



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181024
Reported: 02/01/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 07/11/2002

Age: 25

DOB: 19/09/1977

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal disorder	Caused or prolonged inpatient hospitalisation	Gastrointestinal disorder NOS, Mobility decreased, speech disorder and drooling	
Drooling	Caused or prolonged inpatient hospitalisation		
Mobility decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
COGENTIN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 10/07/2002	Stopped: 03/12/2002	contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181024

Seq: 1

Gender: M

Reported: 02/01/2003

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date: 07/11/2002

DOB: 19/09/1977

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Speech disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
COGENTIN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 10/07/2002	Stopped: 03/12/2002	contin

Laboratory Investigations:

Additional Information:



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Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181100 **Seq:** 1 **Gender:** M
Reported: 03/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 41
Onset Date: 11/11/2002 **DOB:** 21/01/1961
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal failure acute		Hepatic enzyomosis.	Treated with iv fluids rehydration and potassium replacement for the acute renal failure.
Dehydration	Caused or prolonged inpatient hospitalisation		
Hepatic function abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 21/10/2002	Stopped:	14/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/01/2003	ALT = SGPT	<45	14/11/2002	210	
03/01/2003	Creatinine				
03/01/2003	GGT = SGGT =	<50	14/11/2002	552	
03/01/2003	LDH	110 - 250	14/11/2002	203	
03/01/2003	SAP = ALP	40 - 110	14/11/2002	566	

Additional Information:

The patient had previously experienced "hepatic enzyomosis" during these two Clozaril usages and with concomitant Valproate.



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Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181100 **Seq:** 1 **Gender:** M
Reported: 03/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 41
Onset Date: 11/11/2002 **DOB:** 21/01/1961
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 21/10/2002	Stopped:	14/11/2002

Laboratory Investigations:

Additional Information:

The patient had previously experienced "hepatic enzyomosis" during these two Clozaril usages and with concomitant Valproate.



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Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181171

Seq: 1

Gender: M

Reported: 07/01/2003

Weight: 0.00

Hospitalisation:

Age: 32

Onset Date: 19/11/2002

DOB: 28/11/1969

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Raised CK levels, tachycardia	Treated with Benzodiazepines.
Blood creatine phosphokinase incr			
Rhabdomyolysis			
Troponin increased			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram
	Daily
	Oral
Batch:	Started: 31/07/1996
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/01/2003	Creatine kinase		19/11/2002	9000	
07/01/2003	Creatine kinase		16/12/2002	52	
07/01/2003	Electrocardiograph				
07/01/2003	Troponin		16/12/2002	<0.3	
07/01/2003	Troponin		19/11/2002	0.3	

Additional Information:

A cardiologist decided that there was no evidence of neuroleptic malignant syndrome or myocarditis.



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Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181321 **Seq:** 1 **Gender:** M
Reported: 09/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 58
Onset Date: 15/09/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delirium	Caused or prolonged inpatient hospitalisation	Delirium, high clozapine levels, deterioration in functioning and cognitive abilities in Sep 2002 and the patient showed signs of chronic delirium in Oct 2002.	Clozaril was decreased to 200mg daily.
Drug level increased	Caused or prolonged inpatient hospitalisation		
Thinking abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/01/2003	Pharmacokinetics				

Additional Information:



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Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181349

Seq: 1

Gender: F

Reported: 10/01/2003

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date: 05/12/2002

DOB: 26/03/1963

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Agranulocytosis and Neutropenia	clozapine ceased
Neutropenia			

Medicine Details:

CLOZAPINE (Suspected)		Reason:	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 07/11/2002	Stopped: 05/12/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/01/2003	Neutrophils				
10/01/2003	White blood cells		05/12/2002	2.7	
10/01/2003	White blood cells		05/12/2002	1.0	

Additional Information:



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Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181378
Reported: 10/01/2003

Seq: 1

Gender: U

Weight: 0.00

Hospitalisation:

Onset Date:

Age: 43

DOB: 10/09/1959

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal		Dropping things	Stopped Sodium Valproate for 2 days, treated with Cogentin.

Medicine Details:

CIPRAMIL (Other drug)		Reason: Depression	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: CONTIN
SODIUM VALPROATE (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozaril was started sometime in Nov 2001.



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Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181547 **Seq:** 1 **Gender:** F
Reported: 14/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 06/12/2002 **DOB:** 04/05/1973
Outcome: Recovered 06/12/2002 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myoclonus		Myoclonic jerk after first dose, complex partial seizure (severe and distressing) after second, 25mg dose.	

Medicine Details:

ZOLOFT (Other drug)		Reason: Depression	
Tablet	200.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
SEROQUEL (Other drug)		Reason: Unspecified schizophrenia	
	900.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	12.5 Milligram	1 time	Oral
Batch:	Started: 05/12/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181602 **Seq:** 1 **Gender:** F
Reported: 15/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: 05/12/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Neutropenia and Gastroenteritis	Clopine was ceased
Gastroenteritis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1993	Stopped: 05/12/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/01/2003	Neutrophils		05/12/2002	1.0	
15/01/2003	Neutrophils		16/12/2002	3.7	

Additional Information:

Previous history of drug dependence.



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Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181603 **Seq:** 1 **Gender:** M
Reported: 15/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 25Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis and Cardiac Troponin Increased	Transferred to the coronary care unit
Troponin increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)		Reason:	
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181647

Seq: 1

Gender: M

Reported: 15/01/2003

Weight: 0.00

Hospitalisation:

Age: 15

Onset Date: 12/07/2002

DOB: 21/05/1987

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased Enuresis Nausea Nocturia Salivary hypersecretion		Weight gain of 20kg, nocturnal enuresis, excessive drooling and nausea.	

Medicine Details:

CIPRAMIL (Other drug)	Reason: Depression
20.0 Milligram Daily	
Batch:	Started: Stopped:
CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 125.0 Milligram Daily Oral	
Batch:	Started: 12/07/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Already in hospital.



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Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181648

Seq: 1

Gender: M

Reported: 15/01/2003

Weight: 104.00

Hospitalisation:

Age: 15

Onset Date: 16/07/2002

DOB: 21/05/1987

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain Dizziness Fatigue Hyperhidrosis Pallor Tachycardia		Cold sweats, chest pain, tiredness and dizzines with exercise and tchycardia.	Fluvoxamine ceased and nd Clozapine dose decreased.

Medicine Details:

FLUVOXAMINE MALEATE (Other drug)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 12/07/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/01/2003	Pharmacokinetics	250-450			

Additional Information:

Already in hospital.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181657

Seq: 1

Gender: M

Reported: 15/01/2003

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date: 26/09/2002

DOB: 02/01/1960

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Clonic convulsion, Myoclonus; Dropping things from his hands, falling/collapsing	
Myoclonus			

Medicine Details:

METOCLOPRAMIDE HYDROCHLORIDE (Other drug)		Reason: Nausea and vomiting
Batch:	Started:	Stopped:
CLOPINE (Suspected)		Reason:
Tablet	400.0 Milligram	Oral
Batch:	Started:	Stopped: 09/01/2003 contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Fell to the ground with no loss of consciousness. Treated with epilim 200mg bd.



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Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181666

Seq: 1

Gender: M

Reported: 15/01/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date: 10/12/2002

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophil count increased		Increased eosinophilie count	

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/01/2003	Eosinophils				

Additional Information:

Clozaril started in November 2002



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181672

Seq: 1

Gender: M

Reported: 15/01/2003

Weight: 0.00

Hospitalisation:

Age: 38

Onset Date: 01/10/2002

DOB: 20/08/1964

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged Dizziness Dyspnoea Tachycardia		Increased QT interval; shortness of breath; tachycardia; dizziness	Clozaril dose decreased

Medicine Details:

LOSEC (Other drug)		Reason:	
Batch:	Started:	Stopped:	
LIPITOR (Other drug)		Reason:	
Batch:	Started:	Stopped:	
JEZIL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181674
Reported: 15/01/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 01/12/2002

Age: 46

DOB: 28/05/1956

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Life threatening	Hyponatraemia, convulsions, polydipsia. The patient had also been working in the extreme heat.	Clozaril reduced to 750mg daily.
Convulsion	Life threatening		
Polydipsia	Life threatening		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	850.0 Milligram	Daily	Oral
Batch:	Started: 01/05/2000	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/01/2003	Serum drug level				
15/01/2003	Sodium		10/12/2002	119	

Additional Information:

Other drug therapy lithium, diazepam



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Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181675

Seq: 1

Gender: M

Reported: 15/01/2003

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date: 26/09/2002

DOB: 25/05/1956

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejaculation disorder		Ejaculation disorder	Clozaril reduced
Salivary hypersecretion			Clozaril reduced
Somnolence			Clozaril reduced

Medicine Details:

CLONIDINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 13/05/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181679

Seq: 1

Gender: M

Reported: 15/01/2003

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date:

DOB: 05/07/1963

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes mellitus, urinary incontinence	
Urinary incontinence			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 03/08/1994 L TERM	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date of onset 2000.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181681

Seq: 1

Gender: M

Reported: 15/01/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bundle branch block		Mild bundle branch block, creatine phosphokinase increased.	
Blood creatine phosphokinase incr			

Medicine Details:

CLOZARIL (Suspected)		Reason:		
Tablet	450.0 Milligram	Daily	Oral	
Batch:	Started:	Stopped:	CONTIN	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/01/2003	Creatine				

Additional Information:

Dose start date for Clozaril - 10/2002.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181683 **Seq:** 1 **Gender:** M
Reported: 15/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 45Y
Onset Date: 10/12/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain	Caused or prolonged inpatient hospitalisation	Abdominal pain, epigastric pain, vomiting, withdrawal reaction, nausea	Analgesia, cogentin, antiemetics (andansetron). Clozaril recommenced
Abdominal pain upper	Caused or prolonged inpatient hospitalisation		
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 02/05/2002	Stopped: 03/12/2002	
COGENTIN (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred approximately 1 week after ceasing therapy.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181683 **Seq:** 1 **Gender:** M
Reported: 15/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 45Y
Onset Date: 10/12/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea	Caused or prolonged inpatient hospitalisation		
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 02/05/2002	Stopped: 03/12/2002	
COGENTIN (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Reaction occurred approximately 1 week after ceasing therapy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181702

Seq: 1

Gender: M

Reported: 15/01/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia Pyrexia		Neutrophilia and Spiking Fever	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The doctor thought that the events were of an infectious origin and gave the patient a course of broad-spectrum antibodies.



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Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181730
Reported: 16/01/2003

Seq: 1

Gender: F
Weight: 3.90
Age: 28D

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebral haemorrhage neonatal	Required Visit to Doctor	Acute haemorrhage in left basal ganglia of brain.	Phenobarbitone for seizures; ventilation; hyperbilirubinaemia requiring phototherapy
Infantile apnoeic attack		Apnoea and desaturation requiring ventilation for 1st p days of life.	
Congenital foot malformation		Baby dysmorphic - long, thin digits and overlapping 4th toes.	
Hyperbilirubinaemia		Conjugated hyperbilirubinaemia	
Weight decrease neonatal		Feed intolerance (weight dropped by 10% until day 20)	

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified psychosis	
Tablet		Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	
ZUCLOPENTHIXOL DECANOATE (Suspected)		Reason: Unspecified psychosis	
Injection		Intramuscular	
Batch:	Started:	Stopped:	
EPILIM (Suspected)		Reason:	
Tablet	1.2 Gram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/01/2003	Electroencephalog				EEG - seizure from right temporal region.
16/01/2003	Other data				Acute haemorrhage determined by cerebral ultrasound and MRI scan

Additional Information:

Epilim 1200mg started in 1991 (first trimester of pregnancy), then 1500mg/day (at 20 weeks gestation age) and continues.
Clozaril, zyprexa and zuclopenthixol started in 1991.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181730
Reported: 16/01/2003

Seq: 1

Gender: F
Weight: 3.90
Age: 28D

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatosplenomegaly neonatal		Liver disturbances and hepato-splenomegaly.	
Convulsion		Seizures from day 8 onwards	
Hyperammonaemia		Transient hyperammonemia.	
Vomiting		Vomiting	
Hypoxia			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified psychosis
Tablet	Oral
Batch:	Started: Stopped:
ZYPREXA (Suspected)	Reason:
Batch:	Started: Stopped:
ZUCLOPENTHIXOL DECANOATE (Suspected)	Reason: Unspecified psychosis
Injection	Intramuscular
Batch:	Started: Stopped:
EPILIM (Suspected)	Reason:
Tablet	1.2 Gram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

Epilim 1200mg started in 1991 (first trimester of pregnancy), then 1500mg/day (at 20 weeks gestation age) and continues.
Clozaril, zyprexa and zuclopenthixol started in 1991.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181757
Reported: 16/01/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date:

Age: 21

DOB: 26/04/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Platelet count decreased		Patient experienced epistaxis and low platelet count. The patient also experienced intermittent epistaxis and low platelet counts since July 2001, whilst receiving clozapine (generic).	
Epistaxis			

Medicine Details:

RANITIDINE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ENDEP (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 07/05/2001	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/01/2003	Platelets				

Additional Information:

Clozaril start date and onset date 2002.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181761 **Seq:** 1 **Gender:** M
Reported: 16/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 24
Onset Date: 05/12/2002 **DOB:** 20/12/1977
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis Cough Diarrhoea Pleuritic pain Pneumonia primary atypical Pyrexia Vomiting		Myocarditis, fever, diarrhoea, vomiting, pleuritic chest pain, pleurodynia.	Metoprolol and given cardiac monitoring.

Medicine Details:

SEROQUEL (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 20/11/2002	Stopped: 09/12/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/01/2003	Chest X-ray				
16/01/2003	Electrocardiograph				
16/01/2003	Other data				
16/01/2003	Troponin				

Additional Information:

Myocarditis was not mentioned on the hospital adverse reaction report. The patient recovered without sequelae.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181762 **Seq:** 1 **Gender:** M
Reported: 16/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 45
Onset Date: **DOB:** 28/04/1957
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion Somnolence		Salivary hypersecretion, somnolence.	Clonidine.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 04/09/2002 Stopped: 16/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history of mental retardation severity unspecified, and long standing history of seizures.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181763 **Seq:** 1 **Gender:** M
Reported: 16/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 45
Onset Date: **DOB:** 28/04/1957
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Convulsions aggravated.	Patient was on 300mg Clozaril a day which was reduced to 150mg and then ceased 1-2 days later.

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
CLONAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
TIAGABINE (Other drug)	Reason:
Batch:	Started: Stopped:
CLONIDINE HYDROCHLORIDE (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181763 **Seq:** 1

Reported: 16/01/2003

Hospitalisation: Admitted to hospital

Onset Date:

Outcome: Unknown

Gender: M

Weight: 0.00

Age: 45

DOB: 28/04/1957

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Unspecified schizophrenia

Tablet

300.0 Milligram

Daily

Oral

Batch:

Started: 04/09/2002

Stopped: 16/12/2002

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181889

Seq: 1

Gender: M

Reported: 21/01/2003

Weight: 0.00

Hospitalisation:

Age: 27

Onset Date: 22/12/2002

DOB: 19/11/1975

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder	Caused or prolonged inpatient hospitalisation	Cardiac disorder nos, myocarditis nos. The patient experienced fatigue, rigors, palpitations and shortness of breath, cardiac failure.	Ceased Clopine
Cardiac failure	Caused or prolonged inpatient hospitalisation		
Chills	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	800.0 Milligram
	Daily
	Oral
Batch:	Started: 12/12/2002
	Stopped: 23/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/01/2003	Blood culture				
21/01/2003	Creatine		23/12/2002	168	
21/01/2003	Other data				
21/01/2003	Troponin		23/12/2002	0.27	
21/01/2003	White blood cells		23/12/2002	12	

Additional Information:

patient also taking valproate, benztropine, risperidone and flupenthixol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181889

Seq: 1

Gender: M

Reported: 21/01/2003

Weight: 0.00

Hospitalisation:

Age: 27

Onset Date: 22/12/2002

DOB: 19/11/1975

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Fatigue	Caused or prolonged inpatient hospitalisation		
Myocarditis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	800.0 Milligram
	Daily
	Oral
Batch:	Started: 12/12/2002
	Stopped: 23/12/2002

Laboratory Investigations:

Additional Information:

patient also taking valproate, benztropine, risperidone and flupenthixol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181889

Seq: 1

Gender: M

Reported: 21/01/2003

Weight: 0.00

Hospitalisation:

Age: 27

Onset Date: 22/12/2002

DOB: 19/11/1975

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Palpitations	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	800.0 Milligram
	Daily
	Oral
Batch:	Started: 12/12/2002
	Stopped: 23/12/2002

Laboratory Investigations:

Additional Information:

patient also taking valproate, benztropine, risperidone and flupenthixol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182041 **Seq:** 1 **Gender:** M
Reported: 24/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 18
Onset Date: 30/12/2002 **DOB:** 29/05/1984
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin I increased Heart rate increased		Troponin I increased, tachycardia	Clopine ceased

Medicine Details:

CLOPINE (Suspected)	Reason:
	250.0 Milligram Daily
Batch:	Started: 09/12/2002 Stopped: 30/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2003	Creatine kinase	<5%	11/12/2002	84	
24/01/2003	Other data		30/12/2002	0.17	
24/01/2003	Troponin	TroponinI=<2.0n	11/12/2002	<0.04	
24/01/2003	Troponin	TroponinI=<2.0n	30/12/2002	0.17	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182105

Seq: 1

Gender: M

Reported: 28/01/2003

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date: 31/12/2002

DOB: 04/10/1968

Outcome: Death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death			
Death		Asphyxiation, Death Unexplained	

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)		Reason:	
75.0 Milligram		Daily	
Batch:	Started:	Stopped:	
VALIUM (Suspected)		Reason:	
Batch:	Started:	Stopped:	
ALCOHOL (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZAPINE (Suspected)		Reason:	
500.0 Milligram		Daily	
Batch:	Started: 03/07/2001	Stopped: 31/12/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient was caucasian with a medical history of chronic, paranoid schizophrenia with generalised anxiety disorder and panic disorder. Found dead having asphyxiated whilst at a party. Sudden event. The patient was thought to have taken 4 'stabbies of light bear at the time.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182184
Reported: 30/01/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 29/12/2002

Age: 38

DOB: 14/06/1964

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged Bundle branch block right Dizziness Muscle twitching Sinus tachycardia		Patient was diagnosed with mild QTc prolongation (465ms), sinus tachycardia, right bundle branch block, muscle twitching and dizziness when he fainted.	Monitoring, decreasing dose to 300mg/day then ceased.

Medicine Details:

PRAVACHOL (Other drug)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 03/01/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient was also receiving electroconvulsive therapy (ECT) concomitantly.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182196
Reported: 31/01/2003

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 30
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancreatitis		Patient developed pancreatitis during early 2000.	Clozaril ceased.

Medicine Details:

RISPERIDONE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
OLANZAPINE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ALCOHOL (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient developed pancreatitis in 1998, at which time she was on Clozaril but also drinking heavily. She was rechallenged late 1999 and developed pancreatitis again but she was no longer drinking heavily. It was intended to taper the doses of concomitant risperidone and olanzapine as clozapine was slowly increased but as soon as signs of pancreatitis presented, Clozaril was ceased.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182270

Seq: 1

Gender: F

Reported: 03/02/2003

Weight: 0.00

Hospitalisation:

Age: 48

Onset Date: 21/01/2003

DOB: 28/09/1954

Outcome: Unknown

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia		developed leucopenia and neutropenia	

Medicine Details:

CLOZAPINE (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 11/01/2002	Stopped:	contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/02/2003	Neutrophils		21/01/2003	1.4	
03/02/2003	leucocytes		21/01/2003	2.4	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182272

Seq: 1

Gender: M

Reported: 03/02/2003

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date: 21/01/2003

DOB: 12/04/1972

Outcome: Recovered

22/01/2003

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Patient developed severe tachycardia - 160 bpm	Clozaril ceased

Medicine Details:

OLANZAPINE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
LORAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 17/01/2003	Stopped: 21/01/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182308

Seq: 1

Gender: F

Reported: 04/02/2003

Weight: 0.00

Hospitalisation:

Age: 43Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure		Global impairment of left ventricular systolic function on echocardiogram	
Tachycardia		Sinus tachycardia,	Ceased Clopine

Medicine Details:

HALOPERIDOL (Other drug)		Reason:	
	3.0 Milligram	Daily	
Batch:	Started:	Stopped:	
DIAZEPAM (Other drug)		Reason:	
Tablet	7.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
	700.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 27/12/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

patient was also taking Benzhexol, Diabex, Zoton, Bisalax.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182309

Seq: 1

Gender: F

Reported: 04/02/2003

Weight: 0.00

Hospitalisation:

Age: 40

Onset Date: 27/12/2002

DOB: 31/01/1962

Outcome: Recovered

31/12/2002

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia	Clopine discontinued.

Medicine Details:

CLOPINE (Suspected)		Reason:	
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 12/11/2002	Stopped:	27/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/02/2003	Neutrophils		05/11/2002	5.1	
04/02/2003	Neutrophils		17/12/2002	1.5	
04/02/2003	White blood cells		05/11/2002	6.3	
04/02/2003	White blood cells		27/12/2002	3.3	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182312

Seq: 1

Gender: M

Reported: 04/02/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Embolism		Thromboembolism and pain in calf	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182330

Seq: 1

Gender: M

Reported: 04/02/2003

Weight: 0.00

Hospitalisation:

Onset Date: 27/12/2001

Age: 40Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Neutrophil count decreased	
Leukopenia	Caused or prolonged inpatient hospitalisation	White blood cell count decreased	Clozaril was temporarily interrupted and later recommenced. Interferon was discontinued.

Medicine Details:

INTERFERON ALFA-2A (Interaction)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Interaction)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 22/09/1993	Stopped:	contin
RIBAVIRIN (Other drug)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/02/2003	Neutrophils		23/08/2002	2.40	
04/02/2003	Neutrophils		11/12/2002	1.60	
04/02/2003	Neutrophils		09/01/2003	1.30	
04/02/2003	Neutrophils		04/01/2003	1.00	
04/02/2003	White blood cells		23/08/2002	4.50	
04/02/2003	White blood cells		11/12/2002	3.30	
04/02/2003	White blood cells		09/01/2003	2.50	

Additional Information:

Patient developed Hepatitis C approximately 10-15 years ago.
All blood counts were normal until the patient commenced interferon therapy for Hepatitis C.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182355

Seq: 1

Gender: M

Reported: 04/02/2003

Weight: 0.00

Hospitalisation:

Age: 21

Onset Date:

DOB: 07/06/1981

Outcome: Unknown

09/12/2002

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 11/12/2002	Stopped: 09/12/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/02/2003	Troponin				

Additional Information:

The patient received clozaril from 12/03/2003 (12.5mg) to 19/03/2003 and then changed to clopine on 31/03/2003. The patient received clopine 150mg per day from 31/03/2003 to 19/05/2003 and then 125mg per day at night from 27/05/2003 to 30/06/2003. The patient was then non-compliant.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182356

Seq: 1

Gender: M

Reported: 04/02/2003

Weight: 0.00

Hospitalisation:

Age: 45

Onset Date: 15/08/2002

DOB: 09/05/1957

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary gland enlargement	Required Specialist Consultation	Patient developed salivary gland swelling.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	650.0 Milligram
	Daily
	Oral
Batch:	Started: 24/05/2002
	Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Sodium Valproate, Beclometasone and Ventolin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182380 **Seq:** 1 **Gender:** F
Reported: 05/02/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 37
Onset Date: 15/12/2002 **DOB:** 03/07/1965
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Deep vein thrombosis		Deep vein thrombosis.	Patient treated with Warfarin and several investigations were done.

Medicine Details:

NICOTINE TRANSDERMAL PATCH (Other drug)		Reason:	
Patch, dermal			
Batch:	Started:	Stopped:	
EFEXOR (Other drug)		Reason:	
Batch:		Started:	Stopped: Contin
TOPIRAMATE (Other drug)		Reason:	
Batch:		Started: Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet		700.0 Milligram	Daily Oral
Batch:	Started: 02/02/1999	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Obese, Heavy smoker



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182388 **Seq:** 1 **Gender:** F
Reported: 05/02/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 06/12/2002 **DOB:** 04/05/1973
Outcome: Recovered 06/12/2002 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Myoclonic jerk after 1st dose of 12.5mg, complex partial seizure (severe and distressing) after 2nd 25gm dose.	Supportive and Diazepam IV.

Medicine Details:

ZOLOFT (Other drug)		Reason: Depression	
	200.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
SEROQUEL (Other drug)		Reason: Unspecified schizophrenia	
	900.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	25.0 Gram	Daily	Oral
Batch:	Started: 06/12/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182473

Seq: 1

Gender: F

Reported: 06/02/2003

Weight: 0.00

Hospitalisation:

Age: 60

Onset Date: 30/12/2002

DOB: 10/04/1942

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia		Patient experienced eosinophilia.	Clozaril ceased.

Medicine Details:

INSULIN NOS (Other drug)			Reason:	
Batch:	Started:	Stopped:		
CLOZARIL (Suspected)			Reason:	Unspecified schizophrenia
Tablet	400.0 Milligram	Daily	Oral	
Batch:	Started: 22/11/2002		Stopped: 20/01/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/02/2003	Eosinophils		30/12/2002	2.9	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182534 **Seq:** 1 **Gender:** F
Reported: 07/02/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 47
Onset Date: 01/01/2003 **DOB:** 17/10/1955
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		patient experienced a grand mal seizure.	Given Sodium Valproate as seizure prophylaxis

Medicine Details:

ZOLOFT (Other drug)		Reason:	
Batch:	Started:	L TERM	Stopped:
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	500.0 Milligram	Oral	
Batch:	Started: 10/07/1997	L TERM	Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/02/2003	Computerised				
07/02/2003	Electrocardiograph				

Additional Information:

The patient had no past history of seizures and had no myoclonic jerking prior to the grand mal seizure. Dose start date for Clozaril - 08/1998



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182568 **Seq:** 1 **Gender:** M
Reported: 10/02/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 21
Onset Date: 12/08/2002 **DOB:** 20/08/1980
Outcome: Recovered 28/08/2003 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia	Life threatening	Neutropenia and Leucopenia	
Neutropenia	Life threatening	Neutropenia, Leucopenia	

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	375.0 Milligram Daily Oral
Batch:	Started: 03/05/2002 Stopped: 16/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/02/2003	Neutrophils		12/08/2002	1.60	
10/02/2003	Neutrophils		20/08/2002	0.60	
10/02/2003	White blood cells		12/08/2002	3.00	
10/02/2003	White blood cells		20/08/2002	2.00	

Additional Information:

Agranulocytosis secondary to Clozapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182758 **Seq:** 1 **Gender:** U
Reported: 11/02/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 26
Onset Date: 26/01/2003 **DOB:** 25/10/1976
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Severe chest pain which was found to be myocarditis.	Panadol. Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 08/01/2003 Stopped: 26/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/02/2003	C-Reactive Protein				
11/02/2003	Electrocardiograph				
11/02/2003	Troponin				

Additional Information:

Later, on 13 Feb 2003 an ECG showed sinus tachycardia and S-T changes suggestive of pericarditis.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182848

Seq: 1

Gender: M

Reported: 13/02/2003

Weight: 0.00

Hospitalisation:

Age: 35

Onset Date:

DOB: 27/05/1967

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		The patient experienced an increase in creatine kinase (CK) levels after commencing Clozaril therapy. Rhabdomyolysis was initially suspected, but was ruled out by his treating doctors.	Clozaril was ceased.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	100.0 Milligram
	Daily
	Oral
Batch:	Started: 26/08/2002
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was already in hospital. Previous history of suspected neuroleptic malignant syndrome (NMS) (suspected) on typical antipsychotics.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182850
Reported: 13/02/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 30/01/2003

Age: 61

DOB: 08/01/1942

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Loss of consciousness		This patient passed out three hours after taking the morning dose , 8 days after commencing Clozaril. the dose at the time was 50 mg bd. She regained consciousness approximately three hours after passing out.	

Medicine Details:

OLANZAPINE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
DIAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
OXAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 23/01/2003	Stopped:	contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient experienced two seperate occasions of loss of consciousness after commencing clozaril therapy. She regained consciousness of her own accord. After a four day break, clozaril was recommenced slowly.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182903

Seq: 1

Gender: M

Reported: 14/02/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Medication error		Patient accidentally ingested Clozaril. He was being maintained on an unspecified antipsychotic.	Transferred to the Intensive care unit
Accidental exposure			

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	350.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred sometime in January 2003.
Clozaril was given sometime in January 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182941

Seq: 1

Gender: M

Reported: 14/02/2003

Weight: 0.00

Hospitalisation:

Onset Date: 06/01/2003

Age: 38

DOB: 08/10/1964

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest	Caused or prolonged inpatient hospitalisation	Profound constipation, Abdominal discomfort, Ileus paralytic, intestinal perforation, multi-organ failure, necrosis ischaemic, toxic dilatation of colon, streptococcal sepsis and cardiac arrest.	
Constipation	Caused or prolonged inpatient hospitalisation	Profound constipation, Abdominal discomfort, Ileus paralytic, intestinal perforation, multi-organ failure, necrosis ischaemic, toxic dilatation of colon, streptococcal sepsis and cardiac arrest.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/02/2003	Other data				

Additional Information:

Patient started clozaril in August 1994 on dose between 300 and 800mg /d until September 2002. On 31/12/02 dose recorded was 900mg/d. While in casualty patient suffered a cardiac arrest and was resuscitated. A Plain x-ray of the abdomen showed dilated bowel indicative of ileus and an impending perforation of the bowel. The patient developed streptococcal sepsis and died on 06/01/03. Constipation previously at the age of 17 years.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182941

Seq: 1

Gender: M

Reported: 14/02/2003

Weight: 0.00

Hospitalisation:

Onset Date: 06/01/2003

Age: 38

DOB: 08/10/1964

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ileus paralytic	Caused or prolonged inpatient hospitalisation	Profound constipation, Abdominal discomfort, Ileus paralytic, intestinal perforation, multi-organ failure, necrosis ischaemic, toxic dilatation of colon, streptococcal sepsis and cardiac arrest.	
Intestinal ischaemia	Caused or prolonged inpatient hospitalisation	Profound constipation, Abdominal discomfort, Ileus paralytic, intestinal perforation, multi-organ failure, necrosis ischaemic, toxic dilatation of colon, streptococcal sepsis and cardiac arrest.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Batch:	Started:
	Stopped:

Laboratory Investigations:

Additional Information:

Patient started clozaril in August 1994 on dose between 300 and 800mg /d until September 2002. On 31/12/02 dose recorded was 900mg/d. While in casualty patient suffered a cardiac arrest and was resuscitated. A Plain x-ray of the abdomen showed dilated bowel indicative of ileus and an impending perforation of the bowel. The patient developed streptococcal sepsis and died on 06/01/03. Constipation previously at the age of 17 years.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182941

Seq: 1

Gender: M

Reported: 14/02/2003

Weight: 0.00

Hospitalisation:

Onset Date: 06/01/2003

Age: 38

DOB: 08/10/1964

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intestinal perforation	Caused or prolonged inpatient hospitalisation	Profound constipation, Abdominal discomfort, Ileus paralytic, intestinal perforation, multi-organ failure, necrosis ischaemic, toxic dilatation of colon, streptococcal sepsis and cardiac arrest.	
Necrosis ischaemic	Caused or prolonged inpatient hospitalisation	Profound constipation, Abdominal discomfort, Ileus paralytic, intestinal perforation, multi-organ failure, necrosis ischaemic, toxic dilatation of colon, streptococcal sepsis and cardiac arrest.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Batch:	Started:
	Stopped:

Laboratory Investigations:

Additional Information:

Patient started clozaril in August 1994 on dose between 300 and 800mg /d until September 2002. On 31/12/02 dose recorded was 900mg/d. While in casualty patient suffered a cardiac arrest and was resuscitated. A Plain x-ray of the abdomen showed dilated bowel indicative of ileus and an impending perforation of the bowel. The patient developed streptococcal sepsis and died on 06/01/03. Constipation previously at the age of 17 years.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182941

Seq: 1

Gender: M

Reported: 14/02/2003

Weight: 0.00

Hospitalisation:

Age: 38

Onset Date: 06/01/2003

DOB: 08/10/1964

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Streptococcal sepsis	Caused or prolonged inpatient hospitalisation	Profound constipation, Abdominal discomfort, Ileus paralytic, intestinal perforation, multi-organ failure, necrosis ischaemic, toxic dilatation of colon, streptococcal sepsis and cardiac arrest.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Batch:	Started:
	Stopped:

Laboratory Investigations:

Additional Information:

Patient started clozaril in August 1994 on dose between 300 and 800mg /d until September 2002. On 31/12/02 dose recorded was 900mg/d. While in casualty patient suffered a cardiac arrest and was resuscitated. A Plain x-ray of the abdomen showed dilated bowel indicative of ileus and an impending perforation of the bowel. The patient developed streptococcal sepsis and died on 06/01/03. Constipation previously at the age of 17 years.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182976 **Seq:** 1 **Gender:** M
Reported: 17/02/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 28
Onset Date: 29/01/2003 **DOB:** 03/02/1974
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Diagnosed with myocarditis.	Clozaril ceased. Treated with quetiapine
Hyperhidrosis		Patient was also sweating profusely, had slurred speech and a slight decrease in temperature from 37.8 to 37.0 degrees.	
Blood creatine phosphokinase incr		Patient's CK had increased from 36 to 353, Troponin I was 41.8 and WBC increased.	
Dysarthria			
Gait disturbance			
Influenza like illness			

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 29/01/2003	Stopped:	02/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/02/2003	Creatine				
17/02/2003	Electrocardiograph				
17/02/2003	Neutrophils		28/01/2003	6.30x10^9/L	
17/02/2003	Neutrophils		31/01/2003	14.47x10^9/L	
17/02/2003	Neutrophils		04/02/2003	9.76x10^9/L	
17/02/2003	Troponin				
17/02/2003	White blood cells		28/01/2003	8.60x10^9/L	

Additional Information:

The patient experienced these symptoms once the patient commenced on 300mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 182976 **Seq:** 1 **Gender:** M
Reported: 17/02/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 28
Onset Date: 29/01/2003 **DOB:** 03/02/1974
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lethargy Malaise Pyrexia Tachycardia Troponin I increased White blood cell count increased			

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 29/01/2003	Stopped: 02/02/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/02/2003	White blood cells		31/01/2003	16.9x10 ⁹ /L	
17/02/2003	White blood cells		04/02/2003	13.9x10 ⁹ /L	

Additional Information:

The patient experienced these symptoms once the patient commenced on 300mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183001
Reported: 17/02/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 03/02/2003

Age: 38

DOB: 08/03/1964

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutrophil count decreased	Caused or prolonged inpatient hospitalisation	Decreased white blood cell count and Neutrophil count decreased.	
White blood cell count decreased	Caused or prolonged inpatient hospitalisation	Decreased white blood cell count and mental disorder	

Medicine Details:

CLOZARIL (Suspected)	Reason:
350.0 Milligram	Daily
Batch:	Started: 14/11/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/02/2003	Neutrophils		03/02/2003	1.40	
17/02/2003	Neutrophils		09/02/2003	0.90	
17/02/2003	White blood cells		03/02/2003	2.80	
17/02/2003	White blood cells		09/02/2003	2.10	

Additional Information:

The reporter said that the patient's mental state was not related to Clozaril therapy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183075 **Seq:** 1 **Gender:** M
Reported: 19/02/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 44
Onset Date: 03/02/2003 **DOB:** 07/12/1958
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizures.	Patient was intubated, ventilated and commenced on anti-convulsant medication. Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 15/10/2002	Stopped: 03/02/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183084

Seq: 1

Gender: F

Reported: 02/01/2003

Weight: 0.00

Hospitalisation:

Age: 54Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Drug ineffective		Seizures, inadequate response.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 05/09/2001	Stopped:	30/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Non-compliance.

Date of reaction: 2002.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183158
Reported: 21/02/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 13/02/2003

Age: 26

DOB: 13/05/1976

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Influenza like illness	Caused or prolonged inpatient hospitalisation	Flu like symptoms, sinus tachycardia and troponin levels raised	Ceased Clozaril
Myocardial ischaemia	Caused or prolonged inpatient hospitalisation	Flu like symptoms, sinus tachycardia and troponin levels raised	Ceased Clozaril
Sinus tachycardia	Caused or prolonged inpatient hospitalisation	Flu like symptoms, sinus tachycardia and troponin levels raised	Ceased Clozaril

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	300.0 Milligram
	Daily
	Oral
Batch:	Started: 31/01/2003
	Stopped: 14/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/02/2003	Troponin		14/02/2003	6.0	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183188
Reported: 21/02/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 03/01/2003

Age: 27

DOB: 01/02/1975

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Patient returned an abnormal Echocardiogram result.	Ceased Clozaril
Cardiomyopathy		Patient returned an abnormal Echocardiogram result.	Ceased Clozaril
Echocardiogram abnormal	Life threatening	Patient returned an abnormal Echocardiogram result.	Ceased Clozaril

Medicine Details:

AROPAX (Other drug)		Reason:	
Batch:	Started:	Stopped:	
COGENTIN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet		Daily	Oral
Batch:	Started: 09/05/2001	Stopped: 28/02/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

His condition improved and the events were considered related to clozaril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183195
Reported: 24/02/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date:

DOB: 14/03/1963

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Body temperature increased		Cardiac disorder, eosinophilia, ineffective drug	Zuclopenthixol IM/F. Clozapine ceased
C-reactive protein increased		Cardiac disorder, eosinophilia, ineffective drug	Zuclopenthixol IM/F. Clozapine ceased
Cardiac disorder		Cardiac disorder, eosinophilia, ineffective drug	Zuclopenthixol IM/F. Clozapine ceased
Dizziness		Cardiac disorder, eosinophilia, ineffective drug	Zuclopenthixol IM/F. Clozapine ceased
Drug ineffective		Cardiac disorder, eosinophilia, ineffective drug	Zuclopenthixol IM/F. Clozapine ceased
Eosinopenia		Cardiac disorder, eosinophilia, ineffective drug	Zuclopenthixol IM/F. Clozapine ceased

Medicine Details:

CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 24/01/2003	Stopped: 10/02/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/02/2003	Electrocardiograph				
24/02/2003	Eosinophils		13/02/2003	2.44	
24/02/2003	Eosinophils		19/12/2002	0.02	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183195

Seq: 1

Gender: M

Reported: 24/02/2003

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date:

DOB: 14/03/1963

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lethargy		Cardiac disorder, eosinophilia, ineffective drug	Zuclopenthixol IM/F. Clozapine ceased
Orthostatic hypotension		Cardiac disorder, eosinophilia, ineffective drug	Zuclopenthixol IM/F. Clozapine ceased
Red blood cell sedimentation rate i		Cardiac disorder, eosinophilia, ineffective drug	Zuclopenthixol IM/F. Clozapine ceased
Troponin increased		Cardiac disorder, eosinophilia, ineffective drug	Zuclopenthixol IM/F. Clozapine ceased

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram
	Daily
	Oral
Batch:	Started: 24/01/2003
	Stopped: 10/02/2003

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183204
Reported: 24/02/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 24

DOB: 02/09/1978

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder	Caused or prolonged inpatient hospitalisation	Cardiac complication	Ceased Clozapine
Cough	Caused or prolonged inpatient hospitalisation	Cardiac complication	Ceased Clozapine
Electrocardiogram ST-T change		Cardiac complication	Ceased Clozapine
Headache		Cardiac complication	Ceased Clozapine
Hyperhidrosis		Cardiac complication	Ceased Clozapine
Pyrexia		Cardiac complication	Ceased Clozapine

Medicine Details:

SEROQUEL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOPINE (Suspected)		Reason:	Unspecified psychosis
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 03/02/2003	Stopped: 16/02/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Following cessation of Clopine therapy the patient has a normal ECG and echocardiograph.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183469 **Seq:** 1 **Gender:** F
Reported: 26/02/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 66
Onset Date: 13/01/2003 **DOB:** 16/07/1936
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intestinal obstruction Abdominal pain upper Vomiting		Bowel obstruction, upper abdominal pain and vomiting.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	125.0 Milligram Daily Oral
Batch:	Started: 26/02/2001 Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183502 **Seq:** 1 **Gender:** F
Reported: 27/02/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 50
Onset Date: 20/02/2003 **DOB:** 19/06/1952
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Caused or prolonged inpatient hospitalisation	Agranulocytosis.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/02/2003	Neutrophils		19/02/2003	0.8	
27/02/2003	Neutrophils		20/02/2003	0.4	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183503
Reported: 27/02/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Age: 36

Onset Date:

DOB: 01/09/1966

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal haemorrhage Abdominal pain upper Anaemia Nausea Vomiting		Bleeding from bowels (Gastrointestinal haemorrhage) Anaemia, stomach pain, vomiting, nausea.	

Medicine Details:

SOLIAN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 02/07/1999	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking amisulpride



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183504
Reported: 27/02/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 15/12/2002

Age: 45

DOB: 26/10/1957

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes, hyperlipidaemia, drug level decreased.	Atorvastatin
Drug level decreased			
Hyperlipidaemia			

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	600.0 Milligram
	Daily
	Oral
Batch:	Started: 24/10/2000
	Stopped:
	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/02/2003	Glycosylated haemoglobin				
27/02/2003	Neutrophils		24/10/2000	6.1	
27/02/2003	Neutrophils		11/02/2003	7.87	
27/02/2003	Pharmacokinetics				
27/02/2003	Serum glucose				
27/02/2003	White blood cells		24/10/2000	9.1	
27/02/2003	White blood cells		11/02/2003	11.6	

Additional Information:

Pyridoxine and diazepam also being taken. History of diabetes mellitus in parent.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183506 **Seq:** 1 **Gender:** F
Reported: 27/02/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 49
Onset Date: **DOB:** 26/07/1953
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia	Caused or prolonged inpatient hospitalisation	Left lower lobe pneumonia	Treatment with unspecified antibiotics.
Circulatory collapse	Caused or prolonged inpatient hospitalisation		
Dehydration	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
THYROXINE SODIUM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
FRUSEMIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 10/09/2002	Stopped: 11/04/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/02/2003	Neutrophils		14/01/2003	9.1	
27/02/2003	Neutrophils		21/01/2003	6.8	
27/02/2003	Neutrophils		28/01/2003	3.43	
27/02/2003	Neutrophils		04/09/2002	4	
27/02/2003	Neutrophils		14/02/2003	9.10	
27/02/2003	White blood cells		17/04/2003	13.40	
27/02/2003	White blood cells		21/01/2003	11.8	

Additional Information:

Also taking valproate, thyroxine, frusemide, salbutamol, simvastatin, ergocalciferol, calcium carbonate and glibenclamide.
Possible early lymphoproliferative disorder. History of pneumonia NOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183506 **Seq:** 1 **Gender:** F
Reported: 27/02/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 49
Onset Date: **DOB:** 26/07/1953
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Left ventricular dysfunction	Caused or prolonged inpatient hospitalisation		
Lymphocytosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
THYROXINE SODIUM (Other drug)	Reason:
Batch:	Started: Stopped:
FRUSEMIDE (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason:
Tablet 12.5 Milligram Daily Oral	
Batch:	Started: 10/09/2002 Stopped: 11/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/02/2003	White blood cells		28/01/2003	6.5	
27/02/2003	White blood cells		14/01/2003	13.40	
27/02/2003	White blood cells		04/09/2002	7	

Additional Information:

Also taking valproate, thyroxine, frusemide, salbutamol, simvastatin, ergocalciferol, calcium carbonate and glibenclamide.
Possible early lymphoproliferative disorder. History of pneumonia NOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183598

Seq: 1

Gender: M

Reported: 28/02/2003

Weight: 0.00

Hospitalisation:

Age: 40

Onset Date:

DOB: 13/01/1963

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Small intestinal obstruction Vomiting		Small bowel obstruction, vomiting.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
75.0 Milligram	Daily
Batch:	Started:
	Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozaril started in July 2000. History - Congenital intestinal malformation NOS, congenital mild gut rotation. Clozaril therapy was unchanged and ongoing. He had congenital mild gut rotation leading to increase of intestinal obstruction. The outcome was recovered. The reporter causality was suspected, as the mild gut rotation, diet and anticholinergic effects of clozaril could have contributed to the event.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183724

Seq: 1

Gender: F

Reported: 05/03/2003

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date: 25/01/2003

DOB: 25/05/1977

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sepsis Chills Pyrexia Somnolence		Sepsis, pyrexia, rigors, drowsiness	Ceased Clozaril, given antibiotics(unspecified).

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
PROVERA (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 10/01/2003	Stopped: 19/02/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date of onset March 2003



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183752

Seq: 1

Gender: F

Reported: 06/03/2003

Weight: 0.00

Hospitalisation:

Age: 68

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delirium		Delirium and an increase in serum levels.	Clozaril dosage was decreased.
Drug level increased			

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	375.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183816
Reported: 19/02/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Age: 21

Onset Date:

DOB: 19/02/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sedation	Treated in outpatient department only	Sedation, circulatory collapse.	Required assessment and observation overnight in emergency department. Discontinuation of Clozapine
Circulatory collapse	Treated in outpatient department only		

Medicine Details:

CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 24/10/2001	Stopped: 26/12/2002	
SODIUM VALPROATE (Suspected)		Reason:	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183857

Seq: 1

Gender: U

Reported: 10/03/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date: 25/11/2002

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Glucose tolerance impaired		Glucose intolerance	

Medicine Details:

CLOZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 18/11/2002	Stopped:	Contin
OLANZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 09/10/2002	Stopped:	26/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183881
Reported: 10/03/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 03/03/2003

Age: 24

DOB: 02/01/1979

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Cardiac disorder	
Lethargy			
Malaise			
Orthostatic hypotension			

Medicine Details:

CLOPIXOL (Other drug)		Reason:	
Injection	150.0 Milligram	Fortnightly	Intramuscular
Batch:	Started:	Stopped:	
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 06/08/2002	Stopped: 03/03/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183908 **Seq:** 1 **Gender:** F
Reported: 06/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Required Visit to Doctor	Patient developed neuroleptic malignant syndrome and would have sudden seizures which terrified her. Admitted with agranulocytosis.	
Convulsion	Required Visit to Doctor		
Neuroleptic malignant syndrome	Required Visit to Doctor		

Medicine Details:

CLOZAPINE (Suspected)	Reason: Schizophrenia
Batch:	Started: Stopped: 1 Year

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183937 **Seq:** 1 **Gender:** M
Reported: 11/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 42
Onset Date: 20/02/2003 **DOB:** 26/05/1960
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal failure	Caused or prolonged inpatient hospitalisation	Kidney failure, lithium toxicity	IV fluids, dialyses. Clozaril ceased. ICU admission
Blood alkaline phosphatase increased	Caused or prolonged inpatient hospitalisation		
Blood urea increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LITHIUM CARBONATE (Interaction)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Interaction)		Reason: Unspecified schizophrenia	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 13/02/2003	Stopped: 02/03/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking ranitidine, sodium valproate, olanzapine, diazepam, ceclor.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183937 **Seq:** 1 **Gender:** M
Reported: 11/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 42
Onset Date: 20/02/2003 **DOB:** 26/05/1960
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Creatinine urine increased	Caused or prolonged inpatient hospitalisation		
Platelet count increased	Caused or prolonged inpatient hospitalisation		
Therapeutic agent toxicity	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LITHIUM CARBONATE (Interaction)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Interaction)		Reason: Unspecified schizophrenia	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 13/02/2003	Stopped: 02/03/2003	

Laboratory Investigations:

Additional Information:

Patient also taking ranitidine, sodium valproate, olanzapine, diazepam, ceclor.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184012
Reported: 14/03/2003

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 03/03/2003
Outcome: Recovered

Age: 49
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Patient experienced a fit.	Ceased Tryptanol, Clozaril, Lamictal.
Coordination abnormal	Caused or prolonged inpatient hospitalisation		
Depression	Caused or prolonged inpatient hospitalisation		

Medicine Details:

QUESTAN (Other drug)		Reason:	
Batch:	Started:	Stopped: 05/03/2003	
VALIUM (Other drug)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: 05/03/2003 contin
TRYPTANOL (Suspected)		Reason: Depression	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: 05/03/2003
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: 05/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184012

Seq: 1

Gender: F

Reported: 14/03/2003

Weight: 0.00

Hospitalisation:

Age: 49

Onset Date: 03/03/2003

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysarthria	Caused or prolonged inpatient hospitalisation		
Fall	Caused or prolonged inpatient hospitalisation		
Muscular weakness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LAMICTAL (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: 05/03/2003

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184025 **Seq:** 1 **Gender:** M
Reported: 14/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 32
Onset Date: 03/03/2003 **DOB:** 11/11/1970
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mental disorder	Caused or prolonged inpatient hospitalisation	Mental state aggravated with treatment noncompliance	
Treatment noncompliance	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Batch:	Started: 01/07/1994 Stopped: 04/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184029 **Seq:** 1 **Gender:** M
Reported: 14/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 37
Onset Date: **DOB:** 29/04/1965
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Patient experienced low white cells.	

Medicine Details:

BACTRIM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet		Daily	Oral
Batch:	Started: 12/02/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/03/2003	Neutrophils		04/02/2003	2.3	
14/03/2003	Neutrophils		21/02/2003	2.00	
14/03/2003	Neutrophils		24/02/2003	1.50	
14/03/2003	Neutrophils		03/03/2003	1.70	
14/03/2003	Neutrophils		07/03/2003	1.70	
14/03/2003	White blood cells		04/02/2003	4.6	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184059 **Seq:** 1 **Gender:** M
Reported: 13/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 24
Onset Date: 24/02/2003 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin I increased	Caused or prolonged inpatient hospitalisation	Cardiac troponin I increased	Clopine ceased. Patient was referred to a cardiologist and was having an ECG performed.
Myocarditis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 03/02/2003	Stopped: 24/02/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/03/2003	Troponin		24/02/2003	12.3	
13/03/2003	Troponin		30/03/2003	0.0	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184121
Reported: 18/03/2003

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 28/02/2003

Age: 27

DOB: 12/02/1976

Outcome: Recovered

03/03/2003

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Life threatening	3x episodes of central chest pain radiating down arms.	Clozapine ceased, aspirin and brufen started

Medicine Details:

OXAZEPAM (Other drug)	Reason: Otr spec symp psychopathol nec
15.0 Milligram	As necessary
Batch:	Started: 06/02/2003 Stopped:
COLOXYL WITH SENNA (Other drug)	Reason: Constipation
4.0 Dose Unspecified Daily	
Batch:	Started: 11/02/2003 Stopped:
BENZTROPINE MESYLATE (Other drug)	Reason:
0.5 Milligram Daily	
Batch:	Started: 24/02/2003 Stopped:
CLOZAPINE (Suspected)	Reason:
250.0 Milligram Daily	
Batch:	Started: 11/02/2003 Stopped: 01/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/03/2003	Creatine				
18/03/2003	Electrocardiograph				
18/03/2003	Haemoglobin				
18/03/2003	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184136
Reported: 18/03/2003

Seq: 1

Gender: M
Weight: 0.00
Age: 99U

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Asthenia Lethargy		Seizures, weakness, asthenia, lethargy	

Medicine Details:

LAMOTRIGINE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
AMITRIPTYLINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
VALIUM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Experienced weakness and lethargy after commencing Clozaril for schizophrenia. Then, he experienced a seizure. No history of seizure was reported but the patient was taking concomitant lamotrigine



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184138 **Seq:** 1 **Gender:** M
Reported: 18/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 32
Onset Date: 12/02/2003 **DOB:** 25/05/1970
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Neutropenia, mentally unwell	Olanzapine
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation		
Mental disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VALIUM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	275.0 Milligram	Daily	Oral
Batch:	Started: 31/12/1996	Stopped: 12/02/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/03/2003	Neutrophils		31/12/1996	3.4	
18/03/2003	Neutrophils		06/03/2003	0.9	
18/03/2003	Neutrophils		06/03/2003	2.00	
18/03/2003	White blood cells		31/12/1996	5.7	
18/03/2003	White blood cells		06/03/2003	3.2	
18/03/2003	White blood cells		06/03/2003	4.5	

Additional Information:

Historical drug: Thalidomide. Patient was affected by thalidomide - effect unknown



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184141 **Seq:** 1 **Gender:** F
Reported: 18/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 39
Onset Date: 23/01/2003 **DOB:** 30/09/1963
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse		Circulatory collapse, ortholastic hypotension	
Orthostatic hypotension			

Medicine Details:

CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 27/06/2002	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/03/2003	LDH				

Additional Information:

Clozapine was reduced from 250mg to 20mg/daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184142 **Seq:** 1 **Gender:** F
Reported: 18/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 21
Onset Date: 28/02/2003 **DOB:** 02/12/1981
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure	

Medicine Details:

OLANZAPINE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 25/02/2003	Stopped: 03/03/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Seizure occurred approximately 10 days after commencing Clozaril. History - Patient ceased sodium valproate just prior to commencing Clozaril therapy. This could have precipitated the reaction contributing to the seizure



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184191
Reported: 02/01/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 13/12/2002

Age: 22

DOB: 11/01/1980

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal Cardiac enzymes increased Chest pain Dyspnoea Myocarditis Troponin increased		Non-specific ECG changes, troponin level increased, cardiac enzymes abnormal, shortness of breath, chest pain on deep inspiration and myocarditis.	

Medicine Details:

CLOPINE (Suspected)	Reason: Schizophrenia
Tablet	350.0 Milligram
	Daily
	Oral
Batch:	Started: 28/11/2002
	Stopped: 13/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/01/2003	Creatine kinase		14/12/2002	52	
02/01/2003	Creatine		14/12/2002	411	
02/01/2003	Creatine		16/12/2002	122	
02/01/2003	Neutrophils				
02/01/2003	Troponin		14/12/2002	7.72	
02/01/2003	Troponin		16/12/2002	1.97	

Additional Information:

Patient did not require hospitalisation of treatment. The patient recovered fully after discontinuation of Clozapine, with improvement within 3 days. History - On Fluphenazine Decanoate 100mg IM 2/52 from 04/11/02 to 28/11/02 for Schizophrenia, as well as Olanzapine 20mg orally from 29/10/02 to 21/11/02.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184198

Seq: 1

Gender: M

Reported: 12/02/2003

Weight: 0.00

Hospitalisation:

Onset Date:

Age: 40

DOB: 04/08/1962

Outcome: Death, maybe drug

25/12/2002

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism		Probable multiple pulmonary emboli	He became agitated while in hospital, was treated with 5mg IM Haloperidol and developed laryngeal spasm. He went into cardiac arrest as was resuscitated and given oxygen, however, he was left brain damaged.
Venous thrombosis		Superficial thrombi in calf and mild blood loss in gut.	
Anaemia			
Gastrointestinal haemorrhage			

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 14/11/2002	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: The patient had had previous laryngeal spasms after receiving Pimozide and Haloperidol in the past. This patient's death was considered unlikely to be due to Clozaril. It was more likely to be due to the Haloperidol injection and the ensuing complications.

Follow-up received on 31/01/03, 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. Although 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: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184200 **Seq:** 1 **Gender:** F
Reported: 16/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 61
Onset Date: 29/11/2002 **DOB:** 15/03/1941
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intentional overdose	Life threatening	Patient experienced fainting and "slipped into a coma".	
Coma	Life threatening		
Syncope	Life threatening		

Medicine Details:

TAMOXIFEN CITRATE (Other drug)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 03/09/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was hospitalised after a gradual increase in the dose. She confirmed that she had taken an overdose of Clozaril of 600mg total.
Clozaril ceased Dec 03.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184211 **Seq:** 1 **Gender:** F
Reported: 20/03/2003 **Weight:** 68.00
Hospitalisation: Admitted to hospital **Age:** 70
Onset Date: 01/04/2002 **DOB:** 19/03/1932
Outcome: Recovered 04/02/2003 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myoclonus		Myoclonic jerks leading to falls and inability to feed self, atonic episodes causing sudden collapse	
Hypotonia			

Medicine Details:

CLOZAPINE (Suspected)	Reason: Schizophrenia
Tablet	275.0 Milligram Daily Oral
Batch:	Started: 18/03/2002 Stopped: 04/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Also taking - Lithium, Sodium Valproate, Thyroxine, Aspirin and Calcitriol. Has evidence of Tardive Dyskinesia secondary to longterm modcate.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184233

Seq: 1

Gender: F

Reported: 20/03/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date: 17/03/2003

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Accidental overdose		Overdose accidental, bed-bound, dribbling and unable to stand, talk or speak properly. patient was also hypotensive.	
Abasia			
Asthenia			
Salivary hypersecretion			
Speech disorder			

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Decided, without consulting her doctor, to increase her dose on 16/03 from the prescribed 100mg to 600mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184249 **Seq:** 1 **Gender:** M
Reported: 20/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion Overdose		Grand mal seizure and overdose nos.	

Medicine Details:

SERETIDE ACCUHALER NOS (Other drug)		Reason:	
Batch:	Started:	Stopped:	
PANADEINE FORTE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
TRAMAL (Suspected)		Reason:	
Tablet	15.0 Dose Unspecified 1 time	Oral	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	650.0 Milligram Daily	Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Experienced a grand mal seizure after commencing Clozaril. The doctor indicated that he took 15 tablets of Tramal before the event and then experienced the seizure.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184250 **Seq:** 1 **Gender:** M
Reported: 20/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 44
Onset Date: **DOB:** 06/10/1958
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		This patient attempted suicide by stabbing himself in 2003, after having his Clozaril dosage change from 500mg/day to 450mg/day.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	500.0 Milligram
	Daily
	Oral
Batch:	Started: 14/10/1999
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184251

Seq: 1

Gender: M

Reported: 20/03/2003

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date:

DOB: 04/05/1977

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia		Arrythmia	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram
	Daily
	Oral
Batch:	Started: 09/07/2002
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/03/2003	Neutrophils				
20/03/2003	Other data				
20/03/2003	White blood cells				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184369

Seq: 1

Gender: M

Reported: 21/03/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date: 15/03/2003

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutrophil count decreased		Neutrophil count decreased.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/03/2003	Neutrophils				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184371
Reported: 21/03/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 43

Onset Date:

DOB: 17/12/1959

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective	Caused or prolonged inpatient hospitalisation	This patient experienced a lack of effect after commencing Clozaril for schizophrenia.	Ceased Clozaril

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 07/05/2002	Stopped: 06/03/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184500 **Seq:** 1 **Gender:** M
Reported: 08/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: 01/03/2003 **DOB:**
Outcome: Unknown **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Raised CK levels	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/03/2003	Creatine		20/03/2003	Over 1000	
08/03/2003	Troponin				

Additional Information:

Patient history: Patient developed an increase in CK levels after commencing Clozaril therapy. Clozaril therapy was discontinued in fear of the patient developing myocarditis. Cardiologist found no sign of myocarditis so she was restarted on Clozaril. She again experienced an increase in CK levels and was hospitalised.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184585

Seq: 1

Gender: F

Reported: 02/04/2003

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date: 15/10/2002

DOB: 22/08/1960

Outcome: Not yet recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia.	Clozaril ceased.

Medicine Details:

HALOPERIDOL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
OLANZAPINE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 25/11/1993	Stopped: 31/10/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184587

Seq: 1

Gender: F

Reported: 02/04/2003

Weight: 0.00

Hospitalisation:

Age: 33

Onset Date: 04/03/2003

DOB: 04/10/1969

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced a seizure within 2 hours of commencing Clozaril.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 04/03/2003	Stopped: 04/03/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was already hospitalised. Was said to have had 2 additional seizures after the initial seizure on Clozaril. Patient has a history of seizures and experienced seizures on Chlorpromazine therapy. The reporter stated that it was very uncertain if 12.5mg of clozaril could have caused the seizure.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184588 **Seq:** 1 **Gender:** M
Reported: 02/04/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 49
Onset Date: 19/03/2003 **DOB:** 19/12/1953
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutrophil count decreased Leukopenia Neck mass		Neutrophil count decreased, one lump on the side of the neck.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet 450.0 Milligram Daily Oral	
Batch:	Started: 19/12/1994 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/04/2003	Neutrophils		19/03/2003	0.99	
02/04/2003	Neutrophils		20/03/2003	2.34	
02/04/2003	White blood cells		19/03/2003	3.00	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184652 **Seq:** 1 **Gender:** M
Reported: 03/04/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 19/02/2003 **DOB:** 20/05/1973
Outcome: Recovered 27/02/2003 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Severe	Myocarditis, chest pain, cold symptoms, increased body teperature	Clopine ceased.
Body temperature increased	Severe		
Chest pain	Severe		
Nasopharyngitis	Severe		

Medicine Details:

CLOPINE (Suspected)		Reason:	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 07/02/2003	Stopped: 20/02/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/04/2003	C-Reactive Protein		20/02/2003	26	
03/04/2003	Creatine		20/02/2003	92	
03/04/2003	Creatine		21/02/2003	208	
03/04/2003	Creatine		23/02/2003	347	
03/04/2003	Neutrophils		19/02/2003	5.0	
03/04/2003	Other data				
03/04/2003	Troponin		20/02/2003	<0.01	

Additional Information:

On 23 Feb 2003, myocarditis was confirmed following the return of laboratory tests.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184652 **Seq:** 1 **Gender:** M
Reported: 03/04/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 19/02/2003 **DOB:** 20/05/1973
Outcome: Recovered 27/02/2003 **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)		Reason:	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 07/02/2003	Stopped: 20/02/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/04/2003	Troponin		21/02/2003	0.29	
03/04/2003	Troponin		23/02/2003	1.28	
03/04/2003	White blood cells		19/02/2003	7.0	

Additional Information:

On 23 Feb 2003, myocarditis was confirmed following the return of laboratory tests.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184656 **Seq:** 1 **Gender:** F
Reported: 04/04/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 40
Onset Date: 15/03/2003 **DOB:** 14/09/1962
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Respiratory disorder Diarrhoea Gastritis Nausea Vomiting		Increased blood sugar level, proteinurea, respiratory problems, gastritis, urinary tract infection, vomiting, nausea and diarrhoea.	

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 22/02/2003	Stopped: 20/03/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/04/2003	Protein				
04/04/2003	Serum glucose		17/03/2003	28	

Additional Information:

Diabetes mellitus non - insulin - dependent. Prior to commencing Clozaril. Urinary tract infection and hyperglycaemia were not related to clozaril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184688 **Seq:** 1 **Gender:** M
Reported: 07/04/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 47
Onset Date: 24/03/2003 **DOB:** 26/08/1955
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia	Clopine ceased. GCSF treatment, 300mcg per day by subcutaneous injection.

Medicine Details:

CLOPINE (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch: E0158	Started: 17/02/2003	Stopped: 23/03/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/04/2003	Neutrophils		24/03/2003	1.0	
07/04/2003	White blood cells		24/03/2003	2.8	

Additional Information:

Patient also taking Haloperidol, Valproate Sodium and Psyllium Hydrophilic Mucilloid.
Clozapine had previously been administered from 1994 and 1997, with the patient experiencing two episodes of 'amber range'.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184700 **Seq:** 1 **Gender:** M
Reported: 07/04/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: 06/03/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased		Lithium intoxication, high white blood cell count.	
White blood cell count increased			

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	Oral
Batch:	Started: Stopped:
LITHIUM CARBONATE (Suspected)	Reason: Schizophrenia
Tablet	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozaril therapy was ceased and then restarted (date not provided) and the patient was currently on 250mg/day.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184847

Seq: 1

Gender: M

Reported: 09/04/2003

Weight: 0.00

Hospitalisation:

Age: 39Y

Onset Date: 15/10/2002

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level changed		Drug level NOS changed.	Clozaril dosage was decreased from 450mg/day to 400mg/day.

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	450.0 Milligram	Reducing	Oral
Batch:	Started: 26/06/1998	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/04/2003	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184848

Seq: 1

Gender: M

Reported: 09/04/2003

Weight: 0.00

Hospitalisation:

Age: 33

Onset Date:

DOB: 17/08/1969

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion	Caused or prolonged inpatient hospitalisation	Salivary hypersecretion, oedema of the leg.	Ceased Clozaril
Oedema peripheral	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 21/01/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184853

Seq: 1

Gender: M

Reported: 09/04/2003

Weight: 0.00

Hospitalisation:

Age: 32

Onset Date: 23/03/2003

DOB: 01/11/1970

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure Left ventricular hypertrophy Tachycardia		Viral infection.	

Medicine Details:

HALOPERIDOL (Other drug)		Reason:	
	100.0 Milligram	Fortnightly	
Batch:	Started: 28/08/2002	Stopped: 19/03/2003	
CLOPINE (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 13/08/2002	Stopped: 23/03/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/04/2003	Biochemistry				
09/04/2003	Chest X-ray				
09/04/2003	Electrocardiograph				

Additional Information:

Patient also taking antibiotics. The autopsy report states cardiac failure as the cause of death. The reporting doctor considers the causality as possible



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184892

Seq: 1

Gender: M

Reported: 10/04/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date: 26/03/2003

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Left ventricular dysfunction		Early left ventricular dysfunction, tachycardia and orthostatic hypotension.	
Orthostatic hypotension			
Tachycardia			

Medicine Details:

CIPRAMIL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 18/09/1998 L TERM	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/04/2003	LDH				

Additional Information:

Blood pressure of 100.60 when sitting and 90/60 when standing.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184893

Seq: 1

Gender: M

Reported: 10/04/2003

Weight: 0.00

Hospitalisation:

Age: 51

Onset Date:

DOB: 11/10/1951

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes	Given dietary and exercise advise.

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	75.0 Milligram Daily Oral
Batch:	Started: 28/06/1994 L TERM Stopped: 01/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient was said to have had several risk factors for diabetes such as being overweight.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184923 **Seq:** 1 **Gender:** M
Reported: 11/04/2003 **Weight:** 104.00
Hospitalisation: Admitted to hospital **Age:** 54
Onset Date: 01/04/2003 **DOB:** 07/10/1948
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation	Caused or prolonged inpatient hospitalisation	Sudden onset of diabetes and association with biochemical abnormalities	Diabetic diet, Amiodarone, Clexane.
Diabetes mellitus	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 12/03/2003	Stopped: 01/04/2003	
SODIUM VALPROATE (Suspected)		Reason:	
Tablet	1.7 Gram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/04/2003	Serum glucose				

Additional Information:

History of obesity, impaired glucose tolerance.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184934
Reported: 11/04/2003

Seq: 1

Gender: M
Weight: 0.00
Age: 99U

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood glucose increased Diabetes mellitus Polydipsia Polyuria		Raised blood glucose levels.	Diamicron MR and diet

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram
	Daily
	Oral
Batch:	Started: 01/08/2000
	Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/04/2003	Glycosylated		04/04/2003	14.2%	
11/04/2003	Serum glucose				

Additional Information:

Date of reaction 08/2002, The event improved. Clozaril started in august 2000 and is ongoing.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184966

Seq: 1

Gender: F

Reported: 15/04/2003

Weight: 0.00

Hospitalisation:

Age: 38

Onset Date: 22/01/2003

DOB: 24/04/1964

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Body temperature increased		Transient elevation in body temperature	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	50.0 Milligram
	Daily
	Oral
Batch:	Started: 15/01/2003
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/04/2003	Other data				

Additional Information:

Patient was also taking Cipramil, Metformin, Mixtard,



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184967

Seq: 1

Gender: F

Reported: 15/04/2003

Weight: 0.00

Hospitalisation:

Age: 54Y

Onset Date: 01/04/2003

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes, atrial fibrillation	Clozaril was ceased. treated with antiarrhythmics, diabetic diet and electrocardiogram monitoring.
Atrial fibrillation			

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 19/12/1994	Stopped: 01/04/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 185012

Seq: 1

Gender: F

Reported: 26/02/2003

Weight: 0.00

Hospitalisation:

Age: 61

Onset Date: 17/02/2003

DOB: 08/01/1942

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest		Circulatory collapse, cardiac arrest	
Circulatory collapse		Circulatory collapse, cardiac arrest	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	100.0 Milligram
	Daily
	Oral
Batch:	Started: 23/01/2003
	Stopped: 17/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/02/2003	Other data				

Additional Information:

Patient died suddenly, approx. 2-3 weeks after commencing clozaril. Awaiting toxicology and micsoscopy results.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 185112

Seq: 1

Gender: M

Reported: 17/04/2003

Weight: 0.00

Hospitalisation:

Age: 56

Onset Date: 05/04/2003

DOB: 25/06/1946

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Experienced "red" result of neutrophil count	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 08/02/1996	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/04/2003	Neutrophils				

Additional Information:

Patient history - Concomitant disease: leukaemia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 185183

Seq: 1

Gender: M

Reported: 23/04/2003

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date: 15/01/2003

DOB: 11/08/1963

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Body shakes, muscle spasms in arms and neck, profuse sweating	
Muscle spasms		Body shakes, muscle spasms in arms and neck, profuse sweating	
Tremor		Body shakes, muscle spasms in arms and neck, profuse sweating	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	500.0 Milligram
	Daily
	Oral
Batch:	Started: 12/08/1997
	Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 185184

Seq: 1

Gender: M

Reported: 23/04/2003

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date: 08/03/2003

DOB: 10/06/1977

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Persistent tachycardia.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	300.0 Milligram
	Daily
	Oral
Batch:	Started: 06/03/2003
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking antibiotics for a dental abscess.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 185186

Seq: 1

Gender: M

Reported: 23/04/2003

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date:

DOB: 20/04/1969

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood glucose increased		Elevated blood glucose levels of 20.0.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	175.0 Milligram
	Daily
	Oral
Batch:	Started: 06/11/1993
	Stopped:
	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 185340

Seq: 1

Gender: M

Reported: 22/04/2003

Weight: 0.00

Hospitalisation:

Age: 41

Onset Date: 14/04/2003

DOB: 31/01/1962

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia	Caused or prolonged inpatient hospitalisation	Drop in WCC and Neutrophils, Lymphocytes.	haematalogical monitoring at present.
Lymphopenia	Caused or prolonged inpatient hospitalisation	Drop in WCC and Neutrophils, Lymphocytes.	haematalogical monitoring at present.
Neutropenia	Caused or prolonged inpatient hospitalisation	Drop in WCC and Neutrophils, Lymphocytes.	haematalogical monitoring at present.

Medicine Details:

CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 20/04/1998	Stopped: 15/04/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous falls in neutrophil count only.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 185586

Seq: 1

Gender: F

Reported: 07/05/2003

Weight: 0.00

Hospitalisation:

Age: 72Y

Onset Date: 20/01/2003

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Normochromic normocytic anaemia		Normocytic anaemia, white blood cell count low	
Thrombocytopenia		Thrombocytopenia and lymphocyte count decreased.	
Lymphocyte count decreased			
White blood cell count decreased			

Medicine Details:

ATIVAN (Other drug)	Reason:
Tablet	Dose Unspecified
Batch:	Started:
	Stopped:
TEMAZEPAM (Other drug)	Reason:
Oral application	Dose Unspecified
Batch:	Started:
	Stopped:
EFEXOR (Other drug)	Reason:
Oral application	Dose Unspecified
Batch:	Started:
	Stopped:
OLANZAPINE (Suspected)	Reason:
	Dose Unspecified
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/05/2003	Haemoglobin				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 185586

Seq: 1

Gender: F

Reported: 07/05/2003

Weight: 0.00

Hospitalisation:

Age: 72Y

Onset Date: 20/01/2003

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Schizophrenia

Tablet

225.0 Milligram

Daily

Oral

Batch:

Started: 05/02/2002

Stopped:

Contin

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 185642 **Seq:** 1 **Gender:** F
Reported: 03/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 38
Onset Date: 03/02/2003 **DOB:** 08/03/1964
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutrophil count decreased		Decreased white blood cell count, neutrophil count decreased and mental disorder nos.	
White blood cell count decreased		Decreased white blood cell count, neutrophil count decreased and mental disorder nos.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	Oral
Batch:	Started: 14/11/2000 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/03/2003	Neutrophils		03/02/2003	1.4	
03/03/2003	Neutrophils		09/02/2003	0.9	
03/03/2003	Neutrophils		17/02/2003	2.0	
03/03/2003	White blood cells		03/02/2003	2.8	
03/03/2003	White blood cells		09/02/2003	2.1	
03/03/2003	White blood cells		17/02/2003	3.6	

Additional Information:

183803 is a duplicate



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 185671
Reported: 08/05/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 15/07/2001

Age: 36

DOB: 21/02/1965

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level below therapeutic		Enuresis, clozaril levels low	
Enuresis		Enuresis, clozaril levels low	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram
	Daily
	Oral
Batch:	Started: 09/05/2001
	Stopped: 07/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Risperidone, Diazepam, Olanzapine. Bzntropine, Mirtazapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 185786 **Seq:** 1 **Gender:** M
Reported: 12/05/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 25
Onset Date: 22/04/2003 **DOB:** 27/07/1977
Outcome: Unknown **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain		Flu-like symptoms, oesophagitis, chest pain and raised liver function test.	Mylanta. Clozaril ceased. Patient had a relapse of schizophrenia on 28/04/03 and they were looking into re-challenging Clozaril.
Influenza like illness		Flu-like symptoms, oesophagitis, chest pain and raised liver function test.	Mylanta. Clozaril ceased. Patient had a relapse of schizophrenia on 28/04/03 and they were looking into re-challenging Clozaril.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	375.0 Milligram Daily Oral
Batch:	Started: 04/04/2003 Stopped: 24/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/05/2003	ALT = SGPT		23/04/2003	139	
12/05/2003	AST = SGOT		23/04/2003	78	
12/05/2003	Bilirubin				
12/05/2003	GGT = SGGT =		23/04/2003	210	
12/05/2003	SAP = ALP		23/04/2003	192	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 185786 **Seq:** 1 **Gender:** M
Reported: 12/05/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 25
Onset Date: 22/04/2003 **DOB:** 27/07/1977
Outcome: Unknown **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Flu-like symptoms, oesophagitis, chest pain and raised liver function test.	Mylanta. Clozaril ceased. Patient had a relapse of schizophrenia on 28/04/03 and they were looking into re-challenging Clozaril.
Oesophagitis		Flu-like symptoms, oesophagitis, chest pain and raised liver function test.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	375.0 Milligram	Daily	Oral
Batch:	Started: 04/04/2003	Stopped: 24/04/2003	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 185831
Reported: 13/05/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 17/04/2003

Age: 25

DOB: 11/10/1977

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome	Ceased Clozaril
Pyrexia	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome	Ceased Clozaril

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.5 Milligram
	Daily
	Oral
Batch:	Started: 10/09/1998
	Stopped: 21/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 185975 **Seq:** 1 **Gender:** M
Reported: 16/05/2003 **Weight:** 0.00
Hospitalisation: Hospitalisation prolonged **Age:** 25
Onset Date: 02/05/2003 **DOB:** 09/02/1978
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug interaction		Slurred speech, drowsiness, high clozaril level, drug interaction	
Drug toxicity		Slurred speech, drowsiness, high clozaril level, drug interaction	
Dysarthria		Slurred speech, drowsiness, high clozaril level, drug interaction	
Somnolence		Slurred speech, drowsiness, high clozaril level, drug interaction	

Medicine Details:

LUVOX (Interaction)		Reason:	
Tablet	Dose Unspecified	Oral	
Batch:	Started:	Stopped:	
CLOZARIL (Interaction)		Reason: Schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 10/04/2003	Stopped:	Contin
LITHIUM CARBONATE (Other drug)		Reason:	
Tablet	Dose Unspecified	Oral	
Batch:	Started:	Stopped:	
RANITIDINE (Other drug)		Reason:	
Oral application	Dose Unspecified	Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/05/2003	LDH				

Additional Information:

Suspected drug toxicity, high Clozaril level and drug interaction between Clozaril and Luvox.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186062

Seq: 1

Gender: M

Reported: 20/05/2003

Weight: 0.00

Hospitalisation:

Age: 48

Onset Date: 14/05/2003

DOB: 20/11/1954

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle disorder	Caused or prolonged inpatient hospitalisation	Muscle jerks,	Reduced Clozapine dose to 200mg + 400mg.

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	700.0 Milligram
	Daily
	Oral
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/05/2003	Electroencephalog				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186165
Reported: 23/05/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 10/03/2003

Age: 40

DOB: 12/05/1962

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Transient loss of consciousness, seizure, dizziness, lapses in memory, confusion, fluctuating neutrophil counts and excessive tiredness.	Clozaril was ceased. Patient given increase in sodium valproate to 1000mg twice daily.
Depressed level of consciousness	Caused or prolonged inpatient hospitalisation	Transient loss of consciousness, seizure, dizziness, lapses in memory, confusion, fluctuating neutrophil counts and excessive tiredness.	Clozaril was ceased.
Dizziness	Caused or prolonged inpatient hospitalisation	Transient loss of consciousness, seizure, dizziness, lapses in memory, confusion, fluctuating neutrophil counts and excessive tiredness.	Clozaril was ceased.

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
SERTRALINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
HALOPERIDOL (Other drug)	Reason:
Batch:	Started: Stopped:
FRUSEMIDE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/05/2003	Neutrophils		10/03/2003	1.5	
23/05/2003	Neutrophils		01/04/2003	1.5	
23/05/2003	Neutrophils		03/04/2003	2.7	
23/05/2003	Neutrophils		15/04/2003	1.6	
23/05/2003	Neutrophils		23/04/2003	2.7	
23/05/2003	Neutrophils		29/04/2003	1.9	
23/05/2003	Neutrophils		06/05/2003	1.4	

Additional Information:

History of seizures.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186165
Reported: 23/05/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 10/03/2003

Age: 40

DOB: 12/05/1962

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fatigue	Caused or prolonged inpatient hospitalisation	Transient loss of consciousness, seizure, dizziness, lapses in memory, confusion, fluctuating neutrophil counts and excessive tiredness.	Clozaril was ceased.
Memory impairment	Caused or prolonged inpatient hospitalisation	Transient loss of consciousness, seizure, dizziness, lapses in memory, confusion, fluctuating neutrophil counts and excessive tiredness.	Clozaril was ceased.
Neutropenia	Caused or prolonged inpatient hospitalisation	Transient loss of consciousness, seizure, dizziness, lapses in memory, confusion, fluctuating neutrophil counts and excessive tiredness.	Clozaril was ceased.

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 26/04/1995	Stopped: 06/05/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/05/2003	Neutrophils		07/05/2003	2.9	

Additional Information:

History of seizures.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186166
Reported: 23/05/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 12/12/2002

Age: 27

DOB: 12/06/1975

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Suspected myocarditis	Ceased Clozaril and commenced on Olanzapine.
Pericarditis		suspected percarditis	
Chest pain			
Electrocardiogram T wave inversion			
Pyrexia			
Tachycardia			

Medicine Details:

OLANZAPINE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 06/12/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/05/2003	Other data				

Additional Information:

Not myocarditis.
Historical condition Abnormal behaviour Nos.
past history of hostility, violence, paranoid delusions, visual and auditory hallucinations, bizzare behaviour.
Drug Dependence Drug abuser nos
Cannibis and alcohol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186172

Seq: 1

Gender: M

Reported: 23/05/2003

Weight: 0.00

Hospitalisation:

Onset Date: 09/05/2003

Age: 19

DOB: 01/07/1983

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure	Ceased Clozaril

Medicine Details:

NEFAZODONE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 28/10/2002	Stopped: 09/05/2003	
LITHIUM CARBONATE (Suspected)		Reason:	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

09 May 2003: Electroencephalogram (EEG) showed: The findings are much more prominent than those of usually attributed to a postnatal state and suggest an underlying generalised or partial (right) seizure disorder.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186173

Seq: 1

Gender: M

Reported: 23/05/2003

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date:

DOB: 12/07/1963

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug hypersensitivity Diarrhoea Faecal incontinence Inflammatory bowel disease Vomiting		Drug sensitivity, vomiting	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram
	Daily
	Oral
Batch:	Started: 27/01/2003
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/05/2003	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186210

Seq: 1

Gender: F

Reported: 26/05/2003

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date: 08/05/2003

DOB: 13/01/1964

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure	

Medicine Details:

ALCOHOL (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	375.0 Milligram	Daily	Oral
Batch:	Started: 19/09/2001	Stopped: 14/05/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/05/2003	Computerised				
26/05/2003	Serum glucose	(3.6-7.7)	08/05/2003	7.8	

Additional Information:

Patient was also taking Aropax, Clonazepam.
Past history of alcohol related seizures.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186211

Seq: 1

Gender: M

Reported: 26/05/2003

Weight: 0.00

Hospitalisation:

Age: 41

Onset Date: 15/05/2003

DOB: 26/06/1961

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	375.0 Milligram
	Daily
	Oral
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/05/2003	Computerised				
26/05/2003	Pharmacokinetics				

Additional Information:

Patient has cerebral atrophy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186315

Seq: 1

Gender: F

Reported: 29/05/2003

Weight: 0.00

Hospitalisation:

Age: 36

Onset Date: 12/05/2003

DOB: 13/10/1966

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation	Caused or prolonged inpatient hospitalisation	Constipation	Treated with magnesium sulphate and paraffin enemas, also had a long standing addiction and was given 70mg/day of Methadone.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	500.0 Milligram
	Daily
	Oral
Batch:	Started:
	Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186394 **Seq:** 1 **Gender:** M
Reported: 30/05/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 15/04/2003 **DOB:** 07/05/1973
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Cardiac complaints, syncope	
Electrocardiogram QT prolonged		Cardiac complaints, syncope	
Syncope		Cardiac complaints, syncope	

Medicine Details:

METOPROLOL TARTRATE (Other drug)	Reason:
Batch:	Started: Stopped:
AMISULPRIDE (Other drug)	Reason:
Batch:	Started: Stopped:
CHLORPROMAZINE HYDROCHLORIDE (Suspected)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	450.0 Milligram Daily Oral
Batch:	Started: 23/04/2002 Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reporter stated that a beta-blocker was "maybe" related to the increasing QT interval. Medical history of alcohol abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186445 **Seq:** 1 **Gender:** M
Reported: 02/06/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 34
Onset Date: 17/05/2003 **DOB:** 04/01/1969
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Respiratory depression		Respiratory depression, febrile Respiratory depression, febrile	Admitted to ICU and put on the ventilator and treated with Antibiotics.

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 10/03/2003 Stopped: 17/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186545

Seq: 1

Gender: M

Reported: 03/06/2003

Weight: 0.00

Hospitalisation:

Age: 21

Onset Date: 12/05/2003

DOB: 23/08/1981

Outcome: Unknown

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophil count increased		Eosinophil count increased.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 15/04/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/06/2003	Echocardiogram				
03/06/2003	Eosinophils		12/05/2003	2.9	
03/06/2003	Eosinophils		14/05/2003	1.3	

Additional Information:

Clozaril was ceased. Approximately 1 week after re-starting Clozaril therapy the patient's eosinophil count increased again.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186603 **Seq:** 1 **Gender:** F
Reported: 05/06/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 44
Onset Date: 26/05/2003 **DOB:** 14/07/1958
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Agranulocytosis	Treated with a granulocyte colony stimulating factor.

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 10/02/2003 Stopped: 26/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186620

Seq: 1

Gender: M

Reported: 05/06/2003

Weight: 0.00

Hospitalisation:

Age: 50Y

Onset Date: 26/03/2003

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus insulin-depender		Symptoms of diabetes.	Insulin given

Medicine Details:

AMISULPRIDE (Other drug)		Reason: Schizophrenia	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 27/02/2003	
CLOZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	Dose Unspecified	Daily	Oral
Batch:	Started: 27/02/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/06/2003	Serum glucose		15/01/2003	2.2	
05/06/2003	Serum glucose		26/03/2003	32.6	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186621

Seq: 1

Gender: M

Reported: 05/06/2003

Weight: 0.00

Hospitalisation:

Onset Date: 17/03/2003

Age: 52Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonia, parkinsonism. Tardive dyskinesia and ongoing akathisia.	
Akathisia			
Parkinsonism			
Tardive dyskinesia			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Schizophrenia	
Tablet	4.0 Milligram	Oral	
Batch:	Started:	Stopped:	Contin
CLOZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 15/03/2001	L TERM	Stopped: 17/03/2003
AMISULPRIDE (Suspected)		Reason: Schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 10/03/2003	Stopped: 29/04/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Akathisia - patient on 4mg Risperidone, resolved after cessation of Risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186722
Reported: 10/06/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 13/04/2003

Age: 33

DOB: 10/10/1969

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Treated in outpatient department only	The patient experienced 2 episodes of collapse with seizures, dizziness, hand tremor and blurred vision. The symptoms were described as moderate in severity and lasted a few minutes	Ceased Clopine
Dizziness	Treated in outpatient department only		
Tremor	Treated in outpatient department only		

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 31/12/2002	Stopped: 13/04/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/06/2003	Other data				
10/06/2003	Serum drug level				

Additional Information:

Concomitant medication listed: vitamin E, multivitamin, sodium valproate and sertraline.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186722

Seq: 1

Gender: M

Reported: 10/06/2003

Weight: 0.00

Hospitalisation:

Age: 33

Onset Date: 13/04/2003

DOB: 10/10/1969

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vision blurred	Treated in outpatient department only		

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 31/12/2002	Stopped: 13/04/2003	

Laboratory Investigations:

Additional Information:

Concomitant medication listed: vitamin E, multivitamin, sodium valproate and sertraline.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186798

Seq: 1

Gender: M

Reported: 11/06/2003

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date: 30/05/2003

DOB: 06/07/1963

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Observed fit	Admitted to ICU, Valium stat and Dilantin

Medicine Details:

SOLIAN (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 03/07/1994	Stopped: 30/05/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

189532 is a duplicate.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186799

Seq: 1

Gender: F

Reported: 11/06/2003

Weight: 0.00

Hospitalisation:

Age: 54

Onset Date: 26/04/2003

DOB: 20/09/1948

Outcome: Death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intestinal obstruction	Caused or prolonged inpatient hospitalisation	Septicaemia, intestinal obstruction	Received extensive treatment in ICU.
Sepsis	Caused or prolonged inpatient hospitalisation	Septicaemia, intestinal obstruction	Received extensive treatment in ICU.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	500.0 Milligram
	Daily
	Oral
Batch:	Started: 06/08/2001
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died 26/04/03.

Patient was also taking Atorvastatin , ranitidine, Coversyl.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186852

Seq: 1

Gender: F

Reported: 12/06/2003

Weight: 0.00

Hospitalisation:

Age: 36

Onset Date: 26/05/2003

DOB: 02/01/1967

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac function disturbance postd		Cardiac complications	

Medicine Details:

CLOPINE (Suspected)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 01/05/2002 L TERM	Stopped:	26/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/06/2003	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186881 **Seq:** 1 **Gender:** M
Reported: 13/06/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99u
Onset Date: 30/05/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Convulsions nos	Admitted to Intensive Care unit.

Medicine Details:

CLOZAPINE (Suspected)		Reason:	
Batch:	Started:	L TERM	Stopped:
SOLIAN (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: without history of seizure.
Patient has been on Clozapine since 1994.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186886

Seq: 1

Gender: M

Reported: 13/06/2003

Weight: 0.00

Hospitalisation:

Age: 40

Onset Date:

DOB: 31/01/1963

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Caused or prolonged inpatient hospitalisation	Cardiomyopathy	Clozaril was discontinued.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started: 11/04/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient developed possible cardiomyopathy on an unspecified date after commencing Clozaril therapy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186887

Seq: 1

Gender: M

Reported: 13/06/2003

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date: 02/06/2003

DOB: 16/08/1977

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Hypotension, heavily sedated	
Sedation		Hypotension, heavily sedated	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 02/06/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/06/2003	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186889

Seq: 1

Gender: M

Reported: 13/06/2003

Weight: 0.00

Hospitalisation:

Age: 27

Onset Date: 26/05/2003

DOB: 25/02/1976

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation	Myocarditis, Chest pain.	
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis, Chest pain.	Ceased Clozaril. Patient was given cardiac monitoring (Echocardiogram(Echo) and ECG.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	150.0 Milligram
	Daily
	Oral
Batch:	Started: 19/05/2003
	Stopped: 28/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 186927

Seq: 1

Gender: M

Reported: 03/06/2003

Weight: 0.00

Hospitalisation:

Onset Date: 12/05/2003

Age: 21

DOB: 23/08/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dilatation ventricular		Jaw tightness, pericardial effusion, feeling hot and cold and dilation ventricular.	
Feeling hot and cold		Jaw tightness, pericardial effusion, feeling hot and cold and dilation ventricular.	
Pericardial effusion		Jaw tightness, pericardial effusion, feeling hot and cold and dilation ventricular.	
Trismus		Jaw tightness, pericardial effusion, feeling hot and cold and dilation ventricular.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	450.0 Milligram
	Daily
	Oral
Batch:	Started: 15/04/2003
	Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187049

Seq: 1

Gender: F

Reported: 20/06/2003

Weight: 0.00

Hospitalisation:

Age: 28

Onset Date:

DOB: 03/06/1975

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drooling		Tachycardia, glucose tolerance impaired, weight increased, nausea.	Ceased Clopine. Treated with Inderal and Omeprazole.
Glucose tolerance impaired		Tachycardia, glucose tolerance impaired, weight increased, nausea.	
Nausea		Tachycardia, glucose tolerance impaired, weight increased, nausea.	
Salivary hypersecretion		Tachycardia, glucose tolerance impaired, weight increased, nausea.	
Tachycardia		Tachycardia, glucose tolerance impaired, weight increased, nausea.	Ceased Clopine. Treated with Inderal and Omeprazole.
Weight increased		Tachycardia, glucose tolerance impaired, weight increased, nausea.	

Medicine Details:

ETHINYLOESTRADIOL (Other drug)		Reason:	
Batch:	Started: 10/08/2000	Stopped:	Contin
CLOPINE (Suspected)		Reason:	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	29/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clopine was started in November 1999.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187063
Reported: 20/06/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 03/06/2003

Age: 41

DOB: 06/07/1961

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Echocardiogram abnormal Hypertrophic cardiomyopathy Troponin increased		Increased Creatine Kinase levels.	Ceased Clozaril

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram
	Daily
	Oral
Batch:	Started: 16/04/2003
	Stopped: 05/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/06/2003	Creatine		09/06/2003	400	
20/06/2003	Creatine		10/06/2003	300	
20/06/2003	Creatine		19/06/2003	86	
20/06/2003	Creatine		20/06/2005	300	
20/06/2003	Creatine		26/06/2005	500	
20/06/2003	Creatine		23/08/2005	260	
20/06/2003	Creatine		30/08/2005	240	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187063
Reported: 20/06/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 41

Onset Date: 03/06/2003

DOB: 06/07/1961

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 16/04/2003	Stopped: 05/06/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/06/2003	Creatine		25/10/2005	140	Echocardiogram prior to commencing Clozaril: normal but with mild diastolic dysfunction. Later Echocardiogram showed asymmetric hypertrophy of anterior septum and anterior free wall suspicious of hypertrophic cardiomyopathy.
20/06/2003	Echocardiogram				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

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: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187147

Seq: 1

Gender: F

Reported: 20/06/2003

Weight: 0.00

Hospitalisation:

Age: 18

Onset Date:

DOB: 28/03/1985

Outcome: Recovered

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased		Clozaril levels high	

Medicine Details:

CLOZARIL (Suspected)		Reason:		
Tablet	500.0	Milligram	Daily	Oral
Batch:	Started:	Stopped:	Contin	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/06/2003	Other data				

Additional Information:

This report is a seq to 187513



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187513

Seq: 1

Gender: F

Reported: 20/06/2003

Weight: 0.00

Hospitalisation:

Age: 18

Onset Date:

DOB: 28/03/1985

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation		sedation, salivary hypersecretion, constipation	Given Laxatives
Salivary hypersecretion		sedation, salivary hypersecretion, constipation	
Sedation		sedation, salivary hypersecretion, constipation	

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This report is a seq to 187147.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187516 **Seq:** 1 **Gender:** M
Reported: 20/06/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 28
Onset Date: 03/06/2003 **DOB:** 25/09/1974
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia	Caused or prolonged inpatient hospitalisation	Hyperglycaemia NOS	Insulin
Diabetic ketoacidosis	Caused or prolonged inpatient hospitalisation		
Eosinophilia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANADOL (Other drug)		Reason:
Batch:	Started:	Stopped:
CLOZARIL (Suspected)		Reason: Schizophrenia
	275.0 Milligram	
Batch:	Started: 02/10/2002	Stopped: 04/01/2005
CLOZARIL (Suspected)		Reason: Schizophrenia
	275.0 Milligram	Daily
Batch:	Started: 01/12/2001	Stopped: 31/12/2001 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Rechallenge. The recent admission was considered probably due to poor pharmacological treatment of diabetes along with ongoing clozapine treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187516 **Seq:** 1 **Gender:** M
Reported: 20/06/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 28
Onset Date: 03/06/2003 **DOB:** 25/09/1974
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypoxia	Caused or prolonged inpatient hospitalisation		
Lethargy	Caused or prolonged inpatient hospitalisation		
Liver function test abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANADOL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
	275.0 Milligram		
Batch:	Started: 02/10/2002	Stopped: 04/01/2005	
CLOZARIL (Suspected)		Reason: Schizophrenia	
	275.0 Milligram	Daily	
Batch:	Started: 01/12/2001	Stopped: 31/12/2001	0

Laboratory Investigations:

Additional Information:

Rechallenge. The recent admission was considered probably due to poor pharmacological treatment of diabetes along with ongoing clozapine treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187516 **Seq:** 1 **Gender:** M
Reported: 20/06/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 28
Onset Date: 03/06/2003 **DOB:** 25/09/1974
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea	Caused or prolonged inpatient hospitalisation		
Polydipsia	Caused or prolonged inpatient hospitalisation		
Polyuria	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANADOL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
	275.0 Milligram		
Batch:	Started: 02/10/2002	Stopped: 04/01/2005	
CLOZARIL (Suspected)		Reason: Schizophrenia	
	275.0 Milligram	Daily	
Batch:	Started: 01/12/2001	Stopped: 31/12/2001	0

Laboratory Investigations:

Additional Information:

Rechallenge. The recent admission was considered probably due to poor pharmacological treatment of diabetes along with ongoing clozapine treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187516 **Seq:** 1 **Gender:** M
Reported: 20/06/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 28
Onset Date: 03/06/2003 **DOB:** 25/09/1974
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANADOL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
	275.0 Milligram		
Batch:	Started: 02/10/2002	Stopped: 04/01/2005	
CLOZARIL (Suspected)		Reason: Schizophrenia	
	275.0 Milligram	Daily	
Batch:	Started: 01/12/2001	Stopped: 31/12/2001 0	

Laboratory Investigations:

Additional Information:

Rechallenge. The recent admission was considered probably due to poor pharmacological treatment of diabetes along with ongoing clozapine treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187570 **Seq:** 1 **Gender:** M
Reported: 25/06/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 57
Onset Date: 22/05/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Multilobular pneumonia on 22 May 03, followed by a severe neutropenia on 05 June 03.	Clopine ceased. GCSF given.
Pneumonia		Multilobular pneumonia on 22 may 03, followed by a severe neutropenia on 05 June 03.	

Medicine Details:

MAGNESIUM ASPARTATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/06/2003	Neutrophils		05/04/2003	0.9	
25/06/2003	Neutrophils		10/04/2003	3.7	
25/06/2003	Neutrophils		16/05/2003	2.9	
25/06/2003	Neutrophils		03/05/2003	3.7	
25/06/2003	Neutrophils		23/05/2003	6.5	
25/06/2003	Neutrophils		11/06/2003	2.1	
25/06/2003	Neutrophils		03/06/2003	5.5	

Additional Information:

Patient was also taking Ciprofloxacin, Valproate Sodium, Fluconazole, Sertraline, salbutamol, prednisone.
Clopine was given 8-Feb-1996 to 5-Apr-2003/3-May-2003 to 22-may-2003/28-May-2003 to 4-Jun-2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187570

Seq: 1

Gender: M

Reported: 25/06/2003

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 57

Onset Date: 22/05/2003

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

MAGNESIUM ASPARTATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/06/2003	Neutrophils		09/06/2003	4.1	
25/06/2003	Neutrophils		04/06/2003	0.0	
25/06/2003	Neutrophils		16/06/2003	8.9	
25/06/2003	Neutrophils		05/06/2003	0.0	
25/06/2003	White blood cells		05/04/2003	81.0	
25/06/2003	White blood cells		10/04/2003	78.3	
25/06/2003	White blood cells		03/05/2003	79.7	

Additional Information:

Patient was also taking Ciprofloxacin, Valproate Sodium, Fluconazole, Sertraline, salbutamol, prednisone.
Clopine was given 8-Feb-1996 to 5-Apr-2003/3-May-2003 to 22-may-2003/28-May-2003 to 4-Jun-2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187570

Seq: 1

Gender: M

Reported: 25/06/2003

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 57

Onset Date: 22/05/2003

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

MAGNESIUM ASPARTATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/06/2003	White blood cells		16/05/2003	48.8	
25/06/2003	White blood cells		23/05/2003	83.2	
25/06/2003	White blood cells		05/06/2003	94.4	
25/06/2003	White blood cells		11/06/2003	82.8	
25/06/2003	White blood cells		16/06/2003	12.9	
25/06/2003	White blood cells		03/06/2003	94.4	
25/06/2003	White blood cells		04/06/2003	96.3	

Additional Information:

Patient was also taking Ciprofloxacin, Valproate Sodium, Fluconazole, Sertraline, salbutamol, prednisone.
Clopine was given 8-Feb-1996 to 5-Apr-2003/3-May-2003 to 22-may-2003/28-May-2003 to 4-Jun-2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187570

Seq: 1

Gender: M

Reported: 25/06/2003

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 57

Onset Date: 22/05/2003

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

MAGNESIUM ASPARTATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/06/2003	White blood cells		09/06/2003	99.0	

Additional Information:

Patient was also taking Ciprofloxacin, Valproate Sodium, Fluconazole, Sertraline, salbutamol, prednisone.
Clopine was given 8-Feb-1996 to 5-Apr-2003/3-May-2003 to 22-may-2003/28-May-2003 to 4-Jun-2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187638
Reported: 23/06/2003

Seq: 1

Gender: M
Weight: 0.00
Age: 29Y

Hospitalisation:

Onset Date: 11/02/2003
Outcome: Unknown

DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia	Changed o Amisulpride.

Medicine Details:

OMEPRAZOLE (Other drug)		Reason: Other diseases of esophagus	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: Contin
CLOZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/06/2003	Neutrophils		17/03/2003	3.1	
23/06/2003	Neutrophils		25/03/2003	3.9	
23/06/2003	Neutrophils		08/04/2003	4.3	
23/06/2003	White blood cells		17/03/2003	5.2	
23/06/2003	White blood cells		25/03/2003	6.2	
23/06/2003	White blood cells		08/04/2003	7.4	

Additional Information:

Extra blood tests needed in August 2002 as Neutrophils below 2.0 but recovered. Dose start and stop dates: 05/1999 and 03/2003.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187807
Reported: 27/06/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 16/06/2003

Age: 57

DOB: 03/04/1946

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Neutropenia,Leukopenia	Ceased Clozaril
Leukopenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	475.0 Milligram	Daily	Oral
Batch:	Started: 31/03/1998	Stopped: 16/06/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/06/2003	Neutrophils		23/03/1998	2.8	
27/06/2003	Neutrophils		16/06/2003	1.0	
27/06/2003	Neutrophils		07/07/2003	2.1	
27/06/2003	Neutrophils		03/07/2003	1.8	
27/06/2003	White blood cells		23/03/1998	5.8	
27/06/2003	White blood cells		16/06/2003	2.4	
27/06/2003	White blood cells		03/07/2003	3.6	

Additional Information:

Patient also taking risperidone, aspirin, simvastatin. tramadol, amitriptyline.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187807

Seq: 1

Gender: F

Reported: 27/06/2003

Weight: 0.00

Hospitalisation:

Age: 57

Onset Date: 16/06/2003

DOB: 03/04/1946

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Schizophrenia

Tablet

475.0 Milligram

Daily

Oral

Batch:

Started: 31/03/1998

Stopped: 16/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/06/2003	White blood cells		07/07/2003	4.1	

Additional Information:

Patient also taking risperidone, aspirin, simvastatin. tramadol, amitriptyline.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187818 **Seq:** 1 **Gender:** F
Reported: 03/07/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: 04/02/2003 **DOB:**
Outcome: Recovered 14/02/2003 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Colitis	Caused or prolonged inpatient hospitalisation	Colitis nos, nausea, vomiting, diarrhoea.	Fluid replacement.
Diarrhoea	Caused or prolonged inpatient hospitalisation		
Nausea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 12/11/1997	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/07/2003	ALT = SGPT		04/02/2003	51	
03/07/2003	AST = SGOT		04/02/2003	38	
03/07/2003	Albumin		04/02/2003	30	
03/07/2003	Creatine		04/02/2003	297	
03/07/2003	Haematology				
03/07/2003	Pharmacokinetics				
03/07/2003	SAP = ALP		04/02/2003	143	

Additional Information:

Patient was also taking Zoloft.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187818 **Seq:** 1 **Gender:** F
Reported: 03/07/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: 04/02/2003 **DOB:**
Outcome: Recovered 14/02/2003 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 12/11/1997	Stopped:	Contin

Laboratory Investigations:

Additional Information:

Patient was also taking Zoloft.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187821

Seq: 1

Gender: M

Reported: 09/04/2003

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date:

DOB: 08/09/1972

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal	Required Specialist Consultation	Liver functions tests nos abnormal, tremors/jerks, nausea, malaise	Clozapine dose reduced from 700mg/day to 300mg/day.
Malaise	Required Specialist Consultation		
Nausea	Required Specialist Consultation		
Tremor	Required Specialist Consultation		

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 19/06/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/04/2003	Biochemistry				
09/04/2003	Pharmacokinetics				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187962

Seq: 1

Gender: M

Reported: 07/07/2003

Weight: 0.00

Hospitalisation:

Onset Date: 31/05/2003

Age: 25

DOB: 16/07/1977

Outcome: Death, maybe drug

15/06/2003

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Intermittent pyrexia from 1.6.03 to 11.6.03.	
Myocarditis		Myocarditis, pyrexia, sweating increased, myocardial infarction, worsened asthma.	Clozaril ceased.
Chest pain		Slight chest discomfort 13.6.03.	
Asthma			
Hyperhidrosis			
Influenza like illness			
Myocardial infarction			
Tachycardia			
Troponin increased			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	100.0 Milligram
	Daily
	Oral
Batch:	Started: 28/05/2003
	Stopped: 12/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/07/2003	Autopsy report				Toxicology: Ethanol not detected. Clozapine detected in blood at 0.1mg/L. Venlafaxine detected in blood at 0.2mg/L. Paracetamol detected in blood at 5mg/L. Valproic acid metabolites detected. Cause of death: Hypersensitivity myocarditis.
07/07/2003	Creatine kinase		12/06/2003	1.4	

Additional Information:

Patient also taking Risperdal, Venlafaxine, Epilim, Ventolin, Serevent, Pulmicort and Ventolin Nebules PF. An autopsy found the cause of death to be hypersensitivity myocarditis secondary to Clozapine. 24D. Case later published: Report Source Literature, Journal: Australian Doctor Circular, Author: T. James.
the second article concerning the same case was published by A.J.Obrian 2005 in Coornial cummunique, volume 3, issue 1 page 4 :Clozapine-following drug manufactures recommendations



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187962

Seq: 1

Gender: M

Reported: 07/07/2003

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date: 31/05/2003

DOB: 16/07/1977

Outcome: Death, maybe drug

15/06/2003

Causality: Causality certain

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Unspecified schizophrenia

Tablet

100.0 Milligram

Daily

Oral

Batch:

Started: 28/05/2003

Stopped: 12/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/07/2003	Eosinophils		12/06/2003	0.4	
07/07/2003	Haemoglobin		12/06/2003	13.1	

Additional Information:

Patient also taking Risperdal, Venlafaxine, Epilim, Ventolin, Serevent, Pulmicort and Ventolin Nebules PF. An autopsy found the cause of death to be hypersensitivity myocarditis secondary to Clozapine. 24D. Case later published: Report Source Literature, Journal: Australian Doctor Circular, Author: T. James.
the second article concerning the same case was published by A.J.Obrian 2005 in Coornial cummunique, volume 3, issue 1 page 4 :Clozapine-following drug manufactures recommendations



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187962

Seq: 1

Gender: M

Reported: 07/07/2003

Weight: 0.00

Hospitalisation:

Onset Date: 31/05/2003

Age: 25

DOB: 16/07/1977

Outcome: Death, maybe drug

15/06/2003

Causality: Causality certain

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Unspecified schizophrenia

Tablet

100.0 Milligram

Daily

Oral

Batch:

Started: 28/05/2003

Stopped: 12/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/07/2003	Histology				Heart: Sections from all four walls of the left ventricle and from the right ventricle show similar changes. There is a myocarditis characterized by a conspicuous interstitial and perivascular inflammatory infiltrate comprising lymphocytes, histiocytes and numerous eosinophils. There is also evidence ...

Additional Information:

Patient also taking Risperdal, Venlafaxine, Epilim, Ventolin, Serevent, Pulmicort and Ventolin Nebules PF. An autopsy found the cause of death to be hypersensitivity myocarditis secondary to Clozapine. 24D. Case later published: Report Source Literature, Journal: Australian Doctor Circular, Author: T. James.
the second article concerning the same case was published by A.J.Obrian 2005 in Coornial cummunique, volume 3, issue 1 page 4 :Clozapine-following drug manufactures recommendations



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187962

Seq: 1

Gender: M

Reported: 07/07/2003

Weight: 0.00

Hospitalisation:

Onset Date: 31/05/2003

Age: 25

DOB: 16/07/1977

Outcome: Death, maybe drug

15/06/2003

Causality: Causality certain

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Unspecified schizophrenia

Tablet

100.0 Milligram

Daily

Oral

Batch:

Started: 28/05/2003

Stopped: 12/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/07/2003	Neutrophils		12/06/2003	8.2	... of pericardial involvement. Liver: Sections show fatty change with steatohepatitis. Eosinophils and lymphocytes are noted within portal tracts.
07/07/2003	Platelets		12/06/2003	234	

Additional Information:

Patient also taking Risperdal, Venlafaxine, Epilim, Ventolin, Serevent, Pulmicort and Ventolin Nebules PF. An autopsy found the cause of death to be hypersensitivity myocarditis secondary to Clozapine. 24D. Case later published: Report Source Literature, Journal: Australian Doctor Circular, Author: T. James.
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THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187962

Seq: 1

Gender: M

Reported: 07/07/2003

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date: 31/05/2003

DOB: 16/07/1977

Outcome: Death, maybe drug

15/06/2003

Causality: Causality certain

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Unspecified schizophrenia

Tablet

100.0 Milligram

Daily

Oral

Batch:

Started: 28/05/2003

Stopped: 12/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/07/2003	Troponin		12/06/2003	0.47	
07/07/2003	White blood cells		12/06/2003	10.7	

Additional Information:

Patient also taking Risperdal, Venlafaxine, Epilim, Ventolin, Serevent, Pulmicort and Ventolin Nebules PF. An autopsy found the cause of death to be hypersensitivity myocarditis secondary to Clozapine. 24D. Case later published: Report Source Literature, Journal: Australian Doctor Circular, Author: T. James.
the second article concerning the same case was published by A.J.Obrian 2005 in Coornial cummunique, volume 3, issue 1 page 4 :Clozapine-following drug manufactures recommendations



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187965

Seq: 1

Gender: F

Reported: 30/06/2003

Weight: 0.00

Hospitalisation:

Age: 63

Onset Date: 19/06/2003

DOB: 11/06/1940

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Life threatening	Neutropenia , terminal lung cancer	Ceased Clozaril

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 19/02/1998	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/06/2003	Neutrophils		22/04/2003	5.10	
30/06/2003	Neutrophils		20/05/2003	4.40	
30/06/2003	Neutrophils		19/06/2003	1.3	
30/06/2003	White blood cells		20/05/2003	7.70	

Additional Information:

Clozaril was stopped sometime in April 2003.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187971
Reported: 07/03/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 25/10/2002

Age: 44

DOB: 18/08/1958

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal failure acute	Caused or prolonged inpatient hospitalisation	Acute renal failure, vomiting, nausea and vomiting, psychosis, dehydration.	IV Fluids, diazepam, metoclopramide and thiamine. Clozaril was changed to Clozaril.
Dehydration	Caused or prolonged inpatient hospitalisation		
Nausea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.0 Milligram
	Daily
	Oral
Batch:	Started: 15/03/2000
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 187971
Reported: 07/03/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Age: 44

Onset Date: 25/10/2002

DOB: 18/08/1958

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder	Caused or prolonged inpatient hospitalisation		
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.0 Milligram
	Daily
	Oral
Batch:	Started: 15/03/2000
	Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188033

Seq: 1

Gender: F

Reported: 02/07/2003

Weight: 0.00

Hospitalisation:

Onset Date: 09/06/2003

Age: 42

DOB: 22/07/1960

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Obsessive-compulsive disorder	Caused or prolonged inpatient hospitalisation	Obsessive-compulsive disorder	Ceased Clozaril

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started: 26/06/1994	Stopped:	09/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Was rechallenged (date unspecified) but experienced a worsening of obsessive-compulsive symptoms.
Patient was also taking Clonazepam, Celebrex, Levlen ED, Coloxyl with Senna, Citalopram, Thyroxine, lamotrigine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188036

Seq: 1

Gender: F

Reported: 02/07/2003

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date: 09/06/2003

DOB: 22/07/1960

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation	Decompensation (psychiatric symptoms nos) ,Sleep disorder.	Ceased Clozaril

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started: 28/06/1994	Stopped: 09/06/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Citalopram, Thyroxine, Lamotrigine, Clonazepam, celebrex, levlen ED, Coloxyl with Senna.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188162

Seq: 1

Gender: F

Reported: 07/07/2003

Weight: 0.00

Hospitalisation:

Onset Date: 30/06/2003

Age: 61

DOB: 02/07/1941

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Life threatening	Fevers , increased CK, Anorexia , Drowsiness, Tardivedyskinesia, neuroleptic syndrome.	Panadol, IV fluids, NG feeds.
Anorexia	Life threatening		
Blood creatine phosphokinase incr	Life threatening		
Neuroleptic malignant syndrome	Life threatening		
Somnolence	Life threatening		

Medicine Details:

CLOZAPINE (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 12/06/2003	Stopped:	30/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/07/2003	C-Reactive Protein		29/06/2003	151	
07/07/2003	C-Reactive Protein		30/06/2003	230	
07/07/2003	C-Reactive Protein		02/07/2003	185	
07/07/2003	Creatine		29/06/2003	2256	
07/07/2003	Creatine		30/06/2003	2110	
07/07/2003	Creatine		02/07/2003	630	
07/07/2003	Erythrocyte		29/06/2003	53	

Additional Information:

Patient was also taking Diazepam, Chlorvescent, Zoloft.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188162

Seq: 1

Gender: F

Reported: 07/07/2003

Weight: 0.00

Hospitalisation:

Age: 61

Onset Date: 30/06/2003

DOB: 02/07/1941

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	Life threatening		

Medicine Details:

CLOZAPINE (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 12/06/2003	Stopped:	30/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/07/2003	Erythrocyte	(115-165G/L)	30/06/2003	65	
07/07/2003	Erythrocyte		02/07/2003	75	
07/07/2003	Haemoglobin				
07/07/2003	Other data				

Additional Information:

Patient was also taking Diazepam, Chlorvescent, Zoloft.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188179
Reported: 10/07/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 05/04/2003

Age: 24

DOB: 22/06/1978

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancreatitis	Caused or prolonged inpatient hospitalisation	Pancreatitis, appendicitis	
Appendicitis			
Blood glucose increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 26/07/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/07/2003	GGT = SGGT =	0 - 60 U/L	16/04/2003	220	
10/07/2003	GGT = SGGT =	0 - 60 U/L	30/04/2002	78	
10/07/2003	Neutrophils		24/06/2003	5.48	
10/07/2003	Neutrophils		23/07/2002	4.07	
10/07/2003	SAP = ALP	30 - 110 U/L	16/04/2003	136	
10/07/2003	SAP = ALP	30 - 110 U/L	30/04/2002	116	
10/07/2003	Serum glucose	3.8 - 5.5 mmol/L	16/04/2003	6.0	

Additional Information:

History: documented "heavy alcohol drinking" alcoholism. Clozaril stopped in April 2002



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188179
Reported: 10/07/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 05/04/2003

Age: 24

DOB: 22/06/1978

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 26/07/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/07/2003	Serum glucose	3.8 - 5.5 mmol/L	30/04/2002	4.3	
10/07/2003	Urate	0.15 - 0.45	16/04/2003	0.58	
10/07/2003	Urate	0.15 - 0.45	30/04/2002	0.54	
10/07/2003	White blood cells		23/07/2002	10.4	
10/07/2003	White blood cells		24/06/2003	10.00	

Additional Information:

History: documented "heavy alcohol drinking" alcoholism. Clozaril stopped in April 2002



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188203

Seq: 1

Gender: M

Reported: 07/07/2003

Weight: 0.00

Hospitalisation:

Age: 49

Onset Date:

DOB: 11/09/1953

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash			Ceased Clozaril

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram
	Daily
	Oral
Batch:	Started: 02/11/2002
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188248

Seq: 1

Gender: F

Reported: 09/07/2003

Weight: 0.00

Hospitalisation:

Age: 54

Onset Date:

DOB: 25/04/1949

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Respiratory disorder		Respiratory problems	

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 30/08/1995 L TERM	Stopped: 02/06/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188279
Reported: 09/07/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 57

Onset Date:

DOB: 12/06/1946

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Transient ischaemic attack		Transient ischaemic attack, convulsion.	Ceased clopine (clozapine) due to non-compliance and unexplained collapses (transient ischaemic attacks).
Grand mal convulsion			

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 04/03/2002	Stopped:	23/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking quinine, allopurinol, metformin, losec, sodium valproate, lipitor and aspirin. History: Schizophrenia, NIMM, IHD, seizures. Patient developed multiple collapses and seizures April - May 2003. Generalised tonic-clonic seizures. The patient was receiving intermittent Clopine PO from March 2002 until May 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188366 **Seq:** 1 **Gender:** M
Reported: 10/07/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 32
Onset Date: 03/07/2003 **DOB:** 06/03/1971
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Epileptic type seizure, psychotic disorder.	Haloperidol, dilantin, epilim increased from 1500mg to 1900mg/day.
Psychotic disorder			

Medicine Details:

ALCOHOL (Interaction)		Reason:	
Oral application		Dose Unspecified	Oral
Batch:	Started:	Stopped:	
CLOZARIL (Interaction)		Reason: Schizophrenia	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 26/05/2003	Stopped:	
SODIUM VALPROATE (Other drug)		Reason:	
Oral application		Dose Unspecified	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozaril was only recently increased to 500mg/daily. Clozaril was discontinued but recommenced at a lower dose.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188380

Seq: 1

Gender: M

Reported: 11/07/2003

Weight: 0.00

Hospitalisation:

Age: 16

Onset Date: 15/04/2003

DOB: 08/04/1987

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure Echocardiogram abnormal Left ventricular dysfunction Tachycardia Cardiomyopathy		Clozaril induced cardiomyopathy, left ventricular dysfunction, echocardiogram abnormal.	Clozaril was tapered down and ceased in may 2003. Patient was recommenced on Clozaril on 21 May 2003 and weekly echocardiograms were performed.

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 19/03/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/07/2003	Echocardiogram				

Additional Information:

The patient was asymptomatic at the time of reporting (10 Jul 2003).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188425

Seq: 1

Gender: F

Reported: 11/07/2003

Weight: 0.00

Hospitalisation:

Age: 32

Onset Date:

DOB: 09/01/1971

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		Somnolence, aura for 4 days, clozaril blood level increased	Clozaril was reduced.
Aura			
Drug interaction			
Drug level increased			

Medicine Details:

CLOZARIL (Interaction)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 25/07/2000	Stopped:	
FLUVOXAMINE MALEATE (Interaction)		Reason:	
	200.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/07/2003	Serum drug level		15/05/2003	2738 ng/ml	
11/07/2003	Serum drug level		06/06/2003	2600 ng/ml	
11/07/2003	Serum drug level		26/06/2003	3292 ng/ml	
11/07/2003	Serum drug level		09/07/2003	2945 ng/ml	
11/07/2003	Serum drug level		28/07/2003	2040 ng/ml	

Additional Information:

Doctor had increased the dose of clozaril from 300mg to 500mg gradually then the symptoms occurred.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188428
Reported: 11/07/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 02/05/2003

Age: 37

DOB: 04/02/1966

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug toxicity		Drug level nos increased high clozaril blood levels, constipation, drug toxicity Clozaril toxicity.	Ceased Clozaril.
Constipation			Coloxy with senna
Drug level increased			

Medicine Details:

CLOZARIL (Interaction)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 20/09/2000	Stopped: 27/05/2003	
LUVOX (Interaction)		Reason:	
	150.0 Milligram	Daily	
Batch:	Started:	Stopped:	
LITHIUM CARBONATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/07/2003	Pharmacokinetics				

Additional Information:

Concomitant Luvox had elevated the clozapine serum levels.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188464

Seq: 1

Gender: M

Reported: 21/03/2003

Weight: 0.00

Hospitalisation:

Age: 43

Onset Date:

DOB: 17/12/1959

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective	Caused or prolonged inpatient hospitalisation	Drug ineffective	

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 01/02/2003	Stopped: 06/03/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188471

Seq: 1

Gender: M

Reported: 14/07/2003

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date:

DOB: 22/03/1973

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Required Visit to Doctor	Seizures(Convulsions)	

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 04/03/2003	Stopped: 08/07/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/07/2003	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188565
Reported: 17/07/2003

Seq: 1

Gender: M
Weight: 0.00
Age: 37Y

Hospitalisation:

Onset Date:
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Grand mal seizure	Clozapine was withheld for 2 days then restarted at a lower dose of 450mg with addition of Sodium Valproate. The dose of clozapine was gradually increased to 675mg, Sodium Valproate was increased to 1500mg.
Drug level changed			

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	525.0 Milligram
	Daily
	Oral
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/07/2003	Pharmacokinetics				

Additional Information:

24D. Report Source Literature
Journal: Journal of Psychopharmacology
Author: Greenwood-Smith C, Lubman DJ, Cestle DJ
Title: Serum clozapine levels: a review of their clinical utility
Volume: 17(2) Year: 2003 Pages:234-238.
Symptoms occurred when Clozapine was increased to 525ma from 50ma daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188567

Seq: 1

Gender: M

Reported: 17/07/2003

Weight: 0.00

Hospitalisation:

Age: 48Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased		Elevated clozapine levels, fluctuating clozapine level,	Clozapine was reduced slowly to 725 mg over 1 year.
Drug level changed			

Medicine Details:

CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/07/2003	Pharmacokinetics				

Additional Information:

24d. Report Source Literature
Journal: Journal of Psychopharmacology
Author: Greenwood-Smith C, Lubman DJ, Castle DJ
Title: Serum clozapine levels: a review of their clinical utility
Volume: 17 (2) Year: 2003 Pages:234-238.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188683

Seq: 1

Gender: M

Reported: 21/07/2003

Weight: 0.00

Hospitalisation:

Onset Date: 07/07/2003

Age: 29

DOB: 20/06/1974

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fatigue Blood osmolarity decreased Dyspnoea Electrocardiogram abnormal Eosinopenia Feeling hot Haemoglobin decreased Hypochloraemia Hypokalaemia		Fatigue, Dyspnoea, ECG abnormal, eosinophilia, pallor, feeling hot, pyrexia, troponin increased, vomiting, nausea, rash, viral infection, myocarditis.	Ceased Clozaril

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 20/06/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/07/2003	Chest X-ray				
21/07/2003	Creatine				
21/07/2003	Eosinophils		07/07/2003	0.35	
21/07/2003	Eosinophils		10/07/2003	0.39	
21/07/2003	Eosinophils		14/07/2003	1.61	
21/07/2003	Eosinophils		11/07/2003	0.62	
21/07/2003	Haemoglobin	135 - 180 g/L	12/07/2003	127	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188683

Seq: 1

Gender: M

Reported: 21/07/2003

Weight: 0.00

Hospitalisation:

Age: 29

Onset Date: 07/07/2003

DOB: 20/06/1974

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			
Myocarditis			
Nausea			
Pallor			
Pyrexia			
Rash			
Troponin increased			
Viral infection			
Vomiting			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 20/06/2003 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/07/2003	Haemoglobin	135 - 180 g/L	14/07/2003	135	
21/07/2003	Troponin				
21/07/2003	Urine osmolality	270 - 290	10/07/2003	260	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188732

Seq: 1

Gender: M

Reported: 22/07/2003

Weight: 0.00

Hospitalisation:

Onset Date: 13/06/2003

Age: 32

DOB: 03/01/1971

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Convulsions nos, lethargy, asthenia, somnolence, tremor.	Luvox was ceased.
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation	Extrapyramidal disorder, incontinence, drug level nos increased, drug interaction nos.	
Asthenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Interaction)		Reason:	
Tablet	900.0 Milligram	Daily	Oral
Batch:	Started: 13/03/1997	Stopped:	Contin
LUVOX (Interaction)		Reason: Obsessive compulsive neurosis	
	100.0 Milligram	Daily	
Batch:	Started: 13/06/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/07/2003	Computerised				
22/07/2003	Pharmacokinetics	(0.6-1)	07/07/2003	1.48	

Additional Information:

History of intellectual disability, autism (diagnosed 7 years ago) and bipolar disorder (diagnosed 7 years ago).
Patient was also taking Epilim, Lithium,Largactil.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188732

Seq: 1

Gender: M

Reported: 22/07/2003

Weight: 0.00

Hospitalisation:

Age: 32

Onset Date: 13/06/2003

DOB: 03/01/1971

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug interaction	Caused or prolonged inpatient hospitalisation		
Drug level increased	Caused or prolonged inpatient hospitalisation		
Lethargy	Caused or prolonged inpatient hospitalisation		Luvox was ceased.

Medicine Details:

CLOZARIL (Interaction)		Reason:	
Tablet	900.0 Milligram	Daily	Oral
Batch:	Started: 13/03/1997	Stopped:	Contin
LUVOX (Interaction)		Reason: Obsessive compulsive neurosis	
	100.0 Milligram	Daily	
Batch:	Started: 13/06/2003	Stopped:	

Laboratory Investigations:

Additional Information:

History of intellectual disability, autism (diagnosed 7 years ago) and bipolar disorder (diagnosed 7 years ago).
Patient was also taking Epilim, Lithium,Largactil.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188732

Seq: 1

Gender: M

Reported: 22/07/2003

Weight: 0.00

Hospitalisation:

Onset Date: 13/06/2003

Age: 32

DOB: 03/01/1971

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		
Urinary incontinence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Interaction)		Reason:	
Tablet	900.0 Milligram	Daily	Oral
Batch:	Started: 13/03/1997	Stopped:	Contin
LUVOX (Interaction)		Reason: Obsessive compulsive neurosis	
	100.0 Milligram	Daily	
Batch:	Started: 13/06/2003	Stopped:	

Laboratory Investigations:

Additional Information:

History of intellectual disability, autism (diagnosed 7 years ago) and bipolar disorder (diagnosed 7 years ago).
Patient was also taking Epilim, Lithium,Largactil.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188792

Seq: 1

Gender: M

Reported: 25/07/2003

Weight: 0.00

Hospitalisation:

Age: 40

Onset Date:

DOB: 19/11/1962

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizures/(Convulsions)	

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 07/03/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Anti-diabetics.

Patient received Clozaril 100mg qd(reason unknown) on 02 Oct 2002, which was increased fairly rapidly to 450mg qd within three weeks, at which time the patient experienced the first seizures. Clozaril was decreased to approximately 100mg qd and yet the patient continued to experience seizures.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188793

Seq: 1

Gender: M

Reported: 25/07/2003

Weight: 0.00

Hospitalisation:

Onset Date: 08/07/2003

Age: 37

DOB: 04/12/1965

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia	Caused or prolonged inpatient hospitalisation	Pneumonia, Thrombocytopenia, Convulsions.	Ceased Clozaril, commenced on IV antibiotics, platelet transfusions, ceftriaxone, Timentin, Vancomycin.
Convulsion	Caused or prolonged inpatient hospitalisation		
Thrombocytopenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	50.0 Milligram
	Daily
	Oral
Batch:	Started: 01/07/1993
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/07/2003	Neutrophils		16/07/2003	6.00	
25/07/2003	Neutrophils		07/07/2003	9.60	
25/07/2003	Platelets		22/07/2003	100	
25/07/2003	Platelets		19/07/2003	28	
25/07/2003	White blood cells		16/07/2003	7.80	
25/07/2003	White blood cells		07/07/2003	11.10	
25/07/2003	White blood cells		09/06/2003	5.00	

Additional Information:

Patient was also taking Clonazepam, Potassium, Losec, Folic acid.
Concomitant illnesses of malnutrition and pancreatitis.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188795

Seq: 1

Gender: M

Reported: 25/07/2003

Weight: 0.00

Hospitalisation:

Age: 24

Onset Date: 07/07/2003

DOB: 13/04/1979

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delirium Confusional state Overdose Salivary hypersecretion Sedation		Delirium, Salivary Hypersalivation, Confusional State, overdose nos, sedation.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.5 Milligram
	Daily
	Oral
Batch:	Started: 22/04/2002
	Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188998 **Seq:** 1 **Gender:** M
Reported: 29/07/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 56
Onset Date: 16/06/2003 **DOB:** 29/08/1946
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Intermittent temperature of 37.7-38 degrees celsius.	
Tachycardia		Tachycardia, increase in blood pressure.	
Blood pressure increased			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	250.0 Milligram
	Daily
	Oral
Batch:	Started: 11/06/2003
	Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Coversyl, Venlafaxine and Olanzapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 188999

Seq: 1

Gender: F

Reported: 29/07/2003

Weight: 0.00

Hospitalisation:

Age: 28

Onset Date: 13/03/2003

DOB: 02/05/1974

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion Choking		Hypersalivation which lead to choking.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 13/03/2003	Stopped:	15/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189065

Seq: 1

Gender: M

Reported: 31/07/2003

Weight: 0.00

Hospitalisation:

Age: 26

Onset Date:

DOB: 15/12/1976

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia Leukocytosis Neutrophilia		Eosinophilla, leukocytosis, neutrophilia.	Ceased Clozaril.

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 18/06/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
31/07/2003	Neutrophils		23/07/2003	8.00	
31/07/2003	Neutrophils		18/07/2003	10.50	
31/07/2003	Neutrophils		04/07/2003	7.47	
31/07/2003	Neutrophils		18/06/2003	5.70	
31/07/2003	Neutrophils		24/06/2003	4.82	
31/07/2003	Neutrophils		09/07/2003	11.80	
31/07/2003	White blood cells		23/07/2003	19.50	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189065

Seq: 1

Gender: M

Reported: 31/07/2003

Weight: 0.00

Hospitalisation:

Age: 26

Onset Date:

DOB: 15/12/1976

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason:

Tablet

12.5 Milligram

Daily

Oral

Batch:

Started: 18/06/2003

Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
31/07/2003	White blood cells		18/07/2003	23.50	
31/07/2003	White blood cells		09/07/2003	14.80	
31/07/2003	White blood cells		04/07/2003	10.40	
31/07/2003	White blood cells		24/06/2003	7.30	
31/07/2003	White blood cells		18/06/2003	8.30	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189068

Seq: 1

Gender: F

Reported: 31/07/2003

Weight: 0.00

Hospitalisation:

Age: 31

Onset Date:

DOB: 25/04/1972

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Cardiac disorder		Convulsions nos, cardiac disorder.	Ceased Clopine.

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 12/10/2002	Stopped: 09/07/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189069
Reported: 31/07/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 23/05/2003

Age: 36

DOB: 09/02/1967

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction		A peeling rash on the areas exposed to sunlight face, neck, and hands.	Changed for Monoplus to fosinopril alone, treated with steroid creams and moisturisers.

Medicine Details:

MONOPLUS NOS (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CHLORPROMAZINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	200.0 Milligram	Total	Oral
Batch:	Started: 22/05/2003	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started: 13/05/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189070

Seq: 1

Gender: M

Reported: 31/07/2003

Weight: 0.00

Hospitalisation:

Age: 20

Onset Date: 31/05/2003

DOB: 18/10/1982

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure		Failure to Ejaculate	Clozaril was decreased form 500mg to 450mg daily.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 29/05/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189078 **Seq:** 1 **Gender:** F
Reported: 04/08/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99u
Onset Date: 26/07/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased		Relapse to schizophrenia symptoms.	
Drug ineffective			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	Oral
Batch:	Started: 15/01/2003 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/08/2003	Other data				

Additional Information:

Clozaril dose titration down from 400mg to 250mg once daily at night.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189179
Reported: 05/08/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Age: 37

Onset Date:

DOB: 09/08/1965

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Low-grade neuroleptic malignant syndrome, pyrexia, tachycardia, liver function test abnormal, Blood creatine phosphokinase increased	
Blood creatine phosphokinase increased			
Liver function test abnormal			
Pyrexia			
Tachycardia			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	250.0 Milligram
	Daily
	Oral
Batch:	Started: 19/03/2003
	Stopped: 04/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/08/2003	ALT = SGPT	<40	29/03/2003	34	
05/08/2003	ALT = SGPT	<40	28/03/2003	43	
05/08/2003	ALT = SGPT	<40	25/03/2003	100	
05/08/2003	ALT = SGPT	<40	14/03/2003	9	
05/08/2003	Creatine	<160	08/04/2003	654	
05/08/2003	Creatine	<160	07/04/2003	636	
05/08/2003	Creatine	<160	05/04/2003	208	

Additional Information:

Patient also taking: Mirtazapine, Diazepam, Lactulose.
Date of reaction onset: Mar 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189179
Reported: 05/08/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Age: 37

Onset Date:

DOB: 09/08/1965

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Unspecified schizophrenia

Tablet

250.0 Milligram

Daily

Oral

Batch:

Started: 19/03/2003

Stopped: 04/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/08/2003	Creatine	<160	04/04/2003	209	
05/08/2003	Creatine	<160	03/04/2003	286	
05/08/2003	Creatine	<160	01/04/2003	228	
05/08/2003	Creatine	<160	31/03/2003	192	
05/08/2003	Creatine	<160	30/03/2003	169	
05/08/2003	Creatine	<160	14/03/2003	157	
05/08/2003	GGT = SGGT =	<50	08/04/2003	63	

Additional Information:

Patient also taking: Mirtazapine, Diazepam, Lactulose.
Date of reaction onset: Mar 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189179
Reported: 05/08/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Age: 37

Onset Date:

DOB: 09/08/1965

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Unspecified schizophrenia

Tablet

250.0 Milligram

Daily

Oral

Batch:

Started: 19/03/2003

Stopped: 04/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/08/2003	GGT = SGGT =	<50	07/04/2003	54	
05/08/2003	GGT = SGGT =	<50	04/04/2003	64	
05/08/2003	GGT = SGGT =	<50	03/04/2003	70	
05/08/2003	GGT = SGGT =	<50	01/04/2003	70	
05/08/2003	GGT = SGGT =	<50	31/03/2003	68	
05/08/2003	GGT = SGGT =	<50	30/03/2003	73	
05/08/2003	GGT = SGGT =	<50	29/03/2003	79	

Additional Information:

Patient also taking: Mirtazapine, Diazepam, Lactulose.
Date of reaction onset: Mar 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189179

Seq: 1

Gender: F

Reported: 05/08/2003

Weight: 0.00

Hospitalisation:

Age: 37

Onset Date:

DOB: 09/08/1965

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Unspecified schizophrenia

Tablet

250.0 Milligram

Daily

Oral

Batch:

Started: 19/03/2003

Stopped: 04/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/08/2003	GGT = SGGT =	<50	28/03/2003	74	
05/08/2003	GGT = SGGT =	<50	25/03/2003	91	
05/08/2003	GGT = SGGT =	<50	14/03/2003	33	

Additional Information:

Patient also taking: Mirtazapine, Diazepam, Lactulose.
Date of reaction onset: Mar 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189193

Seq: 1

Gender: F

Reported: 06/08/2003

Weight: 0.00

Hospitalisation:

Age: 21

Onset Date: 03/04/2003

DOB: 24/02/1982

Outcome: Unknown

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence Drug level increased Enuresis Fatigue		Drowsiness, nocturnal enuresis, clozapine level increased and fatigue.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	350.0 Milligram
	Daily
	Oral
Batch:	Started: 15/11/2002
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/08/2003	Serum drug level		01/05/2003	888	
06/08/2003	Serum drug level		26/06/2003	1028	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189286

Seq: 1

Gender: M

Reported: 07/08/2003

Weight: 0.00

Hospitalisation:

Age: 68

Onset Date:

DOB: 22/12/1934

Outcome: Not yet recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state		Confusion	
Dizziness		Dizziness	
Drug ineffective		Drug ineffective	
Fall		Fall	
Orthostatic hypotension		Postural hypotension	
Sedation		Sedation	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified neurosis
Tablet	100.0 Milligram
	Daily
	Oral
Batch:	Started: 08/04/2003
	Stopped: 30/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset date: 07/2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189299

Seq: 1

Gender: M

Reported: 08/08/2003

Weight: 0.00

Hospitalisation:

Age: 36

Onset Date:

DOB: 12/07/1967

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Cardiac Disorder.	Switched to an alternative agent.
Dyspnoea			
Fatigue			

Medicine Details:

CLOPINE (Suspected)	Reason: Schizophrenia
Tablet	250.0 Milligram
	Daily
	Oral
Batch:	Started: 20/06/2003
	Stopped: 15/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/08/2003	Other data				
08/08/2003	Troponin		09/07/2003	0.52	

Additional Information:

History: Schizophrenia with limited response to other antipsychotics.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189338

Seq: 1

Gender: M

Reported: 08/08/2003

Weight: 0.00

Hospitalisation:

Age: 22Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion		Salivary hypersalivation, mouth ulcers.	
Mouth ulceration			

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 12/03/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Hypersalivation(date of onset not specified) lead to dose reduction from 200 mg/day to 100mg/day, which in turn resulted in return of psychosis.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189339
Reported: 08/08/2003

Seq: 1

Gender: M
Weight: 0.00
Age: 35Y

Hospitalisation:

Onset Date: 16/07/2003
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fatigue	Caused or prolonged inpatient hospitalisation	Possible viraemia, fatigue, body temperature increased, nausea.	
Body temperature increased	Caused or prolonged inpatient hospitalisation		
Nausea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 16/07/2003	Stopped: 17/07/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/08/2003	White blood cells		23/07/2003	9.40	

Additional Information:

The current diagnosis pointed to viraemia, however, a drug reaction couldn't be excluded according to the patient's treating doctor.
The patient had been on Clozaril previously from 16/07/01 until Aug 01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189368

Seq: 1

Gender: M

Reported: 11/08/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis, body temperature increased, fatigue.	Clozaril ceased, amisulpride started
Body temperature increased			
Fatigue			

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	200.0 Milligram
	Daily
	Oral
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/08/2003	Echocardiogram				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189426 **Seq:** 1 **Gender:** F
Reported: 13/08/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 32
Onset Date: 30/07/2003 **DOB:** 21/01/1971
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sinus tachycardia	Caused or prolonged inpatient hospitalisation	Sinus tachycardia, flu-like symptoms, pyrexia, lethargy, malaise.	Timentin, roxithromycin. Clozaril dose decreased to 200mg/d.
Influenza like illness			
Lethargy			
Malaise			
Pyrexia			

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 22/07/2003	Stopped:	contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/08/2003	Chest X-ray				
13/08/2003	Creatinine		27/06/2003	77	
13/08/2003	Creatinine		31/07/2003	45	
13/08/2003	Creatinine		01/08/2003	48	
13/08/2003	Echocardiogram				
13/08/2003	Electrocardiograph				
13/08/2003	Neutrophils		05/08/2003	5.01	

Additional Information:

Clozaril dose reduced to 200mg/d in August 2003. Concomitant clonazepam was not implicated. She had no clinical features of auto - immune systemic disease, did not show any risk factors for myocardial disease and had no previous history of a current cardiovascular disease.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189426

Seq: 1

Gender: F

Reported: 13/08/2003

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 32

Onset Date: 30/07/2003

DOB: 21/01/1971

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Unspecified schizophrenia

Tablet

250.0 Milligram

Daily

Oral

Batch:

Started: 22/07/2003

Stopped:

contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/08/2003	Neutrophils		29/07/2003	6.08	
13/08/2003	Thyroid				
13/08/2003	Thyroxine		27/06/2003	13	
13/08/2003	White blood cells		05/08/2003	6.3	
13/08/2003	White blood cells		29/07/2003	7.6	

Additional Information:

Clozaril dose reduced to 200mg/d in August 2003. Concomitant clonazepam was not implicated. She had no clinical features of auto - immune systemic disease, did not show any risk factors for myocardial disease and had no previous history of a current cardiovascular disease.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189533

Seq: 1

Gender: M

Reported: 14/08/2003

Weight: 0.00

Hospitalisation:

Age: 45

Onset Date: 04/08/2003

DOB: 18/02/1958

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure (Convulsions).	

Medicine Details:

AROPAX (Suspected)		Reason:	
Batch:	Started:	Stopped:	Contin
CLOZARIL (Suspected)		Reason:	
Tablet	675.0 Milligram	Daily	Oral
Batch:	Started: 21/04/1998	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient stopped taking Clozaril sometime in May 1998



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189555
Reported: 15/08/2003

Seq: 1

Gender: M
Weight: 0.00
Age: 27Y

Hospitalisation:

Onset Date: 08/02/2003
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis C-reactive protein increased Chest pain Dyspnoea Eosinophil count increased		Patient experienced Clozapine-related myocarditis and complain of feeling generally unwell and flu-ey, followed by dyspnoea and/or chest pain. He was febrile, tachycardic, hypotensive and tachypnoic. There was also an elevated ESR, eosinophil count and C-reactive protein, with a decrease in lymphocyte counts.	

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet Batch: Started: Stopped:	12.5 Milligram Daily Oral Unspecified schizophrenia Daily
EPILIM (Suspected)	Reason:
Batch: Started: Stopped:	
RANI 2 (Suspected)	Reason:
Tablet Batch: Started: Stopped:	Daily Oral

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/08/2003	C-Reactive Protein				Increased CRP - 47.
15/08/2003	Creatine				CK - 60.
15/08/2003	Electrocardiograph				ECG - Increased rate, intraventricular conduction delay. Echo-essentially unchanged from baseline.
15/08/2003	Eosinophils				Increased eosinophils - 0.09 to 0.39.
15/08/2003	Lymphocytes				Decreased lymphocytes - 1.73 to 0.73.

Additional Information:

Clozapine dose: 12.5mg daily up to 200mg daily. Eventually published in Australian and New Zealand Journal of Psychiatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropolitan psychiatric service Volume:38 Year:2004 pages:915-922.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189555
Reported: 15/08/2003

Seq: 1

Gender: M
Weight: 0.00
Age: 27Y

Hospitalisation:

Onset Date: 08/02/2003
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension Lymphocyte count decreased Malaise Nausea Pyrexia Red blood cell sedimentation rate i Tachycardia Troponin I increased			

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet 12.5 Milligram	Daily Oral
Batch:	Started: Stopped:
EPILIM (Suspected)	Reason: Unspecified schizophrenia
	Daily
Batch:	Started: Stopped:
RANI 2 (Suspected)	Reason:
Tablet	Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/08/2003	Serum drug level				Clozapine - 150.
15/08/2003	Troponin				Increased Tn-I - 0.8.

Additional Information:

Clozapine dose: 12.5mg daily up to 200mg daily. Eventually published in Australian and New Zealand Journal of Psychiatry. Reinders J, Pasonage W, Lange D, Potter JM, Plevier S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropolitan psychiatric service Volume:38 Year:2004 pages:915-922.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189558
Reported: 15/08/2003

Seq: 1

Gender: M
Weight: 0.00
Age: 26Y

Hospitalisation:

Onset Date: 12/01/2003
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		The patient complained of feeling generally unwell and 'flu-ey', followed by dyspnoea and/or chest pain. Myocarditis was diagnosed, at which time he was febrile, tachycardic, hypotensive and tachypneic. He demonstrated via Echo a tendency to high-normal wall thickness and low-normal ejection fraction. Evidence of an emerging inflammatory or allergic process was also seen through elevated ESR, increases in eosinophil count from baseline and decreases in lymphocyte count from baseline were also demonstrated.	

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.5 Milligram Daily Oral
Batch:	Started: Stopped:
VALIUM (Suspected)	Reason: Schizophrenia
	300.0 Milligram Daily
Batch:	Started: S TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/08/2003	Creatine				CK-49
15/08/2003	Echocardiogram				Echo-LV size and function within normal limits, indeterminate diastolic function.
15/08/2003	Electrocardiograph				ECG- increase rate.
15/08/2003	Eosinophils				Increased eosinophils (0.18 to 0.47)
15/08/2003	Liver function tests				Increase in LFT's, results normal during rechallenge.

Additional Information:

Eventually published in Australian and New Zealand Journal of Psychiatry. Reinders J, Pasonage W, Lange D, Potter JM, Plevier S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropolitan psychiatric service Volume:38 Year:2004 pages:915-922.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189558

Seq: 1

Gender: M

Reported: 15/08/2003

Weight: 0.00

Hospitalisation:

Age: 26Y

Onset Date: 12/01/2003

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
C-reactive protein increased Chest pain Dyspnoea Ejection fraction decreased Eosinophil count increased Hypotension Pyrexia Red blood cell sedimentation rate i Tachycardia			

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.5 Milligram Daily Oral
Batch:	Started: Stopped:
VALIUM (Suspected)	Reason: Schizophrenia
	300.0 Milligram Daily
Batch:	Started: S TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/08/2003	Lymphocytes				Decreased lymphocytes (2.38 to 1.3)
15/08/2003	Other data				Increased Tn-T-0.14.

Additional Information:

Eventually published in Australian and New Zealand Journal of Psychiatry. Reinders J, Pasonage W, Lange D, Potter JM, Plevier S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropolitan psychiatric service Volume:38 Year:2004 pages:915-922.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189567
Reported: 15/08/2003

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 15/09/1999
Outcome: Unknown

Age: 46Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		
Cardiac failure	Caused or prolonged inpatient hospitalisation		
Chest pain	Caused or prolonged inpatient hospitalisation		Perindorphil

Medicine Details:

CLOZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
EPILIM (Suspected)		Reason: Unspecified schizophrenia	
	175.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/08/2003	C-Reactive Protein				CRP - 265
15/08/2003	Creatine kinase				CK -29 & Tn-1 - 0.2
15/08/2003	Electrocardiograph				ECG -^ rate, widespread T wave inversion & ST depression. Echo-biventricular dysfunction.
15/08/2003	Eosinophils				^ eosinophils (0.11 to 0.27)
15/08/2003	Erythrocyte				^ ESR - 140 & ^

Additional Information:

Schizophrenia. Neuroleptic malignant syndrome 2 degrees chlorpromazine - recovered prior to initiation Sodium Valproate. Eventually published in Australian and New Zealand Journal of Psychiatry. Reinders J, Pasonage W, Lange D, Potter JM, Plevier S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropolitan psychiatric service Volume:38 Year:2004 pages:915-922.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189567
Reported: 15/08/2003

Seq: 1

Gender: F
Weight: 0.00
Age: 46Y

Hospitalisation:

Onset Date: 15/09/1999
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cyanosis	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Ejection fraction decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
EPILIM (Suspected)		Reason: Unspecified schizophrenia	
	175.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/08/2003	Lymphocytes				
15/08/2003	Other data				EF 42% (^ to 66% by day 37)
15/08/2003	Other data				increased LFT's

Additional Information:

Schizophrenia. Neuroleptic malignant syndrome 2 degrees chlorpromazine - recovered prior to initiation Sodium Valproate. Eventually published in Australian and New Zealand Journal of Psychiatry. Reinders J, Pasonage W, Lange D, Potter JM, Plevier S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropolitan psychiatric service Volume:38 Year:2004 pages:915-922.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189567
Reported: 15/08/2003

Seq: 1

Gender: F
Weight: 0.00
Age: 46Y

Hospitalisation:

Onset Date: 15/09/1999
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram ST segment depression	Caused or prolonged inpatient hospitalisation		
Electrocardiogram T wave inversion	Caused or prolonged inpatient hospitalisation		
Electrocardiogram abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
EPILIM (Suspected)		Reason: Unspecified schizophrenia	
	175.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Schizophrenia. Neuroleptic malignant syndrome 2 degrees chlorpromazine - recovered prior to initiation Sodium Valproate. Eventually published in Australian and New Zealand Journal of Psychiatry. Reinders J, Pasonage W, Lange D, Potter JM, Plevier S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropolitan psychiatric service Volume:38 Year:2004 pages:915-922.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189567
Reported: 15/08/2003

Seq: 1

Gender: F
Weight: 0.00
Age: 46Y

Hospitalisation:

Onset Date: 15/09/1999
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Red blood cell sedimentation rate i	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
EPILIM (Suspected)		Reason: Unspecified schizophrenia	
	175.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Schizophrenia. Neuroleptic malignant syndrome 2 degrees chlorpromazine - recovered prior to initiation Sodium Valproate. Eventually published in Australian and New Zealand Journal of Psychiatry. Reinders J, Pasonage W, Lange D, Potter JM, Plevier S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropolitan psychiatric service Volume:38 Year:2004 pages:915-922.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189567
Reported: 15/08/2003

Seq: 1

Gender: F
Weight: 0.00
Age: 46Y

Hospitalisation:

Onset Date: 15/09/1999
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)	Reason: Schizophrenia
Tablet	12.5 Milligram Daily Oral
Batch:	Started: Stopped:
EPILIM (Suspected)	Reason: Unspecified schizophrenia
	175.0 Milligram Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

Schizophrenia. Neuroleptic malignant syndrome 2 degrees chlorpromazine - recovered prior to initiation Sodium Valproate. Eventually published in Australian and New Zealand Journal of Psychiatry. Reinders J, Pasonage W, Lange D, Potter JM, Plevier S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropolitan psychiatric service Volume:38 Year:2004 pages:915-922.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189572

Seq: 1

Gender: F

Reported: 15/08/2003

Weight: 0.00

Hospitalisation:

Age: 50Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pulmonary fibrosis Cardiomyopathy		Pulmonary Fibrosis , Cardiomyopathy.	

Medicine Details:

CLOZAPINE (Suspected)	Reason: Pneumonia,unspecified
Tablet	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189585
Reported: 15/08/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Age: 60

Onset Date:

DOB: 20/06/1943

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Asthma		Asthma , Cardiac Failure , Dyspnoea , Pulmonary odema.	salbutamol and iv Lasix
Cardiac failure		Asthma , Cardiac Failure , Dyspnoea , Pulmonary odema.	
Dyspnoea		Asthma , Cardiac Failure , Dyspnoea , Pulmonary odema.	
Pulmonary oedema		Asthma , Cardiac Failure , Dyspnoea , Pulmonary odema.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram
	Daily
	Oral
Batch:	Started: 19/12/2002
	Stopped: 01/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189586

Seq: 1

Gender: F

Reported: 15/08/2003

Weight: 0.00

Hospitalisation:

Age: 21

Onset Date:

DOB: 31/01/1982

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Persistent Tachycardia.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
62.5 Milligram	Daily
Batch:	Started: 28/04/2003 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset of reaction August 2003



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189686
Reported: 19/08/2003

Seq: 1

Gender: M
Weight: 0.00
Age: 27Y

Hospitalisation:

Onset Date: 04/08/2003
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		The patient experienced seizures for 45 Minutes , (Convulsions NOS) whilst receiving 500mg Clozaril (one single dose a day).	

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 27/03/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had commenced Clozaril on 27 March 2003 and prior to the event was receiving a daily dose of 500mg split into 100mg at 4:30pm and 400mg at night.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189689 **Seq:** 1 **Gender:** F
Reported: 19/08/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 37
Onset Date: 18/06/2003 **DOB:** 16/11/1965
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation		Constipation.	Clozaril reduced to 300mg nocte. Treated with aperients including enema.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	650.0 Milligram
	Daily
	Oral
Batch:	Started: 18/06/2003
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

A history of constipation with other neuroleptics.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189730 **Seq:** 1 **Gender:** M
Reported: 20/08/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 28
Onset Date: **DOB:** 15/10/1974
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal rigidity Constipation		Constipation and abdominal rigidity. Constipation and abdominal rigidity.	Treated with enemas and laxatives (stool softener and stimulant laxatives), increased fluids and fibre.

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet 900.0 Milligram Daily Oral	
Batch:	Started: 04/09/1998 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Gastric bypass surgery in 2002. Onset date: 2002. Clazaril was ceased in 03/2001 and recommenced on 27/06/2001.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189732

Seq: 1

Gender: M

Reported: 20/08/2003

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date:

DOB: 04/12/1972

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bundle branch block left		Left anterior fascicular block.	
Electrocardiogram abnormal		Left anterior fascicular block.	
QRS axis abnormal		Left anterior fascicular block.	

Medicine Details:

EPILIM (Suspected)		Reason:	
Batch:	Started:	Stopped:	
SERZONE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
SOLIAN (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 22/11/2001	Stopped:	contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/08/2003	Electrocardiograph				

Additional Information:

Onset date:2001



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189752

Seq: 1

Gender: F

Reported: 21/08/2003

Weight: 0.00

Hospitalisation:

Age: 65

Onset Date: 11/08/2003

DOB: 18/07/1938

Outcome: Recovered

17/08/2003

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Agranulocytosis	
Neutropenia		Neutropenia	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 22/04/1997 Stopped: 11/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/08/2003	Neutrophils		18/04/1997	3.1	
21/08/2003	Neutrophils		14/07/2003	4.50	
21/08/2003	Neutrophils		13/08/2003	0.37	
21/08/2003	Neutrophils		12/08/2003	0.64, 0.55	
21/08/2003	Neutrophils		16/08/2003	1.43	
21/08/2003	Neutrophils		19/08/2003	5.01 x 10^9/L	
21/08/2003	Neutrophils		17/08/2003	2.43	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189752

Seq: 1

Gender: F

Reported: 21/08/2003

Weight: 0.00

Hospitalisation:

Age: 65

Onset Date: 11/08/2003

DOB: 18/07/1938

Outcome: Recovered

17/08/2003

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Schizophrenia

Tablet

100.0 Milligram

Daily

Oral

Batch:

Started: 22/04/1997

Stopped: 11/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/08/2003	Neutrophils		15/08/2003	0.92	
21/08/2003	Neutrophils		14/08/2003	0.37, 0.84	
21/08/2003	White blood cells		18/04/1997	5.4	
21/08/2003	White blood cells		14/07/2003	6.20	
21/08/2003	White blood cells		12/08/2003	2.22, 1.84	
21/08/2003	White blood cells		13/08/2003	1.68	
21/08/2003	White blood cells		14/08/2003	1.68, 2.62	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189752

Seq: 1

Gender: F

Reported: 21/08/2003

Weight: 0.00

Hospitalisation:

Age: 65

Onset Date: 11/08/2003

DOB: 18/07/1938

Outcome: Recovered

17/08/2003

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Schizophrenia

Tablet

100.0 Milligram

Daily

Oral

Batch:

Started: 22/04/1997

Stopped: 11/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/08/2003	White blood cells		15/08/2003	2.36	
21/08/2003	White blood cells		16/08/2003	3.25	
21/08/2003	White blood cells		17/08/2003	4.78	
21/08/2003	White blood cells		19/08/2003	6.77 x 10 ⁹ /L	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189755 **Seq:** 1 **Gender:** F
Reported: 21/08/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 36
Onset Date: 15/05/2003 **DOB:** 27/05/1966
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased		Elevated Clozaril plasma levels.	
Pneumonia		Pneumonia	
Renal failure		Renal failure	
Convulsion		Seizures	

Medicine Details:

CLOZARIL (Suspected)		Reason:		
Tablet	750.0 Milligram	Daily	Oral	
Batch:	Started: 02/09/1998	Stopped:	Contin	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/08/2003	Other data				

Additional Information:

Onset date: 05/2003. History: HIV infection. Long term use of Clozaril - 1998.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189763

Seq: 1

Gender: F

Reported: 21/08/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia		Pneumonia	

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet		Dose Unspecified	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset date: 2002. Current condition: Cardiac disorder Nos. Dose stop date: 06/2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189784

Seq: 1

Gender: M

Reported: 22/08/2003

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date: 15/01/2002

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Helicobacter infection Nausea Somnolence Vomiting	Caused or prolonged inpatient hospitalisation	Helicobacter infection, nausea, vomiting, very drowsy	Amisulpride, Pantoprazole, Losec, Amoxicillin.

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
400.0 Milligram	Daily Oral
Batch:	Started: 01/01/2002 Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/08/2003	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189866

Seq: 1

Gender: M

Reported: 26/08/2003

Weight: 0.00

Hospitalisation:

Onset Date: 18/08/2003

Age: 58

DOB: 24/06/1945

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia, leucopenia	Clopine ceased. Receiving G-CSF.
Leukopenia			

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 03/06/2003	Stopped:	18/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/08/2003	Neutrophils		02/06/2003	3.6	
26/08/2003	Neutrophils		19/08/2003	0.4	
26/08/2003	Neutrophils		21/08/2003	0.2	
26/08/2003	White blood cells		02/06/2003	5.0	
26/08/2003	White blood cells		19/08/2003	2.0	
26/08/2003	White blood cells		21/08/2003	2.9	

Additional Information:

Patient was also taking Thiamine, Mirtazapine, Aspirin, Donepezil, Valproate sodium.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189896

Seq: 1

Gender: F

Reported: 13/06/2003

Weight: 0.00

Hospitalisation:

Age: 35

Onset Date: 04/06/2003

DOB: 09/03/1968

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Increased blood creatinine kinase levels	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/06/2003	Creatine	(0-120)	04/06/2003	875	
13/06/2003	Troponin		04/06/2003	0.10	

Additional Information:

Clozaril was started sometime in march 1994.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189898

Seq: 1

Gender: F

Reported: 27/08/2003

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date: 15/08/2002

DOB: 21/07/1960

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Helicobacter infection		Helicobacter infection, nausea, vomiting	Losec HP7 and the vomiting settled.
Nausea			
Vomiting			

Medicine Details:

CLOZARIL (Suspected)	Reason:
12.0 Milligram	Daily
Batch:	Started: 20/11/1998
	Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/08/2003	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189900

Seq: 1

Gender: M

Reported: 27/08/2003

Weight: 105.00

Hospitalisation:

Age: 25

Onset Date: 11/08/2003

DOB: 23/09/1977

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal Dilatation ventricular Dyspnoea Ejection fraction decreased Sinus tachycardia		Abnormal echocardiogram, Ejection fraction decreased, dyspnoea, sinus tachycardia, dilatation ventricular.	Clozaril was ceased. Treated with a beta-blocker and an ACE-inhibitor.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 05/03/2002	Stopped: 20/08/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/08/2003	Calcium	(2.1-2.6)	16/08/2003	2.49	
27/08/2003	Creatine kinase	(<5.0)	16/08/2003	1.1	
27/08/2003	Creatine	(<130)	16/08/2003	67	
27/08/2003	Creatinine	(0.06-0.12)	16/08/2003	0.10	
27/08/2003	Echocardiogram				
27/08/2003	Eosinophils	(0.2-1.0)	05/08/2003	1.6	
27/08/2003	Eosinophils	(0.2-1.0)	16/08/2003	0.2	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189900

Seq: 1

Gender: M

Reported: 27/08/2003

Weight: 105.00

Hospitalisation:

Onset Date: 11/08/2003

Age: 25

DOB: 23/09/1977

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Unspecified schizophrenia

Tablet

12.5 Milligram

Daily

Oral

Batch:

Started: 05/03/2002

Stopped: 20/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/08/2003	Neutrophils	(2.0-7.5)	05/08/2003	6.94	
27/08/2003	Neutrophils	(2.0-7.5)	16/08/2003	6.1	
27/08/2003	Thyroid	(0.3-4.0)	16/08/2003	1.42	
27/08/2003	Troponin	(0.0-0.12)	16/08/2003	<0.3	
27/08/2003	White blood cells	(4.0-11.0)	05/08/2003	10.34	
27/08/2003	White blood cells	(4.0-11.0)	16/08/2003	8.7	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189915

Seq: 1

Gender: M

Reported: 28/08/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizures.	

Medicine Details:

CLOZAPINE (Suspected)	Reason:
175.0 Milligram	Oral
Batch:	Started: 30/09/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/08/2003	Neutrophils				
28/08/2003	White blood cells				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189945
Reported: 29/08/2003
Hospitalisation:
Onset Date: 06/08/2003
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 48
DOB: 27/12/1954
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Required Specialist Consultation	Chest pain under left breast	
Dizziness		Dizziness	
Headache		Headache	
Tachycardia		Persistent tachycardia	
Orthostatic hypotension		Postural hypotension	
Sedation		Sedation	
Body temperature increased		Temperature of 37.7deg/cel.	
Troponin increased		Troponin mildly increased	
Balance disorder		Unsteady	

Medicine Details:

CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 31/07/2003	Stopped: 20/08/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/08/2003	C-Reactive Protein				
29/08/2003	Electrocardiograph				
29/08/2003	Haemoglobin				
29/08/2003	Neutrophils		27/08/2003	5.59 x 10^9/L	
29/08/2003	Neutrophils		20/08/2003	7.99	
29/08/2003	Other data		17/08/2003	37.7 deg/cel	
29/08/2003	Other data		17/08/2003	110bpm	

Additional Information:

A chronic infection was therefore suspected and the patient was also referred to a haematologist. History: Alcohol abuse and smoker, hypercholesterolaemia, hypothyroidism, Hep B, Hep C. Patient also taking lipitor, thyroxine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 189945

Seq: 1

Gender: M

Reported: 29/08/2003

Weight: 0.00

Hospitalisation:

Age: 48

Onset Date: 06/08/2003

DOB: 27/12/1954

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 31/07/2003	Stopped: 20/08/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/08/2003	Troponin		27/08/2003	<0.01	
29/08/2003	White blood cells		27/08/2003	10.2 x 10 ⁹ /L	
29/08/2003	White blood cells		20/08/2003	12.80	

Additional Information:

A chronic infection was therefore suspected and the patient was also referred to a haematologist. History: Alcohol abuse and smoker, hypercholesterolaemia, hypothyroidism, Hep B, Hep C. Patient also taking lipitor, thyroxine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190118

Seq: 1

Gender: F

Reported: 21/08/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pulmonary fibrosis		Pulmonary fibrosis.	

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet		Dose Unspecified	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset date: 06/2003. Current codition: Cardiac disorder Nos. Dose stop date: 06/2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190145 **Seq:** 1 **Gender:** M
Reported: 01/09/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 44
Onset Date: 15/07/2003 **DOB:** 17/11/1958
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Optic neuropathy	Severe	Optic Neuropathy	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190188

Seq: 1

Gender: M

Reported: 03/09/2003

Weight: 0.00

Hospitalisation:

Age: 37

Onset Date:

DOB: 09/12/1965

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Interstitial lung disease Alveolitis		Interstitial lung disease and alveolitis.	

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 07/08/2001	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/09/2003	Chest X-ray				
03/09/2003	Computerised				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190189

Seq: 1

Gender: M

Reported: 03/09/2003

Weight: 0.00

Hospitalisation:

Age: 50Y

Onset Date: 28/08/2003

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myoclonus		Myoclonic jerks , Neutropenia & Leukopenia.	
Leukopenia			
Neutropenia			

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 23/09/1996	Stopped:	28/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/09/2003	Neutrophils		28/08/2003	1.2 x 10 ⁹ /L	
03/09/2003	Neutrophils		18/08/2003	1.8 x 10 ⁹ /L	
03/09/2003	White blood cells		28/08/2003	2.7 x 10 ⁹ /L	
03/09/2003	White blood cells		18/08/2003	4.1 x 10 ⁹ /L	

Additional Information:

Symptoms appeared seven years after commencing Clozaril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190257

Seq: 1

Gender: M

Reported: 05/09/2003

Weight: 0.00

Hospitalisation:

Age: 57

Onset Date:

DOB: 01/04/1946

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anticholinergic syndrome Constipation Emotional distress Mental disorder		Anticholinergic Effects , Constipation , Destabilisation of mental state , General Distress.	

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 07/05/2003	Stopped: 30/06/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190258
Reported: 05/09/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 07/07/2003

Age: 62

DOB: 23/01/1941

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Query Neuroleptic Malignant Syndrome.	Clozaril ceased
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 04/02/2003	Stopped: 11/07/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/09/2003	C-Reactive Protein	2 - 10 mg/L	11/07/2003	15	
05/09/2003	C-Reactive Protein	2 - 10 mg/L	15/07/2003	7	
05/09/2003	Creatine kinase	1 - 200 IU/L	11/07/2003	890	
05/09/2003	Creatine kinase	1 - 200 IU/L	15/07/2003	68	
05/09/2003	Neutrophils		15/07/2003	4.46x10 ⁹ /L	
05/09/2003	Neutrophils		11/07/2003	13.8x10 ⁹ /L	
05/09/2003	White blood cells		15/07/2003	7x10 ⁹ /L	

Additional Information:

Experienced 'query neuroleptic malignant syndrome. Other drugs taken diazepam, mirtazepam, folic acid. The patient had a history of neurodegenerative dementia for 18 months.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190258

Seq: 1

Gender: M

Reported: 05/09/2003

Weight: 0.00

Hospitalisation:

Age: 62

Onset Date: 07/07/2003

DOB: 23/01/1941

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason:

Tablet

200.0 Milligram

Daily

Oral

Batch:

Started: 04/02/2003

Stopped: 11/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/09/2003	White blood cells		11/07/2003	14.3x10 ⁹ /L	

Additional Information:

Experienced 'query neuroleptic malignant syndrome. Other drugs taken diazepam, mirtazepam, folic acid. The patient had a history of neurodegenerative dementia for 18 months.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190279

Seq: 1

Gender: F

Reported: 08/09/2003

Weight: 0.00

Hospitalisation:

Age: 27

Onset Date: 28/08/2003

DOB: 30/07/1976

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Required Visit to Doctor	Developed neutropaenia.	Cessation of Clozapine

Medicine Details:

EPILIM (Other drug)		Reason:	
	1.5 Gram	Daily	
Batch:	Started:	Stopped:	
CLOPINE (Suspected)		Reason: Schizophrenia	
	200.0 Milligram	Daily	
Batch:	Started:	Stopped: 31/08/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Exacerbated by Epilim



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190343
Reported: 09/09/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 27/08/2003

Age: 46

DOB: 24/09/1956

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gamma-glutamyltransferase increased		Raised liver function tests, mild tachycardia, flu-like symptoms of aches and pains, wheezes, GGT increased.	
Liver function test abnormal		Raised liver function tests, mild tachycardia, flu-like symptoms of aches and pains, wheezes, GGT increased.	
Pyrexia		Raised liver function tests, mild tachycardia, flu-like symptoms of aches and pains, wheezes, GGT increased.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	125.0 Milligram
	Daily
	Oral
Batch:	Started: 12/08/2003
	Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/09/2003	ALT = SGPT		08/09/2003	71	
09/09/2003	ALT = SGPT		05/09/2003	108	
09/09/2003	ALT = SGPT		30/08/2003	91	
09/09/2003	ALT = SGPT		29/07/2003	12	
09/09/2003	GGT = SGGT =		08/09/2003	153	
09/09/2003	GGT = SGGT =		05/11/2003	224	
09/09/2003	GGT = SGGT =		30/08/2003	166	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190343
Reported: 09/09/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 27/08/2003

Age: 46

DOB: 24/09/1956

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Wheezing		Raised liver function tests, mild tachycardia, flu-like symptoms of aches and pains, wheezes, GGT increased.	
Influenza like illness			
Tachycardia			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	125.0 Milligram
	Daily
	Oral
Batch:	Started: 12/08/2003
	Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/09/2003	GGT = SGGT =		29/07/2003	17	
09/09/2003	Neutrophils		01/09/2003	5.2	
09/09/2003	Neutrophils		18/08/2003	2.8	
09/09/2003	Other data				
09/09/2003	SAP = ALP		08/09/2003	313	
09/09/2003	SAP = ALP		29/07/2003	117	
09/09/2003	SAP = ALP		05/09/2003	370	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190343

Seq: 1

Gender: M

Reported: 09/09/2003

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date: 27/08/2003

DOB: 24/09/1956

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 12/08/2003	Stopped:	contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/09/2003	SAP = ALP		30/08/2003	285	
09/09/2003	Troponin				
09/09/2003	White blood cells		01/09/2003	7.89	
09/09/2003	White blood cells		18/08/2003	5.03	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190363

Seq: 1

Gender: M

Reported: 10/09/2003

Weight: 0.00

Hospitalisation:

Age: 37

Onset Date: 17/07/2003

DOB: 21/11/1965

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective Anxiety Depression Emotional distress Obsessive-compulsive disorder		Inadequate response to therapy, obsessive compulsive disorder symptoms.	clozapine ceased. Required ECT to help reduce obsession.

Medicine Details:

CLOZAPINE (Suspected)	Reason:		
	200.0 Milligram	Daily	Oral
Batch:	Started: 08/04/2003	Stopped: 08/08/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190395 **Seq:** 1 **Gender:** M
Reported: 11/09/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 49
Onset Date: 28/08/2003 **DOB:** 24/01/1954
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Bundle branch block Electrocardiogram ST segment abn Electrocardiogram T wave inversio Influenza like illness Leukocytosis Neutrophilia Pneumonitis Tachycardia		Suspected myocarditis, with ECG changes, flu-like symptoms, high temperature.	Treated with antibiotics

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 15/08/2003	Stopped: 06/09/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/09/2003	Electrocardiograph				
11/09/2003	Neutrophils		01/09/2003	4.13	
11/09/2003	Neutrophils		23/08/2003	3.48	
11/09/2003	Other data				
11/09/2003	Troponin				
11/09/2003	White blood cells	4 - 11	01/09/2003	5.80	
11/09/2003	White blood cells	4 - 11	23/08/2003	5.80	

Additional Information:

This patient developed suspected myocarditis. Equivocal troponin levels T wave inversion - did not resolve with cessation of clozaril. No echocardiographic evidence of LV dysfunction. Event occurred within two weeks post commencement of clozapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190395

Seq: 1

Gender: M

Reported: 11/09/2003

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 49

Onset Date: 28/08/2003

DOB: 24/01/1954

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 15/08/2003	Stopped: 06/09/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/09/2003	White blood cells	4 - 11	06/09/2003	11.7	

Additional Information:

This patient developed suspected myocarditis. Equivocal troponin levels T wave inversion - did not resolve with cessation of clozaril. No echocardiographic evidence of LV dysfunction. Event occurred within two weeks post commencement of clozapine.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190435
Reported: 12/09/2003

Seq: 1

Gender: M
Weight: 0.00
Age: 28Y

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic steatosis Alanine aminotransferase increase Drug level increased Eosinophil count increased Lymphocyte count increased White blood cell count increased		Hepatic steatosis, white blood cell count increased and drug level increased.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram
	Daily
	Oral
Batch:	Started: 01/02/2002
	Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/09/2003	Other data				
12/09/2003	Serum drug level				
12/09/2003	White blood cells		29/01/2002	10.8 - pre	
12/09/2003	White blood cells		14/05/2003	16.00	
12/09/2003	White blood cells		11/06/2003	17.30	
12/09/2003	White blood cells		09/07/2003	14.40	
12/09/2003	White blood cells		07/08/2003	9.67	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190435
Reported: 12/09/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 28Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 01/02/2002	Stopped:	contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/09/2003	White blood cells		03/09/2003	15.70	
12/09/2003	White blood cells		01/10/2003	13.40	
12/09/2003	White blood cells		30/10/2003	14.00	
12/09/2003	White blood cells		26/11/2003	12.20	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190484

Seq: 1

Gender: M

Reported: 15/09/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain		Pain in chest, stomach, ribs, heaviness in chest, shortness of breath.	
Dyspnoea			

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient is not obese and an ECG has been performed with no reported cardiac complications.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190515
Reported: 15/09/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 02/06/2003

Age: 28

DOB: 02/03/1975

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Clostridial infection Thrombocythaemia		Severe diarrhoea, thrombocytosis.	Ceased Clozaril

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
		1.0 Dose Unspecified Daily	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet		250.0 Milligram	Daily Oral
Batch:	Started: 28/05/2003	Stopped: 01/07/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/09/2003	Other data				
15/09/2003	White blood cells		15/05/2003	pre-treatment	
15/09/2003	White blood cells		22/06/2003	WBC 9.90	
15/09/2003	White blood cells		02/07/2003	WBC 8.80	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190602

Seq: 1

Gender: M

Reported: 17/09/2003

Weight: 0.00

Hospitalisation:

Age: 32

Onset Date: 15/08/2003

DOB: 11/10/1970

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gastrooesophageal reflux disease Vomiting		Gastro-oesophageal reflux Vomiting	Treated with Gaviscon

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	25.0 Milligram
	Daily
	Oral
Batch:	Started: 22/06/1994
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Longterm risk of Barrett's oesophagus could lead to oesophageal cancer if not treated.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190623

Seq: 1

Gender: M

Reported: 18/09/2003

Weight: 0.00

Hospitalisation:

Age: 24

Onset Date: 15/09/2003

DOB: 13/06/1979

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin I increased		Raised Troponin levels	

Medicine Details:

CLOZAPINE (Suspected)		Reason:	
Tablet	475.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/09/2003	Troponin		01/09/2003	0.04 (baseline)	
18/09/2003	Troponin		15/09/2003	0.7	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190635
Reported: 18/09/2003
Hospitalisation:
Onset Date: 05/09/2003
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 20
DOB: 10/12/1982
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis Angina pectoris Cardiac disorder C-reactive protein increased Electrocardiogram abnormal Pyrexia		Mild myocarditis Scratch marks from chest pain Troponin increased	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	300.0 Milligram
	Daily
	Oral
Batch:	Started: 19/08/2003
	Stopped: 05/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/09/2003	C-Reactive Protein	2-10	11/09/2003	13	
18/09/2003	C-Reactive Protein	2-10	05/09/2003	21	
18/09/2003	Echocardiogram				
18/09/2003	Electrocardiograph				
18/09/2003	Troponin	<0.01	11/09/2003	<0.01	
18/09/2003	Troponin	<0.01	06/09/2003	0.33	
18/09/2003	Troponin	<0.01	05/09/2003	0.24	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190636

Seq: 1

Gender: F

Reported: 18/09/2003

Weight: 0.00

Hospitalisation:

Age: 47

Onset Date:

DOB: 10/06/1956

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension Drug ineffective Coordination abnormal		Hypotension. Lack of drug efficacy Significant ataxia	Ceased Clozaril

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 18/07/2003	Stopped: 10/08/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190655
Reported: 19/09/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 15/08/2003

Age: 26

DOB: 13/08/1977

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myoclonus		Jerking episodes of the jaw and am myoclonus	
Electroencephalogram abnormal			

Medicine Details:

SEROQUEL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 01/04/2003	Stopped:	
CITALOPRAM HYDROBROMIDE (Suspected)		Reason:	
Tablet	60.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/09/2003	Electroencephalog				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190726

Seq: 1

Gender: M

Reported: 22/09/2003

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date: 03/07/2003

DOB: 11/04/1969

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Cardiac complication	

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 26/06/2003	Stopped: 03/07/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Neutrophil and white cell counts were within normal limits.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190784 **Seq:** 1 **Gender:** M
Reported: 23/09/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 47
Onset Date: 11/09/2003 **DOB:** 26/04/1956
Outcome: Recovered 16/09/2003 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder	Caused or prolonged inpatient hospitalisation	Cardiac complications, high temperatures, increased troponin levels.	
Chills			
Malaise			
Pyrexia			
Rash			
Tremor			

Medicine Details:

CLOPINE (Suspected)	Reason: Schizophrenia
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 27/08/2003 Stopped: 11/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/09/2003	C-Reactive Protein				
23/09/2003	Creatine		12/09/2003	356	
23/09/2003	Other data				
23/09/2003	Serum drug level				
23/09/2003	Troponin		12/09/2003	4.75	

Additional Information:

PH of seizure activity, Cannabis use. Also taking quetiapine, clopixol, benztropine and sodium valproate.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190786 **Seq:** 1 **Gender:** M
Reported: 23/09/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 51
Onset Date: **DOB:** 11/09/1952
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure		Cardiac failure	Given Amisulpride.

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	700.0 Dose Unspecified Daily Oral
Batch:	Started: 03/02/1993 L TERM Stopped: 28/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset 07/2002. History: X-smoker.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190809

Seq: 1

Gender: F

Reported: 23/09/2003

Weight: 0.00

Hospitalisation:

Age: 15

Onset Date: 15/08/2003

DOB: 14/09/1987

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		Postural hypotension	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram
	Daily
	Oral
Batch:	Started: 16/06/2003
	Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The daily dose at the time of event onset was 400mg



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190810
Reported: 23/09/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 15/08/2001

Age: 43

DOB: 18/12/1957

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Helicobacter infection		Helicobacter infection, vomiting NOS, nausea	He was treated with Losec HP7.
Nausea			
Vomiting			

Medicine Details:

CLOZARIL (Suspected)	Reason:
12.5 Milligram	Daily
Batch:	Started: 03/08/2001
	Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/09/2003	Other data				
23/09/2003	White blood cells		16/09/2003	6.10 x 10 ⁹ /L	
23/09/2003	White blood cells		14/11/2003	6.4	

Additional Information:

Patient also administered: Seroquel and Valium.
The reporter was unsure whether the vomiting and nausea pre-dated Clozaril commenced.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190814 **Seq:** 1 **Gender:** M
Reported: 23/09/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 51
Onset Date: **DOB:** 11/09/1952
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia Condition aggravated		Pneumonia nos	

Medicine Details:

RANITIDINE (Other drug)		Reason:	
Tablet		Dose Unspecified	Oral
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 03/02/2000 L TERM	Stopped: 28/10/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset 07/2000. History: Patient heavy smoker. Patient had three hospital admissions in 2002, in Jun 2002 for cardiac failure, in July 2002 for pneumonia and in Nov 2002 for agranulocytosis.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190817

Seq: 1

Gender: M

Reported: 24/09/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sinus tachycardia	Caused or prolonged inpatient hospitalisation	Sinus tachycardia	

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Batch:	Started:
Stopped:	Continued:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient continues on clozapine and has been discharged from hospital.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190831

Seq: 1

Gender: M

Reported: 24/09/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Troponin increased		Tachycardia, cardiac triponin increased.	

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	475.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Continues to received clozapine (125 mg morning, 350 mg night) as he is treatment resistant.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190857

Seq: 1

Gender: F

Reported: 24/09/2003

Weight: 0.00

Hospitalisation:

Age: 51

Onset Date:

DOB: 10/11/1951

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia	Caused or prolonged inpatient hospitalisation	Pneumonia	Prednisolone, amoxicillin and Rulide.
Overdose	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:		
	650.0 Milligram	Daily	Oral
Batch:	Started: 09/05/1996	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

On 16 Sep 2003, she took a Clozaril morning dose of 500mg rather than the usual 150mg. She did not experience any signs or symptoms of overdose and Clozaril treatment continued.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190858

Seq: 1

Gender: M

Reported: 24/09/2003

Weight: 0.00

Hospitalisation:

Age: 20

Onset Date:

DOB: 24/02/1983

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Helicobacter infection		Helicobacter pylori infection	Losec HP7

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 19/11/2002	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/09/2003	Other data				

Additional Information:

Had nausea and vomiting prior to commencing Clozaril.
Reaction occurred sometime in 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190859 **Seq:** 1 **Gender:** M
Reported: 24/09/2003 **Weight:** 64.50
Hospitalisation: Treated in outpatient department only. **Age:** 16
Onset Date: 15/08/2003 **DOB:** 20/03/1987
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ventricular hyperkinesia	Treated in outpatient department only	Patient present to emergency dept in Aug 2003 with lightheadedness and bradycardia, he had lost 15 kg in the prior 6 months. Tests suggested mild left ventricular impairment, mild intraventricular conduction delay, mildly impaired left ventricular contractility and mild tricuspid incompetence. Patient was also tired and faint with increased thirst, developed hyperglycaemia and diagnosed with diabetes mellitus type II in March 2004. He had polyuria with nocturia 3-4 times per night.	Patient was placed on a diet, Clozaril was ceased and replaced with amisulpride

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	37.5 Milligram Daily Oral
Batch:	Started: 22/11/2001 Stopped: 21/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/09/2003	Electrocardiograph				A previous ECG in Nov 2001 had been normal. 3 Sep 2003: ECG showed mild left ventricular impairment with an EF of 40-50%; trivial mitral and tricuspid incompetence.20 Nov 2003: ECG showed EF 50%; Holter moitor essentially normal. Nov 2003: ECG showed mild intraventricular conduction delay; QRS complex stayed within normal imits; corrected QT interval of 378 ...

Additional Information:

Reaction occurred sometime in Aug 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190859 **Seq:** 1 **Gender:** M
Reported: 24/09/2003 **Weight:** 64.50
Hospitalisation: Treated in outpatient department only. **Age:** 16
Onset Date: 15/08/2003 **DOB:** 20/03/1987
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood glucose increased	Treated in outpatient department only		
Bradycardia	Treated in outpatient department only		
Diabetes mellitus	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	37.5 Milligram Daily Oral
Batch:	Started: 22/11/2001 Stopped: 21/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/09/2003	Other data				... mn (normal). 4 Feb 2004: ECG showed overall left ventricular contractility mildly impaired (ejection fraction(EF) 45%); right ventricular contractility normal; normal left and right atria; normal aortic and mitral valve; mild tricuspid incompetence; normal right ventricular pressure. (Date not specified) Abnormal thyroid function.

Additional Information:

Reaction occurred sometime in Aug 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190859 **Seq:** 1 **Gender:** M
Reported: 24/09/2003 **Weight:** 64.50
Hospitalisation: Treated in outpatient department only. **Age:** 16
Onset Date: 15/08/2003 **DOB:** 20/03/1987
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness	Caused or prolonged inpatient hospitalisation		
Electrocardiogram abnormal	Treated in outpatient department only		
Fatigue	Treated in outpatient department only		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	37.5 Milligram Daily Oral
Batch:	Started: 22/11/2001 Stopped: 21/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/09/2003	Serum drug level				14 April 2004: Clozapine 0.62 umol/L; norclozapine 0.29 umol/L. 24 March 2004: clozapine 0.99; norclozapine 0.99
24/09/2003	Serum glucose				5 April 2004: Blood sugars increased - non fasting blood glucose 17.6. Settled upon cessation of clozaril

Additional Information:

Reaction occurred sometime in Aug 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190859 **Seq:** 1 **Gender:** M
Reported: 24/09/2003 **Weight:** 64.50
Hospitalisation: Treated in outpatient department only. **Age:** 16
Onset Date: 15/08/2003 **DOB:** 20/03/1987
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Treated in outpatient department only		
Polydipsia	Treated in outpatient department only		
Polyuria	Treated in outpatient department only		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	37.5 Milligram Daily Oral
Batch:	Started: 22/11/2001 Stopped: 21/04/2004

Laboratory Investigations:

Additional Information:

Reaction occurred sometime in Aug 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190859 **Seq:** 1 **Gender:** M
Reported: 24/09/2003 **Weight:** 64.50
Hospitalisation: Treated in outpatient department only. **Age:** 16
Onset Date: 15/08/2003 **DOB:** 20/03/1987
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thyroid function test abnormal	Treated in outpatient department only		
Tricuspid valve incompetence	Treated in outpatient department only		
Weight decreased	Treated in outpatient department only		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	37.5 Milligram Daily Oral
Batch:	Started: 22/11/2001 Stopped: 21/04/2004

Laboratory Investigations:

Additional Information:

Reaction occurred sometime in Aug 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190938

Seq: 1

Gender: M

Reported: 26/09/2003

Weight: 0.00

Hospitalisation:

Age: 31

Onset Date:

DOB: 30/10/1971

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Helicobacter infection		Helicobacter pylori infection, nausea, vomiting.	Patient was treated with Losec HP7.
Nausea			
Vomiting			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 16/02/1999 Stopped: 15/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/09/2003	Other data				

Additional Information:

Patient also taking Seroquel.
Clozaril was commenced on 24/9/1997 but was ceased again in 10/97, reason unknown.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190939

Seq: 1

Gender: M

Reported: 26/09/2003

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date:

DOB: 31/08/1973

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus Blood glucose increased Blood insulin abnormal		Diabetes mellitus.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 02/05/2003	Stopped:	27/08/0203

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 190940 **Seq:** 1 **Gender:** M
Reported: 26/09/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 27
Onset Date: 11/09/2003 **DOB:** 12/04/1976
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes insipidus Blood osmolarity increased Polyuria Urine osmolarity decreased	Caused or prolonged inpatient hospitalisation	Central diabetes insipidus, blood osmolarity increased, polyuria, urine osmolarity decreased.	DDAVP (desmopressin) and his condition improved, with polyuria resolved.

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 14/04/1996	Stopped:	contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191006 **Seq:** 1 **Gender:** M
Reported: 23/09/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 50
Onset Date: 28/10/2002 **DOB:** 11/09/1952
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Agranulocytosis	Given Filgrastim (granulocyte colony-stimulating factor, G-CSF).

Medicine Details:

ASPIRIN (Other drug)		Reason:	
Oral application		Dose Unspecified	Oral
Batch:	Started:	Stopped:	
RANITIDINE (Other drug)		Reason:	
		Dose Unspecified	
Batch:	Started:	Stopped:	
VERAPAMIL HYDROCHLORIDE (Other drug)		Reason:	
		Dose Unspecified	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 26/01/1993 L TERM	Stopped: 28/10/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/09/2003	Neutrophils		26/01/1993	3.8	
23/09/2003	Neutrophils		28/10/2002	0.60	
23/09/2003	Neutrophils		29/10/2002	1.00	
23/09/2003	Neutrophils		31/10/2002	0.30	
23/09/2003	Neutrophils		19/11/2002	4.7	
23/09/2003	Neutrophils		01/11/2002	0.5	
23/09/2003	Neutrophils		30/10/2002	0.60	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191006

Seq: 1

Gender: M

Reported: 23/09/2003

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 50

Onset Date: 28/10/2002

DOB: 11/09/1952

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ASPIRIN (Other drug)		Reason:	
Oral application		Dose Unspecified	Oral
Batch:	Started:	Stopped:	
RANITIDINE (Other drug)		Reason:	
		Dose Unspecified	
Batch:	Started:	Stopped:	
VERAPAMIL HYDROCHLORIDE (Other drug)		Reason:	
		Dose Unspecified	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 26/01/1993 L TERM	Stopped: 28/10/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/09/2003	White blood cells		26/01/1993	7.5	
23/09/2003	White blood cells		28/10/2002	2.40	
23/09/2003	White blood cells		29/10/2002	2.70	
23/09/2003	White blood cells		30/10/2002	2.50	
23/09/2003	White blood cells		31/10/2002	2.50	
23/09/2003	White blood cells		01/11/2002	2.1	
23/09/2003	White blood cells		19/11/2002	6.9	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191043

Seq: 1

Gender: M

Reported: 02/10/2003

Weight: 0.00

Hospitalisation:

Age: 21

Onset Date: 18/07/2003

DOB: 25/09/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea		Nausea	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.5 Milligram
	Daily
	Oral
Batch:	Started: 18/07/2003
	Stopped: Contin on 300m

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191092

Seq: 1

Gender: M

Reported: 07/10/2003

Weight: 0.00

Hospitalisation:

Age: 19

Onset Date: 25/09/2003

DOB: 07/05/1984

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal		Focal ischaemic-like changes on ECG.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	250.0 Milligram
	Daily
	Oral
Batch:	Started: 04/09/2003
	Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/10/2003	Neutrophils		30/09/2003	7.56	
07/10/2003	Other data				
07/10/2003	Troponin				
07/10/2003	White blood cells		30/09/2003	11.90	

Additional Information:

The ECG changes were thought to be spurious changes due to Clozaril treatment.
Reaction onset date Sep 2003.
Clozaril ceased Sep 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191122

Seq: 1

Gender: F

Reported: 07/10/2003

Weight: 0.00

Hospitalisation:

Age: 41

Onset Date: 19/08/2003

DOB: 10/11/1961

Outcome: Not yet recovered

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis		Drug induced hepatitis.	Ceased Clozaril
Liver function test abnormal		Recurred on rechallenge	

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	288.0 Milligram	Daily	Oral
Batch:	Started: 24/07/2003	Stopped:	20/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozaril recommenced on 19 Jan 2005 and subsequently developed raised liver enzymes. Clozaril ceased again.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191135

Seq: 1

Gender: M

Reported: 07/10/2003

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date:

DOB: 20/03/1978

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis		hepatitis nos, Blood lactate dehydrogenase increased, AST increased, Alanine aminotransferase increased, neutropenia.	Ceased Clozaril.
Alanine aminotransferase increase			
Aspartate aminotransferase increa			
Blood lactate dehydrogenase incre			
Blood uric acid increased			
Neutropenia			

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 05/09/1995	Stopped:	22/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/10/2003	ALT = SGPT				
07/10/2003	AST = SGOT				
07/10/2003	Hepatitis A				
07/10/2003	Hepatitis B				
07/10/2003	Hepatitis C				
07/10/2003	LDH				
07/10/2003	Neutrophils				

Additional Information:

Approximately 2 days after ceasing Clozaril, the patients liver enzymes returned to normal.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191135

Seq: 1

Gender: M

Reported: 07/10/2003

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date:

DOB: 20/03/1978

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason:

Tablet

200.0 Milligram

Daily

Oral

Batch:

Started: 05/09/1995

Stopped: 22/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/10/2003	Urate				

Additional Information:

Approximately 2 days after ceasing Clozaril, the patients liver enzymes returned to normal.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191211
Reported: 10/10/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date:

DOB: 03/01/1961

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myoclonus		Myoclonus, confusion.	Fluvoxamine was ceased and then changed to Clonazepam. It was decided to gradually reduce then cease Clozaril.
Confusional state			
Drug level increased			

Medicine Details:

FLUVOXAMINE MALEATE (Other drug)		Reason:	
Batch:	Started: 09/09/2003	Stopped: 29/09/2003	
LITHIUM CARBONATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 12/06/2003	Stopped: 30/09/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/10/2003	Other data				

Additional Information:

Clozapine plasma level was 1994 ng/ml but symptoms remained unchanged (drug level Nos increased).
Reaction occurred sometime in Sep 2003. Clozaril was ceased in approx. October 2003



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191232

Seq: 1

Gender: F

Reported: 13/10/2003

Weight: 0.00

Hospitalisation:

Age: 64

Onset Date: 15/08/2003

DOB: 12/07/1939

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state		Confusion	Ceased Clozaril temporarily.
Hypernatraemia			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	250.0 Milligram
	Daily
	Oral
Batch:	Started: 27/03/1995
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset of reaction was sometime in August 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191233
Reported: 13/10/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 15/09/2003

Age: 44

DOB: 26/02/1959

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure	

Medicine Details:

AMITRIPTYLINE HYDROCHLORIDE (Interaction)		Reason:	
Batch:	Started:	Stopped:	
AMITRIPTYLINE HYDROCHLORIDE (Interaction)		Reason:	
Batch:	Started:	Stopped:	
PAROXETINE HYDROCHLORIDE (Interaction)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Interaction)		Reason:	
Tablet	12.0 Milligram	Daily	Oral
Batch:	Started: 31/05/1993	Stopped:	contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/10/2003	Electroencephalog				
13/10/2003	Other data				

Additional Information:

History of three seizures over the last 30 years but was not receiving anti-epileptic treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191277

Seq: 1

Gender: M

Reported: 14/10/2003

Weight: 90.00

Hospitalisation:

Onset Date: 25/09/2003

Age: 29

DOB: 17/03/1974

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Angioedema	Required Visit to Doctor	Angioedema:- periorbital oedema, facial swelling, tongue swelling.	Ceased Risperidone.
Skin disorder	Required Visit to Doctor	Dry cracking skin on face and hands.	
Erythema	Required Visit to Doctor	Red hands	
Periorbital oedema	Required Visit to Doctor		
Swelling face	Required Visit to Doctor		
Tongue oedema	Required Visit to Doctor		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 25/09/2003	Stopped: 25/09/2003	
FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 23/09/2003	Stopped: 01/10/2003	
CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 24/09/2003	Stopped: 24/09/2003	
Zolpidem Sandoz (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 23/09/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191277

Seq: 1

Gender: M

Reported: 14/10/2003

Weight: 90.00

Hospitalisation:

Age: 29

Onset Date: 25/09/2003

DOB: 17/03/1974

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ATENOLOL (Suspected)

Reason:

Tablet

25.0 Milligram

Daily

Oral

Batch:

Started: 23/09/2003

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191316

Seq: 1

Gender: F

Reported: 13/10/2003

Weight: 0.00

Hospitalisation:

Age: 64

Onset Date: 01/10/2003

DOB: 12/07/1939

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypothermia	Caused or prolonged inpatient hospitalisation	Hypothermia persisted for approx. three days.	Ceased Clozaril temporarily for four days.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191340
Reported: 15/10/2003
Hospitalisation:
Onset Date: 06/10/2003
Outcome: Recovered

Seq: 1

Gender: F
Weight: 0.00
Age: 38
DOB: 19/09/1965
Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness	Caused or prolonged inpatient hospitalisation	Experienced symptoms hypotension,dizziness. syncope, headache.	1 litre of fluids
Hypotension	Caused or prolonged inpatient hospitalisation	Experienced symptoms of hypotension 80/60mmHg, felt lightheaded, slumed to the floor syncope, "voices" and headache.	
Headache	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Interaction)		Reason: Unspecified schizophrenia	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 24/01/2001	Stopped:	
LOVAN (Interaction)		Reason:	
	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient stopped her clozaril treatment for 1-2 weeks, then recommenced and same symptoms occurred.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191340
Reported: 15/10/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 06/10/2003

Age: 38

DOB: 19/09/1965

Outcome: Recovered

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Interaction)		Reason: Unspecified schizophrenia	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 24/01/2001	Stopped:	
LOVAN (Interaction)		Reason:	
	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Patient stopped her clozaril treatment for 1-2 weeks, then recommenced and same symptoms occurred.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191349 **Seq:** 1 **Gender:** F
Reported: 16/10/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 56
Onset Date: **DOB:** 23/06/1947
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Caused or prolonged inpatient hospitalisation	Episode of low blood pressure.	Clozaril was discontinued

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 15/05/1997 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Not suspected for catatonic schizophrenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191352

Seq: 1

Gender: M

Reported: 16/10/2003

Weight: 0.00

Hospitalisation:

Age: 74

Onset Date: 10/09/2003

DOB: 18/02/1929

Outcome: Recovered

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Angina pectoris	Life threatening	Patient had pre-existing tardive dyskinesia, which developed into dysphagia once Clozaril was commenced.	Aspirin and Anginine. Clozaril was ceased.
Dysphagia	Life threatening		
Salivary hypersecretion	Life threatening		
Sedation	Life threatening		

Medicine Details:

CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 04/09/2003	Stopped: 17/09/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs used: Thiamine and Diazepam.
Suspect drug positive rechallenge.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191394

Seq: 1

Gender: M

Reported: 17/10/2003

Weight: 0.00

Hospitalisation:

Age: 35

Onset Date: 02/10/2003

DOB: 16/11/1967

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia		THROMBOCYTOPENIA, FLU.	

Medicine Details:

CLOZAPINE (Suspected)		Reason:	
	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/10/2003	Platelets		02/10/2003	199	
17/10/2003	Platelets		07/10/2003	45	

Additional Information:

Taken clozapine for approximately 2 years. He stopped taking clozapine 4 weeks ago for 2 weeks when he developed a 'flu' and was again re-started on Clopine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191398

Seq: 1

Gender: M

Reported: 17/10/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date: 12/10/2003

DOB:

Outcome: Death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death		DIED OF UNKNOWN CAUSES	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
125.0 Milligram Daily	
Batch:	Started: 05/10/2003 Stopped:
SODIUM VALPROATE (Suspected)	Reason:
1.0 Dose Unspecified Daily	
Batch:	Started: Stopped:
ZANTAC (Suspected)	Reason:
1.0 Dose Unspecified Daily	
Batch:	Started: Stopped:
OXYBUTYNIN HYDROCHLORIDE (Suspected)	Reason:
1.0 Dose Unspecified Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drug therapy: simvastatin



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191412
Reported: 20/10/2003

Seq: 1

Gender: U

Weight: 0.00

Hospitalisation:

Onset Date: 15/07/2003

Age: 52

DOB: 18/04/1951

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level fluctuating		Variable clozapine serum levels, interaction between Clozaril and OTC medication.	Decreased patient's OTC medication and increased supervision.

Medicine Details:

MULTI-B (Suspected)		Reason:	
Batch:	Started:	Stopped:	
HERBAL MEDICINES (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 14/03/1999	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/10/2003	Serum drug level		20/08/2003	serum	
20/10/2003	Serum drug level		07/06/2003	serum	

Additional Information:

Other drugs taken: Magnesium, Calcium, Quinate.

It was believed the variable clozapine serum levels were either due to poor compliance with clozaril or an interaction with the OTC medication which included bach flower.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191483

Seq: 1

Gender: M

Reported: 21/10/2003

Weight: 0.00

Hospitalisation:

Age: 26

Onset Date:

DOB: 12/09/1977

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Cough Dizziness ECG signs of ventricular hypertrop Echocardiogram abnormal Ejection fraction decreased Hypertension		Cardiomyopathy, dizziness, ECG signs of ventricular hypertrophy, ejection fraction decreased, hypertension, cough.	Cardiologists advised ceasing Clozaril, which was slowly reduced and then discontinued on 08 Oct 2003. He was switched to amisulpride.

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
250.0 Milligram	Daily
Batch:	Started: 18/08/2003 Stopped: 08/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/10/2003	Echocardiogram				
21/10/2003	Electrocardiograph				
21/10/2003	Triglyceride				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191483

Seq: 1

Gender: M

Reported: 21/10/2003

Weight: 0.00

Hospitalisation:

Age: 26

Onset Date:

DOB: 12/09/1977

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertriglyceridaemia			

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
250.0 Milligram	Daily
Batch:	Started: 18/08/2003 Stopped: 08/10/2003

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191499

Seq: 1

Gender: M

Reported: 22/10/2003

Weight: 0.00

Hospitalisation:

Onset Date: 10/10/2003

Age: 33

DOB: 26/05/1970

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus non-insulin-depe Weight increased			

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
	1.0 Gram	Daily	Oral
Batch:	Started:	Stopped:	
CLOZAPINE (Suspected)		Reason:	
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/10/2003	Glycosylated		20/05/2003	6.4%	
22/10/2003	Other data				

Additional Information:

Possible contribution Na Valproate.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191501
Reported: 22/10/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 10/10/2003

Age: 55

DOB: 07/10/1948

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes and delerium.	
Delirium			

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
	700.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
CLOZAPINE (Suspected)		Reason:	
Tablet	Dose Unspecified	Daily	Oral
Batch:	Started: 12/03/2003	Stopped: 16/03/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/10/2003	Glycosylated				
22/10/2003	Serum glucose		10/03/2003	4.9	

Additional Information:

Returen to impaired GTT off Clozapine.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191502
Reported: 22/10/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 10/10/2003

Age: 52

DOB: 24/03/1951

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective Glucose tolerance test abnormal Myoclonus Blood glucose increased Cogwheel rigidity		Failure to resolve psychosis. Impaired GTT, Failure to resolve Psychosis, Development of Cogwheel rigidity and Myoclonic jerks. Myoclonic jerks on 450mg.	Reduce dose of Clozapine.

Medicine Details:

CLOZAPINE (Suspected)		Reason:	
Tablet	425.0 Milligram	Daily	Oral
Batch:	Started: 31/01/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/10/2003	Glycosylated		25/03/2003	5.3%	delete
22/10/2003	Other data				
22/10/2003	Serum glucose		25/03/2003	5.2	
22/10/2003	Serum glucose		06/05/2003	6.2	

Additional Information:

Patient also taking Coloxyl and Senna, Duphalal.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191505
Reported: 22/10/2003

Seq: 1

Gender: U

Weight: 0.00

Hospitalisation:

Onset Date: 10/10/2003

Age: 22

DOB: 29/06/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus non-insulin-depe		DEVELOPMENT OF DIABETES	

Medicine Details:

FLUVOXAMINE MALEATE (Interaction)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 16/07/2002	Stopped: 05/02/2003	
CLOZAPINE (Interaction)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 16/07/2002	Stopped: 05/02/2003	
AMISULPRIDE (Other drug)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 16/07/2002	Stopped: 05/02/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/10/2003	Other data				

Additional Information:

? impact of Fluvoxomine causing increased level.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191511 **Seq:** 1 **Gender:** F
Reported: 22/10/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 66
Onset Date: 01/10/2003 **DOB:** 07/12/1936
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Respiratory tract infection	Caused or prolonged inpatient hospitalisation	Respiratory infection, oesophageal ulcers.	
Oesophagitis ulcerative	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
12.5 Milligram	Daily Oral
Batch:	Started: 02/09/2003 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The treating doctor had advised the reporter that the patient's hospital admission and subsequent ulcers were not related to Clozaril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191512

Seq: 1

Gender: M

Reported: 22/10/2003

Weight: 0.00

Hospitalisation:

Age: 43

Onset Date: 15/10/2003

DOB: 09/02/1960

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Seizure, sudden withdrawal of Clozaril.	Patient was admitted to the intensive care unit. Clozaril treatment continued on 200mg/day.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLONAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 08/06/1999	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The seizure was considered possibly due to the sudden withdrawal of Clozaril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191512

Seq: 1

Gender: M

Reported: 22/10/2003

Weight: 0.00

Hospitalisation:

Age: 43

Onset Date: 15/10/2003

DOB: 09/02/1960

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rhabdomyolysis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLONAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 08/06/1999	Stopped:	

Laboratory Investigations:

Additional Information:

The seizure was considered possibly due to the sudden withdrawal of Clozaril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191514
Reported: 22/10/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 01/09/2003

Age: 22

DOB: 05/03/1981

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Fevers and C-creative protein increased.	Treated with Paracetamol prn.
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	12.5 Milligram
	Daily
	Oral
Batch:	Started: 19/08/2003
	Stopped: 01/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/10/2003	C-Reactive Protein				
22/10/2003	Neutrophils		13/08/2003	(Pre-treatment	
22/10/2003	Neutrophils		08/09/2003	$3.60 \times 10^9/L$	
22/10/2003	White blood cells		08/09/2003	$7.00 \times 10^9/L$	
22/10/2003	White blood cells		13/08/2003	(pre-treatment	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191515
Reported: 22/10/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Age: 38

Onset Date:

DOB: 23/04/1965

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope		Intermittent episodes of tachycardia, fainting.	
Tachycardia		Intermittent episodes of tachycardia, fainting.	

Medicine Details:

ZOLOFT (Other drug)		Reason:	
	1.0	Dose Unspecified	Daily
			Oral
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	25.0	Milligram	Daily
			Oral
Batch:	Started: 04/03/1994	Stopped: 01/06/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/10/2003	Electrocardiograph				
22/10/2003	Other data				
22/10/2003	Troponin				

Additional Information:

The Clozaril dose was changed as a result of the events. Daily dose in Apr 2003 was 750 mg, which was slowly decreased to 700 mg and then to 650 mg by 14 Aug 2003. The daily dose at the time of prolonged SVT was 650 mg. She was referred for a cardiology appointment on 09 Oct 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191516
Reported: 22/10/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 28/09/2003

Age: 25

DOB: 07/08/1978

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Congestive cardiomyopathy Cardiac enzymes increased Ejection fraction decreased Influenza like illness Pyrexia Tachycardia		Dilated cardiomyopathy, congestive cardiomyopathy, troponin increased, echocardiogram abnormal nos, ejection fraction decreased, pyrexia, influenza like illness, tachycardia, gastroenteritis nos, diarrhoea nos, vomiting nos.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
12.5 Milligram	Daily Oral
Batch:	Started: 19/09/2003 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/10/2003	Echocardiogram		03/10/2003	Left ventricle	
22/10/2003	Echocardiogram				
22/10/2003	Neutrophils				
22/10/2003	Troponin				
22/10/2003	White blood cells		25/09/2003	6.43 x 10^9/L	
22/10/2003	White blood cells		17/09/2003	(pre-treatment)	

Additional Information:

The diarrhea and vomiting were considered due to gastro-enteritis and resolved quickly.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191524

Seq: 1

Gender: M

Reported: 23/10/2003

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date:

DOB: 13/09/1957

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia		Thrombocytopenia	

Medicine Details:

CLOZAPINE (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/10/2003	Platelets				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191537
Reported: 23/10/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 08/10/2003

Age: 46

DOB: 10/11/1956

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nephritis interstitial	Caused or prolonged inpatient hospitalisation	Interstitial nephritis, dehydrated and febrile with renal impairment and polyuria.	Hydration and support. Clozaril treatment was discontinued.
Blood pressure fluctuation	Caused or prolonged inpatient hospitalisation	Labile blood pressure,	
Dehydration	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 18/09/2003	Stopped: 13/10/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/10/2003	Eosinophils				

Additional Information:

Other drug therapy omeprazole, diazepam, valproate sodium, propranolol, premia 5.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191537

Seq: 1

Gender: F

Reported: 23/10/2003

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date: 08/10/2003

DOB: 10/11/1956

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Polyuria	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	100.0 Milligram
	Daily
	Oral
Batch:	Started: 18/09/2003
	Stopped: 13/10/2003

Laboratory Investigations:

Additional Information:

Other drug therapy omeprazole, diazepam, valproate sodium, propranolol, premia 5.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191603

Seq: 1

Gender: F

Reported: 27/10/2003

Weight: 0.00

Hospitalisation:

Age: 59

Onset Date: 20/10/2003

DOB: 07/04/1944

Outcome: Death

20/10/2003

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death Bronchopneumonia Respiratory failure		Found deceased at home.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	475.0 Milligram
	Daily
	Oral
Batch:	Started: 06/06/1996
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Benzotropine, Folic Acid, Calcitrol, Gaviscon, Esomeprazole. Death was likely to be due to natural causes. This will be a coroner's case and an autopsy will be performed. The patient was a very heavy smoker with COAD.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191604 **Seq:** 1 **Gender:** F
Reported: 27/10/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 48
Onset Date: 15/05/2003 **DOB:** 02/11/1954
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Agranulocytosis	Treated with G-CSF
Leukopenia		Agranulocytosis, infection, leukopenia and weight decreased	
Infection		Infection NOS	
Weight decreased		Weight decreased	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 19/07/1995	Stopped: 14/10/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/10/2003	Neutrophils		19/07/1995	5.30	
27/10/2003	Neutrophils		16/09/2003	2.40	
27/10/2003	Neutrophils		16/10/2003	0.40	
27/10/2003	Neutrophils		14/10/2003	0.60	
27/10/2003	Neutrophils		18/10/2003	0.54	
27/10/2003	Neutrophils		19/10/2003	0.57	
27/10/2003	Neutrophils		21/10/2003	1.73 x 10 ⁹ /L	

Additional Information:

Onset date: 05/2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191604

Seq: 1

Gender: F

Reported: 27/10/2003

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 48

Onset Date: 15/05/2003

DOB: 02/11/1954

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Schizophrenia

Tablet

25.0 Milligram

Daily

Oral

Batch:

Started: 19/07/1995

Stopped: 14/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/10/2003	Neutrophils		20/10/2003	0.68	
27/10/2003	Neutrophils		18/10/2003	0.43 2nd result	
27/10/2003	Neutrophils		17/10/2003	0.59	
27/10/2003	White blood cells		19/07/1995	8.70	
27/10/2003	White blood cells		16/09/2003	5.40	
27/10/2003	White blood cells		14/10/2003	2.40	
27/10/2003	White blood cells		16/10/2003	2.90	

Additional Information:

Onset date: 05/2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191604

Seq: 1

Gender: F

Reported: 27/10/2003

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 48

Onset Date: 15/05/2003

DOB: 02/11/1954

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Schizophrenia

Tablet

25.0 Milligram

Daily

Oral

Batch:

Started: 19/07/1995

Stopped: 14/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/10/2003	White blood cells		17/10/2003	2.50	
27/10/2003	White blood cells		18/10/2003	2.70	
27/10/2003	White blood cells		18/10/2003	3.70 2nd result	
27/10/2003	White blood cells		19/10/2003	2.30	
27/10/2003	White blood cells		20/10/2003	2.20	
27/10/2003	White blood cells		21/10/2003	3.60 x 10^9/L	

Additional Information:

Onset date: 05/2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191605

Seq: 1

Gender: F

Reported: 27/10/2003

Weight: 0.00

Hospitalisation:

Age: 16

Onset Date:

DOB: 27/11/1986

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Enuresis		Nocturnal enuresis.	Given Desmopressin Acetate

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	200.0 Milligram
	Daily
	Oral
Batch:	Started: 24/06/2002
	Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Zoloft, Risperidone and Clonazepam.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191690
Reported: 28/10/2003

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 16/10/2003

Age: 34

DOB: 03/02/1969

Outcome: Recovered

23/10/2003

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation	Possible myocarditis, myalgia, chest pain, troponin increased, pericarditis, pleuritic pain.	
Myocarditis	Caused or prolonged inpatient hospitalisation	Possible myocarditis, myalgia, chest pain, troponin increased, pericarditis, pleuritic pain.	
Pericarditis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	25.0 Milligram
	Daily
	Oral
Batch:	Started: 30/09/2003
	Stopped: 16/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/10/2003	Troponin				

Additional Information:

Patient also administered: Mirtazapine, Diazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191690

Seq: 1

Gender: M

Reported: 28/10/2003

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date: 16/10/2003

DOB: 03/02/1969

Outcome: Recovered

23/10/2003

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pleuritic pain	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	25.0 Milligram
	Daily
	Oral
Batch:	Started: 30/09/2003
	Stopped: 16/10/2003

Laboratory Investigations:

Additional Information:

Patient also administered: Mirtazapine, Diazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191715

Seq: 1

Gender: M

Reported: 29/10/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Epilepsy		Worsening of epilepsy	Dose of Valproate increased.

Medicine Details:

LAMOTRIGINE (Other drug)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
EPILIM (Suspected)		Reason: Epilepsy	
	2.0 Gram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
CLOZARIL (Suspected)		Reason: Unspecified psychosis	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Unspecified beta-blocker, ACE inhibitor and cholesterol lowering agent. Also taking unknown Beta blocker, ACE inhibitor and cholesterol lowering agent. No other details reported.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191747

Seq: 1

Gender: M

Reported: 30/10/2003

Weight: 0.00

Hospitalisation:

Age: 52

Onset Date: 17/10/2003

DOB: 01/03/1951

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome	

Medicine Details:

RISPERIDONE (Suspected)		Reason: Schizophrenia	
Tablet		Dose Unspecified	Oral
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 11/09/2003	Stopped: 17/10/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191751

Seq: 1

Gender: F

Reported: 30/10/2003

Weight: 0.00

Hospitalisation:

Age: 61

Onset Date: 24/06/2003

DOB: 07/04/1942

Outcome: Recovered

24/06/2003

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Choking	Severe	Choking on food, unresponsive, cyanosed.	
Coma			
Cyanosis			

Medicine Details:

CLOPINE (Suspected)	Reason: Schizophrenia		
Tablet	650.0 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Lithium and Simvastatin.

One episode of choking on food on 24 June 2003. She became unresponsive and cyanosed for a few seconds before recovering fully. Neurological examination by a Neurologist was normal.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191818

Seq: 1

Gender: M

Reported: 28/05/2003

Weight: 0.00

Hospitalisation:

Age: 26Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Palpitations		Palpitations	Ceased Clozapine.

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram
	Daily
	Oral
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191820

Seq: 1

Gender: M

Reported: 28/05/2003

Weight: 0.00

Hospitalisation:

Age: 26Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea Drug withdrawal syndrome Vomiting Weight decreased		Nausea, vomiting, weight loss and withdrawal syndrome.	

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram
	Daily
	Oral
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozapine was started sometime in March 2002, and stopped sometime in August 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191821
Reported: 03/11/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 86

Onset Date:

DOB: 18/12/1916

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		Orthostatic hypotension,extrapyramidal disorder	The patients concomitant antihypertensive, frusemide, was also ceased. No other treatment was necessary.
Parkinsonism		Parkinsonian gait, tremor, muscle rigidity.	
Blood pressure decreased			
Extrapyramidal disorder			
Muscle rigidity			
Tremor			

Medicine Details:

FRUSEMIDE (Interaction)		Reason:	
		Dose Unspecified	
Batch:	Started:	Stopped:	
SERTRALINE HYDROCHLORIDE (Interaction)		Reason:	
Tablet		Dose Unspecified Oral	
Batch:	Started:	Stopped:	
CLOZARIL (Interaction)		Reason: Schizophrenia	
Tablet		100.0 Milligram Daily Oral	
Batch:	Started: 20/09/2003	Stopped: 20/10/2003	
DIGOXIN (Other drug)		Reason:	
		Dose Unspecified	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/11/2003	Other data				

Additional Information:

Clozaril was reduced to 75mg and condition improved. Clozaril was increased again and condition worsened. Tremor continued as at 28/10/2003, and therefore the reporter believed the patient's underlying Parkinsonism was probably pre-existing. Initial starting dose of Clozaril was 25mg which was slowly increased to 100mg when reaction occurred.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191831
Reported: 03/11/2003
Hospitalisation:
Onset Date:
Outcome: Unknown

Seq: 1

Gender: M
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Seizure, delirium, liver function tests abnormal, acute relapse of schizophrenia.	Patient was switched to Seroquel.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Blood potassium abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
25.0 Milligram	Daily
Batch:	Started: 16/11/2000 Stopped: 21/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/11/2003	Other data				

Additional Information:

Clozaril dose 25 - 600mg/day. Clozaril was ceased on 21 Oct 03 due to the seizure and clouded consciousness on advice of the medical team.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191831
Reported: 03/11/2003

Seq: 1

Gender: M
Weight: 0.00
Age: 99U

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood sodium abnormal	Caused or prolonged inpatient hospitalisation		
Delirium	Caused or prolonged inpatient hospitalisation		
Liver function test abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
25.0 Milligram	Daily
Batch:	Started: 16/11/2000 Stopped: 21/10/2003

Laboratory Investigations:

Additional Information:

Clozaril dose 25 - 600mg/day. Clozaril was ceased on 21 Oct 03 due to the seizure and clouded consciousness on advice of the medical team.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191831

Seq: 1

Gender: M

Reported: 03/11/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rhabdomyolysis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
25.0 Milligram	Daily
Batch:	Started: 16/11/2000 Stopped: 21/10/2003

Laboratory Investigations:

Additional Information:

Clozaril dose 25 - 600mg/day. Clozaril was ceased on 21 Oct 03 due to the seizure and clouded consciousness on advice of the medical team.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191832

Seq: 1

Gender: M

Reported: 03/11/2003

Weight: 0.00

Hospitalisation:

Age: 28

Onset Date:

DOB: 25/07/1975

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nodal arrhythmia		Junctional tachycardia	
Viral infection		Viral upper respiratory tract infection.	

Medicine Details:

CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 18/03/1999	L TERM	Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/11/2003	Electrocardiograph				
03/11/2003	Other data				

Additional Information:

Onset date:10/2003. The patient was asymptomatic, with no shortness of breath, no evidence of heart failure and no angina. A repeat ECG and an echocardiogram, were to be performed and it was planned to involve a cardiologist. No treatment was necessary as yet and Clozaril treatment continued at the same dose.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191845
Reported: 03/11/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 01/10/2003

Age: 29

DOB: 25/03/1974

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea Blood glucose increased Dizziness Hypotension Liver function test abnormal Pyrexia Tachycardia		Nausea, tachycardia, hypotension, low grade fever and raised liver enzymes, blood glucose increased.	Clozaril reduced to 100mg/day then ceased for two days and symptoms resolved.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 01/10/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/11/2003	Creatine	<160 U/L	15/10/2003	33	
03/11/2003	Creatine	<160 U/L	30/10/2003	18	
03/11/2003	Serum drug level				
03/11/2003	Serum glucose		15/10/2003	8.1 mmol/L	
03/11/2003	Troponin				

Additional Information:

Clozaril continued on reduced dose 100mg/day.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191858
Reported: 04/11/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date:

DOB: 20/12/1977

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pleuritic pain	Caused or prolonged inpatient hospitalisation	Pleuritic chest pain, malaise, flu-like symptoms, myocarditis.	Prednisolone and ACE inhibitor
Influenza like illness	Caused or prolonged inpatient hospitalisation		
Malaise	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram
	Total Oral
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/11/2003	Creatine				
04/11/2003	Echocardiogram				
04/11/2003	Electrocardiograph				
04/11/2003	Other data				
04/11/2003	Troponin				

Additional Information:

Patient ingested approx 400mg of his friend's Clozaril



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191858

Seq: 1

Gender: M

Reported: 04/11/2003

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date:

DOB: 20/12/1977

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation		
Wrong drug administered	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Total	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Patient ingested approx 400mg of his friend's Clozaril



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191935 **Seq:** 1 **Gender:** F
Reported: 06/11/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 50
Onset Date: **DOB:** 19/03/1953
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cholecystitis Abdominal pain upper Blood alkaline phosphatase increa Neutrophil count increased White blood cell count increased	Caused or prolonged inpatient hospitalisation	Cholecystitis, abdominal pain, blood bilirubin increased, white blood cell count increased, increased alkaline phosphatase, increased neutrophils.	Patient underwent a cholecystectomy

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	Oral
Batch:	Started: 13/02/2003 Stopped: 24/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/11/2003	Bilirubin				
06/11/2003	Neutrophils		27/10/2003	11.88	
06/11/2003	Neutrophils		30/10/2003	6.41	
06/11/2003	SAP = ALP				
06/11/2003	White blood cells		27/10/2003	14.60	
06/11/2003	White blood cells		30/10/2003	9.20	

Additional Information:

Patient also taking thyroxine, calcium. The patient had risk factors for gallstones as she was 'fat, female and forty'. Onset date of reaction October 2003



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191951
Reported: 07/11/2003
Hospitalisation:
Onset Date: 11/09/2003
Outcome: Unknown

Seq: 1

Gender: M
Weight: 0.00
Age: 19
DOB: 26/08/1984
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased	Required Specialist Consultation	Elevated prolactin levels, elevated fasting glucose level.	
Blood glucose increased	Required Specialist Consultation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 09/01/2003 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/11/2003	Prolactin		29/10/2003	1510	
07/11/2003	Prolactin		11/09/2003	1520	
07/11/2003	Serum glucose		11/09/2003	Fasting	
07/11/2003	Thyroid		15/08/2003	TSH elevated	

Additional Information:

Patient History : Blood thyroid stimulating hormone increased. Presented with elevated levels of TSH in approximately Oct 2002.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191964
Reported: 07/11/2003
Hospitalisation:
Onset Date: 15/10/2003
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 25
DOB: 01/06/1978
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Patient developed flu-like symptoms and 'tingling over his chest', and was diagnosed with myocarditis.	Clozaril ceased.
Troponin increased	Caused or prolonged inpatient hospitalisation	Troponin increased.	
Electrocardiogram abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 07/10/2003	Stopped: 31/10/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 191964
Reported: 07/11/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date: 15/10/2003

DOB: 01/06/1978

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Influenza like illness	Caused or prolonged inpatient hospitalisation		
Paraesthesia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 07/10/2003	Stopped: 31/10/2003	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192046

Seq: 1

Gender: F

Reported: 11/11/2003

Weight: 85.00

Hospitalisation:

Age: 61

Onset Date: 17/02/2003

DOB: 08/01/1942

Outcome: Death

17/02/2003

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Life threatening	Myocarditis causing death	Unsuccessful resuscitation
Death	Life threatening		

Medicine Details:

CLOZAPINE (Suspected)	Reason: Schizophrenia Daily
Batch:	Started: 04/02/2003 Stopped: 17/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No other cause for the myocarsitis identified (cannot absolutely exclude viral or other infectious causes.
Patient also administered: Haloperidal, Diazepam and Paracetamol. Last dose given was 62.5mg mane and 75mg nocte



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192096

Seq: 1

Gender: M

Reported: 11/11/2003

Weight: 0.00

Hospitalisation:

Age: 22

Onset Date:

DOB: 03/02/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Eosinophil count increased White blood cell count increased		Elevated creatine kinase, eosinophils up to 3.5, WBC went up to 14.	

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
		Dose Unspecified	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
		25.0 Milligram Daily	
Batch:	Started: 08/10/2003	Stopped: contin	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/11/2003	Eosinophils				
11/11/2003	Other data				
11/11/2003	Other data				
11/11/2003	White blood cells		03/11/2003	10.00 x 10 ⁹ /L	
11/11/2003	White blood cells		31/10/2003	14.00	
11/11/2003	White blood cells		27/10/2003	11.30	
11/11/2003	White blood cells		20/10/2003	10.60	

Additional Information:

Onset date October 2003



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192096

Seq: 1

Gender: M

Reported: 11/11/2003

Weight: 0.00

Hospitalisation:

Age: 22

Onset Date:

DOB: 03/02/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
		Dose Unspecified	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
		25.0 Milligram Daily	
Batch:	Started: 08/10/2003	Stopped: contin	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/11/2003	White blood cells		13/10/2003	8.6	
11/11/2003	White blood cells		08/10/2003	8.10	
11/11/2003	White blood cells		02/10/2003	8.10	

Additional Information:

Onset date October 2003



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192097

Seq: 1

Gender: M

Reported: 11/11/2003

Weight: 0.00

Hospitalisation:

Age: 32

Onset Date:

DOB: 03/01/1971

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Viral infection		Developed neck and facial twitching on 30 Oct 2003 and one-sided mouth and eye drooping on 02 Nov 2003. Bell's palsy due to a possible viral infection.	
Facial palsy			
Muscle contractions involuntary			

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	300.0 Milligram
	Daily
	Oral
Batch:	Started: 08/07/2003
	Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Bell's palsy due to a possible viral infection.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192109 **Seq:** 1 **Gender:** M
Reported: 11/11/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 46
Onset Date: **DOB:** 10/04/1957
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ventricular failure	Caused or prolonged inpatient hospitalisation	February 2002. Impaired systolic contractility, convulsions, hypotension, malaise, dyspnoea, fatigue, pyrexia, chest pain, palpitations, tachycardia, ventricular dysfunction, pneumonia aspiration.	Sodium valproate. Clozaril tapered down and ceased.
Chest pain	Life threatening		
Convulsion	Life threatening		
Dyspnoea	Life threatening		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 29/04/1997 Stopped: 05/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/11/2003	Electrocardiograph				
11/11/2003	White blood cells		29/04/1997	9.70	
11/11/2003	White blood cells		10/03/2003	5.90	
11/11/2003	White blood cells		10/10/2003	5.70	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192109 **Seq:** 1 **Gender:** M
Reported: 11/11/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 46
Onset Date: **DOB:** 10/04/1957
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fatigue	Life threatening		
Hypotension	Life threatening		
Palpitations	Life threatening		
Pneumonia aspiration	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 29/04/1997 Stopped: 05/11/2003

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192109 **Seq:** 1 **Gender:** M
Reported: 11/11/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 46
Onset Date: **DOB:** 10/04/1957
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Life threatening		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 29/04/1997 Stopped: 05/11/2003

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192203

Seq: 1

Gender: F

Reported: 14/11/2003

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date: 26/10/2003

DOB: 18/05/1964

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash	Severe	Severe horrible rash, pruritus.	Clozaril treatment discontinued
Pruritus			

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	150.0 Milligram
	Daily
	Oral
Batch:	Started: 01/10/2003
	Stopped: 31/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient 'became itchy' within an hour of taking a Clozaril dose. Clozaril treatment was discontinued and the rash took 'a while' to subside.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192206
Reported: 14/11/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 26/10/2003

Age: 50

DOB: 15/01/1953

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis, night sweats, body temperature increased, tachycardia, chest tightness, troponin increased, blood creatine phosphokinase increased, electrocardiogram abnormal NOS, C-reactive protein increased, eosinophil count increased, blood creatinine increased and blood bilirubin increased.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.5 Gram
	Daily
	Oral
Batch:	Started: 14/10/2003
	Stopped: 27/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/11/2003	Creatine				
14/11/2003	Echocardiogram				
14/11/2003	Electrocardiograph				
14/11/2003	Neutrophils		04/11/2003	7.80	
14/11/2003	Neutrophils		28/10/2003	6.98	
14/11/2003	Neutrophils		26/10/2003	6.17	
14/11/2003	Neutrophils		13/10/2003	4.32	

Additional Information:

Patient also taking Olanzapine, Propanolol and Folic acid.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192206
Reported: 14/11/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 26/10/2003

Age: 50

DOB: 15/01/1953

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood bilirubin increased	Caused or prolonged inpatient hospitalisation		
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Blood creatinine increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.5 Gram
	Daily
	Oral
Batch:	Started: 14/10/2003
	Stopped: 27/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/11/2003	Neutrophils		08/10/2003	4.54	
14/11/2003	Neutrophils		20/10/2003	5.94	
14/11/2003	Troponin				
14/11/2003	White blood cells		04/11/2003	11.80 x 10^9/L	
14/11/2003	White blood cells		28/10/2003	8.70	
14/11/2003	White blood cells		26/10/2003	7.90	
14/11/2003	White blood cells		20/10/2003	8.10	

Additional Information:

Patient also taking Olanzapine, Propanolol and Folic acid.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192206
Reported: 14/11/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 26/10/2003

Age: 50

DOB: 15/01/1953

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		
Chest discomfort	Caused or prolonged inpatient hospitalisation		
Electrocardiogram abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.5 Gram
	Daily
	Oral
Batch:	Started: 14/10/2003
	Stopped: 27/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/11/2003	White blood cells		13/10/2003	8.00	
14/11/2003	White blood cells		08/10/2003	7.30	

Additional Information:

Patient also taking Olanzapine, Propanolol and Folic acid.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192206

Seq: 1

Gender: M

Reported: 14/11/2003

Weight: 0.00

Hospitalisation:

Age: 50

Onset Date: 26/10/2003

DOB: 15/01/1953

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophil count increased	Caused or prolonged inpatient hospitalisation		
Night sweats	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.5 Gram
	Daily
	Oral
Batch:	Started: 14/10/2003
	Stopped: 27/10/2003

Laboratory Investigations:

Additional Information:

Patient also taking Olanzapine, Propanolol and Folic acid.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192206

Seq: 1

Gender: M

Reported: 14/11/2003

Weight: 0.00

Hospitalisation:

Age: 50

Onset Date: 26/10/2003

DOB: 15/01/1953

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.5 Gram
	Daily
	Oral
Batch:	Started: 14/10/2003
	Stopped: 27/10/2003

Laboratory Investigations:

Additional Information:

Patient also taking Olanzapine, Propanolol and Folic acid.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192208

Seq: 1

Gender: M

Reported: 14/11/2003

Weight: 0.00

Hospitalisation:

Age: 48

Onset Date: 02/11/2003

DOB: 05/11/1954

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope	Caused or prolonged inpatient hospitalisation	Faintness/syncope	
Atrial fibrillation	Caused or prolonged inpatient hospitalisation		Sotalol and intravenous digoxin, intravenous amlodarone. Clozaril was discontinued.

Medicine Details:

CLOZARIL (Suspected)		Reason: Schizophrenia	
Oral application	12.5 Milligram	Daily	Oral
Batch:	Started: 28/11/2000	Stopped: 04/11/2003	
SOLIAN (Suspected)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Suspected)		Reason:	
	1.0 Dose Unspecified	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/11/2003	Echocardiogram				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192211
Reported: 14/11/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 23

Onset Date: 30/10/2003

DOB: 18/12/1979

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Ejection fraction decreased		Global cardiomyopathy.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
12.5 Milligram	Daily
Batch:	Started: 03/04/2003 Stopped: 31/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/11/2003	Echocardiogram		30/10/2003	Routine 6	
14/11/2003	Troponin		31/10/2003	Not detected	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192236 **Seq:** 1 **Gender:** M
Reported: 05/11/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 37
Onset Date: 15/07/2003 **DOB:** 31/07/1965
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Congestive cardiomyopathy Cardiac failure Cardiac murmur Cardiomegaly Dyspnoea Ejection fraction decreased Mitral valve incompetence Oedema peripheral Tricuspid valve incompetence	Caused or prolonged inpatient hospitalisation	Dilated cardiomyopathy, cardiomegaly and right dilatation.	Clozapine reduced to 200 mg and tapered to discontinuation in 2 weeks

Medicine Details:

HALOPERIDOL (Other drug)		Reason:
Batch:	Started:	Stopped:
CLOZARIL (Suspected)		Reason: Schizophrenia
	350.0 Milligram Daily	
Batch:	Started: 17/07/1996	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/11/2003	Chest X-ray				
05/11/2003	Electrocardiograph				

Additional Information:

History: Sleep apnoea syndrome, obesity



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192237

Seq: 1

Gender: M

Reported: 14/11/2003

Weight: 0.00

Hospitalisation:

Age: 24

Onset Date: 16/09/2003

DOB: 06/11/1978

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypocalcaemia	Caused or prolonged inpatient hospitalisation	Hypocalcaemia	Treated with iv Calcium.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	37.5 Milligram	Daily	Oral
Batch:	Started: 02/06/1999	Stopped:	Contin
SOLIAN (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192241

Seq: 1

Gender: M

Reported: 17/11/2003

Weight: 0.00

Hospitalisation:

Age: 29

Onset Date:

DOB: 08/06/1974

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Memory impairment		Memory impairment, condition aggravated.	Clozaril was decreased to 50mg daily.
Condition aggravated			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram
	Daily
	Oral
Batch:	Started: 20/11/1996
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Venlafaxine, Valproate sodium, Amisulpride.
Current condition: memory and cognition had been poor prior to Clozaril treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192291

Seq: 1

Gender: M

Reported: 14/11/2003

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date: 14/10/2003

DOB: 26/06/1973

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis	

Medicine Details:

CLOZAPINE (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 26/09/2003	Stopped: 14/10/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/11/2003	Haematology				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192312

Seq: 1

Gender: F

Reported: 18/11/2003

Weight: 0.00

Hospitalisation:

Age: 31

Onset Date:

DOB: 25/01/1972

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abortion spontaneous		Miscarriage.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	6.0 Milligram
	Daily
	Oral
Batch:	Started: 27/11/1997
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Commenced on 27/11/97 (taken from blood monitoring database). Miscarriage (date and details not specified) while on Clozaril. Subsequent pregnancies continued with no adverse events reported to ADRAC (variable Clozapine dose administered).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192346
Reported: 19/11/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 35

Onset Date:

DOB: 19/04/1968

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram T wave inversio		T wave inversion on ECG and creatinine kinase increased.	Clozaril was ceased on 05 Nov 2003 and he was switched to Olanzapine.
Blood creatine phosphokinase incr Troponin increased			

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 14/10/2003	Stopped: 05/11/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/11/2003	Echocardiogram				
19/11/2003	Electrocardiograph				
19/11/2003	Other data				
19/11/2003	Troponin		27/10/2003	0.89	
19/11/2003	White blood cells		03/11/2003	8.00	
19/11/2003	White blood cells		27/10/2003	8.23	
19/11/2003	White blood cells		09/10/2003	(pre-treatment)	

Additional Information:

An echocardiogram showed normal left ventricular function, therefore it was unlikely to have been a myocardial infarction.
Reaction onset date Oct 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192347
Reported: 19/11/2003

Seq: 1

Gender: M
Weight: 0.00
Age: 47
DOB: 21/12/1955
Causality: Causality possible

Hospitalisation:

Onset Date:
Outcome: Unknown

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Unexplained epileptiform seizures. Epilepsy NOS. Loss of consciousness. Abnormal behavior NOS.	Clozaril was not recommenced at the time.
Abnormal behaviour	Caused or prolonged inpatient hospitalisation		
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	100.0 Milligram
	Daily
	Oral
Batch:	Started: 14/04/1998
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

After his supply of Clozaril tablets lapsed for approximately four days.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192347

Seq: 1

Gender: M

Reported: 19/11/2003

Weight: 0.00

Hospitalisation:

Age: 47

Onset Date:

DOB: 21/12/1955

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Loss of consciousness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 14/04/1998 Stopped:

Laboratory Investigations:

Additional Information:

After his supply of Clozaril tablets lapsed for approximately four days.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192349
Reported: 19/11/2003
Hospitalisation:
Onset Date: 01/11/2003
Outcome: Recovered

Seq: 1

Gender: F
Weight: 0.00
Age: 44
DOB: 29/05/1959
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Streptococcal infection	Caused or prolonged inpatient hospitalisation	Like a 'zombie', was almost catatonic, unwell, unresponsive, febrile, hypoxic, and had tachycardia and a dry cough.	Antibiotics. Clozaril was temporarily interrupted due to her inability or unwillingness to ingest the Clozaril orally. Clozaril was eventually crushed and delivered nasogastrically.
Cough	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	550.0 Milligram Daily Oral
Batch:	Started: 16/11/2000 Stopped: 08/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/11/2003	Blood culture		01/11/2003	Blood culture	
19/11/2003	Neutrophils		16/11/2000	(pre-treatment)	
19/11/2003	Neutrophils		23/09/2003	2.20	
19/11/2003	Neutrophils		21/10/2003	5.60 x 10 ⁹ /L	
19/11/2003	White blood cells		21/10/2003	6.60 x 10 ⁹ /L	
19/11/2003	White blood cells		23/09/2003	4.20	
19/11/2003	White blood cells		16/11/2000	(pre-treatment)	

Additional Information:

The cause for her 'zombie like' state was primarily believed to be an exacerbation of psychosis, however, was then found to be severe streptococcal infection, which had progressed from a case of otitis media. Her diagnosis on discharge was streptococcal pneumoniae septicaemia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192349
Reported: 19/11/2003

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 01/11/2003
Outcome: Recovered

Age: 44
DOB: 29/05/1959
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Haemoglobin decreased	Caused or prolonged inpatient hospitalisation		
Hypoxia	Caused or prolonged inpatient hospitalisation		
Malaise	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	550.0 Milligram
	Daily
	Oral
Batch:	Started: 16/11/2000
	Stopped: 08/11/2003

Laboratory Investigations:

Additional Information:

The cause for her 'zombie like' state was primarily believed to be an exacerbation of psychosis, however, was then found to be severe streptococcal infection, which had progressed from a case of otitis media. Her diagnosis on discharge was streptococcal pneumoniae septicaemia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192349
Reported: 19/11/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 01/11/2003

Age: 44

DOB: 29/05/1959

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Movement disorder	Caused or prolonged inpatient hospitalisation		
Otitis media	Caused or prolonged inpatient hospitalisation		
Platelet count decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	550.0 Milligram
	Daily
	Oral
Batch:	Started: 16/11/2000
	Stopped: 08/11/2003

Laboratory Investigations:

Additional Information:

The cause for her 'zombie like' state was primarily believed to be an exacerbation of psychosis, however, was then found to be severe streptococcal infection, which had progressed from a case of otitis media. Her diagnosis on discharge was streptococcal pneumoniae septicaemia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192349
Reported: 19/11/2003

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 01/11/2003
Outcome: Recovered

Age: 44
DOB: 29/05/1959
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation		
Sinus disorder	Caused or prolonged inpatient hospitalisation		
Streptococcal sepsis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	550.0 Milligram
	Daily
	Oral
Batch:	Started: 16/11/2000
	Stopped: 08/11/2003

Laboratory Investigations:

Additional Information:

The cause for her 'zombie like' state was primarily believed to be an exacerbation of psychosis, however, was then found to be severe streptococcal infection, which had progressed from a case of otitis media. Her diagnosis on discharge was streptococcal pneumoniae septicaemia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192349

Seq: 1

Gender: F

Reported: 19/11/2003

Weight: 0.00

Hospitalisation:

Age: 44

Onset Date: 01/11/2003

DOB: 29/05/1959

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	550.0 Milligram	Daily	Oral
Batch:	Started: 16/11/2000	Stopped: 08/11/2003	

Laboratory Investigations:

Additional Information:

The cause for her 'zombie like' state was primarily believed to be an exacerbation of psychosis, however, was then found to be severe streptococcal infection, which had progressed from a case of otitis media. Her diagnosis on discharge was streptococcal pneumoniae septicaemia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192358

Seq: 1

Gender: F

Reported: 20/11/2003

Weight: 0.00

Hospitalisation:

Age: 36

Onset Date: 07/11/2003

DOB: 04/03/1967

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation	Increased CK level, increased drug level, confused, delirious, light hyperreflexia, tachycardic.	
Confusional state	Caused or prolonged inpatient hospitalisation		
Delirium	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Interaction)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 07/11/2003	
Abilify (Interaction)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 07/11/2003	
VALIUM (Other drug)		Reason: Anxiety neurosis	
Tablet	5.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped: 07/11/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192358

Seq: 1

Gender: F

Reported: 20/11/2003

Weight: 0.00

Hospitalisation:

Age: 36

Onset Date: 07/11/2003

DOB: 04/03/1967

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug interaction	Caused or prolonged inpatient hospitalisation		
Drug level increased	Caused or prolonged inpatient hospitalisation		
Hyperreflexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Interaction)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 07/11/2003	
Abilify (Interaction)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 07/11/2003	
VALIUM (Other drug)		Reason: Anxiety neurosis	
Tablet	5.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped: 07/11/2003	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192358

Seq: 1

Gender: F

Reported: 20/11/2003

Weight: 0.00

Hospitalisation:

Age: 36

Onset Date: 07/11/2003

DOB: 04/03/1967

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Interaction)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 07/11/2003	
Abilify (Interaction)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 07/11/2003	
VALIUM (Other drug)		Reason: Anxiety neurosis	
Tablet	5.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped: 07/11/2003	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192419
Reported: 24/11/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 02/11/2003

Age: 23

DOB: 22/02/1980

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis, red blood cell sedimentation rate increased, ventricular dysfunction, pyrexia, headache, tachycardia.	Panadol, aspirin
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		
Headache	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 10/10/2003	Stopped: 05/11/2003	
SEROQUEL (Suspected)		Reason:	
	1.0 Dose Unspecified	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/11/2003	C-Reactive Protein		17/11/2003	<5	
24/11/2003	C-Reactive Protein		11/11/2003	74	
24/11/2003	C-Reactive Protein		10/11/2003	125	
24/11/2003	Creatine				
24/11/2003	Echocardiogram				
24/11/2003	Electrocardiograph				
24/11/2003	Erythrocyte		17/11/2003	40	

Additional Information:

Risk factors for myocardial disease were stated as drug abuse (last time approx. 4 months ago) and clozaril treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192419
Reported: 24/11/2003
Hospitalisation:
Onset Date: 02/11/2003
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 23
DOB: 22/02/1980
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation		
Red blood cell sedimentation rate increased	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 10/10/2003	Stopped: 05/11/2003	
SEROQUEL (Suspected)		Reason:	
	1.0 Dose Unspecified	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/11/2003	Erythrocyte sedimentation rate		10/11/2003	77	
24/11/2003	Hepatitis C				
24/11/2003	Other data				
24/11/2003	Troponin				

Additional Information:

Risk factors for myocardial disease were stated as drug abuse (last time approx. 4 months ago) and clozaril treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192419
Reported: 24/11/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 02/11/2003

Age: 23

DOB: 22/02/1980

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin I increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 10/10/2003	Stopped: 05/11/2003	
SEROQUEL (Suspected)		Reason:	
	1.0 Dose Unspecified	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Risk factors for myocardial disease were stated as drug abuse (last time approx. 4 months ago) and clozaril treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192465
Reported: 24/11/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 13/10/2003

Age: 37

DOB: 23/06/1966

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased		High plasma level of clozapine, possible drug interaction.	

Medicine Details:

LITHIUM CARBONATE (Interaction)		Reason:	
		Dose Unspecified	
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Interaction)		Reason:	
		Dose Unspecified	
Batch:	Started:	Stopped:	
CLOZARIL (Interaction)		Reason: Schizophrenia	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 25/07/2000	Stopped: 15/08/2003	
CAFFEINE (Interaction)		Reason:	
		Dose Unspecified Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/11/2003	Serum drug level				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192466

Seq: 1

Gender: M

Reported: 24/11/2003

Weight: 0.00

Hospitalisation:

Onset Date: 15/11/2003

Age: 45

DOB: 18/06/1958

Outcome: Death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death		Walking with an unsteady gait, behaving incoherently, frothing at the mouth, unexplained death.	
Abnormal behaviour			
Gait disturbance			

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	Oral
Batch:	Started: 11/10/1996 Stopped:
SODIUM VALPROATE (Suspected)	Reason:
	Dose Unspecified
Batch:	Started: Stopped:
OXYBUTYNIN HYDROCHLORIDE (Suspected)	Reason:
	Dose Unspecified
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Coroner's case pending.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192488

Seq: 1

Gender: F

Reported: 25/11/2003

Weight: 0.00

Hospitalisation:

Age: 22

Onset Date:

DOB: 27/05/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation	Caused or prolonged inpatient hospitalisation	Constipation	
Megacolon	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	350.0 Milligram
	Daily
	Oral
Batch:	Started: 23/11/2000
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/11/2003	Other data				

Additional Information:

Patient also administered: Clopine, Paroxetine, Clonazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192489

Seq: 1

Gender: F

Reported: 25/11/2003

Weight: 0.00

Hospitalisation:

Age: 53

Onset Date: 21/01/2001

DOB: 17/06/1947

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension	Caused or prolonged inpatient hospitalisation	Postural hypotension,	
Fall	Caused or prolonged inpatient hospitalisation	Resulted in ankle fracture	X rays

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	25.0 Milligram
	Daily
	Oral
Batch:	Started: 02/11/1994
	Stopped: 14/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/11/2003	Other data				

Additional Information:

Other drugs: Aropax, Losec, Epilm and Diaformin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192519

Seq: 1

Gender: F

Reported: 27/11/2003

Weight: 84.00

Hospitalisation:

Age: 57

Onset Date: 18/11/2003

DOB: 19/01/1946

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Tardive dyskinesia - involuntary mouth movements.	

Medicine Details:

CLOZAPINE (Suspected)	Reason: Schizophrenia
Tablet	250.0 Milligram
	Daily
	Oral
Batch:	Started: 14/08/2003
	Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192597

Seq: 1

Gender: M

Reported: 28/11/2003

Weight: 0.00

Hospitalisation:

Age: 20

Onset Date:

DOB: 11/12/1982

Outcome: Recovered

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting		Nausea and vomiting	Maxolon.

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 09/10/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Stopped Clozaril - symtoms stopped. Restarted Clozaril - symtoms returned. Clozaril started in September 2002



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192598 **Seq:** 1 **Gender:** M
Reported: 28/11/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 40
Onset Date: 15/11/2003 **DOB:** 22/12/1962
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Life threatening	Cardiomyopathy	Inotropic support and ventilation ICU. Clozaril ceased and Adrenaline administered.
Ejection fraction decreased	Life threatening		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	1.0 Gram Daily Oral
Batch:	Started: 19/07/1995 Stopped: 20/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/11/2003	Echocardiogram				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192903

Seq: 1

Gender: M

Reported: 05/12/2003

Weight: 0.00

Hospitalisation:

Age: 60

Onset Date: 15/06/2003

DOB: 11/02/1943

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Cardiomyopathy.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 14/08/2001	Stopped: 17/11/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192906

Seq: 1

Gender: M

Reported: 05/12/2003

Weight: 0.00

Hospitalisation:

Age: 35

Onset Date: 02/10/2002

DOB: 27/05/1967

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension Blood glucose increased Blood triglycerides increased Drug ineffective		Hypertesion, blood glucose increased, blood triglycerides increased, drug ineffective.	Clozaril ceased

Medicine Details:

EPILIM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 26/08/2002	Stopped: 09/07/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 179947 is a seq 1.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192910
Reported: 05/12/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 23/09/2003

Age: 24

DOB: 07/07/1979

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia Platelet count increased Red blood cell count increased		Neutropenia, red cell count increased, platelets increased.	

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	425.0 Milligram	Daily	Oral
Batch:	Started: 28/05/2002	Stopped:	
AUGMENTIN (Suspected)		Reason:	
	1.0 Dose Unspecified	Daily	
Batch:	Started: 15/09/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/12/2003	Neutrophils		21/10/2003	6.98 x 10^9/L	
05/12/2003	Neutrophils		30/09/2003	4.94	
05/12/2003	Neutrophils		25/09/2003	2.20	
05/12/2003	Neutrophils		15/05/2002	5.89	
05/12/2003	Neutrophils		26/08/2003	9.27	
05/12/2003	Neutrophils		23/09/2003	1.86	
05/12/2003	Red blood cells		21/10/2003	5.34 x 10^12/L	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192910
Reported: 05/12/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 23/09/2003

Age: 24

DOB: 07/07/1979

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	425.0 Milligram	Daily	Oral
Batch:	Started: 28/05/2002	Stopped:	
AUGMENTIN (Suspected)		Reason:	
	1.0 Dose Unspecified	Daily	
Batch:	Started: 15/09/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/12/2003	Red blood cells		30/09/2003	5.65	
05/12/2003	Red blood cells		23/09/2003	5.35	
05/12/2003	Red blood cells		02/09/2003	5.20	
05/12/2003	Red blood cells		25/09/2003	5.37	
05/12/2003	White blood cells		21/10/2003	11.00x10 ⁹ /L	
05/12/2003	White blood cells		30/09/2003	8.90	
05/12/2003	White blood cells		25/09/2003	5.90 (Clozaril	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192910
Reported: 05/12/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 23/09/2003

Age: 24

DOB: 07/07/1979

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	425.0 Milligram	Daily	Oral
Batch:	Started: 28/05/2002	Stopped:	
AUGMENTIN (Suspected)		Reason:	
	1.0 Dose Unspecified	Daily	
Batch:	Started: 15/09/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/12/2003	White blood cells		23/09/2003	4.50 (Clozaril	
05/12/2003	White blood cells		26/08/2003	12.40 (Clozaril	
05/12/2003	White blood cells		15/05/2002	10.10	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192968
Reported: 08/12/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 29/11/2003

Age: 25

DOB: 07/07/1978

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Echocardiogram abnormal Ejection fraction decreased Left ventricular failure Tachycardia		Cardiac complications characterised by markedly decreased VF and EF and sinus tachcardia (120 bpm)	Clozapine ceased

Medicine Details:

CLOZAPINE (Suspected)		Reason:	
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 28/11/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/12/2003	Neutrophils				
08/12/2003	White blood cells				

Additional Information:

Patient received Clozapine continuously for a year. History: Polysubstance abuser of marijuana, alcohol and heroin abuser. Asthma.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192973
Reported: 08/12/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 18/11/2003

Age: 22

DOB: 15/05/1981

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
C-reactive protein increased	Caused or prolonged inpatient hospitalisation	C-reactive protein increased, red blood cell sedimentation rate increased, ventricular dysfunction, dyspnoea.	Treated with a beta-blocker and an ACE inhibitor, Clozaril was ceased.
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis, pyrexia, tachycardia, hypotension, hyperhidrosis, C-reactive protein increased, red blood cell rate increased, ventricular dysfunction, dyspnoea, fatigue.	
Dyspnoea	Caused or prolonged inpatient hospitalisation	Ventricular dysfunction	

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 07/11/2003	Stopped: 22/11/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/12/2003	C-Reactive Protein		01/12/2003	7	
08/12/2003	C-Reactive Protein		24/11/2003	132	
08/12/2003	C-Reactive Protein		22/11/2003	190	
08/12/2003	Chest X-ray				
08/12/2003	Echocardiogram				
08/12/2003	Electrocardiograph				

Additional Information:

Patient was also taking Sodium Valproate and Diazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192973
Reported: 08/12/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 18/11/2003

Age: 22

DOB: 15/05/1981

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ventricular failure	Caused or prolonged inpatient hospitalisation	Ventricular dysfunction	
Fatigue	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	125.0 Milligram
	Daily
	Oral
Batch:	Started: 07/11/2003
	Stopped: 22/11/2003

Laboratory Investigations:

Additional Information:

Patient was also taking Sodium Valproate and Diazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192973
Reported: 08/12/2003

Seq: 1

Gender: M
Weight: 0.00
Age: 22
DOB: 15/05/1981
Causality: Causality possible

Hospitalisation:

Onset Date: 18/11/2003
Outcome: Recovered

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Caused or prolonged inpatient hospitalisation		
Palpitations	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	125.0 Milligram Daily Oral
Batch:	Started: 07/11/2003 Stopped: 22/11/2003

Laboratory Investigations:

Additional Information:

Patient was also taking Sodium Valproate and Diazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 192973

Seq: 1

Gender: M

Reported: 08/12/2003

Weight: 0.00

Hospitalisation:

Age: 22

Onset Date: 18/11/2003

DOB: 15/05/1981

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Red blood cell sedimentation rate i	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	125.0 Milligram
	Daily
	Oral
Batch:	Started: 07/11/2003
	Stopped: 22/11/2003

Laboratory Investigations:

Additional Information:

Patient was also taking Sodium Valproate and Diazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193130

Seq: 1

Gender: M

Reported: 15/12/2003

Weight: 0.00

Hospitalisation:

Age: 44

Onset Date: 07/06/2003

DOB: 09/11/1958

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Febrile reaction and confusional state. lung consolidation.	Clozapine stopped. Augmentin Duo Forte 1 bd for 7 days, clarithromycin 500mg bd (2 doses). Clozapine 50mg bd started again on 6/6/03 1 dose and 1 dose 7/6/03. Then dose reduced to 12.5mg bd from 8/06/03-10/06/03, then 25mg bd 11/06/03-12/06/03, 50mg bd from 13/06/03-14/06/03, 100mg bd 15/06/03 to 17/06/03.

Medicine Details:

CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	600.0 Milligram	2 times	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/12/2003	Chest X-ray				

Additional Information:

Patient was also taking Chlorpromazine, Clonazepam, Sodium Valproate.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193130

Seq: 1

Gender: M

Reported: 15/12/2003

Weight: 0.00

Hospitalisation:

Age: 44

Onset Date: 07/06/2003

DOB: 09/11/1958

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state Lung consolidation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	600.0 Milligram 2 times Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

Patient was also taking Chlorpromazine, Clonazepam, Sodium Valproate.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193146

Seq: 1

Gender: F

Reported: 15/12/2003

Weight: 0.00

Hospitalisation:

Age: 72

Onset Date:

DOB: 20/03/1931

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Influenza		Bout of influenza.	
Balance disorder		Unsteady on her feet.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	12.0 Milligram
	Daily
	Oral
Batch: Contin	Started: 13/07/2002
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/12/2003	Serum drug level				

Additional Information:

Patient also administered: Coloxyl with Senna, Macrodantin, Epilim.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193249

Seq: 1

Gender: M

Reported: 08/08/2003

Weight: 0.00

Hospitalisation:

Age: 22Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder Leukocytosis Neutrophilia		Return of psychosis, Leukocytosis, Neutrophilia.	

Medicine Details:

CLOZARIL (Suspected)		Reason:		
Tablet	12.5 Milligram	Daily	Oral	
Batch:	Started: 12/03/2003	Stopped:	Contin	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/08/2003	Neutrophils		01/08/2003	8.40	
08/08/2003	Neutrophils		29/07/2003	17.70	
08/08/2003	White blood cells		01/08/2003	12.40	

Additional Information:

Hypersalivation (date of onset not specified) lead to adose reduction from 200mg/day to 100mg/day, which in turn resulted in the return of psychosis.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193292

Seq: 1

Gender: M

Reported: 18/12/2003

Weight: 0.00

Hospitalisation:

Age: 50

Onset Date:

DOB: 12/07/1953

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Cogwheel rigidity	Caused or prolonged inpatient hospitalisation		
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	175.0 Milligram	Daily	Oral
Batch:	Started: 07/03/2003	Stopped: 26/11/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193292

Seq: 1

Gender: M

Reported: 18/12/2003

Weight: 0.00

Hospitalisation:

Age: 50

Onset Date:

DOB: 12/07/1953

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation		
Convulsion	Caused or prolonged inpatient hospitalisation	Convulsion, Fall, Neuroleptic malignant syndrome, Pyrexia, Blood creatine phosphokinase increased, Cogwheel rigidity.	Ceased Clozaril and reintroduced quetiapine.

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	175.0 Milligram	Daily	Oral
Batch:	Started: 07/03/2003	Stopped: 26/11/2003	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193294
Reported: 18/12/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 16

Onset Date:

DOB: 09/06/1987

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Atrioventricular block second degree Dyspnoea Ejection fraction decreased Eosinophilia Sinus tachycardia		Cardiomyopathy, Sinus tachycardia, Ejection fraction decreased, Eosinophilia.	Clozaril was ceased.

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 07/11/2003	Stopped: 05/12/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/12/2003	Chest X-ray				
18/12/2003	Echocardiogram				
18/12/2003	Eosinophils				
18/12/2003	Other data				
18/12/2003	Troponin				

Additional Information:

Patient also taking benztropine



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193337

Seq: 1

Gender: F

Reported: 19/12/2003

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date: 09/10/2003

DOB: 17/11/1956

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal failure acute		Acute renal failue.	Supportive measures - treated with hydration and short course of antibiotics empirically.
Blood pressure fluctuation		Labile blood pressure	
Pyrexia			

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram
	Daily
	Oral
Batch:	Started: 19/09/2003
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Omeprazole, Diazepam, Sodium Valproate, Propranolol and Premia 5 Continous.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193353
Reported: 19/12/2003
Hospitalisation:
Onset Date: 10/12/2003
Outcome: Recovered

Seq: 1

Gender: F
Weight: 0.00
Age: 24
DOB: 24/10/1979
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Caused or prolonged inpatient hospitalisation	Agranulocytosis.	Clozaril was discontinued, treated with G-CSF.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 02/10/2003	Stopped: 08/12/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/12/2003	Neutrophils		13/12/2003	0.30	
19/12/2003	Neutrophils		10/12/2003	0.40	
19/12/2003	Neutrophils		01/12/2003	3.80	
19/12/2003	White blood cells		13/12/2003	2.70	
19/12/2003	White blood cells		10/12/2003	3.20	
19/12/2003	White blood cells		01/12/2003	6.00	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193407

Seq: 1

Gender: F

Reported: 22/12/2003

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date:

DOB: 13/12/1978

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonia, Diabetes mellitus NOS, Suicidal ideation, Weight increased.	Benzotropine 4mg/day was given to treat Dystonia and also given Benadryl cough syrup and Metformin.
Diabetes mellitus			
Suicidal ideation			
Weight increased			

Medicine Details:

CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 06/09/1996	Stopped:	Contin
SEROQUEL (Suspected)		Reason:	
	550.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Citalopram and Valproate Sodium. Patient needed care 24 hours a day. Onset date 2002. Seroquel initiated on 550mg/day increased to 650mg/day before being discontinued. Clozaril was increased to 300mg/day and continued. This report is a duplicate of 189882.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193474

Seq: 1

Gender: F

Reported: 22/12/2003

Weight: 0.00

Hospitalisation:

Age: 61Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapeutic response decreased		Therapeutic response decreased.	Increase in Clozapine dose, and required haloperidol to be added to regimen.

Medicine Details:

VIOXX (Interaction)		Reason:	
Batch:	Started:	Stopped:	
CLOPINE (Interaction)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193479
Reported: 23/12/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Age: 55

Onset Date:

DOB: 19/09/1948

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Caused or prolonged inpatient hospitalisation	Persistent hypotension, dizziness, fall, transient ischaemic attack, asthenia, reflexes abnormal, mentally unwell.	Ceased Clozaril
Asthenia	Caused or prolonged inpatient hospitalisation		
Dizziness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 23/04/2003	Stopped: 10/12/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/12/2003	Blood pressure				
23/12/2003	Computerised				

Additional Information:

History of angina pectoris, which was being treated with isosorbide dinitrate. Also taking clopidogrel, sodium vaproate, venlafaxine, simvastatin and ranitidine. Patient reported to be improving.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193479
Reported: 23/12/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Age: 55

Onset Date:

DOB: 19/09/1948

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fall	Caused or prolonged inpatient hospitalisation		
Mental disorder	Caused or prolonged inpatient hospitalisation		
Reflexes abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 23/04/2003	Stopped: 10/12/2003	

Laboratory Investigations:

Additional Information:

History of angina pectoris, which was being treated with isosorbide dinitrate. Also taking clopidogrel, sodium vaproate, venlafaxine, simvastatin and ranitidine. Patient reported to be improving.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193479

Seq: 1

Gender: F

Reported: 23/12/2003

Weight: 0.00

Hospitalisation:

Age: 55

Onset Date:

DOB: 19/09/1948

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Transient ischaemic attack	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 23/04/2003	Stopped: 10/12/2003	

Laboratory Investigations:

Additional Information:

History of angina pectoris, which was being treated with isosorbide dinitrate. Also taking clopidogrel, sodium vaproate, venlafaxine, simvastatin and ranitidine. Patient reported to be improving.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193480

Seq: 1

Gender: M

Reported: 23/12/2003

Weight: 0.00

Hospitalisation:

Age: 22

Onset Date:

DOB: 30/09/1981

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest		Cardiac arrest, Hypersalivation, constipation.	
Constipation			
Salivary hypersecretion			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	600.0 Milligram
	Daily
	Oral
Batch:	Started: 19/05/2000
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died 14/11/03.
Patient was on 13-650mg Clozaril daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193481

Seq: 1

Gender: M

Reported: 23/12/2003

Weight: 0.00

Hospitalisation:

Age: 33

Onset Date:

DOB: 05/04/1970

Outcome: Recovered

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Asthma Bronchospasm Eosinophilia Hypersensitivity		Worsening of asthma, eosinophilia, hypersensitivity.	Ceased Clozaril

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	25.0 Milligram
	Daily
	Oral
Batch:	Started: 15/01/2003
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Acute episodes eosinophilla had occurred on both occasions when Clozaril given. The patient had had similar eosinophilla on two occasions in the past twelve months.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193508
Reported: 23/12/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 23

Onset Date:

DOB: 24/04/1980

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Cardiomyopathy, ejection fraction decreased.	Clozaril was to be weaned off and the patient switched to Risperidone.
Ejection fraction decreased			

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	12.5 Milligram
	Daily
	Oral
Batch:	Started: 15/10/2001
	Stopped: 31/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/12/2003	Echocardiogram				
23/12/2003	White blood cells		18/11/2003	7.90 x 10 ⁹ /L	
23/12/2003	White blood cells		26/08/2003	9.90	
23/12/2003	White blood cells		15/10/2001	8.70	

Additional Information:

Ejection fraction of 45% on echocardiogram and was diagnosed with cardiomyopathy in 2003, while on Clozaril. Clozaril was commenced 15 Oct 2001.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193531

Seq: 1

Gender: M

Reported: 24/12/2003

Weight: 0.00

Hospitalisation:

Age: 26

Onset Date: 11/12/2003

DOB: 13/07/1977

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Eosinophil count increased		Tachycardia, eosinophil count increased.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	400.0 Milligram
	Daily
	Oral
Batch:	Started: 11/11/2003
	Stopped:
	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/12/2003	Eosinophils				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2003 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193533

Seq: 1

Gender: M

Reported: 24/12/2003

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date:

DOB: 26/07/1973

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight increased, hungry. 18 Feb 2003 the patient's weight had increased by 20kg.	
Hunger			

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	400.0 Milligram
	Daily
	Oral
Batch:	Started: 16/08/2002
	Stopped:
	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information: