
		_				
ANAFRANIL (Suspected) Tablet		Milligram		ral CONTIN		
3atch:						
_aboratory Investiga	tions: Range Date Tes	sted Result	Τ	Details		

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

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 Case Number:
 147347
 Seq: 1
 Gender: F

 Reported:
 22/12/1999
 Weight:

Hospitalisation: Age: 10Y
Onset Date: 31/12/1999
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Neaction Detai			
Preferred Term	Severity	Report Description	Treatment
Choreoathetosis		Choreoform movements.	
Agitation			
Convulsion			
Hyperkinesia			

Medicine Details:

ANAFRANIL (Suspected)		Reason:	
Tablet	0.0	Oral	
3atch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Case Number: 147718 Seq: 1 Gender: F

Reported: 05/01/2000 Weight: 56.00 Hospitalisation: Age: 28

Onset Date: 25/12/1999 **DOB**: 28/03/1971

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Rash		Rash over arms, legs, trunk.	

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Suspected) Reason: Obsessive compulsive neurosis

50.0 Milligram Daily

3atch: 3tarted: 15/12/1999 3topped: 20/12/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 149029
 Seq: 1
 Gender:
 F

 Reported:
 07/02/2000
 Weight:

Hospitalisation:
Onset Date: 31/01/1997
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

Micarchic Betaris.					
CLOZARIL (Suspected)		Reason:			
Tablet	0.0			Oral	
3atch:	Started:	L TERM	Stopped:	28/10/1998	
ANAFRANIL (Suspected)		Reason:			
	0.0				
3atch:	Started:		Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 149600
 Seq: 1
 Gender:
 F

 Reported:
 23/02/2000
 Weight:

Hospitalisation: Age: 40Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Alcohol intolerance			

Medicine Details:

Medicine Details.				
ANAFRANIL (Interaction)		Reason:		
	0.0			
3atch:	3tarted: 01/01/19	990 L TERM	Stopped:	
ALCOHOL (Interaction)		Reason:		
	0.0			
3atch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data				Patient experienced a positive police alcohol breath test (in the mid range) after consuming six beers over a period of 6 hours

Additional Information:

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



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

Case Number: 149920 Seq: 1 Gender: F
Reported: 03/03/2000 Weight:

Hospitalisation: Age: 30Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hypertension		Bp measured at 150/100 mmhg.	
Tremor		Patient developed muscle tremors.	
Tachycardia		Patient woke up with a rapid heartbeat.	
Dyspepsia			

Medicine Details:

 ANAFRANIL (Suspected)
 Reason:
 Depression

 Tablet
 25.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/06/1993
 \$topped:
 28/06/1993

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking xanax. patient experienced reactions 4 hours after taking one anafranil tablet. when she tried to walk from her bed she collapsed. 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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DOB: 04/10/1955

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 151877
 Seq: 1
 Gender: F

 Reported:
 19/04/2000
 Weight:

Hospitalisation: Age: 44

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Onset Date:

Preferred Term	Severity	Report Description	Treatment
Polyuria		Patient developed high level of urine	

Medicine Details:

MS CONTIN (Other drug)		Reas	on:			
	30.0	Milligram	Daily			
3atch:	Started:			Stopped:		
PERIACTIN (Other drug)		Reas	on:			
Tablet	12.0	Dose Unspecified	Daily		Oral	
3atch:	Started:			Stopped:		
TEGRETOL (Other drug)		₹eas	on.			
- (•			
(3.4.2.4.4.4.4.4.4.4.4.4.4.4.4.4.4.4.4.4.	400.0	Milligram	Daily			
3atch:	400.0 l			Stopped:		
			Daily	Stopped: Depression		
3atch:	Started:	Milligram	Daily	• •	Oral	

Laboratory Investigations:

	,						
Date	Туре	Range	Date Tested	Result	Details		
	Other data		24h urine volume was checked for catechola		24h urine volume was checked for catecholamines.		

Additional Information:

The high level of urine output developed when dose was 50mg, and this has increased with dose increase. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

 Case Number:
 152848
 Seq: 1
 Gender:
 F

 Reported:
 22/05/2000
 Weight:

Hospitalisation: Age: 12

Onset Date: 06/05/2000 **DOB**: 28/02/1988

Outcome: Unknown Causality: Causality possible

Reaction Detai

	1		
Preferred Term	Severity	Report Description	Treatment
Headache		Bad headaches	
Drug withdrawal syndrome			
Fatigue			
Muscle spasms			

Medicine Details:

RITALIN (Other drug)		Reason:	Behavior diso	rders of childhoo	
Tablet	20.0 Milligram	Daily		Oral	
3atch:	Started: 01/01/1981		Stopped:		CONTIN
ANAFRANIL (Suspected)	Reason:				
Tablet	25.0 Milligram	Daily		Oral	
			Stopped:	06/05/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms immediately after ceasing anafranil. had been taking the drug for approximately 2 years. 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: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

Case Number: 153032 Seq: 1 Gender: F

Reported: 22/05/2000 Weight:
Hospitalisation: Age:
Onset Date: 29/03/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Caction Detai			
Preferred Term	Severity	Report Description	Treatment
Agitation		Demanding	
Nervousness		Jiffery especially when handled + arching	
Drug withdrawal syndrome neona		- 	
Nervousness			

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Suspected) Reason: Obsessive compulsive neurosis

150.0 Milligram Daily

3atch: Started: 01/01/2000 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Male baby dob 26/3/00 experienced symptoms post delivery, mother was taking clomipramine. discharged 31/3/00-"continues to arch back and jittery at times". infant breastfed. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 153945 Seq: 1 Gender: F

Reported: 19/06/2000 Weight: 95.00 Hospitalisation: Age: 30

Onset Date: DOB: 31/07/1969

Outcome: Unknown Causality: Causality certain

Reaction Detai

		-	
Preferred Term	Severity	Report Description	Treatment
Anorgasmia			
Micturition disorder			Required a visit to doctor.

Medicine Details:

ANAFRANIL (Suspected) Reason: Obsessive compulsive neurosis

250.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Anafranil was rechallenged. symptoms have occurred everytime patient has taken this medication.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

 Case Number:
 154224
 Seq: 1
 Gender:
 F

 Reported:
 26/06/2000
 Weight:

Hospitalisation: Age: 39

Onset Date: DOB: 23/06/1961

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Intra-uterine death			A curette was performed.

Medicine Details:

Medicine Details.						
ZYPREXA (Suspected)		Reason:	Depression			
Tablet	20.0 Milligram	Daily		Oral		
3atch:	Started: 01/01/2000		Stopped:	31/05/2000		
ANAFRANIL (Suspected)		Reason:	Depression			
	100.0 Milligram	Daily				
3atch:	Started: 17/03/2000		Stopped:		CONTIN	

Laboratory Investigations:

	<u>, </u>	oo agaarene:						
Date	Туре	Range	Date Tested	Result	Details			
	Radiololgy				Mid april 2000 the patient had a miscarriage with a non viable			

Additional Information:

Patient also taking atovastatin, nitrazepam, lipitor and mogadon. the patient's medical history includes an overdose and one normal infant prior to commencing atorvastatin and nitrazepam. the patient has been taking the olanzapine for the entire pregnancy. on 1/6/00, it was reported that the patient lost her baby. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 154409
 Seq: 1
 Gender:
 F

 Reported:
 03/07/2000
 Weight:

Hospitalisation: Age:
Onset Date: 20/06/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis			
Insomnia			

Medicine Details:

OXAZEPAM (Other drug)		Reason: Anxiety neurosis	
	0.0		
3atch:	Started:	Stopped:	
VALIUM (Other drug)		Reason: Anxiety neurosis	
	5.0 Milligram	Daily	
3atch:	Started:	Stopped:	
ANAFRANIL (Suspected)		Reason: Anxiety neurosis	
Tablet	25.0 Milligram	Daily Oral	
3atch:	Started: 20/06/2000	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reactions occurred within 12 hours after commencing anafranil.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 155650
 Seq: 1
 Gender: F

 Reported:
 31/07/2000
 Weight:

Hospitalisation: Age: 18

Onset Date: 08/05/2000 DOB: 03/06/1981

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Coma Convulsion Delirium	Life		lcu admission for 4 days, 3 days mechanical ventilation, thiopentone inf for seizures.
Serotonin syndrome			

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Interaction) Reason: Depression

25.0 Milligram 1 time

3atch: 3tarted: 08/05/2000 3topped: 08/05/2000

PARNATE (Interaction) Reason: Depression

80.0 Milligram Daily

3atch: 3tarted: L TERM **3topped**: 08/05/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking fludrocortisone.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

 Case Number:
 157453
 Seq:
 1
 Gender:
 F

 Reported:
 11/09/2000
 Weight:
 53.00

Hospitalisation: Age: 32

Onset Date: 01/07/2000 **DOB**: 11/05/1968

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Purpura		Bruising legs and arms.	

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Suspected) Reason:

0.0

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking placil.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 157673 Seq: 1 Gender: M
Reported: 13/09/2000 Weight:
Hospitalisation: Age: 45

Onset Date: DOB: 26/05/1955

Outcome: Unknown Causality: Causality possible

Reaction Detai

104011011 20141			=
Preferred Term	Severity	Report Description	Treatment
Headache			Ceased anafranil and treated with aspirin and anaprox.
Visual disturbance			

Medicine Details:

MEGICINE DETAILS.				
MELLERIL (Other drug)		Reason:	Nausea and vomiting	
	0.0			
Зatch:	Started:		Stopped:	
ANAFRANIL (Suspected)		Reason:	Obsessive compulsive neurosis	
Tablet	0.0		Oral	
3atch:	Started: 01/01/1996		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.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 157680 Seq: 1 Gender: F

Reported: 13/09/2000 Weight: 54.00 Hospitalisation: Age: 25

Onset Date: 27/08/2000 DOB: 18/10/1974

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hypoaesthesia			
Hypotension			Ceased anafranil. required a visit to doctor.

Medicine Details:

ANAFRANIL (Suspected) Reason:

100.0 Milligram Daily

3atch: 3tarted: 18/08/2000 3topped: 28/08/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 5/9/00.



Causality: Causality possible

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

 Case Number:
 157736
 Seq: 1
 Gender: M

 Reported:
 15/09/2000
 Weight: 90.00

Hospitalisation: Admitted to hospital Age: 29

Onset Date: DOB: 16/03/1971

Reaction Detai

Outcome: Not yet recovered

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Dilated cardiomyopathy.	Patient hospitalised.

Medicine Details:

Medicine Details.			
VALIUM (Other drug)		Reason:	
	5.0 Milligram	As necessary	
3atch:	Started:	Stopped:	
ANAFRANIL (Suspected)		Reason: Anxiety neurosis	
	150.0 Milligram	Daily	
3atch:	Started: 01/01/1996	Stopped: 28/09/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Hospitalisati Onset Da	ate: 14/12/2000 me: Not yet reco	Seq: vered	1		V		80.00
	ferred Term	Sev	erity	Report	Description		Treatment
Serotonin sy		Life		hreatening re		Pt h	ospitalised icu> ventilation
Rhabdomyol		11 4 -	!				·
Medicine		NF (0	- d)				
AMITRIPIYL	NE HYDROCHLORIE	E (Suspecto		Reaso	on:		
3atch	:	3t	0.0 arted:		Stopped:		
CLOMIPRAM	INE HYDROCHLORII	DE (Suspect	ed)	₹easo			
			0.0				
3atch	:	3t	arted:		Stopped:		
TRAMAL (Su	spected)			Reaso	on:		
			0.0				
3atch		3t	Started: Stopped:				
MERSYNDOL	. (Suspected)		Reason:				
			0.0				
3atch	:	St.	arted:		Stopped:		
Laborator	y Investigatio	ns:					
Date	Туре	Range	Date Tested	Result		Deta	ils
Additiona	l Information:						



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 169556
 Seq: 1
 Gender:
 F

 Reported:
 04/10/2001
 Weight:

Hospitalisation:
Onset Date:

DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Neuropathy		Polyneuropathy	

Medicine Details:

ANAFRANIL (Suspected) Reason:

Tablet 75.0 Milligram Daily Oral **3atch:** 3tarted: 01/01/1994 **3topped:**

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not accurate but indicates the drug was started sometime in the year.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number:173089Seq:1Gender:MReported:25/02/2002Weight:75.00Hospitalisation:Admitted to hospitalAge:42

Onset Date: 17/02/2002 **DOB**: 24/08/1959

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Syncope	Life	Patient found collapsed at home.	Patient admitted to icu for airway protection and haemofiltration. given bromocriptine 5mg tds. zyprexa, largactil, anafranil and xanax ceased. transferred to renal ward for continuing dialysis and management of
Hypertonia	Severe	Severe rigidity.	
Blood creatine phosphokinase in	Life		
Neuroleptic malignant syndrome	Life		
Neuropathy peripheral	Life		
Renal impairment	Life		

Medicine Details:

XANAX (Suspected)		Reason: Obsessive compulsive neurosis
	0.5 Milligram	As necessary
Batch:	Started:	Stopped: 18/02/2002
ZYPREXA (Suspected)		Reason: Obsessive compulsive neurosis
	25.0 Milligram	Daily
Batch:	Started:	Stopped: 18/02/2002
LARGACTIL (Suspected)		Reason: Obsessive compulsive neurosis
	25.0 Milligram	Daily
Batch:	Started:	Stopped: 18/02/2002
ANAFRANIL (Suspected)		Reason: Obsessive compulsive neurosis
	25.0 Milligram	Daily
3atch:	Started:	Stopped: 18/02/2002

Laboratory Investigations:

					
Date	Туре	Range	Date Tested	Result	Details
	Creatine		17/02/2002	130536	

Additional Information:



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number:173089Seq:1Gender:MReported:25/02/2002Weight:75.00Hospitalisation:Admitted to hospitalAge:42

pitalisation: Admitted to hospital Age: 42
Onset Date: 17/02/2002 DOB: 24/08/1959

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Rhabdomyolysis	Life		
Tremor			

Medicine Details:

XANAX (Suspected)		Reason: Obsessive compulsive neurosis
	0.5 Milligram	As necessary
Зatch:	Started:	Stopped: 18/02/2002
ZYPREXA (Suspected)		Reason: Obsessive compulsive neurosis
	25.0 Milligram	Daily
3atch:	Started:	Stopped: 18/02/2002
LARGACTIL (Suspected)		Reason: Obsessive compulsive neurosis
	25.0 Milligram	Daily
3atch:	25.0 Milligram Started:	Daily Stopped: 18/02/2002
3atch: ANAFRANIL (Suspected)	3 -	,
	3 -	Stopped: 18/02/2002

Laboratory Investigations:

Additional Information:



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 180060
 Seq: 1
 Gender: M

 Reported:
 25/10/2002
 Weight:
 35.00

 Hospitalisation:
 Age: 63Y

Onset Date: 22/07/2002 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion Botal		E	
Preferred Term	Severity	Report Description	Treatment
Ventricular tachycardia		In theatre also in post op.	
Hypotension			

Medicine Details:

PENICILLIN NOS (Other drug)		Reason:	Pneumonia,unspecified	
	0.0			
3atch:	Started:		Stopped:	
METRONIDAZOLE (Other drug)		Reason:	Pneumonia,unspecified	
	0.0			
3atch:	Started:		Stopped:	
GENTAMICIN SULPHATE (Other drug)		Reason:	Pneumonia,unspecified	
	0.0			
3atch:	3atch: Started:		Stopped:	
ROCURONIUM BROMIDE (Other drug)		Reason:		
	0.0			
Зatch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient lost 9 litres of blood intra-op. patient also taking ca-chloride, magnesium, morphine, sevoflurane, gelofusine, hartmann's ffp and plt.



Additional Information:

ffp and plt.

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Case Number: Reported:	180060 25/10/2002	Seq: 1			Gender: Weight:	
Hospitalisation:					Age:	63Y
Onset Date:	22/07/2002				DOB:	
	Not yet recovere	d			Causality:	Causality possible
Reaction Detai	İ					
Medicine Det	ails:					
	YDROCHLORIDE (Ot	her drug)		Reason:		
			0.0			
3atch:		Started:			Stopped:	
VANCOMYCIN HY	DROCHLORIDE (Oth	er drug)		Reason:		
			0.0			
3atch:		Started:			Stopped:	
METARAMINOL T	ARTRATE (Other dru	g)		Reason:		
			0.0			
3atch:	- (0)	Started:		_	Stopped:	
NORADRENALINE	: (Other drug)		0.0	Reason:		
3atch:		Started:	0.0		Hannadi	
Saton.		Starteu.			Stopped:	
Laboratory In	vestigations:					

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Patient lost 9 litres of blood intra-op. patient also taking ca-chloride, magnesium, morphine, sevoflurane, gelofusine, hartmann's



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 180060
 Seq: 1
 Gender: M

 Reported:
 25/10/2002
 Weight: 35.00

 Hospitalisation:
 Age: 63Y

Onset Date: 22/07/2002 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

LIGNOCAINE (Other drug)		Reason:
	0.0	
3atch:	Started:	Stopped:
OMEPRAZOLE (Other drug)		Reason: Other diseases of esophagus
	20.0 Milligram	Daily
Зatch:	Started:	Stopped:
CISAPRIDE (Suspected)		Reason: Other diseases of esophagus
Tablet	10.0 Milligram	Daily Oral
Зatch:	Started: 03/07/2002	Stopped: 21/07/2002
CLOMIPRAMINE HYDROCHLORIDE	(Suspected)	Reason:
Tablet	50.0 Milligram	Daily Oral
3atch:	3tarted: 13/07/2002	3topped: 21/07/2002

Laboratory Investigations:

Additional Information:

Patient lost 9 litres of blood intra-op. patient also taking ca-chloride, magnesium, morphine, sevoflurane, gelofusine, hartmann's ffp and plt.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report	t Detail
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 Case Number:
 180847
 Seq: 1
 Gender:
 F

 Reported:
 19/12/2002
 Weight:
 67.00

 Hospitalisation:
 Age: 32

Onset Date: 15/10/2002 DOB: 25/02/1970

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Purpura		purpura, postural hypotension, loss of consciousness, abnormal liver function tests, cramps	Required a visit to doctor
Abdominal pain Hepatic function abnormal Muscle spasms Orthostatic hypotension Syncope			

N	lec	lici	ine	Detai	ils:
H٧				Dota	113.

ANAFRANIL (Suspected) Reason: Obsessive compulsive neurosis

Tablet 50.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

	t De	

Case Number: 185568 Seq: 1 Gender: M

Reported: 07/05/2003 Weight: 0.00 Hospitalisation: Age: 36Y

Onset Date: 15/04/2003 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Detai

touction Botal			
Preferred Term	Severity	Report Description	Treatment
Panic attack		Panic attack, palpitations, sweating	Ceased Anafranil
Hyperhidrosis			
Palpitations			

Medicine Details:

ANAFRANIL (Suspected) Reason: Depression

 Tablet
 25.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 15/04/2003
 3topped:
 16/04/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 190145
 Seq:
 1
 Gender:
 M

 Reported:
 01/09/2003
 Weight:
 0.00

Hospitalisation: Admitted to hospital **Age**: 44

Onset Date: 15/07/2003 DOB: 17/11/1958
Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Optic neuropathy	Severe	Optic Neuropathy	

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Su		Reason:				
Tablet	150.0	Milligram			Oral	
Зatch:	Started:		Stopped:		Contin	
LITHIUM CARBONATE (Suspected)			Reason:			
Tablet	Dose Unspecified				Oral	
Зatch:	Started:			Stopped:		
CLOPINE (Suspected)			Reason:			
Tablet	50.0	Milligram	Daily		Oral	
3atch:	Started:			Stopped:	12/08/2003	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

All suspected drugs administered 12/2002 to 07/2003 and 08/2003.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail

Case Number: 193446 Seq: 1 Gender: F

Reported: 22/12/2003 Weight: 0.00 Hospitalisation: Age: 38

Onset Date: 05/12/2003 **DOB:** 27/06/1965

Outcome: Recovered 17/12/2003 Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Visual disturbance		Could not see, wanted to sleep, could not open eyes, fever, sweating - burning up inside, loss of memory, heart palpitations. Ranting according to husband, unable to remember what said.	
Abnormal behaviour		and to remember what said.	
Amnesia			
Hyperhidrosis			
Incoherent			
Palpitations			
Pyrexia			
Sleep disorder			

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Suspected) Reason: Depression

 Tablet
 50.0 Milligram
 1 time
 Oral

 3atch:
 3tarted:
 05/12/2003
 3topped:
 05/12/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

One dose taken only. Symptoms occurred within 2 hours of first dose and gradually resolved over 7-10 days. Still has some dizziness and tiredness, Lamictal stopped one day prior.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 196114 Seq: 1 Gender: M

Reported: 31/03/2004 Weight: 0.00 Hospitalisation: Age: 28

Onset Date: 10/03/2004 DOB: 11/08/1975

Outcome: Unknown Causality: Causality possible

Reaction Detai

		ā.	
Preferred Term	Severity	Report Description	Treatment
Anxiety	Severe	Patient developed more severe anxiety.	
Drug therapy changed	Severe		

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Suspected) Reason: Obsessive compulsive neurosis

Tablet 350.0 Milligram Daily Oral Startet: L TERM Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient had been using Anafranil since 1996 without a reaction. When switched to the generic developed more severe anxiety



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 198132 Seq: 1 Gender: F

Reported: 15/06/2004 Weight: 0.00 Hospitalisation: Age: 42

Onset Date: 23/04/2004 DOB: 13/02/1962

Outcome: Recovered 28/04/2004 Causality: Causality possible

Reaction Detai

todotion Botal		-	
Preferred Term	Severity	Report Description	Treatment
Confusional state	Required Visit to Doctor	Confusion, memory lapses, sweating, flushing and muscle cramps.	
Amnesia	Required Visit to Doctor		
Flushing	Required Visit to Doctor		
Hyperhidrosis	Required Visit to Doctor		
Muscle spasms	Required Visit to Doctor		

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
	10.0 Milligram	Daily	
3atch:	Started:	Stopped:	
CLOMIPRAMINE HYDROCHLORID	E (Suspected)	Reason: Obsessive co	mpulsive neurosis
Tablet	150.0 Milligram	Daily	Oral
3atch:	Started: 19/03/2004	Stopped:	23/04/2004
QUETIAPINE (Suspected)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
3atch:	Started:	Stopped:	28/04/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



DOB:

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 198381
 Seq: 1
 Gender:
 F

 Reported:
 21/06/2004
 Weight:
 0.00

 Hospitalisation:
 Age: 57Y

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Onset Date:

todotion Dotal			
Preferred Term	Severity	Report Description	Treatment
	Required Visit to Doctor	Asthma aggravate.	

Medicine Details:

PLACIL (Suspected)		₹eason:	Depression	
Tablet	100.0 Milligra	m Daily		Oral
3atch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Increased asthma persisted until Paroxetine ceased. Same pattern with Clomipramine as dose increased.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 201793
 Seq:
 1
 Gender:
 F

 Reported:
 18/10/2004
 Weight:
 44.40

 Hospitalisation:
 Age:
 41

Onset Date: 10/10/2004 **DOB**: 16/09/1963

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Cachon Detai			
Preferred Term	Severity	Report Description	Treatment
Wheezing	to Doctor	Patient experienced wheezing, sweating, shortness of breath, palpitations, swelling and puffy eyes/face and no energy.	
Dyspnoea	Required Visit to Doctor		
Face oedema	Required Visit to Doctor		
Hyperhidrosis	Required Visit to Doctor		
Palpitations	Required Visit to Doctor		

Medicine Details:

PLACIL (Suspected)		Reason: Anxie	ty neurosis
Tablet	50.0 Milligram	Daily	Oral
3atch:	Started: 09/10/2004	3to	pped: 11/10/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



DOB: 16/09/1963

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report	Detail
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 Case Number:
 201793
 Seq:
 1
 Gender:
 F

 Reported:
 18/10/2004
 Weight:
 44.40

Hospitalisation: Age: 41

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Onset Date: 10/10/2004

todotion Dotal			
Preferred Term	Severity	Report Description	Treatment
Periorbital oedema	Required Visit to Doctor		

Medicine Details:

PLACIL (Suspected)

Tablet

50.0 Milligram

Daily

Oral

3atch:

\$tarted: 09/10/2004

\$topped: 11/10/2004

Laboratory Investigations:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Case Number: 205965 Gender: M Seq: 1 Weight: 0.00 Reported: 11/03/2005 Hospitalisation: Age: 65 **Onset Date: DOB**: 12/10/1939 Outcome: Not yet recovered Causality: Causality certain Reaction Detai Severity Preferred Term Report Description Treatment Dizziness The patient experienced dizziness, dry mouth, sweating and nightmares whilst on Anafranil. He also experienced a feeling of general tiredness when he took 2 Anafranil tablets at once, said that Anafranil was impeding his urinary tract and recently scored a high result in his prostate test. Dry mouth Fatigue Hyperhidrosis Nightmare **Medicine Details:** ATACAND (Other drug) Reason: Started: 3atch: Stopped: **ANAFRANIL** (Suspected) Reason: Anxiety neurosis Tablet 25.0 Milligram Daily Oral Continuing. 3atch: Started: Stopped: **Laboratory Investigations:** Туре Date Tested Result Details Date Range **Additional Information:** Suspect drug certain rechallenge.

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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Report Detail Case Number: 215334 Gender: F Seq: 1 Reported: 27/01/2006 Weight: 65.00 Hospitalisation: Admitted to hospital Age: 60 Onset Date: 05/09/2005 **DOB:** 07/01/1945 Outcome: Recovered 08/09/2005 Causality: Causality probable Reaction Detai Preferred Term Severity Report Description Treatment Caused or Hyponatraemia Patient developed hyponatreamia, Ceased Clomipramine, given prolonged hypokalaemia, vomiting, prosphate inpatient hospitalisation Blood phosphorus decreased Caused or prolonged inpatient hospitalisation Caused or Hypokalaemia prolonged inpatient hospitalisation **Medicine Details:** MS CONTIN (Other drug) Reason: Pain 3atch: Started: Stopped: PANADEINE FORTE (Other drug) Reason: Pain Started: 3atch: Stopped: **ORDINE** (Other drug) Pain Reason: 3atch: Started: Stopped: IMIGRAN (Other drug) Reason: Migraine 3atch: Started: Stopped: **Laboratory Investigations:** Type Range **Date Tested** Result Details Date 0.55 27/01/2006 Phosphate 05/09/2005 27/01/2006 Potassium 05/09/2005 3.3 27/01/2006 05/09/2005 Sodium 110 Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Case Number: 215334	Seq: 1			Gender:	F	
Reported: 27/01/2006		Weight: 65.00				
Hospitalisation: Admitted to he	ospital			Age:	60	
Onset Date: 05/09/2005				DOB:	07/01/1945	
Outcome: Recovered		08/09/2005	C	ausality:	Causality proba	able
Reaction Detai				<u> </u>		
Preferred Term	Severity	Report Descr	ription		Treatment	
Vomiting	Caused or prolonged inpatient hospitalisation					
Medicine Details:						
DIAZEPAM (Other drug)		Reason:	Specific disord	ders of sleep		
Batch:	Started:		Stopped:			
CLOMIPRAMINE HYDROCHLORIDI	E (Suspected)	Reason:				
Tablet	50.0 Mi	lligram Daily		Oral		
3atch:	Started:		Stopped:	05/09/2005		
Laboratory Investigation	ıs:					
Additional Information:						
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Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number:218879Seq:1Gender:UReported:02/06/2006Weight:0.00Hospitalisation:Admitted to hospitalAge:73

Onset Date: DOB: 14/12/1932

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Cognitive disorder	Caused or prolonged inpatient hospitalisation		Metofrmin, Clomipramine and Ogen ceased.
Dysphagia	Caused or prolonged inpatient hospitalisation		
Hyperglycaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

METFORMIN HYDROCHLORIDE (Suspec	ted)	Reason:			
Tablet	500.0 Milligram	Daily		Oral	
3atch:	Started: 25/04/2006	}to	pped:	02/05/2006	0
CLOMIPRAMINE HYDROCHLORIDE (Sus	pected)	Reason:			
Tablet	50.0 Milligram	Daily		Oral	
3atch:	3tarted: 18/11/2005	3to	pped:	02/05/2006	
OGEN (Suspected)		Reason:			
OGEN (Suspected)	1.3 Milligram	Reason: Daily			
OGEN (Suspected) 3atch:	1.3 Milligram 3tarted: 16/03/2006	Daily	pped:	02/05/2006	
	3	Daily	pped:	02/05/2006	
3atch:	3	Daily	pped:	02/05/2006 Oral	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number:218879Seq:1Gender:UReported:02/06/2006Weight:0.00Hospitalisation:Admitted to hospitalAge:73

Onset Date: **DOB**: 14/12/1932

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Mobility decreased	Caused or prolonged inpatient hospitalisation		
Oedema	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)		Reason:	Explosive personality disorder
	10.0 Milligram	Daily	
Зatch:	3tarted: 26/09/2005		Stopped: 02/05/2006 0
EPILIM (Suspected)		Reason:	Explosive personality disorder
	1.5 Gram	Daily	
3atch:	3tarted: 26/06/2005		Stopped: 02/05/2006
LASIX (Suspected)		Reason:	Edema and dropsy
	80.0 Milligram	Daily	
3atch:	3tarted: 26/09/2005		Stopped: 02/05/2006
ALDACTONE (Suspected)		Reason:	Edema and dropsy
Tablet	50.0 Milligram	Daily	Oral

Laboratory Investigations:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Case Number:	218879	Seq: 1		Gender:	U
Reported:		-		Weight:	0.00
Hospitalisation:	Admitted to hosp	ital		Age:	
Onset Date:					14/12/1932
Outcome:	Not yet recovered	d		Causality:	Causality possible
Reaction Detai					
Medicine Deta					
SEROQUEL (Suspe	ected)	400.0	Reason:	Explosive personality diso	rder
Tablet		400.0 M			
3atch:		3tarted: 26/09	/2005	\$topped: 02/05/2006	
Laboratory In	vestigations:				
-	•				
Additional Info	ormotion.				
Additional info	ormation:				
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DOB: 16/04/1963

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

 Case Number:
 221323
 Seq:
 1
 Gender:
 F

 Reported:
 04/09/2006
 Weight:
 0.00

Hospitalisation: Age: 43

Outcome: Recovered Causality: Causality possible

Reaction Detai

Onset Date: 15/05/2006

Cucion Betai			-
Preferred Term	Severity	Report Description	Treatment
Drug level above therapeutic	Caused or prolonged inpatient hospitalisation		
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MULTIVITAMINS (Other drug)		Reason:
	1.0 Dose Unsp	ecified
Заtch:	Started:	Stopped:
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia
Tablet	6.0 Milligram	Daily Oral
Зatch:	Started:	Stopped:
CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia
Tablet	900.0 Milligram	Daily Oral
Зatch:	3tarted: 28/04/2006	Stopped:
CLOMIPRAMINE HYDROCHLORIDE (Su	spected)	Reason: Depression
Tablet	150.0 Milligram	Daily Oral
Заtch:	Started:	Stopped:

Laboratory Investigations:

-		<u> </u>				
	Date	Туре	Range	Date Tested	Result	Details
	04/09/2006	Pharmacokinetics				Clozapine level 4.24, Norchlozapine 2.77 micromol/L 19/05/2006. (recommenced level 1.1-1.3). Increased risk of seizure if more then 3micromol/L.



Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE, PLACIL

Report Detail

Case Number: 221930 Seq: 1 Gender: M Reported: 26/09/2006 Weight: 0.00 Hospitalisation: **Age:** 99u

Onset Date: DOB: Causality: Causality possible

Outcome: Unknown

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Patient's speech had deteriorated and he had started stuttering and showing "disfluency". Patient was also experiencing hypertonia	
Concomitant disease aggravated			
Speech disorder			

Medicine Details:

ANAFRANIL (Suspected)	₹	Reason:				
Tablet	75.0 Milligram	Daily	Oral			
3atch:	Started:	Stopped	d:	0		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Current condtion: Deafness and speech disorder.



Hospitalisation:

Case Number: 228762

Reported: 22/05/2007

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight: 0.00

Age: 76

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANAFRANIL,CLOMIPRAMINE HYDROCHLORIDE,PLACIL

Seq: 1

Onset Date: 22/02/2007				DB : 26/04/1930		
Outcome: Recovered		2	23/02/2007 Causal		lity: Causality possible	
action D	etai					
Pref	ferred Term	Seve	erity	Report	Description	Treatment
Confusional state		be red Patier paran	ase in confusicently started nt was alread noid delusions ened afterwares ive.			
ggression						
elirium						
ledicine l	Details: i-нургосньогот	FHIAZIDE (Othe	ər drug)	Reaso	on:	
3atch	:	3ta	rted:		Stopped:	
SPIRIN (Oth	er drug)					
3atch	:	€ta	rted:			
OLOXYL WI	TH SENNA (Other	drug)		₹easc	Stopped:	
3atch	: INE HYDROCHLOR		rted:	Reaso	Stopped:	
Table		IDE (Suspecte	u)	\case	Oral	
3atch: Started:		3ta	rted:		Stopped:	
Julon	•					
		one:				
	y Investigatio	ons:	Date Tested	Result		Details