THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 1766 **Seq:** 1 **Gender:** M
Reported: 11/11/1988 **Weight:** 67.00
Hospitalisation: **Age:** 38Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Orthostatic hypotension Vomiting			

Medicine Details:

SERENACE (Suspected)		**Reason:**	
Tablet	25.0 Milligram	Daily	Oral
Batch:	**Started:** 01/09/1988		**Stopped:** 20/10/1988
LITHICARB (Suspected)		**Reason:**	
Tablet	1.5 Gram	Daily	Oral
Batch:	**Started:**		**Stopped:** 20/10/1988
COGENTIN (Suspected)		**Reason:**	
Tablet	8.0 Milligram	Daily	Oral
Batch:	**Started:** 01/09/1988		**Stopped:** 20/10/1988

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. Case Sequenced to: 57481/2

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 1946 **Seq:** 1 **Gender:** F
Reported: 28/06/1989 **Weight:** 82.00
Hospitalisation: **Age:** 70Y
Onset Date: 31/03/1989 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Jaundice Oedema			

Medicine Details:

DILANTIN (Suspected)			**Reason:** Convulsions	
Oral application	400.0 Milligram		Daily	Oral
Batch:	**Started:** 01/01/1985			**Stopped:** 27/01/1989
DILANTIN (Suspected)			**Reason:** Convulsions	
Oral application	300.0 Milligram		Daily	Oral
Batch:	**Started:** 04/02/1989			**Stopped:** 10/02/1989
DILANTIN (Suspected)			**Reason:** Convulsions	
Oral application	400.0 Milligram		Daily	Oral
Batch:	**Started:** 10/02/1989			**Stopped:** 17/03/1989
DILANTIN (Suspected)			**Reason:** Convulsions	
Oral application	300.0 Milligram		Daily	Oral
Batch:	**Started:** 17/03/1989			**Stopped:** 03/04/1989

Laboratory Investigations:

Date	Type	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. Case Sequenced to: 59834/2

Report Details:

Case Number: 1946 **Seq:** 1 **Gender:** F
Reported: 28/06/1989 **Weight:** 82.00
Hospitalisation: **Age:** 70Y
Onset Date: 31/03/1989 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

SERENACE (Suspected)			**Reason:**	
Tablet	6.0 Milligram	Daily		Oral
Batch:	**Started:** 01/01/1985		**Stopped:**	27/01/1989
SERENACE (Suspected)			**Reason:**	
Tablet	6.0 Milligram	Daily		Oral
Batch:	**Started:** 02/02/1989		**Stopped:**	20/03/1989
BACTRIM DS (Suspected)			**Reason:**	Othr diseases of urinary tract
Oral application	2.0 Dose Unspecified	Daily		Oral
Batch:	**Started:** 10/02/1989		**Stopped:**	20/02/1989

Laboratory Investigations:

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. Case Sequenced to: 59834/2

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 1963 **Seq:** 1
Reported: 20/03/1989
Hospitalisation:
Onset Date:
Outcome: Unknown

Gender: M
Weight: 73.00
Age: 42
DOB: 01/04/1946
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Catatonia Neuroleptic malignant syndrome			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
10.0 Milligram Daily
Batch: **Started:** 30/08/1988 **Stopped:** 13/09/1988

DIAZEPAM (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 30/08/1988 **Stopped:** 13/09/1988

TEMAZEPAM (Suspected) **Reason:** Specific disorders of sleep
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 01/09/1988 **Stopped:** 02/09/1988

BENZTROPINE MESYLATE (Suspected) **Reason:**
2.0 Milligram Daily
Batch: **Started:** 04/09/1988 **Stopped:** 14/09/1988

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Ck 612 u/l (r 60-270), raised liver enzymes

Additional Information:

Case Sequenced to: 60130/2

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 2189 **Seq:** 1 **Gender:** M
Reported: 31/10/1989 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: 28/10/1989 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash			Calamine, polaramine 2mg 6/24 prn.

Medicine Details:

ASPIRIN (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

HEPARIN SODIUM (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PANADOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

MAXOLON (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Case Sequenced to: 63009/2

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 2189 **Seq:** 1 **Gender:** M
Reported: 31/10/1989 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: 28/10/1989 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	
CORDARONE X 200 (Suspected)			**Reason:**	
Oral application	800.0	Milligram	Daily	Oral
Batch:	**Started:**	13/10/1989	**Stopped:**	28/10/1989
AZTREONAM (Suspected)			**Reason:**	
Injection	2.0	Gram	Daily	Intravenous
Batch:	**Started:**	19/10/1989	**Stopped:**	
VANCOMYCIN HYDROCHLORIDE (Suspected)			**Reason:**	
Injection	1.0	Gram	Daily	Intravenous
Batch:	**Started:**	19/10/1989	**Stopped:**	

Laboratory Investigations:

Additional Information:

Case Sequenced to: 63009/2

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 2427 **Seq:** 1 **Gender:** F
Reported: 09/07/1990 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: 17/06/1990 **DOB:** 19/06/1962
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Benztropine

Medicine Details:

TEMAZEPAM (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 16/06/1990 **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:**
Injection 15.0 Milligram Total Intramuscular
Batch: **Started:** 16/06/1990 **Stopped:** 17/06/1990

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Case Sequenced to: 66648/2

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 55056 **Seq:** 1 **Gender:** M
Reported: 25/06/1988 **Weight:** 150.00
Hospitalisation: **Age:** 32Y
Onset Date: 25/06/1988 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Cogentin 2mg imi/o

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
Oral application 5.0 Milligram As necessary Oral
Batch: **Started:** 25/06/1988 **Stopped:** 25/06/1988

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 55057 **Seq:** 1 **Gender:** M
Reported: 30/06/1988 **Weight:**
Hospitalisation: **Age:** 25Y
Onset Date: 27/06/1988 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation			Cogentin 1mg iv with no effect

Medicine Details:

LORAZEPAM (Suspected) **Reason:** Premedication
Oral application 2.5 Milligram 1 time Oral
Batch: **Started:** 27/06/1988 **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Premedication
Injection 2.5 Milligram 1 time Intravenous
Batch: **Started:** 27/06/1988 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 55102 **Seq:** 1 **Gender:** M
Reported: 05/07/1988 **Weight:**
Hospitalisation: **Age:**
Onset Date: 01/07/1988 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cyanosis Dystonia Oculogyration			Im benztropine regular therapy of 5mg diazepam daily oxygen

Medicine Details:

DIAZEPAM (Suspected)			**Reason:**	
Oral application	5.0 Milligram		3 times	Oral
Batch:	**Started:** 30/06/1988		**Stopped:**	
SERENACE (Suspected)			**Reason:**	
Injection	10.0 Milligram		1 time	Intravenous
Batch:	**Started:** 30/06/1988		**Stopped:**	
HYPNOVEL (Suspected)			**Reason:**	
Injection	10.0 Milligram		1 time	Intravenous
Batch:	**Started:** 30/06/1988		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 55267 **Seq:** 1 **Gender:** M
Reported: 21/07/1988 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: 28/06/1988 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Serenace and rivotril.
Productive cough			
Pyrexia			
Salivary hypersecretion			Benztropine not significantly effective. reduction and withdrawal of

Medicine Details:

COGENTIN (Suspected) **Reason:** Hered dystonia musculor deform
Injection 10.0 Milligram Total Intramuscular
Batch: **Started:** 26/06/1988 **Stopped:**

SERENACE (Suspected) **Reason:** Unspecified psychosis
Injection 6.0 Milligram Daily Intramuscular
Batch: **Started:** 26/06/1988 **Stopped:** 03/07/1988

RIVOTRIL (Suspected) **Reason:** Otr spec symp psychopathol nec
Injection 6.0 Milligram Daily Intramuscular
Batch: **Started:** 24/06/1988 **Stopped:** 30/07/1988

AMOXYCILLIN TRIHYDRATE (Suspected) **Reason:** Pyrexia of unknown origin
Injection 2.0 Gram Daily Intramuscular
Batch: **Started:** 26/06/1988 **Stopped:** 01/07/1988

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 55568 **Seq:** 1 **Gender:** F
Reported: 17/08/1988 **Weight:**
Hospitalisation: **Age:** 31Y
Onset Date: 09/04/1988 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			

Medicine Details:

STEMETIL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Anxiety neurosis
Injection 1.0 Dose Unspecified 1 time Intravenous
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 57460 **Seq:** 1 **Gender:** F
Reported: 17/11/1988 **Weight:**
Hospitalisation: **Age:** 73Y
Onset Date: 13/11/1988 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state Extrapyramidal disorder			

Medicine Details:

TRYPTANOL (Suspected) **Reason:**
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 16/11/1988

MOGADON (Suspected) **Reason:**
5.0 Milligram Daily
Batch: **Started:** **Stopped:**

ASCORBIC ACID (Suspected) **Reason:**
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

SERENACE (Suspected) **Reason:**
1.0 Milligram Daily
Batch: **Started:** 01/09/1988 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 57460 **Seq:** 1 **Gender:** F
Reported: 17/11/1988 **Weight:**
Hospitalisation: **Age:** 73Y
Onset Date: 13/11/1988 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

MODURETIC (Suspected) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 57480 **Seq:** 1 **Gender:** M
Reported: 14/11/1988 **Weight:**
Hospitalisation: **Age:** 63Y
Onset Date: 15/10/1988 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Priapism			Surgery sequelae: pulmonary embolus

Medicine Details:

SERENACE (Other drug)			**Reason:**	
Injection	10.0 Milligram		1 time	Intravenous
Batch:	**Started:** 13/10/1988		**Stopped:**	
VALIUM (Other drug)			**Reason:**	
Injection	10.0 Milligram		1 time	Intravenous
Batch:	**Started:** 13/10/1988		**Stopped:**	
COGENTIN (Other drug)			**Reason:**	
Injection	2.0 Milligram		1 time	Intravenous
Batch:	**Started:** 13/10/1988		**Stopped:**	
SERENACE (Suspected)			**Reason:**	Unspecified psychosis
Tablet	20.0 Milligram		Daily	Oral
Batch:	**Started:** 14/10/1988		**Stopped:**	18/10/1988

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 57481 **Seq:** 1 **Gender:** M
Reported: 11/11/1988 **Weight:** 67.00
Hospitalisation: **Age:** 38Y
Onset Date: 19/10/1988 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

SERENACE (Suspected)		**Reason:**	
Tablet	25.0 Milligram	Daily	Oral
Batch:	**Started:** 01/09/1988		**Stopped:** 20/10/1988
LITHICARB (Suspected)		**Reason:**	
Tablet	1.5 Gram	Daily	Oral
Batch:	**Started:**		**Stopped:** 20/10/1988
COGENTIN (Suspected)		**Reason:**	
Tablet	8.0 Milligram	Daily	Oral
Batch:	**Started:** 01/09/1988		**Stopped:** 20/10/1988

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 58197 **Seq:** 1 **Gender:** F
Reported: 24/01/1989 **Weight:**
Hospitalisation: **Age:** 78Y
Onset Date: 17/01/1989 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Benztropine, haloperidol ceased, commenced chlorpromazine, lithium was recommenced 250mg daily

Medicine Details:

SERENACE (Suspected) **Reason:** Other paranoid states
3.0 Milligram Daily
Batch: **Started:** 12/01/1989 **Stopped:** 20/01/1989

LITHIUM CARBONATE (Suspected) **Reason:** Unspecifid affective psychosis
750.0 Milligram Daily
Batch: **Started:** **Stopped:** 29/12/1988

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Pharmacokinetics				Lithium toxic on admission 1.98 (0.7 - 1.5)

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 60131 **Seq:** 1 **Gender:** F
Reported: 24/04/1989 **Weight:** 45.00
Hospitalisation: **Age:** 55
Onset Date: 03/10/1988 **DOB:** 24/05/1933
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anaemia Lymphopenia			 Sulphasalazine ceased

Medicine Details:

FEFOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** L TERM

DI-GESIC (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** L TERM

OXAZEPAM (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** L TERM

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** L TERM

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology				1 5/9/88 1/10 3/10 5/10 8/10 8/11 10/11 leucocytes (4-10) 12.8 4.9 2.8 2.2 5.3 6.7 8.0 lymphocytes (1500-3500) 640 500 756 550 11000 1200 700 neutrophils (2500-7500) 11776 4300 1960 1364 3800 5400 6600 hb 9-10 g/l

Additional Information:

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

Report Details:

Case Number: 60131 **Seq:** 1 **Gender:** F
Reported: 24/04/1989 **Weight:** 45.00
Hospitalisation: **Age:** 55
Onset Date: 03/10/1988 **DOB:** 24/05/1933
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

BENZTROPINE MESYLATE (Suspected)		**Reason:**	
	0.0		
Batch:	**Started:**	**Stopped:**	L TERM
PARACETAMOL (Suspected)		**Reason:**	
	0.0		
Batch:	**Started:**	**Stopped:**	L TERM
SULFASALAZINE (Suspected)		**Reason:**	Other rheumatoid arthritis
Tablet	2.0 Gram	Daily	Oral
Batch:	**Started:** 01/09/1988	**Stopped:**	01/10/1988

Laboratory Investigations:

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 60825 **Seq:** 1 **Gender:** F
Reported: 14/06/1989 **Weight:**
Hospitalisation: **Age:**
Onset Date: 15/05/1989 **DOB:**
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Sequelae: damage to teeth.

Medicine Details:

EUHYPNOS (Other drug) **Reason:**
Capsule 10.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:** CONTIN

SERENACE (Suspected) **Reason:** Unspecified neurosis
Injection 5.0 Milligram Daily Intramuscular
Batch: **Started:** 15/05/1989 **Stopped:** 16/05/1989

PETHIDINE HYDROCHLORIDE (Suspected) **Reason:**
600.0 Milligram Daily
Batch: **Started:** 15/05/1989 **Stopped:** 16/05/1989

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 61008 **Seq:** 1 **Gender:** M
Reported: 16/06/1989 **Weight:**
Hospitalisation: **Age:** 37
Onset Date: 16/06/1989 **DOB:** 01/07/1951
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anxiety			

Medicine Details:

LORAZEPAM (Other drug) **Reason:** Nausea and vomiting
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 16/06/1989 **Stopped:**

DEXAMETHASONE (Other drug) **Reason:** Nausea and vomiting
Injection 8.0 Milligram Daily Intravenous
Batch: **Started:** 16/06/1989 **Stopped:**

SERENACE (Suspected) **Reason:** Nausea and vomiting
Injection 2.5 Milligram 1 time Intravenous
Batch: **Started:** 16/06/1989 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 61252 **Seq:** 1 **Gender:** M
Reported: 19/06/1989 **Weight:**
Hospitalisation: **Age:** 24Y
Onset Date: 09/01/1989 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension Hypertonia Respiratory disorder Tachycardia Tardive dyskinesia			Benztropine 2mg i/v

Medicine Details:

CHLORMETHIAZOLE (Suspected) **Reason:** Otr spec symp psychopathol nec
0.0
Batch: **Started:** 04/01/1989 **Stopped:** 08/01/1989

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
Injection 10.0 Milligram 1 time Intravenous
Batch: **Started:** 08/01/1989 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 61357 **Seq:** 1 **Gender:** M
Reported: 04/07/1989 **Weight:** 66.00
Hospitalisation: **Age:** 58Y
Onset Date: 11/05/1989 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Haloperidol 5-10mg im 6/24 prn ceased haloperidol and commenced sinemet m 100/10 o tds. slowly resolving

Medicine Details:

PHENYTOIN SODIUM (Other drug)				**Reason:**	Subarach hemor w benign hypert
Oral application	350.0	Milligram	Daily		Oral
Batch:	**Started:** 07/03/1989			**Stopped:**	
SENOKOT (Other drug)				**Reason:**	
Oral application	2.0	Dose Unspecified	Daily		Oral
Batch:	**Started:** 19/03/1989			**Stopped:**	
HALOPERIDOL (Suspected)				**Reason:**	Otr spec symp psychopathol nec
Injection	5.0	Milligram	As necessary		Intramuscular
Batch:	**Started:** 13/03/1989			**Stopped:**	15/05/1989
ATENOLOL (Suspected)				**Reason:**	Essential benign hypertension
Oral application	50.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	13/05/1989

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 61607 **Seq:** 1
Reported: 26/07/1989
Hospitalisation:
Onset Date: 22/05/1989
Outcome: Death, maybe drug

Gender: M
Weight: 68.00
Age: 62
DOB: 27/07/1926
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure Hepatic function abnormal			Note: recent encoscopy followed by elevated cardiac and hepatic enzymes.- query hypotension.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PETHIDINE HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

RANITIDINE (Suspected) **Reason:** Ulcer of stomach w/o ment perf
Injection 600.0 Milligram Daily Intravenous
Batch: **Started:** 22/05/1989 **Stopped:** 26/05/1989

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				26/5/89 30/5/89 range total bili: 62 218 umol/l (3-20) alp: 111 81 iu/l (30-120) gmt: 129 96 iu/l (10-60) alt:2093 972 iu/l (5-45)
	Misclassified at [illegible]				Ast:4290(10.00) 1933(21.25) 320 iu/l (10-55) ld:3355(10.00) 2387(21.25) iu/l (100-200) ck: 540(10.00) 74(21.25) iu/l (30-200)

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 62274 **Seq:** 1 **Gender:** M
Reported: 08/08/1989 **Weight:** 77.00
Hospitalisation: **Age:** 28Y
Onset Date: 24/07/1989 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Ceased haloperidol. given cogentin 1mg im

Medicine Details:

TEMAZEPAM (Other drug) **Reason:**
Capsule 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 15/07/1989 **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
Injection 5.0 Milligram As necessary Intramuscular
Batch: **Started:** 22/07/1989 **Stopped:** 23/07/1989

PANADOL (Suspected) **Reason:**
1.0 Dose Unspecified As necessary
Batch: **Started:** 16/07/1989 **Stopped:** 24/07/1989

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 62669 **Seq:** 1 **Gender:** M
Reported: 14/08/1989 **Weight:**
Hospitalisation: **Age:** 66Y
Onset Date: 11/07/1989 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating Dehydration Hypernatraemia Renal impairment			Rehydration

Medicine Details:

LITHIUM CARBONATE (Suspected) **Reason:** Unspecifid affective psychosis
Tablet 1.0 Gram Daily Oral
Batch: **Started:** **Stopped:** 17/07/1989

DOXEPIN HYDROCHLORIDE (Suspected) **Reason:** Unspecifid affective psychosis
125.0 Milligram Daily
Batch: **Started:** **Stopped:** 17/07/1989

HALOPERIDOL (Suspected) **Reason:** Unspecifid affective psychosis
0.5 Milligram Daily
Batch: **Started:** **Stopped:** 17/07/1989

THEO-DUR (Suspected) **Reason:** Otr respiratory systm diseases
600.0 Milligram Daily
Batch: **Started:** **Stopped:** 17/07/1989

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 62669 **Seq:** 1 **Gender:** M
Reported: 14/08/1989 **Weight:**
Hospitalisation: **Age:** 66Y
Onset Date: 11/07/1989 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

MODECATE (Suspected) **Reason:** Unspecifid affective psychosis
Injection 6.2 Milligram Alternate weeks Intramuscular
Batch: **Started:** **Stopped:** 17/07/1989

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 63061 **Seq:** 1 **Gender:** M
Reported: 25/10/1989 **Weight:** 79.00
Hospitalisation: **Age:** 26Y
Onset Date: 29/09/1989 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash			

Medicine Details:

LITHIUM CARBONATE (Other drug) **Reason:** Unspecified schizophrenia
1.0 Gram Daily
Batch: **Started:** **Stopped:**

COGENTIN (Other drug) **Reason:** Unspecified schizophrenia
2.0 Milligram Daily
Batch: **Started:** **Stopped:**

SERENACE (Suspected) **Reason:** Unspecified schizophrenia
60.0 Milligram Daily
Batch: **Started:** 18/09/1989 **Stopped:** 29/09/1989

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 63164 **Seq:** 1 **Gender:** F
Reported: 25/10/1989 **Weight:** 36.00
Hospitalisation: **Age:** 74Y
Onset Date: 24/09/1989 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation Anorexia Jaundice Malaise			

Medicine Details:

PREDNISOLONE (Suspected) **Reason:** Nephritis,unqualified
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
Tablet 4.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

FLUCLOXACILLIN SODIUM (Suspected) **Reason:** Cellul&absc otr,mult&nos sites
Capsule 2.0 Gram Daily Oral
Batch: **Started:** 14/08/1989 **Stopped:** 20/08/1989

FLUCLOXACILLIN SODIUM (Suspected) **Reason:** Cellul&absc otr,mult&nos sites
2.0 Gram Daily
Batch: **Started:** 13/09/1989 **Stopped:** 19/09/1989

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Current lfts: alp 1953, ggt 794, ast 128, bili 807, tp 47, alb 34 on admission lft's: alp 483(30-120), ggt 410(5-45), ast 152(15-45), bili 66(3-20).
	Liver biopsy				Liver biopsy suggestive of drug injury. ante mortem liver biopsy and post mortem biopsy histology showed "a progressive picture of parenchymal cholestasis with evidence of bile duct damage and disappearance."

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 63357 **Seq:** 1 **Gender:** M
Reported: 13/11/1989 **Weight:**
Hospitalisation: **Age:** 82Y
Onset Date: 21/06/1989 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension Pyrexia			

Medicine Details:

SERENACE (Suspected) **Reason:**
Injection 5.0 Milligram 1 time Intramuscular
Batch: **Started:** 21/06/1989 **Stopped:**

SERENACE (Suspected) **Reason:**
Injection 0.5 Milligram 1 time Intravenous
Batch: **Started:** 21/06/1989 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 63438 **Seq:** 1 **Gender:** M
Reported: 23/11/1989 **Weight:** 99.00
Hospitalisation: **Age:** 46Y
Onset Date: 17/11/1989 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia Hyperhidrosis Hypotension Pallor Somnolence			

Medicine Details:

DECADRON (Suspected)			**Reason:** Premedication	
Oral application	20.0 Milligram		1 time	Oral
Batch:	**Started:** 17/11/1989		**Stopped:**	
ATIVAN (Suspected)			**Reason:** Premedication	
Tablet	2.5 Milligram		1 time	Oral
Batch:	**Started:** 17/11/1989		**Stopped:**	
MAXOLON (Suspected)			**Reason:** Premedication	
Injection	20.0 Milligram		1 time	Intravenous
Batch:	**Started:** 17/11/1989		**Stopped:**	
SERENACE (Suspected)			**Reason:** Premedication	
Oral application	2.5 Milligram		1 time	Oral
Batch:	**Started:** 17/11/1989		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 63438 **Seq:** 1 **Gender:** M
Reported: 23/11/1989 **Weight:** 99.00
Hospitalisation: **Age:** 46Y
Onset Date: 17/11/1989 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

VINCRISTINE SULPHATE (Suspected)			**Reason:**	Malignant neopla bronchus&lung
Injection	2.0 Milligram	1 time		Intravenous
Batch:	**Started:** 17/11/1989		**Stopped:**	
CYCLOPHOSPHAMIDE (Suspected)			**Reason:**	Malignant neopla bronchus&lung
Injection	1.6 Gram	1 time		Intravenous
Batch:	**Started:** 17/11/1989		**Stopped:**	

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 64439 **Seq:** 1 **Gender:** F
Reported: 05/12/1989 **Weight:**
Hospitalisation: **Age:** 59
Onset Date: 28/11/1989 **DOB:** 17/02/1930
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Flushing Tremor			Oxycodone stopped. pt reassured. 02 6l/min given.

Medicine Details:

OXYCODONE HYDROCHLORIDE (Suspected)			**Reason:**	
Tablet	5.0 Milligram		1 time	Oral
Batch:	**Started:** 28/11/1989		**Stopped:**	
SERENACE (Suspected)			**Reason:**	
Injection	5.0 Milligram		1 time	Intramuscular
Batch:	**Started:** 28/11/1989		**Stopped:**	
VALIUM (Suspected)			**Reason:**	
Tablet	10.0 Milligram		1 time	Oral
Batch:	**Started:** 28/11/1989		**Stopped:**	
OXYCODONE PECTINATE (Suspected)			**Reason:**	
Suppository	90.0 Milligram		Total	Rectal
Batch:	**Started:** 27/11/1989		**Stopped:**	28/11/1989

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 64439 **Seq:** 1 **Gender:** F
Reported: 05/12/1989 **Weight:**
Hospitalisation: **Age:** 59
Onset Date: 28/11/1989 **DOB:** 17/02/1930
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

PHENERGAN (Suspected) **Reason:**
Injection 25.0 Milligram Daily Intramuscular
Batch: **Started:** 27/11/1989 **Stopped:** 28/11/1989

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 64568 **Seq:** 1 **Gender:** F
Reported: 08/01/1990 **Weight:** 50.00
Hospitalisation: **Age:** 36Y
Onset Date: 21/07/1989 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Benztropine

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified schizophrenia
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 21/07/1989 **Stopped:** 24/07/1989

HALOPERIDOL (Suspected) **Reason:**
Oral application 10.0 Milligram Daily Oral
Batch: **Started:** 20/07/1989 **Stopped:** 21/07/1989

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 64622 **Seq:** 1 **Gender:** F
Reported: 27/02/1990 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: 22/01/1990 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Extrapyramidal disorder Hypertonia Hypokinesia Hypotension Neuroleptic malignant syndrome Pyrexia Somnolence			Paracetamol, heparin, parlodel.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
5.0 Milligram Daily
Batch: **Started:** **Stopped:**

THIORIDAZINE HYDROCHLORIDE (Suspected) **Reason:**
50.0 Milligram Daily
Batch: **Started:** **Stopped:**

CLONAZEPAM (Suspected) **Reason:**
2.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Creat ck 22/1/90 83 1190 23/1/90 53 700 24/1/90 59 348 *note ck-mb=22 u/l, 1.8% of total ck.

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 64702 **Seq:** 1 **Gender:** F
Reported: 27/02/1990 **Weight:**
Hospitalisation: **Age:** 86Y
Onset Date: 25/10/1989 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension			Ceased therapy

Medicine Details:

CARDIPRIN 100 (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

MELLERIL (Suspected) **Reason:** Unspecified psychosis
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 24/10/1989 **Stopped:** 25/10/1989

SERENACE (Suspected) **Reason:** Unspecified psychosis
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 25/10/1989

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Details:

Case Number: 65141 **Seq:** 1 **Gender:** M
Reported: 19/04/1990 **Weight:** 25.00
Hospitalisation: **Age:** 11Y
Onset Date: 20/07/1989 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Dystonia			Cogentin.

Medicine Details:

MAXOLON (Other drug) **Reason:**
Injection 1.0 Dose Unspecified 1 time Intramuscular
Batch: **Started:** 19/07/1989 **Stopped:**

AMOXIL (Other drug) **Reason:**
Injection 375.0 Milligram Daily Intravenous
Batch: **Started:** 19/07/1989 **Stopped:** 26/07/1989

DILANTIN (Other drug) **Reason:**
Injection 150.0 Milligram Daily Intravenous
Batch: **Started:** 19/07/1989 **Stopped:** 26/07/1989

SERENACE (Suspected) **Reason:** Otr spec symp psychopathol nec
Oral Liquid 4.0 Milligram As necessary Oral
Batch: **Started:** 19/07/1989 **Stopped:** 26/07/1989

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 66487 **Seq:** 1 **Gender:** F
Reported: 20/06/1990 **Weight:**
Hospitalisation: **Age:** 20Y
Onset Date: 05/04/1990 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
Injection 10.0 Milligram 1 time Intramuscular
Batch: **Started:** 04/04/1990 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 66583 **Seq:** 1 **Gender:** F
Reported: 12/07/1990 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state			

Medicine Details:

RANITIDINE (Suspected) **Reason:**
Oral application 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 06/07/1990

AMITRIPTYLINE HYDROCHLORIDE (Suspected) **Reason:**
Oral application 25.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 03/07/1990

ATENOLOL (Suspected) **Reason:**
Oral application 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 03/07/1990

HALOPERIDOL (Suspected) **Reason:**
Injection 5.0 Milligram Daily Intramuscular
Batch: **Started:** 28/06/1990 **Stopped:** 03/07/1990

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 66911 **Seq:** 1 **Gender:** F
Reported: 13/08/1990 **Weight:**
Hospitalisation: **Age:** 20Y
Onset Date: 11/05/1990 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Benztropine 2mg im then 1mg o bd thereafter.

Medicine Details:

DILANTIN (Other drug)			**Reason:** Convulsions	
Oral application	300.0 Milligram	Daily		Oral
Batch:	**Started:** 30/04/1990		**Stopped:**	
EUHYPNOS (Other drug)			**Reason:**	
Oral application	10.0 Milligram	Daily		Oral
Batch:	**Started:** 30/04/1990		**Stopped:**	
PREDNISOLONE (Other drug)			**Reason:** Systemic lupus erythematosus	
Oral application	30.0 Milligram	Daily		Oral
Batch:	**Started:** 06/05/1990		**Stopped:**	
SERENACE (Suspected)			**Reason:** Unspecified psychosis	
Oral application	15.0 Milligram	Daily		Oral
Batch:	**Started:** 10/05/1990		**Stopped:** 05/06/1990	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 67092 **Seq:** 1 **Gender:** F
Reported: 22/08/1990 **Weight:**
Hospitalisation: **Age:** 54Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) **Reason:** Unspecified psychosis
Oral application 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 67182 **Seq:** 1 **Gender:** M
Reported: 30/08/1990 **Weight:**
Hospitalisation: **Age:**
Onset Date: 24/08/1990 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Anxiety neurosis
Injection 23.0 Milligram Total Intravenous
Batch: **Started:** 23/08/1990 **Stopped:** 24/08/1990

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 67202 **Seq:** 1 **Gender:** F
Reported: 08/08/1990 **Weight:**
Hospitalisation: **Age:** 23Y
Onset Date: 17/05/1990 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Parenteral benztropine

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
15.0 Milligram Total
Batch: **Started:** 16/05/1990 **Stopped:** 17/05/1990

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 67336 **Seq:** 1 **Gender:** M
Reported: 31/07/1990 **Weight:** 51.00
Hospitalisation: **Age:** 82Y
Onset Date: 21/07/1990 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash erythematous			Ceased serenace,started application of topical celestone-m ointment daily and paraffin cream-bd-to rash.

Medicine Details:

SERENACE (Suspected)			**Reason:** Unspecified psychosis	
Oral application	10.0 Milligram	Daily	Oral	
Batch:	**Started:** 11/07/1990		**Stopped:**	
SERENACE (Suspected)			**Reason:** Unspecified psychosis	
Oral application	15.0 Milligram	Daily	Oral	
Batch:	**Started:** 12/07/1990		**Stopped:** 24/07/1990	
TRYPTANOL (Suspected)			**Reason:** Incontinence of urine	
	30.0 Milligram	Daily		
Batch:	**Started:** 19/03/1990		**Stopped:** 17/07/1990	
MELLERIL (Suspected)			**Reason:** Disturbance of sleep	
	50.0 Milligram	Daily		
Batch:	**Started:** 05/06/1990		**Stopped:** 11/07/1990	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 67607 **Seq:** 1 **Gender:** F
Reported: 10/09/1990 **Weight:**
Hospitalisation: **Age:** 67Y
Onset Date: 26/05/1990 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Haloperidol ceased

Medicine Details:

CHLORDIAZEPOXIDE HYDROCHLORIDE (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

LASIX (Other drug) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

CHLORAL HYDRATE (Other drug) **Reason:**
1.0 Gram Daily
Batch: **Started:** **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 67607 **Seq:** 1 **Gender:** F
Reported: 10/09/1990 **Weight:**
Hospitalisation: **Age:** 67Y
Onset Date: 26/05/1990 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

PARACETAMOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Report Details:

Case Number: 67909 **Seq:** 1 **Gender:** F
Reported: 17/10/1990 **Weight:** 58.00
Hospitalisation: **Age:** 66Y
Onset Date: 19/09/1990 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Choreoathetosis Hypertonia Neuroleptic malignant syndrome Opisthotonus Pyrexia			Patient has severe alzheimers disease.

Medicine Details:

SERENACE (Suspected) **Reason:** Otr spec symp psychopathol nec

Tablet 3.0 Milligram Daily Oral

Batch: **Started:** 09/09/1990 **Stopped:** 17/09/1990

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Misclassified at [illegible]				22/9/90 5/10/90 12/10/90 range ck: - 338 239 (25-200) white cells: 12.9 - - (4.0-200) neutrophils: 9.4 - - (2.0-7.50)

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 68255 **Seq:** 1 **Gender:** M
Reported: 08/11/1990 **Weight:** 67.00
Hospitalisation: **Age:** 31Y
Onset Date: 15/10/1990 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			Prednisone

Medicine Details:

STELAZINE (Other drug) **Reason:** Unspecified schizophrenia
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 23/09/1990 **Stopped:** CONTIN

COGENTIN (Other drug) **Reason:** Paralysis agitans
Tablet 4.0 Milligram Daily Oral
Batch: **Started:** 23/09/1990 **Stopped:** CONTIN

HALDOL DECANOATE (Suspected) **Reason:** Unspecified schizophrenia
Injection 100.0 Milligram Monthly Intramuscular
Batch: **Started:** 15/10/1990 **Stopped:** 15/10/1990

DIAZEPAM (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 23/09/1990 **Stopped:** 24/10/1990

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 68499 **Seq:** 1 **Gender:** M
Reported: 30/11/1990 **Weight:** 73.00
Hospitalisation: **Age:** 45Y
Onset Date: 10/11/1990 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema			

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) **Reason:** Unspecified psychosis
Oral application 0.0 Oral
Batch: **Started:** 10/11/1990 **Stopped:** 22/11/1990

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
Oral application 50.0 Milligram Daily Oral
Batch: **Started:** 05/11/1990 **Stopped:** 10/11/1990

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 68646 **Seq:** 1 **Gender:** F
Reported: 14/11/1990 **Weight:**
Hospitalisation: **Age:** 74Y
Onset Date: 13/08/1990 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state Orthostatic hypotension			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) **Reason:**
30.0 Milligram 1 time
Batch: **Started:** 03/07/1990 **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Manic depressive psycho, depre
1.5 Milligram Daily
Batch: **Started:** 23/07/1990 **Stopped:** 30/08/1990

MIANSERIN HYDROCHLORIDE (Suspected) **Reason:**
60.0 Milligram Daily
Batch: **Started:** 04/07/1990 **Stopped:** 09/07/1990

MIANSERIN HYDROCHLORIDE (Suspected) **Reason:**
90.0 Milligram Daily
Batch: **Started:** 10/07/1990 **Stopped:** 26/07/1990

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 68646 **Seq:** 1 **Gender:** F
Reported: 14/11/1990 **Weight:**
Hospitalisation: **Age:** 74Y
Onset Date: 13/08/1990 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected) **Reason:**
60.0 Milligram Daily
Batch: **Started:** 26/07/1990 **Stopped:** 13/08/1990

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 68657 **Seq:** 1 **Gender:** F
Reported: 04/12/1990 **Weight:**
Hospitalisation: **Age:** 54Y
Onset Date: 20/10/1990 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder Hyperkinesia			Medicine changed to thioridazine

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
3.0 Milligram Daily
Batch: **Started:** **Stopped:** 29/10/1990

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Details:

Case Number: 68745 **Seq:** 1 **Gender:** M
Reported: 02/11/1990 **Weight:**
Hospitalisation: **Age:** 18Y
Onset Date: 31/10/1990 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Dystonia			Cogentin 4 mg+4mg iv stat

Medicine Details:

ATIVAN (Other drug)			**Reason:**	
Tablet	3.0	Milligram	1 time	Oral
Batch:	**Started:**			**Stopped:**
DEXAMETHASONE (Other drug)			**Reason:**	
Tablet	8.0	Milligram	1 time	Oral
Batch:	**Started:**			**Stopped:**
SERENACE (Suspected)			**Reason:**	
Tablet	5.0	Milligram	1 time	Oral
Batch:	**Started:** 31/10/1990			**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 68982 **Seq:** 1 **Gender:** M
Reported: 17/12/1990 **Weight:**
Hospitalisation: **Age:** 61Y
Onset Date: 29/10/1990 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

TETRABENAZINE (Suspected)			**Reason:**		
Tablet	50.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	01/11/1990
HALOPERIDOL (Suspected)			**Reason:**		
Oral application	15.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	01/11/1990
FOLIC ACID (Suspected)			**Reason:**		
Tablet	5.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Details:

Case Number: 69140 **Seq:** 1 **Gender:** M
Reported: 21/12/1990 **Weight:** 64.00
Hospitalisation: **Age:** 84Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression Confusional state Renal impairment			

Medicine Details:

INDOMETHACIN (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

FRUSEMIDE (Suspected) **Reason:**
80.0 Milligram Daily
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
7.5 Milligram Daily
Batch: **Started:** **Stopped:**

KAY CIEL (Suspected) **Reason:**
1.2 Gram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Creatinine on admission 187 mmol/l, following treatment with indomethacin creatinine rose to 287 mmol/l.

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 69140 **Seq:** 1 **Gender:** M
Reported: 21/12/1990 **Weight:** 64.00
Hospitalisation: **Age:** 84Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

AUGMENTIN FORTE (Suspected)		**Reason:**	
	1.5 Gram	Daily	
Batch:	**Started:**		**Stopped:**
SULPHINPYRAZONE (Suspected)		**Reason:**	
	100.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 69330 **Seq:** 1 **Gender:** F
Reported: 31/01/1991 **Weight:** 95.00
Hospitalisation: **Age:** 68Y
Onset Date: 10/12/1990 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			

Medicine Details:

METAMUCIL (Suspected) **Reason:** Constipation
2.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** 04/01/1991

COLOXYL WITH SENNA (Suspected) **Reason:**
4.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** 04/01/1991

FLUCLOXACILLIN SODIUM (Suspected) **Reason:**
1.0 Gram Daily
Batch: **Started:** 01/01/1987 **Stopped:** 04/01/1991

DEXAMETHASONE (Suspected) **Reason:**
Tablet 8.0 Milligram Daily Oral
Batch: **Started:** 01/10/1990 **Stopped:** 11/01/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 69330 **Seq:** 1 **Gender:** F
Reported: 31/01/1991 **Weight:** 95.00
Hospitalisation: **Age:** 68Y
Onset Date: 10/12/1990 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

STEMETIL (Suspected)			**Reason:**	
Tablet	30.0 Milligram		Daily	Oral
Batch:	**Started:**		**Stopped:**	
TEGRETOL (Suspected)			**Reason:**	
	750.0 Milligram		Daily	
Batch:	**Started:** 01/10/1990		**Stopped:**	04/01/1991
SERENACE (Suspected)			**Reason:**	
	12.0 Milligram		Daily	
Batch:	**Started:** 14/11/1990		**Stopped:**	10/12/1990
MODURETIC (Suspected)			**Reason:**	Essential benign hypertension
	50.0 Milligram		Daily	
Batch:	**Started:** 01/01/1987		**Stopped:**	05/01/1991

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 69638 **Seq:** 1 **Gender:** M
Reported: 15/02/1991 **Weight:** 69.00
Hospitalisation: **Age:** 37Y
Onset Date: 14/02/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Benztropine

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
15.0 Milligram Daily
Batch: **Started:** 11/02/1991 **Stopped:** 14/02/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 69743 **Seq:** 1 **Gender:** M
Reported: 03/03/1991 **Weight:** 70.00
Hospitalisation: **Age:** 43Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension			
Neuroleptic malignant syndrome			Iv fluids, withdrawal of haloperidol
Pneumonia			Iv penicillin and gentamicin
Productive cough			
Pyrexia			
Tachycardia			
Urinary retention			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified schizophrenia
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1970 **Stopped:** 29/01/1991

COGENTIN (Suspected) **Reason:**
Tablet 4.0 Milligram Daily Oral
Batch: **Started:** 01/01/1970 **Stopped:** 29/01/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine phosphokinase	24-204 U/L	22/01/1991	938	
	Creatine phosphokinase	24-204 U/L	30/01/1991	1494	
	Creatine phosphokinase	24-204 U/L	30/01/1991	1708	
	Creatine phosphokinase	24-204 U/L	31/01/1991	1274	
	Creatine phosphokinase	24-204 U/L	01/02/1991	685	
	Creatine phosphokinase	24-204 U/L	03/02/1991	245	
	Creatine phosphokinase	24-204 U/L	04/02/1991	141	

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.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 69743 **Seq:** 1 **Gender:** M
Reported: 03/03/1991 **Weight:** 70.00
Hospitalisation: **Age:** 43Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)			**Reason:**	Unspecified schizophrenia
Oral application	20.0 Milligram		Daily	Oral
Batch:	**Started:** 01/01/1970		**Stopped:**	29/01/1991
COGENTIN (Suspected)			**Reason:**	
Tablet	4.0 Milligram		Daily	Oral
Batch:	**Started:** 01/01/1970		**Stopped:**	29/01/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine	24-204 U/L	06/02/1991	311	

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.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 69817 **Seq:** 1 **Gender:** F
Reported: 05/03/1991 **Weight:** 50.00
Hospitalisation: **Age:** 61Y
Onset Date: 01/09/1990 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Dyskinesia Gait disturbance Psychotic disorder Pupillary reflex impaired			

Medicine Details:

HALOPERIDOL (Suspected)		**Reason:**	Manic depressive psycho, depre
Oral application	20.0 Milligram	Daily	Oral
Batch:	**Started:** 01/08/1990		**Stopped:** 19/09/1990
LITHIUM CARBONATE (Suspected)		**Reason:**	Manic depressive psycho, depre
	500.0 Milligram	Daily	
Batch:	**Started:** 01/06/1989		**Stopped:** 19/09/1990
CLONAZEPAM (Suspected)		**Reason:**	Manic depressive psycho, depre
	2.0 Milligram	Daily	
Batch:	**Started:** 01/08/1990		**Stopped:** 19/09/1990

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 70074 **Seq:** 1 **Gender:** F
Reported: 21/03/1991 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

HALDOL DECANOATE (Suspected) **Reason:** Unspecified schizophrenia
Injection 300.0 Milligram Weekly Intramuscular
Batch: **Started:** 15/01/1991 **Stopped:**

SERENACE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 03/12/1990 **Stopped:**

COGENTIN (Suspected) **Reason:** Unspecified schizophrenia
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 29/01/1991 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 70182 **Seq:** 1 **Gender:** F
Reported: 03/04/1991 **Weight:** 50.00
Hospitalisation: **Age:** 68Y
Onset Date: 23/02/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Iv fluids dantrolene sodium

Medicine Details:

THIAMINE (Other drug)				**Reason:**	
Tablet	100.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
CHLOROMYCETIN (Other drug)				**Reason:**	Conjunctivitis and ophthalmia
Eye Drops	6.0	Dose Unspecified	Daily		Ophthalmic
Batch:	**Started:**	16/02/1991		**Stopped:**	08/03/1991
MULTIVITE (Other drug)				**Reason:**	
Tablet	1.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**	18/02/1991		**Stopped:**	
SERENACE (Suspected)				**Reason:**	
Injection	5.0	Milligram	1 time		Intramuscular
Batch:	**Started:**	22/02/1991		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology				1 15/2/91 1/3/91 4/3/91 6/3/91 11/3/91 range creat: 0.18 0.11 0.09 - - (0.06-0.11) ck (total): - 1944 754 - - (25-165) ck-mb: - 20 - - - (0-5) wbc: - - - 6.96 13.63 (3.0-10.0)

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 70182 **Seq:** 1 **Gender:** F
Reported: 03/04/1991 **Weight:** 50.00
Hospitalisation: **Age:** 68Y
Onset Date: 23/02/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

SERENACE (Suspected)		**Reason:**	
Tablet	12.0 Milligram	Daily	Oral
Batch:	**Started:** 21/02/1991		**Stopped:** 21/02/1991
SERENACE (Suspected)		**Reason:**	
Tablet	6.0 Milligram	Daily	Oral
Batch:	**Started:** 21/02/1991		**Stopped:** 25/02/1991

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 70219 **Seq:** 1 **Gender:** F
Reported: 12/03/1991 **Weight:** 48.00
Hospitalisation: **Age:** 24Y
Onset Date: 29/01/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia			

Medicine Details:

HALOPERIDOL (Suspected)			**Reason:** Otr spec symp psychopathol nec	
	1.0 Milligram	As necessary		
Batch:	**Started:** 28/01/1991		**Stopped:** 30/01/1991	
IMIPENEM (Suspected)			**Reason:** Otr&nos infec&parasit diseases	
Injection	2.0 Gram	Daily	Intravenous	
Batch:	**Started:** 23/01/1991		**Stopped:** 30/01/1991	
HEPARIN SODIUM (Suspected)			**Reason:**	
Injection	10.0 Thousand Internal	Daily	Intravenous	
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 70307 **Seq:** 1 **Gender:** M
Reported: 28/02/1991 **Weight:**
Hospitalisation: **Age:** 68Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

LIBRIUM (Other drug) **Reason:** Explosive personality disorder
30.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

ECOTRIN (Other drug) **Reason:** Other prophylactic procedures
1.3 Gram Daily
Batch: **Started:** **Stopped:** CONTIN

SERENACE (Suspected) **Reason:** Explosive personality disorder
3.0 Milligram Daily
Batch: **Started:** 01/11/1990 **Stopped:** 19/02/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 70311 **Seq:** 1 **Gender:** F
Reported: 20/03/1991 **Weight:** 46.00
Hospitalisation: **Age:** 77Y
Onset Date: 09/02/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder Tardive dyskinesia			Haloperidol ceased. cigarette abuse, alcohol abuse, coad

Medicine Details:

THIAMINE (Other drug)			**Reason:**	
Tablet	0.0			Oral
Batch:	**Started:** 01/01/1989		**Stopped:**	
THEO-DUR (Other drug)			**Reason:**	
Capsule	600.0 Milligram	Daily		Oral
Batch:	**Started:** 01/01/1986		**Stopped:**	
TEGRETOL (Other drug)			**Reason:**	
Tablet	800.0 Milligram	Daily		Oral
Batch:	**Started:** 01/01/1987		**Stopped:**	
HALOPERIDOL (Suspected)			**Reason:**	
Tablet	5.0 Milligram	Daily		Oral
Batch:	**Started:** 01/01/1988		**Stopped:**	09/02/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 70311 **Seq:** 1 **Gender:** F
Reported: 20/03/1991 **Weight:** 46.00
Hospitalisation: **Age:** 77Y
Onset Date: 09/02/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

MOGADON (Suspected)			**Reason:**	
Tablet	10.0	Milligram	Daily	Oral
Batch:	**Started:**		**Stopped:**	09/02/1991

Laboratory Investigations:

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 70505 **Seq:** 1 **Gender:** M
Reported: 24/04/1991 **Weight:**
Hospitalisation: **Age:** 25Y
Onset Date: 14/02/1991 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Hyperventilation Hypoglycaemia Leukocytosis Neuroleptic malignant syndrome Pyrexia			

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified psychosis
Oral Liquid 15.0 Milligram Daily Oral
Batch: **Started:** 11/02/1991 **Stopped:** 14/02/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Elevated creatinine.

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 70627 **Seq:** 1 **Gender:** M
Reported: 26/04/1991 **Weight:**
Hospitalisation: **Age:** 14Y
Onset Date: 26/02/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Torticollis Tremor			

Medicine Details:

HALOPERIDOL (Suspected)			**Reason:**	
Injection	7.5 Milligram		Total	Intramuscular
Batch:	**Started:** 25/02/1991		**Stopped:**	
METOCLOPRAMIDE HYDROCHLORIDE (Suspected)			**Reason:**	
Injection	10.0 Milligram		As necessary	Intravenous
Batch:	**Started:** 25/02/1991		**Stopped:**	26/02/1991
CEFOTAXIME SODIUM (Suspected)			**Reason:**	
Injection, intravenous infusion	3.0 Gram		Daily	Intravenous
Batch:	**Started:** 24/02/1991		**Stopped:**	26/02/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 71050 **Seq:** 1 **Gender:** F
Reported: 28/05/1991 **Weight:** 67.00
Hospitalisation: **Age:** 64Y
Onset Date: 05/11/1990 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Conjunctivitis Visual disturbance			

Medicine Details:

FLUANXOL (Other drug)		**Reason:** Unspecified schizophrenia	
Injection	80.0 Milligram	Weekly	Intramuscular
Batch:	**Started:** 08/02/1988		**Stopped:** 05/12/1990
SERENACE (Suspected)		**Reason:**	
Tablet	1.5 Milligram	Daily	Oral
Batch:	**Started:** 01/11/1990		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 71354 **Seq:** 1
Reported: 14/06/1991
Hospitalisation: Admitted to hospital
Onset Date: 23/05/1991
Outcome: Death, maybe drug

Gender: F
Weight:
Age: 79Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state Dysuria Sudden death			Tofranil ceased

Medicine Details:

TOFRANIL (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CAPOTEN (Suspected) **Reason:**
25.0 Milligram Daily
Batch: **Started:** **Stopped:**

LANOXIN PG (Suspected) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

SERENACE (Suspected) **Reason:**
4.5 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 71376 **Seq:** 1 **Gender:** F
Reported: 15/06/1991 **Weight:** 40.00
Hospitalisation: **Age:** 85Y
Onset Date: 05/06/1991 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Jaundice			

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 3.0 Milligram Daily Oral
Batch: **Started:** 30/03/1988 **Stopped:** 06/06/1991

DISIPAL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 30/03/1988 **Stopped:** 06/06/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Bili alk ggt alt ast 07/06/91 112 412 293 349 645 14/06/91 13 205 101 54 11

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 71389 **Seq:** 1 **Gender:** M
Reported: 12/06/1991 **Weight:** 80.00
Hospitalisation: **Age:** 48Y
Onset Date: 03/05/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria			Prednisolone orally, antihistamines

Medicine Details:

HALDOL DECANOATE (Suspected) **Reason:** Hallucinations

Injection 100.0 Milligram Monthly Intramuscular

Batch: **Started:** 07/03/1991 **Stopped:** 30/05/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 71879 **Seq:** 1 **Gender:** M
Reported: 29/07/1991 **Weight:** 74.00
Hospitalisation: **Age:** 79Y
Onset Date: 22/07/1991 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Parkinsonian features	

Medicine Details:

SERENACE (Suspected) **Reason:** Reactive confusion
Oral application 6.0 Milligram Daily Oral
Batch: **Started:** 10/07/1991 **Stopped:** 26/07/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Alcoholic for 30 years.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 72161 **Seq:** 1 **Gender:** M
Reported: 30/07/1991 **Weight:** 60.00
Hospitalisation: **Age:** 70Y
Onset Date: 02/07/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Chills Headache		Febrile illness to 39 c	

Medicine Details:

TEGRETOL (Suspected) **Reason:** Manic-depression psycho,manic
400.0 Milligram Daily
Batch: **Started:** 11/06/1991 **Stopped:** 02/07/1991

HALOPERIDOL (Suspected) **Reason:** Manic-depression psycho,manic
10.0 Milligram Daily
Batch: **Started:** 09/06/1991 **Stopped:** 02/07/1991

SENOKOT (Suspected) **Reason:** Constipation
2.0 Dose Unspecified Daily
Batch: **Started:** 09/06/1991 **Stopped:** 02/07/1991

ORPHENADRINE HYDROCHLORIDE (Suspected) **Reason:**
100.0 Milligram Daily
Batch: **Started:** 19/06/1991 **Stopped:** 02/07/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT = SAP = ALP		02/07/1991 02/07/1991	646U/L 392U/L	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 72161 **Seq:** 1 **Gender:** M
Reported: 30/07/1991 **Weight:** 60.00
Hospitalisation: **Age:** 70Y
Onset Date: 02/07/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

NITRAZEPAM (Suspected)		**Reason:**	Specific disorders of sleep
	5.0 Milligram	Daily	
Batch:	**Started:** 09/06/1991		**Stopped:** 02/07/1991
CLONAZEPAM (Suspected)		**Reason:**	Manic-depression psycho,manic
	1.0 Milligram	Daily	
Batch:	**Started:** 22/06/1991		**Stopped:** 02/07/1991

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 72220 **Seq:** 1 **Gender:** F
Reported: 01/08/1991 **Weight:** 64.00
Hospitalisation: **Age:** 62Y
Onset Date: 25/07/1991 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Euphoric mood		Elevated mood/disinhibition/very giggly	
Mania		Hypomania	
Insomnia		Poor sleep	
Thinking abnormal		Thoughts racing	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 18/07/1991 **Stopped:** 27/07/1991

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
Tablet 1.5 Milligram Daily Oral
Batch: **Started:** 18/07/1991 **Stopped:** 24/07/1991

THIAMINE (Suspected) **Reason:** Alcoholism
Oral application 50.0 Milligram Daily Oral
Batch: **Started:** 02/05/1991 **Stopped:** CONTIN

FOLIC ACID (Suspected) **Reason:**
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 02/05/1991 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No history of mania.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 72220 **Seq:** 1 **Gender:** F
Reported: 01/08/1991 **Weight:** 64.00
Hospitalisation: **Age:** 62Y
Onset Date: 25/07/1991 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

ASPIRIN (Suspected)			**Reason:**	Transient cereb isch no hypert	
Tablet	150.0	Milligram	Daily	Oral	
Batch:	**Started:**	L TERM	**Stopped:**	CONTIN	
TEMAZEPAM (Suspected)			**Reason:**		
	10.0	Milligram	Daily		
Batch:	**Started:**	L TERM	**Stopped:**	CONTIN	

Laboratory Investigations:

Additional Information:

No history of mania.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 72240 **Seq:** 1 **Gender:** F
Reported: 08/08/1991 **Weight:** 65.00
Hospitalisation: **Age:** 34Y
Onset Date: 05/08/1991 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle contractions involuntary Insomnia		Involuntary movements of arms.	Temazepam 2 capsules was given but didnt help

Medicine Details:

ETHRANE (Other drug) **Reason:** Premedication
0.0
Batch: **Started:** **Stopped:**

FENTANYL CITRATE (Other drug) **Reason:** Premedication
0.0
Batch: **Started:** **Stopped:**

DOTHIEPIN HYDROCHLORIDE (Other drug) **Reason:**
25.0 Milligram Daily
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Premedication
2.5 Milligram 1 time
Batch: **Started:** 05/08/1991 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 72776 **Seq:** 1 **Gender:** F
Reported: 11/09/1991 **Weight:** 74.00
Hospitalisation: **Age:** 39Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) **Reason:** Other atyp forms schizophrenia
Oral application 1.2 Gram Daily Oral
Batch: **Started:** L TERM **Stopped:** 11/09/1991

HALOPERIDOL (Suspected) **Reason:** Other atyp forms schizophrenia
Oral application 30.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 11/09/1991

CHLORPROMAZINE HYDROCHLORIDE (Suspected) **Reason:** Other atyp forms schizophrenia
Oral application 800.0 Milligram Daily Oral
Batch: **Started:** 11/09/1991 **Stopped:**

THIORIDAZINE HYDROCHLORIDE (Suspected) **Reason:**
Oral application 800.0 Milligram Daily Oral
Batch: **Started:** 11/09/1991 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 72799 **Seq:** 1 **Gender:** F
Reported: 03/09/1991 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: 15/08/1991 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cataract		Eye deterioration.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 72881 **Seq:** 1 **Gender:** F
Reported: 10/09/1991 **Weight:**
Hospitalisation: **Age:** 49Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Severe	Dystonic - laro-pharyngeal w/tongue, jaw	Benztropine 2mg im x 3 doses.

Medicine Details:

CLONAZEPAM (Other drug) **Reason:**
Oral application 2.0 Milligram Daily Oral
Batch: **Started:** 31/08/1991 **Stopped:** CONTIN

LITHIUM CARBONATE (Other drug) **Reason:** Manic-depression psycho,manic
Oral application 1.0 Gram Daily Oral
Batch: **Started:** 31/08/1991 **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
Oral application 10.0 Milligram Daily Oral
Batch: **Started:** 31/08/1991 **Stopped:** 31/08/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 73010 **Seq:** 1 **Gender:** M
Reported: 03/09/1991 **Weight:**
Hospitalisation: **Age:** 8Y
Onset Date: 06/08/1991 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Extrapyramidal disorder			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
Oral application 750.0 Microgram Daily Oral
Batch: **Started:** 05/08/1991 **Stopped:** 06/08/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 73382 **Seq:** 1 **Gender:** M
Reported: 30/09/1991 **Weight:**
Hospitalisation: **Age:** 79Y
Onset Date: 12/08/1991 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Pyrexia		Rigid limbs	

Medicine Details:

SALBUTAMOL (Suspected) **Reason:** Dyspnea
Inhalation 10.0 Milligram Daily Inhalation
Batch: **Started:** **Stopped:** 29/08/1991

STEMETIL (Suspected) **Reason:** Nausea and vomiting
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 02/08/1991 **Stopped:** 09/08/1991

SERENACE (Suspected) **Reason:** Nausea and vomiting
Injection 1.5 Milligram Daily Subcutaneous
Batch: **Started:** 11/08/1991 **Stopped:** 12/08/1991

PROLADONE (Suspected) **Reason:** Pain
Suppository 45.0 Milligram Daily Rectal
Batch: **Started:** 11/08/1991 **Stopped:** 15/08/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died 15/8/91 patient had allergy to morphine - vomiting

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 73409 **Seq:** 1 **Gender:** F
Reported: 09/10/1991 **Weight:** 42.00
Hospitalisation: **Age:** 81Y
Onset Date: 05/06/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Febrile, shivering, agitated	

Medicine Details:

PANADOL (Other drug) **Reason:**
Tablet 2.0 Dose Unspecified As necessary Oral
Batch: **Started:** **Stopped:**

LANOXIN PG (Other drug) **Reason:**
Oral application 1.0 Dose Unspecified Daily Oral
Batch: **Started:** L TERM **Stopped:** 04/06/1991

SENOKOT (Other drug) **Reason:**
Oral application 2.0 Dose Unspecified Alternate days Oral
Batch: **Started:** L TERM **Stopped:**

SERENACE (Suspected) **Reason:** Otr spec symp psychopathol nec
Injection 2.0 Milligram 1 time Intramuscular
Batch: **Started:** 05/06/1991 **Stopped:** 05/06/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Misclassified at				Ck visc to 500's

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 73409 **Seq:** 1 **Gender:** F
Reported: 09/10/1991 **Weight:** 42.00
Hospitalisation: **Age:** 81Y
Onset Date: 05/06/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Suspected) **Reason:** Paranoid type schizophrenia

Tablet	25.0 Milligram	Daily	Oral
Batch:	**Started:** 04/06/1991	**Stopped:**	05/06/1991

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 73860 **Seq:** 1 **Gender:** M
Reported: 30/10/1991 **Weight:** 75.00
Hospitalisation: **Age:** 20Y
Onset Date: 29/10/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Cyanosis Laryngospasm		Laryngeal dystonia	 Cogentin

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis

Oral application 10.0 Milligram Daily Oral

Batch: **Started:** 28/10/1991 **Stopped:** 29/10/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 74024 **Seq:** 1 **Gender:** M
Reported: 03/09/1991 **Weight:**
Hospitalisation: **Age:** 62Y
Onset Date: 15/07/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Other paranoid states
Tablet 80.0 Milligram Daily Oral
Batch: **Started:** 01/07/1991 **Stopped:** 15/07/1991

CHLORPROMAZINE HYDROCHLORIDE (Suspected) **Reason:**
Oral application 300.0 Milligram Daily Oral
Batch: **Started:** 15/07/1991 **Stopped:** 31/07/1991

MYLANTA (Suspected) **Reason:**
Oral application 30.0 Millilitre Daily Oral
Batch: **Started:** 13/07/1991 **Stopped:** 02/08/1991

AMOXYCILLIN TRIHYDRATE (Suspected) **Reason:**
Oral application 1.5 Gram Daily Oral
Batch: **Started:** 10/07/1991 **Stopped:** 21/07/1991

Laboratory Investigations:

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

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 74024 **Seq:** 1 **Gender:** M
Reported: 03/09/1991 **Weight:**
Hospitalisation: **Age:** 62Y
Onset Date: 15/07/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 74024 **Seq:** 1 **Gender:** M
Reported: 03/09/1991 **Weight:**
Hospitalisation: **Age:** 62Y
Onset Date: 15/07/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium	137-145	30/07/1991	125	
	Sodium	137-145	02/08/1991	135	
	Sodium	137-145	09/08/1991	140	
	Sodium	137-145	19/08/1991	142	
	Sodium	137-145	16/09/1991	134	
	Urine Potassium	44 MMOL/L	31/07/1991	33	Urine osmolality (549 mmol/l) 31/07/91, 02/08/91, 09/08/91 515 660 911

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 74024 **Seq:** 1 **Gender:** M
Reported: 03/09/1991 **Weight:**
Hospitalisation: **Age:** 62Y
Onset Date: 15/07/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 74346 **Seq:** 1 **Gender:** F
Reported: 26/11/1991 **Weight:** 40.00
Hospitalisation: **Age:** 16Y
Onset Date: 21/11/1991 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			

Medicine Details:

SERENACE (Suspected) **Reason:** Anxiety neurosis
Tablet 4.5 Milligram Total Oral
Batch: **Started:** 20/11/1991 **Stopped:** 21/11/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has same reactions when serenace was taken 2-3 years ago.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 74935 **Seq:** 1 **Gender:** M
Reported: 04/12/1991 **Weight:**
Hospitalisation: **Age:** 31Y
Onset Date: 02/12/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Jaw tightness/spasm in arm and shoulder	Cogentin 2mg iv, oxygen.

Medicine Details:

PETHIDINE HYDROCHLORIDE (Other drug)			**Reason:**	
Injection	100.0	Milligram	Daily	Intramuscular
Batch:	**Started:** 02/12/1991		**Stopped:**	03/12/1991
CEFOTAXIME SODIUM (Other drug)			**Reason:**	
Injection	3.0	Gram	Daily	Intravenous
Batch:	**Started:** 28/11/1991		**Stopped:**	03/12/1991
FLAGYL (Other drug)			**Reason:**	
Injection	1.5	Gram	Daily	Intravenous
Batch:	**Started:** 28/11/1991		**Stopped:**	03/12/1991
GENTAMICIN SULPHATE (Other drug)			**Reason:**	
Injection	240.0	Milligram	Daily	Intravenous
Batch:	**Started:** 30/11/1991		**Stopped:**	03/12/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 74935 **Seq:** 1 **Gender:** M
Reported: 04/12/1991 **Weight:**
Hospitalisation: **Age:** 31Y
Onset Date: 02/12/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

DILANTIN (Other drug)			**Reason:**	
Injection	250.0 Milligram		Daily	Intravenous
Batch:	**Started:** 29/11/1991			**Stopped:** 03/12/1991
HALOPERIDOL (Suspected)			**Reason:**	
Injection	5.0 Milligram		Daily	Intramuscular
Batch:	**Started:** 02/12/1991			**Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 75800 **Seq:** 1 **Gender:** F
Reported: 26/02/1992 **Weight:** 50.00
Hospitalisation: **Age:** 88Y
Onset Date: 06/11/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Hyponatraemia			

Medicine Details:

SERENACE (Suspected) **Reason:** Reactive confusion
Injection 2.5 Milligram As necessary Intramuscular
Batch: **Started:** 05/11/1991 **Stopped:** 07/11/1991

AMOXIL (Suspected) **Reason:** Pyrexia of unknown origin
Injection 1.5 Gram Daily Intravenous
Batch: **Started:** 05/11/1991 **Stopped:** 06/11/1991

AMOXIL (Suspected) **Reason:** Pyrexia of unknown origin
Capsule 1.5 Gram Daily Oral
Batch: **Started:** 06/11/1991 **Stopped:** 07/11/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium	MMOL/L	06/11/1991	125	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 75868 **Seq:** 1 **Gender:** M
Reported: 09/03/1992 **Weight:** 90.00
Hospitalisation: **Age:** 36Y
Onset Date: 05/03/1992 **DOB:**
Outcome: Death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest Dyspnoea Sudden death Syncope			

Medicine Details:

HALDOL DECANOATE (Suspected)		**Reason:**	
Injection	50.0 Milligram	1 time	Intramuscular
Batch:	**Started:** 28/02/1992		**Stopped:**
TEGRETOL (Suspected)		**Reason:**	
Tablet	400.0 Milligram	Daily	Oral
Batch:	**Started:** 01/01/1990		**Stopped:**
DIGOXIN (Suspected)		**Reason:**	Congestive heart failure
Tablet	312.0 Microgram	Daily	Oral
Batch:	**Started:** 01/01/1990		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

In 1989 patient developed atrial fibrillation, specialist cardiological opinion remained unclear whether this was a result of mitral valve disease or an underlying electrical tissue problem. patient was also treated in 1989 with warfarin for a deep venous thrombosis. 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.

Report Details:

Case Number: 76310 **Seq:** 1 **Gender:** M
Reported: 31/03/1992 **Weight:**
Hospitalisation: **Age:** 49Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

BENZTROPINE MESYLATE (Other drug) **Reason:**
2.0 Milligram As necessary
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 76346 **Seq:** 1 **Gender:** M
Reported: 19/02/1992 **Weight:** 68.00
Hospitalisation: **Age:** 23Y
Onset Date: 19/02/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction	Cogentin 2mg iv.

Medicine Details:

TEGRETOL (Other drug) **Reason:** Other&unspecified epilepsy
Oral application 1.8 Gram Daily Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

EPILIM (Other drug) **Reason:** Other&unspecified epilepsy
Oral application 1.5 Gram Daily Oral
Batch: **Started:** 01/11/1991 **Stopped:** CONTIN

CLONAZEPAM (Other drug) **Reason:** Other&unspecified epilepsy
Injection 3.0 Milligram Daily Intravenous
Batch: **Started:** 15/02/1992 **Stopped:** 17/02/1992

DILANTIN (Other drug) **Reason:** Other&unspecified epilepsy
Oral application 300.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 76346 **Seq:** 1 **Gender:** M
Reported: 19/02/1992 **Weight:** 68.00
Hospitalisation: **Age:** 23Y
Onset Date: 19/02/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis

Oral application	5.0 Milligram	Daily	Oral
Batch:	**Started:** 16/02/1992	**Stopped:**	19/02/1992

Laboratory Investigations:

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 76575 **Seq:** 1 **Gender:** M
Reported: 01/04/1992 **Weight:**
Hospitalisation: **Age:** 84Y
Onset Date: 11/12/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus Tremor			 Cogentin, hismanal.

Medicine Details:

RANITIDINE (Other drug) **Reason:**
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 22/05/1991 **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:**
Oral application 2.0 Milligram Daily Oral
Batch: **Started:** 06/11/1991 **Stopped:** 11/12/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 77198 **Seq:** 1 **Gender:** F
Reported: 22/05/1992 **Weight:** 59.00
Hospitalisation: **Age:** 32Y
Onset Date: 02/12/1991 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tinnitus			

Medicine Details:

HALDOL DECANOATE (Suspected) **Reason:**
Injection 1.0 Milligram 1 time Intramuscular
Batch: **Started:** 30/11/1991 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 77261 **Seq:** 1 **Gender:** M
Reported: 23/04/1992 **Weight:**
Hospitalisation: **Age:** 44Y
Onset Date: 21/04/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			Pt responded after being given 2 mg benztropine iv.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Premedication
Injection, intravenous infusion 2.5 Milligram 1 time Intravenous
Batch: **Started:** 21/04/1992 **Stopped:**

LORAZEPAM (Suspected) **Reason:** Premedication
Tablet 2.0 Milligram 1 time Oral
Batch: **Started:** 21/04/1992 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 77729 **Seq:** 1 **Gender:** M
Reported: 15/06/1992 **Weight:** 72.00
Hospitalisation: **Age:** 91Y
Onset Date: 13/06/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coma Hyporeflexia Hypotonia Miosis			Oxygen by facial mask, benztropine 1mg im (cogentin).

Medicine Details:

COLOXYL WITH SENNA (Other drug)			**Reason:** Constipation		
Tablet	1.0	Dose Unspecified	As necessary	Oral	
Batch:	**Started:**		**Stopped:**		CONTIN
ALDAZINE (Other drug)			**Reason:**		
Solution	10.0	Millilitre	As necessary	Oral	
Batch:	**Started:** 10/06/1992		**Stopped:**		
MYLANTA (Other drug)			**Reason:**		
Solution	10.0	Millilitre	As necessary	Oral	
Batch:	**Started:** 10/06/1992		**Stopped:**		
DUPHALAC (Other drug)			**Reason:** Constipation		
Solution	10.0	Millilitre	Daily	Oral	
Batch:	**Started:**		**Stopped:**		CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred within 1 hour of haloperidol.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 77729 **Seq:** 1 **Gender:** M
Reported: 15/06/1992 **Weight:** 72.00
Hospitalisation: **Age:** 91Y
Onset Date: 13/06/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

TEMAZEPAM (Other drug)			**Reason:**	
Capsule	10.0 Milligram		Daily	Oral
Batch:	**Started:** 10/06/1992		**Stopped:**	
SERENACE (Other drug)			**Reason:**	
Tablet	20.0 Milligram		Daily	Oral
Batch:	**Started:** 12/06/1992		**Stopped:**	
HALOPERIDOL (Suspected)			**Reason:**	
Tablet	0.5 Milligram		1 time	Oral
Batch:	**Started:** 13/06/1992		**Stopped:**	

Laboratory Investigations:

Additional Information:

Reaction occurred within 1 hour of haloperidol.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 78507 **Seq:** 1 **Gender:** M
Reported: 24/07/1992 **Weight:** 82.00
Hospitalisation: **Age:** 45Y
Onset Date: 17/07/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination Confusional state Consciousness fluctuating Delusion Paranoia		Auditory, visual and olfactory hallucinations	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Delirium
15.0 Milligram Daily
Batch: **Started:** 16/07/1992 **Stopped:** 22/07/1992

COGENTIN (Suspected) **Reason:**
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 20/07/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 78820 **Seq:** 1 **Gender:** M
Reported: 01/08/1992 **Weight:**
Hospitalisation: **Age:** 11Y
Onset Date: 30/04/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blepharospasm		Screwing up eyes	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
Oral application 1.0 Milligram Oral
Batch: **Started:** 01/10/1990 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 79090 **Seq:** 1 **Gender:** F
Reported: 01/09/1992 **Weight:** 43.00
Hospitalisation: **Age:** 91Y
Onset Date: 05/08/1992 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state Dehydration Hyponatraemia			

Medicine Details:

SERENACE (Suspected)			**Reason:**	
Tablet	2.1	Milligram	Daily	Oral
Batch:	**Started:** 01/01/1989		**Stopped:**	04/08/1992
FRUSEMIDE (Suspected)			**Reason:**	
Tablet	40.0	Milligram	Daily	Oral
Batch:	**Started:** 23/07/1992		**Stopped:**	05/08/1992
MODURETIC (Suspected)			**Reason:**	
Tablet	1.0	Dose Unspecified	Daily	Oral
Batch:	**Started:** 23/07/1992		**Stopped:**	05/08/1992
BRUFEN (Suspected)			**Reason:**	
Tablet	400.0	Milligram	Daily	Oral
Batch:	**Started:** 23/07/1992		**Stopped:**	05/08/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		14/07/1992	131	
	Sodium		05/08/1992	114	

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 79090 **Seq:** 1
Reported: 01/09/1992
Hospitalisation:
Onset Date: 05/08/1992
Outcome: Not yet recovered

Gender: F
Weight: 43.00
Age: 91Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

KAY CIEL (Suspected)			**Reason:**		
Oral Liquid	15.0	Millilitre	Daily		Oral
Batch:	**Started:** 23/07/1992			**Stopped:**	05/08/1992
TEARS NATURALE (Suspected)			**Reason:**		
Eye Drops	1.0	Dose Unspecified	Daily		Ophthalmic
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 79284 **Seq:** 1 **Gender:** F
Reported: 07/09/1992 **Weight:**
Hospitalisation: **Age:** 85Y
Onset Date: 03/09/1992 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Haematemesis		Coffee ground vomiting	

Medicine Details:

PROTHIADEN (Suspected) **Reason:** Anxiety neurosis
100.0 Milligram Daily
Batch: **Started:** **Stopped:**

SERENACE (Suspected) **Reason:** Depression
Tablet 500.0 Microgram Daily Oral
Batch: **Started:** **Stopped:**

FELDENE (Suspected) **Reason:**
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 79441 **Seq:** 1 **Gender:** M
Reported: 12/08/1992 **Weight:**
Hospitalisation: **Age:** 20Y
Onset Date: 01/08/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Dystonia		Difficulty breathing	 Cogentin, oxygen

Medicine Details:

SERENACE (Suspected) **Reason:**
Injection 2.5 Milligram Daily Intramuscular
Batch: **Started:** 31/07/1992 **Stopped:** 01/08/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 79465 **Seq:** 1 **Gender:** M
Reported: 05/06/1992 **Weight:**
Hospitalisation: **Age:** 49Y
Onset Date: 31/05/1992 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			

Medicine Details:

VANCOMYCIN HYDROCHLORIDE (Other drug) **Reason:**
Injection 0.0 Intravenous
Batch: **Started:** 30/05/1992 **Stopped:**

HALOPERIDOL (Other drug) **Reason:**
Oral application 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

PHENYTOIN SODIUM (Other drug) **Reason:**
Injection 400.0 Milligram Daily Intravenous
Batch: **Started:** 30/05/1992 **Stopped:**

RANITIDINE (Other drug) **Reason:**
Injection 150.0 Milligram Daily Intravenous
Batch: **Started:** 30/05/1992 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Details:

Case Number: 79465 **Seq:** 1 **Gender:** M
Reported: 05/06/1992 **Weight:**
Hospitalisation: **Age:** 49Y
Onset Date: 31/05/1992 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

CEFOTAXIME SODIUM (Other drug)			**Reason:**	
Injection	3.0 Gram		Daily	Intravenous
Batch:	**Started:** 30/05/1992		**Stopped:**	
VENTOLIN NEBULES (Other drug)			**Reason:**	
Inhalation	60.0 Milligram		Daily	Inhalation
Batch:	**Started:** 30/05/1992		**Stopped:**	
HALOPERIDOL (Suspected)			**Reason:**	
Injection	50.0 Milligram		1 time	Intravenous
Batch:	**Started:** 27/05/1992		**Stopped:**	

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 80657 **Seq:** 1 **Gender:** M
Reported: 22/10/1992 **Weight:** 69.00
Hospitalisation: **Age:** 67Y
Onset Date: 31/05/1992 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Malignant melanoma		Recurrence of melanoma excised 21yrs ago	

Medicine Details:

MADOPAR (Suspected) **Reason:** Paralysis agitans
6.0 Dose Unspecified Daily
Batch: **Started:** 01/12/1990 **Stopped:** 03/05/1992

MADOPAR (Suspected) **Reason:** Paralysis agitans
3.0 Dose Unspecified Daily
Batch: **Started:** 03/05/1992 **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:** Paralysis agitans
3.5 Milligram Daily
Batch: **Started:** 04/05/1992 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Attempted changing madopar to bromocriptine therapy but poorly tolerated by patient: confusion and rigidity. madopar recommenced 25/6. - 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.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 80892 **Seq:** 1 **Gender:** F
Reported: 25/10/1992 **Weight:**
Hospitalisation: **Age:** 66Y
Onset Date: 08/09/1992 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction Pruritus Skin exfoliation			

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified schizophrenia

Tablet 1.5 Milligram Daily Oral

Batch: **Started:** 04/09/1992 **Stopped:** 14/10/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Photosensitivity to largactil in 1984. photosenitivity to melleril in 1984 photosensivity to steraskin in 1984. photosenitivity to serenace in 1985. this is a rechallenge.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 81490 **Seq:** 1 **Gender:** F
Reported: 13/12/1992 **Weight:** 53.00
Hospitalisation: **Age:** 35Y
Onset Date: 30/06/1992 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Extrapyramidal disorder		Stiffness	

Medicine Details:

HALDOL DECANOATE (Suspected)			**Reason:**	
Injection	50.0 Milligram		3 times	Intramuscular
Batch:	**Started:** 16/06/1992		**Stopped:**	30/06/1992
MODECATE (Suspected)			**Reason:**	Unspecified schizophrenia
Injection	50.0 Milligram		Weekly	Intramuscular
Batch:	**Started:** 27/05/1992		**Stopped:**	16/06/1992
MELLERIL (Suspected)			**Reason:**	
Tablet	100.0 Milligram		Daily	Oral
Batch:	**Started:** 29/06/1992		**Stopped:**	30/06/1992
KEMADRIN (Suspected)			**Reason:**	
Tablet	100.0 Milligram		Daily	Oral
Batch:	**Started:** 25/06/1992		**Stopped:**	05/07/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 81906 **Seq:** 1 **Gender:** M
Reported: 31/12/1992 **Weight:**
Hospitalisation: **Age:** 17Y
Onset Date: 29/11/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Cogentin iv

Medicine Details:

STEMETIL (Suspected) **Reason:** Nausea and vomiting
Injection 12.0 Milligram 2 times Intravenous
Batch: **Started:** 28/11/1992 **Stopped:**

SERENACE (Suspected) **Reason:** Nausea and vomiting
Injection 2.5 Milligram 1 time Subcutaneous
Batch: **Started:** 28/11/1992 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 82089 **Seq:** 1 **Gender:** M
Reported: 19/01/1993 **Weight:** 77.00
Hospitalisation: **Age:** 30Y
Onset Date: 04/12/1992 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuritis Pain Paraesthesia			Bioglan vitamin supplement.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
Injection 25.0 Milligram Monthly Intramuscular
Batch: **Started:** 13/10/1992 **Stopped:** 15/12/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 82137 **Seq:** 1 **Gender:** F
Reported: 21/01/1993 **Weight:** 56.00
Hospitalisation: **Age:** 28Y
Onset Date: 21/01/1993 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Cogentin

Medicine Details:

SERENACE (Suspected) **Reason:** Migraine

Injection 5.0 Milligram 1 time Intramuscular

Batch: **Started:** 20/01/1993 **Stopped:** 20/01/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 82668 **Seq:** 1 **Gender:** F
Reported: 18/02/1993 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Polydactyly			

Medicine Details:

MODECATE (Suspected) **Reason:** Unspecified schizophrenia
0.0
Batch: **Started:** **Stopped:**

SERENACE (Suspected) **Reason:** Unspecified schizophrenia
0.0
Batch: **Started:** **Stopped:**

PIMOZIDE (Suspected) **Reason:** Unspecified schizophrenia
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Bilateral bifid thumbs (complete polydactyly thumbs) of baby of mother with past history of schizophrenia on these medications prior to pregnancy. no treatment during pregnancy.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 82768 **Seq:** 1 **Gender:** F
Reported: 02/02/1993 **Weight:**
Hospitalisation: **Age:** 90Y
Onset Date: 09/01/1993 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

COGENTIN (Suspected) **Reason:** Depression
1.0 Milligram As necessary
Batch: **Started:** 17/12/1992 **Stopped:** 11/01/1993

SERENACE (Suspected) **Reason:** Depression
1.5 Milligram As necessary
Batch: **Started:** 18/12/1992 **Stopped:** 11/01/1993

PANADOL (Suspected) **Reason:** Pain
2.0 Dose Unspecified As necessary
Batch: **Started:** 02/01/1993 **Stopped:**

MACRODANTIN (Suspected) **Reason:** Othr diseases of urinary tract
Capsule 50.0 Milligram Daily Oral
Batch: **Started:** 17/12/1992 **Stopped:** 11/01/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 82768 **Seq:** 1
Reported: 02/02/1993
Hospitalisation:
Onset Date: 09/01/1993
Outcome: Not yet recovered

Gender: F
Weight:
Age: 90Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

PROZAC (Suspected)		**Reason:**	Depression
	20.0 Milligram	Daily	
Batch:	**Started:** 17/12/1992		**Stopped:**
OROXINE (Suspected)		**Reason:**	Thyrotoxicosis w/o ment goiter
	75.0 Microgram	Daily	
Batch:	**Started:** 17/12/1992		**Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 83181 **Seq:** 1 **Gender:** F
Reported: 08/03/1993 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: 21/12/1992 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site reaction			

Medicine Details:

HALDOL DECANOATE (Suspected) **Reason:**
Injection 50.0 Milligram 1 time Intramuscular
Batch: **Started:** 21/12/1992 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced similar reaction after each injection.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 83410 **Seq:** 1 **Gender:** F
Reported: 22/03/1993 **Weight:** 67.00
Hospitalisation: **Age:** 21Y
Onset Date: 11/03/1993 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination Neuroleptic malignant syndrome			Stop medication, symptomatic treatment

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified psychosis
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 05/03/1993 **Stopped:** 11/03/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 83576 **Seq:** 1 **Gender:** M
Reported: 25/03/1993 **Weight:**
Hospitalisation: **Age:** 49Y
Onset Date: 31/05/1992 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Rash on upper trunk and limbs.	

Medicine Details:

VANCOMYCIN HYDROCHLORIDE (Other drug)			**Reason:**	
Injection	0.0			Intravenous
Batch:	**Started:** 30/05/1992		**Stopped:**	
VENTOLIN (Other drug)			**Reason:**	
Inhalation	60.0 Milligram	Daily		Inhalation
Batch:	**Started:** 30/05/1992		**Stopped:**	
PHENYTOIN SODIUM (Other drug)			**Reason:**	
Injection	400.0 Milligram	Daily		Intravenous
Batch:	**Started:** 30/05/1992		**Stopped:**	
RANITIDINE (Other drug)			**Reason:**	
Injection	150.0 Milligram	Daily		Intravenous
Batch:	**Started:** 30/05/1992		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 83576 **Seq:** 1 **Gender:** M
Reported: 25/03/1993 **Weight:**
Hospitalisation: **Age:** 49Y
Onset Date: 31/05/1992 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

CEFOTAXIME SODIUM (Other drug)		**Reason:**	
Injection	3.0 Gram	Daily	Intravenous
Batch:	**Started:** 30/05/1992		**Stopped:**
HALOPERIDOL (Suspected)		**Reason:**	
	20.0 Milligram	Daily	
Batch:	**Started:** 27/05/1992		**Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 83666 **Seq:** 1 **Gender:** F
Reported: 25/04/1993 **Weight:**
Hospitalisation: **Age:** 58Y
Onset Date: 12/03/1993 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gingivitis Lymphopenia Mouth ulceration			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 01/01/1993 **Stopped:** 13/03/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Lymphocytes		13/03/1993	0.8	

Additional Information:

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

Report Details:

Case Number: 84274 **Seq:** 1 **Gender:** M
Reported: 03/05/1993 **Weight:**
Hospitalisation: **Age:** 73Y
Onset Date: 25/04/1993 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Prothrombin level decreased			Vitamin k

Medicine Details:

AURORIX (Suspected) **Reason:** Depression
450.0 Milligram Daily
Batch: **Started:** 17/04/1993 **Stopped:**

WARFARIN SODIUM (Suspected) **Reason:** Otr&nos disord of heart rhythm
2.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

LASIX (Suspected) **Reason:** Congestive heart failure
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

SLOW-K (Suspected) **Reason:** Congestive heart failure
4.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	International		22/04/1993	2.3	
	International		25/04/1993	4.7	
	International		26/04/1993	6.2	
	International		27/04/1993	8.0	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 84274 **Seq:** 1
Reported: 03/05/1993
Hospitalisation:
Onset Date: 25/04/1993
Outcome: Not yet recovered

Gender: M
Weight:
Age: 73Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

LANOXIN (Suspected)			**Reason:**	Otr&nos disord of heart rhythm
	125.0	Microgram	Daily	
Batch:	**Started:**			**Stopped:**
CAPOTEN (Suspected)			**Reason:**	Congestive heart failure
	75.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:** 25/04/1993
SERENACE (Suspected)			**Reason:**	Depression
	1.5	Milligram	Daily	
Batch:	**Started:** 17/04/1993			**Stopped:** 26/04/1993

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 84373 **Seq:** 1 **Gender:** M
Reported: 04/05/1993 **Weight:**
Hospitalisation: **Age:** 83Y
Onset Date: 24/04/1993 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Glossitis		Desquamation of tongue	
Conjunctivitis			Eye ointments, tpn.
Dermatitis bullous			
Mouth ulceration			
Oedema peripheral			
Rash maculo-papular			
Toxic epidermal necrolysis			Iv cyclophosphamide x 5days, iv hydrocortisone iv, antibiotics, eye oint &tpn.

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified psychosis
Injection 5.0 Dose Unspecified Total Intramuscular
Batch: **Started:** **Stopped:** 24/04/1993

BISALAX (Suspected) **Reason:** Constipation
Tablet 5.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:** 24/04/1993

STELAZINE (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 16/04/1993 **Stopped:** 24/04/1993

TENORMIN (Suspected) **Reason:** Essential benign hypertension
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 24/04/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 84373 **Seq:** 1 **Gender:** M
Reported: 04/05/1993 **Weight:**
Hospitalisation: **Age:** 83Y
Onset Date: 24/04/1993 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

ZYLOPRIM (Suspected) **Reason:** Gout

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:** 24/04/1993

Laboratory Investigations:

Additional Information:

Report Details:

Case Number: 84390 **Seq:** 1 **Gender:** M
Reported: 05/05/1993 **Weight:** 82.00
Hospitalisation: **Age:** 71Y
Onset Date: 19/04/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradycardia			
Coma			
Dysphagia			
Leukocytosis			
Neuroleptic malignant syndrome			Dobutamine inf 25mg per hour.
Tardive dyskinesia			

Medicine Details:

PEXID (Other drug) **Reason:** Chron isch heart dis no hyper
300.0 Milligram Daily
Batch: **Started:** 01/01/1992 **Stopped:** CONTIN

CARDIZEM (Other drug) **Reason:** Chron isch heart dis no hyper
270.0 Milligram Daily
Batch: **Started:** 01/01/1991 **Stopped:** CONTIN

AMITRIPTYLINE HYDROCHLORIDE (Other drug) **Reason:**
75.0 Milligram Daily
Batch: **Started:** 01/01/1992 **Stopped:** 19/04/1993

RENITEC (Other drug) **Reason:** Congestive heart failure
2.5 Milligram Daily
Batch: **Started:** 01/01/1992 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine [illegible]	50-120 U/L	19/04/1993	12,474	Ck was predominantly of skeletal muscle origin (98%).
	Creatine [illegible]	50-120 U/L	22/04/1993	177	Ck was predominantly of skeletal muscle origin (98%).
	Electrocardiograph				Ecg revealed bradycardia but no p waves.
	LDH	U/L	22/04/1993	177	
	White blood cells		19/04/1993	13.0	

Additional Information:

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

Report Details:

Case Number: 84390 **Seq:** 1 **Gender:** M
Reported: 05/05/1993 **Weight:** 82.00
Hospitalisation: **Age:** 71Y
Onset Date: 19/04/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

SOLPRIN (Other drug)		**Reason:**	Chron isch heart dis no hyper
	150.0 Milligram	Daily	
Batch:	**Started:** 01/01/1991	**Stopped:**	CONTIN
HALDOL DECANOATE (Suspected)		**Reason:**	Manic-depression psycho,manic
	10.0 Milligram	Daily	
Batch:	**Started:** 15/04/1993	**Stopped:**	19/04/1993
MELLERIL (Suspected)		**Reason:**	Manic-depression psycho,manic
	150.0 Milligram	Daily	
Batch:	**Started:** 19/04/1993	**Stopped:**	19/04/1993
VALIUM (Suspected)		**Reason:**	Manic-depression psycho,manic
	15.0 Milligram	Daily	
Batch:	**Started:** 19/04/1993	**Stopped:**	19/04/1993

Laboratory Investigations:

Additional Information:

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

Report Details:

Case Number: 85063 **Seq:** 1 **Gender:** M
Reported: 01/06/1993 **Weight:**
Hospitalisation: **Age:** 77Y
Onset Date: 31/07/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular Face oedema Hepatic function abnormal Hepatomegaly Lymphadenopathy Pyrexia Skin exfoliation		Rash over legs, trunk, arms & head	Skin emollients, prednisolone 50 mg daily for three days.

Medicine Details:

LITHIUM CARBONATE (Other drug) **Reason:** Unspecifid affective psychosis
Tablet 125.0 Milligram Daily Oral
Batch: **Started:** 01/06/1992 **Stopped:** 28/08/1992

SINEMET (Other drug) **Reason:** Paralysis agitans
Tablet 4.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

DILANTIN (Suspected) **Reason:**
Capsule 300.0 Milligram Daily Oral
Batch: **Started:** 24/04/1992 **Stopped:** 02/08/1992

HALOPERIDOL (Suspected) **Reason:** Unspecifid affective psychosis
Tablet 4.0 Milligram Daily Oral
Batch: **Started:** 01/06/1992 **Stopped:** 02/08/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	10 - 50 U/L	02/08/1992	97	
	AST = SGOT	10 - 50 U/L	10/08/1992	133	
	AST = SGOT	10 - 50 U/L	17/08/1992	45	
	AST = SGOT	10 - 50 U/L	13/08/1992	130	
	AST = SGOT	10 - 50 U/L	24/08/1992	41	
	Bilirubin	< 17 UMOL/L	02/08/1992	13	
	Bilirubin	< 17 UMOL/L	24/08/1992	10	

Additional Information:

General anaesthetic on 24/06/92 for evacuation of a right subdural haematoma. 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.

Report Details:

Case Number: 85063 **Seq:** 1 **Gender:** M
Reported: 01/06/1993 **Weight:**
Hospitalisation: **Age:** 77Y
Onset Date: 31/07/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

LITHIUM CARBONATE (Other drug)				**Reason:**	Unspecifid affective psychosis
Tablet	125.0	Milligram	Daily		Oral
Batch:	**Started:** 01/06/1992			**Stopped:**	28/08/1992
SINEMET (Other drug)				**Reason:**	Paralysis agitans
Tablet	4.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	
DILANTIN (Suspected)				**Reason:**	
Capsule	300.0	Milligram	Daily		Oral
Batch:	**Started:** 24/04/1992			**Stopped:**	02/08/1992
HALOPERIDOL (Suspected)				**Reason:**	Unspecifid affective psychosis
Tablet	4.0	Milligram	Daily		Oral
Batch:	**Started:** 01/06/1992			**Stopped:**	02/08/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin	< 17 UMOL/L	10/08/1992	24	
	Bilirubin	< 17 UMOL/L	13/08/1992	52	
	Bilirubin	< 17 UMOL/L	17/08/1992	22	
	GGT = SGGT =	< 50 IU/L	02/08/1992	493	
	GGT = SGGT =	< 50 IU/L	10/08/1992	670	
	SAP = ALP	30 - 120 U/L	02/08/1992	324	
	SAP = ALP	30 - 120 U/L	10/08/1992	466	

Additional Information:

General anaesthetic on 24/06/92 for evacuation of a right subdural haematoma. 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.

Report Details:

Case Number: 85063 **Seq:** 1 **Gender:** M
Reported: 01/06/1993 **Weight:**
Hospitalisation: **Age:** 77Y
Onset Date: 31/07/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

LITHIUM CARBONATE (Other drug)				**Reason:**	Unspecifid affective psychosis
Tablet	125.0	Milligram	Daily		Oral
Batch:	**Started:** 01/06/1992			**Stopped:**	28/08/1992
SINEMET (Other drug)				**Reason:**	Paralysis agitans
Tablet	4.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	
DILANTIN (Suspected)				**Reason:**	
Capsule	300.0	Milligram	Daily		Oral
Batch:	**Started:** 24/04/1992			**Stopped:**	02/08/1992
HALOPERIDOL (Suspected)				**Reason:**	Unspecifid affective psychosis
Tablet	4.0	Milligram	Daily		Oral
Batch:	**Started:** 01/06/1992			**Stopped:**	02/08/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP	30 - 120 U/L	17/08/1992	375	
	SAP = ALP	30 - 120 U/L	24/08/1992	203	
	SAP = ALP	30 - 120 U/L	13/08/1992	536	
	Skin biopsy				Skin biopsy (13/8/92):"superfical perivascular and interface dermatitis drug reaction favoured". (r) axillary node biopsy (21/8/92): "immunoblastic adenopathy, consistant with phenytoin reaction. no evidence of lymphoma."

Additional Information:

General anaesthetic on 24/06/92 for evacuation of a right subdural haematoma. 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.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 85063 **Seq:** 1 **Gender:** M
Reported: 01/06/1993 **Weight:**
Hospitalisation: **Age:** 77Y
Onset Date: 31/07/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

LITHIUM CARBONATE (Other drug)				**Reason:**	Unspecifid affective psychosis
Tablet	125.0	Milligram	Daily		Oral
Batch:	**Started:** 01/06/1992			**Stopped:**	28/08/1992
SINEMET (Other drug)				**Reason:**	Paralysis agitans
Tablet	4.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	
DILANTIN (Suspected)				**Reason:**	
Capsule	300.0	Milligram	Daily		Oral
Batch:	**Started:** 24/04/1992			**Stopped:**	02/08/1992
HALOPERIDOL (Suspected)				**Reason:**	Unspecifid affective psychosis
Tablet	4.0	Milligram	Daily		Oral
Batch:	**Started:** 01/06/1992			**Stopped:**	02/08/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells	4.00 - 11.00	02/08/1992	8.6	
	White blood cells	4.00 - 11.00	10/08/1992	29	
	White blood cells	4.00 - 11.00	13/08/1992	30.43	

Additional Information:

General anaesthetic on 24/06/92 for evacuation of a right subdural haematoma. 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.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 85262 **Seq:** 1 **Gender:** F
Reported: 15/06/1993 **Weight:**
Hospitalisation: **Age:** 78Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysphagia Extrapyramidal disorder			 Madopar.

Medicine Details:

TRANSIDERM-NITRO (Other drug) **Reason:** Chron isch heart dis no hyper
Cream 25.0 Milligram 1 time Transdermal
Batch: **Started:** **Stopped:**

SOLPRIN (Other drug) **Reason:** Chron isch heart dis no hyper
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

OROXINE (Other drug) **Reason:** Myxedema
Tablet 75.0 Microgram Daily Oral
Batch: **Started:** **Stopped:**

CARDIZEM (Other drug) **Reason:** Chron isch heart dis no hyper
Tablet 120.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 85262 **Seq:** 1 **Gender:** F
Reported: 15/06/1993 **Weight:**
Hospitalisation: **Age:** 78Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Paranoid type schizophrenia

Oral application	1.0 Milligram	Daily	Oral
Batch:	**Started:** 01/03/1992	**Stopped:**	28/09/1992

Laboratory Investigations:

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: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 85584 **Seq:** 1 **Gender:** M
Reported: 28/06/1993 **Weight:** 80.00
Hospitalisation: **Age:** 35Y
Onset Date: 22/10/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Torticollis			Bentropine 2mg oral and im.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Paranoid type schizophrenia
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 20/10/1992 **Stopped:** 22/10/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 85857 **Seq:** 1 **Gender:** M
Reported: 06/07/1993 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: 26/05/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia	Severe		

Medicine Details:

HALDOL DECANOATE (Suspected)			**Reason:** Unspecified schizophrenia	
Injection	50.0 Milligram		1 time	Intramuscular
Batch:	**Started:** 12/05/1993		**Stopped:**	
SERENACE (Suspected)			**Reason:**	
Tablet	5.0 Milligram		1 time	Oral
Batch:	**Started:** 21/05/1993		**Stopped:**	
HALDOL DECANOATE (Suspected)			**Reason:** Unspecified schizophrenia	
Injection	12.5 Milligram		Daily	Intramuscular
Batch:	**Started:** 01/01/1991		**Stopped:** 03/03/1993	

Laboratory Investigations:

Date	Type	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: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 85860 **Seq:** 1 **Gender:** M
Reported: 06/07/1993 **Weight:**
Hospitalisation: **Age:** 23Y
Onset Date: 04/05/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

LARGACTIL (Suspected) **Reason:** Manic-depression psycho,manic
Oral application 50.0 Milligram 1 time Oral
Batch: **Started:** 03/05/1993 **Stopped:**

SERENACE (Suspected) **Reason:** Manic-depression psycho,manic
Injection 10.0 Milligram 1 time Intramuscular
Batch: **Started:** 03/05/1993 **Stopped:**

SERENACE (Suspected) **Reason:** Manic-depression psycho,manic
Injection 5.0 Milligram 1 time Intramuscular
Batch: **Started:** 04/05/1993 **Stopped:**

MELLERIL (Suspected) **Reason:** Manic-depression psycho,manic
Oral application 150.0 Milligram Daily Oral
Batch: **Started:** 03/05/1993 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 85885 **Seq:** 1 **Gender:** M
Reported: 06/07/1993 **Weight:**
Hospitalisation: **Age:** 17Y
Onset Date: 12/06/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction affecting jaw & neck.	4mg cogentin imi.

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified psychosis
Oral application 15.0 Milligram Daily Oral
Batch: **Started:** 09/06/1993 **Stopped:** 10/06/1993

STELAZINE (Suspected) **Reason:** Unspecified psychosis
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 10/06/1993 **Stopped:** 14/06/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 85964 **Seq:** 1
Reported: 12/07/1993
Hospitalisation: Admitted to hospital
Onset Date: 18/09/1992
Outcome: Recovered

Gender: F
Weight:
Age: 43
DOB: 27/08/1949
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state Dyskinesia Neuroleptic malignant syndrome Pyrexia			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Depression

Injection	0.0	3 times	Intramuscular

Batch: **Started:** 18/09/1992 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine phosphokinase	30 - 180 U/L	18/09/1992	69	
	Creatine phosphokinase	30 - 180 U/L	19/09/1992	101	
	Creatine phosphokinase	30 - 180 U/L	21/09/1992	43	
	White blood cells	4 - 11	12/09/1992	9.2	
	White blood cells	4 - 11	18/09/1992	12.9	
	White blood cells	4 - 11	19/09/1992	9.7	
	White blood cells	4 - 11	21/09/1992	10.2	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 85964 **Seq:** 1
Reported: 12/07/1993
Hospitalisation: Admitted to hospital
Onset Date: 18/09/1992
Outcome: Recovered

Gender: F
Weight:
Age: 43
DOB: 27/08/1949
Causality: Causality probable

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)		**Reason:** Depression	
Injection	0.0	3 times	Intramuscular
Batch:	**Started:** 18/09/1992	**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells	4 - 11	24/09/1992	8.6	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 85999 **Seq:** 1 **Gender:** M
Reported: 12/07/1993 **Weight:** 54.00
Hospitalisation: **Age:** 52Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delirium Hypotension Somnolence			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 85999 **Seq:** 1 **Gender:** M
Reported: 12/07/1993 **Weight:** 54.00
Hospitalisation: **Age:** 52Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) **Reason:** Delirium

Oral application 400.0 Milligram Daily Oral

Batch: **Started:** 09/06/1993 **Stopped:** 09/06/1993

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 86011 **Seq:** 1 **Gender:** M
Reported: 12/07/1993 **Weight:**
Hospitalisation: **Age:** 65Y
Onset Date: 02/03/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

PERTOFRAN (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 12/02/1993 **Stopped:** 05/03/1993

SERENACE (Suspected) **Reason:** Depression
Oral application 4.0 Milligram Daily Oral
Batch: **Started:** 24/02/1993 **Stopped:** 01/03/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT		06/02/1993	16	
	AST = SGOT		02/03/1993	100	
	AST = SGOT		02/04/1993	44	
	AST = SGOT		21/04/1993	36	
	AST = SGOT		06/04/1993	33	
	Bilirubin		06/02/1993	8	
	Bilirubin		02/03/1993	11	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 86011 **Seq:** 1 **Gender:** M
Reported: 12/07/1993 **Weight:**
Hospitalisation: **Age:** 65Y
Onset Date: 02/03/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

PERTOFRAN (Suspected)			**Reason:** Depression	
Tablet	100.0 Milligram		Daily	Oral
Batch:	**Started:** 12/02/1993			**Stopped:** 05/03/1993
SERENACE (Suspected)			**Reason:** Depression	
Oral application	4.0 Milligram		Daily	Oral
Batch:	**Started:** 24/02/1993			**Stopped:** 01/03/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin		02/04/1993	8	
	GGT = SGGT =		06/02/1993	-	
	GGT = SGGT =		02/04/1993	-	
	GGT = SGGT =		06/04/1993	21	
	GGT = SGGT =		02/03/1993	56	
	SAP = ALP		06/02/1993	43	
	SAP = ALP		02/03/1993	79	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 86011 **Seq:** 1 **Gender:** M
Reported: 12/07/1993 **Weight:**
Hospitalisation: **Age:** 65Y
Onset Date: 02/03/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

PERTOFRAN (Suspected)			**Reason:** Depression	
Tablet	100.0 Milligram		Daily	Oral
Batch:	**Started:** 12/02/1993			**Stopped:** 05/03/1993
SERENACE (Suspected)			**Reason:** Depression	
Oral application	4.0 Milligram		Daily	Oral
Batch:	**Started:** 24/02/1993			**Stopped:** 01/03/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP		02/04/1993	52	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 86012 **Seq:** 1 **Gender:** M
Reported: 12/07/1993 **Weight:**
Hospitalisation: **Age:** 65Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified psychosis
Oral application 4.0 Milligram Daily Oral
Batch: **Started:** 24/02/1993 **Stopped:** 01/03/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 86035 **Seq:** 1 **Gender:** M
Reported: 12/07/1993 **Weight:** 70.00
Hospitalisation: **Age:** 32Y
Onset Date: 14/06/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			

Medicine Details:

SUXAMETHONIUM NOS (Suspected)			**Reason:**	
Injection	100.0 Milligram		1 time	Intravenous
Batch:	**Started:** 13/06/1993		**Stopped:**	
HYPNOVEL (Suspected)			**Reason:**	
Injection	10.0 Milligram		Per hour	Intravenous
Batch:	**Started:** 13/06/1993		**Stopped:**	14/06/1993
HALDOL DECANOATE (Suspected)			**Reason:**	
Injection	17.5 Milligram		Daily	Intramuscular
Batch:	**Started:** 13/06/1993		**Stopped:**	13/06/1993
DIPRIVAN (Suspected)			**Reason:**	
Injection	250.0 Milligram		Daily	Intravenous
Batch:	**Started:** 13/06/1993		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 86035 **Seq:** 1 **Gender:** M
Reported: 12/07/1993 **Weight:** 70.00
Hospitalisation: **Age:** 32Y
Onset Date: 14/06/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

PAVULON (Suspected) **Reason:**
Injection 8.0 Milligram Daily Intravenous
Batch: **Started:** 13/06/1993 **Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 86891 **Seq:** 1 **Gender:** F
Reported: 18/08/1993 **Weight:**
Hospitalisation: **Age:** 20
Onset Date: 14/04/1993 **DOB:** 06/12/1972
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Cogentin.

Medicine Details:

SERENACE (Suspected)			**Reason:**	Depression
Oral application	7.5 Milligram	Daily		Oral
Batch:	**Started:** 13/04/1993		**Stopped:**	15/04/1993
CLONAZEPAM (Suspected)			**Reason:**	Otr spec symp psychopathol nec
Oral application	1.0 Milligram	Daily		Oral
Batch:	**Started:** 13/04/1993		**Stopped:**	14/04/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 86993 **Seq:** 1 **Gender:** M
Reported: 23/08/1993 **Weight:** 65.00
Hospitalisation: **Age:** 17Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypoglycaemia Convulsion		Collapsed while running. Shaking violently.	

Medicine Details:

HALDOL DECANOATE (Suspected) **Reason:** Unspecified schizophrenia
Injection 50.0 Milligram Monthly Intramuscular
Batch: **Started:** 18/02/1993 **Stopped:**

PROZAC (Suspected) **Reason:** Depression
Capsule 40.0 Milligram Daily Oral
Batch: **Started:** 14/05/1993 **Stopped:**

NEULACTIL (Suspected) **Reason:** Acute schizophrenia episode
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 30/11/1990 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 87715 **Seq:** 1 **Gender:** M
Reported: 14/09/1993 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 40Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuropathy peripheral			

Medicine Details:

BENZTROPINE MESYLATE (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 87914 **Seq:** 1 **Gender:** M
Reported: 28/09/1993 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: 21/06/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cyanosis Dystonia Opisthotonus Speech disorder Tremor			Cogentin 2mg imi.

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified psychosis
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 20/06/1993 **Stopped:** 21/06/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 87916 **Seq:** 1 **Gender:** M
Reported: 28/09/1993 **Weight:**
Hospitalisation: **Age:** 32Y
Onset Date: 06/07/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psoriasis			

Medicine Details:

LITHICARB (Suspected) **Reason:** Unspecifid affective psychosis
Tablet 1.0 Gram Daily Oral
Batch: **Started:** 03/07/1993 **Stopped:**

SERENACE (Suspected) **Reason:** Unspecified psychosis
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 03/07/1993 **Stopped:** 08/07/1993

RIVOTRIL (Suspected) **Reason:** Unspecifid affective psychosis
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 03/07/1993 **Stopped:** 08/07/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 87944 **Seq:** 1 **Gender:** F
Reported: 28/09/1993 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: 19/09/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Face oedema Pyrexia Rash Tachycardia			

Medicine Details:

RIVOTRIL (Suspected) **Reason:**
Solution 20.0 Milligram As necessary Oral
Batch: **Started:** 17/09/1993 **Stopped:**

LARGACTIL (Suspected) **Reason:** Unspecified psychosis
Oral Liquid 600.0 Milligram Daily Oral
Batch: **Started:** 17/09/1993 **Stopped:** 18/09/1993

MODECATE (Suspected) **Reason:** Unspecified psychosis
Injection 50.0 Milligram Daily Intramuscular
Batch: **Started:** 16/09/1993 **Stopped:**

SERENACE (Suspected) **Reason:** Unspecified psychosis
Oral Liquid 20.0 Milligram Daily Oral
Batch: **Started:** 17/09/1993 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has had same reaction to chlorpromazine.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 87947 **Seq:** 1 **Gender:** F
Reported: 28/09/1993 **Weight:**
Hospitalisation: **Age:**
Onset Date: 28/07/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Hyperreflexia Hypertonia Hypotension Tachycardia	Severe		

Medicine Details:

SERENACE (Suspected)		**Reason:** Unspecified psychosis	
Oral application	20.0 Milligram	1 time	Oral
Batch:	**Started:** 26/07/1993		**Stopped:**
RIVOTRIL (Suspected)		**Reason:** Unspecified psychosis	
Tablet	2.0 Milligram	1 time	Oral
Batch:	**Started:** 26/07/1993		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has grade iv cortical atrophy, due to cerebral palsy.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 87953 **Seq:** 1 **Gender:** M
Reported: 28/09/1993 **Weight:**
Hospitalisation: **Age:** 33Y
Onset Date: 01/10/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Severe		Iv cogentin 2mg x 2.

Medicine Details:

LARGACTIL (Other drug) **Reason:** Unspecified psychosis
Oral application 150.0 Milligram 1 time Oral
Batch: **Started:** 29/09/1991 **Stopped:**

SERENACE (Suspected) **Reason:** Unspecified psychosis
Injection 30.0 Milligram 1 time Intravenous
Batch: **Started:** 30/09/1991 **Stopped:**

HYPNOVEL (Suspected) **Reason:** Unspecified psychosis
Injection 15.0 Milligram 1 time Intravenous
Batch: **Started:** 30/09/1991 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 88475 **Seq:** 1 **Gender:** F
Reported: 13/10/1993 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: 26/11/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			

Medicine Details:

HALOPERIDOL (Suspected)		**Reason:** Cereb spastic infantile paraly	
Oral application	10.0 Milligram	As necessary	Oral
Batch:	**Started:** 22/11/1992	**Stopped:**	26/11/1992
MIDAZOLAM (Suspected)		**Reason:** Otr spec symp psychopathol nec	
Injection	0.0	As necessary	Intramuscular
Batch:	**Started:**	**Stopped:**	
LITHIUM CARBONATE (Suspected)		**Reason:**	
Tablet	1.6 Gram	Daily	Oral
Batch:	**Started:** 24/11/1992	**Stopped:**	27/11/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine phosphokinase	(25-200)U/L	27/11/1992	9482	
	Creatine phosphokinase	(25-200)U/L	28/11/1992	6937	
	Creatine phosphokinase	(25-200)U/L	30/11/1992	1989	
	Creatine phosphokinase	(25-200)U/L	01/12/1992	706	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 88573 **Seq:** 1 **Gender:** F
Reported: 19/10/1993 **Weight:** 70.00
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia Anxiety		Restlessness, inability to sit still.	

Medicine Details:

MAXOLON (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

SERENACE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

STEMETIL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ONCOVIN (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 88573 **Seq:** 1 **Gender:** F
Reported: 19/10/1993 **Weight:** 70.00
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CYCLOPHOSPHAMIDE (Suspected)		**Reason:**
	0.0	
Batch:	**Started:**	**Stopped:**
ZYLOPRIM (Suspected)		**Reason:**
	0.0	
Batch:	**Started:**	**Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 88641 **Seq:** 1 **Gender:** M
Reported: 22/10/1993 **Weight:**
Hospitalisation: **Age:** 72Y
Onset Date: 25/05/1993 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash erythematous			Metronidazole top.

Medicine Details:

VIBRAMYCIN (Suspected) **Reason:**
0.0
Batch: **Started:** 25/05/1993 **Stopped:**

ALLOPURINOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ASPIRIN (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

THIAMINE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 88641 **Seq:** 1 **Gender:** M
Reported: 22/10/1993 **Weight:**
Hospitalisation: **Age:** 72Y
Onset Date: 25/05/1993 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)		**Reason:**
	0.0	
Batch:	**Started:**	**Stopped:**
TEMAZEPAM (Suspected)		**Reason:**
	0.0	
Batch:	**Started:**	**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 88741 **Seq:** 1 **Gender:** M
Reported: 28/10/1993 **Weight:**
Hospitalisation: **Age:** 21Y
Onset Date: 25/08/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration Syncope		Eyes rolled up.	 Benztropine imi 2mg stat.

Medicine Details:

HALOPERIDOL (Suspected)			**Reason:** Unspecifid affective psychosis	
Injection	2.5 Milligram		1 time	Intravenous
Batch:	**Started:** 24/08/1993		**Stopped:**	
DIAZEPAM (Suspected)			**Reason:** Unspecified schizophrenia	
Injection	2.5 Milligram		1 time	Intravenous
Batch:	**Started:** 24/08/1993		**Stopped:**	
HALOPERIDOL (Suspected)			**Reason:** Unspecifid affective psychosis	
Oral application	5.0 Milligram		As necessary	Oral
Batch:	**Started:** 24/08/1993		**Stopped:** 01/09/1993	
BENZTROPINE MESYLATE (Suspected)			**Reason:**	
Oral application	2.0 Milligram		Daily	Oral
Batch:	**Started:** 25/08/1993		**Stopped:** 08/09/1993	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 88987 **Seq:** 1 **Gender:** F
Reported: 02/11/1993 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mouth ulceration Blood alkaline phosphatase increa Rash		Throat and mouth ulceration.	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
Oral application 80.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) **Reason:** Unspecified psychosis
0.0 Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 89271 **Seq:** 1 **Gender:** M
Reported: 16/11/1993 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: 17/06/1993 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Pyrexia			

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified schizophrenia
Oral application 10.0 Milligram Oral
Batch: **Started:** 17/06/1993 **Stopped:** 24/06/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 89327 **Seq:** 1 **Gender:** M
Reported: 18/11/1993 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: 26/02/1993 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Severe	Dystonic reaction	Benztropine 2mg imi - 2df 12 hours apart

Medicine Details:

SERENACE (Suspected) **Reason:** Otr spec symp psychopathol nec
Injection 10.0 Milligram 1 time Intramuscular
Batch: **Started:** **Stopped:**

SERENACE (Suspected) **Reason:** Otr spec symp psychopathol nec
Injection 10.0 Milligram 1 time Intravenous
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 89348 **Seq:** 1 **Gender:** F
Reported: 18/11/1993 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: 23/04/1993 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Laryngospasm	Severe		Benztropine 2mg imi 3 times

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified psychosis
Injection 20.0 Milligram Total Intramuscular
Batch: **Started:** 23/04/1993 **Stopped:** 23/04/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient hep c positive + compromised liver function

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 89696 **Seq:** 1 **Gender:** M
Reported: 07/12/1993 **Weight:**
Hospitalisation: **Age:** 22Y
Onset Date: 18/11/1993 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Cogentin 2 oral doses of 0.5 mg and 1 mg im

Medicine Details:

ALVERCOL (Other drug) **Reason:** Constipation

Granules	5.0	Millilitre	Daily	Oral

Batch: **Started:** L TERM **Stopped:**

SERENACE (Suspected) **Reason:**

Oral application	4.5	Milligram	Daily	Oral

Batch: **Started:** 18/11/1993 **Stopped:** 19/11/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 89721 **Seq:** 1 **Gender:** M
Reported: 07/12/1993 **Weight:** 82.00
Hospitalisation: **Age:** 28
Onset Date: 19/11/1993 **DOB:** 22/09/1965
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pharyngitis Pyrexia Rash morbilliform			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
5.0 Milligram As necessary
Batch: **Started:** **Stopped:**

CLOZAPINE (Suspected) **Reason:**
Oral application 650.0 Milligram Daily Oral
Batch: **Started:** 29/04/1993 **Stopped:** 19/11/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		17/11/1993	3.6	
	Neutrophils		19/11/1993	2.8	
	Neutrophils		20/11/1993	2.4	
	Neutrophils		29/11/1993	3.3	
	Neutrophils		24/11/1993	2	
	White blood cells		17/11/1993	5.1	
	White blood cells		19/11/1993	4	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 89721 **Seq:** 1 **Gender:** M
Reported: 07/12/1993 **Weight:** 82.00
Hospitalisation: **Age:** 28
Onset Date: 19/11/1993 **DOB:** 22/09/1965
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
5.0 Milligram As necessary
Batch: **Started:** **Stopped:**

CLOZAPINE (Suspected) **Reason:**
Oral application 650.0 Milligram Daily Oral
Batch: **Started:** 29/04/1993 **Stopped:** 19/11/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		20/11/1993	4.5	
	White blood cells		24/11/1993	4.5	
	White blood cells		29/11/1993	5.8	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 90021 **Seq:** 1 **Gender:** F
Reported: 23/12/1993 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: 27/07/1993 **DOB:** 22/02/1960
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Intravenous rehydration

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
26.0 Milligram Total
Batch: **Started:** 23/07/1993 **Stopped:**

THIORIDAZINE HYDROCHLORIDE (Suspected) **Reason:**
50.0 Milligram Total
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 90033 **Seq:** 1 **Gender:** M
Reported: 24/12/1993 **Weight:** 92.00
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea Pyrexia Vomiting			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZAPINE (Suspected) **Reason:** Unspecified psychosis
Oral application 225.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 90378 **Seq:** 1 **Gender:** M
Reported: 07/01/1994 **Weight:**
Hospitalisation: **Age:** 18Y
Onset Date: 20/12/1993 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified schizophrenia
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 17/12/1993 **Stopped:** 21/12/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 90763 **Seq:** 1 **Gender:** F
Reported: 28/01/1994 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: 17/01/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			Diazepam iv, clonazepam oral.

Medicine Details:

CLONAZEPAM (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
800.0 Milligram Daily
Batch: **Started:** 29/12/1993 **Stopped:** 18/01/1994

HALOPERIDOL (Suspected) **Reason:**
45.0 Milligram Daily
Batch: **Started:** **Stopped:**

TEMAZEPAM (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 90764 **Seq:** 1 **Gender:** M
Reported: 28/01/1994 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypoxia			
Pyrexia			
Rash maculo-papular			
Respiratory disorder			
Somnolence			
Tachycardia			Ventilation in icu.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Oral application 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 15/01/1994

HALOPERIDOL (Suspected) **Reason:** Unspecified schizophrenia
10.0 Milligram Daily
Batch: **Started:** 10/12/1993 **Stopped:** 17/01/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Mild decrease left ventricular ejection fraction cpk - 600

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 91157 **Seq:** 1 **Gender:** M
Reported: 18/02/1994 **Weight:** 68.00
Hospitalisation: **Age:** 23Y
Onset Date: 08/02/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Details:

Case Number: 91177 **Seq:** 1 **Gender:** M
Reported: 21/02/1994 **Weight:** 66.00
Hospitalisation: **Age:** 59Y
Onset Date: 09/02/1994 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Acne		Acne on central forehead	

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified schizophrenia
Oral application 10.0 Milligram Daily Oral
Batch: **Started:** 30/01/1994 **Stopped:** 15/02/1994

COGENTIN (Suspected) **Reason:**
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 30/01/1994 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergy to penicillin - rash

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 91354 **Seq:** 1 **Gender:** F
Reported: 01/03/1994 **Weight:**
Hospitalisation: **Age:** 51Y
Onset Date: 14/02/1994 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder Hypertonia			

Medicine Details:

KEMADRIN (Other drug) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 09/02/1994 **Stopped:**

SERENACE (Suspected) **Reason:** Unspecified schizophrenia
0.0
Batch: **Started:** 11/06/1993 **Stopped:** 15/02/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 91430 **Seq:** 1 **Gender:** F
Reported: 07/03/1994 **Weight:**
Hospitalisation: **Age:** 54Y
Onset Date: 11/02/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Jaundice Weight decreased			

Medicine Details:

COGENTIN (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

MOGADON (Other drug) **Reason:**
0.0 As necessary
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** 10/02/1994

SODIUM VALPROATE (Suspected) **Reason:** Depression
1.2 Gram Daily
Batch: **Started:** 11/01/1994 **Stopped:** 11/02/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT		11/02/1994	902	
	Albumin		11/02/1994	26	
	Bilirubin		11/02/1994	201	
	GGT = SGGT = SGTP		11/02/1994	524	
	SAP = ALP		11/02/1994	355	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 91430 **Seq:** 1 **Gender:** F
Reported: 07/03/1994 **Weight:**
Hospitalisation: **Age:** 54Y
Onset Date: 11/02/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

LITHIUM CARBONATE (Suspected) **Reason:**
700.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Report Details:

Case Number: 91466 **Seq:** 1
Reported: 07/03/1994
Hospitalisation: Admitted to hospital
Onset Date: 26/02/1994
Outcome: Recovered

Gender: F
Weight: 108.00
Age: 54
DOB: 01/03/1939
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fatigue			
Neutropenia			Supportive therapy

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Oral application 400.0 Milligram Daily Oral
Batch: **Started:** 06/01/1994 **Stopped:** 26/02/1994

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
30.0 Milligram Daily
Batch: **Started:** 06/01/1994 **Stopped:** 06/02/1994

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
20.0 Milligram Daily
Batch: **Started:** 07/02/1994 **Stopped:** 26/02/1994

INDAPAMIDE HEMIHYDRATE (Suspected) **Reason:** Essential benign hypertension
2.5 Milligram Daily
Batch: **Started:** 06/01/1994 **Stopped:** 26/02/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		06/02/1994	5.8	
	Neutrophils		23/02/1994	2.6	
	Neutrophils		09/03/1994	27%	
	Neutrophils		27/02/1994	0.54 17%	
	White blood cells	4.0-11.0	09/02/1994	8.1	
	White blood cells	4.0-11.0	23/02/1994	4.8	
	White blood cells	4.0-11.0	27/02/1994	3.2	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 91466 **Seq:** 1
Reported: 07/03/1994
Hospitalisation: Admitted to hospital
Onset Date: 26/02/1994
Outcome: Recovered

Gender: F
Weight: 108.00
Age: 54
DOB: 01/03/1939
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:**	Unspecified schizophrenia
Oral application	400.0 Milligram	Daily		Oral
Batch:	**Started:** 06/01/1994		**Stopped:**	26/02/1994
HALOPERIDOL (Suspected)			**Reason:**	Unspecified psychosis
	30.0 Milligram	Daily		
Batch:	**Started:** 06/01/1994		**Stopped:**	06/02/1994
HALOPERIDOL (Suspected)			**Reason:**	Unspecified psychosis
	20.0 Milligram	Daily		
Batch:	**Started:** 07/02/1994		**Stopped:**	26/02/1994
INDAPAMIDE HEMIHYDRATE (Suspected)			**Reason:**	Essential benign hypertension
	2.5 Milligram	Daily		
Batch:	**Started:** 06/01/1994		**Stopped:**	26/02/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells	4.0-11.0	09/03/1994	3.9	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 91826 **Seq:** 1 **Gender:** F
Reported: 28/03/1994 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: 14/03/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Cogentin im and por.

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified psychosis
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 12/03/1994 **Stopped:** 14/03/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 92318 **Seq:** 1
Reported: 22/04/1994
Hospitalisation:
Onset Date: 27/03/1994
Outcome: Not yet recovered

Gender: M
Weight: 70.00
Age: 29Y
DOB:
Causality: Causality possible

Reaction Details:

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

Medicine Details:

AGAROL (Suspected) **Reason:** Hemorrhoids
Solution 10.0 Millilitre 2 times Oral
Batch: **Started:** 25/03/1994 **Stopped:**

CLOZAPINE (Suspected) **Reason:**
300.0 Milligram Daily
Batch: **Started:** 21/03/1994 **Stopped:** 30/03/1994

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

ALPRAZOLAM (Suspected) **Reason:** Unspecified psychosis
1.0 Milligram Daily
Batch: **Started:** 09/01/1994 **Stopped:** 04/03/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 92318 **Seq:** 1
Reported: 22/04/1994
Hospitalisation:
Onset Date: 27/03/1994
Outcome: Not yet recovered

Gender: M
Weight: 70.00
Age: 29Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 92393 **Seq:** 1 **Gender:** F
Reported: 20/04/1994 **Weight:** 70.00
Hospitalisation: **Age:** 41Y
Onset Date: 04/03/1994 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary gland enlargement	Required Specialist Consultation		

Medicine Details:

DIAZEPAM (Suspected) **Reason:**
0.0
Batch: **Started:** 01/08/1993 **Stopped:** CONTIN

SERENACE (Suspected) **Reason:**
0.0
Batch: **Started:** 01/02/1994 **Stopped:** CONTIN

CLOZARIL (Suspected) **Reason:**
Tablet 350.0 Milligram Daily Oral
Batch: **Started:** 07/07/1993 **Stopped:** CONTIN

EPILIM (Suspected) **Reason:**
500.0 Milligram Daily
Batch: **Started:** 01/08/1993 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 92416 **Seq:** 1 **Gender:** F
Reported: 26/04/1994 **Weight:**
Hospitalisation: **Age:** 84Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder Tardive dyskinesia			

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified psychosis
Oral application 3.0 Milligram Daily Oral
Batch: **Started:** 01/01/1981 **Stopped:**

TETRABENAZINE (Suspected) **Reason:** Paralysis agitans
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** 01/01/1992 **Stopped:**

ARTANE (Suspected) **Reason:** Paralysis agitans
Oral application 4.0 Milligram Daily Oral
Batch: **Started:** 01/01/1992 **Stopped:**

CARDIPRIN 100 (Suspected) **Reason:** Transient cereb isch no hypert
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 01/01/1986 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 92873 **Seq:** 1 **Gender:** F
Reported: 09/05/1994 **Weight:** 50.00
Hospitalisation: **Age:** 78Y
Onset Date: 23/04/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			Phenergan 45mg daily.

Medicine Details:

COLOXYL WITH SENNA (Other drug) **Reason:** Constipation
2.0 Dose Unspecified Daily
Batch: **Started:** 13/04/1994 **Stopped:** CONTIN

TEMAZE (Other drug) **Reason:**
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

XYLOCAINE (Suspected) **Reason:** Pain
Solution 6.0 Millilitre Daily Topical
Batch: **Started:** 22/04/1994 **Stopped:** 23/04/1994

SERENACE (Suspected) **Reason:** Nausea and vomiting
Oral application 3.0 Milligram Daily Oral
Batch: **Started:** 07/04/1994 **Stopped:** 23/04/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Details:

Case Number: 92873 **Seq:** 1 **Gender:** F
Reported: 09/05/1994 **Weight:** 50.00
Hospitalisation: **Age:** 78Y
Onset Date: 23/04/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

NILSTAT (Suspected)			**Reason:**	Glossitis	
Solution	4.0	Millilitre	Daily		Oral
Batch:	**Started:**	21/04/1994		**Stopped:**	24/04/1994
DYMADON FORTE (Suspected)			**Reason:**	Pain	
Tablet	12.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**	11/04/1994		**Stopped:**	24/04/1994

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 92903 **Seq:** 1 **Gender:** M
Reported: 11/05/1994 **Weight:** 65.00
Hospitalisation: **Age:** 18Y
Onset Date: 21/04/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Cogentin im.

Medicine Details:

FLUCLOXACILLIN SODIUM (Other drug) **Reason:**
Oral application 2.0 Gram Daily Oral
Batch: **Started:** 20/04/1994 **Stopped:**

DILANTIN (Other drug) **Reason:** Other&unspecified epilepsy
Oral application 250.0 Milligram Daily Oral
Batch: **Started:** 20/04/1994 **Stopped:**

RANITIDINE (Other drug) **Reason:** Ulcer of stomach w/o ment perf
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 20/04/1994 **Stopped:**

TEGRETOL (Other drug) **Reason:** Other&unspecified epilepsy
400.0 Milligram Daily
Batch: **Started:** 20/04/1994 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 92903 **Seq:** 1 **Gender:** M
Reported: 11/05/1994 **Weight:** 65.00
Hospitalisation: **Age:** 18Y
Onset Date: 21/04/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
5.0 Milligram 2 times
Batch: **Started:** 20/04/1994 **Stopped:** 21/04/1994

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 92904 **Seq:** 1 **Gender:** M
Reported: 11/05/1994 **Weight:** 166.00
Hospitalisation: **Age:** 50Y
Onset Date: 23/04/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal			

Medicine Details:

DIAZEPAM (Other drug) **Reason:** Specific disorders of sleep
Injection 55.0 Milligram Total Intravenous
Batch: **Started:** **Stopped:**

HEPARIN CALCIUM (Other drug) **Reason:** Other prophylactic procedures
Injection 10.0 Thousand Internal Daily Subcutaneous
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
120.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics				Prolonged qt interval

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 92999 **Seq:** 1 **Gender:** M
Reported: 16/05/1994 **Weight:**
Hospitalisation: **Age:** 22Y
Onset Date: 27/04/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Tremor	Severe		Cogentin

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified schizophrenia
40.0 Milligram Reducing
Batch: **Started:** 23/03/1994 **Stopped:** 26/04/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 93073 **Seq:** 1 **Gender:** F
Reported: 17/05/1994 **Weight:**
Hospitalisation: **Age:** 55
Onset Date: 08/09/1993 **DOB:** 20/10/1937
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

ENALAPRIL MALEATE (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 08/07/1993 **Stopped:** CONTIN

CLONAZEPAM (Other drug) **Reason:**
1.0 Milligram Daily
Batch: **Started:** 22/07/1993 **Stopped:** 29/09/1993

FLUOXETINE HYDROCHLORIDE (Other drug) **Reason:**
40.0 Milligram Daily
Batch: **Started:** 11/07/1993 **Stopped:** 20/09/1993

HALOPERIDOL (Suspected) **Reason:**
15.0 Milligram Total
Batch: **Started:** 12/07/1993 **Stopped:** 14/07/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 93073 **Seq:** 1
Reported: 17/05/1994
Hospitalisation:
Onset Date: 08/09/1993
Outcome: Not yet recovered

Gender: F
Weight:
Age: 55
DOB: 20/10/1937
Causality: Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)		**Reason:**	
	5.0 Milligram	Daily	
Batch:	**Started:** 15/07/1993		**Stopped:** 26/07/1993
HALOPERIDOL (Suspected)		**Reason:**	
	2.5 Milligram	Daily	
Batch:	**Started:** 26/07/1993		**Stopped:** 08/09/1993

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 93121 **Seq:** 1 **Gender:** F
Reported: 17/05/1994 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 13/10/1993 **DOB:** 06/05/1972
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Stiff neck	Benztropine

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
1.5 Milligram 1 time
Batch: **Started:** 10/10/1993 **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
12.0 Milligram Total
Batch: **Started:** 11/10/1993 **Stopped:** 13/10/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 93272 **Seq:** 1
Reported: 27/05/1994
Hospitalisation: Admitted to hospital
Onset Date: 22/12/1993
Outcome: Not yet recovered

Gender: M
Weight:
Age: 24
DOB: 30/10/1969
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Embolism	Severe		Warfarinized

Medicine Details:

PARACETAMOL (Suspected) **Reason:** Headache
2.0 Dose Unspecified As necessary
Batch: **Started:** 14/12/1993 **Stopped:** 21/12/1993

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Oral application 300.0 Milligram Daily Oral
Batch: **Started:** 03/12/1993 **Stopped:** CONTIN

RANITIDINE (Suspected) **Reason:** Other diseases of esophagus
600.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

CISAPRIDE (Suspected) **Reason:** Other diseases of esophagus
20.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				Angiogram at panch: (r) mid brachial embolus and further embolus at origin of radial artery.

Additional Information:

Clozapine commenced 3/12/93 at dose of 25mg nocte. incremental dosing up 25mg daily to 300mg daily on 23/12/93. continued at 300mg daily until 10/2/94 with subsequent increases in dosage.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 93272 **Seq:** 1
Reported: 27/05/1994
Hospitalisation: Admitted to hospital
Onset Date: 22/12/1993
Outcome: Not yet recovered

Gender: M
Weight:
Age: 24
DOB: 30/10/1969
Causality: Causality possible

Reaction Details:

Medicine Details:

SALBUTAMOL (Suspected)				**Reason:**	Asthma	
Inhalation	4.0	Dose Unspecified	Daily		Inhalation	
Batch:	**Started:**			**Stopped:**		CONTIN
BENZTROPINE MESYLATE (Suspected)				**Reason:**		
	1.0	Milligram	Daily			
Batch:	**Started:**			**Stopped:**	29/12/1993	
HALOPERIDOL (Suspected)				**Reason:**	Unspecified psychosis	
	5.0	Milligram	Daily			
Batch:	**Started:**	07/12/1993		**Stopped:**	29/12/1993	

Laboratory Investigations:

Additional Information:

Clozapine commenced 3/12/93 at dose of 25mg nocte. incremental dosing up 25mg daily to 300mg daily on 23/12/93. continued at 300mg daily until 10/2/94 with subsequent increases in dosage.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 93427 **Seq:** 1 **Gender:** F
Reported: 01/06/1994 **Weight:** 78.00
Hospitalisation: **Age:** 28Y
Onset Date: 10/05/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria			Promethazine 12.5mg iv.

Medicine Details:

METOCLOPRAMIDE HYDROCHLORIDE (Other drug) **Reason:** Nausea and vomiting
Oral application 10.0 Milligram As necessary Oral
Batch: **Started:** 07/05/1994 **Stopped:** 15/05/1994

PAPAVERETUM (Suspected) **Reason:** Other disturbance of sensation
Injection 20.0 Milligram As necessary Intramuscular
Batch: **Started:** 10/05/1994 **Stopped:** 10/05/1994

PETHIDINE HYDROCHLORIDE (Suspected) **Reason:** Other disturbance of sensation
Injection 100.0 Milligram As necessary Intramuscular
Batch: **Started:** 07/05/1994 **Stopped:** 11/05/1994

SERENACE (Suspected) **Reason:** Anxiety neurosis
Injection 2.5 Milligram As necessary Intramuscular
Batch: **Started:** 07/05/1994 **Stopped:** 09/05/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has had allergies to penicillin, sulpha, erythromycin, gentamicin, chlorpramazine, hyoscine-n-butyl bromide, codine and sticking plasters.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 93427 **Seq:** 1 **Gender:** F
Reported: 01/06/1994 **Weight:** 78.00
Hospitalisation: **Age:** 28Y
Onset Date: 10/05/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

TORADOL (Suspected) **Reason:**
Injection 30.0 Milligram As necessary Intramuscular
Batch: **Started:** 08/05/1994 **Stopped:** 09/05/1994

Laboratory Investigations:

Additional Information:

Patient has had allergies to penicillin, sulpha, erythromycin, gentamicin, chlorpramazine, hyoscine-n-butyl bromide, codine and sticking plasters.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 93524 **Seq:** 1 **Gender:** F
Reported: 07/06/1994 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: 06/03/1994 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) **Reason:** Unspecified psychosis
Injection 150.0 Milligram Daily Intravenous
Batch: **Started:** 21/02/1994 **Stopped:** 08/03/1994

FERRO-GRADUMET (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 23/02/1994 **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
5.0 Milligram Daily
Batch: **Started:** 24/02/1994 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 93702 **Seq:** 1 **Gender:** M
Reported: 14/06/1994 **Weight:**
Hospitalisation: **Age:** 92Y
Onset Date: 24/05/1994 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion		Excessive dribbling.	
Gait disturbance		Shuffling gait	
Laryngospasm			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
Tablet 3.0 Milligram Daily Oral
Batch: **Started:** 14/05/1994 **Stopped:** 09/06/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 93992 **Seq:** 1 **Gender:** F
Reported: 27/06/1994 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: 20/05/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state Extrapyramidal disorder Hypertonia Somnolence			

Medicine Details:

ISOSORBIDE MONONITRATE (Other drug) **Reason:** Chron isch heart dis no hyper
60.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

RANITIDINE (Other drug) **Reason:**
300.0 Milligram Daily
Batch: **Started:** 17/05/1994 **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
4.5 Milligram Daily
Batch: **Started:** **Stopped:** 21/05/1994

BENZTROPINE MESYLATE (Suspected) **Reason:** Unspecified psychosis
Injection 1.0 Milligram Daily Intravenous
Batch: **Started:** **Stopped:** 21/05/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 93992 **Seq:** 1 **Gender:** F
Reported: 27/06/1994 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: 20/05/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

TEMAZEPAM (Suspected) **Reason:** Specific disorders of sleep
10.0 Milligram Daily
Batch: **Started:** **Stopped:** 20/05/1994

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 94166 **Seq:** 1 **Gender:** F
Reported: 01/07/1994 **Weight:** 59.00
Hospitalisation: **Age:** 54Y
Onset Date: 06/06/1994 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

THYROXINE SODIUM (Other drug) **Reason:** Myxedema
Tablet 100.0 Microgram Daily Oral
Batch: **Started:** 01/01/1986 **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Unspecifid affective psychosis
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 01/01/1992 **Stopped:** 16/06/1994

Laboratory Investigations:

Date	Type	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.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 94880 **Seq:** 1 **Gender:** M
Reported: 08/08/1994 **Weight:** 68.00
Hospitalisation: **Age:** 28
Onset Date: 26/07/1994 **DOB:** 01/06/1966
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			Hismanal

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:**
1.0 Gram Daily
Batch: **Started:** 18/07/1994 **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:**
5.0 Milligram As necessary
Batch: **Started:** 26/07/1994 **Stopped:** 30/07/1994

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 18/07/1994 **Stopped:** 30/07/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 94881 **Seq:** 1
Reported: 08/08/1994
Hospitalisation: Admitted to hospital
Onset Date: 30/07/1994
Outcome: Recovered

Gender: M
Weight: 68.00
Age: 28
DOB: 01/06/1966
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation	Required Specialist Consultation		
Blood creatine phosphokinase incr	Required Specialist Consultation		
Cold sweat	Required Specialist Consultation		
Hyperhidrosis	Required Specialist Consultation		

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:**
1.0 Gram Daily
Batch: **Started:** 18/07/1994 **Stopped:** CONTIN

HISMANAL (Suspected) **Reason:** Rash
0.0
Batch: **Started:** 26/07/1994 **Stopped:** 02/08/1994

HALOPERIDOL (Suspected) **Reason:**
5.0 Milligram As necessary
Batch: **Started:** 26/07/1994 **Stopped:** 30/07/1994

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 18/07/1994 **Stopped:** 30/07/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatinine	30-200	30/07/1994	341	
	Creatinine	30-200	31/07/1994	328	
	Creatinine	30-200	01/08/1994	201	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 94881 **Seq:** 1
Reported: 08/08/1994
Hospitalisation: Admitted to hospital
Onset Date: 30/07/1994
Outcome: Recovered

Gender: M
Weight: 68.00
Age: 28
DOB: 01/06/1966
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperreflexia	Required Specialist Consultation		
Hypertonia	Required Specialist Consultation		

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:**
1.0 Gram Daily
Batch: **Started:** 18/07/1994 **Stopped:** CONTIN

HISMANAL (Suspected) **Reason:** Rash
0.0
Batch: **Started:** 26/07/1994 **Stopped:** 02/08/1994

HALOPERIDOL (Suspected) **Reason:**
5.0 Milligram As necessary
Batch: **Started:** 26/07/1994 **Stopped:** 30/07/1994

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 18/07/1994 **Stopped:** 30/07/1994

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 95378 **Seq:** 1 **Gender:** F
Reported: 29/08/1994 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: 01/01/1994 **DOB:** 27/04/1945
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Stomatitis Toxic epidermal necrolysis			Calamine lotion, diprosone, logoderm, prednisolone, ssd.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ONDANSETRON HYDROCHLORIDE DIHYDRATE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PROCHLORPERAZINE MALEATE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 95423 **Seq:** 1 **Gender:** F
Reported: 26/08/1994 **Weight:** 44.00
Hospitalisation: **Age:** 37Y
Onset Date: 23/08/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gait disturbance Coordination abnormal Dysarthria Dystonia Opisthotonus Tremor		Shuffling gait	Cogentin

Medicine Details:

SERENACE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

SEREPAX (Suspected) **Reason:** Specific disorders of sleep
30.0 Milligram As necessary
Batch: **Started:** 26/05/1994 **Stopped:**

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 18/07/1994 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 95671 **Seq:** 1 **Gender:** F
Reported: 05/09/1994 **Weight:**
Hospitalisation: **Age:** 52Y
Onset Date: 27/07/1994 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation Anxiety Cold sweat Tremor			

Medicine Details:

MS CONTIN (Other drug)			**Reason:** Pain	
Tablet	40.0 Milligram	Daily	Oral	
Batch:	**Started:** 26/07/1994		**Stopped:** 16/08/1994	
PANADOL (Other drug)			**Reason:** Pain	
Tablet	6.0 Gram	Daily	Oral	
Batch:	**Started:** 27/07/1994		**Stopped:**	CONTIN
SERENACE (Suspected)			**Reason:** Anxiety neurosis	
Injection	2.5 Milligram	As necessary	Subcutaneous	
Batch:	**Started:** 27/07/1994		**Stopped:** 27/07/1994	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergic to omnopon-vomiting reaction occurred one and a half hours after serenace injection.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 95730 **Seq:** 1
Reported: 07/09/1994
Hospitalisation: Admitted to hospital
Onset Date: 15/01/1994
Outcome: Recovered

Gender: M
Weight:
Age: 39
DOB: 23/04/1954
Causality: Causality possible

Reaction Details:

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

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) **Reason:**
600.0 Milligram
Batch: **Started:** **Stopped:**

MODECATE (Suspected) **Reason:**
75.0 Milligram Fortnightly
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 04/01/1994 **Stopped:** 11/01/1994

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 12/01/1994 **Stopped:** 15/01/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozapine was restarted at 25 mgd on 7.2.94.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 95730 **Seq:** 1
Reported: 07/09/1994
Hospitalisation: Admitted to hospital
Onset Date: 15/01/1994
Outcome: Recovered

Gender: M
Weight:
Age: 39
DOB: 23/04/1954
Causality: Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Clozapine was restarted at 25 mgd on 7.2.94.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 96346 **Seq:** 1 **Gender:** F
Reported: 11/10/1994 **Weight:**
Hospitalisation: **Age:** 52Y
Onset Date: 05/10/1994 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest Convulsion			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Schizophrenia
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Schizophrenia
50.0 Milligram Daily
Batch: **Started:** 28/09/1994 **Stopped:** 05/10/1994

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
250.0 Milligram Daily
Batch: **Started:** 05/10/1994 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozaril commenced at 25mg bd, increasing dosage regime - 5/10/94 at 250mg/d 150 mg mane, 100 mg nocte. longstanding psychogenic polydipsia - sodium = 118

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 96574 **Seq:** 1 **Gender:** F
Reported: 17/10/1994 **Weight:** 65.00
Hospitalisation: **Age:** 23Y
Onset Date: 28/08/1993 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Cogentin injection

Medicine Details:

LARGACTIL (Other drug)			**Reason:**	
Oral application	600.0	Milligram	Daily	Oral
Batch:	**Started:**		**Stopped:**	
VALIUM (Other drug)			**Reason:**	
Tablet	10.0	Milligram	Daily	Oral
Batch:	**Started:**		**Stopped:**	
SERENACE (Suspected)			**Reason:**	
Oral application	80.0	Milligram	Daily	Oral
Batch:	**Started:**		**Stopped:**	29/08/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 96611 **Seq:** 1 **Gender:** F
Reported: 21/10/1994 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 16/03/1956
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

HALDOL DECANOATE (Suspected) **Reason:** Unspecified psychosis

Injection 50.0 Milligram Monthly Intramuscular

Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 96612 **Seq:** 1 **Gender:** M
Reported: 21/10/1994 **Weight:**
Hospitalisation: **Age:** 65
Onset Date: **DOB:** 01/12/1928
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation Oculogyration			Benztropine 0.5mg iv stat.

Medicine Details:

FLUCLOXACILLIN SODIUM (Other drug) **Reason:** Pneumonia,unspecified
Injection 2.0 Gram Daily Intravenous
Batch: **Started:** 02/08/1994 **Stopped:** 10/08/1994

GENTAMICIN SULPHATE (Other drug) **Reason:** Pneumonia,unspecified
Injection 160.0 Milligram Daily Intravenous
Batch: **Started:** 02/08/1994 **Stopped:**

METRONIDAZOLE (Other drug) **Reason:** Pneumonia,unspecified
Injection 1.5 Gram Daily Intravenous
Batch: **Started:** 02/08/1994 **Stopped:**

CEFTRIAXONE (Other drug) **Reason:** Pneumonia,unspecified
Injection 1.0 Gram Daily Intravenous
Batch: **Started:** 06/08/1994 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 96612 **Seq:** 1 **Gender:** M
Reported: 21/10/1994 **Weight:**
Hospitalisation: **Age:** 65
Onset Date: **DOB:** 01/12/1928
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

FRAGMIN (Other drug)			**Reason:** Prophylaxis	
	5.0 Thousand Internal	Daily		
Batch:	**Started:** 04/08/1994		**Stopped:**	
SERENACE (Suspected)			**Reason:**	
Injection	5.0 Milligram	1 time		Intravenous
Batch:	**Started:** 09/08/1994		**Stopped:**	

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 96665 **Seq:** 1 **Gender:** M
Reported: 24/10/1994 **Weight:** 70.00
Hospitalisation: **Age:** 21Y
Onset Date: 06/10/1994 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence			

Medicine Details:

HALDOL DECANOATE (Suspected) **Reason:** Unspecified psychosis

Injection 100.0 Milligram 1 time Intramuscular

Batch: **Started:** 29/09/1994 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 96676 **Seq:** 1 **Gender:** F
Reported: 27/10/1994 **Weight:**
Hospitalisation: **Age:** 32Y
Onset Date: 16/05/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Cogentin stat

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

THYROXINE SODIUM (Other drug) **Reason:** Myxedema
Oral application 100.0 Microgram Daily Oral
Batch: **Started:** **Stopped:**

DIAZEPAM (Other drug) **Reason:** Otr spec symp psychopathol nec
Oral application 30.0 Milligram Daily Oral
Batch: **Started:** 07/05/1994 **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Unspecified schizophrenia
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 15/05/1994 **Stopped:** 16/05/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 96873 **Seq:** 1 **Gender:** F
Reported: 02/11/1994 **Weight:**
Hospitalisation: **Age:** 82Y
Onset Date: 23/08/1994 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Delirium
Oral application 1.0 Milligram Daily Oral
Batch: **Started:** 19/08/1994 **Stopped:** 30/08/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		17/08/1994	133	Admitted to hospital with na 135
	Sodium		23/08/1994	130	Admitted to hospital with na 135
	Sodium		31/08/1994	118	Admitted to hospital with na 135
	Sodium		01/09/1994	117	Admitted to hospital with na 135

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 96882 **Seq:** 1 **Gender:** M
Reported: 02/11/1994 **Weight:** 82.00
Hospitalisation: **Age:** 39Y
Onset Date: 08/09/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash erythematous			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
Oral application 3.0 Milligram As necessary Oral
Batch: **Started:** 04/09/1994 **Stopped:** 08/09/1994

PHENYTOIN SODIUM (Suspected) **Reason:** Convulsions
500.0 Milligram Daily
Batch: **Started:** 13/08/1994 **Stopped:** 08/09/1994

CEFOTAXIME SODIUM (Suspected) **Reason:** Other diseases of lung
Injection 3.0 Gram Daily Intravenous
Batch: **Started:** 08/09/1994 **Stopped:** 08/09/1994

NIFEDIPINE (Suspected) **Reason:** Essential benign hypertension
80.0 Milligram Daily
Batch: **Started:** 21/08/1994 **Stopped:** 09/09/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other medication.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 96882 **Seq:** 1 **Gender:** M
Reported: 02/11/1994 **Weight:** 82.00
Hospitalisation: **Age:** 39Y
Onset Date: 08/09/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

METOCLOPRAMIDE HYDROCHLORIDE (Suspected)			**Reason:**	
Injection	40.0 Milligram		Daily	Intravenous
Batch:	**Started:** 16/08/1994			**Stopped:** 09/09/1994
KAY CIEL (Suspected)			**Reason:**	Alkalosis
Oral Liquid	30.0 Millilitre		Daily	Oral
Batch:	**Started:** 08/09/1994			**Stopped:** 08/09/1994
GENTAMICIN SULPHATE (Suspected)			**Reason:**	Other diseases of lung
Injection	240.0 Milligram		Daily	Intravenous
Batch:	**Started:** 08/09/1994			**Stopped:** 09/09/1994

Laboratory Investigations:

Additional Information:

See original report for other medication.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 97075 **Seq:** 1 **Gender:** M
Reported: 16/11/1994 **Weight:** 80.00
Hospitalisation: **Age:** 47Y
Onset Date: 20/10/1994 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site reaction		Red indurated inflamed oedematous reactn	

Medicine Details:

HALOPERIDOL DECANOATE (Suspected) **Reason:** Unspecified schizophrenia
0.0
Batch: **Started:** 01/01/1993 **Stopped:** 20/10/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Blood dyscrosia to fluphenazine decanoate. the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 97504 **Seq:** 1
Reported: 01/12/1994
Hospitalisation: Hospitalisation prolonged
Onset Date:
Outcome: Recovered

Gender: F
Weight: 60.00
Age: 84Y
DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

LASIX (Other drug) **Reason:** Congestive heart failure
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

SLOW-K (Other drug) **Reason:**
4.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

TEMAZEPAM (Other drug) **Reason:** Specific disorders of sleep
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
500.0 Microgram Daily
Batch: **Started:** 17/10/1994 **Stopped:** 08/11/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 97591 **Seq:** 1 **Gender:** M
Reported: 06/12/1994 **Weight:**
Hospitalisation: **Age:**
Onset Date: 08/11/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Rash on back and legs.	

Medicine Details:

HEPARIN SODIUM (Other drug)		**Reason:**	
Injection, intravenous infusion	0.0		Intravenous
Batch:	**Started:**		**Stopped:**
WARFARIN SODIUM (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
PLENDIL (Other drug)		**Reason:**	
	10.0 Milligram	Daily	
Batch:	**Started:** 06/11/1994		**Stopped:**
VALIUM (Suspected)		**Reason:**	
Tablet	5.0 Milligram	1 time	Oral
Batch:	**Started:** 07/11/1994		**Stopped:** 08/11/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient's medications were reviewed and recommenced at a later date.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 97591 **Seq:** 1 **Gender:** M
Reported: 06/12/1994 **Weight:**
Hospitalisation: **Age:**
Onset Date: 08/11/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

SERENACE (Suspected)			**Reason:**	
Injection	50.0 Milligram		1 time	Intramuscular
Batch:	**Started:** 07/11/1994		**Stopped:**	
TAGAMET (Suspected)			**Reason:**	
	400.0 Milligram		Daily	
Batch:	**Started:** 06/11/1994		**Stopped:**	08/11/1994
BURINEX (Suspected)			**Reason:**	
	1.0 Milligram		Daily	
Batch:	**Started:** 04/11/1994		**Stopped:**	08/11/1994
SERENACE (Suspected)			**Reason:**	
Tablet	4.5 Milligram		Daily	Oral
Batch:	**Started:** 07/11/1994		**Stopped:**	08/11/1994

Laboratory Investigations:

Additional Information:

Patient's medications were reviewed and recommenced at a later date.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 97906 **Seq:** 1 **Gender:** F
Reported: 19/12/1994 **Weight:** 64.00
Hospitalisation: **Age:** 28Y
Onset Date: 24/09/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

HALDOL DECANOATE (Suspected) **Reason:** Otr spec symp psychopathol nec
Injection 50.0 Milligram 1 time Intramuscular
Batch: **Started:** 20/09/1994 **Stopped:**

SERENACE (Suspected) **Reason:**
5.0 Milligram Daily
Batch: **Started:** 24/09/1994 **Stopped:** 03/10/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 97914 **Seq:** 1 **Gender:** M
Reported: 19/12/1994 **Weight:** 73.00
Hospitalisation: **Age:** 22Y
Onset Date: 02/12/1994 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Neuroleptic malignant syndrome Pyrexia Tachycardia			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
5.0 Milligram Daily
Batch: **Started:** 02/12/1994 **Stopped:** 04/12/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		02/12/1994	12,000	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 98123 **Seq:** 1 **Gender:** M
Reported: 03/01/1995 **Weight:**
Hospitalisation: **Age:** 92
Onset Date: 22/08/1994 **DOB:** 28/09/1901
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

COLOXYL WITH SENNA (Other drug)			**Reason:**	Constipation	
Tablet	2.0	Dose Unspecified	As necessary		Oral
Batch:	**Started:**	L TERM		**Stopped:**	
FERRO-GRADUMET (Other drug)			**Reason:**	Unspecified anemia	
Tablet, modified release	1.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**	L TERM		**Stopped:**	
ACTRAPID HM (Other drug)			**Reason:**	Diabetes mellitus	
Injection	8.0	Unit	Daily		Subcutaneous
Batch:	**Started:**	L TERM		**Stopped:**	
TEMAZEPAM (Other drug)			**Reason:**	Specific disorders of sleep	
Capsule	10.0	Milligram	Daily		Oral
Batch:	**Started:**	L TERM		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died on 25/08/94.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 98123 **Seq:** 1
Reported: 03/01/1995
Hospitalisation:
Onset Date: 22/08/1994
Outcome: Death, maybe drug

Gender: M
Weight:
Age: 92
DOB: 28/09/1901
Causality: Causality possible

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

Additional Information:

Patient died on 25/08/94.

Report Details:

Case Number: 98745 **Seq:** 1
Reported: 07/02/1995
Hospitalisation: Admitted to hospital
Onset Date: 30/08/1994
Outcome: Recovered

Gender: F
Weight:
Age: 32
DOB: 28/02/1962
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Severe		
Nausea	Severe		
Pyrexia	Severe		
Rash	Severe		
Tachycardia	Severe		
Thrombocytopenia	Severe		
Vomiting	Severe		

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 175.0 Milligram Daily Oral
Batch: **Started:** 18/08/1994 **Stopped:** 25/08/1994

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
50.0 Milligram Daily
Batch: **Started:** 15/08/1994 **Stopped:** 29/08/1994

SODIUM VALPROATE (Suspected) **Reason:**
500.0 Milligram Daily
Batch: **Started:** 15/08/1994 **Stopped:** 27/08/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Platelets	150 - 450	16/08/1994	144	
	Platelets	150 - 450	24/08/1994	138	
	Platelets	150 - 450	30/08/1994	86	
	Platelets	150 - 450	31/08/1994	64	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 99160 **Seq:** 1 **Gender:** U
Reported: 27/02/1995 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: 09/01/1995 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Cogentin 1 amp im

Medicine Details:

SERENACE (Suspected) **Reason:**
Injection 5.0 Milligram 1 time Intramuscular
Batch: **Started:** 08/01/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 99679 **Seq:** 1 **Gender:** M
Reported: 20/03/1995 **Weight:**
Hospitalisation: **Age:** 61Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

BENZTROPINE MESYLATE (Other drug) **Reason:**
Oral application 1.0 Milligram As necessary Oral
Batch: **Started:** 09/02/1995 **Stopped:** CONTIN

CLONAZEPAM (Other drug) **Reason:** Specific disorders of sleep
0.0 As necessary
Batch: **Started:** 09/02/1995 **Stopped:** CONTIN

TEMAZEPAM (Other drug) **Reason:** Anxiety neurosis
0.0 As necessary
Batch: **Started:** 09/02/1995 **Stopped:** CONTIN

RANITIDINE (Other drug) **Reason:** Other diseases of esophagus
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 30/01/1995 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 99679 **Seq:** 1 **Gender:** M
Reported: 20/03/1995 **Weight:**
Hospitalisation: **Age:** 61Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**

Oral application 15.0 Milligram As necessary Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 100017 **Seq:** 1 **Gender:** M
Reported: 03/04/1995 **Weight:** 101.00
Hospitalisation: **Age:** 36
Onset Date: **DOB:** 07/01/1959
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Excessive weight gain 90 --> 101 kg.	

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 15/11/1994 **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

SODIUM VALPROATE (Suspected) **Reason:**
2.0 Gram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

CLONAZEPAM (Suspected) **Reason:**
3.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 100198 **Seq:** 1 **Gender:** F
Reported: 11/04/1995 **Weight:** 50.00
Hospitalisation: **Age:** 37Y
Onset Date: 08/04/1995 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state Convulsion Cyanosis Grand mal convulsion			

Medicine Details:

ACTRAPID HM (Other drug)			**Reason:**	Diabetes mellitus
Injection	10.0	Unit	Daily	Subcutaneous
Batch:	**Started:**	01/01/1983	**Stopped:**	
ULTRATARD HM (Other drug)			**Reason:**	Diabetes mellitus
Injection	18.0	Unit	Daily	Subcutaneous
Batch:	**Started:**	01/01/1983	**Stopped:**	
ANAFRANIL (Other drug)			**Reason:**	
Tablet	150.0	Milligram	Daily	Oral
Batch:	**Started:**	01/01/1993	**Stopped:**	
CLOZARIL (Suspected)			**Reason:**	Unspecified schizophrenia
Tablet	75.0	Milligram	Daily	Oral
Batch:	**Started:**	06/01/1995	**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of epilepsy , cessation of anti-convulsant 3 days prior to seizure. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 100198 **Seq:** 1 **Gender:** F
Reported: 11/04/1995 **Weight:** 50.00
Hospitalisation: **Age:** 37Y
Onset Date: 08/04/1995 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

RIVOTRIL (Suspected)			**Reason:**	Convulsions	
Tablet	500.0	Microgram	Daily		Oral
Batch:	**Started:**	01/01/1993		**Stopped:**	05/04/1995
NORDETTE NOS (Suspected)			**Reason:**	Contraception	
Pill	1.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	
CLONAZEPAM (Suspected)			**Reason:**	Convulsions	
	500.0	Microgram	Daily		
Batch:	**Started:**			**Stopped:**	
SERENACE (Suspected)			**Reason:**		
	5.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	12/01/1995

Laboratory Investigations:

Additional Information:

History of epilepsy , cessation of anti-convulsant 3 days prior to seizure. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Report Details:

Case Number: 100198 **Seq:** 1 **Gender:** F
Reported: 11/04/1995 **Weight:** 50.00
Hospitalisation: **Age:** 37Y
Onset Date: 08/04/1995 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

COGENTIN (Suspected) **Reason:**
2.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

History of epilepsy , cessation of anti-convulsant 3 days prior to seizure. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 100283 **Seq:** 1 **Gender:** M
Reported: 20/04/1995 **Weight:** 79.00
Hospitalisation: **Age:** 35Y
Onset Date: 16/04/1995 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified psychosis
600.0 Milligram Daily
Batch: **Started:** 07/09/1993 **Stopped:**

SERENACE (Suspected) **Reason:** Unspecified psychosis
5.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

COGENTIN (Suspected) **Reason:**
2.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 100404 **Seq:** 1 **Gender:** M
Reported: 28/04/1995 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: 02/04/1995 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Hyperkinesia Oculogyration			Benztropine 1mg imi x 2

Medicine Details:

TIMOLOL MALEATE (Other drug) **Reason:** Unspecified glaucoma
Eye Drops 0.0 Ophthalmic
Batch: **Started:** **Stopped:**

SORBILAX (Other drug) **Reason:** Constipation
0.0
Batch: **Started:** **Stopped:**

BISACODYL (Other drug) **Reason:** Constipation
Oral application 10.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

TEMAZEPAM (Other drug) **Reason:** Specific disorders of sleep
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 100404 **Seq:** 1 **Gender:** M
Reported: 28/04/1995 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: 02/04/1995 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

PARACETAMOL (Other drug)			**Reason:**	Other disturbance of sensation	
Tablet	2.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**	L TERM		**Stopped:**	
KETOPROFEN (Other drug)			**Reason:**		
	200.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	
HALOPERIDOL (Suspected)			**Reason:**	Nausea and vomiting	
Injection	7.5	Milligram	Daily		Subcutaneous
Batch:	**Started:**	12/03/1995		**Stopped:**	03/04/1995
STEMETIL (Suspected)			**Reason:**	Nausea and vomiting	
Tablet	15.0	Milligram	Daily		Oral
Batch:	**Started:**	30/03/1995		**Stopped:**	03/04/1995

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 100513 **Seq:** 1 **Gender:** F
Reported: 01/05/1995 **Weight:**
Hospitalisation: **Age:** 22Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Visual disturbance	Severe		

Medicine Details:

AROPAX (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:** Depression
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 100726 **Seq:** 1
Reported: 10/05/1995
Hospitalisation:
Onset Date: 20/04/1995
Outcome: Death, maybe drug

Gender: M
Weight: 64.00
Age: 60Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating Extrapyramidal disorder Neuroleptic malignant syndrome Somnolence			

Medicine Details:

FOLIC ACID (Other drug) **Reason:**
15.0 Milligram Daily
Batch: **Started:** **Stopped:**

BENZHEXOL HYDROCHLORIDE (Other drug) **Reason:**
4.0 Milligram Daily
Batch: **Started:** 01/01/1994 **Stopped:**

DOTHIEPIN HYDROCHLORIDE (Other drug) **Reason:**
75.0 Milligram Daily
Batch: **Started:** 01/01/1994 **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 01/02/1994 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died 4/5/95 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.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 100726 **Seq:** 1
Reported: 10/05/1995
Hospitalisation:
Onset Date: 20/04/1995
Outcome: Death, maybe drug

Gender: M
Weight: 64.00
Age: 60Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** 01/09/1994 **Stopped:**

Laboratory Investigations:

Additional Information:

Patient died 4/5/95 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.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 101162 **Seq:** 1
Reported: 29/05/1995
Hospitalisation: Hospitalisation prolonged
Onset Date: 30/04/1995
Outcome: Recovered

Gender: F
Weight:
Age: 82Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness Somnolence			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 29/04/1995 **Stopped:** 02/05/1995

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec

Oral application 2.5 Milligram Daily Oral

Batch: **Started:** 22/04/1995 **Stopped:** 02/05/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 101503 **Seq:** 1 **Gender:** M
Reported: 08/06/1995 **Weight:**
Hospitalisation: **Age:** 65
Onset Date: 15/03/1995 **DOB:** 24/03/1929
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary retention			

Medicine Details:

BENZTROPINE MESYLATE (Other drug) **Reason:**
2.0 Milligram As necessary
Batch: **Started:** L TERM **Stopped:**

HALOPERIDOL (Other drug) **Reason:**
Tablet 6.0 Milligram Daily Oral
Batch: **Started:** 03/03/1995 **Stopped:** 15/05/1995

HALDOL DECANOATE (Suspected) **Reason:**
Injection 50.0 Milligram 1 time Intramuscular
Batch: **Started:** 14/03/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 101518 **Seq:** 1 **Gender:** F
Reported: 14/06/1995 **Weight:** 72.00
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

AROPAX (Other drug) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 12/01/1995 **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Paranoia
Tablet 3.0 Milligram Daily Oral
Batch: **Started:** 21/12/1994 **Stopped:** 19/01/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 101746 **Seq:** 1 **Gender:** M
Reported: 26/06/1995 **Weight:**
Hospitalisation: **Age:** 60
Onset Date: 04/04/1995 **DOB:** 23/01/1935
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Benztropine.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
Injection 10.0 Milligram 1 time Intramuscular
Batch: **Started:** **Stopped:**

AURORIX (Suspected) **Reason:** Depression
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 14/03/1995 **Stopped:** 04/04/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 101832 **Seq:** 1 **Gender:** M
Reported: 30/06/1995 **Weight:**
Hospitalisation: **Age:** 62Y
Onset Date: 29/05/1995 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Jaundice			

Medicine Details:

CARBAMAZEPINE (Other drug)			**Reason:**	Other&unspecified epilepsy	
Tablet	800.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
SODIUM VALPROATE (Other drug)			**Reason:**	Other&unspecified epilepsy	
Tablet	800.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
ATENOLOL (Other drug)			**Reason:**	Essential benign hypertension	
Tablet	50.0	Milligram	Daily	Oral	
Batch:	**Started:** 01/01/1990			**Stopped:**	CONTIN
HALOPERIDOL (Suspected)			**Reason:**	Otr spec symp psychopathol nec	
Tablet	5.0	Milligram	As necessary	Oral	
Batch:	**Started:** 03/05/1995			**Stopped:**	30/05/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		29/05/1995	150	
	AST = SGOT		29/05/1995	48	
	Bilirubin		29/05/1995	26	
	GGT = SGGT =		29/05/1995	522	
	SAP = ALP		29/05/1995	202	

Additional Information:

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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 102125 **Seq:** 1 **Gender:** F
Reported: 12/07/1995 **Weight:** 46.00
Hospitalisation: **Age:** 29Y
Onset Date: 04/07/1995 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Purpura Angioedema Epistaxis Face oedema		Petechae on tongue	

Medicine Details:

ANTENEX (Suspected) **Reason:**
5.0 Milligram 1 time
Batch: **Started:** 03/07/1995 **Stopped:**

COGENTIN (Suspected) **Reason:**
1.0 Milligram As necessary
Batch: **Started:** 03/07/1995 **Stopped:** 04/07/1995

ANTENEX (Suspected) **Reason:**
5.0 Milligram As necessary
Batch: **Started:** 03/07/1995 **Stopped:** 04/07/1995

SERENACE (Suspected) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 03/07/1995 **Stopped:** 04/07/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 102526 **Seq:** 1 **Gender:** F
Reported: 21/07/1995 **Weight:** 100.00
Hospitalisation: **Age:** 39Y
Onset Date: 05/07/1995 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus			

Medicine Details:

HALDOL DECANOATE (Suspected) **Reason:** Unspecified psychosis
Injection 250.0 Milligram Monthly Intravenous
Batch: **Started:** 01/01/1992 **Stopped:** 28/06/1995

Laboratory Investigations:

Date	Type	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.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 102880 **Seq:** 1 **Gender:** F
Reported: 15/08/1995 **Weight:**
Hospitalisation: **Age:** 87Y
Onset Date: 01/08/1995 **DOB:**
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Patient cooled, bromocriptine, iv dopamine.

Medicine Details:

Keflin Neutral (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ZANTAC (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CAPOTEN (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ROCALTROL (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Ck peak > 5,000u

Additional Information:

Sequelae: pulomary oedema.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 102880 **Seq:** 1
Reported: 15/08/1995
Hospitalisation:
Onset Date: 01/08/1995
Outcome: Recovered with sequelae

Gender: F
Weight:
Age: 87Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

CLEXANE (Other drug)			**Reason:**		
Injection	20.0	Milligram	Daily		Subcutaneous
Batch:	**Started:**			**Stopped:**	
DIGOXIN (Other drug)			**Reason:**		
	2.0	Dose Unspecified	Daily		
Batch:	**Started:**			**Stopped:**	
SERENACE (Suspected)			**Reason:**		
Injection	12.5	Milligram	Total		Intramuscular
Batch:	**Started:**	30/07/1995		**Stopped:**	01/08/1995
MAXOLON (Suspected)			**Reason:**		
Injection	30.0	Milligram	Total		Intramuscular
Batch:	**Started:**	29/07/1995		**Stopped:**	30/07/1995

Laboratory Investigations:

Additional Information:

Sequelae: pulomary oedema.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 103250 **Seq:** 1
Reported: 04/09/1995
Hospitalisation:
Onset Date: 31/12/1984
Outcome: Not yet recovered

Gender: F
Weight: 66.00
Age: 43Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Infertility female			

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified schizophrenia
5.0 Milligram Daily
Batch: **Started:** 01/01/1976 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	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.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 103502 **Seq:** 1 **Gender:** M
Reported: 12/09/1995 **Weight:** 53.00
Hospitalisation: **Age:** 81Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation Confusional state			

Medicine Details:

SERENACE (Suspected) **Reason:**
2.5 Milligram Daily
Batch: **Started:** 22/08/1995 **Stopped:** 27/08/1995

BENZTROPINE MESYLATE (Suspected) **Reason:**
500.0 Microgram Daily
Batch: **Started:** 24/08/1995 **Stopped:** 27/08/1995

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 23/08/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 103594 **Seq:** 1 **Gender:** F
Reported: 18/09/1995 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: 28/06/1995 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Congenital hand malformation		Baby born with six fingers on hand.	

Medicine Details:

LITHIUM CARBONATE (Suspected) **Reason:** Unspecified schizophrenia
0.0
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Unspecified schizophrenia
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mother was also taking illegal/illicit drugs during pregnancy.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 103597 **Seq:** 1 **Gender:** F
Reported: 18/09/1995 **Weight:** 42.00
Hospitalisation: **Age:** 86Y
Onset Date: 04/09/1995 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

TENORMIN (Other drug) **Reason:** Essential benign hypertension
25.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

MIANSERIN HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 13/07/1995 **Stopped:** 05/09/1995

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
500.0 Microgram Daily
Batch: **Started:** 21/08/1995 **Stopped:** 05/09/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		01/09/1995	2.97	
	Neutrophils		08/09/1995	0.34	
	Neutrophils		04/09/1995	0.94	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 103995 **Seq:** 1 **Gender:** M
Reported: 12/10/1995 **Weight:** 57.00
Hospitalisation: **Age:** 85Y
Onset Date: 13/09/1995 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Leukocytosis Neuroleptic malignant syndrome Pyrexia			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
2.5 Milligram As necessary
Batch: **Started:** 12/09/1995 **Stopped:** 20/09/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Ck 1825

Additional Information:

Patient had similar reaction to haloperidol in the past.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 104398 **Seq:** 1 **Gender:** M
Reported: 02/11/1995 **Weight:**
Hospitalisation: **Age:** 67Y
Onset Date: 30/10/1995 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

HALDOL DECANOATE (Suspected) **Reason:** Paranoia
Injection 0.0 Intramuscular
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Developed facial swelling six days after first injection see sequence one for other drugs

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 104426 **Seq:** 1 **Gender:** M
Reported: 03/11/1995 **Weight:** 55.00
Hospitalisation: **Age:** 18Y
Onset Date: 07/03/1994 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gingivitis Nausea Vomiting			

Medicine Details:

EPILIM (Other drug) **Reason:**
Oral application 2.0 Gram Daily Oral
Batch: **Started:** **Stopped:** 28/06/1994

COGENTIN (Other drug) **Reason:**
Oral application 4.0 Milligram Daily Oral
Batch: **Started:** 07/03/1994 **Stopped:** 17/10/1994

DOXYCYCLINE HYDROCHLORIDE (Other drug) **Reason:** Other acne of sebaceous glands
Oral application 100.0 Milligram Daily Oral
Batch: **Started:** 01/08/1992 **Stopped:**

SERENACE (Suspected) **Reason:**
2.0 Milligram Daily
Batch: **Started:** 07/03/1994 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Serenace dose related increased dose=increased vomiting/nausea and gingivitis, decreased dystonia decreased dose= decreased vomiting/nausea and gingivitis, increased dystonia 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.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 105014 **Seq:** 1
Reported: 30/11/1995
Hospitalisation:
Onset Date: 02/10/1995
Outcome: Not yet recovered

Gender: M
Weight: 90.00
Age: 42
DOB: 31/12/1952
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coma Grand mal convulsion Syncope	Severe		Given stat dose of oral valium

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 0.0 Oral
Batch: **Started:** 21/09/1995 **Stopped:** CONTIN

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 27/07/1995 **Stopped:** 03/10/1995

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
20.0 Milligram Daily
Batch: **Started:** 09/07/1995 **Stopped:** 03/10/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 105161 **Seq:** 1 **Gender:** M
Reported: 07/12/1995 **Weight:**
Hospitalisation: **Age:** 74Y
Onset Date: 06/08/1995 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression Agitation Confusional state Hypertonia Hyporeflexia Urinary incontinence			Rehydrated, benzodiazepine for sedation if needed.

Medicine Details:

SERENACE (Suspected) **Reason:** Otr spec symp psychopathol nec

0.0

Batch: **Started:** 21/07/1995 **Stopped:** 13/08/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 105166 **Seq:** 1 **Gender:** M
Reported: 07/12/1995 **Weight:**
Hospitalisation: **Age:** 25Y
Onset Date: 05/08/1995 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Pain			Im cogentin.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
1.0 Dose Unspecified Daily
Batch: **Started:** 04/08/1995 **Stopped:** 05/08/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 105350 **Seq:** 1
Reported: 14/12/1995
Hospitalisation: Hospitalisation prolonged
Onset Date: 18/08/1995
Outcome: Recovered with sequelae

Gender: M
Weight: 63.00
Age: 73
DOB: 01/01/1922
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypokinesia		Bradykinesia	
Extrapyramidal disorder		Extrapyramidal reaction	Supportive.
Confusional state			
Hypertonia			
Tardive dyskinesia			

Medicine Details:

ASPIRIN (Other drug) **Reason:** Angina pectoris
150.0 Milligram Daily
Batch: **Started:** **Stopped:**

IMDUR (Other drug) **Reason:** Angina pectoris
60.0 Milligram Daily
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Ment dis asso w phys cond nos
Injection, intravenous infusion 22.5 Milligram Total Intravenous
Batch: **Started:** 18/08/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 105358 **Seq:** 1
Reported: 19/12/1995
Hospitalisation: Hospitalisation prolonged
Onset Date:
Outcome: Recovered with sequelae

Gender: M
Weight:
Age: 41
DOB: 07/05/1954
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Inotrope support in icu. imipenem, vancomycin and ceftriaxone started empirically for fever.

Medicine Details:

HALOPERIDOL (Suspected)		**Reason:**	Otr spec symp psychopathol nec
Injection, intravenous infusion	0.0		Intravenous
Batch:	**Started:**		**Stopped:**
TEMAZEPAM (Suspected)		**Reason:**	Otr spec symp psychopathol nec
	0.0		
Batch:	**Started:**		**Stopped:**
PHENERGAN (Suspected)		**Reason:**	Otr spec symp psychopathol nec
	0.0		
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 105866 **Seq:** 1 **Gender:** F
Reported: 15/01/1996 **Weight:** 76.00
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased			

Medicine Details:

HALDOL DECANOATE (Suspected) **Reason:**
Injection 0.0 Intramuscular
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 105941 **Seq:** 1 **Gender:** F
Reported: 18/01/1996 **Weight:**
Hospitalisation: **Age:** 75Y
Onset Date: 27/10/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis Fatigue Neutropenia Somnolence			G-csf.

Medicine Details:

CARBIMAZOLE (Suspected) **Reason:** Myxedema
30.0 Milligram Daily
Batch: **Started:** **Stopped:** 27/10/1994

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
1.0 Milligram Daily
Batch: **Started:** **Stopped:** 27/10/1994

LITHIUM CARBONATE (Suspected) **Reason:**
Tablet 125.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 27/10/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils	2.0 - 8.0	27/10/1995	0.00	
	Neutrophils	2.0 - 8.0	29/10/1995	0.00	
	Neutrophils	2.0 - 8.0	30/10/1995	0.24	
	Neutrophils	2.0 - 8.0	01/11/1995	7.2	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 106190 **Seq:** 1 **Gender:** M
Reported: 01/02/1996 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: 20/12/1995 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis		White cell count 20.4.	
Apnoea			
Coma			
Convulsion			
Hyperreflexia			
Hypertonia			
Hyperventilation			
Neuroleptic malignant syndrome			
Pneumonia			
Pyrexia			
Urinary incontinence			

Medicine Details:

SERENACE (Suspected) **Reason:** Reactive confusion
34.5 Milligram Total
Batch: **Started:** 17/12/1995 **Stopped:** 18/12/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died 9/1/96.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 106727 **Seq:** 1 **Gender:** M
Reported: 28/02/1996 **Weight:** 55.00
Hospitalisation: **Age:** 90
Onset Date: 15/02/1996 **DOB:** 10/01/1906
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chills Hyperhidrosis Hypertonia Neuroleptic malignant syndrome Pyrexia			Bromocriptine

Medicine Details:

THYROXINE SODIUM (Other drug)			**Reason:**	
Tablet	100.0	Microgram	Daily	Oral
Batch:	**Started:**		**Stopped:**	
HALOPERIDOL (Suspected)			**Reason:**	
Tablet	30.0	Milligram	Daily	Oral
Batch:	**Started:**		**Stopped:**	15/02/1996
COGENTIN (Suspected)			**Reason:**	
Tablet	2.0	Milligram	Daily	Oral
Batch:	**Started:**		**Stopped:**	15/02/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 106974 **Seq:** 1 **Gender:** F
Reported: 07/03/1996 **Weight:**
Hospitalisation: **Age:** 20
Onset Date: **DOB:** 24/05/1975
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective Hypertonia Somnolence Tremor			

Medicine Details:

HALOPERIDOL (Suspected)		**Reason:**	
Oral application	0.0		Oral
Batch:	**Started:**		**Stopped:**
HALOPERIDOL (Suspected)		**Reason:**	
Injection	0.0		Intravenous
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 107630 **Seq:** 1 **Gender:** F
Reported: 01/04/1996 **Weight:**
Hospitalisation: **Age:** 71
Onset Date: **DOB:** 10/07/1924
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

METOPROLOL TARTRATE (Other drug)			**Reason:**	
Tablet	50.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:** 10/08/1995
ISORDIL (Other drug)			**Reason:**	
Tablet	30.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:** 10/08/1995
HALOPERIDOL (Suspected)			**Reason:**	
Injection	1.5	Milligram	Daily	Intravenous
Batch:	**Started:** 07/07/1995			**Stopped:** 12/07/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 107908 **Seq:** 1 **Gender:** M
Reported: 15/04/1996 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: 04/02/1996 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			
Diarrhoea	Required Specialist Consultation		
Pharyngitis			
Pyrexia			
Red blood cell sedimentation rate i			
Tachycardia			
Tremor			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

CLOZAPINE (Suspected) **Reason:**
225.0 Milligram Daily
Batch: **Started:** 26/01/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine phosphokinase		04/02/1996	82	
	Creatine phosphokinase		06/02/1996	373	
	Creatine phosphokinase		07/02/1996	980	
	Creatine phosphokinase		12/02/1996	80	
	Eosinophils				Eosinophils were normal (0.2) but rised to 0.8 on the 6th day, peaked at 0.9 on 9th day and have since returned to normal.
	Erythrocyte sedimentation rate		06/02/1996	25	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 107908 **Seq:** 1 **Gender:** M
Reported: 15/04/1996 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: 04/02/1996 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

CLOZAPINE (Suspected) **Reason:**
225.0 Milligram Daily
Batch: **Started:** 26/01/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		04/02/1996	7.86	
	Neutrophils		07/02/1996	4.59	
	White blood cells		04/02/1996	9.7	
	White blood cells		06/02/1996	13.1	
	White blood cells		09/02/1996	13.3	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 107910 **Seq:** 1 **Gender:** M
Reported: 15/04/1996 **Weight:**
Hospitalisation: **Age:** 23Y
Onset Date: 07/11/1995 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified schizophrenia

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 107914 **Seq:** 1 **Gender:** M
Reported: 15/04/1996 **Weight:**
Hospitalisation: **Age:** 18Y
Onset Date: 04/11/1995 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified schizophrenia

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 108437 **Seq:** 1
Reported: 13/05/1996
Hospitalisation: Admitted to hospital
Onset Date: 18/07/1995
Outcome: Recovered

Gender: F
Weight:
Age: 81
DOB: 13/08/1913
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coma Confusional state Hypokalaemia Hyponatraemia			Rehydrated.

Medicine Details:

COLOXYL WITH SENNA (Other drug) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** CONTIN

ROCALTROL (Other drug) **Reason:** Osteoporosis
250.0 Microgram Daily
Batch: **Started:** **Stopped:** CONTIN

PANADEINE (Other drug) **Reason:**
8.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** CONTIN

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 18/07/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Potassium		19/07/1995	3.3	
	Potassium		20/07/1995	3.1	
	Potassium		21/07/1995	3.5	
	Potassium		24/07/1995	4.5	
	Potassium		22/07/1995	4.4	
	Sodium		18/07/1995	123	
	Sodium		19/07/1995	128	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 108437 **Seq:** 1
Reported: 13/05/1996
Hospitalisation: Admitted to hospital
Onset Date: 18/07/1995
Outcome: Recovered

Gender: F
Weight:
Age: 81
DOB: 13/08/1913
Causality: Causality possible

Reaction Details:

Medicine Details:

SERENACE (Suspected)			**Reason:**	
	500.0	Microgram	Daily	
Batch:	**Started:**			**Stopped:** 18/07/1995
VOLTAREN (Suspected)			**Reason:**	Osteoporosis
	50.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:** 18/07/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		20/07/1995	130	
	Sodium		21/07/1995	131	
	Sodium		22/07/1995	136	
	Sodium		24/07/1995	136	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 108643 **Seq:** 1 **Gender:** F
Reported: 22/05/1996 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: 21/08/1995 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Speech disorder Visual disturbance			 Cogentin

Medicine Details:

SERENACE (Suspected) **Reason:**
0.0
Batch: **Started:** 14/08/1995 **Stopped:**

ROHYPNOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PANADOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 109142 **Seq:** 1 **Gender:** M
Reported: 14/06/1996 **Weight:**
Hospitalisation: **Age:** 52
Onset Date: 22/05/1996 **DOB:** 19/04/1944
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Required Visit to Doctor	Temp 39.4	
Blood creatine phosphokinase incr			
Confusional state	Required Visit to Doctor		
Coordination abnormal	Required Visit to Doctor		
Dehydration	Required Visit to Doctor		
Leukocytosis	Required Visit to Doctor		

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:** Depression
0.0
Batch: **Started:** **Stopped:**

CLONAZEPAM (Other drug) **Reason:** Depression
6.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

CLOZAPINE (Suspected) **Reason:** Schizophrenia
400.0 Milligram Daily
Batch: **Started:** **Stopped:** 22/05/1996

HALOPERIDOL (Suspected) **Reason:** Depression
80.0 Milligram Daily
Batch: **Started:** 01/05/1996 **Stopped:** 19/05/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Ck 6500

Additional Information:

Haloperidol used for many years without problems.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 109142 **Seq:** 1 **Gender:** M
Reported: 14/06/1996 **Weight:**
Hospitalisation: **Age:** 52
Onset Date: 22/05/1996 **DOB:** 19/04/1944
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Required Visit to Doctor		Iv rehydation/supportive care/cessation of clozapine and haloperidol
Tachycardia	Required Visit to Doctor		
Urinary incontinence	Required Visit to Doctor		

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:** Depression
0.0
Batch: **Started:** **Stopped:**

CLONAZEPAM (Other drug) **Reason:** Depression
6.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

CLOZAPINE (Suspected) **Reason:** Schizophrenia
400.0 Milligram Daily
Batch: **Started:** **Stopped:** 22/05/1996

HALOPERIDOL (Suspected) **Reason:** Depression
80.0 Milligram Daily
Batch: **Started:** 01/05/1996 **Stopped:** 19/05/1996

Laboratory Investigations:

Additional Information:

Haloperidol used for many years without problems.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 109614 **Seq:** 1 **Gender:** F
Reported: 01/07/1996 **Weight:** 81.00
Hospitalisation: **Age:** 42
Onset Date: 05/01/1995 **DOB:** 29/02/1952
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic neoplasm malignant		Hepatocellular carcinoma	Right hemihepatectomy.

Medicine Details:

TAMOXIFEN CITRATE (Suspected) **Reason:** Malignant neoplasm of breast
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 19/03/1993 **Stopped:** 05/01/1995

CYCLOPHOSPHAMIDE (Suspected) **Reason:** Malignant neoplasm of breast
Injection 4.0 Gram Daily Intravenous
Batch: **Started:** 14/01/1993 **Stopped:** 18/03/1993

EPIRUBICIN HYDROCHLORIDE (Suspected) **Reason:** Malignant neoplasm of breast
Injection 560.0 Milligram Daily Intravenous
Batch: **Started:** 14/01/1993 **Stopped:** 18/03/1993

DEXAMETHASONE (Suspected) **Reason:** Nausea and vomiting
Injection 32.0 Milligram Daily Intravenous
Batch: **Started:** 14/01/1993 **Stopped:** 25/02/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Histology				Cellular changes of hepatocellular carcinoma.

Additional Information:

Bilateral breast cancer left node negative, right node postive.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 109614 **Seq:** 1
Reported: 01/07/1996
Hospitalisation:
Onset Date: 05/01/1995
Outcome: Recovered

Gender: F
Weight: 81.00
Age: 42
DOB: 29/02/1952
Causality: Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)			**Reason:**	Nausea and vomiting
Injection	10.0 Milligram	Daily		Intravenous
Batch:	**Started:** 14/01/1993		**Stopped:**	18/03/1993
ONDANSETRON HYDROCHLORIDE DIHYDRATE (Suspected)			**Reason:**	Nausea and vomiting
Oral application	8.0 Milligram	Daily		Oral
Batch:	**Started:** 18/03/1993		**Stopped:**	

Laboratory Investigations:

Additional Information:

Bilateral breast cancer left node negative, right node postive.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 110143 **Seq:** 1 **Gender:** M
Reported: 23/07/1996 **Weight:** 76.00
Hospitalisation: **Age:** 42Y
Onset Date: 31/12/1995 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence			

Medicine Details:

ZOLOFT (Other drug)			**Reason:** Depression	
Tablet	200.0 Milligram		Daily	Oral
Batch:	**Started:** 01/09/1995		**Stopped:**	
RIVOTRIL (Other drug)			**Reason:**	
	1.0 Milligram		Daily	
Batch:	**Started:**		**Stopped:**	
SERENACE (Suspected)			**Reason:**	
Oral application	2.0 Milligram		Daily	Oral
Batch:	**Started:** 01/12/1995		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Adverse event related to increase in dose of serenace. event ceased when dose reduced to 1mg/day. - 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.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 110314 **Seq:** 1 **Gender:** M
Reported: 29/07/1996 **Weight:** 80.00
Hospitalisation: **Age:** 54Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Acneiform eruption anterior chest	
Abscess		Has abscesses groin and axillae	

Medicine Details:

HALDOL DECANOATE (Suspected) **Reason:** Unspecified schizophrenia
Injection 100.0 Milligram Weekly Intramuscular
Batch: **Started:** L TERM **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:** Unspecified schizophrenia
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

RISPERIDONE (Suspected) **Reason:**
8.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 110397 **Seq:** 1 **Gender:** M
Reported: 01/08/1996 **Weight:** 86.00
Hospitalisation: **Age:** 63Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			

Medicine Details:

SERENACE (Suspected) **Reason:** Explosive personality disorder
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 19/07/1996 **Stopped:** 24/07/1996

HEMINEURIN (Suspected) **Reason:**
Capsule 2.0 Dose Unspecified Daily Oral
Batch: **Started:** 18/07/1996 **Stopped:** 23/07/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Details:

Case Number: 111161 **Seq:** 1 **Gender:** M
Reported: 26/08/1996 **Weight:**
Hospitalisation: **Age:** 86Y
Onset Date: 08/05/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state Hepatitis	Required Visit to Doctor		

Medicine Details:

PANADEINE FORTE (Other drug) **Reason:**
0.0 As necessary
Batch: **Started:** **Stopped:**

MAXOLON (Other drug) **Reason:** Nausea and vomiting
Injection 30.0 Milligram Daily Intramuscular
Batch: **Started:** 08/05/1996 **Stopped:** CONTIN

COGENTIN (Other drug) **Reason:**
Tablet 500.0 Microgram Daily Oral
Batch: **Started:** 08/05/1996 **Stopped:** 07/06/1996

PANADEINE (Other drug) **Reason:** Pain
Tablet 4.0 Dose Unspecified Daily Oral
Batch: **Started:** 08/05/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		08/05/1996	12	
	ALT = SGPT		06/06/1996	96	
	ALT = SGPT		13/06/1996	21	
	Albumin		08/05/1996	40	
	Albumin		06/06/1996	28	
	Albumin		13/06/1996	31	
	GGT = SGGT =		08/05/1996	0.9	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 111161 **Seq:** 1 **Gender:** M
Reported: 26/08/1996 **Weight:**
Hospitalisation: **Age:** 86Y
Onset Date: 08/05/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

HEPARIN SODIUM (Other drug)			**Reason:** Prophylaxis	
Injection	10.0 Thousand Internat	Daily		Subcutaneous
Batch:	**Started:** 08/05/1996		**Stopped:**	
HALOPERIDOL (Suspected)			**Reason:** Reactive confusion	
	1.0 Milligram	Daily		
Batch:	**Started:** 08/05/1996		**Stopped:** 07/06/1996	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT = [illegible]		06/06/1996	1070	
	GGT = SGGT = [illegible]		13/06/1996	466	
	SAP = ALP		08/05/1996	84	
	SAP = ALP		06/06/1996	1532	
	SAP = ALP		13/06/1996	516	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 111392 **Seq:** 1
Reported: 04/09/1996
Hospitalisation: Admitted to hospital
Onset Date: 30/07/1996
Outcome: Recovered

Gender: M
Weight: 85.00
Age: 79Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating Confusional state Hypertonia Muscle twitching Tremor		Reduced responsiveness	

Medicine Details:

CAPADEX (Other drug) **Reason:**
1.2 Gram As necessary
Batch: **Started:** 10/07/1996 **Stopped:** 03/08/1996

CODALGIN (Other drug) **Reason:**
1.0 Dose Unspecified As necessary
Batch: **Started:** 14/07/1996 **Stopped:** 06/08/1996

PETHIDINE HYDROCHLORIDE (Other drug) **Reason:**
1.0 Dose Unspecified As necessary
Batch: **Started:** 25/07/1996 **Stopped:** 31/07/1996

IBILEX (Other drug) **Reason:**
Capsule 2.0 Gram Daily Oral
Batch: **Started:** 29/07/1996 **Stopped:** 15/08/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 111392 **Seq:** 1
Reported: 04/09/1996
Hospitalisation: Admitted to hospital
Onset Date: 30/07/1996
Outcome: Recovered

Gender: M
Weight: 85.00
Age: 79Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

SERENACE (Suspected)		**Reason:**	Otr spec symp psychopathol nec
	12.5 Milligram	Total	
Batch:	**Started:** 29/07/1996		**Stopped:** 30/07/1996
ZOLOFT (Suspected)		**Reason:**	Depression
Tablet	100.0 Milligram	Daily	Oral
Batch:	**Started:** 11/07/1996		**Stopped:** 30/07/1996

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
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Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 111429 **Seq:** 1 **Gender:** F
Reported: 05/09/1996 **Weight:**
Hospitalisation: **Age:** 76
Onset Date: **DOB:** 15/01/1920
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Somnolence		Stiff and immobile	

Medicine Details:

ASPIRIN (Other drug)			**Reason:**	
Oral application	150.0	Milligram	Daily	Oral
Batch:	**Started:** 01/01/1996			**Stopped:**
BETAMIN (Other drug)			**Reason:**	Otr&unspec nutritional deficn
Tablet	100.0	Milligram	Daily	Oral
Batch:	**Started:** 01/01/1996			**Stopped:**
F.G.F. (Other drug)			**Reason:**	Iron deficiency anemias
Tablet	1.0	Dose Unspecified	Daily	Oral
Batch:	**Started:** 01/01/1996			**Stopped:**
SERENACE (Suspected)			**Reason:**	Hallucinations
Oral application	500.0	Microgram	Daily	Oral
Batch:	**Started:** 03/06/1996			**Stopped:** 15/07/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 111997 **Seq:** 1 **Gender:** F
Reported: 01/10/1996 **Weight:**
Hospitalisation: **Age:** 30
Onset Date: 01/08/1996 **DOB:** 17/11/1965
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Acute dystonic reaction-sore eyes, neck stiffness	Benztropine

Medicine Details:

OXYBUTYNIN HYDROCHLORIDE (Other drug) **Reason:** Retention of urine
Tablet 1.0 Dose Unspecified As necessary Oral
Batch: **Started:** 01/04/1996 **Stopped:**

FLUOXETINE HYDROCHLORIDE (Other drug) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 31/07/1996 **Stopped:**

NITROFURANTOIN (Other drug) **Reason:** Chronic pyelonephritis
Oral application 50.0 Milligram Daily Oral
Batch: **Started:** 29/07/1996 **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Depnd synth analg w morph effx
Oral application 5.0 Milligram Daily Oral
Batch: **Started:** 31/07/1996 **Stopped:** 01/08/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 111999 **Seq:** 1 **Gender:** F
Reported: 01/10/1996 **Weight:**
Hospitalisation: **Age:** 49
Onset Date: 21/07/1996 **DOB:** 13/11/1946
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Pain		Unable to open mouth, difficulty focusing	Benztropine administered imi

Medicine Details:

PREDNISOLONE (Other drug)				**Reason:**	Systemic lupus erythematosus
Tablet	25.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
AZATHIOPRINE (Other drug)				**Reason:**	Systemic lupus erythematosus
Tablet	100.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
MENOPREM (Other drug)				**Reason:**	Menopausal symptoms
Tablet	1.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
FOLIC ACID (Other drug)				**Reason:**	Other vitamin b deficiency
Oral application	5.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 111999 **Seq:** 1 **Gender:** F
Reported: 01/10/1996 **Weight:**
Hospitalisation: **Age:** 49
Onset Date: 21/07/1996 **DOB:** 13/11/1946
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

DIAZEPAM (Other drug)			**Reason:**	
	5.0 Milligram	Daily		
Batch:	**Started:**	L TERM	**Stopped:**	
HALOPERIDOL (Suspected)			**Reason:**	
Oral application	10.0 Milligram	Daily		Oral
Batch:	**Started:** 21/07/1996		**Stopped:**	

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 112315 **Seq:** 1
Reported: 16/10/1996
Hospitalisation: Admitted to hospital
Onset Date: 24/07/1996
Outcome: Unknown

Gender: M
Weight:
Age: 45Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Dantrolene

Medicine Details:

COGENTIN (Suspected) **Reason:**
Injection 2.0 Milligram 1 time Intramuscular
Batch: **Started:** 24/07/1996 **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
Injection 2.5 Milligram As necessary Intramuscular
Batch: **Started:** 20/07/1996 **Stopped:** 24/07/1996

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
15.0 Milligram Daily
Batch: **Started:** 20/07/1996 **Stopped:** 24/07/1996

HEMINEURIN (Suspected) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** 18/07/1996 **Stopped:** 24/07/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 112330 **Seq:** 1 **Gender:** F
Reported: 17/10/1996 **Weight:** 50.00
Hospitalisation: **Age:** 73Y
Onset Date: 02/09/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal Pancytopenia			

Medicine Details:

SERENACE (Suspected) **Reason:**
1.5 Milligram Daily
Batch: **Started:** 04/07/1996 **Stopped:** 29/08/1996

AURORIX (Suspected) **Reason:** Depression
600.0 Milligram Daily
Batch: **Started:** 25/06/1996 **Stopped:** 29/08/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		02/09/1996	63	
	ALT = SGPT		13/09/1996	17	
	Haemoglobin	(120-160)	02/09/1996	95	
	Haemoglobin	(120-160)	13/09/1996	117	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 112354 **Seq:** 1 **Gender:** M
Reported: 18/10/1996 **Weight:**
Hospitalisation: **Age:** 75Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aphasia		Incoherent speech.	
Paresis		Loss of ability to mobilize.	
Somnolence			

Medicine Details:

SERENACE (Suspected) **Reason:** Specific disorders of sleep
Oral application 5.0 Milligram Daily Oral
Batch: **Started:** 07/09/1996 **Stopped:** 15/10/1996

LITHIUM CARBONATE (Suspected) **Reason:** Manic-depression psycho,manic
2.5 Gram Daily
Batch: **Started:** 01/09/1996 **Stopped:**

VALIUM (Suspected) **Reason:** Specific disorders of sleep
10.0 Milligram Daily
Batch: **Started:** 07/09/1996 **Stopped:** CONTIN

COGENTIN (Suspected) **Reason:** Paralysis agitans
2.0 Milligram Daily
Batch: **Started:** 07/09/1996 **Stopped:** 14/10/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 112354 **Seq:** 1
Reported: 18/10/1996
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight:
Age: 75Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

PANADEINE (Suspected) **Reason:** Pain
8.0 Dose Unspecified Daily
Batch: **Started:** 07/09/1996 **Stopped:** 14/10/1996

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 112529 **Seq:** 1 **Gender:** M
Reported: 25/10/1996 **Weight:** 63.00
Hospitalisation: **Age:** 74
Onset Date: 08/10/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Suspected SIADH	

Medicine Details:

TEGRETOL (Suspected) **Reason:** Explosive personality disorder
200.0 Milligram Daily
Batch: **Started:** 19/09/1996 **Stopped:** 04/10/1996

SERENACE (Suspected) **Reason:** Explosive personality disorder
4.5 Milligram Daily
Batch: **Started:** 19/08/1996 **Stopped:** 04/10/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 112774 **Seq:** 1 **Gender:** M
Reported: 04/11/1996 **Weight:**
Hospitalisation: **Age:** 86Y
Onset Date: 05/09/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Increased tone.	
Muscle twitching		On/off jerks.	
Anorexia			
Blood creatine phosphokinase incr			
Confusional state			
Constipation			
Coordination abnormal			
Urinary incontinence			

Medicine Details:

SOLPRIN (Other drug)				**Reason:**	Chron isch heart dis no hyper	
Oral application	150.0	Milligram	Daily		Oral	
Batch:	**Started:**		L TERM	**Stopped:**		CONTIN
AURORIX (Other drug)				**Reason:**		
Tablet	450.0	Milligram	Daily		Oral	
Batch:	**Started:**		L TERM	**Stopped:**		CONTIN
FOLIC ACID (Other drug)				**Reason:**		
Oral application	5.0	Milligram	Daily		Oral	
Batch:	**Started:**		L TERM	**Stopped:**		CONTIN
RULIDE (Other drug)				**Reason:**	Influenza,unqualified	
Tablet	300.0	Milligram	Daily		Oral	
Batch:	**Started:**	30/08/1996		**Stopped:**	05/09/1996	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergy to penicillin.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 112774 **Seq:** 1 **Gender:** M
Reported: 04/11/1996 **Weight:**
Hospitalisation: **Age:** 86Y
Onset Date: 05/09/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

SERENACE (Suspected)			**Reason:**		
Oral application	1.0	Milligram	Daily	Oral	
Batch:	**Started:**		L TERM	**Stopped:**	09/09/1996

Laboratory Investigations:

Additional Information:

Allergy to penicillin.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 112832 **Seq:** 1
Reported: 01/11/1996
Hospitalisation:
Onset Date: 18/05/1996
Outcome: Unknown

Gender: M
Weight: 39.00
Age: 8
DOB: 10/03/1988
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Choreoathetosis			Carbamazepine ceased

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Other drug) **Reason:**
Oral application 50.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** 07/05/1996

CARBAMAZEPINE (Suspected) **Reason:**
200.0 Milligram Daily
Batch: **Started:** 07/05/1996 **Stopped:** 31/05/1996

PHENERGAN (Suspected) **Reason:**
Oral application 25.0 Milligram Daily Oral
Batch: **Started:** 28/04/1996 **Stopped:** 07/05/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 113331 **Seq:** 1 **Gender:** F
Reported: 22/11/1996 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: 24/07/1996 **DOB:** 21/02/1956
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia	Required Specialist Consultation		

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia
700.0 Milligram Daily
Batch: **Started:** 01/03/1995 **Stopped:** 29/07/1996

CLONAZEPAM (Suspected) **Reason:**
2.0 Milligram Daily
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
5.0 Milligram Daily
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
100.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils	1.5 - 2.0	11/04/1995	2.4	
	Neutrophils	1.5 - 2.0	26/06/1996	6.8	
	Neutrophils	1.5 - 2.0	25/07/1996	1.3	
	Neutrophils	1.5 - 2.0	24/07/1996	1.5	
	White blood cells	3.0 - 3.5	11/04/1995	5.8	
	White blood cells	3.0 - 3.5	26/06/1996	11.5	
	White blood cells	3.0 - 3.5	24/07/1996	4.6	

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 113331 **Seq:** 1 **Gender:** F
Reported: 22/11/1996 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: 24/07/1996 **DOB:** 21/02/1956
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:** Schizophrenia	
	700.0 Milligram	Daily		
Batch:	**Started:** 01/03/1995		**Stopped:** 29/07/1996	
CLONAZEPAM (Suspected)			**Reason:**	
	2.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:**	
HALOPERIDOL (Suspected)			**Reason:**	
	5.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:**	
ZOLOFT (Suspected)			**Reason:**	
	100.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells	3.0 - 3.5	25/07/1996	5.0	

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 113895 **Seq:** 1 **Gender:** F
Reported: 12/12/1996 **Weight:**
Hospitalisation: **Age:** 76
Onset Date: 06/08/1996 **DOB:** 24/04/1920
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

HUMULIN NPH (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

DICLOFENAC SODIUM (Other drug) **Reason:**
50.0 Milligram Daily
Batch: **Started:** **Stopped:**

TRIMETHOPRIM-SULFAMETHOXAZOLE (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** 06/08/1996 **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:** 06/08/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 113895 **Seq:** 1
Reported: 12/12/1996
Hospitalisation:
Onset Date: 06/08/1996
Outcome: Not yet recovered

Gender: F
Weight:
Age: 76
DOB: 24/04/1920
Causality: Causality possible

Reaction Details:

Medicine Details:

POTASSIUM CHLORIDE (Suspected)			**Reason:**	
	1.8	Gram	Daily	
Batch:	**Started:**		**Stopped:**	12/08/1996
AMLODIPINE (Suspected)			**Reason:**	
	5.0	Milligram	Daily	
Batch:	**Started:**		**Stopped:**	12/08/1996
FRUSEMIDE (Suspected)			**Reason:**	
	40.0	Milligram	Daily	
Batch:	**Started:**		**Stopped:**	12/08/1996

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 114906 **Seq:** 1 **Gender:** F
Reported: 03/02/1997 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: 29/01/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Numb tongue, difficulty speaking.	Cogentin

Medicine Details:

NORVASC (Other drug)				**Reason:**	Essential benign hypertension
Tablet	5.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
SERENACE (Suspected)				**Reason:**	
Tablet	5.0	Milligram	Daily		Oral
Batch:	**Started:**	28/01/1997		**Stopped:**	29/01/1997
TEMAZE (Suspected)				**Reason:**	
Capsule	10.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
AURORIX (Suspected)				**Reason:**	Depression
Tablet	300.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 115284 **Seq:** 1 **Gender:** M
Reported: 14/02/1997 **Weight:**
Hospitalisation: **Age:** 73
Onset Date: 25/09/1996 **DOB:** 07/07/1923
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pharyngitis Tongue oedema			

Medicine Details:

ANTENEX (Other drug) **Reason:**
Tablet 2.0 Milligram As necessary Oral
Batch: **Started:** 22/09/1996 **Stopped:** 26/09/1996

LOSEC (Other drug) **Reason:**
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

VITAMINORUM B.P.C. (Other drug) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** L TERM **Stopped:**

NORMISON (Other drug) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 22/09/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Daughter experienced similar problem with same drug.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 115284 **Seq:** 1 **Gender:** M
Reported: 14/02/1997 **Weight:**
Hospitalisation: **Age:** 73
Onset Date: 25/09/1996 **DOB:** 07/07/1923
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

METOCLOPRAMIDE HYDROCHLORIDE (Other drug)		**Reason:**	Nausea and vomiting
	40.0 Milligram	Daily	
Batch:	**Started:** 23/09/1996		**Stopped:**
EPREX (Other drug)		**Reason:**	Unspecified anemia
	12.0 Thousand Internal	Daily	
Batch:	**Started:** L TERM		**Stopped:**
AUGMENTIN (Other drug)		**Reason:**	Pneumonia,unspecified
	750.0 Milligram	Daily	
Batch:	**Started:** 24/09/1996		**Stopped:** 26/09/1996
CARDOL (Other drug)		**Reason:**	Otr&nos disord of heart rhythm
	160.0 Milligram	Daily	
Batch:	**Started:** L TERM		**Stopped:**

Laboratory Investigations:

Additional Information:

Daughter experienced similar problem with same drug.

Report Details:

Case Number: 115284 **Seq:** 1 **Gender:** M
Reported: 14/02/1997 **Weight:**
Hospitalisation: **Age:** 73
Onset Date: 25/09/1996 **DOB:** 07/07/1923
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

IMIPENEM (Other drug)			**Reason:** Peritonitis	
	250.0 Milligram		Daily	
Batch:	**Started:** 22/09/1996		**Stopped:** 25/09/1996	
CALTRATE (Other drug)			**Reason:**	
Tablet	1.0 Dose Unspecified		Alternate days	Oral
Batch:	**Started:**	L TERM	**Stopped:**	
SERENACE (Suspected)			**Reason:**	
Tablet	1.5 Milligram		Daily	Oral
Batch:	**Started:** 24/09/1996		**Stopped:** 25/09/1996	

Laboratory Investigations:

Additional Information:

Daughter experienced similar problem with same drug.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 115815 **Seq:** 1 **Gender:** F
Reported: 05/03/1997 **Weight:** 60.00
Hospitalisation: **Age:** 33Y
Onset Date: 06/02/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Blood creatine phosphokinase incr Hypertonia Mydriasis Neuroleptic malignant syndrome Pyrexia		Increased heart rate	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
10.0 Milligram Daily
Batch: **Started:** 01/02/1997 **Stopped:** 03/02/1997

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
4.0 Milligram Daily
Batch: **Started:** 03/02/1997 **Stopped:** 06/02/1997

KEFLEX (Suspected) **Reason:** Othr diseases of urinary tract
2.0 Gram Daily
Batch: **Started:** 03/02/1997 **Stopped:** 06/02/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatinine		06/02/1997	3372	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 115917 **Seq:** 1 **Gender:** M
Reported: 12/03/1997 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: 22/01/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradykinesia Extrapyramidal disorder Headache Salivary hypersecretion Tremor			

Medicine Details:

TEMAZEPAM (Suspected) **Reason:**
20.0 Milligram 1 time
Batch: **Started:** 21/01/1997 **Stopped:** 22/01/1997

RISPERIDONE (Suspected) **Reason:** Otr spec symp psychopathol nec
1.0 Milligram Daily
Batch: **Started:** 22/01/1997 **Stopped:** 23/01/1997

HALOPERIDOL (Suspected) **Reason:**
6.0 Milligram Daily
Batch: **Started:** 05/01/1997 **Stopped:** 19/01/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 116045 **Seq:** 1 **Gender:** F
Reported: 14/03/1997 **Weight:** 78.00
Hospitalisation: **Age:** 43Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		Continuous movement of the legs and feet.	
Dyskinesia		Orolingual dyskinesia	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
5.0 Milligram As necessary
Batch: **Started:** 01/05/1996 **Stopped:** 28/12/1996

THIORIDAZINE HYDROCHLORIDE (Suspected) **Reason:**
50.0 Milligram As necessary
Batch: **Started:** 01/05/1996 **Stopped:** 28/12/1996

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
200.0 Milligram Daily
Batch: **Started:** 01/05/1996 **Stopped:** 28/03/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 117117 **Seq:** 1 **Gender:** U
Reported: 30/04/1997 **Weight:**
Hospitalisation: **Age:** 69
Onset Date: 04/03/1997 **DOB:** 08/01/1928
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Hyperhidrosis Hypertonia Pyrexia			Benzodrozepines, bromocriptine, panadol

Medicine Details:

HALOPERIDOL (Interaction) **Reason:** Otr spec symp psychopathol nec
1.0 Milligram As necessary
Batch: **Started:** 13/02/1997 **Stopped:** 04/03/1997

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 18/02/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine phosphokinase		04/03/1997	1400	
	Creatine phosphokinase		05/03/1997	2600	

Additional Information:

Report Details:

Case Number: 117733 **Seq:** 1 **Gender:** M
Reported: 21/05/1997 **Weight:** 76.00
Hospitalisation: **Age:**
Onset Date: 14/05/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Lock jaw	
Bradycardia			
Hyperhidrosis			
Hypertonia			
Hypotension			
Paraesthesia			Cogentin

Medicine Details:

ZOTON (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

SERENACE (Suspected) **Reason:** Nausea and vomiting
Injection 5.0 Milligram 1 time Intramuscular
Batch: **Started:** 13/05/1997 **Stopped:** 13/05/1997

STEMETIL (Suspected) **Reason:** Nausea and vomiting
Oral application 5.0 Milligram Daily Oral
Batch: **Started:** 12/05/1997 **Stopped:** 13/05/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred after first and second tab of zoton.

Report Details:

Case Number: 117781 **Seq:** 1 **Gender:** F
Reported: 23/05/1997 **Weight:**
Hospitalisation: **Age:** 74Y
Onset Date: 11/05/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Jaundice			

Medicine Details:

FUCIDIN (Suspected) **Reason:** Bacterial disease nec
1.0 Gram Daily
Batch: **Started:** 02/05/1997 **Stopped:** 11/05/1997

RIFAMPICIN (Suspected) **Reason:** Bacterial disease nec
450.0 Milligram Daily
Batch: **Started:** 02/05/1997 **Stopped:** 11/05/1997

RANITIDINE (Suspected) **Reason:** Peptic ulcer nos w/o ment perf
300.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

AMIODARONE HYDROCHLORIDE (Suspected) **Reason:** Otr&nos disord of heart rhythm
100.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		22/04/1997	11	
	ALT = SGPT		14/05/1997	17	
	ALT = SGPT		16/05/1997	14	
	Bilirubin		22/04/1997	11	
	Bilirubin		14/05/1997	111	
	Bilirubin		16/05/1997	62	
	SAP = ALP		22/04/1997	102	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 117781 **Seq:** 1 **Gender:** F
Reported: 23/05/1997 **Weight:**
Hospitalisation: **Age:** 74Y
Onset Date: 11/05/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)			**Reason:**		
	1.5	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	CONTIN
FRUSEMIDE (Suspected)			**Reason:**	Congestive heart failure	
Tablet	80.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
FERROUS SULPHATE (Suspected)			**Reason:**	Unspecified anemia	
Oral application	350.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
THYROXINE SODIUM (Suspected)			**Reason:**	Myxedema	
	125.0	Microgram	Daily		
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP		14/05/1997	133	
	SAP = ALP		16/05/1997	173	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 117781 **Seq:** 1
Reported: 23/05/1997
Hospitalisation:
Onset Date: 11/05/1997
Outcome: Not yet recovered

Gender: F
Weight:
Age: 74Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

TEMAZEPAM (Suspected)			**Reason:**		
	10.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	
ASPIRIN (Suspected)			**Reason:**		
Oral application	100.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 118433 **Seq:** 1 **Gender:** F
Reported: 20/06/1997 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: 01/06/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vascular malformation peripheral		Born with vascular malformation of legs	Oxygen
Bradycardia		Low heart rate for 2 days.	

Medicine Details:

PROZAC (Suspected)			**Reason:**	Unspecified schizophrenia
Oral application	20.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**
ARTANE (Suspected)			**Reason:**	Unspecified schizophrenia
Tablet	15.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**
HALOPERIDOL (Suspected)			**Reason:**	
Oral application	2.5	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Baby boy 3.2kg born with extensive truncal --> legs vascular malformation also had low heart rate for 2 days with little variability. no ekg was obtained. hr then increased on days 3-4 and was normal at discharge. also needed 12 hour oxygen supplement. all medications were taken throughout pregnancy and on morning of delivery.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 118531 **Seq:** 1 **Gender:** M
Reported: 25/06/1997 **Weight:** 89.00
Hospitalisation: **Age:** 49Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

SERENACE (Interaction) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ZANTAC (Interaction) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Decreased effectivness of serenace when taken within 2 hours of zantac.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 118605 **Seq:** 1 **Gender:** M
Reported: 30/06/1997 **Weight:**
Hospitalisation: **Age:** 20Y
Onset Date: 11/06/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Malaise		Patient felt "unwell" after inj on 11/06/1997	

Medicine Details:

COGENTIN (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

SERENACE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLONIDINE HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

NEO-CYTAMEN (Suspected) **Reason:**
Injection 1.0 Milligram 1 time Intramuscular
Batch: **Started:** 11/06/1997 **Stopped:** 11/06/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient used neo cytamen due to unavailability of cytamen injection, which he has used for 5 years without incident.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 118858 **Seq:** 1 **Gender:** F
Reported: 07/07/1997 **Weight:** 61.00
Hospitalisation: **Age:** 29Y
Onset Date: 01/07/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Agitation Headache		Dystonic reaction	Oral analgesia

Medicine Details:

SERENACE (Suspected) **Reason:**
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** 30/06/1997 **Stopped:** 01/07/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient allergic to prochlorperazine and metoclopramide

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 119009 **Seq:** 1 **Gender:** F
Reported: 11/07/1997 **Weight:** 55.00
Hospitalisation: **Age:** 75Y
Onset Date: 07/06/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Marked neutropenia	

Medicine Details:

NEULACTIL (Other drug)		**Reason:**	
Tablet	10.0 Milligram	Daily	Oral
Batch:	**Started:** 17/05/1997		**Stopped:**
KSR (Other drug)		**Reason:**	Alkalosis
Tablet	1.2 Gram	Daily	Oral
Batch:	**Started:** 17/05/1997		**Stopped:**
ACTRAPID HM (Other drug)		**Reason:**	Diabetes mellitus
Injection	0.0	Daily	Subcutaneous
Batch:	**Started:**		**Stopped:**
HUMULIN UL (Other drug)		**Reason:**	
Injection	0.0	Daily	Subcutaneous
Batch:	**Started:** 23/05/1997		**Stopped:** 27/05/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 119009 **Seq:** 1 **Gender:** F
Reported: 11/07/1997 **Weight:** 55.00
Hospitalisation: **Age:** 75Y
Onset Date: 07/06/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

MIXTARD 30/70 (Other drug)			**Reason:**	
Injection	0.0		Daily	Subcutaneous
Batch:	**Started:** 19/05/1997			**Stopped:**
PROTAPHANE (Other drug)			**Reason:**	Diabetes mellitus
Injection	0.0		Daily	Subcutaneous
Batch:	**Started:** 27/05/1997			**Stopped:**
PROPYLTHIOURACIL (Other drug)			**Reason:**	
Tablet	300.0	Milligram	Daily	Oral
Batch:	**Started:** 04/06/1997			**Stopped:**
NEO-MERCAZOLE (Suspected)			**Reason:**	Thyrotoxicosis w/o ment goiter
Tablet	60.0	Milligram	Daily	Oral
Batch:	**Started:** 19/05/1997			**Stopped:** 04/06/1997

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 119009 **Seq:** 1
Reported: 11/07/1997
Hospitalisation:
Onset Date: 07/06/1997
Outcome: Recovered

Gender: F
Weight: 55.00
Age: 75Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

UREX (Suspected)			**Reason:**	
Tablet	40.0 Milligram		Daily	Oral
Batch:	**Started:** 18/05/1997			**Stopped:** 19/06/1997
SERENACE (Suspected)			**Reason:**	Otr spec symp psychopathol nec
	5.0 Milligram		Daily	
Batch:	**Started:** 04/06/1997			**Stopped:** 16/06/1997

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 119255 **Seq:** 1 **Gender:** M
Reported: 18/07/1997 **Weight:** 65.00
Hospitalisation: **Age:** 70Y
Onset Date: 01/07/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tooth discolouration		Teeth staining black colour	

Medicine Details:

SLOW-K (Other drug) **Reason:** Congestive heart failure
Tablet, modified release 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** CONTIN

LASIX (Other drug) **Reason:** Congestive heart failure
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

ADALAT (Other drug) **Reason:** Congestive heart failure
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

ARISTOCORT (Other drug) **Reason:** Otr ecz&der due otr&unsp cause
Ointment 2.0 Dose Unspecified Daily Topical
Batch: **Started:** 25/06/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Teeth staining black colour. intact teeth had a greyish film, broken/eroded teeth showed deeper black staining.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 119255 **Seq:** 1
Reported: 18/07/1997
Hospitalisation:
Onset Date: 01/07/1997
Outcome: Recovered

Gender: M
Weight: 65.00
Age: 70Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

SERZONE (Suspected)		**Reason:**	
	300.0 Milligram	Daily	
Batch:	**Started:** 20/06/1997		**Stopped:**
HALOPERIDOL (Suspected)		**Reason:**	
Tablet	500.0 Microgram	Daily	Oral
Batch:	**Started:** 20/06/1997		**Stopped:** 30/06/1997

Laboratory Investigations:

Additional Information:

Teeth staining black colour. intact teeth had a greyish film, broken/eroded teeth showed deeper black staining.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 119425 **Seq:** 1 **Gender:** F
Reported: 25/07/1997 **Weight:** 70.00
Hospitalisation: **Age:** 99Y
Onset Date: 11/07/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Speech disorder		Slurred speech	
Depression		Tearful & extremely morose.	
Coordination abnormal		Unsteady on feet	
Agitation		Very aggitated	
Somnolence		Very drowsy	

Medicine Details:

NORMISON (Suspected) **Reason:**
Oral application 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 12/06/1997 **Stopped:** 12/07/1997

SERENACE (Suspected) **Reason:**
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** 11/07/1997 **Stopped:** 13/07/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 119513 **Seq:** 1 **Gender:** F
Reported: 28/07/1997 **Weight:**
Hospitalisation: **Age:** 42Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Haloperidol ceased and risperidone commenced.

Medicine Details:

ZOLOFT (Other drug) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:**
Oral application 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 119660 **Seq:** 1 **Gender:** M
Reported: 04/08/1997 **Weight:**
Hospitalisation: **Age:** 28Y
Onset Date: 12/07/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 119956 **Seq:** 1 **Gender:** U
Reported: 15/08/1996 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder Neuroleptic malignant syndrome Tardive dyskinesia			Withdraw haloperidol

Medicine Details:

HALOPERIDOL DECANOATE (Suspected) **Reason:** Unspecified schizophrenia
Injection 0.0 Intravenous
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 119965 **Seq:** 1 **Gender:** M
Reported: 15/08/1997 **Weight:**
Hospitalisation: **Age:** 75
Onset Date: 12/07/1997 **DOB:** 13/01/1922
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Eyes rolling, jerking	Benztropine 2mg x 3 admitted to icu

Medicine Details:

LEVODOPA (Other drug) **Reason:**
600.0 Milligram Daily
Batch: **Started:** **Stopped:**

BENSERAZIDE (Other drug) **Reason:**
50.0 Milligram Daily
Batch: **Started:** **Stopped:**

RANITIDINE (Other drug) **Reason:**
150.0 Milligram Daily
Batch: **Started:** **Stopped:**

LISINOPRIL (Other drug) **Reason:**
5.0 Milligram Daily
Batch: **Started:** 08/07/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Confused, incontinent patient crying out in pain 9 days after aaa repair. coexisting parkinson's, niddm, ihd, cal, pvd

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 119965 **Seq:** 1
Reported: 15/08/1997
Hospitalisation:
Onset Date: 12/07/1997
Outcome: Unknown

Gender: M
Weight:
Age: 75
DOB: 13/01/1922
Causality: Causality possible

Reaction Details:

Medicine Details:

ISOSORBIDE MONONITRATE (Other drug)		**Reason:**	
	30.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:**
HALOPERIDOL (Suspected)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Confused, incontinent patient crying out in pain 9 days after aaa repair. coexisting parkinson's, niddm, ihd, cal, pvd

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 120087 **Seq:** 1 **Gender:** M
Reported: 20/08/1997 **Weight:** 76.00
Hospitalisation: **Age:** 63Y
Onset Date: 16/08/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Reduced b.p.	
Rash maculo-papular		Symetrical rash arms, legs,trunk, face	Phenergan 10mg tds, iv hydrocortisone, prednisolone 60mg daily, i.v. fluid replacement, vitamin k replacement.
Pyrexia			
Syncope			
Vasodilatation			

Medicine Details:

CLONAZEPAM (Suspected) **Reason:** Unspecified schizophrenia
4.0 Milligram 1 time
Batch: **Started:** 06/08/1997 **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Unspecified schizophrenia
10.0 Milligram As necessary
Batch: **Started:** 05/08/1997 **Stopped:**

BENZTROPINE MESYLATE (Suspected) **Reason:** Unspecified schizophrenia
2.0 Milligram As necessary
Batch: **Started:** 05/08/1997 **Stopped:**

OLANZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 06/08/1997 **Stopped:** 16/08/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 120087 **Seq:** 1 **Gender:** M
Reported: 20/08/1997 **Weight:** 76.00
Hospitalisation: **Age:** 63Y
Onset Date: 16/08/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CARBIMAZOLE (Suspected) **Reason:** Myxedema

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** 05/08/1997 **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 120158 **Seq:** 1
Reported: 22/08/1997
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 70.00
Age: 71Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Admitted to hospital, nasogastric feeding,

Medicine Details:

ZANTAC (Other drug) **Reason:**
3.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

COLOXYL (Other drug) **Reason:**
3.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

TAZAC (Other drug) **Reason:**
600.0 Milligram Daily
Batch: **Started:** 23/01/1997 **Stopped:**

LARGACTIL (Suspected) **Reason:** Otr spec symp psychopathol nec
Injection 50.0 Milligram 1 time Intramuscular
Batch: **Started:** 09/02/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 120158 **Seq:** 1
Reported: 22/08/1997
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 70.00
Age: 71Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 121336 **Seq:** 1
Reported: 03/10/1997
Hospitalisation: Hospitalisation prolonged
Onset Date: 02/09/1997
Outcome: Recovered

Gender: M
Weight:
Age: 54Y
DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		Became drowsy, sedated	
Gait disturbance		Gait: narrow based, shuffling	
Hyperhidrosis		Increased perspiration	
Thinking abnormal		Slowed thought process	
Tremor		Tremulous, shakey	
Coordination abnormal		Unsteady on feet/multiple falls	
Blood creatine phosphokinase incr			
Bradykinesia			
Hypertension			

Medicine Details:

LITHIUM CARBONATE (Other drug) **Reason:**
1.7 Gram Daily
Batch: **Started:** 01/09/1997 **Stopped:**

ASPIRIN (Other drug) **Reason:** Transient cereb isch no hypert
150.0 Milligram Daily
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** 01/08/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Creatine kinase 1184

Additional Information:

Patient history of bipolar disorder --> multiple suicide attempts. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 121400 **Seq:** 1 **Gender:** M
Reported: 08/10/1997 **Weight:** 61.00
Hospitalisation: **Age:** 75Y
Onset Date: 02/08/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancytopenia			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec

Oral application 0.5 Milligram Daily Oral

Batch: **Started:** 30/07/1997 **Stopped:** 06/08/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haemoglobin		02/08/1997	10.3	
	Neutrophils		02/08/1997	1.62	
	Platelets		02/08/1997	122	
	White blood cells		02/08/1997	2.9	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 121714 **Seq:** 1 **Gender:** M
Reported: 20/10/1997 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: 29/08/1997 **DOB:** 03/08/1968
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Ceased prepulsid and dicloxacillin

Medicine Details:

ENOXAPARIN (Other drug) **Reason:** Prophylaxis
Injection 40.0 Milligram Daily Subcutaneous
Batch: **Started:** **Stopped:** 16D

SALBUTAMOL (Other drug) **Reason:** Asthma
12.0 Millilitre Daily
Batch: **Started:** **Stopped:** 17D

OMEPRAZOLE (Other drug) **Reason:** Peptic ulcer nos w/o ment perf
Capsule 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

GENTAMICIN SULPHATE (Other drug) **Reason:**
Injection 320.0 Milligram Daily Intravenous
Batch: **Started:** **Stopped:** 07D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	0-40	16/08/1997	70	
	ALT = SGPT	0-40	28/08/1997	104	
	ALT = SGPT	0-40	01/09/1997	250	
	ALT = SGPT	0-40	03/09/1997	375	
	ALT = SGPT	0-40	15/09/1997	310	
	ALT = SGPT	0-40	08/09/1997	450	
	ALT = SGPT	0-40	05/09/1997	440	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 121714 **Seq:** 1 **Gender:** M
Reported: 20/10/1997 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: 29/08/1997 **DOB:** 03/08/1968
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

BENZTROPINE MESYLATE (Other drug)				**Reason:**		
Tablet	1.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN
RISPERIDONE (Other drug)				**Reason:**	Unspecified psychosis	
Tablet	1.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		10D
AMITRIPTYLINE HYDROCHLORIDE (Other drug)				**Reason:**		
Tablet	50.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		09D
PREPULSID (Suspected)				**Reason:**		
Tablet	60.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		10D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	0-40	04/09/1997	480	
	AST = SGOT	0-40	16/08/1997	90	
	AST = SGOT	0-40	28/08/1997	100	
	AST = SGOT	0-40	01/09/1997	254	
	AST = SGOT	0-40	03/09/1997	320	
	AST = SGOT	0-40	04/09/1997	390	
	AST = SGOT	0-40	05/09/1997	270	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 121714 **Seq:** 1 **Gender:** M
Reported: 20/10/1997 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: 29/08/1997 **DOB:** 03/08/1968
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis

Injection 10.0 Milligram Daily Intravenous

Batch: **Started:** L TERM **Stopped:**

DICLOXACILLIN SODIUM (Suspected) **Reason:** Bacterial disease nec

Injection 8.0 Gram Daily Intravenous

Batch: **Started:** **Stopped:** 07D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	0-40	08/09/1997	230	
	AST = SGOT	0-40	15/09/1997	120	
	Bilirubin	0-20	16/08/1997	7	
	Bilirubin	0-20	03/09/1997	217	
	Bilirubin	0-20	04/09/1997	165	
	Bilirubin	0-20	05/09/1997	120	
	Bilirubin	0-20	15/09/1997	40	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 121714 **Seq:** 1 **Gender:** M
Reported: 20/10/1997 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: 29/08/1997 **DOB:** 03/08/1968
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

ENOXAPARIN (Other drug)			**Reason:**	Prophylaxis		
Injection	40.0	Milligram	Daily		Subcutaneous	
Batch:	**Started:**			**Stopped:**		16D
SALBUTAMOL (Other drug)			**Reason:**	Asthma		
	12.0	Millilitre	Daily			
Batch:	**Started:**			**Stopped:**		17D
OMEPRAZOLE (Other drug)			**Reason:**	Peptic ulcer nos w/o ment perf		
Capsule	40.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN
GENTAMICIN SULPHATE (Other drug)			**Reason:**			
Injection	320.0	Milligram	Daily		Intravenous	
Batch:	**Started:**			**Stopped:**		07D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin	0-20	08/09/1997	80	
	Bilirubin	0-20	01/09/1997	226	
	Bilirubin	0-20	28/08/1997	421	
	GGT = SGGT =	0-60	16/08/1997	18	
	GGT = SGGT =	0-60	28/08/1997	40	
	GGT = SGGT =	0-60	01/09/1997	160	
	GGT = SGGT =	0-60	03/09/1997	304	

Additional Information:

Report Details:

Case Number: 121714 **Seq:** 1 **Gender:** M
Reported: 20/10/1997 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: 29/08/1997 **DOB:** 03/08/1968
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

BENZTROPINE MESYLATE (Other drug)				**Reason:**		
Tablet	1.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN
RISPERIDONE (Other drug)				**Reason:**	Unspecified psychosis	
Tablet	1.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		10D
AMITRIPTYLINE HYDROCHLORIDE (Other drug)				**Reason:**		
Tablet	50.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		09D
PREPULSID (Suspected)				**Reason:**		
Tablet	60.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		10D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =	0-60	04/09/1997	380	
	GGT = SGGT =	0-60	05/09/1997	270	
	GGT = SGGT =	0-60	08/09/1997	160	
	GGT = SGGT =	0-60	15/09/1997	84	
	SAP = ALP	35-115	16/08/1997	93	
	SAP = ALP	35-115	28/08/1997	133	
	SAP = ALP	35-115	01/09/1997	216	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 121714 **Seq:** 1 **Gender:** M
Reported: 20/10/1997 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: 29/08/1997 **DOB:** 03/08/1968
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis

Injection 10.0 Milligram Daily Intravenous

Batch: **Started:** L TERM **Stopped:**

DICLOXACILLIN SODIUM (Suspected) **Reason:** Bacterial disease nec

Injection 8.0 Gram Daily Intravenous

Batch: **Started:** **Stopped:** 07D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP	35-115	03/09/1997	346	
	SAP = ALP	35-115	04/09/1997	400	
	SAP = ALP	35-115	05/09/1997	320	
	SAP = ALP	35-115	08/09/1997	260	
	SAP = ALP	35-115	15/09/1997	190	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 122458 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:** 75.00
Hospitalisation: **Age:** 47Y
Onset Date: 19/07/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		Oversleeping	Haloperidol ceased
Tremor		Tremulousness	
Headache			
Nausea			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug) **Reason:** Depression
300.0 Milligram Daily
Batch: **Started:** 01/01/1996 **Stopped:**

BENZHEXOL HYDROCHLORIDE (Other drug) **Reason:** Unspecified schizophrenia
2.0 Milligram Daily
Batch: **Started:** 01/01/1996 **Stopped:** 17/07/1997

TEMAZEPAM (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/01/1996 **Stopped:**

CLONAZEPAM (Other drug) **Reason:** Otr spec symp psychopathol nec
5.0 Milligram Daily
Batch: **Started:** 01/01/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 122458 **Seq:** 1
Reported: 18/11/1997
Hospitalisation:
Onset Date: 19/07/1997
Outcome: Recovered

Gender: F
Weight: 75.00
Age: 47Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)			**Reason:**	Unspecified schizophrenia
Tablet	10.0 Milligram	Daily		Oral
Batch:	**Started:** 18/07/1997		**Stopped:**	21/07/1997
HALOPERIDOL (Suspected)			**Reason:**	Unspecified schizophrenia
Injection	5.0 Milligram	Daily		Intravenous
Batch:	**Started:** 01/01/1996		**Stopped:**	17/07/1997

Laboratory Investigations:

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 122958 **Seq:** 1 **Gender:** M
Reported: 02/12/1997 **Weight:**
Hospitalisation: **Age:** 22Y
Onset Date: 07/11/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Oculogyration		Dystonic reaction and rigid arms. Eyes rolling upwards.	Cogentin 1mg iv.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
Injection 15.0 Milligram Daily Intravenous
Batch: **Started:** 06/11/1997 **Stopped:** 07/11/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 123050 **Seq:** 1 **Gender:** F
Reported: 03/12/1997 **Weight:**
Hospitalisation: **Age:** 76Y
Onset Date: 24/10/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope Confusional state Extrapyramidal disorder Faecal incontinence Urinary incontinence		Falls	

Medicine Details:

DIGOXIN (Other drug) **Reason:**
250.0 Microgram Daily
Batch: **Started:** L TERM **Stopped:**

FOLIC ACID (Other drug) **Reason:**
5.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
1.5 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 24/10/1997

LARGACTIL (Suspected) **Reason:**
Oral application 25.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 24/10/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 123050 **Seq:** 1
Reported: 03/12/1997
Hospitalisation:
Onset Date: 24/10/1997
Outcome: Not yet recovered

Gender: F
Weight:
Age: 76Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

VALIUM (Suspected)			**Reason:**	
	7.5 Milligram		Daily	
Batch:	**Started:**	L TERM		**Stopped:**
ALDOMET (Suspected)			**Reason:**	
	1.5 Gram		Daily	
Batch:	**Started:**	L TERM		**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 123241 **Seq:** 1 **Gender:** M
Reported: 10/12/1997 **Weight:**
Hospitalisation: **Age:** 77Y
Onset Date: 30/07/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state		Altered mental state, decreased mobility.	Bromocriptine 2.5mg bd for 1/12.
Hepatic function abnormal		Elevated lfts.	
Tachycardia		Increased heart rate.	
Pyrexia		Increased temperature	
Blood creatine phosphokinase incr			
Hypertension			
Pneumonia			

Medicine Details:

THIAMINE (Other drug) **Reason:**
100.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

MULTIVITAMINS (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
1.0 Gram Daily
Batch: **Started:** 23/07/1997 **Stopped:** 30/07/1997

CHLORAL HYDRATE (Suspected) **Reason:**
1.0 Gram Daily
Batch: **Started:** 23/07/1997 **Stopped:** 30/07/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 123332 **Seq:** 1 **Gender:** F
Reported: 15/12/1997 **Weight:**
Hospitalisation: **Age:** 72
Onset Date: 01/11/1997 **DOB:** 19/09/1925
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Flickering involuntary movements of tongue	

Medicine Details:

DIAZEPAM (Other drug) **Reason:**
5.0 Milligram As necessary
Batch: **Started:** **Stopped:**

VENLAFAXINE HYDROCHLORIDE (Other drug) **Reason:**
75.0 Milligram Daily
Batch: **Started:** 21/10/1997 **Stopped:**

TEMAZEPAM (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

BENZTROPINE MESYLATE (Suspected) **Reason:**
2.0 Milligram As necessary
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 123332 **Seq:** 1 **Gender:** F
Reported: 15/12/1997 **Weight:**
Hospitalisation: **Age:** 72
Onset Date: 01/11/1997 **DOB:** 19/09/1925
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)		**Reason:**	
	5.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:**
TRIMETHOPRIM (Suspected)		**Reason:**	Othr diseases of urinary tract
	300.0 Milligram	Daily	
Batch:	**Started:** 21/10/1997		**Stopped:**

Laboratory Investigations:

Additional Information:

Report Details:

Case Number: 123487 **Seq:** 1 **Gender:** M
Reported: 17/12/1997 **Weight:**
Hospitalisation: **Age:** 85Y
Onset Date: 29/11/1997 **DOB:**
Outcome: Death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension Cardiac arrest Sudden death		Bp 90/	Debrillator and adrenaline

Medicine Details:

FERRO-GRADUMET (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

MINIDIAB (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

FOLIC ACID (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

RENITEC (Other drug) **Reason:**
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died 29/11/97.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 123487 **Seq:** 1 **Gender:** M
Reported: 17/12/1997 **Weight:**
Hospitalisation: **Age:** 85Y
Onset Date: 29/11/1997 **DOB:**
Outcome: Death **Causality:** Causality possible

Reaction Details:

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)			**Reason:** Depression	
Tablet	50.0 Milligram		Daily	Oral
Batch:	**Started:** 28/11/1997			**Stopped:**
HALOPERIDOL (Suspected)			**Reason:**	
Tablet	2.0 Milligram		Daily	Oral
Batch:	**Started:** 28/11/1997			**Stopped:**
ZANTAC (Suspected)			**Reason:**	
Tablet	300.0 Milligram		Daily	Oral
Batch:	**Started:** 27/11/1997			**Stopped:**

Laboratory Investigations:

Additional Information:

Patient died 29/11/97.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 125360 **Seq:** 1
Reported: 26/02/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight:
Age: 24Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation Dysphonia Respiratory disorder			Intravenous adrenaline was administered in aliquots of 0.1-0.5 mg (total dose 3.2 mg over 90 minutes) he also received hydrocortisone, metoclopramide and ranitidine intravenously as well as oral antihistamine and diazepam. he was discharged next morning on prednisolone 50 mg orally.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
3.0 Milligram Daily
Batch: **Started:** S TERM **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 125360 **Seq:** 1
Reported: 26/02/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight:
Age: 24Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tongue oedema			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**

3.0 Milligram Daily

Batch: **Started:** S TERM **Stopped:** CONTIN

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 125361 **Seq:** 1
Reported: 26/02/1998
Hospitalisation: Hospitalisation prolonged
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight:
Age: 24Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea			Adrenaline

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
3.0 Milligram Daily
Batch: **Started:** S TERM **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 125362 **Seq:** 1 **Gender:** M
Reported: 26/02/1998 **Weight:**
Hospitalisation: **Age:** 24Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Dystonia			Intravenous diazepam, icu for 24hrs.

Medicine Details:

ADRENALINE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
3.0 Milligram Daily
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 125557 **Seq:** 1 **Gender:** M
Reported: 05/03/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Splenomegaly		Hypersplenism	All medication ceased
Hepatic function abnormal		Increased liver function test	
Leukopenia		Neutrophil count decreased	

Medicine Details:

VALPRO (Suspected)			**Reason:**		
Tablet	0.0			Oral	
Batch:	**Started:**			**Stopped:**	28/02/1998
HALOPERIDOL (Suspected)			**Reason:**		
Tablet	0.0			Oral	
Batch:	**Started:**			**Stopped:**	28/02/1998
ZYPREXA (Suspected)			**Reason:**		
Tablet	20.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	28/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has experinced prior alcohol abuse and is hepatitis b positive the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 125602 **Seq:** 1 **Gender:** M
Reported: 06/03/1998 **Weight:** 70.00
Hospitalisation: **Age:** 59Y
Onset Date: 18/11/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		Heavily sedated	
Coma		Patient became unresponsive	
Respiratory disorder		Tachypnoeic	
Blood creatine phosphokinase incr			
Hyperhidrosis			
Hyponatraemia			
Neuroleptic malignant syndrome			Clozapine and haliperidol ceased
Orthostatic hypotension			
Pyrexia			
Tachycardia			

Medicine Details:

ENALAPRIL MALEATE (Other drug) **Reason:** Essential benign hypertension
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CLONAZEPAM (Other drug) **Reason:** Otr spec symp psychopathol nec
Tablet 3.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

BENZTROPINE MESYLATE (Other drug) **Reason:**
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
2.5 Milligram As necessary
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Raised ck 6,000

Additional Information:

Dose of clozapine increased to 112mg on 19 and 20th. at this stage ck raised to 6,000 and patient became unresponsive (? coma).

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 125602 **Seq:** 1
Reported: 06/03/1998
Hospitalisation:
Onset Date: 18/11/1997
Outcome: Recovered

Gender: M
Weight: 70.00
Age: 59Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZAPINE (Suspected)			**Reason:**	Unspecified schizophrenia
Tablet	100.0 Milligram	Daily		Oral
Batch:	**Started:** 17/11/1997		**Stopped:**	20/11/1997

Laboratory Investigations:

Additional Information:

Dose of clozapine increased to 112mg on 19 and 20th. at this stage ck raised to 6,000 and patient became unresponsive (? coma).

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 125698 **Seq:** 1
Reported: 10/03/1998
Hospitalisation: Treated in outpatient department only.
Onset Date: 02/01/1998
Outcome: Recovered

Gender: F
Weight:
Age: 23
DOB: 07/04/1974
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration		Dysfunctional eyes	
Dyskinesia		Out of control tongue	Given cogentin and no further doses of serenace given.
Dyspnoea			
Extrapyramidal disorder			
Muscle twitching			
Speech disorder			
Tremor			
Visual disturbance			

Medicine Details:

SERENACE (Suspected) **Reason:** Disturbance of sleep

Tablet 5.0 Milligram 1 time Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 125879 **Seq:** 1
Reported: 17/03/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Death, maybe drug

Gender: F
Weight:
Age: 77Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			
Confusional state			
Hepatic function abnormal			
Hypertonia			
Hypochloraemia			
Hypomagnesaemia			
Hyponatraemia			
Neuroleptic malignant syndrome			Treatment: valium, gentamicin and ciproxin
Pyrexia			

Medicine Details:

RISPERIDONE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** 25/02/1998

TRYPTANOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** 25/02/1998

HALOPERIDOL (Suspected) **Reason:** Reactive confusion
2.0 Milligram Daily
Batch: **Started:** 25/02/1998 **Stopped:** 26/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	<30 U/L	13/03/1994	8	
	ALT = SGPT	<30 U/L	22/02/1998	30	
	ALT = SGPT	<30 U/L	02/03/1998	42	
	AST = SGOT	<30 U/L	13/03/1994	17	
	AST = SGOT	<30 U/L	22/02/1998	48	
	AST = SGOT	<30 U/L	02/03/1998	70	
	Bilirubin	<20 UMOL/L	13/03/1994	5	

Additional Information:

Patient was treated for uti. died on 08/03/98.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 125879 **Seq:** 1
Reported: 17/03/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Death, maybe drug

Gender: F
Weight:
Age: 77Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** 25/02/1998

TRYPTANOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** 25/02/1998

HALOPERIDOL (Suspected) **Reason:** Reactive confusion
2.0 Milligram Daily
Batch: **Started:** 25/02/1998 **Stopped:** 26/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin	<20 UMOL/L	22/02/1998	27	
	Bilirubin	<20 UMOL/L	02/03/1998	12	
	Chloride	100 - 111 MMOL/L	13/03/1994	92	
	Chloride	100 - 111 MMOL/L	22/02/1998	85	
	Chloride	100 - 111 MMOL/L	02/03/1998	122	
	Creatine phosphokinase	<200 U/L	22/02/1998	1190	
	Creatine phosphokinase	<200 U/L	02/03/1998	1159	

Additional Information:
Patient was treated for uti. died on 08/03/98.

Report Details:

Case Number: 125879 **Seq:** 1
Reported: 17/03/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Death, maybe drug

Gender: F
Weight:
Age: 77Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)		**Reason:**
	0.0	
Batch:	**Started:**	**Stopped:** 25/02/1998
TRYPTANOL (Suspected)		**Reason:**
	0.0	
Batch:	**Started:**	**Stopped:** 25/02/1998
HALOPERIDOL (Suspected)		**Reason:** Reactive confusion
	2.0 Milligram	Daily
Batch:	**Started:** 25/02/1998	**Stopped:** 26/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine phosphokinase	<200 U/L	04/03/1998	1875	
	Creatine phosphokinase	<200 U/L	01/03/1998	831	
	GGT = SGGT = SGOTD	<35 U/L	13/03/1994	25	
	GGT = SGGT = SGOTD	<35 U/L	02/03/1998	57	
	GGT = SGGT = SGOTD	<35 U/L	22/02/1998	65	
	LDH	<400 U/L	22/02/1998	652	
	LDH	<400 U/L	04/03/1998	677	

Additional Information:

Patient was treated for uti. died on 08/03/98.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 125879 **Seq:** 1
Reported: 17/03/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Death, maybe drug

Gender: F
Weight:
Age: 77Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)		**Reason:**
	0.0	
Batch:	**Started:**	**Stopped:** 25/02/1998
TRYPTANOL (Suspected)		**Reason:**
	0.0	
Batch:	**Started:**	**Stopped:** 25/02/1998
HALOPERIDOL (Suspected)		**Reason:** Reactive confusion
	2.0 Milligram	Daily
Batch:	**Started:** 25/02/1998	**Stopped:** 26/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Magnesium	0.70 - 1.00 MMOL/L	22/02/1998	0.63	
	SAP = ALP	35 - 120 U/L	13/03/1994	127	
	SAP = ALP	35 - 120 U/L	02/03/1998	68	
	SAP = ALP	35 - 120 U/L	22/02/1998	87	
	Sodium	136 - 145 MMOL/L	13/03/1994	134	
	Sodium	136 - 145 MMOL/L	22/02/1998	124	
	Sodium	136 - 145 MMOL/L	02/03/1998	156	

Additional Information:

Patient was treated for uti. died on 08/03/98.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 126005 **Seq:** 1 **Gender:** F
Reported: 19/03/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 14/02/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction - stiff jaw	Benztrpopine 2mg oral given, imi cogentin 2mg. haloperidol dose reduced to 2.5mg on 16/02/98.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)			**Reason:** Depression		
Tablet	50.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
CALTRATE (Other drug)			**Reason:**		
Tablet	600.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
MYADEC (Other drug)			**Reason:**		
Tablet	1.0	Dose Unspecified	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
MICROGYNON 30 ED (Other drug)			**Reason:** Contraception		
Tablet	1.0	Dose Unspecified	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 126005 **Seq:** 1 **Gender:** F
Reported: 19/03/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 14/02/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis

Tablet	5.0 Milligram	Daily	Oral

Batch: **Started:** 13/02/1998 **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 126428 **Seq:** 1 **Gender:** F
Reported: 06/04/1998 **Weight:** 109.00
Hospitalisation: **Age:** 40Y
Onset Date: 25/02/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood pressure fluctuation Blood creatine phosphokinase incr Confusional state Hyperhidrosis Leukocytosis Neuroleptic malignant syndrome Pyrexia Urinary tract infection		Autonomic instability with bp 130/80, 140/90.	

Medicine Details:

DIAZEPAM (Other drug) **Reason:** Manic-depression psycho,manic
15.0 Milligram Daily
Batch: **Started:** 25/02/1998 **Stopped:** 31/03/1998

LITHIUM CARBONATE (Suspected) **Reason:** Manic-depression psycho,manic
Tablet 1.0 Gram Daily Oral
Batch: **Started:** 19/02/1998 **Stopped:** 26/02/1998

HALOPERIDOL (Suspected) **Reason:** Manic-depression psycho,manic
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 14/02/1998 **Stopped:** 24/02/1998

THIORIDAZINE HYDROCHLORIDE (Suspected) **Reason:** Manic-depression psycho,manic
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 24/02/1998 **Stopped:** 25/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		14/03/1998	2100	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 126519 **Seq:** 1 **Gender:** F
Reported: 08/04/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/03/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Increased dystinic reaction when zoloft increased.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

SERENACE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

COGENTIN (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 127263 **Seq:** 1 **Gender:** M
Reported: 07/05/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Zyprexa and haloperidol ceased

Medicine Details:

ZYPREXA (Suspected) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 127861 **Seq:** 1 **Gender:** F
Reported: 27/05/1998 **Weight:**
Hospitalisation: **Age:** 20Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Catatonia			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 128345 **Seq:** 1 **Gender:** M
Reported: 11/06/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 02/04/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Autonomic dysfunction resulted in elevated ck.	
Extrapyramidal disorder		Parkinson's disease	
Hyperhidrosis		Profuse sweating	
Dystonia		Stiff in movement (dystonia)	
Hypertonia			
Neuroleptic malignant syndrome	Required Specialist Consultation		Haloperidol ceased and put on ect and cogentin.

Medicine Details:

OLANZAPINE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
10.0 Milligram Daily
Batch: **Started:** 26/03/1998 **Stopped:** 07/04/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 128378 **Seq:** 1
Reported: 15/06/1998
Hospitalisation: Admitted to hospital
Onset Date: 06/03/1998
Outcome: Recovered

Gender: M
Weight:
Age: 33Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction	Benztropine iv ceased haloperidol, commence risperidone

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 04/03/1998 **Stopped:** 06/03/1998

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 04/03/1998 **Stopped:** 06/03/1998

TEMAZEPAM (Suspected) **Reason:** Specific disorders of sleep
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 04/03/1998 **Stopped:** 06/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 128491 **Seq:** 1 **Gender:** M
Reported: 18/06/1998 **Weight:**
Hospitalisation: **Age:** 55
Onset Date: **DOB:** 01/01/1943
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delirium			Ceased oxybutinin

Medicine Details:

OXYBUTYNIN HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

FLEET READY-TO-USE ENEMA (Suspected) **Reason:**
Suppository 1.0 Dose Unspecified As necessary Rectal
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
3.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

THIAMINE (Suspected) **Reason:**
50.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Background of chronic organic brain impairment

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 128491 **Seq:** 1 **Gender:** M
Reported: 18/06/1998 **Weight:**
Hospitalisation: **Age:** 55
Onset Date: **DOB:** 01/01/1943
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

VITAMIN B COMPLEX (Suspected)			**Reason:**		
	1.0	Dose Unspecified	Daily		
Batch:	**Started:**			**Stopped:**	CONTIN
LACTULOSE (Suspected)			**Reason:**		
Oral Liquid	20.0	Millilitre	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

Background of chronic organic brain impairment

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 129104 **Seq:** 1
Reported: 13/07/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 50.00
Age: 90Y
DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gait disturbance		Shuffling gait	Haloperidol ceased

Medicine Details:

COVERSYL (Other drug) **Reason:** Essential benign hypertension
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

RANI 2 (Other drug) **Reason:**
300.0 Milligram Daily
Batch: **Started:** **Stopped:**

OROXINE (Other drug) **Reason:** Myxedema
100.0 Microgram Daily
Batch: **Started:** **Stopped:**

SERENACE (Suspected) **Reason:**
1.0 Milligram Daily
Batch: **Started:** 09/06/1998 **Stopped:** 30/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 129165 **Seq:** 1 **Gender:** M
Reported: 13/07/1998 **Weight:** 74.00
Hospitalisation: **Age:** 87
Onset Date: **DOB:** 21/04/1911
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hair colour changes		Change in hair colour to salmon/pink/orange	

Medicine Details:

SERENACE (Suspected) **Reason:**
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 129181 **Seq:** 1 **Gender:** M
Reported: 13/07/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness			

Medicine Details:

ZYPREXA (Suspected) **Reason:**
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:**
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	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: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 129509 **Seq:** 1
Reported: 24/07/1998
Hospitalisation: Admitted to hospital
Onset Date: 20/07/1998
Outcome: Death

Gender: F
Weight:
Age: 70Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia		Abnormal rhythms.	
Somnolence		Pt slept for 2 days	
Hypotension	Severe	Severe hypotensive attack	Haloperidol ceased
Sudden death			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Depression
Tablet 4.5 Milligram Daily Oral
Batch: **Started:** 18/07/1998 **Stopped:** 20/07/1998

ARICEPT (Suspected) **Reason:** Presenile dementia
Tablet 5.0 Microgram Daily Oral
Batch: **Started:** 01/01/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died 25/7/98. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 129645 **Seq:** 1 **Gender:** F
Reported: 27/07/1998 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: 31/12/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Insomnia Tremor			

Medicine Details:

ZOLOFT (Suspected)			**Reason:**	Depression	
Tablet	100.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
SERENACE (Suspected)			**Reason:**		
Tablet	500.0	Microgram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
ZOCOR (Suspected)			**Reason:**		
Tablet	20.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 129701 **Seq:** 1 **Gender:** M
Reported: 28/07/1998 **Weight:**
Hospitalisation: **Age:** 23Y
Onset Date: 16/07/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypothermia		34.5 degrees	

Medicine Details:

SERENACE (Other drug) **Reason:** Otr spec symp psychopathol nec
Tablet 10.0 Milligram 1 time Oral
Batch: **Started:** 13/07/1998 **Stopped:** 13/07/1998

RIVOTRIL (Other drug) **Reason:** Otr spec symp psychopathol nec
Tablet 2.0 Milligram 1 time Oral
Batch: **Started:** 13/07/1998 **Stopped:** 13/07/1998

STELAZINE (Other drug) **Reason:** Unspecified psychosis
Oral application 5.0 Milligram 1 time Oral
Batch: **Started:** 14/07/1998 **Stopped:** 14/07/1998

ZUCLOPENTHIXOL ACETATE (Suspected) **Reason:** Otr spec symp psychopathol nec
Injection 150.0 Milligram 1 time Intramuscular
Batch: **Started:** 15/07/1998 **Stopped:** 15/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 129701 **Seq:** 1 **Gender:** M
Reported: 28/07/1998 **Weight:**
Hospitalisation: **Age:** 23Y
Onset Date: 16/07/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

SERENACE (Suspected) **Reason:** Otr spec symp psychopathol nec

Injection	10.0 Milligram	1 time	Intramuscular
Batch:	**Started:** 14/07/1998	**Stopped:**	14/07/1998

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 130185 **Seq:** 1 **Gender:** M
Reported: 11/08/1998 **Weight:** 90.00
Hospitalisation: **Age:** 37Y
Onset Date: 24/07/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Generalised tonic clonic seizure	Observation

Medicine Details:

PANADEINE (Other drug) **Reason:** Headache

Oral application	2.0	Dose Unspecified	As necessary	Oral

Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**

Injection	10.0	Milligram	As necessary	Intravenous

Batch: **Started:** **Stopped:**

DIHYDROERGOTAMINE (Suspected) **Reason:**

Injection	500.0	Microgram	As necessary	Intravenous

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Details:

Case Number: 130302 **Seq:** 1 **Gender:** M
Reported: 19/08/1998 **Weight:** 105.00
Hospitalisation: **Age:** 19Y
Onset Date: 31/07/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		Heavily sedated.	

Medicine Details:

FLUMAZENIL (Suspected)			**Reason:**	
Injection	500.0	Microgram	1 time	Intravenous
Batch:	**Started:** 31/07/1998		**Stopped:**	
HALOPERIDOL (Suspected)			**Reason:**	
Injection	20.0	Milligram	1 time	Intravenous
Batch:	**Started:** 31/07/1998		**Stopped:**	
DIAZEPAM (Suspected)			**Reason:**	
Injection	20.0	Milligram	1 time	Intravenous
Batch:	**Started:** 31/07/1998		**Stopped:**	
MIDAZOLAM (Suspected)			**Reason:**	
Injection	15.0	Milligram	1 time	Intravenous
Batch:	**Started:** 31/07/1998		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See seq 01 for other drugs.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 130777 **Seq:** 1
Reported: 03/09/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight:
Age: 70Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradykinesia Confusional state Extrapyramidal disorder Urinary incontinence			Ceased haloperidol and commenced sinemet.

Medicine Details:

PANAMAX (Other drug) **Reason:** Pain
500.0 Milligram As necessary
Batch: **Started:** **Stopped:**

NORMISON (Other drug) **Reason:** Specific disorders of sleep
10.0 Milligram As necessary
Batch: **Started:** **Stopped:**

DUROLAX (Other drug) **Reason:** Constipation
Suppository 0.0 As necessary Rectal
Batch: **Started:** **Stopped:**

GOPTEN (Other drug) **Reason:** Essential benign hypertension
2.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 130777 **Seq:** 1
Reported: 03/09/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight:
Age: 70Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

TRYPTANOL (Other drug)			**Reason:**	Depression
	25.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
RISPERIDONE (Other drug)			**Reason:**	Otr spec symp psychopathol nec
	1.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
COLOXYL WITH SENNA (Other drug)			**Reason:**	Constipation
	2.0	Dose Unspecified	Daily	
Batch:	**Started:**			**Stopped:**
HALOPERIDOL (Suspected)			**Reason:**	
	0.0			
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 130777 **Seq:** 1
Reported: 03/09/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight:
Age: 70Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

SERZONE (Suspected) **Reason:** Otr spec symp psychopathol nec
500.0 Microgram As necessary
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 131142 **Seq:** 1 **Gender:** M
Reported: 11/09/1998 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: 27/01/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myalgia		Muscle cramps in feet	Haloperidol ceased and changed to risperidone

Medicine Details:

PAROXETINE HYDROCHLORIDE (Other drug) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/06/1997 **Stopped:** CONTIN

TEMAZEPAM (Other drug) **Reason:** Specific disorders of sleep
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 01/06/1998

HALOPERIDOL (Suspected) **Reason:** Anxiety neurosis
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 01/06/1997 **Stopped:** 27/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 131328 **Seq:** 1 **Gender:** M
Reported: 16/09/1998 **Weight:** 60.00
Hospitalisation: **Age:** 77Y
Onset Date: 01/09/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia		Raised eosinophils	
Jaundice	Severe		Discontinued all medication and used midazolam im for agitation.

Medicine Details:

RISPERDAL (Suspected) **Reason:** Otr spec symp psychopathol nec
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** 27/07/1998 **Stopped:** 01/09/1998

PARALGIN (Suspected) **Reason:** Pain
Tablet 3.0 Gram Daily Oral
Batch: **Started:** 16/07/1998 **Stopped:** 03/09/1998

SERENACE (Suspected) **Reason:** Anxiety neurosis
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** 03/08/1998 **Stopped:** 03/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	U/L	17/07/1998	41	
	ALT = SGPT	U/L	01/09/1998	530	
	ALT = SGPT	U/L	03/09/1998	517	
	ALT = SGPT	U/L	09/09/1998	414	
	AST = SGOT	U/L	17/07/1998	30	
	AST = SGOT	U/L	01/09/1998	261	
	AST = SGOT	U/L	09/09/1998	192	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 131328 **Seq:** 1
Reported: 16/09/1998
Hospitalisation:
Onset Date: 01/09/1998
Outcome: Not yet recovered

Gender: M
Weight: 60.00
Age: 77Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)			**Reason:**	Otr spec symp psychopathol nec
Tablet	1.0 Milligram	Daily		Oral
Batch:	**Started:** 27/07/1998		**Stopped:**	01/09/1998
PARALGIN (Suspected)			**Reason:**	Pain
Tablet	3.0 Gram	Daily		Oral
Batch:	**Started:** 16/07/1998		**Stopped:**	03/09/1998
SERENACE (Suspected)			**Reason:**	Anxiety neurosis
Tablet	1.0 Milligram	Daily		Oral
Batch:	**Started:** 03/08/1998		**Stopped:**	03/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	U/L	03/09/1998	238	
	Bilirubin	UMOL/L	17/07/1998	4	
	Bilirubin	UMOL/L	01/09/1998	97	
	Bilirubin	UMOL/L	09/09/1998	183	
	Bilirubin	UMOL/L	03/09/1998	125	
	Biochemistry		17/07/1998	8	Total bilirubin umol/l
	Biochemistry		01/09/1998	107	Total bilirubin umol/l

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 131328 **Seq:** 1
Reported: 16/09/1998
Hospitalisation:
Onset Date: 01/09/1998
Outcome: Not yet recovered

Gender: M
Weight: 60.00
Age: 77Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)			**Reason:**	Otr spec symp psychopathol nec
Tablet	1.0 Milligram	Daily		Oral
Batch:	**Started:** 27/07/1998		**Stopped:**	01/09/1998
PARALGIN (Suspected)			**Reason:**	Pain
Tablet	3.0 Gram	Daily		Oral
Batch:	**Started:** 16/07/1998		**Stopped:**	03/09/1998
SERENACE (Suspected)			**Reason:**	Anxiety neurosis
Tablet	1.0 Milligram	Daily		Oral
Batch:	**Started:** 03/08/1998		**Stopped:**	03/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry		03/09/1998	134	Total bilirubin umol/l
	Biochemistry		09/09/1998	211	Total bilirubin umol/l
	GGT = SGGT =	U/L	17/07/1998	67	
	GGT = SGGT =	U/L	01/09/1998	2018	
	GGT = SGGT =	U/L	09/09/1998	1471	
	GGT = SGGT =	U/L	03/09/1998	1798	
	SAP = ALP	U/L	17/07/1998	199	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 131328 **Seq:** 1
Reported: 16/09/1998
Hospitalisation:
Onset Date: 01/09/1998
Outcome: Not yet recovered

Gender: M
Weight: 60.00
Age: 77Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERDAL (Suspected)			**Reason:**	Otr spec symp psychopathol nec
Tablet	1.0 Milligram	Daily		Oral
Batch:	**Started:** 27/07/1998		**Stopped:**	01/09/1998
PARALGIN (Suspected)			**Reason:**	Pain
Tablet	3.0 Gram	Daily		Oral
Batch:	**Started:** 16/07/1998		**Stopped:**	03/09/1998
SERENACE (Suspected)			**Reason:**	Anxiety neurosis
Tablet	1.0 Milligram	Daily		Oral
Batch:	**Started:** 03/08/1998		**Stopped:**	03/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP	U/L	01/09/1998	1507	
	SAP = ALP	U/L	03/09/1998	1457	
	SAP = ALP	U/L	09/09/1998	1451	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 131693 **Seq:** 1 **Gender:** M
Reported: 28/09/1998 **Weight:**
Hospitalisation: **Age:** 89
Onset Date: 03/08/1998 **DOB:** 28/12/1908
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Agitation Constipation Dry mouth		Unable to stand	Glycerin supp, senafcot, iv rehydration, s/c heparin for dvt prophylaxis

Medicine Details:

SINEMET (Other drug) **Reason:**
4.0 Dose Unspecified Daily
Batch: **Started:** 01/01/1994 **Stopped:** 09/08/1998

CELLUFRESH (Other drug) **Reason:**
Eye Drops 1.0 Dose Unspecified Daily Ophthalmic
Batch: **Started:** 01/01/1994 **Stopped:**

LACRI-LUBE (Other drug) **Reason:**
Eye Drops 1.0 Dose Unspecified Daily Ophthalmic
Batch: **Started:** 01/01/1994 **Stopped:**

SERENACE (Suspected) **Reason:** Reactive confusion
Injection 5.0 Milligram 1 time Intramuscular
Batch: **Started:** 02/08/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Decreasing mobility, delirious, 08/08/98 aspiration pneumonia. patient died 18/08/98. 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.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 131693 **Seq:** 1
Reported: 28/09/1998
Hospitalisation:
Onset Date: 03/08/1998
Outcome: Death, maybe drug

Gender: M
Weight:
Age: 89
DOB: 28/12/1908
Causality: Causality possible

Reaction Details:

Medicine Details:

SERENACE (Suspected) **Reason:** Reactive confusion

Injection 10.0 Milligram 1 time Intramuscular

Batch: **Started:** 03/08/1998 **Stopped:**

Laboratory Investigations:

Additional Information:

Decreasing mobility, delirious, 08/08/98 aspiration pneumonia. patient died 18/08/98. 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.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 131712 **Seq:** 1 **Gender:** M
Reported: 28/09/1998 **Weight:** 76.00
Hospitalisation: **Age:** 21
Onset Date: 26/08/1998 **DOB:** 26/04/1977
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction	Benztropine 2mg im

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
5.0 Milligram As necessary
Batch: **Started:** 23/08/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 132002 **Seq:** 1 **Gender:** M
Reported: 15/10/1998 **Weight:**
Hospitalisation: **Age:** 90
Onset Date: 26/08/1998 **DOB:** 06/04/1908
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Neuroleptic malignant syndrome			Ceased haloperidol and received supportive management.

Medicine Details:

SPIRONOLACTONE (Other drug) **Reason:**
0.0
Batch: **Started:** 24/08/1998 **Stopped:**

SALBUTAMOL (Other drug) **Reason:**
Inhalation 0.0 Inhalation
Batch: **Started:** L TERM **Stopped:**

IPRATROPIUM BROMIDE (Other drug) **Reason:**
Inhalation 0.0 Inhalation
Batch: **Started:** 01/01/1996 **Stopped:**

COLCHICINE (Other drug) **Reason:**
1.0 Milligram Daily
Batch: **Started:** 24/08/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Ck peak to 376

Additional Information:

Pt suffers severe dementia the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 132002 **Seq:** 1
Reported: 15/10/1998
Hospitalisation:
Onset Date: 26/08/1998
Outcome: Recovered

Gender: M
Weight:
Age: 90
DOB: 06/04/1908
Causality: Causality probable

Reaction Details:

Medicine Details:

FRUSEMIDE (Other drug)			**Reason:**	
	80.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
HALOPERIDOL (Suspected)			**Reason:**	Otr spec symp psychopathol nec
Injection	2.5	Milligram	3 times	Intramuscular
Batch:	**Started:**			**Stopped:** 26/08/1998

Laboratory Investigations:

Additional Information:

Pt suffers severe dementia the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 132181 **Seq:** 1 **Gender:** F
Reported: 21/10/1998 **Weight:** 60.00
Hospitalisation: **Age:** 80Y
Onset Date: 11/10/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state Hyponatraemia	Severe		Ceased serenace

Medicine Details:

ANTENEX (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CARTIA (Other drug) **Reason:** Transient cereb isch no hypert
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 04/10/1998 **Stopped:**

NOTEN (Other drug) **Reason:** Angina pectoris w/o hyperten
50.0 Milligram Daily
Batch: **Started:** **Stopped:**

TRANSIDERM-NITRO (Other drug) **Reason:** Angina pectoris w/o hyperten
50.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		11/10/1998	121	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 132181 **Seq:** 1 **Gender:** F
Reported: 21/10/1998 **Weight:** 60.00
Hospitalisation: **Age:** 80Y
Onset Date: 11/10/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

PEPCIDINE (Other drug)		**Reason:** Other diseases of esophagus	
2.0 Dose Unspecified	Daily		
Batch:	**Started:**		**Stopped:**
DIAZEPAM (Other drug)		**Reason:**	
10.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:**
SERENACE (Suspected)		**Reason:**	
500.0 Microgram	As necessary		
Batch:	**Started:** 04/10/1998		**Stopped:** 12/10/1998

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 132586 **Seq:** 1 **Gender:** M
Reported: 30/10/1998 **Weight:**
Hospitalisation: **Age:** 58Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia Tremor			Ceased haloperal and changed to olanzaoine.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
0.0
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 132796 **Seq:** 1 **Gender:** F
Reported: 05/11/1998 **Weight:**
Hospitalisation: **Age:** 53
Onset Date: **DOB:** 01/10/1945
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia	Required Specialist Consultation	Occasional lingual or bucco-lingual dyskinesia	

Medicine Details:

AROPAX (Suspected)			**Reason:** Depression		
Tablet	20.0	Milligram	Daily	Oral	
Batch:	**Started:** 07/04/1998			**Stopped:**	CONTIN
SERENACE (Suspected)			**Reason:**		
Tablet	20.0	Milligram	Daily	Oral	
Batch:	**Started:** 01/04/1998			**Stopped:** 28/05/1998	
HALOPERIDOL (Suspected)			**Reason:** Headache		
Injection	5.0	Milligram	Alternate days	Intravenous	
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 132994 **Seq:** 1
Reported: 02/11/1998
Hospitalisation: Admitted to hospital
Onset Date: 04/10/1998
Outcome: Not yet recovered

Gender: M
Weight:
Age: 66Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Chills Cyanosis Hypertension Neuroleptic malignant syndrome	Severe	Stiffness (axial rigidity)	Haloperidol ceased

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec

Tablet 1.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:** 04/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 133230 **Seq:** 1 **Gender:** M
Reported: 13/11/1998 **Weight:**
Hospitalisation: **Age:** 30
Onset Date: **DOB:** 16/05/1968
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Ceased haloperidol

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Schizophrenia
0.0
Batch: **Started:** **Stopped:** 28/06/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 133352 **Seq:** 1 **Gender:** F
Reported: 19/11/1998 **Weight:**
Hospitalisation: **Age:** 66Y
Onset Date: 13/05/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Amnesia Hyponatraemia		Epileptiform fits x 2	Ceased all medications. restarted seranace and sodium droped again.

Medicine Details:

NEO-MERCAZOLE (Other drug) **Reason:** Thyrotoxicosis w/o ment goiter
2.5 Milligram Daily
Batch: **Started:** **Stopped:** 13/05/1998

LARGACTIL (Other drug) **Reason:**
Oral Liquid 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 13/05/1998

ANAFRANIL (Other drug) **Reason:**
75.0 Milligram Daily
Batch: **Started:** **Stopped:** 13/05/1998

SERENACE (Suspected) **Reason:** Anxiety neurosis
3.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** 13/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt ceased all medications, restarted haloperidol and reaction occurred again.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 133508 **Seq:** 1 **Gender:** F
Reported: 20/11/1998 **Weight:** 50.00
Hospitalisation: **Age:** 42Y
Onset Date: 18/09/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Cogentin 2mg iv.

Medicine Details:

EPOETIN ALFA (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

FOLIC ACID (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CATAPRES (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

METOPROLOL TARTRATE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 133508 **Seq:** 1 **Gender:** F
Reported: 20/11/1998 **Weight:** 50.00
Hospitalisation: **Age:** 42Y
Onset Date: 18/09/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

LOSEC (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
FELODIPINE (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
KEFLEX (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
FLAGYL (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 133508 **Seq:** 1 **Gender:** F
Reported: 20/11/1998 **Weight:** 50.00
Hospitalisation: **Age:** 42Y
Onset Date: 18/09/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**

Injection	2.5 Milligram	1 time	Intramuscular

Batch: **Started:** 17/09/1998 **Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 134110 **Seq:** 1 **Gender:** F
Reported: 08/12/1998 **Weight:** 70.00
Hospitalisation: **Age:** 18Y
Onset Date: 11/11/1998 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness			
Drug withdrawal syndrome			
Headache			
Malaise			
Myalgia			
Nausea			
Tremor			

Medicine Details:

SERENACE (Suspected) **Reason:**
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 01/02/1998 **Stopped:** 09/11/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms occurred previously when serenace was suddenly stopped. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 134512 **Seq:** 1 **Gender:** M
Reported: 21/12/1998 **Weight:** 66.00
Hospitalisation: **Age:** 63
Onset Date: 26/09/1998 **DOB:** 24/03/1935
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash erythematous			Canesten cream tds, betamethasone cream, phenergan. ceased ramipril, phenytoin, haloperidol, diazepam.

Medicine Details:

WARFARIN SODIUM (Other drug) **Reason:** Acute,ill-def cerebrovascular disease w/o hyperte
Tablet 3.0 Milligram Daily Oral
Batch: **Started:** 03/09/1998 **Stopped:** CONTIN

SERTRALINE HYDROCHLORIDE (Other drug) **Reason:**
50.0 Milligram Daily
Batch: **Started:** 31/08/1998 **Stopped:** CONTIN

RAMIPRIL (Suspected) **Reason:** Essential benign hypertension
10.0 Milligram Daily
Batch: **Started:** 24/08/1998 **Stopped:** 11/11/1998

PHENYTOIN SODIUM (Suspected) **Reason:** Prophylaxis
200.0 Milligram Daily
Batch: **Started:** 23/08/1998 **Stopped:** 30/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 134512 **Seq:** 1
Reported: 21/12/1998
Hospitalisation:
Onset Date: 26/09/1998
Outcome: Recovered

Gender: M
Weight: 66.00
Age: 63
DOB: 24/03/1935
Causality: Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)		**Reason:**	
	2.0 Milligram	Daily	
Batch:	**Started:** 24/08/1998		**Stopped:** 06/10/1998
DIAZEPAM (Suspected)		**Reason:**	
	5.0 Milligram	Daily	
Batch:	**Started:** 31/08/1998		**Stopped:** 09/11/1998

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 135006 **Seq:** 1 **Gender:** M
Reported: 11/01/1999 **Weight:**
Hospitalisation: **Age:** 10Y
Onset Date: 10/08/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Angioedema Urticaria			Prozac & serenace ceased. oral steroids given, prednisolone & claratyne.

Medicine Details:

PROZAC (Suspected) **Reason:** Otr spec symp psychopathol nec
Oral application 0.0 Oral
Batch: **Started:** 01/07/1998 **Stopped:** 18/08/1998

SERENACE (Suspected) **Reason:** Otr spec symp psychopathol nec
Oral application 0.0 Oral
Batch: **Started:** 01/07/1998 **Stopped:** 14/08/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected agent prozac - prev reports of urticaral & angioedema. 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.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 135770 **Seq:** 1 **Gender:** F
Reported: 03/02/1999 **Weight:** 68.00
Hospitalisation: **Age:** 29Y
Onset Date: 23/01/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation Confusional state Dystonia Muscle twitching Nausea Vomiting			

Medicine Details:

MERSYNDOL (Other drug)		**Reason:**	Other disturbance of sensation
	2.0 Dose Unspecified	As necessary	
Batch:	**Started:** 01/01/1997		**Stopped:**
VALIUM (Other drug)		**Reason:**	Otr spec symp psychopathol nec
	15.0 Milligram	Daily	
Batch:	**Started:** 01/01/1996		**Stopped:**
SERENACE (Suspected)		**Reason:**	Otr spec symp psychopathol nec
	4.5 Milligram	Daily	
Batch:	**Started:** 21/01/1999		**Stopped:** 23/01/1999

Laboratory Investigations:

Date	Type	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.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 135879 **Seq:** 1 **Gender:** M
Reported: 08/02/1999 **Weight:** 90.00
Hospitalisation: **Age:** 28Y
Onset Date: 24/09/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria		Urticaria near drip site	

Medicine Details:

ISOFLURANE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PHENYTOIN SODIUM (Other drug) **Reason:**
Capsule 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 6M

MAXOLON (Suspected) **Reason:**
Injection, intravenous infusion 20.0 Millilitre Total Intravenous
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
Injection, intravenous infusion 1.0 Millilitre Total Intravenous
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Details:

Case Number: 135879 **Seq:** 1 **Gender:** M
Reported: 08/02/1999 **Weight:** 90.00
Hospitalisation: **Age:** 28Y
Onset Date: 24/09/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

PROPOFOL (Suspected)			**Reason:**	
Injection, intravenous infusion	400.0	Millilitre	Total	Intravenous
Batch:	**Started:**			**Stopped:**
FENTANYL CITRATE (Suspected)			**Reason:**	
Injection, intravenous infusion	100.0	Millilitre	Total	Intravenous
Batch:	**Started:**			**Stopped:**
MORPHINE NOS (Suspected)			**Reason:**	
Injection, intravenous infusion	10.0	Milligram	Total	Intravenous
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 136019 **Seq:** 1 **Gender:** F
Reported: 08/02/1999 **Weight:**
Hospitalisation: **Age:** 79Y
Onset Date: 25/10/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder Hypertonia			Ceased haloperidol.

Medicine Details:

ESTRADERM (Other drug) **Reason:** Menopausal symptoms
Cream 2.0 Dose Unspecified Weekly Transdermal
Batch: **Started:** **Stopped:** CONTIN

CARTIA (Other drug) **Reason:** Transient cereb isch no hypert
Oral application 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

LABETALOL HYDROCHLORIDE (Other drug) **Reason:** Essential benign hypertension
Oral application 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

AMLODIPINE (Other drug) **Reason:** Essential benign hypertension
Tablet 2.5 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous allergies.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 136019 **Seq:** 1 **Gender:** F
Reported: 08/02/1999 **Weight:**
Hospitalisation: **Age:** 79Y
Onset Date: 25/10/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

CALCITRIOL (Other drug)			**Reason:** Osteoporosis	
	0.5 Microgram	Daily		
Batch:	**Started:**		**Stopped:**	CONTIN
OMEPRAZOLE (Other drug)			**Reason:** Other diseases of esophagus	
	20.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:**	CONTIN
PANADOL (Other drug)			**Reason:** Fracture of carpal bone(s)	
	4.0 Gram	Daily		
Batch:	**Started:**		**Stopped:**	CONTIN
HALOPERIDOL (Suspected)			**Reason:** Anxiety neurosis	
	0.5 Milligram	As necessary		
Batch:	**Started:** 23/10/1998		**Stopped:** 25/10/1998	

Laboratory Investigations:

Additional Information:

No previous allergies.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 136055 **Seq:** 1 **Gender:** M
Reported: 10/02/1999 **Weight:** 55.00
Hospitalisation: **Age:** 14
Onset Date: 23/12/1998 **DOB:** 01/03/1984
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Cogentin

Medicine Details:

PARACETAMOL (Other drug)			**Reason:**	
Oral application	1.0	Gram	As necessary	Oral
Batch:	**Started:** 22/12/1998		**Stopped:**	29/12/1998
DIAZEPAM (Other drug)			**Reason:**	
Oral application	10.0	Milligram	As necessary	Oral
Batch:	**Started:** 22/12/1998		**Stopped:**	27/12/1998
IBUPROFEN (Other drug)			**Reason:**	
Oral application	100.0	Milligram	As necessary	Oral
Batch:	**Started:** 22/12/1998		**Stopped:**	29/12/1998
METRONIDAZOLE (Other drug)			**Reason:**	
Oral application	1.0	Gram	Daily	Oral
Batch:	**Started:** 22/12/1998		**Stopped:**	23/12/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of heroin use->withdrawal.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 136055 **Seq:** 1
Reported: 10/02/1999
Hospitalisation:
Onset Date: 23/12/1998
Outcome: Unknown

Gender: M
Weight: 55.00
Age: 14
DOB: 01/03/1984
Causality: Causality possible

Reaction Details:

Medicine Details:

CEPHALEXIN (Other drug)			**Reason:**	
Oral application	1.0 Gram		Daily	Oral
Batch:	**Started:** 22/12/1998		**Stopped:**	23/12/1998
HALOPERIDOL (Suspected)			**Reason:**	
Injection	5.0 Milligram		1 time	Intramuscular
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Additional Information:

History of heroin use->withdrawal.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 136292 **Seq:** 1 **Gender:** F
Reported: 17/02/1999 **Weight:**
Hospitalisation: **Age:** 53
Onset Date: 02/11/1998 **DOB:** 04/10/1945
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction	Benztropine given.

Medicine Details:

DIAZEPAM (Other drug) **Reason:**
10.0 Milligram As necessary
Batch: **Started:** 20/10/1998 **Stopped:** CONTIN

TEMAZEPAM (Suspected) **Reason:**
20.0 Milligram As necessary
Batch: **Started:** 01/11/1998 **Stopped:** CONTIN

LITHIUM CARBONATE (Suspected) **Reason:**
1.0 Gram Daily
Batch: **Started:** 20/10/1998 **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:**
15.0 Milligram Daily
Batch: **Started:** 20/10/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 136481 **Seq:** 1 **Gender:** M
Reported: 18/02/1999 **Weight:**
Hospitalisation: **Age:** 77
Onset Date: 17/08/1998 **DOB:** 06/02/1921
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Stridor		Airway obstruction due to neck dystonia.	
Dystonia		Neck dystonia.	
Tardive dyskinesia			Haloperidol ceased. benztropine & diazepam given.

Medicine Details:

VENTOLIN (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ATROVENT (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

OMEPRAZOLE (Other drug) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

PREDNISOLONE (Other drug) **Reason:**
50.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 136481 **Seq:** 1 **Gender:** M
Reported: 18/02/1999 **Weight:**
Hospitalisation: **Age:** 77
Onset Date: 17/08/1998 **DOB:** 06/02/1921
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

PULMICORT (Other drug)			**Reason:**		
Inhalation	1.0 Milligram		Daily	Inhalation	
Batch:	**Started:** 11/08/1998			**Stopped:**	CONTIN
HALOPERIDOL (Suspected)			**Reason:**		
Injection	10.0 Milligram		Daily	Intravenous	
Batch:	**Started:** 11/08/1998			**Stopped:**	17/08/1998
VANCOMYCIN HYDROCHLORIDE (Suspected)			**Reason:**		
Injection	2.0 Gram		Daily	Intravenous	
Batch:	**Started:** 15/08/1998			**Stopped:**	17/08/1998

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 137579 **Seq:** 1 **Gender:** M
Reported: 19/03/1999 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash Pyrexia		Rash on neck and under arms.	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology				White cells and neutrophils noted to be normal.

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 138278 **Seq:** 1
Reported: 01/04/1999
Hospitalisation: Admitted to hospital
Onset Date: 22/02/1999
Outcome: Unknown

Gender: M
Weight:
Age:
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatomegaly Pancytopenia Sepsis Splenomegaly			Haloperidol was initiated to control the patient's symptoms. clozaril was ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 0.0 Oral
Batch: **Started:** **Stopped:** 22/02/1999 14M

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient presented to the hospital with septic shock. within 4 weeks of the discontinuation of clozapine, the patient developed splenomegaly, hepatomegaly and pancytopenia.

Report Details:

Case Number: 138529 **Seq:** 1
Reported: 16/04/1999
Hospitalisation: Admitted to hospital
Onset Date: 08/02/1999
Outcome: Unknown

Gender: F
Weight: 70.00
Age: 64Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Fever of 39 degrees	
Mania		Mania	
Agranulocytosis			
Anorexia			
Delusion			
Insomnia			
Nervousness			
Thinking abnormal			

Medicine Details:

HALOPERIDOL (Interaction) **Reason:** Unspecified psychosis
0.0
Batch: **Started:** **Stopped:**

OROXINE (Interaction) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No past history of psychiatric illness.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 138718 **Seq:** 1
Reported: 23/04/1999
Hospitalisation: Admitted to hospital
Onset Date: 31/12/1999
Outcome: Recovered

Gender: F
Weight:
Age: 50Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal Confusional state		Acute cognitive disorder	Zoloft discontinued

Medicine Details:

HALOPERIDOL (Interaction) **Reason:**

0.0

Batch: **Started:** **Stopped:**

ZOLOFT (Interaction) **Reason:** Depression

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	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: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 138832 **Seq:** 1
Reported: 28/04/1999
Hospitalisation: Admitted to hospital
Onset Date: 22/05/1998
Outcome: Unknown

Gender: M
Weight: 86.00
Age: 49Y
DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation		2 hours of agitation.	
Dystonia		Dystonic reaction.	Creased im 5-10mg haloperidol dose, oral haloperidol, cisapide, diazepam, midazolam & ranitidine.
Convulsion		Patient had seizure.	
Hypertonia			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**

Injection 570.0 Milligram As necessary Intravenous

Batch: **Started:** 22/05/1998 **Stopped:** 22/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms following 5mg im dose of haloperidol.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 140401 **Seq:** 1 **Gender:** M
Reported: 10/06/1999 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: 18/05/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea		Difficulty breathing.	
Dysphagia		Difficuly in swallowing.	
Rash		Rash on hands.	Calamine lotion & phenergan oral
Face oedema		Swollen lip & eyelids.	

Medicine Details:

HALOPERIDOL (Suspected)			**Reason:**	
Tablet	5.0 Milligram		1 time	Oral
Batch:	**Started:** 18/05/1999		**Stopped:**	
RISPERIDONE (Suspected)			**Reason:**	
Tablet	2.0 Milligram		Daily	Oral
Batch:	**Started:** 18/05/1999		**Stopped:**	18/05/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient developed rash on 18.5.99. unsure if is due to risperidone or haloperidol.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 140505 **Seq:** 1 **Gender:** F
Reported: 16/06/1999 **Weight:**
Hospitalisation: **Age:** 90Y
Onset Date: 07/04/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash erythematous Face oedema		Legs, arms, trunk and face red.	 Phenergan

Medicine Details:

CIPROXIN (Suspected) **Reason:**
7.5 Milligram 1 time
Batch: **Started:** 06/04/1999 **Stopped:** 06/04/1999

SERENACE (Suspected) **Reason:**
2.5 Milligram 1 time
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 140818 **Seq:** 1
Reported: 18/06/1999
Hospitalisation: Admitted to hospital
Onset Date: 30/05/1999
Outcome: Recovered

Gender: F
Weight:
Age: 62Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diplopia Weight decreased			 Cogentin

Medicine Details:

HALOPERIDOL (Suspected)		**Reason:** Unspecified psychosis	
	16.0 Milligram	Daily	
Batch:	**Started:** 30/05/1999		**Stopped:** 03/06/1999
HALOPERIDOL (Suspected)		**Reason:** Unspecified psychosis	
	4.0 Milligram	Daily	
Batch:	**Started:** 28/05/1999		**Stopped:** 30/05/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drugs" sertraline and diazepam.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 144203 **Seq:** 1
Reported: 29/09/1999
Hospitalisation: Admitted to hospital
Onset Date: 24/08/1999
Outcome: Unknown

Gender: F
Weight:
Age: 23Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			Physical observations qid.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** 24/08/1999 **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 08/09/1998 **Stopped:** 11/08/1999

LARGACTIL (Suspected) **Reason:**
25.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 144234 **Seq:** 1 **Gender:** M
Reported: 30/09/1999 **Weight:**
Hospitalisation: **Age:** 85
Onset Date: 22/07/1999 **DOB:** 07/04/1914
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Drug induced extrapyramidal syndrome.	Haloperidol ceased.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
1.5 Milligram Daily
Batch: **Started:** 14/07/1999 **Stopped:** 22/07/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - paracetamol, imdur, digoxin, frusemide, slow-k and aspirin. patient history of nfa.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 144419 **Seq:** 1 **Gender:** F
Reported: 05/10/1999 **Weight:**
Hospitalisation: **Age:** 31
Onset Date: **DOB:** 04/10/1968
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic steatosis Nausea Vomiting			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 01/07/1998 **Stopped:** CONTIN

LOSEC (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/07/1998 **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:** Unspecified schizophrenia
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				An abdominal ultrasound showed a 'fatty liver'.

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.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 144543 **Seq:** 1 **Gender:** M
Reported: 11/10/1999 **Weight:**
Hospitalisation: **Age:** 38Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tinnitus			Zoloft dose reduced from 100mg to 75mg.

Medicine Details:

SERENACE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 144890 **Seq:** 1 **Gender:** M
Reported: 19/10/1999 **Weight:**
Hospitalisation: **Age:** 23Y
Onset Date: 19/05/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction	Cease haloperidol - substituted stelazine.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
Oral application 5.0 Milligram Daily Oral
Batch: **Started:** 17/05/1999 **Stopped:** 20/05/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drugs - chlorpromazine, diazepam.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 144896 **Seq:** 1
Reported: 19/10/1999
Hospitalisation: Admitted to hospital
Onset Date: 30/06/1999
Outcome: Recovered

Gender: M
Weight:
Age: 69Y
DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Haloperidol ceased.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis

Oral application 3.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drugs - prothiaden, temazepam, valium, ural.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 145544 **Seq:** 1 **Gender:** F
Reported: 08/11/1999 **Weight:**
Hospitalisation: **Age:** 88
Onset Date: 13/09/1999 **DOB:** 28/08/1911
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating Hypertonia		Decreased conscious state	Iv clonazepam. suspected drugs withdrawn.

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 01/09/1999

AROPAX (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** 01/09/1999 **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
0.5 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reactions occurred 12 days after increasing dose of aropax from 20mg to 40mg.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 145604 **Seq:** 1 **Gender:** M
Reported: 11/11/1999 **Weight:**
Hospitalisation: **Age:** 14Y
Onset Date: 05/10/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Back pain Gait disturbance Oculogyration Torticollis			Treated with stat dose iv benztropine 0.8mg

Medicine Details:

CLONIDINE HYDROCHLORIDE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

DEXAMPHETAMINE SULPHATE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

SERENACE (Suspected) **Reason:** Behavior disorders of childhod
1.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Accidentaly pt received increased dose of serenace total of 15mg over 36hrs.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 146006 **Seq:** 1 **Gender:** F
Reported: 18/11/1999 **Weight:**
Hospitalisation: **Age:** 37Y
Onset Date: 31/12/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia			Ceased haldol.

Medicine Details:

HALDOL DECANOATE (Suspected) **Reason:**
Injection 0.0 Intravenous
Batch: **Started:** 01/01/1993 **Stopped:** 31/01/1995

Laboratory Investigations:

Date	Type	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. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 146196 **Seq:** 1
Reported: 26/11/1999
Hospitalisation:
Onset Date: 20/11/1999
Outcome: Not yet recovered

Gender: M
Weight: 64.00
Age: 36Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Apathy		Flattened effect	
Extrapyramidal disorder		Gross parkinsonism	
Tremor		Tremor, both arms	All antivirals ceased, haloperidol dose reduced, & given procyclidine.
Extrapyramidal disorder			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
10.0 Milligram Daily
Batch: **Started:** 01/01/1999 **Stopped:** CONTIN

RITONAVIR (Suspected) **Reason:** Hiv infection
200.0 Milligram Daily
Batch: **Started:** 12/11/1999 **Stopped:** 20/11/1999

INDINAVIR SULFATE (Suspected) **Reason:** Hiv infection
1.2 Gram Daily
Batch: **Started:** 12/11/1999 **Stopped:** 20/11/1999

STAVUDINE (Suspected) **Reason:** Hiv infection
80.0 Milligram Daily
Batch: **Started:** 12/11/1999 **Stopped:** 20/11/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details: oxazepam, imdur, omeprazole, azithromycin, & pentamidine. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 146196 **Seq:** 1
Reported: 26/11/1999
Hospitalisation:
Onset Date: 20/11/1999
Outcome: Not yet recovered

Gender: M
Weight: 64.00
Age: 36Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

LAMIVUDINE (Suspected) **Reason:** Hiv infection
300.0 Milligram Daily
Batch: **Started:** 12/11/1999 **Stopped:** 20/11/1999

Laboratory Investigations:

Additional Information:

See original report for other drug details: oxazepam, imdur, omeprazole, azithromycin, & pentamidine. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 147212 **Seq:** 1 **Gender:** M
Reported: 17/12/1999 **Weight:**
Hospitalisation: **Age:** 16
Onset Date: 03/08/1999 **DOB:** 10/10/1982
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Gross dystonia	Cogentin
Dyskinesia		Shaking and jerking head and neck.	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 01/08/1999 **Stopped:** 03/08/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 147367 **Seq:** 1 **Gender:** F
Reported: 23/12/1999 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 77Y
Onset Date: 15/06/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Generalised rigidity	
Bradykinesia			
Extrapyramidal disorder			Cogentin, valproate dose halved then slowly ceased and changed to carbamazepin e.
Gait disturbance			
Tardive dyskinesia			
Thinking abnormal			

Medicine Details:

EPILIM (Suspected)				**Reason:**	Other&unspecified epilepsy
Oral application	2.0	Gram	Daily		Oral
Batch:	**Started:** 09/06/1999			**Stopped:**	26/06/1999
EPILIM (Suspected)				**Reason:**	Other&unspecified epilepsy
Oral application	500.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	29/05/1999
SERENACE (Suspected)				**Reason:**	Specific disorders of sleep
Tablet	500.0	Microgram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	31/05/1999
CLONAZEPAM (Suspected)				**Reason:**	
Oral application	500.0	Microgram	Daily		Oral
Batch:	**Started:**			**Stopped:**	09/06/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrolytes				Creatinine clearance estimated - 60mls/min.
	Serum drug level	350 - 700	15/06/1999	1469	Sodium valproate level
	Serum drug level	350 - 700	17/06/1999	660	Sodium valproate level

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 147482 **Seq:** 1
Reported: 30/12/1999
Hospitalisation: Admitted to hospital
Onset Date: 06/12/1999
Outcome: Not yet recovered

Gender: F
Weight:
Age: 78Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness		Falls - fracture of left colles.	Serenace ceased.

Medicine Details:

SERENACE (Suspected) **Reason:**
7.5 Milligram Daily
Batch: **Started:** 06/12/1999 **Stopped:** 08/12/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt also taking theo-dur, lanoxin, lasix, capoten, slow-k, oroxine.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 148028 **Seq:** 1 **Gender:** F
Reported: 18/01/2000 **Weight:** 54.00
Hospitalisation: **Age:** 34Y
Onset Date: 23/11/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Severe drug induced parkinsonism	
Tremor		Upper and lower limb tremor	
Headache			
Hyperacusis			
Visual disturbance			

Medicine Details:

HALDOL DECANOATE (Suspected) **Reason:**
25.0 Milligram Fortnightly
Batch: **Started:** 30/10/1999 **Stopped:**

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 23/11/1999 **Stopped:** 26/11/1999

LITHIUM CARBONATE (Suspected) **Reason:** Depression
530.0 Milligram Daily
Batch: **Started:** 12/11/1999 **Stopped:** 25/11/1999

BENZTROPINE MESYLATE (Suspected) **Reason:**
2.0 Milligram Daily
Batch: **Started:** 13/11/1999 **Stopped:** 26/11/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 148028 **Seq:** 1
Reported: 18/01/2000
Hospitalisation:
Onset Date: 23/11/1999
Outcome: Not yet recovered

Gender: F
Weight: 54.00
Age: 34Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

NICOTINE TRANSDERMAL PATCH (Suspected)			**Reason:**	
Cream	10.0	Milligram	Daily	Transdermal
Batch:	**Started:** 03/11/1999		**Stopped:**	

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 148836 **Seq:** 1 **Gender:** F
Reported: 11/02/2000 **Weight:** 75.00
Hospitalisation: **Age:** 20
Onset Date: 02/07/1999 **DOB:** 08/06/1979
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Jaw tightness	Cogentin

Medicine Details:

RISPERDAL (Suspected) **Reason:**
2.0 Milligram Daily
Batch: **Started:** 01/07/1999 **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
5.0 Milligram Daily
Batch: **Started:** 01/07/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking zoloft and panamax.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 150328 **Seq:** 1 **Gender:** M
Reported: 13/03/2000 **Weight:**
Hospitalisation: **Age:** 32
Onset Date: 15/02/2000 **DOB:** 01/02/1968
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

TEGRETOL CR (Suspected) **Reason:**
Tablet 800.0 Milligram Daily Oral
Batch: **Started:** 01/08/1999 **Stopped:**

SERENACE (Suspected) **Reason:**
2.5 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		15/02/2000	1.9	
	Neutrophils		16/03/2000	3.5	

Additional Information:

Symptoms occurred 4 to 5 months after patient commenced therapy with tegretol cr.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 150994 **Seq:** 1 **Gender:** M
Reported: 28/03/2000 **Weight:**
Hospitalisation: **Age:** 24
Onset Date: 26/01/2000 **DOB:** 19/05/1975
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gait disturbance Dystonia		Stiffness of gait.	Patient given benztropine 2 mg oral.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
15.0 Milligram Daily
Batch: **Started:** 25/01/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Haloperidol dose was increased from 10 mg/day to 15 mg/day. patient also taking- benztropine, diazepam and midazolam.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 150996 **Seq:** 1 **Gender:** M
Reported: 28/03/2000 **Weight:**
Hospitalisation: **Age:** 32
Onset Date: 30/01/2000 **DOB:** 08/04/1967
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea		Hard to breath.	
Salivary hypersecretion		Hypersalivation.	
Speech disorder		Slurred speech.	Patient given conentin 2 mg. haloperidol ceased.
Tongue oedema		Swollen tongue.	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
5.0 Milligram As necessary
Batch: **Started:** 28/01/2000 **Stopped:**

CLOZAPINE (Suspected) **Reason:** Unspecified psychosis
350.0 Milligram Daily
Batch: **Started:** 28/01/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking - panadeine forte and diazepam. clozapine was increased from 325 mg/d to 350 mg/d.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 152211 **Seq:** 1 **Gender:** M
Reported: 01/05/2000 **Weight:** 0.00
Hospitalisation: **Age:** 49Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Platelet aggregation abnormal Thrombocytopenia		Abnormal platelet aggregation	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

BENZTROPINE MESYLATE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

DESIPRAMINE HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Platelets				Platelets count 112.

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 152977 **Seq:** 1 **Gender:** F
Reported: 24/05/2000 **Weight:**
Hospitalisation: **Age:** 15
Onset Date: 22/03/2000 **DOB:** 03/03/1985
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Acute dystonic raction - jaw spasm.	Cogentin.

Medicine Details:

HALOPERIDOL (Suspected)			**Reason:**	
Injection	30.0 Milligram		Total	Intravenous
Batch:	**Started:** 20/03/2000			**Stopped:** 21/03/2000
MIDAZOLAM (Suspected)			**Reason:**	
Injection	30.0 Milligram		Total	Intravenous
Batch:	**Started:** 20/03/2000			**Stopped:** 21/03/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history of marijuana abuse, personality disorder x1 year and grandmother: bipolar disorder.

Report Details:

Case Number: 154215 **Seq:** 1
Reported: 26/06/2000
Hospitalisation: Admitted to hospital
Onset Date: 15/06/2000
Outcome: Recovered

Gender: M
Weight:
Age: 38Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure		Heart failure	
Pyrexia		Temperature of 41 degrees c.	
Blood creatine phosphokinase incr			
Cardiomyopathy			
Hypotension			
Leukocytosis			Lanoxin, frusemide and trandolapril, oxygen therapy, multiple antibiotics and dexamethasone.
Myocarditis			
Pneumonia			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 02/06/2000 **Stopped:** 14/06/2000

HALOPERIDOL (Suspected) **Reason:** Unspecified schizophrenia

4.0 Milligram Daily

Batch: **Started:** 23/05/2000 **Stopped:** 14/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chest X-ray				Chest x-ray 19/6/00: the heart is enlarged. there are bilateral lower zone changes which are consistent with both air space and interstitial abnormality. there is some collapse at the left base with small bilateral pleural effusions the findings are most likely consistent with cardiac failure however infection can never be excluded and clinical correlation is suggested.

Additional Information:

Patient also taking complan

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 154215 **Seq:** 1
Reported: 26/06/2000
Hospitalisation: Admitted to hospital
Onset Date: 15/06/2000
Outcome: Recovered

Gender: M
Weight:
Age: 38Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:** Unspecified schizophrenia	
Tablet	200.0 Milligram		Daily	Oral
Batch:	**Started:** 02/06/2000			**Stopped:** 14/06/2000
HALOPERIDOL (Suspected)			**Reason:** Unspecified schizophrenia	
	4.0 Milligram		Daily	
Batch:	**Started:** 23/05/2000			**Stopped:** 14/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chest X-ray				Chest x-ray 20/6/00: the cardiac shadow is prominent. there is consolidation seen over the left lung base. compared with the previous study on the 19/6/00, there is almost complete resolution of the left basal pneumonia.
	Creatine		13/06/2000	964	

Additional Information:
Patient also taking complan

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 154215 **Seq:** 1
Reported: 26/06/2000
Hospitalisation: Admitted to hospital
Onset Date: 15/06/2000
Outcome: Recovered

Gender: M
Weight:
Age: 38Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:** Unspecified schizophrenia	
Tablet	200.0 Milligram		Daily	Oral
Batch:	**Started:** 02/06/2000			**Stopped:** 14/06/2000
HALOPERIDOL (Suspected)			**Reason:** Unspecified schizophrenia	
	4.0 Milligram		Daily	
Batch:	**Started:** 23/05/2000			**Stopped:** 14/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Electrocardiogram 15/6/00: sinus rhythm. right axis deviation.incomplete right bundle branch block. widespread non specific st t-wave changes. ecg 16/6/00: sinus tachycardia. widespread non specific st t-wave changes. incomplete right bundle branch block.

Additional Information:

Patient also taking complan

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 154215 **Seq:** 1
Reported: 26/06/2000
Hospitalisation: Admitted to hospital
Onset Date: 15/06/2000
Outcome: Recovered

Gender: M
Weight:
Age: 38Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:** Unspecified schizophrenia	
Tablet	200.0 Milligram		Daily	Oral
Batch:	**Started:** 02/06/2000			**Stopped:** 14/06/2000
HALOPERIDOL (Suspected)			**Reason:** Unspecified schizophrenia	
	4.0 Milligram		Daily	
Batch:	**Started:** 23/05/2000			**Stopped:** 14/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Ecg 17/6/00: sinus tachycardia with frequent atrial ectopics. incomplete right bundle branch block. widespread non specific st t-wave changes. ecg 18/6/00: sinus tachycardia. incomplete right bundle branch block. wides- spread non specific st t-wave changes slightly more marked than on the previous tracing on the 17/6/00.
	Immunology				All viral titres negative.

Additional Information:

Patient also taking complan

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 154215 **Seq:** 1
Reported: 26/06/2000
Hospitalisation: Admitted to hospital
Onset Date: 15/06/2000
Outcome: Recovered

Gender: M
Weight:
Age: 38Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:** Unspecified schizophrenia	
Tablet	200.0 Milligram		Daily	Oral
Batch:	**Started:** 02/06/2000			**Stopped:** 14/06/2000
HALOPERIDOL (Suspected)			**Reason:** Unspecified schizophrenia	
	4.0 Milligram		Daily	
Batch:	**Started:** 23/05/2000			**Stopped:** 14/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		13/06/2000	8.3	
	Other data				Electrocardiogram and echocardiogram showed myocarditis first echocardiogram 16/6/00: mildly enlarged left ventricle with moderate to moderately severe global systolic dysfunction. second echocardiogram: normal systolic function with small residual effusion.

Additional Information:

Patient also taking complan

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 156288 **Seq:** 1
Reported: 14/08/2000
Hospitalisation:
Onset Date: 12/07/2000
Outcome: Not yet recovered

Gender: F
Weight: 50.00
Age: 71Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Purpura Face oedema		Ecchymoses over legs and feet. Sudden onset of swelling of face and body.	

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected)		**Reason:** Depression	
	10.0 Milligram	Daily	
Batch:	**Started:** 11/07/2000		**Stopped:** 12/07/2000
HALOPERIDOL (Suspected)		**Reason:** Depression	
	0.5 Milligram	Daily	
Batch:	**Started:** 11/07/2000		**Stopped:** 12/07/2000
IMOVANE (Suspected)		**Reason:** Specific disorders of sleep	
	3.7 Milligram	Daily	
Batch:	**Started:** 11/07/2000		**Stopped:** 12/07/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking fentanyl patch, maxolon, coloxyl with senna and losec. patient suffers from multiple myeloma / dementia.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 157156 **Seq:** 1 **Gender:** F
Reported: 30/08/2000 **Weight:**
Hospitalisation: **Age:** 21Y
Onset Date: 10/08/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Lockjaw, tongue spasm, discomfort.	Given cogentin 2mg im.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
2.0 Milligram Daily
Batch: **Started:** 07/08/2000 **Stopped:** 10/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking cipramil, diazepam, keflex. patient was taking haloperidol for high risk suicide, distressed. patient recovered 10.8.00.

Report Details:

Case Number: 157249 **Seq:** 1 **Gender:** F
Reported: 31/08/2000 **Weight:**
Hospitalisation: **Age:** A7
Onset Date: 31/08/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state			Rest

Medicine Details:

EUHYPNOS (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

OROXINE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

SERZONE (Suspected) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Recently husband died and patient was admitted to a nursing home. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 157249 **Seq:** 1 **Gender:** F
Reported: 31/08/2000 **Weight:**
Hospitalisation: **Age:** A7
Onset Date: 31/08/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

VALIUM (Suspected) **Reason:**
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Recently husband died and patient was admitted to a nursing home. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 157545 **Seq:** 1 **Gender:** F
Reported: 11/09/2000 **Weight:** 65.00
Hospitalisation: **Age:** 62
Onset Date: 03/09/2000 **DOB:** 01/08/1938
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged Torsade de pointes Ventricular tachycardia			Mgso4 infusion 1.5mmol/hr. date of recovery 4.9.00.

Medicine Details:

MIDAZOLAM (Suspected) **Reason:**
Injection, intravenous infusion 0.0 Intravenous
Batch: **Started:** 26/08/2000 **Stopped:** 05/09/2000

HALOPERIDOL (Suspected) **Reason:**
Injection, intravenous infusion 10.0 Milligram Per hour Intravenous
Batch: **Started:** 31/08/2000 **Stopped:** 04/09/2000

PROPOFOL (Suspected) **Reason:**
100.0 Milligram Per hour
Batch: **Started:** 02/09/2000 **Stopped:** 03/09/2000

DIGOXIN (Suspected) **Reason:** Otr&nos disord of heart rhythm
Injection 250.0 Microgram Daily Intravenous
Batch: **Started:** 29/08/2000 **Stopped:** 05/09/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking losec, canesten, clonidine, panadol, nilstat and imiperem.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 157786 **Seq:** 1 **Gender:** F
Reported: 13/09/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: 07/05/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysarthria Hyperkinesia			Benztropine.

Medicine Details:

SERENACE (Suspected) **Reason:**
0.4 Millilitre Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 158125 **Seq:** 1 **Gender:** M
Reported: 26/09/2000 **Weight:**
Hospitalisation: **Age:** 53
Onset Date: 13/09/2000 **DOB:** 23/12/1946
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain Myocarditis Orthostatic hypotension			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 22/06/1998 **Stopped:** 19/09/2000

HALOPERIDOL (Suspected) **Reason:**
2.5 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Myocarditis diagnosed on echocardiogram. ejection fraction was 30%.

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 159301 **Seq:** 1 **Gender:** M
Reported: 16/11/2000 **Weight:**
Hospitalisation: **Age:** 18Y
Onset Date: 04/10/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Tongue was stiff & protruding, then curled up.	Given im benztropine

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
Injection 10.0 Milligram 1 time Intramuscular
Batch: **Started:** **Stopped:**

RISPERIDONE (Suspected) **Reason:** Unspecified psychosis
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 03/10/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking midazolam, diazepam.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 159307 **Seq:** 1 **Gender:** M
Reported: 16/11/2000 **Weight:**
Hospitalisation: **Age:** 23Y
Onset Date: 25/05/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Torticollis Dystonia		Stiff neck and held at an angle.	Im benztropine. therapy changed to risperidone.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
5.0 Milligram As necessary
Batch: **Started:** 23/05/2000 **Stopped:** 02/06/2000

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
Oral application 15.0 Milligram Daily Oral
Batch: **Started:** 23/05/2000 **Stopped:** 26/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking diazepam.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 160200 **Seq:** 1 **Gender:** M
Reported: 22/12/2000 **Weight:** 60.00
Hospitalisation: **Age:** 68Y
Onset Date: 04/12/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder Hypertonia Tremor			Halopperidol ceased. date of recovery 06/12/00.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
5.0 Milligram Daily
Batch: **Started:** 27/09/2000 **Stopped:** 04/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Dose of haloperidol changed from 1mg scbd to 2.5mg bd on 16/10/00, then increa sed to 2.5mg mane and 5mg nocte on 01/11/00. patient also taking sertraline, lorazepam, fentanyl patch, losec, panadol, celebrex.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 160525 **Seq:** 1 **Gender:** M
Reported: 11/01/2001 **Weight:** 55.00
Hospitalisation: **Age:** 72
Onset Date: 28/12/2000 **DOB:** 10/07/1928
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			Replaced haloperidol with risperidone. date of recovery 05/01/01. patient hospitalised.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
Injection 4.0 Milligram Daily Subcutaneous
Batch: **Started:** 27/12/2000 **Stopped:** 02/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking clonazepam, midazolam, morphine, gentamicin, trimethoprim.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 161478 **Seq:** 1 **Gender:** F
Reported: 14/02/2001 **Weight:** 40.00
Hospitalisation: **Age:** 78Y
Onset Date: 26/10/2000 **DOB:**
Outcome: Unrelated death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Pyrexia			Bromocriptine. date of death 30/10/00 - unrelated.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Anxiety neurosis
Oral application 0.5 Milligram As necessary Oral
Batch: **Started:** 20/10/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking pethidine, heparin sodium, aspirin, digoxin, metoprolol, moclobemide, ranitidine, oxazepam, pexid, norvasc. cause of death - cerebrovascular accident.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 162183 **Seq:** 1 **Gender:** M
Reported: 24/01/2001 **Weight:**
Hospitalisation: **Age:** 28
Onset Date: 08/01/2001 **DOB:** 28/01/1972
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Tachycardia		Asymptomatic of cardiac illness	Urgent cardiology assessment. required a visit to doctor.

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
500.0 Milligram Daily
Batch: **Started:** 01/11/1998 **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:**
1.5 Milligram Daily
Batch: **Started:** 01/11/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph Other data				Ecg 12/00 - sinus tachycardia Cardiac echo (08/01/01): mild global left ventricular systolic dysfunction.

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.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 162377 **Seq:** 1 **Gender:** F
Reported: 08/03/2001 **Weight:**
Hospitalisation: **Age:** 91Y
Onset Date: 20/02/2001 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coma Hypertonia			 Monitoring, coma position.

Medicine Details:

SERENACE (Suspected) **Reason:**
Tablet 0.5 Milligram Daily Oral
Batch: **Started:** 19/02/2001 **Stopped:** 20/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking - solprin, ksr, lanoxin pg, febridol, panadeine, coloxyl with senna and frusemide.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 162481 **Seq:** 1 **Gender:** F
Reported: 09/03/2001 **Weight:** 69.00
Hospitalisation: **Age:** 32Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		50 kg in 1996. 69-70kg in 2001	Therapy changed to quetiapine.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
3.0 Milligram Daily
Batch: **Started:** 01/06/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sequelae: decreased seft esteem. doesn't socialise. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Details:

Case Number: 163047 **Seq:** 1
Reported: 27/03/2001
Hospitalisation: Admitted to hospital
Onset Date: 27/01/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 33
DOB: 25/05/1967
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coma Neuroleptic malignant syndrome Syncope	Life threatening	Multi organ failure.	Life support, icu admission, intubation-> tracheo, iv fluids,/electrolyte balance. patient in icu 42 days now in medical ward.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
475.0 Milligram Daily
Batch: **Started:** 10/11/1998 **Stopped:** 27/01/2001

HALOPERIDOL (Suspected) **Reason:** Schizophrenia
5.0 Milligram Daily
Batch: **Started:** 01/09/2000 **Stopped:** 27/01/2001

LITHIUM CARBONATE (Suspected) **Reason:** Schizophrenia
1.0 Gram Daily
Batch: **Started:** 01/09/2000 **Stopped:** 27/01/2001

BENZTROPINE MESYLATE (Suspected) **Reason:** Schizophrenia
2.0 Milligram Daily
Batch: **Started:** 01/09/2000 **Stopped:** 28/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not necessarily accurate but indicates the drug was started sometime in the month. sequelae: evidence of brain damage.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 163524 **Seq:** 1 **Gender:** U
Reported: 09/04/2001 **Weight:**
Hospitalisation: **Age:** 84
Onset Date: 29/01/2001 **DOB:** 11/05/1916
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor		Prominent intentional tremor.(parkinson's dis).	Withdrawn haloperidol and metoclopramide therapy.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

METOCLOPRAMIDE HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Haloperidol used for confusional state associated with 3 weeks sedation and ventilation.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 163648 **Seq:** 1
Reported: 12/04/2001
Hospitalisation: Admitted to hospital
Onset Date: 09/08/2000
Outcome: Recovered

Gender: M
Weight:
Age: 17
DOB: 08/12/1982
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gait disturbance		Difficulty in walking.	
Dystonia		Muscle tightness in foot / ankle.	Patient was hospitalised. cease serenace. add benztropine, diazepam. date of recovery: 10/8/2000.
Pharyngitis		Sore jaw and throat.	
Agitation			
Anxiety			
Dyspnoea			
Stridor			
Torticollis			

Medicine Details:

SERENACE (Suspected) **Reason:** Otr spec symp psychopathol nec

Injection 10.0 Milligram 1 time Intramuscular

Batch: **Started:** 09/08/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 163762 **Seq:** 1 **Gender:** F
Reported: 17/04/2001 **Weight:**
Hospitalisation: **Age:** 57
Onset Date: 03/04/2001 **DOB:** 23/10/1943
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Neuroleptic malignant syndrome			Dantrolene, cogentin, bromocriptine, sinemet.

Medicine Details:

CEFTRIAXONE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:** 30/03/2001

GENTAMICIN SULPHATE (Other drug) **Reason:**
0.0
Batch: **Started:** 27/03/2001 **Stopped:**

AMOXYCILLIN SODIUM (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:** 04/04/2001

PROTAPHANE (Other drug) **Reason:**
44.0 Unit Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine phosphokinase		26/03/2001	52	
	Creatine phosphokinase		03/04/2001	333	
	Creatine phosphokinase		04/04/2001	316	
	Creatine phosphokinase		05/04/2001	252	
	Creatine phosphokinase		06/04/2001	1347	
	Creatine phosphokinase		06/04/2001	1623	
	Creatine phosphokinase		07/04/2001	1367	

Additional Information:

Previous nms secondary to haloperidol.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 163762 **Seq:** 1
Reported: 17/04/2001
Hospitalisation:
Onset Date: 03/04/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 57
DOB: 23/10/1943
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Other drug)			**Reason:**	
	0.5 Milligram		Daily	
Batch:	**Started:** 26/03/2001		**Stopped:**	
CLONAZEPAM (Other drug)			**Reason:**	
	75.0 Milligram		Daily	
Batch:	**Started:** 26/03/2001		**Stopped:**	
HALOPERIDOL (Suspected)			**Reason:**	
Injection	0.5 Milligram		1 time	Intramuscular
Batch:	**Started:** 28/03/2001		**Stopped:**	
RISPERIDONE (Suspected)			**Reason:**	
Oral application	1.0 Milligram		Daily	Oral
Batch:	**Started:** 30/03/2001		**Stopped:**	04/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		09/04/2001	403	

Additional Information:

Previous nms secondary to haloperidol.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 163762 **Seq:** 1
Reported: 17/04/2001
Hospitalisation:
Onset Date: 03/04/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 57
DOB: 23/10/1943
Causality: Causality possible

Reaction Details:

Medicine Details:

METFORMIN HYDROCHLORIDE (Suspected)		**Reason:** Diabetes mellitus	
	2.0 Gram	Daily	
Batch:	**Started:** 29/03/2001		**Stopped:** 04/04/2001

Laboratory Investigations:

Additional Information:

Previous nms secondary to haloperidol.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 163981 **Seq:** 1
Reported: 26/04/2001
Hospitalisation: Admitted to hospital
Onset Date: 04/04/2001
Outcome: Unknown

Gender: M
Weight:
Age: 52
DOB: 03/03/1949
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Choking Dysphagia Tongue oedema			Patient hospitalised. serenace stopped.

Medicine Details:

SULFAMETHOXAZOLE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

DUPHALAC (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

COLOXYL WITH SENNA (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ERGOCALCIFEROL (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 163981 **Seq:** 1
Reported: 26/04/2001
Hospitalisation: Admitted to hospital
Onset Date: 04/04/2001
Outcome: Unknown

Gender: M
Weight:
Age: 52
DOB: 03/03/1949
Causality: Causality possible

Reaction Details:

Medicine Details:

ALENDRONATE SODIUM (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
SERENACE (Suspected)		**Reason:**	
	5.0 Milligram	Daily	
Batch:	**Started:** 02/04/2001		**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 164437 **Seq:** 1
Reported: 11/05/2001
Hospitalisation: Admitted to hospital
Onset Date: 04/03/2001
Outcome: Recovered

Gender: F
Weight: 55.00
Age: 74
DOB: 15/01/1927
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia Extrapyramidal disorder			Patient was hospitalised. changed to olanzapine.

Medicine Details:

ASTRIX 100 (Other drug) **Reason:** Chron isch heart dis no hyper
100.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

ATENOLOL (Other drug) **Reason:** Essential benign hypertension
50.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

PERINDOPRIL (Other drug) **Reason:** Essential benign hypertension
4.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

DIGOXIN (Other drug) **Reason:** Otr&nos disord of heart rhythm
125.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 164437 **Seq:** 1
Reported: 11/05/2001
Hospitalisation: Admitted to hospital
Onset Date: 04/03/2001
Outcome: Recovered

Gender: F
Weight: 55.00
Age: 74
DOB: 15/01/1927
Causality: Causality possible

Reaction Details:

Medicine Details:

ATORVASTATIN (Other drug)			**Reason:**	Othr&unspec metabolic diseases	
	20.0	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	CONTIN
FERRO-GRADUMET (Other drug)			**Reason:**	Anorexia	
	350.0	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	CONTIN
DOXEPIN HYDROCHLORIDE (Other drug)			**Reason:**	Specific disorders of sleep	
	25.0	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	CONTIN
HALOPERIDOL (Suspected)			**Reason:**	Hallucinations	
	3.0	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	02/03/2001

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 164438 **Seq:** 1
Reported: 11/05/2001
Hospitalisation: Admitted to hospital
Onset Date: 04/03/2001
Outcome: Recovered

Gender: F
Weight: 55.00
Age: 74
DOB: 15/01/1927
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope		Found collapsed on floor.	
Coordination abnormal		Loss of balance.	
Confusional state		Rapid deterioration in mental state.	Patient was hospitalised. ceased olanzapine on admission.

Medicine Details:

ASTRIX 100 (Other drug) **Reason:** Chron isch heart dis no hyper
100.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

ATENOLOL (Other drug) **Reason:** Essential benign hypertension
50.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

PERINDOPRIL (Other drug) **Reason:** Essential benign hypertension
4.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

DIGOXIN (Other drug) **Reason:** Otr&nos disord of heart rhythm
125.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 164438 **Seq:** 1
Reported: 11/05/2001
Hospitalisation: Admitted to hospital
Onset Date: 04/03/2001
Outcome: Recovered

Gender: F
Weight: 55.00
Age: 74
DOB: 15/01/1927
Causality: Causality possible

Reaction Details:

Medicine Details:

ATORVASTATIN (Other drug)			**Reason:**	Othr&unspec metabolic diseases	
	20.0	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	CONTIN
FERRO-GRADUMET (Other drug)			**Reason:**	Anorexia	
	350.0	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	CONTIN
DOXEPIN HYDROCHLORIDE (Other drug)			**Reason:**	Specific disorders of sleep	
	25.0	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	CONTIN
HALOPERIDOL (Suspected)			**Reason:**	Hallucinations	
	3.0	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	02/03/2001

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 164438 **Seq:** 1
Reported: 11/05/2001
Hospitalisation: Admitted to hospital
Onset Date: 04/03/2001
Outcome: Recovered

Gender: F
Weight: 55.00
Age: 74
DOB: 15/01/1927
Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected) **Reason:** Unspecified psychosis
5.0 Milligram Daily
Batch: **Started:** 02/03/2001 **Stopped:** 05/03/2001

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 164821 **Seq:** 1 **Gender:** M
Reported: 24/05/2001 **Weight:**
Hospitalisation: **Age:** 33Y
Onset Date: 03/05/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Given im benztropine 3mg.

Medicine Details:

DIAZEPAM (Other drug) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 01/05/2001 **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Schizophrenia
Oral application 10.0 Milligram Daily Oral
Batch: **Started:** 01/05/2001 **Stopped:** 04/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 4/5/01.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 164887 **Seq:** 1 **Gender:** U
Reported: 28/05/2001 **Weight:**
Hospitalisation: **Age:** 91
Onset Date: 21/02/2001 **DOB:** 13/05/1909
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coma Hypertonia			

Medicine Details:

PANADEINE (Other drug) **Reason:**
2.0 Dose Unspecified As necessary
Batch: **Started:** 18/01/2001 **Stopped:**

COLOXYL WITH SENNA (Other drug) **Reason:**
2.0 Dose Unspecified As necessary
Batch: **Started:** 18/01/2001 **Stopped:**

SOLPRIN (Other drug) **Reason:**
150.0 Milligram Daily
Batch: **Started:** 18/01/2001 **Stopped:**

POTASSIUM CHLORIDE (Other drug) **Reason:**
Oral application 1.2 Gram Daily Oral
Batch: **Started:** 18/01/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 164887 **Seq:** 1 **Gender:** U
Reported: 28/05/2001 **Weight:**
Hospitalisation: **Age:** 91
Onset Date: 21/02/2001 **DOB:** 13/05/1909
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

DIGOXIN (Other drug)			**Reason:**	
Tablet	3.0	Dose Unspecified	Daily	Oral
Batch:	**Started:** 08/02/2001		**Stopped:**	
FRUSEMIDE (Other drug)			**Reason:**	
Tablet	40.0	Milligram	Daily	Oral
Batch:	**Started:** 18/01/2001		**Stopped:**	
HALOPERIDOL (Suspected)			**Reason:**	
	0.5	Milligram	Daily	
Batch:	**Started:** 19/02/2001		**Stopped:**	20/02/2001

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 164904 **Seq:** 1 **Gender:** M
Reported: 28/05/2001 **Weight:**
Hospitalisation: **Age:** 72
Onset Date: **DOB:** 18/04/1929
Outcome: Unknown **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction.	Resolved without treatment.

Medicine Details:

DIAZEPAM (Other drug) **Reason:**
5.0 Milligram As necessary
Batch: **Started:** **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:** Paralysis agitans
Injection 0.0 1 time Intramuscular
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 166444 **Seq:** 1 **Gender:** M
Reported: 17/07/2001 **Weight:**
Hospitalisation: **Age:** 24
Onset Date: 16/05/2001 **DOB:** 27/10/1976
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia			Given im benzytropine 2mg.

Medicine Details:

HALOPERIDOL (Suspected)		**Reason:**	
Injection	10.0 Milligram	1 time	Intravenous
Batch:	**Started:** 15/05/2001		**Stopped:**
MIDAZOLAM (Suspected)		**Reason:**	
Injection	15.0 Milligram	1 time	Intravenous
Batch:	**Started:** 15/05/2001		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient described as lying on bed in regid position, head arched back, mouth wide open and deep gutteral sounds at 7.00am, approx 18 1/2 - 19 hours post iv haloperidol dose.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 166474 **Seq:** 1 **Gender:** M
Reported: 17/07/2001 **Weight:**
Hospitalisation: **Age:** 35
Onset Date: 18/05/2001 **DOB:** 20/02/1966
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tetany		Stiffness in jaw	Given benztropine

Medicine Details:

TIMOLOL MALEATE (Other drug) **Reason:**
1.0 Milligram Daily
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
Injection 15.0 Milligram 1 time Intravenous
Batch: **Started:** 18/05/2001 **Stopped:** 18/05/2001

MIDAZOLAM (Suspected) **Reason:**
Injection 8.0 Milligram 1 time Intravenous
Batch: **Started:** 18/05/2001 **Stopped:** 18/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 166489 **Seq:** 1 **Gender:** F
Reported: 17/07/2001 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: 18/05/2001 **DOB:** 10/09/1950
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction	
Hypertonia		Stiffness, hyper extension neck, increased tone	Given benztropine. ceased metoclopramide, haloperidol and olanzapine.

Medicine Details:

CIPROFLOXACIN (Other drug) **Reason:**
600.0 Milligram Daily
Batch: **Started:** 15/05/2001 **Stopped:** 23/05/2001

TRAMADOL HYDROCHLORIDE (Other drug) **Reason:** Pain
400.0 Milligram Daily
Batch: **Started:** 17/05/2001 **Stopped:**

SORBILAX (Other drug) **Reason:**
40.0 Millilitre Daily
Batch: **Started:** 13/05/2001 **Stopped:**

COLOXYL WITH SENNA (Other drug) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** 13/05/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 166489 **Seq:** 1 **Gender:** F
Reported: 17/07/2001 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: 18/05/2001 **DOB:** 10/09/1950
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

FLUCLOXACILLIN SODIUM (Other drug)			**Reason:**	
Injection	4.0 Gram		Daily	Intravenous
Batch:	**Started:** 15/05/2001		**Stopped:**	23/05/2001
METOCLOPRAMIDE HYDROCHLORIDE (Suspected)			**Reason:**	
Injection	30.0 Milligram		Daily	Intravenous
Batch:	**Started:** 15/05/2001		**Stopped:**	18/05/2001
HALOPERIDOL (Suspected)			**Reason:**	Anxiety neurosis
	10.0 Milligram		Daily	
Batch:	**Started:** 17/05/2001		**Stopped:**	18/05/2001
OLANZAPINE (Suspected)			**Reason:**	Anxiety neurosis
	5.0 Milligram		Daily	
Batch:	**Started:** 18/05/2001		**Stopped:**	18/05/2001

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 167089 **Seq:** 1 **Gender:** M
Reported: 01/08/2001 **Weight:** 102.00
Hospitalisation: **Age:** 84
Onset Date: **DOB:** 02/02/1917
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence			Patient already hospitalised. haloperidol reduced to 2mg daily.

Medicine Details:

NITROLINGUAL PUMPSPRAY (Other drug)			**Reason:**	
Inhalation	400.0	Microgram	As necessary	Inhalation
Batch:	**Started:**			**Stopped:**
ASTRIX 100 (Other drug)			**Reason:**	
Tablet	100.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**
ATENOLOL (Other drug)			**Reason:**	
Tablet	25.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**
COGENTIN (Other drug)			**Reason:**	
Tablet	4.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous history of cardiac arrest with some intellectual impairment.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 167089 **Seq:** 1
Reported: 01/08/2001
Hospitalisation:
Onset Date:
Outcome: Unknown

Gender: M
Weight: 102.00
Age: 84
DOB: 02/02/1917
Causality: Causality possible

Reaction Details:

Medicine Details:

NAPROSYN (Other drug)			**Reason:**	
Tablet	750.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**
PROGOUT (Other drug)			**Reason:**	
Tablet	300.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**
SLOW-K (Other drug)			**Reason:**	
Tablet	1.2	Gram	Daily	Oral
Batch:	**Started:**			**Stopped:**
HALOPERIDOL (Suspected)			**Reason:**	Explosive personality disorder
Oral application	3.0	Milligram	Daily	Oral
Batch:	**Started:**	28/06/2001		**Stopped:**

Laboratory Investigations:

Additional Information:

Previous history of cardiac arrest with some intellectual impairment.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 167090 **Seq:** 1
Reported: 01/08/2001
Hospitalisation:
Onset Date: 24/07/2001
Outcome: Not yet recovered

Gender: M
Weight: 102.00
Age: 84
DOB: 02/02/1917
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia			Benztropine 2mg orally single dose, ampicillin 500mg imi.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**

Injection 0.5 Milligram Daily Intramuscular

Batch: **Started:** 18/07/2001 **Stopped:** 19/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 167517 **Seq:** 1 **Gender:** M
Reported: 03/08/2001 **Weight:**
Hospitalisation: **Age:** 32
Onset Date: 28/02/2001 **DOB:** 26/08/1968
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

BENZTROPINE MESYLATE (Suspected) **Reason:**
0.5 Milligram Daily
Batch: **Started:** **Stopped:**

SODIUM VALPROATE (Suspected) **Reason:**
500.0 Milligram Daily
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
15.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 167775 **Seq:** 1
Reported: 22/08/2001
Hospitalisation: Admitted to hospital
Onset Date: 25/07/2001
Outcome: Not yet recovered

Gender: M
Weight: 90.00
Age: 22
DOB: 24/12/1978
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Pneumonia Pyrexia Respiratory disorder Tachycardia			Patient hospitalised.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified psychosis
350.0 Milligram Daily
Batch: **Started:** 01/05/2001 **Stopped:** 04/08/2001

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
5.0 Milligram Daily
Batch: **Started:** 11/07/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Echo (cardiac) - showed 30% ejection fraction and signs of cardiomyopathy. on 31/07/01 patient developed right lower lobe consolidation tachypnoea, tachycardia and fever.

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 168115 **Seq:** 1 **Gender:** F
Reported: 04/09/2001 **Weight:**
Hospitalisation: **Age:** 57
Onset Date: 10/08/2001 **DOB:** 17/02/1944
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gait disturbance		Stiff gait	Required a visit to doctor. ceased serenace.
Hypertonia		Stiff heavy arms, can not swing them.	
Dystonia			
Tremor			

Medicine Details:

AVAPRO (Other drug) **Reason:** Essential benign hypertension
75.0 Milligram Daily
Batch: **Started:** 03/08/2001 **Stopped:** 10/08/2001

DICHLOTRIDE (Other drug) **Reason:** Essential benign hypertension
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/03/2001 **Stopped:**

CARDIZEM CD (Other drug) **Reason:** Essential benign hypertension
Capsule 180.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

CARTIA (Other drug) **Reason:** Acute myocard infarc,no hypert
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 168115 **Seq:** 1
Reported: 04/09/2001
Hospitalisation:
Onset Date: 10/08/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 57
DOB: 17/02/1944
Causality: Causality possible

Reaction Details:

Medicine Details:

PREMARIN (Other drug)				**Reason:**	Menopausal symptoms
Tablet	1.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**	L TERM		**Stopped:**	
PRAVACHOL (Other drug)				**Reason:**	Othr&unspec metabolic diseases
	20.0	Milligram	Daily		
Batch:	**Started:**	03/05/2001		**Stopped:**	
SERENACE (Suspected)				**Reason:**	Cough
Tablet	1.0	Milligram	Daily		Oral
Batch:	**Started:**	26/06/2001		**Stopped:**	10/08/2001

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 168450 **Seq:** 1
Reported: 14/09/2001
Hospitalisation: Admitted to hospital
Onset Date: 24/08/2001
Outcome: Recovered

Gender: F
Weight:
Age: 31
DOB: 24/07/1970
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Chills Neuroleptic malignant syndrome Orthostatic hypotension Tachycardia		Temperature of 39.5 degrees.	Admitted to hospital.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified schizophrenia

2.5 Milligram As necessary

Batch: **Started:** 25/07/2001 **Stopped:** 12/08/2001

CLOZARIL (Suspected) **Reason:**

Tablet 250.0 Milligram Daily Oral

Batch: **Started:** 10/08/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozaril was ongoing, but the patient had subsequently ceased therapy.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 168977 **Seq:** 1 **Gender:** F
Reported: 05/10/2001 **Weight:**
Hospitalisation: **Age:** 39
Onset Date: 22/09/2001 **DOB:** 11/11/1961
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

CLOPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 162.5 Milligram Total Oral
Batch: **Started:** 20/09/2001 **Stopped:** 23/09/2001

HALOPERIDOL (Suspected) **Reason:** Unspecified neurosis
Injection 5.0 Milligram As necessary Intramuscular
Batch: **Started:** 20/09/2001 **Stopped:** 24/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	1-40	22/09/2001	253	
	ALT = SGPT	1-40	24/09/2001	385	
	AST = SGOT	1-30	22/09/2001	-	
	AST = SGOT	1-30	24/09/2001	189	
	GGT = SGGT =	1-25	22/09/2001	341	
	GGT = SGGT =	1-25	24/09/2001	322	
	SAP = ALP	25-100	22/09/2001	-	

Additional Information:

Previously raised lft's following olanzapine and epilim. the patient is hep c positive and hep c rna positive.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 168977 **Seq:** 1
Reported: 05/10/2001
Hospitalisation:
Onset Date: 22/09/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 39
DOB: 11/11/1961
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)			**Reason:**	Unspecified schizophrenia
Tablet	162.5 Milligram		Total	Oral
Batch:	**Started:** 20/09/2001		**Stopped:**	23/09/2001
HALOPERIDOL (Suspected)			**Reason:**	Unspecified neurosis
Injection	5.0 Milligram		As necessary	Intramuscular
Batch:	**Started:** 20/09/2001		**Stopped:**	24/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP	25-100	24/09/2001	254	

Additional Information:

Previously raised lft's following olanzapine and epilim. the patient is hep c positive and hep c rna positive.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 169813 **Seq:** 1 **Gender:** M
Reported: 07/11/2001 **Weight:** 72.00
Hospitalisation: **Age:** 78
Onset Date: 13/08/2001 **DOB:** 25/03/1923
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema			Mirtazapine decreased to 15mg.

Medicine Details:

CAPOTEN (Other drug) **Reason:**
150.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** 26/06/2001 **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
500.0 Microgram Daily
Batch: **Started:** 06/08/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Details:

Case Number: 169820 **Seq:** 1 **Gender:** F
Reported: 07/11/2001 **Weight:**
Hospitalisation: **Age:** 51Y
Onset Date: 19/07/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Required Visit to Doctor	Moderate dystonia.	Benztropine 1-2mg iv/im prn.

Medicine Details:

BUSCOPAN (Other drug) **Reason:**
10.0 Milligram As necessary
Batch: **Started:** **Stopped:**

PARACETAMOL (Other drug) **Reason:**
Suppository 1.0 Dose Unspecified As necessary Rectal
Batch: **Started:** **Stopped:**

ATIVAN (Other drug) **Reason:** Nausea and vomiting
Tablet 1.5 Milligram As necessary Sublingual
Batch: **Started:** 11/07/2001 **Stopped:**

PREMARIN (Other drug) **Reason:**
1.2 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 169820 **Seq:** 1 **Gender:** F
Reported: 07/11/2001 **Weight:**
Hospitalisation: **Age:** 51Y
Onset Date: 19/07/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

HEPARIN SODIUM (Other drug)			**Reason:**		
Injection	10.0	Thousand Internal	Daily		Subcutaneous
Batch:	**Started:** 27/06/2001			**Stopped:**	
AMITRIPTYLINE HYDROCHLORIDE (Other drug)			**Reason:**		
	50.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	
FENTANYL TRANSDERMAL (Suspected)			**Reason:**		
Cream	300.0	Microgram	Weekly		Transdermal
Batch:	**Started:** 06/07/2001			**Stopped:**	
PROMETHAZINE HYDROCHLORIDE (Suspected)			**Reason:**		
Injection	100.0	Milligram	Daily		Intramuscular
Batch:	**Started:** 13/07/2001			**Stopped:**	

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 169820 **Seq:** 1 **Gender:** F
Reported: 07/11/2001 **Weight:**
Hospitalisation: **Age:** 51Y
Onset Date: 19/07/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)			**Reason:** Nausea and vomiting	
Injection	3.0 Milligram	Daily	Subcutaneous	
Batch:	**Started:** 16/07/2001		**Stopped:**	

Laboratory Investigations:

Additional Information:

Report Details:

Case Number: 170144 **Seq:** 1 **Gender:** M
Reported: 21/11/2001 **Weight:**
Hospitalisation: **Age:** 76Y
Onset Date: 04/09/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Ceased dicloxacillin, had a liver ultrasound.

Medicine Details:

WARFARIN SODIUM (Other drug) **Reason:**
2.0 Milligram As necessary
Batch: **Started:** 30/08/2001 **Stopped:** CONTIN

OXYCONTIN (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 31/08/2001 **Stopped:** CONTIN

DICLOXACILLIN SODIUM (Suspected) **Reason:** Chronic ulcer of skin
1.0 Gram Daily
Batch: **Started:** 30/08/2001 **Stopped:** 06/09/2001

HALOPERIDOL (Suspected) **Reason:** Nausea and vomiting
1.0 Milligram Daily
Batch: **Started:** 03/09/2001 **Stopped:** 06/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT = [illegible]		12/08/2001	62	
	GGT = SGGT = [illegible]		04/09/2001	142	
	GGT = SGGT = [illegible]		05/09/2001	150	
	GGT = SGGT = [illegible]		19/09/2001	92	
	GGT = SGGT = [illegible]		11/09/2001	139	
	SAP = ALP		12/08/2001	108	
	SAP = ALP		04/09/2001	213	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 170144 **Seq:** 1 **Gender:** M
Reported: 21/11/2001 **Weight:**
Hospitalisation: **Age:** 76Y
Onset Date: 04/09/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

METRONIDAZOLE (Suspected)		**Reason:**	
	1.2 Gram	Daily	
Batch:	**Started:** 04/09/2001		**Stopped:** 10/09/2001
NORFLOXACIN (Suspected)		**Reason:**	Othr diseases of urinary tract
	1.0 Gram	Daily	
Batch:	**Started:** 03/09/2001		**Stopped:** 10/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP		05/09/2001	232	
	SAP = ALP		11/09/2001	166	
	SAP = ALP		19/09/2001	100	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 170678 **Seq:** 1
Reported: 29/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 03/04/2001
Outcome: Not yet recovered

Gender: F
Weight: 100.00
Age: 57Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Constipation Somnolence Vomiting			Hydration, metoclopramide, sorbitol, movicol. hospital admission.

Medicine Details:

PROZAC (Other drug)			**Reason:**	Depression	
Tablet	60.0	Milligram	Daily	Oral	
Batch:	**Started:**	L TERM	**Stopped:**		CONTIN
METHADONE HYDROCHLORIDE (Other drug)			**Reason:**	Pain	
Oral application	30.0	Milligram	Daily	Oral	
Batch:	**Started:** 12/02/2001		**Stopped:**		CONTIN
COLOXYL WITH SENNA (Other drug)			**Reason:**		
Oral application	4.0	Dose Unspecified	Daily	Oral	
Batch:	**Started:**		**Stopped:**		
CARBOPLATIN (Suspected)			**Reason:**	Malignant neoplasm of ovary	
Injection	740.0	Milligram	Daily	Intravenous	
Batch:	**Started:** 29/03/2001		**Stopped:**	29/03/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Third cycle of chemotherapy; 3-week cycles

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 170678 **Seq:** 1
Reported: 29/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 03/04/2001
Outcome: Not yet recovered

Gender: F
Weight: 100.00
Age: 57Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

PACLITAXEL (Suspected)			**Reason:**	Malignant neoplasm of ovary
Injection	350.0	Milligram	Daily	Intravenous
Batch:	**Started:**	29/03/2001	**Stopped:**	29/03/2001
DEXAMETHASONE (Suspected)			**Reason:**	Nausea and vomiting
Oral application	8.0	Milligram	Daily	Oral
Batch:	**Started:**	30/03/2001	**Stopped:**	01/04/2001
ONDANSETRON HYDROCHLORIDE DIHYDRATE (Suspected)			**Reason:**	Nausea and vomiting
Oral application	16.0	Milligram	Daily	Oral
Batch:	**Started:**	29/03/2001	**Stopped:**	30/03/2001
STEMETIL (Suspected)			**Reason:**	Nausea and vomiting
Oral application	15.0	Milligram	Daily	Oral
Batch:	**Started:**	01/03/2001	**Stopped:**	

Laboratory Investigations:

Additional Information:

Third cycle of chemotherapy; 3-week cycles

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 170678 **Seq:** 1
Reported: 29/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 03/04/2001
Outcome: Not yet recovered

Gender: F
Weight: 100.00
Age: 57Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)		**Reason:**	Other disturbance of sensation
Oral application	2.5 Milligram	Daily	Oral
Batch:	**Started:** 01/03/2001	**Stopped:**	

Laboratory Investigations:

Additional Information:

Third cycle of chemotherapy; 3-week cycles

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 170870 **Seq:** 1 **Gender:** M
Reported: 07/12/2001 **Weight:** 67.00
Hospitalisation: **Age:** 21
Onset Date: 23/11/2001 **DOB:** 08/09/1980
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation Headache			Cogentin. required a visit to doctor

Medicine Details:

SERENACE (Suspected) **Reason:**
5.0 Milligram Daily
Batch: **Started:** 23/11/2001 **Stopped:** 23/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 171949 **Seq:** 1 **Gender:** M
Reported: 06/12/2001 **Weight:**
Hospitalisation: **Age:** 83
Onset Date: 13/11/2001 **DOB:** 08/11/1918
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Haloperidol ceased.

Medicine Details:

DIAZEPAM (Other drug) **Reason:** Neuroses
Oral application 0.0 Oral
Batch: **Started:** **Stopped:**

ATENOLOL (Other drug) **Reason:** Essential benign hypertension
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

PERHEXILINE MALEATE (Other drug) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

HALDOL DECANOATE (Suspected) **Reason:**
Injection 1.0 Dose Unspecified 4 times Intravenous
Batch: **Started:** 05/11/2001 **Stopped:** 09/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 171949 **Seq:** 1
Reported: 06/12/2001
Hospitalisation:
Onset Date: 13/11/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 83
DOB: 08/11/1918
Causality: Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)			**Reason:**	
Injection	2.0 Milligram		1 time	Intramuscular
Batch:	**Started:** 05/11/2001		**Stopped:**	09/11/2001
RISPERDAL (Suspected)			**Reason:**	
Tablet	1.0 Milligram		Daily	Oral
Batch:	**Started:** 05/11/2001		**Stopped:**	12/11/2001

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 172482 **Seq:** 1
Reported: 04/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 13/11/2001
Outcome: Not yet recovered

Gender: M
Weight: 77.00
Age: 83
DOB: 08/11/1918
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension Neuroleptic malignant syndrome Weight decreased			Midazolam. patient hospitalised.

Medicine Details:

WARFARIN SODIUM (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
Injection 4.0 Dose Unspecified Total Intravenous
Batch: **Started:** 05/11/2001 **Stopped:** 09/11/2001

GALANTAMINE HYDROBROMIDE (Suspected) **Reason:**
Tablet 24.0 Milligram Daily Oral
Batch: **Started:** 08/12/2000 **Stopped:** 10/11/2001

RISPERIDONE (Suspected) **Reason:**
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** 05/11/2001 **Stopped:** 12/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 172697 **Seq:** 1 **Gender:** F
Reported: 11/02/2002 **Weight:**
Hospitalisation: **Age:** 83Y
Onset Date: 05/12/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state		Increased confusion.	Serenace ceased.
Tremor		Resting temor and cogwhiil rigidity.	
Asthenia		Weakness of legs.	
Back pain			
Hallucination			
Hypertonia			

Medicine Details:

BETALOC (Other drug) **Reason:**
100.0 Milligram Daily
Batch: **Started:** **Stopped:**

COVERSYL (Other drug) **Reason:**
2.0 Milligram Daily
Batch: **Started:** **Stopped:**

DEPTRAN (Other drug) **Reason:**
25.0 Milligram Daily
Batch: **Started:** **Stopped:**

DIABEX (Other drug) **Reason:**
1.0 Gram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 172697 **Seq:** 1
Reported: 11/02/2002
Hospitalisation:
Onset Date: 05/12/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 83Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

LOSEC (Other drug)			**Reason:**	
	20.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
MELIZIDE (Other drug)			**Reason:**	
	5.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
SERENACE (Suspected)			**Reason:**	
	2.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:** 08/12/2001

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 172730 **Seq:** 1
Reported: 13/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 06/02/2002
Outcome: Not yet recovered

Gender: F
Weight:
Age: 57
DOB: 13/12/1944
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation		Agitated pacing.	
Dysuria		Difficulty in passing urine.	
Dysarthria		Slurred speech.	
Agitation			Patient was hospitalised. ceased medications.
Hyperhidrosis			
Hypertonia			
Tremor			

Medicine Details:

ANTENEX (Other drug) **Reason:**
5.0 Milligram As necessary
Batch: **Started:** **Stopped:**

TALOHEXAL (Suspected) **Reason:** Depression
80.0 Milligram Daily
Batch: **Started:** 01/02/2002 **Stopped:** 06/02/2002

HALOPERIDOL (Suspected) **Reason:**
7.5 Milligram Daily
Batch: **Started:** **Stopped:** 06/02/2002

COGENTIN (Suspected) **Reason:**
2.0 Milligram Daily
Batch: **Started:** **Stopped:** 01/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Two year history of depression with recent change in medications. anticholinergie - artane/congentin. ssri, serotinergic syndrone - citalopram. tardive dyskinesia - halopendol.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 172730 **Seq:** 1
Reported: 13/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 06/02/2002
Outcome: Not yet recovered

Gender: F
Weight:
Age: 57
DOB: 13/12/1944
Causality: Causality possible

Reaction Details:

Medicine Details:

TEMAZE (Suspected)		**Reason:**	
	10.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:** 06/02/2002
PRAVACHOL (Suspected)		**Reason:**	Othr&unspec metabolic diseases
	10.0 Milligram	Daily	
Batch:	**Started:** 01/02/2002		**Stopped:** 06/02/2002
ARTANE (Suspected)		**Reason:**	
	10.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:** 06/02/2002

Laboratory Investigations:

Additional Information:

Two year history of depression with recent change in medications. anticholinergie - artane/congentin. ssri, serotinergic syndrone - citalopram. tardive dyskinesia - halopendol.

Report Details:

Case Number: 172973 **Seq:** 1 **Gender:** F
Reported: 20/02/2002 **Weight:**
Hospitalisation: **Age:** 78Y
Onset Date: 12/12/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence			

Medicine Details:

HYDROCORTISONE (Other drug)				**Reason:**		
Eye Drops	2.0	Dose Unspecified	Daily		Ophthalmic	
Batch:	**Started:**			**Stopped:**		CONTIN
TIMOLOL MALEATE EYE DROPS (Other drug)				**Reason:**	Unspecified glaucoma	
Eye Drops	2.0	Dose Unspecified	Daily		Ophthalmic	
Batch:	**Started:**			**Stopped:**		CONTIN
BRIMONIDINE TARTRATE (Other drug)				**Reason:**	Unspecified glaucoma	
Eye Drops	2.0	Dose Unspecified	Daily		Ophthalmic	
Batch:	**Started:**			**Stopped:**		CONTIN
IRBESARTAN (Other drug)				**Reason:**	Essential benign hypertension	
Tablet	300.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**	17/12/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: low tolerance to anticholinergic drugs, poor renal function. sequelae: bedridden now, still drowsy, incoherent.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 172973 **Seq:** 1
Reported: 20/02/2002
Hospitalisation:
Onset Date: 12/12/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 78Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

LABETALOL HYDROCHLORIDE (Other drug)			**Reason:** Essential benign hypertension		
Tablet	200.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
CLOPIDOGREL (Other drug)			**Reason:**		
Tablet	75.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
HALOPERIDOL (Suspected)			**Reason:** Otr spec symp psychopathol nec		
Injection	2.5	Milligram	As necessary	Intravenous	
Batch:	**Started:** 12/12/2001			**Stopped:**	13/12/2001

Laboratory Investigations:

Additional Information:

Patient history: low tolerance to anticholinergic drugs, poor renal function. sequelae: bedridden now, still drowsy, incoherent.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 173278 **Seq:** 1
Reported: 01/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 24/01/2002
Outcome: Recovered

Gender: F
Weight: 98.00
Age: 43Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Decreased bp.	
Blood creatine phosphokinase incr		Elevated ck.	
Anuria		Not passing urine.	
Dyspnoea			
Generalised oedema			Patient was hospitalised. medication was reviewed and some withdrawn with polypharmacy being the major factor.
Peripheral ischaemia			

Medicine Details:

DERALIN (Other drug)			**Reason:** Anxiety neurosis	
Tablet	40.0 Milligram	Daily	Oral	
Batch:	**Started:** 24/01/2002		**Stopped:**	CONTIN
DERALIN (Suspected)			**Reason:** Anxiety neurosis	
Tablet	80.0 Milligram	Daily	Oral	
Batch:	**Started:** 17/01/2002		**Stopped:** 24/01/2002	
CIPRAMIL (Suspected)			**Reason:** Depression	
Tablet	40.0 Milligram	Daily	Oral	
Batch:	**Started:** 17/01/2002		**Stopped:** 24/01/2002	
PAXAM (Suspected)			**Reason:** Other disturbance of sensation	
Tablet	4.0 Milligram	Daily	Oral	
Batch:	**Started:** 17/01/2002		**Stopped:** 24/01/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 173278 **Seq:** 1
Reported: 01/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 24/01/2002
Outcome: Recovered

Gender: F
Weight: 98.00
Age: 43Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

PAXAM (Suspected)			**Reason:**	Other disturbance of sensation	
Tablet	2.0	Milligram	Daily		Oral
Batch:	**Started:**	24/01/2002		**Stopped:**	24/01/2002
NEURONTIN (Suspected)			**Reason:**		
Capsule	1.8	Gram	Daily		Oral
Batch:	**Started:**	21/01/2002		**Stopped:**	24/01/2002
NEURONTIN (Suspected)			**Reason:**		
Capsule	300.0	Milligram	Daily		Oral
Batch:	**Started:**	24/01/2002		**Stopped:**	28/01/2002
DROLEPTAN (Suspected)			**Reason:**	Otr spec symp psychopathol nec	
Injection	5.0	Milligram	Daily		Intravenous
Batch:	**Started:**	17/01/2002		**Stopped:**	26/01/2002

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 173278 **Seq:** 1
Reported: 01/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 24/01/2002
Outcome: Recovered

Gender: F
Weight: 98.00
Age: 43Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)			**Reason:**	Unspecified schizophrenia
Oral application	20.0 Milligram	Daily		Oral
Batch:	**Started:** 15/01/2002		**Stopped:**	24/01/2002
SEROQUEL (Suspected)			**Reason:**	Unspecified schizophrenia
Tablet	400.0 Milligram	Daily		Oral
Batch:	**Started:** 21/01/2002		**Stopped:**	24/01/2002
SERENACE (Suspected)			**Reason:**	Unspecified psychosis
Tablet	10.0 Milligram	Daily		Oral
Batch:	**Started:** 21/01/2002		**Stopped:**	24/01/2002

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 173995 **Seq:** 1
Reported: 27/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 15/03/2002
Outcome: Not yet recovered

Gender: F
Weight: 102.00
Age: 53
DOB: 01/01/1949
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Temp 37.7 degrees c	Haloperidol ceased and dantrolene on standby.
Blood creatine phosphokinase incr			
Delirium			
Diabetes insipidus			
Hypernatraemia			
Neuroleptic malignant syndrome			

Medicine Details:

LITHICARB (Interaction) **Reason:**
0.0
Batch: **Started:** **Stopped:**

SERENACE (Interaction) **Reason:** Unspecified schizophrenia
50.0 Milligram Daily
Batch: **Started:** **Stopped:** 18/03/2002

MIDAMOR (Other drug) **Reason:**
5.0 Milligram Daily
Batch: **Started:** **Stopped:** 13/03/2002

EPILIM (Other drug) **Reason:**
800.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine phosphokinase		16/03/2002	6851	
	Creatine phosphokinase		18/03/2002	2834	
	Creatine phosphokinase		21/03/2002	371	
	Creatinine	50 - 90	27/02/2002	290	
	Sodium	134 - 145	27/02/2002	160	

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 173995 **Seq:** 1
Reported: 27/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 15/03/2002
Outcome: Not yet recovered

Gender: F
Weight: 102.00
Age: 53
DOB: 01/01/1949
Causality: Causality possible

Reaction Details:

Medicine Details:

BETAMIN (Other drug)			**Reason:**	
	100.0	Milligram	Daily	
Batch:	**Started:**		**Stopped:**	CONTIN
COLOXYL WITH SENNA (Other drug)			**Reason:**	Constipation
	4.0	Dose Unspecified	Daily	
Batch:	**Started:**		**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 176473 **Seq:** 1 **Gender:** F
Reported: 20/06/2002 **Weight:**
Hospitalisation: **Age:** 81Y
Onset Date: 12/03/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Parkinsonism and associated decreased mobility.	Ceased haloperidol.

Medicine Details:

NIFEDIPINE (Other drug)			**Reason:**			
Oral application	10.0	Milligram	Daily	Oral		
Batch:	**Started:**			**Stopped:**		CONTIN
PREMARIN (Other drug)			**Reason:**	Menopausal symptoms		
	625.0	Microgram	Daily			
Batch:	**Started:**			**Stopped:**		CONTIN
CALTRATE (Other drug)			**Reason:**			
Tablet	600.0	Milligram	Daily	Oral		
Batch:	**Started:**			**Stopped:**		CONTIN
ASPIRIN (Other drug)			**Reason:**			
Oral application	100.0	Milligram	Daily	Oral		
Batch:	**Started:**			**Stopped:**		CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 176473 **Seq:** 1 **Gender:** F
Reported: 20/06/2002 **Weight:**
Hospitalisation: **Age:** 81Y
Onset Date: 12/03/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)			**Reason:**	
Oral application	2.0	Milligram	Daily	Oral
Batch:	**Started:**		**Stopped:**	12/03/2002

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 176991 **Seq:** 1 **Gender:** M
Reported: 10/07/2002 **Weight:** 64.00
Hospitalisation: **Age:**
Onset Date: 15/05/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chills	Life threatening	Life threatening.	
Neuroleptic malignant syndrome		Suspected.	
Chills			
Myopathy			
Pyrexia			

Medicine Details:

BROMOCRIPTINE MESYLATE (Other drug) **Reason:**
5.0 Milligram 1 time
Batch: **Started:** 15/05/2002 **Stopped:**

GENTAMICIN SULPHATE (Other drug) **Reason:**
180.0 Milligram Daily
Batch: **Started:** 13/05/2002 **Stopped:** 15/05/2002

TRAMADOL HYDROCHLORIDE (Other drug) **Reason:**
400.0 Milligram Daily
Batch: **Started:** 10/05/2002 **Stopped:** CONTIN

ENOXAPARIN (Other drug) **Reason:**
40.0 Milligram Daily
Batch: **Started:** 10/05/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 176991 **Seq:** 1 **Gender:** M
Reported: 10/07/2002 **Weight:** 64.00
Hospitalisation: **Age:**
Onset Date: 15/05/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)		**Reason:**	
	5.0 Milligram	As necessary	
Batch:	**Started:** 12/05/2002	**Stopped:**	15/05/2002

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 178734 **Seq:** 1 **Gender:** F
Reported: 05/09/2002 **Weight:**
Hospitalisation: **Age:** 51
Onset Date: 28/06/2001 **DOB:** 04/10/1949
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pain Aphasia Dystonia Muscle twitching		Neck tightnes	Cogentin

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

178734 is a seq of 178733. the date of onset is not necessarily accurate but indicates onset sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 178947 **Seq:** 1 **Gender:** M
Reported: 11/09/2002 **Weight:**
Hospitalisation: **Age:** 74Y
Onset Date: 01/08/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Extrapyramidal disorder Gait disturbance		Decreased mobility.	Ceased haloperidol

Medicine Details:

GLUCOSAMINE HYDROCHLORIDE (Other drug) **Reason:**
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

VITAMIN B COMPLEX (Other drug) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** CONTIN

OLANZAPINE (Other drug) **Reason:** Otr spec symp psychopathol nec
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:** CONTIN

OMEPRAZOLE (Other drug) **Reason:** Ulcer of duodenum w/o ment perf
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 178947 **Seq:** 1 **Gender:** M
Reported: 11/09/2002 **Weight:**
Hospitalisation: **Age:** 74Y
Onset Date: 01/08/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 179289 **Seq:** 1 **Gender:** M
Reported: 20/09/2002 **Weight:**
Hospitalisation: **Age:** 79
Onset Date: 28/08/2002 **DOB:** 15/01/1923
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion		Drooling.	Haloperidol cease.

Medicine Details:

MOGADON (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

LASIX (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

EXELON (Suspected) **Reason:** Unspecified psychosis
Capsule 6.0 Milligram Daily Oral
Batch: **Started:** 01/07/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for exelon is not necessarily accurate but indicates the drug was started sometime in the month. the date of onset is not necessarily accurate but indicates onset sometime in the month.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 179294 **Seq:** 1 **Gender:** M
Reported: 20/09/2002 **Weight:**
Hospitalisation: **Age:** 74Y
Onset Date: 05/04/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysphagia Confusional state Convulsion Hypertonia Neuroleptic malignant syndrome		Swallow slightly impaired.	Ceased serenace.

Medicine Details:

FRUSEMIDE (Other drug)			**Reason:**	
Tablet	20.0	Milligram	Daily	Oral
Batch:	**Started:**		**Stopped:**	05/04/2002
FAMOTIDINE (Other drug)			**Reason:**	
Tablet	40.0	Milligram	Daily	Oral
Batch:	**Started:**		**Stopped:**	
SERENACE (Suspected)			**Reason:**	
Tablet	5.0	Milligram	As necessary	Oral
Batch:	**Started:**		**Stopped:**	05/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of advance alzheimers, tia's, ihd, ht, sepsis, ami, dyspepsia, bph.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 179412 **Seq:** 1
Reported: 26/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 06/08/2002
Outcome: Recovered

Gender: F
Weight:
Age: 49
DOB: 08/11/1952
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt Coma Delirium Hallucination		Non-accidental overdose.	Patient was admitted to hospital and admitted to icu, treated with iv fluids, was ventilated and given other medicines in icu.

Medicine Details:

TRIFEME 28 (Other drug) **Reason:** Contraception
Oral application 0.0 Oral
Batch: **Started:** 01/06/2002 **Stopped:**

BEKUNIS-TABLET (Other drug) **Reason:** Constipation
Tablet 0.0 Oral
Batch: **Started:** 01/06/2002 **Stopped:**

ZYPREXA (Suspected) **Reason:** Unspecified schizophrenia
Tablet 2.5 Gram Total Oral
Batch: **Started:** **Stopped:**

EPILIM (Suspected) **Reason:**
Tablet 10.0 Gram Total Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 179412 **Seq:** 1
Reported: 26/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 06/08/2002
Outcome: Recovered

Gender: F
Weight:
Age: 49
DOB: 08/11/1952
Causality: Causality possible

Reaction Details:

Medicine Details:

SERENACE (Suspected)			**Reason:**	
Tablet	100.0	Gram	Total	Oral
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 179988 **Seq:** 1 **Gender:** M
Reported: 21/10/2002 **Weight:**
Hospitalisation: **Age:** 71
Onset Date: 19/09/2002 **DOB:** 12/02/1931
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Confusional state Oculogyration		Myoclonic jerks.	Given cogentin oral/im/iv for 4 - 5 days.

Medicine Details:

PARACETAMOL (Other drug) **Reason:**
8.0 Dose Unspecified As necessary
Batch: **Started:** **Stopped:**

FERRO-GRADUMET (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

AMIODARONE HYDROCHLORIDE (Other drug) **Reason:**
200.0 Milligram Daily
Batch: **Started:** **Stopped:**

CALTRATE (Other drug) **Reason:**
3.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sequelae yes: icu intubated. haemofiltration.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 179988 **Seq:** 1
Reported: 21/10/2002
Hospitalisation:
Onset Date: 19/09/2002
Outcome: Recovered with sequelae

Gender: M
Weight:
Age: 71
DOB: 12/02/1931
Causality: Causality possible

Reaction Details:

Medicine Details:

CIPRAMIL (Other drug)			**Reason:**		
	20.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	
HEPARIN SODIUM (Other drug)			**Reason:**		
Injection	10.0	Thousand Internal	Daily	Subcutaneous	
Batch:	**Started:**			**Stopped:**	
HALOPERIDOL (Suspected)			**Reason:**	Hallucinations	
Tablet	0.5	Milligram	1 time	Oral	
Batch:	**Started:**	19/09/2002		**Stopped:**	

Laboratory Investigations:

Additional Information:

Sequelae yes: icu intubated. haemofiltration.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 180470 **Seq:** 1
Reported: 11/11/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight:
Age: 19
DOB: 23/08/1983
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Blood creatine phosphokinase incr Blood pressure fluctuation Leukocytosis Neuroleptic malignant syndrome		Auroneunic instability.	Ceased neuroleptics. patient hospitalised.

Medicine Details:

OLANZAPINE (Suspected) **Reason:** Unspecified psychosis
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 30/09/2002 **Stopped:** 17/10/2002

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 30/09/2002 **Stopped:** 17/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 180686 **Seq:** 1 **Gender:** F
Reported: 15/11/2002 **Weight:**
Hospitalisation: **Age:** 25
Onset Date: 27/04/2001 **DOB:** 06/11/1975
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia Dystonia		Neck stiffness grinding of teeth, limbs rigid.	Iv valium, cogentin.

Medicine Details:

ALCOHOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
Injection 1.5 Milligram Daily Intramuscular
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Pharmacokinetics				Etgh 0-172%

Additional Information:

Drug overdose.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 181732 **Seq:** 1 **Gender:** F
Reported: 16/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 28Y
Onset Date: 10/08/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Infertility female	Required Visit to Doctor	Infertility and elevated prolactin levels.	
Anxiety	Required Visit to Doctor		
Blood prolactin increased	Required Visit to Doctor		

Medicine Details:

SERENACE (Suspected) **Reason:**
Tablet 3.7 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

trying to fall pregnant for a year without success

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 181778 **Seq:** 1
Reported: 17/01/2003
Hospitalisation:
Onset Date: 10/12/2002
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 66
DOB: 27/09/1936
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder Hypertonia Somnolence		Extrapyramidal Disorder, drowsiness and profoundly hypertonic with cogwheeling	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Personality disorders
10.0 Milligram Daily
Batch: **Started:** 10/12/2002 **Stopped:** 13/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Also taking selenium, vitamin C, zinc, telmisartan, diclofenac and oxycontin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 181834 **Seq:** 1 **Gender:** F
Reported: 21/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 50Y
Onset Date: 25/02/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination	Required Visit to Doctor	Hallucinations.	Morphine driver changed to Fentanyl patch.

Medicine Details:

CEFTRIAXONE (Suspected)			**Reason:**	Pneumonia,unspecified
Injection, powder for	1.0	Gram	Daily	Intravenous
Batch:	**Started:**	24/02/2001	**Stopped:**	24/02/2001
MORPHINE SULPHATE (Suspected)			**Reason:**	Other disturbance of sensation
Injection	30.0	Milligram	Daily	
Batch:	**Started:**	23/02/2001	**Stopped:**	25/02/2001
HALOPERIDOL (Suspected)			**Reason:**	Other disturbance of sensation
Injection	2.5	Milligram	Daily	
Batch:	**Started:**	23/02/2001	**Stopped:**	25/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Spironolactone, Dexamethasone, Ranitidine, Frusemide, Moclobemide and Lactulose.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 181855 **Seq:** 1 **Gender:** M
Reported: 21/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 30
Onset Date: 21/09/2002 **DOB:** 25/11/1971
Outcome: Recovered 27/09/2002 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome Blood creatine phosphokinase incr Pyrexia		Creatine phosphokinase increased, neuroleptic malignant syndrome and temp of 42 degress celsius.	Cessation of Haloperidol. Bromocriptine and Dantralene commenced. Haemofiltration.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
2.0 Milligram Per hour
Batch: **Started:** **Stopped:** 21/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/01/2003	Creatine				

Additional Information:

Patient also taking Noradrenaline, Omeprazole, Salbutamol, Ipratroprium bromide, Imipenem, Hydrocortisone and Vancomycin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 182536 **Seq:** 1 **Gender:** M
Reported: 07/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 59Y
Onset Date: 18/12/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome, consciousness fluctuating and creatine phosphokinase increased	Haloperidol ceased. Treated with cefotaxime 2g tds iv, benzylpen. 2.4gm iv 4/24, Acyclovir 500mg iv tds, metronidazole 500mg iv tds.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Consciousness fluctuating	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CYCLOSPORIN-A (Other drug) **Reason:**
Oral Liquid, suspension 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ASPIRIN (Other drug) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
500.0 Microgram Daily
Batch: **Started:** 11/11/2002 **Stopped:** 11/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/02/2003	Creatine				

Additional Information:

Patient was also taking Azathioprine, Atorvastatin, Diltiazem, Lactulose, Prednisolone, vit e caps, Aricept.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 182570 **Seq:** 1 **Gender:** M
Reported: 10/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 80
Onset Date: 23/09/2002 **DOB:** 19/12/1921
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cogwheel rigidity	Life threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given
Dehydration	Life threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given
Delirium	Life threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given
Hypertension	Life threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given

Medicine Details:

METOCLOPRAMIDE HYDROCHLORIDE (Suspected) **Reason:** Nausea and vomiting
Oral application 10.0 Milligram 1 time
Batch: **Started:** 22/09/2002 **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
1.0 Milligram As necessary
Batch: **Started:** 22/09/2002 **Stopped:** 24/09/2002

AMISULPRIDE (Suspected) **Reason:** Unspecified schizophrenia
400.0 Milligram Daily
Batch: **Started:** 21/09/2002 **Stopped:** 30/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/02/2003	Creatine phosphokinase		02/10/2002	19	
10/02/2003	Creatine phosphokinase		03/10/2002	210	
10/02/2003	Creatine phosphokinase		04/10/2002	79	

Additional Information:

Patient als otaking gentamicin, quetiapine, ampicillin, augmentin duo forte, thyroxine, multivitamins, coloxyl with senna

Report Details:

Case Number: 182570 **Seq:** 1 **Gender:** M
Reported: 10/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 80
Onset Date: 23/09/2002 **DOB:** 19/12/1921
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given and GTN patch
Somnolence	Life threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given
Urinary retention	Life threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given
Vomiting	Life threatening	Neuroleptic Malignant Syndrome, dehydration, vomiting, cogwheel rigidity, urinary retention, hypertension	Amisulpride and haloperidol ceased, iv fluids given

Medicine Details:

METOCLOPRAMIDE HYDROCHLORIDE (Suspected) **Reason:** Nausea and vomiting
Oral application 10.0 Milligram 1 time
Batch: **Started:** 22/09/2002 **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
1.0 Milligram As necessary
Batch: **Started:** 22/09/2002 **Stopped:** 24/09/2002

AMISULPRIDE (Suspected) **Reason:** Unspecified schizophrenia
400.0 Milligram Daily
Batch: **Started:** 21/09/2002 **Stopped:** 30/09/2002

Laboratory Investigations:

Additional Information:
Patient als otaking gentamicin, quetiapine, ampicillin, augmentin duo forte, thyroxine, multivitamins, coloxyl with senna

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 182655 **Seq:** 1 **Gender:** F
Reported: 11/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 38
Onset Date: 23/11/2002 **DOB:** 05/02/1964
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonia and oculogyric crisis	Cogentin 1mg +1mg IV by intensivist.
Oculogyration		Dystonia and oculogyric crisis	Cogentin 1mg +1mg IV by intensivist.

Medicine Details:

GENTAMICIN SULPHATE (Other drug) **Reason:**
Injection 160.0 Milligram Daily Intravenous
Batch: **Started:** **Stopped:**

SERENACE (Suspected) **Reason:** Unspecified psychosis
Injection 2.5 Milligram 1 time Intravenous
Batch: **Started:** **Stopped:**

AMOXIL (Suspected) **Reason:**
Injection 3.0 Gram Daily Intravenous
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking metronidazole.
182655 is seq 02 of 182654 seq 01.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 182740 **Seq:** 1
Reported: 11/02/2003
Hospitalisation: Admitted to hospital
Onset Date: 18/11/2002
Outcome: Recovered

Gender: U
Weight: 0.00
Age: 51
DOB: 04/12/1950
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Patients BP dropped significantly post IV sedation in ED.	IV normal saline infused, 1000ml.

Medicine Details:

HALOPERIDOL (Interaction) **Reason:** Otr spec symp psychopathol nec
Injection 5.0 Milligram 1 time Intravenous
Batch: **Started:** 18/11/2002 **Stopped:** 18/11/2002

MIDAZOLAM (Interaction) **Reason:** Otr spec symp psychopathol nec
Injection 12.5 Milligram 1 time Intravenous
Batch: **Started:** 18/11/2002 **Stopped:** 18/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 183615 **Seq:** 1 **Gender:** F
Reported: 03/03/2003 **Weight:** 57.00
Hospitalisation: **Age:** 80
Onset Date: 20/02/2003 **DOB:** 15/01/1923
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness Cogwheel rigidity		Marked Stiffness and Cogwheel Rigidity.	Haloperidol ceased.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
Tablet 0.5 Milligram As necessary Oral
Batch: **Started:** 19/02/2003 **Stopped:** 19/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Aspirin, Fusemide, Perindopril, Pantoprazole, Lactulose, Asasantin SR, Coloxyl with Senna and Multivitamins.
Patient history of confusion, advanced dementia, constipation, urinary retention and AMI (while in hospital).
Reactions occured while patient was in hospital. Admitted 12.2.03.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 184953 **Seq:** 1 **Gender:** M
Reported: 12/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 40
Onset Date: **DOB:** 04/08/1962
Outcome: Death, maybe drug 25/12/2002 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation		Cariac arrest, brain damage, laryngospasm and agitation.	
Brain damage		Cariac arrest, brain damage, laryngospasm and agitation.	
Cardiac arrest		Cariac arrest, brain damage, laryngospasm and agitation.	
Laryngospasm		Cariac arrest, brain damage, laryngospasm and agitation.	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
Injection 5.0 Milligram Total Intramuscular
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: The patient had had previous laryngeal spams after receiving Pimozide and haloperidol in the past. This patient's death was considered unlikely to do due to Clozaril. It was more likely to be due to the Haloperidol injection and the ensuing complications.
Follow-up received on 31.1.03, with further information gained on 7.2.03: this patient commenced Clozaril for the first time in 1993. He had a pulmonary embolus in 1997 after a fundoplasty. Althought the pulmonary embolus was considered unlikely to be due to Clozaril and more likely to be due to the operation.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 185217 **Seq:** 1 **Gender:** M
Reported: 24/04/2003 **Weight:** 56.00
Hospitalisation: **Age:** 16
Onset Date: 22/04/2002 **DOB:** 30/08/1985
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation	Extrapyramidal, marked tremor at rest,	Haloperidol weaned over 4 days.
Hypertonia	Caused or prolonged inpatient hospitalisation	Hypertonicity of limbs. drooling	
Parkinsonism	Caused or prolonged inpatient hospitalisation	Slow, crouched over gait,	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
Tablet 7.5 Milligram Daily Oral
Batch: **Started:** **Stopped:** 27/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

mental and motor retardation, ataxia since 3 years of age.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 185217 **Seq:** 1 **Gender:** M
Reported: 24/04/2003 **Weight:** 56.00
Hospitalisation: **Age:** 16
Onset Date: 22/04/2002 **DOB:** 30/08/1985
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drooling	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
Tablet 7.5 Milligram Daily Oral
Batch: **Started:** **Stopped:** 27/04/2002

Laboratory Investigations:

Additional Information:

mental and motor retardation, ataxia since 3 years of age.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 185808 **Seq:** 1 **Gender:** M
Reported: 12/05/2003 **Weight:** 0.00
Hospitalisation: Hospitalisation prolonged **Age:** 75
Onset Date: 02/05/2003 **DOB:** 05/08/1927
Outcome: Recovered 03/05/2003 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Extrapyramidal reaction and convulsions. Patient was found lying across the bed between bars with his body shifting and jerking	
Extrapyramidal disorder		Extrapyramidal reaction and convulsions. Patient was found lying across the bed between bars with his body shifting and jerking	Given Benztropine total 4mg IV and Diazepam total 5.5mg IV.

Medicine Details:

SERENACE (Suspected) **Reason:**
8.0 Milligram As necessary
Batch: **Started:** 02/05/2003 **Stopped:** 02/05/2003

CAPADEX (Suspected) **Reason:** Pain
Capsule 6.0 Milligram As necessary Oral
Batch: **Started:** 01/05/2003 **Stopped:** 02/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient already in hospital. Other drugs: Doxylin, Norvasc, Noten and Enahexal.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 186598 **Seq:** 1 **Gender:** M
Reported: 04/06/2003 **Weight:** 0.00
Hospitalisation: **Age:** 73Y
Onset Date: 24/05/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle rigidity		Neuroleptic malignant syndrome, stiffness and sedation.	
Neuroleptic malignant syndrome		Neuroleptic malignant syndrome, stiffness and sedation.	
Sedation		Neuroleptic malignant syndrome, stiffness and sedation.	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
Tablet 6.0 Milligram Daily Oral
Batch: **Started:** 15/05/2003 **Stopped:** 24/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/06/2003	Creatine				
04/06/2003	Creatinine				

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 187139 **Seq:** 1 **Gender:** F
Reported: 19/06/2003 **Weight:** 0.00
Hospitalisation: **Age:** 37
Onset Date: 05/04/2003 **DOB:** 16/11/1965
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose		Patient overdose with approximately 20 100mg of Clozaril tablets. The patient did not experience any reported side effects.	

Medicine Details:

EPILIM (Suspected) **Reason:**
Oral application Dose Unspecified Oral
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
Dose Unspecified
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 21/02/2003 **Stopped:** Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 188722 **Seq:** 1
Reported: 23/07/2003
Hospitalisation:
Onset Date: 12/07/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 86
DOB: 08/12/1916
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonism	Required Visit to Doctor	Acute Parkinsonian Crisis	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Hallucinations
1.0 Milligram Daily
Batch: **Started:** 04/06/2003 **Stopped:** 12/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking paroxetine, Di-gesic, Aspirin, Karvezide.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 188990 **Seq:** 1
Reported: 28/07/2003
Hospitalisation: Admitted to hospital
Onset Date: 16/02/2003
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 61
DOB: 15/04/1941
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Grand Mal Seizure , Liver Enzyme Abnormal , Anorexia.	Zyprexa and Haloperidol ceased.
Weight decreased		Weight loss of 14kg over 5 months.	
Anorexia			
Liver function test abnormal			
Red blood cell sedimentation rate i			
Somnolence			

Medicine Details:

ZYPREXA (Suspected) **Reason:** Otr spec symp psychopathol nec
10.0 Milligram Daily Oral
Batch: **Started:** 05/09/2002 **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
Tablet 1.2 Milligram Daily Oral
Batch: **Started:** 02/06/2002 **Stopped:** 16/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/07/2003	ALT = SGPT		18/02/2003	246	
28/07/2003	Erythrocyte [illegible]		18/02/2003	114	
28/07/2003	GGT = SGGT = [illegible]		18/02/2003	127	
28/07/2003	SAP = ALP		18/02/2003	350	

Additional Information:

Patient also taking sustagen.
History included: Early onset dementia and agitation.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 189003 **Seq:** 1 **Gender:** F
Reported: 29/07/2003 **Weight:** 0.00
Hospitalisation: **Age:** 75Y
Onset Date: 15/06/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Rash	Changed Antipsychotic medication to Quetiapine.

Medicine Details:

BENZTROPINE MESYLATE (Other drug) **Reason:**
Tablet 0.5 Milligram Total Oral
Batch: **Started:** 14/05/2003 **Stopped:**

DIAZEPAM (Other drug) **Reason:**
Tablet 5.0 Milligram As necessary Oral
Batch: **Started:** 14/05/2003 **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 12/06/2003 **Stopped:** 17/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 189276 **Seq:** 1
Reported: 07/08/2003
Hospitalisation: Admitted to hospital
Onset Date: 27/03/2003
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 80
DOB: 17/10/1922
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fall		Fall and hypotension	Recommended to use Haloperidol.
Hypotension		Fall and hypotension	

Medicine Details:

MINAX (Suspected)			**Reason:**	Essential benign hypertension	
Tablet	100.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
KARVEZIDE 150/12.5 (Suspected)			**Reason:**	Essential benign hypertension	
Tablet	1.0	Dose Unspecified	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
SERENACE (Suspected)			**Reason:**	Otr spec symp psychopathol nec	
Tablet	1000.0	Microgram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Persantin, Astrix and Vatifem.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 189497 **Seq:** 1 **Gender:** F
Reported: 14/08/2003 **Weight:** 0.00
Hospitalisation: **Age:** 57
Onset Date: 09/04/2003 **DOB:** 07/10/1945
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Angioedema		Angioedema	Dexamethasone given 4mg IM stat.

Medicine Details:

SERENACE (Suspected) **Reason:** Otr spec symp psychopathol nec

Injection 5.0 Milligram 2 times Intramuscular

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/08/2003	ALT = SGPT				
14/08/2003	Albumin				
14/08/2003	Bilirubin				
14/08/2003	GGT = SGGT =				
14/08/2003	International				
14/08/2003	Protein				
14/08/2003	SAP = ALP				

Additional Information:

Patient also taking Lactulose syrup, Spironolactone, Oxazepam, Ranitidine and Aciclovir.

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Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 190182 **Seq:** 1
Reported: 03/09/2003
Hospitalisation: Admitted to hospital
Onset Date: 26/08/2003
Outcome: Recovered

Gender: U
Weight: 65.00
Age: 26
DOB: 23/12/1976
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Tongue oedema	Life threatening	Angiooedema, SOB	Adrenaline, hydrocortisone, promethazine

Medicine Details:

OXAZEPAM (Other drug) **Reason:**
15.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 190223 **Seq:** 1 **Gender:** F
Reported: 04/09/2003 **Weight:** 65.00
Hospitalisation: **Age:** 47
Onset Date: 06/08/2003 **DOB:** 10/03/1956
Outcome: Recovered 22/08/2003 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration Headache Musculoskeletal stiffness Salivary hypersecretion		Oculogyric crisis, stiffness, hypersalivation, headache.	Benztropine 2mg bd.

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified psychosis
2.5 Milligram Daily
Batch: **Started:** 04/08/2003 **Stopped:** 06/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other medication taken: Trimethoprin. Patient now on Seroquel (quetiapine) with no adverse effects.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 190736 **Seq:** 1 **Gender:** F
Reported: 22/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 84
Onset Date: 16/09/2003 **DOB:** 23/02/1919
Outcome: Recovered 17/09/2003 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Medication error	Caused or prolonged inpatient hospitalisation	Lip smacking, dyskinesia of trunk and limbs lasting 40-60mins	Benztopine
Dyskinesia	Caused or prolonged inpatient hospitalisation		
Tardive dyskinesia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
Injection 1.0 Milligram Daily Subcutaneous
Batch: **Started:** **Stopped:** 16/09/2003

KETAMINE HYDROCHLORIDE (Suspected) **Reason:** Pain
Injection 30.0 Milligram Daily Subcutaneous
Batch: **Started:** 12/09/2003 **Stopped:** 17/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Morphine, Paracetamol, Movicol, Rulide.

THERAPEUTIC GOODS ADMINISTRATION
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Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 191134 **Seq:** 1 **Gender:** M
Reported: 07/10/2003 **Weight:** 0.00
Hospitalisation: **Age:** 53
Onset Date: 28/08/2003 **DOB:** 14/05/1950
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Condition aggravated		Worsening of pre-existing prolongation of QT interval on ECG	Olanzapine was ceased and his concomitant haloperidol was reduced from 2.5mg tds to treatment as needed.

Medicine Details:

OLANZAPINE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
75.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/10/2003	Creatine kinase MB				
07/10/2003	Electrocardiograph				
07/10/2003	Troponin				

Additional Information:

Patient also administered: Clozaril, Imipramine, Benztropine Mesylate, Atenolol, Clopidogrel.

Prior to recommencing Clozaril, an echocardiogram was performed on 28 Aug 2003 due to his cardiac and hypertension history. This echocardiogram showed features of moderate ischaemic dilated cardiomyopathy, a left ventricular ejection fraction of approximately 35%, and regional wall motion abnormalities consistent with previous extensive anterior, anteroseptal and apical myocardial infarcts. The dilated cardiomyopathy was considered most likely pre-existing, and Clozaril was not suspected to have

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Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 191526 **Seq:** 1 **Gender:** U
Reported: 23/10/2003 **Weight:** 0.00
Hospitalisation: **Age:** 83
Onset Date: 20/06/2003 **DOB:** 10/07/1919
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cogwheel rigidity		Cogwheeling	Ceased haloperidol.

Medicine Details:

DIGOXIN (Other drug) **Reason:** Otr&nos disord of heart rhythm
Dose Unspecified
Batch: **Started:** 17/06/2003 **Stopped:** 17/06/2003

HALOPERIDOL (Suspected) **Reason:**
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 18/06/2003 **Stopped:** 20/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
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Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 191997 **Seq:** 1 **Gender:** M
Reported: 10/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 75Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome.	
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Leukocytosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected) **Reason:** Otr spec symp psychopathol nec
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History included: Agitation and dementia.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 192136 **Seq:** 1
Reported: 12/11/2003
Hospitalisation:
Onset Date: 19/10/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 20
DOB: 07/04/1983
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea	Required Specialist Consultation	Nausea, followed a few days later by raised liver function tests and jaundice (pale stools, dark urine, yellow sclera).	Cessation of sodium valproate (Epilim) and metoclopramide (Pramin) for nausea.
Jaundice	Required Specialist Consultation		
Liver function test abnormal	Required Specialist Consultation		

Medicine Details:

NILSTAT (Other drug)			**Reason:**	
Solution	1.0 Millilitre		4 times	Oral
Batch:	**Started:** 12/10/2003		**Stopped:**	11/11/2003
ZYPREXA (Other drug)			**Reason:**	
Tablet	10.0 Milligram		1 time	Oral
Batch:	**Started:** 14/10/2003		**Stopped:**	
EPILIM (Suspected)			**Reason:**	
Tablet	700.0 Milligram		1 time	Oral
Batch:	**Started:** 16/10/2003		**Stopped:**	05/11/2003
EPILIM (Suspected)			**Reason:**	
Tablet	1000.0 Milligram		1 time	Oral
Batch:	**Started:** 16/10/2003		**Stopped:**	05/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/11/2003	Albumin				

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 192136 **Seq:** 1
Reported: 12/11/2003
Hospitalisation:
Onset Date: 19/10/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 20
DOB: 07/04/1983
Causality: Causality possible

Reaction Details:

Medicine Details:

SERENACE (Suspected)			**Reason:**	
Injection	10.0	Milligram	As necessary	Intramuscular
Batch:	**Started:** 09/10/2003		**Stopped:**	11/11/2003
LARGACTIL (Suspected)			**Reason:**	
Tablet	150.0	Milligram	As necessary	Oral
Batch:	**Started:** 09/10/2003		**Stopped:**	11/11/2003
HYPNOVEL (Suspected)			**Reason:**	
Injection	7.5	Milligram	As necessary	Intramuscular
Batch:	**Started:** 09/10/2003		**Stopped:**	11/11/2003
ANTENEX (Suspected)			**Reason:**	
Tablet	10.0	Milligram	As necessary	Oral
Batch:	**Started:** 12/10/2003		**Stopped:**	11/11/2003

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 194020 **Seq:** 1 **Gender:** M
Reported: 21/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 32
Onset Date: **DOB:** 06/03/1971
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Extrapyramidal symptoms	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 194213 **Seq:** 1 **Gender:** F
Reported: 03/02/2004 **Weight:** 50.00
Hospitalisation: **Age:** 48Y
Onset Date: 26/08/2003 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Formication		Patient had a crawling sensation all over her skin.	Haloperidol ceased.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Nausea and vomiting

Tablet 0.5 Milligram 3 times Oral

Batch: **Started:** 26/08/2003 **Stopped:** 27/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred after first dose of Haloperidol. Patient also taking Atorvastatin, Ranitidine, Nicotine, Citalopram, Aspirin, Atenolol, Thyroxine, Metoclopramide, Paracetamol, Macrogols, Docusate-Senna, Frusemide, Insulin - Soluble, Insulin - Isophane and Fludrocortisone.

THERAPEUTIC GOODS ADMINISTRATION
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Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 194751 **Seq:** 1 **Gender:** M
Reported: 19/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 14/02/2004 **DOB:**
Outcome: Recovered 15/02/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life threatening	Neuroleptic malignant syndrome.	Benztropine

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
5.7 Milligram Daily
Batch: **Started:** 06/02/2004 **Stopped:** 11/02/2004

QUETIAPINE (Suspected) **Reason:** Unspecified psychosis
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 06/02/2004 **Stopped:** 14/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Paracetamol and Sodium Valproate.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 194777 **Seq:** 1 **Gender:** F
Reported: 20/02/2004 **Weight:** 65.00
Hospitalisation: **Age:** 53
Onset Date: 04/02/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mutism	Caused or prolonged inpatient hospitalisation	Mutism, depressive symptom, tardive dyskinesia, treatment non compliance, ALT increased.	Commenced on mirtazapine, haloperidol was ceased.
Alanine aminotransferase increase	Caused or prolonged inpatient hospitalisation		
Depressive symptom	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:**
1.0 Gram Daily
Batch: **Started:** **Stopped:**

HALDOL DECANOATE (Suspected) **Reason:** Unspecified schizophrenia
Injection
Batch: **Started:** **Stopped:**

Risperdal Consta (Suspected) **Reason:** Unspecified schizophrenia
Injection 25.0 Milligram Fortnightly Intramuscular
Batch: **Started:** 02/02/2004 **Stopped:** contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient 's problem is considered to be behavioural.

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Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 194777 **Seq:** 1 **Gender:** F
Reported: 20/02/2004 **Weight:** 65.00
Hospitalisation: **Age:** 53
Onset Date: 04/02/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	Caused or prolonged inpatient hospitalisation		
Treatment noncompliance	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:**
1.0 Gram Daily
Batch: **Started:** **Stopped:**

HALDOL DECANOATE (Suspected) **Reason:** Unspecified schizophrenia
Injection
Batch: **Started:** **Stopped:**

Risperdal Consta (Suspected) **Reason:** Unspecified schizophrenia
Injection 25.0 Milligram Fortnightly Intramuscular
Batch: **Started:** 02/02/2004 **Stopped:** contin

Laboratory Investigations:

Additional Information:
The patient 's problem is considered to be behavioural.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 194795 **Seq:** 1 **Gender:** M
Reported: 20/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Muscle rigidity Speech disorder Trismus		Dystonia, rigidity, jaw spasm, speech impaired.	

Medicine Details:

MIDAZOLAM (Suspected)			**Reason:**	
Injection	7.0	Milligram		Intravenous
Batch:	**Started:**			**Stopped:**
HALOPERIDOL (Suspected)			**Reason:**	
Injection	10.0	Milligram		Intravenous
Batch:	**Started:**			**Stopped:**
RISPERDAL (Suspected)			**Reason:**	
Tablet	1.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 196387 **Seq:** 1 **Gender:** F
Reported: 13/04/2004 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: **DOB:** 12/08/1968
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	Caused or prolonged inpatient hospitalisation	Ocoter 2003 Tardive dyskinesia	Amantadine and vitamin E

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 27/03/2004 **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
5.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

In Nov/Dec 2003 haloperidol was ceased (reason not specified) and the tardive dyskinesia become more exacerbated.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 196817 **Seq:** 1 **Gender:** U
Reported: 27/04/2004 **Weight:** 0.00
Hospitalisation: **Age:** 29Y
Onset Date: 06/04/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anxiety Agitation Hallucination Tension		Anxiety, agitation and hallucinations. Felt like "time bombs waiting to go off"	Ceased haloperidol

Medicine Details:

SEROQUEL (Other drug) **Reason:** Schizophrenia
1.4 Gram Daily
Batch: **Started:** **Stopped:**

PROZAC (Other drug) **Reason:** Depression
60.0 Milligram Daily
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
5.0 Milligram Daily
Batch: **Started:** **Stopped:** 07/04/2004

CLOZAPINE (Suspected) **Reason:** Unspecified psychosis
100.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced hallucinations similar to when he used to take LSD or ecstasy

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 196817 **Seq:** 1
Reported: 27/04/2004
Hospitalisation:
Onset Date: 06/04/2004
Outcome: Unknown

Gender: U
Weight: 0.00
Age: 29Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

CLONAZEPAM (Suspected) **Reason:** Unspecified psychosis
6.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Patient experienced hallucinations similar to when he used to take LSD or ecstasy

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Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 197216 **Seq:** 1 **Gender:** M
Reported: 10/05/2004 **Weight:** 0.00
Hospitalisation: **Age:** 80Y
Onset Date: 26/09/2003 **DOB:**
Outcome: Recovered 29/09/2003 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancytopenia	Caused or prolonged inpatient hospitalisation	Pancytopenia.	Methotrexate withheld then ceased.

Medicine Details:

FOLIC ACID (Suspected) **Reason:**
10.0 Milligram Oral
Batch: **Started:** **Stopped:** 10/09/2003

HALOPERIDOL (Suspected) **Reason:**
As necessary Oral
Batch: **Started:** **Stopped:** 26/09/2003

METHOTREXATE (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:** 10/09/2003

NITROFURANTOIN (Suspected) **Reason:** Othr diseases of urinary tract
200.0 Milligram Daily Oral
Batch: **Started:** 19/09/2003 **Stopped:** 26/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/05/2004	Platelets		21/08/2003	288	
10/05/2004	Platelets		03/09/2003	81	
10/05/2004	White blood cells		21/08/2003	9.1	
10/05/2004	White blood cells		03/09/2003	2.4	

Additional Information:

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Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 197216 **Seq:** 1 **Gender:** M
Reported: 10/05/2004 **Weight:** 0.00
Hospitalisation: **Age:** 80Y
Onset Date: 26/09/2003 **DOB:**
Outcome: Recovered 29/09/2003 **Causality:** Causality possible

Reaction Details:

Medicine Details:

AUGMENTIN DUO FORTE (Suspected)				**Reason:**	Pneumonia,unspecified
Tablet	2.0	Dose Unspecified	Daily		Oral
Batch:	**Started:** 19/09/2003			**Stopped:**	26/09/2003
DIGOXIN (Suspected)				**Reason:**	Otr&nos disord of heart rhythm
Tablet	125.0	Microgram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
ASPIRIN (Suspected)				**Reason:**	Transient cereb isch no hypert
	150.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
PERSANTIN SR (Suspected)				**Reason:**	Transient cereb isch no hypert
	400.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

Report Details:

Case Number: 197216 **Seq:** 1 **Gender:** M
Reported: 10/05/2004 **Weight:** 0.00
Hospitalisation: **Age:** 80Y
Onset Date: 26/09/2003 **DOB:**
Outcome: Recovered 29/09/2003 **Causality:** Causality possible

Reaction Details:

Medicine Details:

LOSEC (Suspected) **Reason:** Peptic ulcer nos w/o ment perf

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 197301 **Seq:** 1 **Gender:** F
Reported: 12/05/2004 **Weight:** 0.00
Hospitalisation: **Age:** 54
Onset Date: 09/05/2004 **DOB:** 26/06/1949
Outcome: Recovered 09/05/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Melanodermia	Required Visit to Doctor	"Seeing black spots", feeling dizzy	Cogentin 2mg.
Dizziness	Required Visit to Doctor		

Medicine Details:

SERENACE (Suspected) **Reason:** Nausea and vomiting
Injection 2.5 Milligram Subcutaneous
Batch: **Started:** 07/05/2004 **Stopped:** 09/05/2004

PHENERGAN (Suspected) **Reason:** Nausea and vomiting
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 07/05/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 198468 **Seq:** 1 **Gender:** M
Reported: 24/06/2004 **Weight:** 29.00
Hospitalisation: **Age:** 10
Onset Date: 10/11/2003 **DOB:** 28/12/1992
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Required Visit to Doctor	Extrapyramidal symptoms - more dystonic than usual, eye rolling, fisting and foot extension.	Haloperidol ceased.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**

Batch: **Started:** **Stopped:** 10/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Haloperidol was taken for cerbal palsy.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 198552 **Seq:** 1 **Gender:** M
Reported: 28/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 19
Onset Date: 29/05/2004 **DOB:** 07/11/1984
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration		Oculogyric - with maximal upward deviation of both eyes to left side.	Ceased Metoclopramide and Haloperidol. 2mg Benztropine given.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
Injection 10.0 Milligram Daily Intravenous
Batch: **Started:** 28/05/2004 **Stopped:** 28/05/2004

METOCLOPRAMIDE HYDROCHLORIDE (Suspected) **Reason:**
Injection 30.0 Milligram Daily Intravenous
Batch: **Started:** 21/05/2004 **Stopped:** 28/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs taken: Heparin, Mg804, Ku, Tramadol, Timentin and Ranitidine.

Report Details:

Case Number: 199033 **Seq:** 1 **Gender:** M
Reported: 16/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 94
Onset Date: 19/08/2001 **DOB:**
Outcome: Recovered 19/08/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Respiratory arrest	Life threatening	Patient developed respiratory arrest and altered conscious state (pupils non - reactive).	Nitrazepam, Haopreidol, Tramadol and Panadeine Forte ceased. Naloxone 4mg IV given.
Altered state of consciousness	Life threatening		

Medicine Details:

PANADEINE FORTE (Suspected)			**Reason:** Pain	
Tablet	1.0 Dose Unspecified	As necessary		Oral
Batch:	**Started:** 18/08/2001		**Stopped:** 18/08/2001	
MORPHINE SULPHATE (Suspected)			**Reason:** Pain	
Injection	2.5 Milligram	As necessary		Intravenous
Batch:	**Started:** 17/08/2001		**Stopped:** 18/08/2001	
HALOPERIDOL (Suspected)			**Reason:** Otr spec symp psychopathol nec	
	2.0 Milligram	Daily		Oral
Batch:	**Started:** 17/08/2001		**Stopped:** 18/08/2001	
NITRAZEPAM (Suspected)			**Reason:** Otr spec symp psychopathol nec	
Tablet	5.0 Milligram	Daily		Oral
Batch:	**Started:** 17/08/2001		**Stopped:** 18/08/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs taken: Captopril, Thyroxine, Allopurinol and Trimethoprim.

Report Details:

Case Number: 199033 **Seq:** 1 **Gender:** M
Reported: 16/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 94
Onset Date: 19/08/2001 **DOB:**
Outcome: Recovered 19/08/2004 **Causality:** Causality possible

Reaction Details:

Medicine Details:

TRAMADOL HYDROCHLORIDE (Suspected)		**Reason:** Pain	
	200.0 Milligram	Daily	Oral
Batch:	**Started:** 18/08/2001		**Stopped:** 19/08/2001
OLANZAPINE (Suspected)		**Reason:** Otr spec symp psychopathol nec	
Tablet	50.0 Milligram	Daily	Oral
Batch:	**Started:** 18/08/2001		**Stopped:** 20/08/2001

Laboratory Investigations:

Additional Information:
Other drugs taken: Captopril, Thyroxine, Allopurinol and Trimethoprim.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 199170 **Seq:** 1 **Gender:** F
Reported: 19/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 56
Onset Date: 13/05/2004 **DOB:** 04/12/1947
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure.	Midazolam 5mg IM, Cyclizine and haloperidol ceased

Medicine Details:

CYCLIZINE (Suspected) **Reason:** Nausea and vomiting
25.0 Milligram As necessary
Batch: **Started:** 13/05/2004 **Stopped:** 14/05/2004

CYCLIZINE (Suspected) **Reason:** Nausea and vomiting
150.0 Milligram Daily
Batch: **Started:** 08/04/2004 **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Nausea and vomiting
2.0 Milligram Daily Oral
Batch: **Started:** 13/05/2004 **Stopped:** 20/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drug therapy: Ranitidine, phenytoin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 199798 **Seq:** 1 **Gender:** F
Reported: 09/08/2004 **Weight:** 78.00
Hospitalisation: **Age:** 20Y
Onset Date: 23/07/2004 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Severe extrapyramidal and dystonic reactions involving face/knees/legs.	
Confusional state		CNS disturbances - confusion/speech impairment/disorientation.	
Dystonia		Severe dystonia of facial muscles.	Went to hospital and received Cogentin IM. Sent home with Cogentin tablets.
Dystonia			
Speech disorder			

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Painful menstruation

Injection 1.0 Dose Unspecified 1 time Intramuscular

Batch: **Started:** 21/06/2004 **Stopped:** 21/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 200599 **Seq:** 1
Reported: 07/09/2004
Hospitalisation:
Onset Date: 27/08/2004
Outcome: Recovered with sequelae

Gender: M
Weight: 0.00
Age: 26
DOB: 21/03/1978
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	Patient was found with tonic-clonic seizures on the floor, biting through his top lip (mucosal surface only) and hitting the left side of his forehead on a skirting board.	Haloperidol was immediately ceased, following that, Sertraline was ceased. He was commenced on Diazepam 5mg and had his nightly Clozaril dose withheld. Clozaril continued as per usual the following day.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
As necessary
Batch: **Started:** **Stopped:** 27/08/2004

CLOZARIL (Suspected) **Reason:**
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 19/08/2004 **Stopped:** Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 201895 **Seq:** 1 **Gender:** M
Reported: 21/10/2004 **Weight:** 72.00
Hospitalisation: **Age:** 75
Onset Date: 27/09/2004 **DOB:** 19/02/1929
Outcome: Recovered 06/10/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life threatening	The patient developed confusion, agitation, incontinence, muscle rigidity, hyperreflexia, hyperthermia at 38.5 degrees Celsius and elevated CPK at 515. The diagnosis of neuroleptic malignant syndrome was made.	Amisulpride ceased.
Agitation	Life threatening		
Confusional state	Life threatening		
Hyperreflexia	Life threatening		

Medicine Details:

SOLIAN (Suspected) **Reason:** Unspecified psychosis
200.0 Milligram Daily Oral
Batch: **Started:** 22/09/2004 **Stopped:** 24/09/2004 0

RISPERDAL (Suspected) **Reason:** Unspecified psychosis
1.0 Milligram Daily
Batch: **Started:** 24/09/2004 **Stopped:** 26/09/2004 0

SOLIAN (Suspected) **Reason:** Unspecified psychosis
400.0 Milligram Daily Oral
Batch: **Started:** 24/09/2004 **Stopped:** 26/09/2004

RISPERDAL (Suspected) **Reason:** Unspecified psychosis
2.0 Milligram Daily Oral
Batch: **Started:** 23/09/2004 **Stopped:** 23/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 201895 **Seq:** 1 **Gender:** M
Reported: 21/10/2004 **Weight:** 72.00
Hospitalisation: **Age:** 75
Onset Date: 27/09/2004 **DOB:** 19/02/1929
Outcome: Recovered 06/10/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Incontinence	Life threatening		
Muscle rigidity	Life threatening		
Pyrexia	Life threatening		

Medicine Details:

RISPERDAL (Suspected) **Reason:** Unspecified psychosis
3.0 Milligram Daily Oral
Batch: **Started:** 22/09/2004 **Stopped:** 22/09/2004

SERENACE (Suspected) **Reason:** Unspecified psychosis
500.0 Microgram Daily
Batch: **Started:** 26/08/2004 **Stopped:** 26/08/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 201979 **Seq:** 1 **Gender:** F
Reported: 25/10/2004 **Weight:** 0.00
Hospitalisation: **Age:** 71
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence Confusional state		Patient experienced somnolence - she could not wake up, also confused.	

Medicine Details:

Ebixa (Suspected) **Reason:** Unspecified psychosis
1.0 Dose Unspecified Daily Oral
Batch: Continued **Started:** 15/10/2004 **Stopped:**

SERENACE (Suspected) **Reason:** Explosive personality disorder
1.0 Milligram Daily
Batch: **Started:** 15/10/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 202486 **Seq:** 1 **Gender:** M
Reported: 11/11/2004 **Weight:** 0.00
Hospitalisation: Treated in Accident/Emergency Department **Age:** 23
Onset Date: 10/06/2001 **DOB:** 26/06/1977
Outcome: Recovered 13/06/2001 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Retching	Caused or prolonged inpatient hospitalisation	Gagging/choking due to swollen tongue.	Anti-dote administered - name of medication not known.
Paranoia	Caused or prolonged inpatient hospitalisation	this reaction exacerbated the mental state to the point of danger to the patient and others. The patient was placed in a guarded room	
Swollen tongue	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SERENACE (Suspected) **Reason:**

Batch: **Started:** 10/06/2001 **Stopped:** 12/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 202691 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Homicidal ideation		Suicidal and homicidal ideation.	

Medicine Details:

QUETIAPINE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
Capsule Oral
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

EFEXOR (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 202795 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation.	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

CIPRAMIL (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 203689 **Seq:** 1
Reported: 21/12/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation	Patient experienced extrapyramidal symptoms.	

Medicine Details:

DIAZEPAM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

BENZTROPINE MESYLATE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

LITHIUM CARBONATE (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Abilify (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 08/11/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Details:

Case Number: 203689 **Seq:** 1
Reported: 21/12/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**

8.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 203902 **Seq:** 1 **Gender:** F
Reported: 04/01/2005 **Weight:** 0.00
Hospitalisation: **Age:** 21
Onset Date: 09/12/2004 **DOB:** 06/04/1983
Outcome: Recovered 09/12/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		The patient experienced a dystonic reaction - jaw and facial muscles cramping suddenly. It progressed to arms and legs within half an hour of oral Benztropine. Hence given subcutaneous Benztropine with almost immediate relief.	Benztropine 2mg oral and Benztropine 2mg subcutaneous.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
2.0 Milligram Daily
Batch: **Started:** 07/12/2004 **Stopped:** 09/12/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 203904 **Seq:** 1 **Gender:** M
Reported: 04/01/2005 **Weight:** 75.00
Hospitalisation: **Age:** 32
Onset Date: 02/10/2004 **DOB:** 17/01/1972
Outcome: Recovered 02/10/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Within 4 hours of receiving Haloperidol by mouth the patient's jaw clenched and tongue felt 'swollen'. He was also receiving Olanzapine at the time.	Benztropine 2mg IMI given.

Medicine Details:

OLANZAPINE (Other drug)		**Reason:**	Unspecified psychosis
Tablet	8.0 Milligram	Daily	Oral
Batch:	**Started:** 15/09/2004		**Stopped:** 01/10/2004
OLANZAPINE (Other drug)		**Reason:**	Unspecified psychosis
Tablet	20.0 Milligram	Daily	Oral
Batch:	**Started:** 01/10/2004		**Stopped:** 15/10/2004
HALOPERIDOL (Suspected)		**Reason:**	Otr spec symp psychopathol nec
Tablet	10.0 Milligram	Daily	Oral
Batch:	**Started:** 02/10/2004		**Stopped:** 02/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 203949 **Seq:** 1 **Gender:** F
Reported: 05/01/2005 **Weight:** 0.00
Hospitalisation: **Age:** 19
Onset Date: 19/08/2004 **DOB:**
Outcome: Recovered 20/08/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration	Required Visit to Doctor	The patient experienced an oculogyric crisis, right arm and left leg stiffness, oversedation, severe agitation and disorientation.	Cogentin 1mg IM x 2 doses. Haloperidol ceased.
Agitation	Required Visit to Doctor		
Disorientation	Required Visit to Doctor		
Hypertonia	Required Visit to Doctor		
Sedation	Required Visit to Doctor		

Medicine Details:

AUGMENTIN DUO FORTE (Other drug) **Reason:** Othr diseases of urinary tract
Tablet 2.0 Dose Unspecified Oral
Batch: **Started:** 16/08/2004 **Stopped:** 22/08/2004

TEMAZEPAM (Other drug) **Reason:**
10.0 Milligram Oral
Batch: **Started:** 17/08/2004 **Stopped:**

PREMIA (Other drug) **Reason:** Menopausal symptoms
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** L TERM **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
Injection 5.0 Milligram As necessary Intravenous
Batch: **Started:** 18/08/2004 **Stopped:** 19/08/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 203949 **Seq:** 1 **Gender:** F
Reported: 05/01/2005 **Weight:** 0.00
Hospitalisation: **Age:** 19
Onset Date: 19/08/2004 **DOB:**
Outcome: Recovered 20/08/2004 **Causality:** Causality possible

Reaction Details:

Medicine Details:

DIAZEPAM (Suspected) **Reason:**
5.0 Milligram As necessary Oral
Batch: **Started:** 18/08/2004 **Stopped:** 19/08/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 204079 **Seq:** 1 **Gender:** U
Reported: 11/01/2005 **Weight:** 50.00
Hospitalisation: **Age:** 99U
Onset Date: 30/11/2004 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		The patient experienced acute dystonia.	Benzotropine

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
8.0 Milligram Daily
Batch: **Started:** 29/11/2004 **Stopped:** 30/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 204256 **Seq:** 1
Reported: 14/01/2005
Hospitalisation: Admitted to hospital
Onset Date: 03/12/2004
Outcome: Not yet recovered

Gender: U
Weight: 0.00
Age: 69
DOB: 25/10/1935
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	The patient experienced myocarditis, increased troponin and ejection fraction decreased.	Olanzapine ceased, ACE inhibitors, supportive.
Ejection fraction decreased	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected) **Reason:** Unspecified schizophrenia
10.0 Milligram Daily
Batch: **Started:** 22/11/2004 **Stopped:** 03/12/2004

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 15/01/2004 **Stopped:** 03/12/2004

KEFLEX (Suspected) **Reason:** Othr diseases of urinary tract
2.0 Milligram Daily Oral
Batch: **Started:** 24/11/2004 **Stopped:** 07/12/2004

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
2.0 Milligram Daily
Batch: **Started:** 22/11/2004 **Stopped:** 07/12/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/01/2005	Other data				LV impariment EF 30%
14/01/2005	Troponin				troponin rised 4.4

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 204336 **Seq:** 1 **Gender:** U
Reported: 18/01/2005 **Weight:** 78.00
Hospitalisation: **Age:** 13
Onset Date: 20/11/2004 **DOB:** 01/07/1991
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Haloperidol induced seizure.	

Medicine Details:

CEFOTAXIME SODIUM (Other drug) **Reason:**
3.0 Gram
Batch: **Started:** 18/11/2004 **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
10.0 Milligram Daily
Batch: **Started:** 15/11/2004 **Stopped:** 20/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Recent onse encephalopathy of unknown origin.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 204831 **Seq:** 1
Reported: 02/02/2005
Hospitalisation:
Onset Date: 12/12/2004
Outcome: Not yet recovered

Gender: M
Weight: 70.00
Age: 36
DOB: 02/02/1968
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest	Life threatening	Cardiac arrest (asystole) and psychosis with severe dehydration.	
Cardiac arrest	Life threatening		
Dehydration	Life threatening		
Psychotic disorder	Life threatening		

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Other disturbance of sensation
Injection 10.0 Milligram Daily Intravenous
Batch: **Started:** 12/12/2004 **Stopped:** 12/12/2004 0

DIAZEPAM (Suspected) **Reason:** Other disturbance of sensation
Injection 10.0 Milligram Daily Intravenous
Batch: **Started:** 12/12/2004 **Stopped:** 12/12/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 204838 **Seq:** 1
Reported: 02/02/2005
Hospitalisation: Admitted to hospital
Onset Date: 06/12/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 78
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delirium	Caused or prolonged inpatient hospitalisation	Delirum, confusion, decreased conscious state.	Ceased Talam, Serenace, Aricept.
Confusional state	Caused or prolonged inpatient hospitalisation		
Depressed level of consciousness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANADOL (Other drug) **Reason:** Pain
500.0 Milligram As necessary
Batch: **Started:** **Stopped:**

LACTULOSE (Other drug) **Reason:** Constipation
10.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:**

SEREPAX (Suspected) **Reason:** Anxiety neurosis
15.0 Milligram As necessary
Batch: **Started:** **Stopped:** 06/12/2004

Talam (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 29/11/2004 **Stopped:** 06/12/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 204838 **Seq:** 1
Reported: 02/02/2005
Hospitalisation: Admitted to hospital
Onset Date: 06/12/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 78
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

SERENACE (Suspected)			**Reason:**	Otr spec symp psychopathol nec	
Tablet	0.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	06/12/2004
ARICEPT (Suspected)			**Reason:**	Unspecified psychosis	
Tablet	5.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	06/12/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 204844 **Seq:** 1 **Gender:** M
Reported: 02/02/2005 **Weight:** 0.00
Hospitalisation: **Age:** 41
Onset Date: 14/12/2004 **DOB:** 22/11/1963
Outcome: Recovered 14/12/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Respiratory arrest	Life threatening	Respiratory arrest, unusual reaction? due to hypokalaemia and intoxication, maybe the result of administering the drugs too quickly intravenously.	CPR, intubated, ventilated.

Medicine Details:

FLUCLOXACILLIN SODIUM (Suspected)			**Reason:** Otr loc skin&subcut tis infect	
Injection	1.0 Gram	Daily		Intravenous
Batch:	**Started:** 14/12/2004		**Stopped:** 14/12/2004	
PROBENECID (Suspected)			**Reason:**	
Tablet	1.0 Gram	Daily		Oral
Batch:	**Started:** 14/10/2004		**Stopped:** 14/12/2004	
HALOPERIDOL (Suspected)			**Reason:**	
Injection	5.0 Milligram	Daily		Intravenous
Batch:	**Started:** 14/12/2004		**Stopped:** 14/12/2004	
DIAZEPAM (Suspected)			**Reason:**	
Injection	10.0 Milligram	Daily		Intravenous
Batch:	**Started:** 14/12/2004		**Stopped:** 14/12/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 205125 **Seq:** 1 **Gender:** M
Reported: 09/02/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 84
Onset Date: 25/11/2004 **DOB:**
Outcome: Recovered 06/01/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life threatening	Patient developed neuroleptic malignant syndrome.	Haloperidol and Olanzapine ceased.

Medicine Details:

HALOPERIDOL (Interaction) **Reason:** Otr spec symp psychopathol nec
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 20/11/2004 **Stopped:** 21/11/2004

OLANZAPINE (Interaction) **Reason:** Otr spec symp psychopathol nec
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 22/11/2004 **Stopped:** 25/11/2004

AMPICILLIN (Other drug) **Reason:**
Injection 1.0 Gram Intravenous
Batch: **Started:** 19/11/2004 **Stopped:** 20/11/2004

OXAZEPAM (Other drug) **Reason:**
Tablet 8.0 Milligram Oral
Batch: **Started:** 20/11/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/02/2005	Creatine		25/11/2004	2973	CKMB=27

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 205795 **Seq:** 1
Reported: 07/03/2005
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 56
DOB: 07/03/1949
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Systemic lupus erythematosus Activated partial thromboplastin tim Antiphospholipid antibodies positiv Contusion Galactorrhoea		The patient developed systemic lupus erythematosus/lupus coagulation inhibitor. Initially, this presented as bruising.	

Medicine Details:

HALDOL DECANOATE (Suspected) **Reason:**
Injection
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the patient probably developed galactorrhoea at least 5 years ago

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 205805 **Seq:** 1 **Gender:** M
Reported: 07/03/2005 **Weight:** 42.00
Hospitalisation: Admitted to hospital **Age:** 13
Onset Date: 17/02/2005 **DOB:** 22/07/1991
Outcome: Recovered 17/02/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Admitted to Hospital	Dystonic reaction: eyes rolled up, all muscles flexed and spasm, swollen tongue.	Cogentin x 2 and Midazolam.
Muscle spasms	Admitted to Hospital		
Oculogyration	Admitted to Hospital		
Swollen tongue	Admitted to Hospital		

Medicine Details:

PROPRANOLOL HYDROCHLORIDE (Suspected) **Reason:** Other disturbance of sensation
Batch: **Started:** 17/02/2005 **Stopped:** 17/02/2005

HALOPERIDOL (Suspected) **Reason:** Other disturbance of sensation
Batch: **Started:** 17/02/2005 **Stopped:** 17/02/2005

CANNABIS PREPARATION (Suspected) **Reason:**
3.0 Dose Unspecified Daily Inhalation
Batch: **Started:** **Stopped:** 17/02/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Known IV drug user and marijuana user.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 206004 **Seq:** 1 **Gender:** M
Reported: 14/03/2005 **Weight:** 0.00
Hospitalisation: **Age:** 66
Onset Date: 09/02/2005 **DOB:** 23/01/1939
Outcome: Recovered 20/02/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state	Life threatening	Patient developed mental changes-> confusion with agitation, sustained rapid eye movements resembling nystagmus, serotonin syndrome, myoclonus and hyper-reflexia.	Ceased Cipramil.
Agitation	Life threatening		
Hyperreflexia	Life threatening		
Myoclonus	Life threatening		

Medicine Details:

AMLODIPINE (Other drug) **Reason:** Essential benign hypertension
Batch: **Started:** **Stopped:**

PRAZOSIN HYDROCHLORIDE (Other drug) **Reason:** Essential benign hypertension
Batch: **Started:** **Stopped:**

CELECOXIB (Other drug) **Reason:** Pain
Batch: **Started:** **Stopped:**

TEMAZEPAM (Other drug) **Reason:** Specific disorders of sleep
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 206004 **Seq:** 1 **Gender:** M
Reported: 14/03/2005 **Weight:** 0.00
Hospitalisation: **Age:** 66
Onset Date: 09/02/2005 **DOB:** 23/01/1939
Outcome: Recovered 20/02/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nystagmus	Life threatening		
Serotonin syndrome	Life threatening		

Medicine Details:

PANADOL (Other drug) **Reason:** Pain
Batch: **Started:** **Stopped:**

GABAPENTIN (Other drug) **Reason:** Pain
Batch: **Started:** **Stopped:**

CIPROFLOXACIN (Other drug) **Reason:** Otr&nos infec&parasit diseases
Batch: **Started:** **Stopped:**

DEXAMETHASONE (Other drug) **Reason:** Pain
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 206004 **Seq:** 1 **Gender:** M
Reported: 14/03/2005 **Weight:** 0.00
Hospitalisation: **Age:** 66
Onset Date: 09/02/2005 **DOB:** 23/01/1939
Outcome: Recovered 20/02/2005 **Causality:** Causality possible

Reaction Details:

Medicine Details:

MOXIFLOXACIN (Other drug) **Reason:** Other diseases of lung

Batch: **Started:** **Stopped:**

CIPRAMIL (Suspected) **Reason:** Depression

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** 08/02/2005 **Stopped:** 17/02/2005

HYDROMORPHONE HYDROCHLORIDE (Suspected) **Reason:** Pain

440.0 Milligram Daily

Batch: **Started:** S TERM **Stopped:** Contin

KETAMINE HYDROCHLORIDE (Suspected) **Reason:** Pain

400.0 Milligram Daily

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 206004 **Seq:** 1 **Gender:** M
Reported: 14/03/2005 **Weight:** 0.00
Hospitalisation: **Age:** 66
Onset Date: 09/02/2005 **DOB:** 23/01/1939
Outcome: Recovered 20/02/2005 **Causality:** Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Pain
1.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 206147 **Seq:** 1 **Gender:** F
Reported: 17/03/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 99u
Onset Date: **DOB:**
Outcome: Recovered 10/03/2005 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence Agitation Asthenia Confusional state Constipation Dizziness Dyspepsia		The patient experienced drowsiness, restlessness, agitation, confusion, inability to sleep, muscle weakness, difficulty speaking, indigestion, constipation, increased salivation, blurred vision, sunburn and dizziness.	

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified psychosis
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 27/02/2005 **Stopped:** 07/03/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 206147 **Seq:** 1 **Gender:** F
Reported: 17/03/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 99u
Onset Date: **DOB:**
Outcome: Recovered 10/03/2005 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Insomnia Restlessness Salivary hypersecretion Speech disorder Sunburn Vision blurred			

Medicine Details:

SERENACE (Suspected) **Reason:** Unspecified psychosis
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 27/02/2005 **Stopped:** 07/03/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 206212 **Seq:** 1 **Gender:** U
Reported: 22/03/2005 **Weight:** 0.00
Hospitalisation: **Age:** 28
Onset Date: 04/03/2005 **DOB:** 22/11/1976
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tongue paralysis Speech disorder		The patient experienced a stiff tongue and struggled with conversation.	Benztropine 2mg IM.

Medicine Details:

MIDAZOLAM (Suspected)			**Reason:** Otr spec symp psychopathol nec	
Injection	20.0 Milligram	1 time		Intravenous
Batch:	**Started:** 03/03/2005		**Stopped:**	
CLONAZEPAM (Suspected)			**Reason:** Otr spec symp psychopathol nec	
Injection	1.0 Milligram	1 time		Intravenous
Batch:	**Started:**		**Stopped:**	
HALOPERIDOL (Suspected)			**Reason:** Otr spec symp psychopathol nec	
Injection	10.0 Milligram	1 time		Intravenous
Batch:	**Started:** 03/03/2005		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 206403 **Seq:** 1
Reported: 31/03/2005
Hospitalisation: Hospitalisation prolonged
Onset Date: 01/02/2004
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 71Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonism	Caused or prolonged inpatient hospitalisation	Parkinsonism.	Serenace ceased; Sinemet.

Medicine Details:

LANOXIN PG (Other drug) **Reason:** Otr&nos disord of heart rhythm
Batch: **Started:** **Stopped:**

SOTALOL HYDROCHLORIDE (Other drug) **Reason:** Otr&nos disord of heart rhythm
Batch: **Started:** **Stopped:**

METFORMIN HYDROCHLORIDE (Other drug) **Reason:** Diabetes mellitus
Batch: **Started:** **Stopped:**

RAMIPRIL (Other drug) **Reason:** No reason given
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 206403 **Seq:** 1
Reported: 31/03/2005
Hospitalisation: Hospitalisation prolonged
Onset Date: 01/02/2004
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 71Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

GLICLAZIDE (Other drug)		**Reason:**	Diabetes mellitus
Batch:	**Started:**		**Stopped:**
GLUCOBAY (Other drug)		**Reason:**	Diabetes mellitus
Batch:	**Started:**		**Stopped:**
COSOPT EYE DROPS (Other drug)		**Reason:**	Unspecified glaucoma
Batch:	**Started:**		**Stopped:**
ATROPT (Other drug)		**Reason:**	Unspecified glaucoma
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 206403 **Seq:** 1
Reported: 31/03/2005
Hospitalisation: Hospitalisation prolonged
Onset Date: 01/02/2004
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 71Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

SERENACE (Suspected)				**Reason:**	Unspecified psychosis
Tablet	0.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	27/02/2004

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 206432 **Seq:** 1 **Gender:** F
Reported: 01/04/2005 **Weight:** 0.00
Hospitalisation: **Age:** 26Y
Onset Date: 09/02/2005 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		The patient experienced a severe dystonic reaction.	Cogentin 2mg IM.

Medicine Details:

PAXAM (Other drug)			**Reason:**	
Tablet	3.0 Milligram			Oral
Batch:	**Started:**		**Stopped:**	14/02/2005
EPILIM (Other drug)			**Reason:**	
Tablet	1.0 Gram			Oral
Batch:	**Started:**		**Stopped:**	
SERENACE (Suspected)			**Reason:**	
Injection	2.0 Milligram	As necessary		Intramuscular
Batch:	**Started:** 08/02/2005		**Stopped:**	14/02/2005
SEROQUEL (Suspected)			**Reason:**	Unspecified schizophrenia
Tablet	600.0 Milligram	Daily		Oral
Batch:	**Started:** 08/02/2005		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Discharged on 14/02/05 with Seroquel 400, Epilim 1000.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 207058 **Seq:** 1 **Gender:** M
Reported: 14/04/2005 **Weight:** 0.00
Hospitalisation: **Age:** 79
Onset Date: 04/01/2005 **DOB:** 05/02/1925
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Unresponsive to stimuli	Caused or prolonged inpatient hospitalisation	Patient unresponsive, eye rolling, dystonic reaction suspected.	Trialed 1mg IV stat, Benztropine and Haloperidol ceased.
Dystonia	Caused or prolonged inpatient hospitalisation		
Eye rolling	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ASPIRIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

OXAZEPAM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

DILTIAZEM HYDROCHLORIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

CLOPIDOGREL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 207058 **Seq:** 1
Reported: 14/04/2005
Hospitalisation:
Onset Date: 04/01/2005
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 79
DOB: 05/02/1925
Causality: Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)			**Reason:**	Otr spec symp psychopathol nec
Tablet	0.0 Milligram		As necessary	Oral
Batch:	**Started:** 04/01/2005		**Stopped:**	04/01/2005

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 207802 **Seq:** 1 **Gender:** M
Reported: 13/05/2005 **Weight:** 62.00
Hospitalisation: **Age:** 37
Onset Date: 23/04/2005 **DOB:** 05/04/1968
Outcome: Recovered 23/04/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sleep disorder Back pain Musculoskeletal stiffness Pain Sleep disorder Somnolence		The patient experienced stiffness and worsened pain, chronic back pain, broken sleep and drowsiness by day.	Given Benztropine.

Medicine Details:

OLANZAPINE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

SOMAC (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PARACETAMOL (Other drug) **Reason:** Pain
Batch: **Started:** **Stopped:**

TRAMADOL HYDROCHLORIDE (Other drug) **Reason:** Pain
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 207802 **Seq:** 1 **Gender:** M
Reported: 13/05/2005 **Weight:** 62.00
Hospitalisation: **Age:** 37
Onset Date: 23/04/2005 **DOB:** 05/04/1968
Outcome: Recovered 23/04/2005 **Causality:** Causality possible

Reaction Details:

Medicine Details:

MELOXICAM (Other drug) **Reason:** Pain

Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**

2.5 Milligram Daily

Batch: **Started:** 18/04/2005 **Stopped:** 21/04/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 207821 **Seq:** 1 **Gender:** M
Reported: 13/05/2005 **Weight:** 82.00
Hospitalisation: **Age:** 99u
Onset Date: 07/12/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia	Caused or prolonged inpatient hospitalisation	The patient experienced akathisia.	Risperdal ceased.
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LORAZEPAM (Other drug) **Reason:**
2.0 Milligram
Batch: **Started:** 18/11/1998 **Stopped:** 05/12/1998

BENZTROPINE MESYLATE (Other drug) **Reason:**
0.5 Milligram Daily
Batch: **Started:** 26/11/1998 **Stopped:**

CLONAZEPAM (Other drug) **Reason:**
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 29/11/1998 **Stopped:**

RISPERDAL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 4.0 Milligram Daily Oral
Batch: **Started:** 18/11/1998 **Stopped:** 08/12/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical Trial RODOS WAVE I; RODOS

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 207821 **Seq:** 1
Reported: 13/05/2005
Hospitalisation:
Onset Date: 07/12/1998
Outcome: Unknown

Gender: M
Weight: 82.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)			**Reason:**	
Tablet	5.0 Milligram		Daily	Oral
Batch:	**Started:** 06/12/1998		**Stopped:**	08/12/1998

Laboratory Investigations:

Additional Information:

Clinical Trial RODOS WAVE I; RODOS

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 207831 **Seq:** 1 **Gender:** F
Reported: 16/05/2005 **Weight:** 46.00
Hospitalisation: **Age:** 29Y
Onset Date: 18/03/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	Caused or prolonged inpatient hospitalisation	The patient experienced generalised mild stiffness.	Benztropine given.
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

UNISOM SLEEPGELS (Other drug) **Reason:**
1.0 Dose Unspecified Oral
Batch: **Started:** 11/03/1999 **Stopped:**

RISPERDAL (Suspected) **Reason:** Unspecified schizophrenia
6.0 Milligram Daily Oral
Batch: **Started:** 01/03/1999 **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
6.0 Milligram Daily
Batch: **Started:** 18/03/1999 **Stopped:** Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I:RODOS.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 208349 **Seq:** 1
Reported: 01/06/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 03/03/2005
Outcome: Not yet recovered

Gender: F
Weight: 76.00
Age: 36
DOB: 17/06/1968
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Depressed level of consciousness Extrapyramidal disorder		Severe CNS depression effect, dose reduction and drug induced extrapyramidal side effects.	Dose reduction 3-1 daily now reducing by half daily weekly.

Medicine Details:

SERENACE (Suspected) **Reason:** Anxiety neurosis

1.0 Dose Unspecified Daily

Batch: **Started:** 15/08/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 208759 **Seq:** 1 **Gender:** F
Reported: 20/06/2005 **Weight:** 63.00
Hospitalisation: **Age:** 56Y
Onset Date: 17/09/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness Urinary retention		The patient experienced stiffness and urinary retention.	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified schizophrenia
10.0 Milligram Daily Oral
Batch: **Started:** 17/09/1997 **Stopped:** 22/09/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS.

Report Details:

Case Number: 208761 **Seq:** 1 **Gender:** F
Reported: 20/06/2005 **Weight:** 53.00
Hospitalisation: **Age:** 99u
Onset Date: 16/08/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle spasms	Caused or prolonged inpatient hospitalisation	Following an increase in Haloperidol dosage from 10mg to 15mg the patient experienced leg cramps.	
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LITHIUM CARBONATE (Other drug) **Reason:**
500.0 Milligram Oral
Batch: **Started:** 14/08/1997 **Stopped:**

BENZTROPINE MESYLATE (Other drug) **Reason:**
1.0 Milligram Oral
Batch: **Started:** 14/08/1997 **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Unspecified schizophrenia
15.0 Milligram Daily
Batch: **Started:** 14/08/1997 **Stopped:** 14/08/1997 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 209251 **Seq:** 1
Reported: 29/06/2005
Hospitalisation: Admitted to hospital
Onset Date: 27/02/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 24
DOB: 15/07/1980
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lethargy	Life threatening	Admitted to PA 10/02 for decreased behaviour (intellectual impairment) constant screaming. No treatable reason found, CT clear. Risperidone commenced 18/02 at 0.5mg. Patient more settle and discharged on same 22/02. OK for 1/52. 27/03 - listless and lethargic 28/03 - sudden collapse. Seizure suspected, whole back very hot and red with cold peripheries. Admitted to hospital - severe rhbdomyolysis and ARF, 2 days in ICU. Episode noted as possible neuroleptic malignant syndrome secondary Risperidone or Haloperidol.	

Medicine Details:

BISACODYL (Other drug) **Reason:** Constipation
20.0 Milligram
Batch: **Started:** **Stopped:**

FOLIC ACID (Other drug) **Reason:**
5.0 Milligram
Batch: **Started:** **Stopped:**

PANTOPRAZOLE (Other drug) **Reason:**
40.0 Milligram
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
As necessary
Batch: **Started:** 15/12/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 209251 **Seq:** 1
Reported: 29/06/2005
Hospitalisation: Admitted to hospital
Onset Date: 27/02/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 24
DOB: 15/07/1980
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Life threatening		
Neuroleptic malignant syndrome	Life threatening		
Renal failure acute	Life threatening		
Rhabdomyolysis	Life threatening		

Medicine Details:

RISPERIDONE (Suspected) **Reason:** Otr spec symp psychopathol nec

0.5 Milligram Daily

Batch: **Started:** 18/02/2005 **Stopped:** 27/02/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 209722 **Seq:** 1
Reported: 11/07/2005
Hospitalisation: Admitted to hospital
Onset Date: 23/05/2004
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 84Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fall	Caused or prolonged inpatient hospitalisation	Patient experienced multiple falls and confusion.	Haloperidol ceased.
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ANDROCUR (Other drug) **Reason:** Malignant neoplasm of prostate
Batch: **Started:** **Stopped:**

RIVASTIGMINE (Other drug) **Reason:** Unspecified psychosis
Batch: **Started:** **Stopped:**

LACTULOSE (Other drug) **Reason:** Constipation
Batch: **Started:** **Stopped:**

NITRAZEPAM (Other drug) **Reason:** Specific disorders of sleep
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 209722 **Seq:** 1
Reported: 11/07/2005
Hospitalisation: Admitted to hospital
Onset Date: 23/05/2004
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 84Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
5.0 Milligram Daily
Batch: **Started:** 13/05/2004 **Stopped:** 25/05/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 210550 **Seq:** 1
Reported: 10/08/2005
Hospitalisation: Admitted to hospital
Onset Date: 12/07/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 43
DOB: 03/05/1962
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose	Caused or prolonged inpatient hospitalisation	Patient experienced prescribed overdose, cardiac failure and cardiomyopathy.	Olanzapine dose reduced to 10mg daily and Trifluoperazine dose reduced to 5mg daily.
Cardiac failure	Caused or prolonged inpatient hospitalisation		
Cardiomyopathy	Caused or prolonged inpatient hospitalisation		

Medicine Details:

STELAZINE (Other drug) **Reason:** Unspecified psychosis
10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
Batch: **Started:** **Stopped:** 0

ZYPREXA (Suspected) **Reason:** Unspecified psychosis
30.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 210998 **Seq:** 1 **Gender:** M
Reported: 22/08/2005 **Weight:** 72.00
Hospitalisation: **Age:** 75Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonism	Caused or prolonged inpatient hospitalisation	The patient developed drug-induced Parkinsonian syndrome. He was noted to have weakness, experienced increased dysphagia, developed slurred speech and had a 'cerebral infarction'.	Cogentin given.
Cerebral infarction	Caused or prolonged inpatient hospitalisation		

Medicine Details:

HEPARIN SODIUM (Other drug) **Reason:**
Injection 4.2 Thousand Internal Intravenous
Batch: **Started:** 14/04/2005 **Stopped:** 14/04/2005

SERENACE (Suspected) **Reason:**
Injection 10.0 Milligram Daily Intramuscular
Batch: **Started:** 25/04/2005 **Stopped:** 25/04/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 211902 **Seq:** 1
Reported: 23/09/2005
Hospitalisation: Admitted to hospital
Onset Date: 16/07/2005
Outcome: Recovered with sequelae

Gender: M
Weight: 0.00
Age: 42Y
DOB:
Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Injection site reaction	Caused or prolonged inpatient hospitalisation	The patient experienced an injection site reaction after receiving Haloperidol Decanoate. He developed a large lump, redness and soreness. The next time he received Haloperidol he again experienced an injection site reaction.	Antibiotics.

Medicine Details:

HALDOL DECANOATE (Suspected) **Reason:** Unspecified schizophrenia

Injection 50.0 Milligram Alternate weeks Intramuscular

Batch: **Started:** 16/12/2004 S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug positive rechallenge.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 212051 **Seq:** 1 **Gender:** U
Reported: 28/09/2005 **Weight:** 0.00
Hospitalisation: **Age:** 40
Onset Date: 08/07/2005 **DOB:** 05/10/1964
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia Therapy regimen changed		The patient developed akathisia. Haloperidol dosage had been increased to 0.5 mg tds orally on 30 June 2005, then 0.75 mg orally tds on 7 July 2005.	Cogentin and Diazepam. Haloperidol dose reduced on 9 July 2005, then ceased on 19 July 2005.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
2.3 Milligram Daily Oral
Batch: **Started:** **Stopped:** 19/07/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/09/2005	Serum drug level				Haloperidol increased to 0.5mg TDS oral on 30/06/05, then 0.75mg oral TDS on 07/07/05.

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 212194 **Seq:** 1 **Gender:** F
Reported: 05/10/2005 **Weight:** 60.80
Hospitalisation: **Age:** 74
Onset Date: 16/09/2005 **DOB:** 12/01/1931
Outcome: Recovered 17/09/2005 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression Condition aggravated		Patient became aggressive verbally and physically and severity worsened after adding in Haloperidol.	Haloperidol ceased.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Explosive personality disorder
Tablet 3.0 Milligram Daily Oral
Batch: **Started:** 15/09/2005 **Stopped:** 16/09/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 214313 **Seq:** 1 **Gender:** M
Reported: 14/12/2005 **Weight:** 0.00
Hospitalisation: **Age:** 61
Onset Date: 11/11/2005 **DOB:** 02/07/1944
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Hyperhidrosis Pain Tachycardia		Patient experienced dystonias, arching back, pain, hypertensive, draphoretic, tachycardic.	Benztropine 1mg IV stat x 1, Morphine 2.5mg IV stat, Clonazepam 1.5mg at nocte, Domperidone 10mg qid prn.

Medicine Details:

BACLOFEN (Other drug)		**Reason:**
Batch:	**Started:**	**Stopped:**
HEPARIN SODIUM (Other drug)		**Reason:**
Batch:	**Started:**	**Stopped:**
SPIRONOLACTONE (Other drug)		**Reason:**
Batch:	**Started:**	**Stopped:**
MAGMIN (Other drug)		**Reason:**
Batch:	**Started:**	**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 214313 **Seq:** 1
Reported: 14/12/2005
Hospitalisation:
Onset Date: 11/11/2005
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 61
DOB: 02/07/1944
Causality: Causality possible

Reaction Details:

Medicine Details:

FLUCLOXACILLIN SODIUM (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
HALOPERIDOL (Suspected)		**Reason:**	
	2.0 Milligram		
Batch:	**Started:** 26/10/2005		**Stopped:**
METOCLOPRAMIDE HYDROCHLORIDE (Suspected)		**Reason:**	Nausea and vomiting
	10.0 Milligram		As necessary
Batch:	**Started:**		**Stopped:** 11/11/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 214393 **Seq:** 1 **Gender:** F
Reported: 19/12/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 68Y
Onset Date: 25/08/2005 **DOB:**
Outcome: Recovered 03/09/2005 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation	The patient's creatine kinase increased.	Haloperidol ceased. Changed to Amisulpride.

Medicine Details:

IRBESARTAN (Other drug) **Reason:** Essential benign hypertension
Batch: **Started:** **Stopped:**

PERINDOPRIL (Other drug) **Reason:** Essential benign hypertension
Batch: **Started:** **Stopped:**

OMEPRAZOLE (Other drug) **Reason:** Other diseases of esophagus
Batch: **Started:** **Stopped:**

LACTULOSE (Other drug) **Reason:** Constipation
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 214393 **Seq:** 1 **Gender:** F
Reported: 19/12/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 68Y
Onset Date: 25/08/2005 **DOB:**
Outcome: Recovered 03/09/2005 **Causality:** Causality probable

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified schizophrenia
10.0 Milligram Daily Oral
Batch: **Started:** 16/12/2004 **Stopped:** 25/08/2005 0

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 214595 **Seq:** 1
Reported: 05/01/2006
Hospitalisation: Admitted to hospital
Onset Date: 08/12/2005
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Small for dates baby	Caused or prolonged inpatient hospitalisation	The patient's baby was small for his gestational age and he experienced mild respiratory distress.	IV antibiotics.
Respiratory distress	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Risperdal Consta (Suspected) **Reason:**
Injection 25.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

HALOPERIDOL (Suspected) **Reason:**
Tablet 3.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 216863 **Seq:** 1
Reported: 31/03/2006
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Patient experienced neuroleptic malignant syndrome.	Transferred to ICU.

Medicine Details:

ZYPREXA (Suspected)		**Reason:**	
Batch:	**Started:**		**Stopped:**
HALOPERIDOL (Suspected)		**Reason:**	
Batch:	**Started:**		**Stopped:**
VALIUM (Suspected)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 217086 **Seq:** 1
Reported: 06/04/2006
Hospitalisation: Admitted to hospital
Onset Date: 01/01/2002
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 33
DOB: 24/05/1968
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Feeling abnormal	Caused or prolonged inpatient hospitalisation	Patient felt indifferent and felt frustrated. Slept all day/night, anxious, did not sleep, confused	Ceased medication. Returned to hospital for medication adjustment. Patient now on Abilify, Seroquel and Lithium.
Anxiety	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LITHIUM CARBONATE (Suspected) **Reason:** Unspecified schizophrenia
Tablet Oral
Batch: **Started:** L TERM **Stopped:**

VALIUM (Suspected) **Reason:** Anxiety neurosis
Batch: **Started:** **Stopped:**

RISPERDAL (Suspected) **Reason:** Unspecified schizophrenia
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 217086 **Seq:** 1
Reported: 06/04/2006
Hospitalisation: Admitted to hospital
Onset Date: 01/01/2002
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 33
DOB: 24/05/1968
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Frustration	Caused or prolonged inpatient hospitalisation		
Insomnia	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PROZAC (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

LARGACTIL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 217214 **Seq:** 1
Reported: 10/04/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 03/01/2006
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 74Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle rigidity Agitation Confusional state Extrapyramidal disorder Movement disorder		Patient experienced rigidity and movement difficulties-extrapyramidal side effects, confusion and agitation.	Haloperidol ceased.

Medicine Details:

LIPITOR (Other drug) **Reason:** Othr&unspec metabolic diseases
Batch: **Started:** **Stopped:**

PROPRANOLOL HYDROCHLORIDE (Other drug) **Reason:** Abnormal involuntary movement
Batch: **Started:** **Stopped:**

OXYCONTIN (Other drug) **Reason:** Other disturbance of sensation
Batch: **Started:** **Stopped:**

PARACETAMOL (Other drug) **Reason:** Other disturbance of sensation
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Tramadol, Clexane and Cephazolin.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 217214 **Seq:** 1
Reported: 10/04/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 03/01/2006
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 74Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

OMEPRAZOLE (Other drug)		**Reason:** Other diseases of esophagus	
Batch:	**Started:**		**Stopped:**
COLOXYL WITH SENNA (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
HALOPERIDOL (Suspected)		**Reason:** Otr spec symp psychopathol nec	
	2.0 Milligram	As necessary	
Batch:	**Started:** 03/01/2006		**Stopped:** 05/01/2006

Laboratory Investigations:

Additional Information:

Patient also taking Tramadol, Clexane and Cephazolin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 217295 **Seq:** 1 **Gender:** F
Reported: 11/04/2006 **Weight:** 0.00
Hospitalisation: **Age:** 48Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Respiratory arrest		Patient experienced a "bordering" respiratory arrest.	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

MIDAZOLAM (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Risperdal Consta (Suspected) **Reason:**
Injection 25.0 Milligram Daily Intramuscular
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 218100 **Seq:** 1 **Gender:** M
Reported: 08/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Visual disturbance Oculogyration		Patient experienced optical blackness/spotting, approximately 5 episodes per week.	Haloperidol ceased.

Medicine Details:

HALDOL DECANOATE (Suspected) **Reason:** Unspecified schizophrenia
Injection
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 219458 **Seq:** 1 **Gender:** F
Reported: 26/06/2006 **Weight:** 0.00
Hospitalisation: **Age:** 11
Onset Date: 05/01/2006 **DOB:** 08/10/1994
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Patient experienced rash.	Ceased Haloperidol

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
Injection Intravenous
Batch: **Started:** 05/01/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 219506 **Seq:** 1
Reported: 26/06/2006
Hospitalisation: Treated in Accident/Emergency Department
Onset Date: 23/09/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 77
DOB: 12/04/1928
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Condition aggravated Hypertonia Musculoskeletal stiffness		Patient admitted to emergency department and given IM Haloperidol 1mg for agitation - caused increased stiffness.	No further treatment with Haloperidol and Midazolam.

Medicine Details:

MORPHINE TARTRATE (Other drug)				**Reason:**	
Capsule	10.0	Milligram			Oral
Batch:	**Started:**			**Stopped:**	
MIRTAZAPINE (Other drug)				**Reason:**	
Tablet	30.0	Milligram			Oral
Batch:	**Started:**			**Stopped:**	
PARACETAMOL (Other drug)				**Reason:**	
Tablet	4.0	Gram			Oral
Batch:	**Started:**			**Stopped:**	
Levodopa-Benserazide (Other drug)				**Reason:**	
Tablet	4.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of Parkinson's Disease.

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 219506 **Seq:** 1
Reported: 26/06/2006
Hospitalisation: Treated in Accident/Emergency Department
Onset Date: 23/09/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 77
DOB: 12/04/1928
Causality: Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)			**Reason:**	Otr spec symp psychopathol nec
Injection	1.0 Milligram	1 time		
Batch:	**Started:** 23/09/2005		**Stopped:**	23/09/2005 0
MIDAZOLAM (Suspected)			**Reason:**	Otr spec symp psychopathol nec
Injection	2.0 Milligram	1 time		
Batch:	**Started:** 23/09/2005		**Stopped:**	23/09/2005

Laboratory Investigations:

Additional Information:

History of Parkinson's Disease.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 223805 **Seq:** 1 **Gender:** M
Reported: 05/12/2006 **Weight:** 0.00
Hospitalisation: Treated in Accident/Emergency Department **Age:** 24Y
Onset Date: 14/07/2006 **DOB:**
Outcome: Recovered 14/07/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Caused or prolonged inpatient hospitalisation	"Locked jaw", extrapyramidal side effects, tightening of jaw and feeling of swelling of tongue.	Benztropine
Swollen tongue	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DORYX (Other drug) **Reason:**
100.0 Milligram Oral
Batch: **Started:** **Stopped:**

BUPRENORPHINE HYDROCHLORIDE (Other drug) **Reason:**
Oral
Batch: **Started:** **Stopped:**

SERTRALINE HYDROCHLORIDE (Other drug) **Reason:**
50.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

HALOPERIDOL (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 12/07/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 226199 **Seq:** 1 **Gender:** M
Reported: 28/02/2007 **Weight:** 85.00
Hospitalisation: **Age:** 69
Onset Date: 06/02/2007 **DOB:** 31/10/1937
Outcome: Recovered 06/02/2007 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination Sleep talking		Hallucinations during the night, sleep talking.	Drugs ceased.

Medicine Details:

MAXOLON (Other drug) **Reason:** Nausea and vomiting
Batch: **Started:** **Stopped:** 0

ANZEMET (Other drug) **Reason:** Nausea and vomiting
Batch: **Started:** **Stopped:**

UREMIDE (Other drug) **Reason:** Edema and dropsy
Batch: **Started:** **Stopped:** Onoing.

FELODUR ER (Other drug) **Reason:** Essential benign hypertension
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient already in hospital. In hospital for abdominal aneurysm.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 226199 **Seq:** 1 **Gender:** M
Reported: 28/02/2007 **Weight:** 85.00
Hospitalisation: **Age:** 69
Onset Date: 06/02/2007 **DOB:** 31/10/1937
Outcome: Recovered 06/02/2007 **Causality:** Causality possible

Reaction Details:

Medicine Details:

ACTRAPID (Other drug)			**Reason:**	Othr&unspec metabolic diseases
Batch:	**Started:**		**Stopped:**	
Zolpidem Sandoz (Suspected)			**Reason:**	Specific disorders of sleep
Tablet	10.0 Milligram	Daily		Oral
Batch:	**Started:** 05/02/2007		**Stopped:**	07/02/2007
HYPNOVEL (Suspected)			**Reason:**	Otr spec symp psychopathol nec
Injection	12.0 Milligram	Daily		Intravenous
Batch:	**Started:** 05/02/2007		**Stopped:**	06/02/2007
MORPHINE SULPHATE (Suspected)			**Reason:**	Pain
Injection	5.0 Milligram	Daily		Intravenous
Batch:	**Started:** 05/02/2007		**Stopped:**	07/02/2007 0

Laboratory Investigations:

Additional Information:
Patient already in hospital. In hospital for abdominal aneurysm.

Report Details:

Case Number: 226199 **Seq:** 1 **Gender:** M
Reported: 28/02/2007 **Weight:** 85.00
Hospitalisation: **Age:** 69
Onset Date: 06/02/2007 **DOB:** 31/10/1937
Outcome: Recovered 06/02/2007 **Causality:** Causality possible

Reaction Details:

Medicine Details:

SERENACE (Suspected) **Reason:** Nausea and vomiting

Injection	5.0 Milligram	Daily	Intravenous
Batch:	**Started:** 05/02/2007	**Stopped:**	06/02/2007

Laboratory Investigations:

Additional Information:
Patient already in hospital. In hospital for abdominal aneurysm.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 25 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: HALDOL DECANOATE,HALOPERIDOL,HALOPERIDOL DECANOATE,PACEDOL,SERENACE

Report Details:

Case Number: 226975 **Seq:** 1 **Gender:** M
Reported: 26/03/2007 **Weight:** 0.00
Hospitalisation: **Age:** 39Y
Onset Date: **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Brugada syndrome Electrocardiogram QT prolonged Sudden death		brugada syndrome, prolonged QT interval, sudden death	

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

AMITRIPTYLINE HYDROCHLORIDE (Suspected) **Reason:**
200.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

SODIUM VALPROATE (Suspected) **Reason:**
1.0 Gram Daily
Batch: **Started:** **Stopped:** 0

LITHIUM CARBONATE (Suspected) **Reason:**
400.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/03/2007	Electrocardiograph				Electrocardiogram ST-T segment abnormal, ECG QT prolonged, Bundle branch block right, ECG ST segment elevation, ECG T wave inversion.
26/03/2007	Serum drug level				Amitriptyline level was 1.36 mmol/L (NR 0.27 - 0.72), nortriptyline was 3.92 (NR 0.19 - 0.57) and Lithium level was 0.2 (NR 0.5 - 1.0)
26/03/2007	Troponin				Troponin I was undetectable.

Additional Information:

The authors considered the QT prolongation related to treatment with amitriptyline and haloperidol. The authors comment that Brugada syndrome "has been associated with mutations in the sodium channel, SCN5A and may be unmasked by medications with sodium channel blocking activity". Furthermore, "in this case, all four medications may inactivate the cardiac sodium channels".
Roberts-Thomson KC et al. Drug-induced Brugada syndrome with ST-T wave alternans and long QT. Intern Med J 2007; 37(3):199-200.