



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 14 Sep 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ANATENSOL,ANATENSOL ENANTHATE FOR INJECTION,FLUPHENAZINE ENANTHATE,FLUPHENAZINE HYDROCHLORIDE

Report Details:

Case Number: 62521

Seq: 1

Gender: F

Reported: 14/09/1989

Weight: 70.00

Hospitalisation:

Age: 43Y

Onset Date: 05/08/1989

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain			

Medicine Details:

NORMISON (Other drug)	Reason: Specific disorders of sleep
10.0 Milligram	Daily
Batch:	Started: 12/12/1986
Stopped:	
NICORETTE GUM (Suspected)	Reason:
0.0	
Batch:	Started:
Stopped:	
ANATENSOL (Suspected)	Reason: Unspecified schizophrenia
4.0 Milligram	Daily
Batch:	Started: 30/09/1986
Stopped:	03/08/1989

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Report Details:

Case Number: 63449	Seq: 1	Gender: F
Reported: 24/11/1989		Weight: 55.00
Hospitalisation:		Age: 76Y
Onset Date: 18/11/1989		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradycardia Dysphagia Sleep disorder Speech disorder Tremor			Cogentin im followed by cogentin 2mg tds.

Medicine Details:

FELDENE (Suspected)		Reason:	
Oral application	10.0 Milligram	Daily	Oral
Batch:	Started: 01/11/1988	Stopped:	CONTIN
SEREPAX (Suspected)		Reason:	
Oral application	30.0 Milligram	Daily	Oral
Batch:	Started: 01/11/1987	Stopped:	CONTIN
ANATENSOL (Suspected)		Reason: Depression	
Oral application	2.0 Milligram	Daily	Oral
Batch:	Started: 05/10/1989	Stopped:	21/11/1989
DEPTRAN (Suspected)		Reason: Paranoia	
Oral application	25.0 Milligram	Daily	Oral
Batch:	Started: 05/10/1989	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Report Details:

Case Number: 64660

Seq: 1

Gender: F

Reported: 09/03/1990

Weight: 66.00

Hospitalisation:

Onset Date: 10/02/1990

Age: 24Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Headache			Anatensol given dec 88/jan 89 with some elevation of lft.
Hepatitis cholestatic			
Nausea			
Pyrexia			
Vomiting			

Medicine Details:

TEGRETOL (Suspected)		Reason: Manic-depression psycho,manic
	600.0 Milligram	Daily
Batch:	Started: 16/01/1990	Stopped: CONTIN
RIVOTRIL (Suspected)		Reason: Manic-depression psycho,manic
	6.0 Milligram	Daily
Batch:	Started: 11/01/1990	Stopped: 08/02/1990
ANATENSOL (Suspected)		Reason: Manic-depression psycho,manic
	20.0 Milligram	Daily
Batch:	Started: 05/02/1990	Stopped: 14/02/1990

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Alp 235, ggt 735, alt 217, ast 70, bilirubin 17.

Additional Information:



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Report Details:

Case Number: 75898	Seq: 1	Gender: M
Reported: 10/03/1992		Weight:
Hospitalisation:		Age: 39Y
Onset Date: 26/02/1992		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aplastic anaemia			
Retinal haemorrhage			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application	0.0 Daily Oral
Batch:	Started: 01/07/1991 Stopped: 21/02/1992
PROZAC (Suspected)	Reason: Depression
Tablet	0.0 Daily Oral
Batch:	Started: 01/10/1991 Stopped: 4D
PROZAC (Suspected)	Reason: Depression
Tablet	0.0 Daily Oral
Batch:	Started: 24/02/1992 Stopped: 26/02/1992
ANATENSOL (Suspected)	Reason: Paranoid states
Tablet	0.0 Daily Oral
Batch:	Started: 01/11/1991 Stopped: 28/12/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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ANATENSOL,ANATENSOL ENANTHATE FOR INJECTION,FLUPHENAZINE ENANTHATE,FLUPHENAZINE HYDROCHLORIDE

Report Details:

Case Number: 89078	Seq: 1	Gender: F
Reported: 05/11/1993		Weight:
Hospitalisation:		Age: 42Y
Onset Date: 20/01/1993		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			Antibiotics, isolation and sterile foods.

Medicine Details:

FLUPHENAZINE DECANOATE (Suspected)		Reason: Unspecified psychosis	
Injection	74.0 Milligram	Weekly	Intramuscular
Batch:	Started: 01/10/1992	Stopped: 11/01/1993	
CARBAMAZEPINE (Suspected)		Reason: Manic-depression psycho,manic	
Oral application	600.0 Milligram	Daily	Oral
Batch:	Started: 13/01/1993	Stopped: 21/01/1993	
FLUPHENAZINE HYDROCHLORIDE (Suspected)		Reason: Unspecified psychosis	
Oral application	5.0 Milligram	Daily	Oral
Batch:	Started: 01/10/1992	Stopped: 22/01/1993	
PROPRANOLOL HYDROCHLORIDE (Suspected)		Reason: Abnormal involuntary movement	
Tablet	80.0 Milligram	Daily	Oral
Batch:	Started: 15/12/1992	Stopped: 25/01/1993	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium	>4.07	20/01/1993	1.77	Baseline 4.07
	Sodium	>4.07	31/01/1993	1.48	Baseline 4.07
	Sodium	>4.07	28/01/1993	0.86	Baseline 4.07
	Sodium	>4.07	02/02/1993	1.1	Baseline 4.07
	Sodium	>4.07	12/02/1993	11.21	Baseline 4.07
	Sodium	>4.07	09/02/1993	1.13	Baseline 4.07
	Sodium	>4.07	29/01/1993	0.4	Baseline 4.07

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Report Details:

Case Number: 89078	Seq: 1	Gender: F
Reported: 05/11/1993		Weight:
Hospitalisation:		Age: 42Y
Onset Date: 20/01/1993		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Medicine Details:

BENZTROPINE MESYLATE (Suspected)		Reason: Abnormal involuntary movement	
Oral application	2.0 Milligram	Daily	Oral
Batch:	Started: 15/12/1992	Stopped: 25/01/1993	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells	>10.8	20/01/1993	3.1	Baseline 10.8
	White blood cells	>10.8	21/01/1993	2.8	Baseline 10.8
	White blood cells	>10.8	28/01/1993	3.3	Baseline 10.8
	White blood cells	>10.8	29/01/1993	2.0	Baseline 10.8
	White blood cells	>10.8	02/02/1993	4.2	Baseline 10.8
	White blood cells	>10.8	09/02/1993	4.2	Baseline 10.8
	White blood cells	>10.8	12/02/1993	13.5	Baseline 10.8

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ANATENSOL,ANATENSOL ENANTHATE FOR INJECTION,FLUPHENAZINE ENANTHATE,FLUPHENAZINE HYDROCHLORIDE

Report Details:

Case Number: 89476	Seq: 1	Gender: M
Reported: 30/11/1993		Weight:
Hospitalisation:		Age: 34Y
Onset Date: 31/12/1993		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis	Severe		

Medicine Details:

ANATENSOL (Suspected)	Reason:
10.0 Milligram	Daily
Oral	
Batch:	Started:
	Stopped: 28/10/1993
PROTHIADEN (Suspected)	Reason:
Oral application	25.0 Milligram
Daily	Oral
Batch:	Started: 01/07/1989
	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	0-40	15/03/1993	148	
	ALT = SGPT	0-40	13/07/1993	219	
	ALT = SGPT	0-40	24/08/1993	265	
	ALT = SGPT	0-40	23/09/1993	166	
	AST = SGOT	0-40	15/03/1993	NORMAL	
	AST = SGOT	0-40	13/07/1993	86	
	AST = SGOT	0-40	24/08/1993	106	

Additional Information:

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



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ANATENSOL,ANATENSOL ENANTHATE FOR INJECTION,FLUPHENAZINE ENANTHATE,FLUPHENAZINE HYDROCHLORIDE

Report Details:

Case Number: 89476

Seq: 1

Gender: M

Reported: 30/11/1993

Weight:

Hospitalisation:

Age: 34Y

Onset Date: 31/12/1993

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ANATENSOL (Suspected)		Reason:	
	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	28/10/1993
PROTHIADEN (Suspected)		Reason:	
Oral application	25.0 Milligram	Daily	Oral
Batch:	Started: 01/07/1989	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	0-40	23/09/1993	66	
	LDH	>225	15/03/1993	NORMAL	
	LDH	>225	13/07/1993	NORMAL	
	LDH	>225	24/08/1993	248	

Additional Information:

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Report Details:

Case Number: 119555	Seq: 1	Gender: M
Reported: 31/07/1997		Weight:
Hospitalisation:		Age: 27
Onset Date: 30/06/1997		DOB: 26/12/1969
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension Hypertonia Blood creatine phosphokinase incr Leukocytosis Neuroleptic malignant syndrome		Raised blood pressure Stiff	Withheld fluphenazine, orphenadrine, thyroxine. given fluids, benztropine 2mg twice a day and observation

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started: 20/06/1997	Stopped:	
FLUPHENAZINE HYDROCHLORIDE (Suspected)		Reason: Unspecified psychosis	
	10.0 Milligram	Daily	
Batch:	Started: 20/06/1997	Stopped: 30/06/1997	
ORPHENADRINE CITRATE (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 20/06/1997	Stopped: 30/06/1997	
THYROXINE SODIUM (Suspected)		Reason:	
Tablet	100.0 Microgram	Daily	Oral
Batch:	Started: 20/06/1997	Stopped: 30/06/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine			Ck > 2000	

Additional Information:

Had long previous exposure. nil known allergies.



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Report Details:

Case Number: 125761	Seq: 1	Gender: M
Reported: 12/03/1998		Weight:
Hospitalisation:		Age: 27Y
Onset Date: 01/07/1997		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension Pyrexia Blood creatine phosphokinase incr Hypertonia Neuroleptic malignant syndrome		150/120 bp. 37.7 degrees c.	Fluphenazine ceased

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason: Unspecified schizophrenia
1.0 Gram	Daily
Batch:	Started:
Batch:	Stopped:
THYROXINE SODIUM (Other drug)	Reason: Unspecified schizophrenia
100.0 Microgram	Daily
Batch:	Started:
Batch:	Stopped:
FLUPHENAZINE HYDROCHLORIDE (Suspected)	Reason: Unspecified schizophrenia
10.0 Milligram	Daily
Batch:	Started: 30/06/1997
	Stopped: 01/07/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine	< 200	01/07/1997	2309	

Additional Information:



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Report Details:

Case Number: 141467 **Seq:** 1 **Gender:** M
Reported: 13/07/1999 **Weight:** 82.00
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia			

Medicine Details:

FLUPHENAZINE HYDROCHLORIDE (Suspected)	Reason:
0.0	
Batch:	Started: L TERM Stopped: 28/07/1994
CHLORPROMAZINE HYDROCHLORIDE (Suspected)	Reason:
0.0	
Batch:	Started: L TERM Stopped: 28/07/1994
RISPERIDONE (Suspected)	Reason:
6.0 Milligram Daily	
Batch:	Started: 01/02/1994 Stopped: 08/07/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - metoprolol. had previous tardive dyskinesia 1993-1994 which seemed to resolve after change to clozapine, then reappeared. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



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Report Details:

Case Number: 193507
Reported: 23/12/2003

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 12/07/2003
Outcome: Unknown

Age: 49Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intestinal perforation	Caused or prolonged inpatient hospitalisation	Intestinal perforation.	

Medicine Details:

NAPROSYN (Suspected)		Reason: Pain
Tablet	Dose Unspecified	Oral
Batch:	Started:	Stopped:
FLUPHENAZINE HYDROCHLORIDE (Suspected)		Reason:
Tablet	1.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 12/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Developed a perforated bowel requiring a colostomy while receiving an expired stock (many years old that were discontinued) of Fluphenazine 1mg tablets. At a later stage, colostomy was removed. Patient was evaluated for ulcers due to Naprosyn therapy, however, no ulcer was found.