



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193568

Seq: 1

Gender: M

Reported: 05/01/2004

Weight: 0.00

Hospitalisation:

Onset Date: 13/12/2003

Age: 35

Outcome: Unknown

DOB: 09/03/1968

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Raised GGT, ALT, AST and LDH.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 05/10/1998	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/01/2004	ALT = SGPT		13/12/2003	645	
05/01/2004	AST = SGOT		13/12/2003	456	
05/01/2004	GGT = SGGT = GGT		13/12/2003	530	
05/01/2004	Low density		13/12/2003	348	

Additional Information:

This patient with a history of hepatitis C and alcohol abuse (6 standard drinks per day).



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Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193637 **Seq:** 1

Gender: M

Reported: 06/01/2004

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date: 09/09/2003

DOB: 18/08/1973

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain 24 kg in 19 months.	Diet and exercise. Decrease Clozapine from 450mg to 350mg.

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 11/02/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/01/2004	Other data				

Additional Information:

Motivation to lose weight was a factor.



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Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193643	Seq: 1	Gender: F
Reported: 06/01/2004		Weight: 0.00
Hospitalisation:		Age: 25
Onset Date:		DOB: 27/01/1978
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Viral infection	Caused or prolonged inpatient hospitalisation	Possible viral infection, abdominal pain, white blood cell count increased, neutrophil count increased, nausea, ALP slightly raised, albumin slightly raised.	Stemetil prn, then Maxolon and now Losec.
Abdominal pain			On 20/12/03 the patient experienced acute abdominal pain and was hospitalised. Abdominal pain resolved.
Blood albumin increased Blood alkaline phosphatase increa			

Medicine Details:

CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started: 08/09/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/01/2004	ALT = SGPT		21/12/2003	114	
06/01/2004	Albumin		21/12/2003	slightly rasied	
06/01/2004	Neutrophils		04/09/2003	4.86	
06/01/2004	Neutrophils		21/12/2003	18.58 x 10 ⁹ /L	
06/01/2004	Neutrophils		10/11/2003	8.06	
06/01/2004	Protein		21/12/2003	slightly raised	
06/01/2004	White blood cells		04/09/2003	9.00	

Additional Information:

Onset 2003.



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CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193643
Reported: 06/01/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 25
DOB: 27/01/1978
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea	Caused or prolonged inpatient hospitalisation		Patient developed nausea in Sep/2003 after commencing Clozaril.
White blood cell count decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started: 08/09/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/01/2004	White blood cells		10/11/2003	11.90	
06/01/2004	White blood cells		21/12/2003	21.30 x 10 ⁹ /L	

Additional Information:

Onset 2003.



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Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193646

Seq: 1

Gender: M

Reported: 06/01/2004

Weight: 0.00

Hospitalisation:

Onset Date: 15/11/2003

Age: 53

DOB: 11/06/1950

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug eruption	Severe	Exanthematous drug reaction.	
Rash	Severe	Rash on his arm in the 7th week after commencing Clozaril.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 28/10/2003 Stopped: 12/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/01/2004	Other data				

Additional Information:

The date of onset is not necessarily accurate but indicates that it occurred sometime in the month. Patient also taking perindopril, aspirin, pantoprazole, venlafaxine, cyproterone and diazepam.



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Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193661

Seq: 1

Gender: M

Reported: 07/01/2004

Weight: 0.00

Hospitalisation:

Age: 26

Onset Date:

DOB: 29/10/1977

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes mellitus, weight gain in excess of 60kg.	
Weight increased			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 06/09/1996 Stopped: 18/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Experienced weight gain of 60+ kilos since commencing Clozaril on 06 Sep 1996. Once Clozaril was ceased, he lost approximately 25kg in three months and the diabetes mellitus resolved.



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Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193662	Seq: 1	Gender: M
Reported: 07/01/2004		Weight: 0.00
Hospitalisation:		Age: 49
Onset Date:		DOB: 13/02/1954
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Suspected neuroleptic malignant syndrome, delirium, depressed level of consciousness, pyrexia, blood creatine phosphokinase increased.	The patient required ventilation in intensive care. No treatment other than supportive treatment was given. Clozaril was ceased. He was extubated on 29 Dec 2003 and his condition slowly improved.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason: Schizo-affective type psychos	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 29/01/2003	Stopped:	
QUILONUM SR (Suspected)		Reason:	
Tablet	1.3 Gram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/01/2004	Creatine				
07/01/2004	Neutrophils		11/11/2003	9.79	
07/01/2004	Neutrophils		20/01/2003	6.31	
07/01/2004	White blood cells		11/11/2003	12.70	
07/01/2004	White blood cells		20/01/2003	9.00	

Additional Information:



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Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193662
Reported: 07/01/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 49
DOB: 13/02/1954
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delirium	Caused or prolonged inpatient hospitalisation		
Depressed level of consciousness	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizo-affective type psychos		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 29/01/2003	Stopped:	
QUILONUM SR (Suspected)	Reason:		
Tablet	1.3 Gram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



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Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193679

Seq: 1

Gender: M

Reported: 07/01/2004

Weight: 0.00

Hospitalisation:

Age: 56

Onset Date: 11/12/2003

DOB: 07/07/1947

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure		Dilatation ventricular, dyspnoea, dilatation atrial.	
Dyspnoea			

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 08/10/2003	Stopped: 30/12/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/01/2004	Echocardiogram		11/12/2003	Enlarged left	

Additional Information:

Patient also administered: Ventolin and Perindopril.



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Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193692

Seq: 1

Gender: M

Reported: 08/01/2004

Weight: 0.00

Hospitalisation:

Age: 57

Onset Date: 31/12/2003

DOB: 09/05/1946

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse	Caused or prolonged inpatient hospitalisation	Circulatory collapse, loss of consciousness, obstructive airways disorder, lower respiratory tract infection, cough, somnolence.	Morphine and Midazolam.
Loss of consciousness	Caused or prolonged inpatient hospitalisation		
Lower respiratory tract infection	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 02/10/2000	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozaril was stopped sometime in December 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193692

Seq: 1

Gender: M

Reported: 08/01/2004

Weight: 0.00

Hospitalisation:

Age: 57

Onset Date: 31/12/2003

DOB: 09/05/1946

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Obstructive airways disorder	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	450.0 Milligram Daily Oral
Batch:	Started: 02/10/2000 Stopped:

Laboratory Investigations:

Additional Information:

Clozaril was stopped sometime in December 2003.



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Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193767	Seq: 1	Gender: M
Reported: 09/01/2004		Weight: 0.00
Hospitalisation:		Age: 25
Onset Date: 21/11/2003		DOB: 10/11/1978
Outcome: Unknown		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest discomfort	Caused or prolonged inpatient hospitalisation	Chest discomfort, ventricular dysfunction.	Ramipril. Clozaril ceased.
Cardiomyopathy	Caused or prolonged inpatient hospitalisation		
Ventricular failure	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 28/02/2000	Stopped: 28/11/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/01/2004	Echocardiogram		21/11/2003	Moderate to	

Additional Information:

Risk factors for myocardial disease: history of a viral upper respiratory tract infection and history of polysubstance abuse (e.g. marijuana, speed) and, alcohol abuse..



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Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193887	Seq: 1	Gender: M
Reported: 14/01/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 34
Onset Date: 15/11/2003		DOB: 03/03/1969
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood glucose increased		Blood glucose increased, malaise, blood cholesterol increased, blood triglycerides increased. Six week history of polydipsia, nausea, vomiting and polyuria before hospitalisation.	Treated initially with an insulin drip and Clozaril dose was reduced, commenced on oral medication (not specified)
Blood cholesterol increased	Caused or prolonged inpatient hospitalisation		
Blood triglycerides increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)		Reason:	
Tablet	100.0 Milligram	Oral	
Batch:	Started:	Stopped:	
ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 11/05/1998	Stopped: 14/12/2004	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/01/2004	Cholesterol				3 Jan 2004: 112 (03 Jan 2004): 91
14/01/2004	Creatinine				
14/01/2004	Serum glucose				
14/01/2004	Triglyceride				

Additional Information:

The patient was obese and had a history of gastroesophageal reflux and glycaemic dysregulation. The date of onset is not necessarily accurate but indicates that onset occurred sometime in the month.



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Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193887	Seq: 1	Gender: M
Reported: 14/01/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 34
Onset Date: 15/11/2003		DOB: 03/03/1969
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Malaise	Caused or prolonged inpatient hospitalisation		
Nausea			
Polydipsia			
Polyuria			
Tremor			
Vomiting			
Weight increased			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)		Reason:	
Tablet	100.0 Milligram		Oral
Batch:	Started:	Stopped:	
ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 11/05/1998	Stopped: 14/12/2004	0

Laboratory Investigations:

Additional Information:

The patient was obese and had a history of gastroesophageal reflux and glycaemic dysregulation. The date of onset is not necessarily accurate but indicates that onset occurred sometime in the month.



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Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193947 **Seq:** 1 **Gender:** F
Reported: 16/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 45
Onset Date: 06/12/2003 **DOB:** 19/08/1958
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Grand Mal Seizure	Clozaril dose was reduced

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	650.0 Milligram Daily Oral
Batch:	Started: 25/10/1996 Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/01/2004	Chest X-ray				
16/01/2004	Electroencephalog				
16/01/2004	Other data				

Additional Information:

Patient was also taking Cogentin, Pyridoxine, Thyroxine.
No past history of seizures experienced.
Clozaril treatment was continued and the dose was reduced to mg and then 550mg/day. Epilim was added and no further seizures occurred.



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Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 193968
Reported: 19/01/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 07/10/2003
Outcome: Unknown

Age: 47
DOB: 01/06/1956
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia	Caused or prolonged inpatient hospitalisation	October 2003. Patient experienced eosinophilia and cardiac complications.	Clopine ceased.
Cardiac disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 07/05/2003 Stopped: 10/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/01/2004	Haematology				

Additional Information:

The patient had been on continuous Clopine (350mg daily PO) for over 8 months until he ceased on 10 January 2004 due to the adverse events which had been ongoing since at least 7 October 2003.



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Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194007
Reported: 21/01/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 15/07/2003
Outcome: Recovered

Age: 50
DOB: 02/05/1953
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sedation	Severe	Patient experienced hypersalivation and sedation, the sedation included double incontinence during waking hours.	Clopine ceased.
Faecal incontinence	Severe		
Salivary hypersecretion	Severe		
Urinary incontinence	Severe		

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 16/06/2003 Stopped: 02/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/01/2004	Other data				

Additional Information:

Events were severe and lasted for approximately 5 months. Patient was previously on Clozaril from 11 March 2003 until June 2003.



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Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194022	Seq: 1	Gender: M
Reported: 21/01/2004		Weight: 0.00
Hospitalisation:		Age: 29
Onset Date:		DOB: 15/10/1974
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anxiety	Caused or prolonged inpatient hospitalisation	Anxiety and swallowing difficulties.	Commenced on Diazepam
Dysphagia	Caused or prolonged inpatient hospitalisation	Anxiety and swallowing difficulties.	
Ejaculation failure	Caused or prolonged inpatient hospitalisation	The patient expereinced a sensation of being unable to swallow over the christmas period. he was also unable to ejaculate but did reach orgasm	

Medicine Details:

CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	425.0 Milligram	Daily	Oral
Batch:	Started: 02/06/2000	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Alcoholism and drug abuser. Although the reporting physician believed it to be anxiety related , the swallowing difficulty was to be investigated further to rule out other possible causes. Onset Nov/Dec 2003. Non compliant over christmas 2005



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Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194023

Seq: 1

Gender: F

Reported: 21/01/2004

Weight: 0.00

Hospitalisation:

Onset Date: 19/11/2003

Age: 31

DOB: 25/08/1972

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Raised CK levels of 470.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 29/10/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/01/2004	Creatine	0 - 140 U/L	19/11/2003	470	
21/01/2004	Creatine	0 - 140 U/L	10/12/2003	120	
21/01/2004	Creatine	0 - 140 U/L	17/12/2003	300	
21/01/2004	Creatine	0 - 140 U/L	23/12/2003	320	
21/01/2004	Creatine	0 - 140 U/L	14/01/2004	610	
21/01/2004	Electrocardiograph				
21/01/2004	Troponin		19/11/2003	<0.01	

Additional Information:

The patient did not have any other signs of symptoms of cardiac or muscular nature.



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Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194024	Seq: 1	Gender: M
Reported: 21/01/2004		Weight: 0.00
Hospitalisation:		Age: 25
Onset Date: 18/11/2003		DOB: 11/01/1978
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood homocysteine increased		Thrombocytopenia, moderate homocysteinaemia and vitamin B12 deficiency.	
Thrombocytopenia		Thrombocytopenia, moderate homocysteinaemia and vitamin B12 deficiency.	Given oral Iron supplements and Vitamin B12
Vitamin B12 deficiency		Thrombocytopenia, moderate homocysteinaemia and vitamin B12 deficiency.	

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 24/01/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/01/2004	Other data	>210; deficient <	11/12/2003	109	
21/01/2004	Other data	>210; deficient <	13/01/2004	273	
21/01/2004	Other data	5.0 - 15.0	13/01/2004	22.2 umol/L	
21/01/2004	Platelets	150 -450	18/11/2003	139	
21/01/2004	Platelets	150 -450	11/12/2003	127	
21/01/2004	Platelets	150 -450	13/01/2004	107 x 10 ⁹ /L	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194025

Seq: 1

Gender: F

Reported: 21/01/2004

Weight: 0.00

Hospitalisation:

Age: 18

Onset Date: 20/11/2003

DOB: 09/05/1985

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain of approximately 20kg since commencing Clozaril on 20/11/03	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 20/11/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs taken: epilim, reboxetine, benztropine.



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Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194028

Seq: 1

Gender: M

Reported: 22/01/2004

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date: 09/10/2003

DOB: 25/06/1957

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Caused or prolonged inpatient hospitalisation	Cardiomyopathy.	Clozapine titrated over past two months to cease on 30/12/2003, commencing on amisulpride and quetiapine.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 03/09/1996 L TERM Stopped: 30/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/01/2004	Echocardiogram				

Additional Information:

Patient has been on Clopine for over 7 years. The patient has been titrated off Clozapine over the past two months to cease. Other drug therapy: mirtazapine, atorvastatin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194070
Reported: 23/01/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 06/11/2003
Outcome: Recovered

Age: 20
DOB: 08/03/1983
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinopenia	Caused or prolonged inpatient hospitalisation	Eosinophilia.	Ceased Clopine

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 17/10/2003 Stopped: 10/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/01/2004	Eosinophils		06/11/2003	4.6	
23/01/2004	Neutrophils		23/10/2003	3.3	
23/01/2004	Neutrophils		06/11/2003	6.5	
23/01/2004	Neutrophils		20/11/2003	4.9	
23/01/2004	Neutrophils		13/11/2003	9.9	
23/01/2004	White blood cells		23/10/2003	6.8	
23/01/2004	White blood cells		06/11/2003	11.5	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194070
Reported: 23/01/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 06/11/2003
Outcome: Recovered

Age: 20
DOB: 08/03/1983
Causality: Causality probable

Reaction Details:

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 17/10/2003 Stopped: 10/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/01/2004	White blood cells		13/11/2003	17.8	
23/01/2004	White blood cells		20/11/2003	8.8	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194123

Seq: 1

Gender: M

Reported: 29/01/2004

Weight: 0.00

Hospitalisation:

Onset Date: 07/10/2003

Age: 34

Outcome: Unknown

DOB: 23/08/1969

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes mellitus, blood glucose increased.	
Blood glucose increased			

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	900.0 Milligram	Daily	Oral
Batch:	Started: 29/06/1999	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/01/2004	Serum glucose		07/10/2003	15	

Additional Information:

His diabetes was considered likely to be pre-existing and not Clozapine induced. No further information was provided.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194146
Reported: 29/01/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 18/09/2003
Outcome: Recovered

Age: 34
DOB: 11/06/1969
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain upper Diarrhoea Liver function test abnormal Nausea Cholestasis		Cholestasis, abdominal pain upper, nausea, diarrhoea, liver function test abnormal.	Clozaril was ceased.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 15/07/2003	Stopped: 04/10/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/01/2004	Biochemistry				
29/01/2004	GGT = SGGT =				

Additional Information:

The patient completely recovered. he was not rechallenged on Clozaril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194164

Seq: 1

Gender: M

Reported: 30/01/2004

Weight: 0.00

Hospitalisation:

Age: 24

Onset Date:

DOB: 05/10/1979

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Movement disorder		Patient experienced a marked increase in movement disorder.	Ceased Clopine

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 24/03/2003 Stopped: 08/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194195
Reported: 02/02/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 20
DOB: 08/05/1983
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cataplexy Asthenia Electroencephalogram abnormal Hypotonia		December 2003 Cataplexy, Hypotonia, Asthenia, Drug interaction, EEG showed some spikes.	Clozaril dose to be reduced

Medicine Details:

AMISULPRIDE (Other drug)	Reason:		
400.0 Milligram	Daily		
Batch:	Started:	Stopped: 15/01/2004	
CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 28/08/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/02/2004	Electroencephalog				

Additional Information:

Clozaril dose decreased to 500mg/day and her condition improved.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194235
Reported: 03/02/2004

Seq: 1

Gender: U
Weight: 0.00
Age: 99U

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Violent ideation	Caused or prolonged inpatient hospitalisation	Violent thoughts, Withdrawl reaction.	Admitted within days.
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)	Reason: Dose Unspecified	
Batch:	Started:	Stopped:
CIPRAMIL (Suspected)	Reason: Dose Unspecified	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

An alcoholic and poly substance abuser - Cannabis and Speed.
History: Diagnosed him as not schizophrenic.
Stopped all meds and he was immediately better.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194347

Seq: 1

Gender: M

Reported: 04/02/2004

Weight: 0.00

Hospitalisation:

Onset Date: 21/01/2004

Age: 26

Outcome: Unknown

DOB: 30/04/1977

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Cardiomyopathy - dilation ventricular, ejection fraction decreased, ventricular dysfunction. Cholinergic syndrome.	Clozaril ceased
Cholinergic syndrome			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram
	Daily
	Oral
Batch:	Started: 01/07/2003
	Stopped: 23/01/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/02/2004	Echocardiogram		23/01/2004	Mildly dilated	
04/02/2004	Other data				

Additional Information:

Patient remained asymptomatic with respect to his cardiomyopathy as at 29 Jan 2004.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194412

Seq: 1

Gender: M

Reported: 09/02/2004

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date: 03/02/2004

DOB: 12/02/1978

Outcome: Death

03/02/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intentional overdose		Overdose leading to death.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	450.0 Milligram Daily Oral
Batch:	Started: 27/06/2003 Stopped: 03/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reported to have had at least forty 100mg and 25mg tablets in total and once unconscious was not able to be revived.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194443

Seq: 1

Gender: M

Reported: 09/02/2004

Weight: 0.00

Hospitalisation:

Age: 22

Onset Date:

DOB: 13/05/1981

Outcome: Unknown

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Elevated CK.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 29/07/1998	Stopped: 24/12/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/02/2004	Creatine				

Additional Information:

Daily dose was between 12.5 - 500mg / day.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194469
Reported: 10/02/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 28/01/2004
Outcome: Unknown

Age: 25
DOB: 19/12/1978
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 23/01/2004 Stopped: 28/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/02/2004	Neutrophils		28/01/2004	0.6 x 10 ⁹ L	
10/02/2004	Neutrophils		21/01/2004	2.2 x 10 ⁹ L	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194472	Seq: 1	Gender: M
Reported: 10/02/2004		Weight: 0.00
Hospitalisation:		Age: 47
Onset Date:		DOB: 02/04/1956
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis, blood creatine phosphokinase increased, hyperhidrosis.	
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 31/12/2003	Stopped:	23/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194537 **Seq:** 1 **Gender:** M
Reported: 11/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 25Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Tachycardia.	

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	650.0 Milligram Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194590

Seq: 1

Gender: M

Reported: 13/02/2004

Weight: 0.00

Hospitalisation:

Age: 23

Onset Date: 12/01/2004

DOB: 06/09/1980

Outcome: Recovered

Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 19/12/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/02/2004	Eosinophils				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194601	Seq: 1	Gender: F
Reported: 13/02/2004		Weight: 0.00
Hospitalisation:		Age: 43
Onset Date:		DOB: 05/05/1960
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cytomegalovirus infection		Patient developed a cytomegalovirus infection, with high temperature and raised monocytes and eosinophils.	
Eosinophil count increased		Patient developed a cytomegalovirus infection, with high temperature and raised monocytes and eosinophils.	
Feeling abnormal		Patient developed a cytomegalovirus infection, with high temperature and raised monocytes and eosinophils.	

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	175.0 Milligram	Daily	Oral
Batch:	Started: 19/01/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/02/2004	Other data				

Additional Information:

Onset date: 01/2002. Dose stop date: 01/2002. The monocytes and eosinophils continued rising after cessation of Clozaril, indicating that they were caused by the vial infection. Patient was already in hospital due to management of her mental state at the time of the event.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194601
Reported: 13/02/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 43
DOB: 05/05/1960
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Monocyte count increased		Patient developed a cytomegalovirus infection, with high temperature and raised monocytes and eosinophils.	
Pyrexia		Patient developed a cytomegalovirus infection, with high temperature and raised monocytes and eosinophils.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	175.0 Milligram Daily Oral
Batch:	Started: 19/01/2002 Stopped:

Laboratory Investigations:

Additional Information:

Onset date: 01/2002. Dose stop date: 01/2002. The monocytes and eosinophils continued rising after cessation of Clozaril, indicating that they were caused by the vial infection. Patient was already in hospital due to management of her mental state at the time of the event.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194666 **Seq:** 1 **Gender:** M
Reported: 16/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 27
Onset Date: **DOB:** 06/10/1976
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain		Chest pain.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 21/11/2003 Stopped: 20/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194701 **Seq:** 1 **Gender:** M
Reported: 17/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 21
Onset Date: **DOB:** 02/10/1982
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejaculation disorder		Retrograde ejaculation.	

Medicine Details:

RISPERIDONE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 01/08/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/02/2004	Serum glucose		05/01/2004	7.4	
17/02/2004	Serum glucose		08/10/2001	6.1	

Additional Information:

Past history of erectile dysfunction while on risperidone prior to commencing Clozaril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194702

Seq: 1

Gender: M

Reported: 17/02/2004

Weight: 0.00

Hospitalisation:

Age: 57

Onset Date: 12/01/2004

DOB: 23/11/1946

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ventricular extrasystoles		Ventricular extrasystoles, orthostatic hypotension 64/46 mmHg, heart rate irregular.	
Heart rate irregular			
Hypotension			
Orthostatic hypotension			

Medicine Details:

CLOZARIL (Suspected)	Reason:
	150.0 Milligram Daily
Batch:	Started: 31/12/2003 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/02/2004	Electrocardiograph				
17/02/2004	Other data				

Additional Information:

The daily dose had recently been increased from 50mg bd to 50mg mane and 100mg nocte.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194737	Seq: 1	Gender: F
Reported: 18/02/2004		Weight: 0.00
Hospitalisation:		Age: 40
Onset Date: 05/02/2004		DOB: 29/01/1964
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis, Tachycardia and Echocardiogram abnormal.	
Echocardiogram abnormal	Caused or prolonged inpatient hospitalisation		
Electrocardiogram T wave inversion	Caused or prolonged inpatient hospitalisation		

Medicine Details:

HALOPERIDOL (Other drug)		Reason:	
		Dose Unspecified	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 28/01/2004	Stopped: 05/02/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/02/2004	C-Reactive Protein				21 mg/l (NR: 0 - 8)
18/02/2004	Creatine				39, 49
18/02/2004	Electrocardiograph				T-wave inversion (V3, V4 and V5) on ECG. Consistent with myocarditis according to the cardiologist. Normal left ventricular size and systolic function; no structural heart disease. Myocardial muscle enlargement

Additional Information:

The patient was asymptomatic. Also taking Serenace, Hypnovel and Antenex. Risk factors: high cholesterol (8 mmol/l), heavy smoker and high triglycerides (2.3).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194737
Reported: 18/02/2004
Hospitalisation:
Onset Date: 05/02/2004
Outcome: Recovered

Seq: 1

Gender: F
Weight: 0.00
Age: 40
DOB: 29/01/1964
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

HALOPERIDOL (Other drug)	Reason: Dose Unspecified		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 28/01/2004	Stopped: 05/02/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/02/2004	Other data				Heart rate: 130 bpm
18/02/2004	Other data				Temperature: 35.1
18/02/2004	Troponin				<0.01

Additional Information:

The patient was asymptomatic. Also taking Serenace, Hypnovel and Antenex. Risk factors: high cholesterol (8 mmol/l), heavy smoker and high triglycerides (2.3).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194738	Seq: 1	Gender: M
Reported: 18/02/2004		Weight: 0.00
Hospitalisation:		Age: 44
Onset Date:		DOB: 08/10/1959
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Convulsion, restless legs syndrome, drug level increased, gamma-glutamyltransferase increased.	Was commenced on Diltantin. Clozaril was reduced to 300mg bd.
Drug level increased	Caused or prolonged inpatient hospitalisation		
Gamma-glutamyltransferase increas	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM (Other drug)		Reason:	
Batch:	Started:	Stopped:	Contin
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 11/07/1996	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/02/2004	GGT = SGGT =		12/02/2004	60	
18/02/2004	GGT = SGGT =		06/02/2004	160	
18/02/2004	Pharmacokinetics				

Additional Information:

Seizure within the first few weeks after Clozaril initiation.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194738
Reported: 18/02/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 44
DOB: 08/10/1959
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Restless legs syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM (Other drug)	Reason:		
Batch:	Started:	Stopped:	Contin
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 11/07/1996	Stopped:	

Laboratory Investigations:

Additional Information:

Seizure within the first few weeks after Clozaril initiation.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194745
Reported: 19/02/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 11/02/2004
Outcome: Recovered

Age: 53
DOB: 20/11/1950
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased Agranulocytosis Neutrophil count decreased	Caused or prolonged inpatient hospitalisation	Low white cell count and low neutrophil count.	Ceased Clopine. Treated with IV antibiotics, GCSF 300mcg/sc/7days, reverse barrier nursing.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 18/12/2003 Stopped: 11/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/02/2004	Neutrophils		16/12/2003	2.4	
19/02/2004	Neutrophils		14/02/2004	5.6	
19/02/2004	Neutrophils		12/02/2004	0.1	
19/02/2004	White blood cells		16/12/2003	3.8	
19/02/2004	White blood cells		14/01/2004	8.4	
19/02/2004	White blood cells		12/02/2004	1.2	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194807

Seq: 1

Gender: F

Reported: 23/02/2004

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date:

DOB: 30/10/1957

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Cardiomyopathy, ejection fraction decreased.	
Ejection fraction decreased			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 04/08/1998 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/02/2004	Echocardiogram				

Additional Information:

Patient was also taking Valproate sodium , Omeprazole.
She had an intellectual disability and a history of Rubella embroyopathy, with a bicuspid aotic valve and a heart murmur.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194873

Seq: 1

Gender: F

Reported: 24/02/2004

Weight: 0.00

Hospitalisation:

Onset Date: 07/11/2003

Age: 38

DOB: 30/08/1965

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased		WBC count decreased, accidental overdose.	
Accidental overdose			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified septicemia		
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 22/07/1994	Stopped: 07/11/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/02/2004	Neutrophils		10/11/2003	2.51	
24/02/2004	Neutrophils		07/11/2003	1.43	
24/02/2004	Neutrophils		29/10/2003	2.53	
24/02/2004	White blood cells		10/11/2003	5.70	
24/02/2004	White blood cells		09/11/2003	1.98	
24/02/2004	White blood cells		29/10/2003	4.70	

Additional Information:

Patient was also taking Metformin and Glucobay.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194875
Reported: 25/02/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 37
DOB: 22/12/1966
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mental disorder	Caused or prolonged inpatient hospitalisation	February 2004 Relapse of psychosis and depression, mental disorder, aphasia, tachycardia, pyrexia, UTI, blood creatinine phodphokinase increased.	Treated with benzodiazepines and urinary antiseptics. Clozaril was pemporarily interrupted
Aphasia	Caused or prolonged inpatient hospitalisation		
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 22/08/1996	Stopped:	11/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194875
Reported: 25/02/2004

Seq: 1

Gender: F
Weight: 0.00
Age: 37
DOB: 22/12/1966
Causality: Causality possible

Hospitalisation:

Onset Date:
Outcome: Recovered

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		
Urinary tract infection	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 22/08/1996	Stopped:	11/02/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194914
Reported: 26/02/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 15/12/2003
Outcome: Unknown

Age: 19
DOB: 09/04/1984
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level decreased	Caused or prolonged inpatient hospitalisation	Drug level decreased, disease progression, treatment noncompliance	Clozaril discontinued
Disease progression	Caused or prolonged inpatient hospitalisation		
Treatment noncompliance	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 04/06/2003	Stopped: 09/03/2004	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/02/2004	Serum drug level				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194932	Seq: 1	Gender: M
Reported: 26/02/2004		Weight: 103.00
Hospitalisation:		Age: 46
Onset Date: 19/02/2004		DOB: 14/05/1957
Outcome: Recovered	20/02/2004	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Patient presented with 3 day history of pyrexia to 41C, agitation, increased myoclonic jerks and hyperventilation.	IV rehydration and reducing Sertraline dose to 100mg.
Agitation	Caused or prolonged inpatient hospitalisation		
Hyperventilation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Interaction)		Reason: Unspecified schizophrenia
Tablet	650.0 Milligram	Daily Oral
Batch:	Started: L TERM	Stopped:
SERTRALINE HYDROCHLORIDE (Interaction)		Reason: Unspecified schizophrenia
Tablet	200.0 Milligram	Daily Oral
Batch:	Started: 15/12/2003	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pathology -> elevated CK, Trop I - ND, anaemia and thrombocytopenia. Patient also taking Clonazepam, Omeprazole, Propranolol and Ferrous Sulphate.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194932

Seq: 1

Gender: M

Reported: 26/02/2004

Weight: 103.00

Hospitalisation:

Age: 46

Onset Date: 19/02/2004

DOB: 14/05/1957

Outcome: Recovered

20/02/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myoclonus	Caused or prolonged inpatient hospitalisation		
Serotonin syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Interaction)	Reason: Unspecified schizophrenia		
Tablet	650.0 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped:	
SERTRALINE HYDROCHLORIDE (Interaction)	Reason: Unspecified schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 15/12/2003	Stopped:	

Laboratory Investigations:

Additional Information:

Pathology -> elevated CK, Trop I - ND, anaemia and thrombocytopenia. Patient also taking Clonazepam, Omeprazole, Propranolol and Ferrous Sulphate.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194985	Seq: 1	Gender: M
Reported: 27/02/2004		Weight: 0.00
Hospitalisation:		Age: 55
Onset Date:		DOB: 09/07/1948
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder	Caused or prolonged inpatient hospitalisation	Severe cardiac complications with areas of cardiac hypokinesia and 30% LVEF, lower limb peripheral myopathy. Normal echocardiogram in 2001.	ICU admission Ceased Clopine. Commenced on ramipril, sodium valproate, carvedilol, clexane.
Cardiomyopathy Myopathy			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 06/03/2002 Stopped: 09/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/02/2004	Echocardiogram				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194986

Seq: 1

Gender: M

Reported: 27/02/2004

Weight: 0.00

Hospitalisation:

Age: 18

Onset Date: 19/02/2004

DOB: 14/01/1986

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension		Hypertension and tachycardia.	ceased Clopine
Tachycardia			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 16/01/2004 Stopped: 19/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 194987 **Seq:** 1 **Gender:** M
Reported: 27/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 31
Onset Date: 21/01/2004 **DOB:** 16/11/1972
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Completed suicide Agitation Malaise Weight increased		Patient committed suicide.	

Medicine Details:

VALIUM (Suspected)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason:		
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 28/10/1996	Stopped: 18/01/2004	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/02/2004	Autopsy report				an autopsy was performed and the cause of death was suicide.

Additional Information:

Patient died 21/01/04. Patient ceased Clozaril on 18 Jan 2004 but recommenced the same day at 12.5mg bd. He suicided on the second day of recommencement.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195011

Seq: 1

Gender: M

Reported: 01/03/2004

Weight: 0.00

Hospitalisation:

Age: 35

Onset Date: 01/01/2004

DOB: 27/09/1968

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus non-insulin-depe	Caused or prolonged inpatient hospitalisation	Type 2 diabetes.	Oral hypoglycaemic medication, metformin 500mg bd.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	700.0 Milligram Daily Oral
Batch:	Started: 01/01/2002 Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195021

Seq: 1

Gender: M

Reported: 01/03/2004

Weight: 0.00

Hospitalisation:

Age: 55

Onset Date:

DOB: 11/07/1948

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Caused or prolonged inpatient hospitalisation	Cardiomyopathy, myopathy (suspected), thromboembolism (CVA).	
Embolism	Caused or prolonged inpatient hospitalisation		
Myopathy	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)	Reason: Schizophrenia
Tablet	600.0 Milligram Daily
Batch:	Started: 15/04/2000 Stopped: 09/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195061
Reported: 04/02/2004
Hospitalisation:
Onset Date: 06/02/2004
Outcome: Unknown

Seq: 1

Gender: F
Weight: 0.00
Age: 38
DOB: 29/08/1965
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea	Caused or prolonged inpatient hospitalisation	Nausea, diarrhoea vomiting, dizziness, feeling abnormal.	
Diarrhoea	Caused or prolonged inpatient hospitalisation		
Dizziness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	400.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Metformin and Glucobay.



Therapeutic Goods Administration Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195061
Reported: 04/02/2004
Hospitalisation:
Onset Date: 06/02/2004
Outcome: Unknown

Seq: 1

Gender: F
Weight: 0.00
Age: 38
DOB: 29/08/1965
Causality: Causality probable

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram 1 time Oral
Batch:	Started: Stopped: Contin

Laboratory Investigations:

Additional Information:

Patient was also taking Metformin and Glucobay.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195063
Reported: 02/03/2004
Hospitalisation:
Onset Date: 07/01/2004
Outcome: Recovered

Seq: 1

Gender: F
Weight: 0.00
Age: 20
DOB: 21/12/1983
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia	Caused or prolonged inpatient hospitalisation	Hyperglycaemia, polydipsia, tachycardia, polyuria, bronchitis, asthma, psychotic disorder.	Ceased Clozaril, treated with Prednisone 50mg per day, oral hypoglycaemics.
Asthma	Caused or prolonged inpatient hospitalisation		
Bronchitis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 28/11/2003	Stopped: 07/01/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/03/2004	ALT = SGPT	(<40)	07/01/2004	131	
02/03/2004	ALT = SGPT	(<40)	08/01/2004	109	
02/03/2004	Cholesterol	(<5.5)	08/01/2004	5.9	
02/03/2004	GGT = SGGT =	(<50)	07/01/2004	324	
02/03/2004	GGT = SGGT =	(<50)	08/01/2004	290	
02/03/2004	Haemoglobin	(<6.0%)	08/01/2004	7.5	
02/03/2004	LDH	(2.0-3.4)	08/01/2004	4.1	

Additional Information:

Patient was also taking Prednisone, Efexor, Tolvon.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195063
Reported: 02/03/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 07/01/2004
Outcome: Recovered

Age: 20
DOB: 21/12/1983
Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 28/11/2003	Stopped: 07/01/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/03/2004	SAP = ALP	(30-100)	07/01/2004	172	
02/03/2004	SAP = ALP	(30-100)	08/01/2004	158	
02/03/2004	Serum glucose	(3.0-7.8)	07/01/2004	9.2	
02/03/2004	Serum glucose	(3.0-7.8)	08/01/2004	6.6	

Additional Information:

Patient was also taking Prednisone, Efexor, Tolvon.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195063
Reported: 02/03/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 07/01/2004
Outcome: Recovered

Age: 20
DOB: 21/12/1983
Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 28/11/2003	Stopped: 07/01/2004	

Laboratory Investigations:

Additional Information:

Patient was also taking Prednisone, Efexor, Tolvon.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195128

Seq: 1

Gender: M

Reported: 04/03/2004

Weight: 0.00

Hospitalisation:

Age: 37

Onset Date:

DOB: 06/08/1966

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder Echocardiogram abnormal		October 2003 Cardiac complications.	Ceased Clopine

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 14/05/2003 Stopped: 31/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/03/2004	Echocardiogram				

Additional Information:

Patient also taking sertraline, ranitidine. Patient did not have any symptoms



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195190

Seq: 1

Gender: M

Reported: 08/03/2004

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date: 01/03/2004

DOB: 09/03/1973

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death Myocardial infarction		Death unexplained.	

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 13/03/2002	Stopped: 01/03/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195257	Seq: 1	Gender: M
Reported: 11/03/2004		Weight: 0.00
Hospitalisation:		Age: 26
Onset Date: 01/03/2004		DOB: 05/01/1978
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Caused or prolonged inpatient hospitalisation	Patient developed agranulocytosis, leucopaenia, neutropenia.	Clozaril was ceased. Given Tmentin and Gentamycin, fluconazole, nystatin mouthwash and sodium bicarbonate .
Leukopenia	Caused or prolonged inpatient hospitalisation		
Neutropenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 09/01/2004	Stopped: 01/03/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/03/2004	Neutrophils	2-7.5	08/03/2004	0.70	
11/03/2004	Neutrophils	2-7.5	05/03/2004	0.00	
11/03/2004	Neutrophils	2-7.5	09/01/2004	14.50	
11/03/2004	Neutrophils	2-7.5	01/03/2004	0.02	
11/03/2004	White blood cells	4-11	08/03/2004	3.60	
11/03/2004	White blood cells	4-11	05/03/2004	1.00	
11/03/2004	White blood cells	4-11	01/03/2004	0.50	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195257
Reported: 11/03/2004

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 26

Onset Date: 01/03/2004

DOB: 05/01/1978

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 09/01/2004	Stopped: 01/03/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/03/2004	White blood cells	4-11	09/01/2004	18.60	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195454	Seq: 1	Gender: F
Reported: 12/03/2004		Weight: 0.00
Hospitalisation:		Age: 32
Onset Date:		DOB: 28/04/1971
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatomegaly Abdominal pain Alanine aminotransferase increase Aspartate aminotransferase increa Diabetes mellitus Nausea		Enlarged liver, alanine aminotransferase increased, aspartate aminotransferase increased, nausea, abdominal pain, triglycerides elevated, diabetes mellitus, blood glucose increased.	

Medicine Details:

CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 03/06/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Hepatitis C, Emphysema, was overweight, heavy drinker and drug taker.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195726	Seq: 1	Gender: M
Reported: 19/03/2004		Weight: 0.00
Hospitalisation:		Age: 33
Onset Date:		DOB: 15/03/1971
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Depression Hallucination, auditory Obsessive-compulsive disorder Salivary hypersecretion		Convulsion (shakes and falls), auditory hallucinations, obsessive compulsive disorder, depression.	Clozaril decreased to 600mg daily, commenced on Sodium Valproate.

Medicine Details:

CLOZARIL (Interaction)		Reason: Unspecified schizophrenia	
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 19/06/2003	Stopped:	
SERTRALINE HYDROCHLORIDE (Interaction)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/03/2004	Electroencephalog				
19/03/2004	Other data				

Additional Information:

There were a total of four episodes of seizures



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195727
Reported: 19/03/2004
Hospitalisation:
Onset Date: 05/03/2004
Outcome: Unknown

Seq: 1

Gender: M
Weight: 0.00
Age: 42
DOB: 14/07/1961
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal	Caused or prolonged inpatient hospitalisation	Hepatic failure, renal insufficiency, lung empyema, right pleural effusion.	The lung abscess was treated with surgery.
Pleural effusion	Caused or prolonged inpatient hospitalisation		
Pyothorax	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 16/11/1994	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drug therapy: valproate sodium, isosorbide, atenolol, aspirin, fluoxetine, lipitor.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195727

Seq: 1

Gender: M

Reported: 19/03/2004

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date: 05/03/2004

DOB: 14/07/1961

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal failure			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 16/11/1994	Stopped:	

Laboratory Investigations:

Additional Information:

Other drug therapy: valproate sodium, isosorbide, atenolol, aspirin, fluoxetine, lipitor.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195835
Reported: 22/03/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 19
DOB: 01/06/1984
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sleep apnoea syndrome Eosinophil count increased Exercise tolerance decreased Neutrophil count increased Weight increased White blood cell count increased		Sleep apnoea, pericardial effusion, gained 40kg, white blood cell count elevated, transient elevation in eosinophils and neutrophil count increased.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started: 10/01/2003	Stopped:	Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/03/2004	Echocardiogram				
22/03/2004	Neutrophils		10/03/2004	10.61	
22/03/2004	Neutrophils		11/02/2004	7.64	
22/03/2004	Neutrophils		20/11/2003	8.87	
22/03/2004	Neutrophils		19/12/2003	7.73	
22/03/2004	Neutrophils		14/01/2004	12.86	
22/03/2004	Neutrophils		22/10/2003	9.53	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195835
Reported: 22/03/2004

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 19

DOB: 01/06/1984

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	75.0 Milligram
	Daily
	Oral
Batch:	Started: 10/01/2003
	Stopped: Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/03/2004	Neutrophils		22/09/2003	9.60	
22/03/2004	Neutrophils		25/07/2003	8.95	
22/03/2004	Neutrophils		07/01/2003	7.08	
22/03/2004	Neutrophils		04/06/2003	12.80	
22/03/2004	Neutrophils		26/06/2003	10.30	
22/03/2004	Neutrophils		21/08/2003	10.90	
22/03/2004	Neutrophils		16/10/2003	8.58	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195835
Reported: 22/03/2004

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 19

Onset Date:

DOB: 01/06/1984

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	75.0 Milligram
	Daily
	Oral
Batch:	Started: 10/01/2003
	Stopped: Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/03/2004	White blood cells		10/03/2004	15.70	
22/03/2004	White blood cells		11/02/2004	12.20	
22/03/2004	White blood cells		14/01/2004	16.40	
22/03/2004	White blood cells		19/12/2003	12.70	
22/03/2004	White blood cells		20/11/2003	14.40	
22/03/2004	White blood cells		22/10/2003	14.40	
22/03/2004	White blood cells		16/10/2003	13.40	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195835
Reported: 22/03/2004

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 19

Onset Date:

DOB: 01/06/1984

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	75.0 Milligram
	Daily
	Oral
Batch:	Started: 10/01/2003
	Stopped: Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/03/2004	White blood cells		22/09/2003	14.10	
22/03/2004	White blood cells		21/08/2003	15.10	
22/03/2004	White blood cells		25/07/2003	13.00	
22/03/2004	White blood cells		26/06/2003	15.00	
22/03/2004	White blood cells		04/06/2003	17.60	
22/03/2004	White blood cells		07/01/2003	12.20	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195836
Reported: 22/03/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 56
DOB: 29/10/1947
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dilatation ventricular	Severe	Dilated left ventricle and moderately severe systolic dysfunction.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 07/11/1997 L TERM Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/03/2004	Other data				

Additional Information:

History: Myocardial Ischaemia heart diseased and Cardiac failure congestive diagnosed in 1993.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195873	Seq: 1	Gender: F
Reported: 23/03/2004		Weight: 0.00
Hospitalisation:		Age: 53
Onset Date:		DOB: 21/05/1950
Outcome: Not yet recovered		Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	High fevers (>40 degrees celcius), abdominal discomfort and diarrhoea.	
Abdominal discomfort	Caused or prolonged inpatient hospitalisation		
Diarrhoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
	Dose Unspecified	Oral	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 16/02/2004	Stopped: 19/03/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozaril was ceased temporarily and patient recovered. When Clozaril was recommenced patient's fever returned and Clozaril was permanently ceased.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195876	Seq: 1	Gender: M
Reported: 23/03/2004		Weight: 0.00
Hospitalisation:		Age: 20
Onset Date: 10/03/2004		DOB: 22/04/1983
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Neutropenia, Leucopenia, neutrophil count increased and white blood count increased.	Treated with G-CSF.
Leukopenia	Caused or prolonged inpatient hospitalisation		
Neutrophil count increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 05/01/2004	Stopped: 10/03/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/03/2004	Neutrophils		18/03/2004	22.80 x 10 ⁹ /L	
23/03/2004	Neutrophils		11/03/2004	0.90	
23/03/2004	Neutrophils		29/12/2003	(pre-treatment	
23/03/2004	White blood cells		18/03/2004	28.70 x 10 ⁹ /L	
23/03/2004	White blood cells		11/03/2004	3.50	
23/03/2004	White blood cells		29/12/2003	(pre-treatment	

Additional Information:

History: Tuberculosis. Patient underwent treatment for tuberculosis.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195876

Seq: 1

Gender: M

Reported: 23/03/2004

Weight: 0.00

Hospitalisation:

Age: 20

Onset Date: 10/03/2004

DOB: 22/04/1983

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
White blood cell count increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 05/01/2004	Stopped:	10/03/2004

Laboratory Investigations:

Additional Information:

History: Tuberculosis. Patient underwent treatment for tuberculosis.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195919
Reported: 24/03/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 27Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Drug level increased		Patient experienced seizures.	

Medicine Details:

SOLIAN (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: Stopped:
CLOZAPINE (Suspected)	Reason:
Tablet	900.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/03/2004	Other data				

Additional Information:

Patient known to be a fast metaboliser of Clozapine experienced seizures while he was treated in monotherapy.
Reaction onset date: Oct 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195928	Seq: 1	Gender: F
Reported: 25/03/2004		Weight: 0.00
Hospitalisation:		Age: 38
Onset Date: 06/10/2003		DOB: 20/09/1965
Outcome: Recovered	13/10/2003	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness	Caused or prolonged inpatient hospitalisation	Lightheaded, slumped to the floor, remained conscious, headache and BP 80/60mmHg.	IV Fluids. Withheld Clozaril briefly.
Circulatory collapse	Caused or prolonged inpatient hospitalisation		
Headache	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LOVAN (Other drug)	Reason: Depression
20.0 Milligram	Daily
Batch:	Started: 15/09/2003 Stopped:
CLOZARIL (Suspected)	Reason: Schizophrenia
50.0 Milligram	Daily
Batch:	Started: 15/09/2003 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozaril was ceased sometime in Oct 03.
 Patient decided to stop Clozaril treatment for 1-2 weeks - psychosis relapsed - recommenced Clozaril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195928

Seq: 1

Gender: F

Reported: 25/03/2004

Weight: 0.00

Hospitalisation:

Age: 38

Onset Date: 06/10/2003

DOB: 20/09/1965

Outcome: Recovered

13/10/2003

Causality: Causality possible

Reaction Details:

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

Medicine Details:

LOVAN (Other drug)	Reason: Depression
20.0 Milligram	Daily
Batch:	Started: 15/09/2003
Stopped:	
CLOZARIL (Suspected)	Reason: Schizophrenia
50.0 Milligram	Daily
Batch:	Started: 15/09/2003
Stopped:	

Laboratory Investigations:

Additional Information:

Clozaril was ceased sometime in Oct 03.

Patient decided to stop Clozaril treatment for 1-2 weeks - psychosis relapsed - recommenced Clozaril.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195984

Seq: 1

Gender: M

Reported: 26/03/2004

Weight: 0.00

Hospitalisation:

Age: 42Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Two grand mal seizures.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
700.0 Milligram	Daily
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced two grand mal seizures after commencing Clozaril (clozapine) for schizophrenia



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195991

Seq: 1

Gender: M

Reported: 26/03/2004

Weight: 0.00

Hospitalisation:

Age: 35

Onset Date:

DOB: 16/10/1968

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myoclonus		Myoclonic jerking.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 12/03/1996	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 195992	Seq: 1	Gender: M
Reported: 26/03/2004		Weight: 0.00
Hospitalisation:		Age: 32
Onset Date: 03/03/2004		DOB: 01/01/1972
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Asthma Bronchospasm Dyspnoea Ejection fraction decreased Productive cough Upper respiratory tract infection Wheezing		Patient complained of shortness of breath and recently had a chest infection.	Treated with antibiotic Rulide. Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 11/09/2003	Stopped: 17/03/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/03/2004	Echocardiogram		15/09/2003	Baseline	
26/03/2004	Echocardiogram		17/03/2004	Echocardiogra	
26/03/2004	Serum drug level		15/03/2004	Clozapine	
26/03/2004	Troponin				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196004	Seq: 1	Gender: M
Reported: 29/03/2004		Weight: 0.00
Hospitalisation:		Age: 64
Onset Date: 16/03/2004		DOB: 06/09/1939
Outcome: Recovered		Causality: Causality probable

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 18/02/1998 Stopped: 14/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/03/2004	Neutrophils		18/02/1998	pre-treatment	
29/03/2004	Neutrophils		30/01/2004	$2.80 \times 10^9/L$	
29/03/2004	Neutrophils		14/03/2004	$1.50 \times 10^9/L$	
29/03/2004	Neutrophils		17/03/2004	$1.90 \times 10^9/L$	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196038

Seq: 1

Gender: M

Reported: 29/03/2004

Weight: 0.00

Hospitalisation:

Age: 28

Onset Date:

DOB: 30/06/1975

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizures.	Clopine was ceased for 2 days only, has now recommenced treatment on 12.5mg daily.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 03/09/2002 Stopped: 21/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196066

Seq: 1

Gender: F

Reported: 29/03/2004

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date: 24/03/2004

DOB: 06/09/1964

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased		Patient developed a low white cell count and low neutrophil count.	
Neutrophil count decreased			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 16/04/2002 L TERM Stopped: 24/03/2004 1yr 49wks 1day

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose of Clopine had been escalated from 150mg to 800mg on 2003 (800mg from 05/03/03 - 30/04/03).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196096	Seq: 1	Gender: F
Reported: 30/03/2004		Weight: 0.00
Hospitalisation:		Age: 57
Onset Date: 15/02/2004		DOB: 03/03/1946
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Small intestinal obstruction	Caused or prolonged inpatient hospitalisation	Small intestinal obstruction, psychotic disorder and abdominal symptom.	
Abdominal pain	Caused or prolonged inpatient hospitalisation		
Constipation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	550.0 Milligram	Daily	Oral
Batch:	Started: 10/05/2000	Stopped: 03/05/2004	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced two occurrences of small bowel obstruction in 2004 while on Clorazil. The small bowel obstruction was considered either due to adhesions after surgery or due to Clozaril treatment. Clozaril was commenced on 25 January 1996, was ceased May 1996 (reason not given), and was recommenced on 10 May 2000. Clozapine was recommenced on 14 May 2004 and discontinued on 2 Nov 2004 due to ongoing bowel problems.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196096
Reported: 30/03/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 15/02/2004
Outcome: Recovered

Age: 57
DOB: 03/03/1946
Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	550.0 Milligram	Daily	Oral
Batch:	Started: 10/05/2000	Stopped: 03/05/2004	0

Laboratory Investigations:

Additional Information:

Patient experienced two occurrences of small bowel obstruction in 2004 while on Clorazil. The small bowel obstruction was considered either due to adhesions after surgery or due to Clozaril treatment. Clozaril was commenced on 25 January 1996, was ceased May 1996 (reason not given), and was recommenced on 10 May 2000. Clozapine was recommenced on 14 May 2004 and discontinued on 2 Nov 2004 due to ongoing bowel problems.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196160 **Seq:** 1 **Gender:** M
Reported: 02/04/2004 **Weight:** 0.00
Hospitalisation: **Age:** 27
Onset Date: 20/02/2004 **DOB:** 03/12/1976
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Patient developed tachycardia with a heart rate of 120 bpm.	

Medicine Details:

AMITRIPTYLINE HYDROCHLORIDE (Interaction)		Reason:	
		Dose Unspecified	Oral
Batch:	Started:	Stopped:	
CLOZARIL (Interaction)		Reason: Schizophrenia	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 20/08/2001	Stopped: 01/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/04/2004	Other data		20/02/2004	Heart rate of 120 bpm	

Additional Information:

Clozaril was ceased in approx 01/2002 and was recommenced on 27/10/2003



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196192 **Seq:** 1 **Gender:** M
Reported: 02/04/2004 **Weight:** 0.00
Hospitalisation: **Age:** 19
Onset Date: **DOB:** 28/09/1984
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure and increased seizures.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 09/10/2003	Stopped: 19/03/2004	163 days

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196244 **Seq:** 1 **Gender:** F
Reported: 05/04/2004 **Weight:** 0.00
Hospitalisation: **Age:** 81
Onset Date: 05/03/2004 **DOB:** 10/11/1922
Outcome: Recovered 10/03/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension Balance disorder Hyperhidrosis Pyrexia Sedation		Postural hypotension, sedation.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 03/03/2004 Stopped: 06/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drug therapy taken: entacapone, madopar.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196245
Reported: 05/04/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 13/03/2004
Outcome: Unknown

Age: 31
DOB: 25/05/1972
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizures, increased drug level.	Clopine dose reduced to 300mg daily in addition to Valproate.
Drug level increased			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 18/11/2002 Stopped: Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/04/2004	Serum drug level		13/03/2004	3545	

Additional Information:

Patient also taking Haloperidol and is a known Codeine abuser.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196247

Seq: 1

Gender: F

Reported: 05/04/2004

Weight: 0.00

Hospitalisation:

Age: 32

Onset Date: 23/03/2004

DOB: 17/03/1972

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin I increased		Troponin level increased.	Clopine was discontinued.

Medicine Details:

CLOPIXOL (Other drug)	Reason: Unspecified psychosis		
Injection	150.0 Milligram	Weekly	Intramuscular
Batch:	Started: 16/01/2004	Stopped:	
CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 25/02/2004	Stopped: 23/03/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/04/2004	Troponin		23/03/2004	Troponin I leve	

Additional Information:

History of amphetamine dependence.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196295

Seq: 1

Gender: M

Reported: 06/04/2004

Weight: 0.00

Hospitalisation:

Onset Date: 04/02/2004

Age: 28

Outcome: Unknown

DOB: 13/05/1975

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Creatine kinase increased. Asymptomatic	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 16/03/1999	Stopped:	contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/04/2004	Creatine		13/02/2004	200	
06/04/2004	Creatine		04/04/2004	340	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196368

Seq: 1

Gender: M

Reported: 08/04/2004

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date: 25/03/2004

DOB: 06/12/1978

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Haemolytic anaemia		Haemolytic anaemia.	Ceased Clopine

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	175.0 Milligram Daily Oral
Batch:	Started: 17/09/2003 Stopped: 25/04/0304

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196379

Seq: 1

Gender: M

Reported: 08/04/2004

Weight: 0.00

Hospitalisation:

Age: 40

Onset Date: 08/03/2004

DOB: 18/09/1963

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder Cardiac output decreased		Cardiac complications	Clopine ceased

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 29/04/2002 Stopped: 08/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drug therapy atorvastatin, lansoprazole.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196387
Reported: 13/04/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 35
DOB: 12/08/1968
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	Caused or prolonged inpatient hospitalisation	Ocoter 2003 Tardive dyskinesia	Amantadine and vitamin E

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 27/03/2004	Stopped:	
HALOPERIDOL (Suspected)	Reason:		
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

In Nov/Dec 2003 haloperidol was ceased (reason not specified) and the tardive dyskinesia become more exacerbated.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196406
Reported: 13/04/2004
Hospitalisation:
Onset Date: 23/03/2004
Outcome: Unknown

Seq: 1

Gender: M
Weight: 0.00
Age: 29
DOB: 09/01/1975
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia	Caused or prolonged inpatient hospitalisation	Involuntary shuddering and jerks of head, neck, shoulders, arms, clenched fists, slurring speech, staggering and could not be roused for a short period.	
Depressed level of consciousness	Caused or prolonged inpatient hospitalisation		
Drug withdrawal syndrome			
Dysarthria			
Gait disturbance			

Medicine Details:

EPILIM (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	400.0 Milligram
Batch:	Daily
	Oral
	Started: 21/01/2002
	Stopped: 22/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/04/2004	Other data				
13/04/2004	Serum drug level	350-700			

Additional Information:

The patient had a history of seizures, substance abuse, heavy smoking and heavy caffeine intake. Urine screens were negative for substance abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196465

Seq: 1

Gender: F

Reported: 14/04/2004

Weight: 0.00

Hospitalisation:

Age: 56

Onset Date: 16/03/2004

DOB: 22/06/1947

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal necrosis	Caused or prolonged inpatient hospitalisation	Gastrointestinal necrosis, colostomy, pyrexia, subcutaneous abscess, deep vein thrombosis.	Warfarin, admitted to intensive care and a colostomy was performed, gentamycin every second day.
Urinary tract infection	Caused or prolonged inpatient hospitalisation	UTI and other chronic infections	
Blood glucose increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 19/08/2003	Stopped: 01/09/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Cause of death unknown



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196465

Seq: 1

Gender: F

Reported: 14/04/2004

Weight: 0.00

Hospitalisation:

Age: 56

Onset Date: 16/03/2004

DOB: 22/06/1947

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Deep vein thrombosis	Caused or prolonged inpatient hospitalisation		
Gastrointestinal haemorrhage	Caused or prolonged inpatient hospitalisation		
Haemoglobin decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 19/08/2003	Stopped: 01/09/2006	

Laboratory Investigations:

Additional Information:

Cause of death unknown



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196465

Seq: 1

Gender: F

Reported: 14/04/2004

Weight: 0.00

Hospitalisation:

Onset Date: 16/03/2004

Age: 56

DOB: 22/06/1947

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation		
Sepsis	Caused or prolonged inpatient hospitalisation		
Subcutaneous abscess	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 19/08/2003	Stopped: 01/09/2006	

Laboratory Investigations:

Additional Information:

Cause of death unknown



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196465 **Seq:** 1 **Gender:** F
Reported: 14/04/2004 **Weight:** 0.00
Hospitalisation: **Age:** 56
Onset Date: 16/03/2004 **DOB:** 22/06/1947
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
White blood cell count increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 19/08/2003 Stopped: 01/09/2006

Laboratory Investigations:

Additional Information:

Cause of death unknown



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196514
Reported: 16/04/2004
Hospitalisation:
Onset Date: 31/03/2004
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 30
DOB: 08/03/1974
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intentional overdose	Caused or prolonged inpatient hospitalisation	Overdose of Clozaril, mild neutropenia.	Monitored for symptoms of overdose. Clozaril was recommenced on 07/04/04 on 12.5mg/day.
Neutropenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 25/09/2003 L TERM Stopped: 04/04/2004 193 days

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/04/2004	Neutrophils		07/04/2004	3.16 x 10 ⁹ /L	
16/04/2004	Neutrophils		31/03/2004	1.92	
16/04/2004	White blood cells		07/04/2004	5.80 x 10 ⁹ /L	
16/04/2004	White blood cells		31/03/2004	4.60	

Additional Information:

Patient had a history of overdose on Temazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196515

Seq: 1

Gender: F

Reported: 16/04/2004

Weight: 0.00

Hospitalisation:

Age: 37

Onset Date: 03/04/2004

DOB: 23/11/1966

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Agranulocytosis, concurrent infection, viral infection, body temperature increased.	Patient already in hospital.
Body temperature increased			
Infection			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	750.0 Milligram Daily Oral
Batch:	Started: 27/03/2000 L TERM Stopped: 03/04/2004 1469 days

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/04/2004	Neutrophils		13/04/2004	2.50 x 10 ⁹ /L	
16/04/2004	Neutrophils		03/04/2004	0.43	
16/04/2004	Neutrophils		04/11/1996	pre-treatment	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196573
Reported: 19/04/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 12/03/2004
Outcome: Recovered

Age: 66
DOB: 28/10/1937
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia	Life threatening	Life-threatening cardiac arrhythmia.	Clozaril ceased.

Medicine Details:

VERAPAMIL HYDROCHLORIDE (Other drug)	Reason:
Batch:	Dose Unspecified Oral
Started:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	550.0 Milligram Daily Oral
Batch:	Started: 17/01/1997 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset date: 03/2004. Patient with pre-existing problems developed a life-threatening cardiac arrhythmia not specified. Current condition: Cardiac disorder and pre-existing heart problems.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196579

Seq: 1

Gender: M

Reported: 19/04/2004

Weight: 0.00

Hospitalisation:

Age: 48

Onset Date:

DOB: 02/09/1955

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Patient experienced abnormal liver function tests.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 26/11/2001 L TERM Stopped: 14/04/2004 2yrs 20w 1day

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196599

Seq: 1

Gender: M

Reported: 19/04/2004

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date: 19/03/2004

DOB: 16/08/1969

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Feet swollen and red, unwell, pitting oedema bilateral to the knee.	Ceased Clozaril
Malaise			
Oedema			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 24/01/2003	Stopped: 28/03/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Coloxyl with senna and Diazepam.
July 1998 previous trial of Clozapine, stopped because of hypotension and tachycardia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196669

Seq: 1

Gender: F

Reported: 21/04/2004

Weight: 0.00

Hospitalisation:

Age: 38

Onset Date:

DOB: 29/08/1965

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Influenza like illness		April 2003 A mild flu like illness, floridy spychotic	
Psychotic disorder			

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	550.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozaril reintroduced in April 2003



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196674

Seq: 1

Gender: M

Reported: 21/04/2004

Weight: 0.00

Hospitalisation:

Onset Date: 10/04/2004

Age: 40

DOB: 22/07/1963

Outcome: Unrelated death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Leucopenia and neutropenia.	
Neutropenia			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	325.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped: Ongoing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/04/2004	Neutrophils		02/03/2004	22.0 x 10 ⁹ L	
21/04/2004	Neutrophils		10/04/2004	0.1 x 10 ⁹ L	
21/04/2004	White blood cells		02/03/2004	22.6 x 10 ⁹ L	
21/04/2004	White blood cells		10/04/2004	0.1 x 10 ⁹ L	

Additional Information:

History: Burkett's lymphoma.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196720

Seq: 1

Gender: F

Reported: 22/04/2004

Weight: 0.00

Hospitalisation:

Age: 31

Onset Date: 09/03/2004

DOB: 10/09/1972

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Caused or prolonged inpatient hospitalisation	Cardiomyopathy, hypertension, feeling abnormal, heart rate increased, cold sweat, chest pain, mild renal impairment and hypotension.	4mg perindopril and 25 mg bd Metoprolol. She was reviewed as an outpatient and it was decided to taper off Clozaril over a couple of weeks with view to cease. Perindopril was decreased again to 2mg/day and Metoprolol continued unchanged.

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	550.0 Milligram Daily Oral
Batch:	Started: 21/02/2000 Stopped: 13/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/04/2004	Blood pressure		09/03/2004	210/145	
22/04/2004	Echocardiogram				
22/04/2004	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196720

Seq: 1

Gender: F

Reported: 22/04/2004

Weight: 0.00

Hospitalisation:

Onset Date: 09/03/2004

Age: 31

DOB: 10/09/1972

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation		
Cold sweat	Caused or prolonged inpatient hospitalisation		
Feeling abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	550.0 Milligram Daily Oral
Batch:	Started: 21/02/2000 Stopped: 13/04/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196720

Seq: 1

Gender: F

Reported: 22/04/2004

Weight: 0.00

Hospitalisation:

Age: 31

Onset Date: 09/03/2004

DOB: 10/09/1972

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension	Caused or prolonged inpatient hospitalisation		
Hypotension	Caused or prolonged inpatient hospitalisation		
Renal impairment	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	550.0 Milligram Daily Oral
Batch:	Started: 21/02/2000 Stopped: 13/04/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196720

Seq: 1

Gender: F

Reported: 22/04/2004

Weight: 0.00

Hospitalisation:

Age: 31

Onset Date: 09/03/2004

DOB: 10/09/1972

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	550.0 Milligram Daily Oral
Batch:	Started: 21/02/2000 Stopped: 13/04/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196776

Seq: 1

Gender: F

Reported: 23/04/2004

Weight: 0.00

Hospitalisation:

Onset Date: 14/04/2004

Age: 22

DOB: 03/08/1981

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Increase in heart rate from 60 - 70 to 120 bpm, blood pressure was 110/70 at baseline and was now 140/100	Propranolol.
Blood pressure increased			

Medicine Details:

FLUPENTHIXOL DECANOATE (Other drug)	Reason:	
Batch:	Started:	Stopped:
BENZTROPINE MESYLATE (Suspected)	Reason:	
	Dose Unspecified	
Batch:	Started:	Stopped:
CLOZARIL (Suspected)	Reason: Schizophrenia	
Tablet	25.0 Milligram	Alternate days Oral
Batch:	Started: 23/03/2004	Stopped: Ongoing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/04/2004	Blood pressure				
23/04/2004	Electrocardiograph		05/04/2004	ECG showed	
23/04/2004	Electrocardiograph		29/03/2004	ECG showed	

Additional Information:

Onset date: 04/2004.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196778
Reported: 23/04/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 15/03/2002
Outcome: Recovered

Age: 28
DOB: 21/06/1973
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus insulin-depender	Caused or prolonged inpatient hospitalisation	Diabetes, weight gain, hypersalivation, oversedation, diabetic ketoacidosis.	Clozaril ceased. Treated with mixtard 30/70
Diabetic ketoacidosis	Caused or prolonged inpatient hospitalisation		
Hyperglycaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 13/05/2001 L TERM Stopped: 20/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drug therapy valproate sodium, diane-35, thyroxine. She was non-diabetic prior to clozaril treatment and had a family history of maternal non-insulin dependant diabetes mellitus. The patient also suffered from severe obesity.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196778

Seq: 1

Gender: F

Reported: 23/04/2004

Weight: 0.00

Hospitalisation:

Age: 28

Onset Date: 15/03/2002

DOB: 21/06/1973

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion			
Sedation			
Weight increased			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 13/05/2001 L TERM Stopped: 20/12/2003

Laboratory Investigations:

Additional Information:

Other drug therapy valproate sodium, diane-35, thyroxine. She was non-diabetic prior to clozaril treatment and had a family history of maternal non-insulin dependant diabetes mellitus. The patient also suffered from severe obesity.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196817 **Seq:** 1 **Gender:** U
Reported: 27/04/2004 **Weight:** 0.00
Hospitalisation: **Age:** 29Y
Onset Date: 06/04/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anxiety Agitation Hallucination Tension		Anxiety, agitation and hallucinations. Felt like "time bombs waiting to go off"	Ceased haloperidol

Medicine Details:

SEROQUEL (Other drug)	Reason: Schizophrenia
1.4 Gram	Daily
Batch:	Started: Stopped:
PROZAC (Other drug)	Reason: Depression
60.0 Milligram	Daily
Batch:	Started: Stopped:
HALOPERIDOL (Suspected)	Reason: Unspecified psychosis
5.0 Milligram	Daily
Batch:	Started: Stopped: 07/04/2004
CLOZAPINE (Suspected)	Reason: Unspecified psychosis
100.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced hallucinations similar to when he used to take LSD or ecstasy



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196817

Seq: 1

Gender: U

Reported: 27/04/2004

Weight: 0.00

Hospitalisation:

Age: 29Y

Onset Date: 06/04/2004

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLONAZEPAM (Suspected)

Reason: Unspecified psychosis

6.0 Milligram

Daily

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:

Patient experienced hallucinations similar to when he used to take LSD or ecstasy



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196827	Seq: 1	Gender: M
Reported: 27/04/2004		Weight: 0.00
Hospitalisation:		Age: 33
Onset Date: 15/01/2004		DOB: 15/08/1970
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal	Treated in outpatient department only	Ataxia, abnormal gait, abnormal coordination, multiple falls. Wide based gait with legs collapsing beneath him suddenly. Utensils and cigarettes falling out of hands suddenly while using them. The reactions occur in clusters usually when the patient is physically unwell with a chest infection.	
Drug level increased	Treated in outpatient department only	Clozapine level noted to be high prior to admission to hospital for chest infection. 5.1micromol/L	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
OMEPRAZOLE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOPINE (Suspected)	Reason:
Tablet	450.0 Milligram
Batch:	Daily
	Oral
	Started: 04/04/2003
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196827

Seq: 1

Gender: M

Reported: 27/04/2004

Weight: 0.00

Hospitalisation:

Age: 33

Onset Date: 15/01/2004

DOB: 15/08/1970

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Fall Gait disturbance			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
OMEPRAZOLE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOPINE (Suspected)	Reason:		
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 04/04/2003	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196912 **Seq:** 1
Reported: 29/04/2004

Gender: U
Weight: 0.00

Hospitalisation:

Onset Date: 18/04/2004
Outcome: Not yet recovered

Age: 33
DOB: 02/11/1970
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Tachycardia	Ceased Clozapine. Patient has been referred to a cardiologist.

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	150.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/04/2004	Electrocardiograph				

Additional Information:

The patient had been restarted on Clozapine for a third time, he stopped because of lack of effect the first time and ceased due to tachycardia the second time, and has once again developed tachycardia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196921
Reported: 30/04/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 15/12/2003
Outcome: Recovered

Age: 48
DOB: 30/10/1955
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		3 seizures from December 2003 to March 2004	Clozaril ceased. Treated with unspecified anti-epileptics.
Treatment noncompliance			

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	1.0 Dose Unspecified Daily Oral
Batch:	Started: 14/09/2003 S TERM Stopped: 26/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had 3 seizures from December 2003 to March 2004



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196950
Reported: 13/04/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 16/12/2003
Outcome: Recovered

Age: 25
DOB: 18/10/1978

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myoclonic epilepsy		Focal offset epilepsy manifesting as myoclonus, hallucination visual, dyskinesia, loss of consciousness, blood creatine phosphokinase increased, drug level increased, neutrophil count decreased, white blood cell count decreased, ovarian cyst and lower limb jerking.	Commenced on Lamotrigine 25mg. Clozaril ceased.
Blood creatine phosphokinase increased			
Drug level increased			
Dyskinesia			
Hallucination, visual			

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 10/12/2003	Stopped: 25/03/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/04/2004	Creatine kinase	<25	19/12/2003	19	
13/04/2004	Creatine kinase	<25	17/12/2003	26	
13/04/2004	Creatine kinase	<25	16/12/2003	29	
13/04/2004	Creatine	<145	02/04/2004	138	
13/04/2004	Creatine	<145	19/12/2003	330	
13/04/2004	Creatine	<145	17/12/2003	575	
13/04/2004	Creatine	<145	16/12/2003	638	

Additional Information:

Coeliac disease diagnosed in late 2002.
Patient also taking Quilonum and Efexor XR.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196950
Reported: 13/04/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 16/12/2003
Outcome: Recovered

Age: 25
DOB: 18/10/1978
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Loss of consciousness			
Neutrophil count decreased			
Ovarian cyst			
White blood cell count decreased			

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 10/12/2003	Stopped: 25/03/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/04/2004	Electroencephalog				
13/04/2004	Lymphocytes	1.5-4.0	31/03/2004	1.4	
13/04/2004	Lymphocytes	1.5-4.0	25/03/2004	0.8	
13/04/2004	Lymphocytes	1.5-4.0	26/03/2004	1.0	
13/04/2004	Neutrophils		31/03/2004	2.60	
13/04/2004	Neutrophils		28/03/2004	1.20	
13/04/2004	Neutrophils		25/03/2004	0.80	

Additional Information:

Coeliac disease diagnosed in late 2002.
Patient also taking Quilonum and Efexor XR.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196950
Reported: 13/04/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 16/12/2003
Outcome: Recovered

Age: 25
DOB: 18/10/1978
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 10/12/2003	Stopped: 25/03/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/04/2004	Other data				
13/04/2004	White blood cells		31/03/2004	4.30	
13/04/2004	White blood cells		28/03/2004	3.10	
13/04/2004	White blood cells		25/03/2004	1.90	

Additional Information:

Coeliac disease diagnosed in late 2002.
Patient also taking Quilonum and Efexor XR.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196968

Seq: 1

Gender: M

Reported: 03/05/2004

Weight: 0.00

Hospitalisation:

Age: 51

Onset Date: 26/04/2004

DOB: 09/06/1952

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin increased		Cardiac troponin increased, sedation and creatine kinase increased.	Clozapine dose reduced to 200mg daily.
Blood creatine phosphokinase increased			
Sedation			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 09/04/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/05/2004	Troponin				

Additional Information:

Other drug therapy taken: caltrate, prednisolone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 196987 **Seq:** 1 **Gender:** M
Reported: 03/05/2004 **Weight:** 0.00
Hospitalisation: **Age:** 21
Onset Date: **DOB:** 10/01/1983
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Blood pressure increased Neutrophil count increased White blood cell count increased		Persistent tachycardia, Blood pressure increased, white blood cell count increased and neutrophil count increased.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 18/02/2004	Stopped:	Ongoing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/05/2004	Neutrophils		20/04/2004	22.81x10 ⁹ /L	
03/05/2004	White blood cells		20/04/2004	26.10x10 ⁹ /L	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197002

Seq: 1

Gender: M

Reported: 04/05/2004

Weight: 0.00

Hospitalisation:

Age: 29

Onset Date: 20/04/2004

DOB: 02/03/1975

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sinus tachycardia		Sinus Tachycardia, dyspnoea and fatigue.	Clozaril was gradually decreased to 200mg and was then ceased on 13 may 2004
Dyspnoea			
Fatigue			

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	950.0 Milligram	Daily	Oral
Batch:	Started: 23/10/2000	Stopped: 13/05/2004	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197109

Seq: 1

Gender: F

Reported: 07/05/2004

Weight: 125.00

Hospitalisation:

Age: 34

Onset Date: 21/02/2004

DOB: 14/01/1970

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased Asthma		Drug level increased, asthma attack.	

Medicine Details:

WARFARIN SODIUM (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason:		
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 09/10/2001	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Efexor, Topamax, Serenase.

Patient died 22/2/04.

The cause of death unknown the police are still investigating. The coroners report was pending.

Increased Clozapine level found on autopsy report.

The patients schizophrenia was described as chronic/paranoid. She had a history of morbid obesity, severe asthma and deep venous thrombosis/pulmonary embolism.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197155
Reported: 10/05/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 01/05/2004
Outcome: Recovered

04/05/2004

Age: 39
DOB: 20/02/1965
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin I increased Body temperature increased Electrocardiogram abnormal Eosinophilia Heart rate increased Influenza like illness		Increased troponin levels, ST changes in ECG	Clopine ceased

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified psychosis		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 15/04/2004	Stopped: 04/05/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/05/2004	Electrocardiograph				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197185

Seq: 1

Gender: F

Reported: 10/05/2004

Weight: 0.00

Hospitalisation:

Age: 60

Onset Date:

DOB: 22/10/1943

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Tachycardia.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 06/04/2004 Stopped: 20/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197308
Reported: 13/05/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 03/05/2004
Outcome: Recovered

Age: 36
DOB: 16/04/1968
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic enzyme increased		Rapid high increase in liver transaminases since baseline, spiking temperatures, tachycardia, T-wave abnormality on ECG.	Clozaril ceased.
Electrocardiogram T wave abnorm			
Pyrexia			
Tachycardia			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.5 Milligram 5 times Oral
Batch:	Started: 15/04/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197327

Seq: 1

Gender: F

Reported: 13/05/2004

Weight: 0.00

Hospitalisation:

Age: 35

Onset Date: 07/04/2004

DOB: 08/07/1968

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus Blood cholesterol increased Blood triglycerides increased Fatigue High density lipoprotein decreased		Diabetes mellitus, blood cholesterol increased, high density lipoprotein decreased and blood triglycerides increased.	Diet and exercise

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started: 08/08/2000	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/05/2004	Cholesterol				
13/05/2004	Serum glucose				
13/05/2004	Triglyceride				

Additional Information:

Patient also taking Valproate Sodium and Zocor.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197328

Seq: 1

Gender: F

Reported: 13/05/2004

Weight: 0.00

Hospitalisation:

Age: 28

Onset Date: 09/09/2003

DOB: 20/02/1975

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes mellitus.	Diet and exercise.
Fatigue			
Hyperglycaemia			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	475.0 Milligram Daily Oral
Batch:	Started: 10/10/1994 Stopped: Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/05/2004	Serum glucose				

Additional Information:

Patient also taking Sodium Valproate and Aropax.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197329
Reported: 13/05/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 30/03/2004
Outcome: Unknown

Age: 99U
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes mellitus.	Diet and exercise.

Medicine Details:

ZOCOR (Other drug)	Reason:
Batch:	Started:
Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	350.0 Milligram
	Daily
	Oral
Batch:	Started: 28/04/2003
	Stopped: Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/05/2004	Serum glucose				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197331
Reported: 13/05/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 02/09/2003
Outcome: Unknown

Age: 33
DOB: 12/04/1970
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus Blood glucose increased Blood triglycerides increased		Diabetes mellitus and blood triglycerides increased, blood glucose increased.	Diet and exercise.

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 01/09/1994 Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/05/2004	Cholesterol		10/10/2003	4.8	
13/05/2004	Serum glucose				
13/05/2004	Triglyceride		10/10/2003	4.6	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197379

Seq: 1

Gender: M

Reported: 14/05/2004

Weight: 0.00

Hospitalisation:

Age: 59

Onset Date: 27/04/2004

DOB: 13/06/1944

Outcome: Death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death		Unexplained death	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	700.0 Milligram Daily Oral
Batch:	Started: 21/01/2004 S TERM Stopped: 27/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died 27/04/04.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197385

Seq: 1

Gender: M

Reported: 17/05/2004

Weight: 0.00

Hospitalisation:

Onset Date: 12/09/2003

Age: 20

Outcome: Unknown

DOB: 15/06/1983

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level decreased		Drug level decreased.	
Drug level decreased		Very low clozapine level	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 21/07/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/05/2004	Pharmacokinetics				

Additional Information:

The doctor was unsure as to whether the patient was compliant with the taking of Clozaril. Clozaril treatment continued on an unchanged dose of 500 mg/day. Patient was also taking Omeprazole, wart and Anti-corn preparations, Clonazepam, Propanolol, Seretide.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197386
Reported: 17/05/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 03/05/2004
Outcome: Recovered

Age: 29
DOB: 11/11/1974
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal Chest pain Electrocardiogram T wave inversion Palpitations Sinus tachycardia		ST changes and T wave inversion. Sinus tachycardia	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram
	Daily
	Oral
Batch:	Started: 15/04/2004
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/05/2004	Electrocardiograph				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197405
Reported: 17/05/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 30/04/2004
Outcome: Unknown

Age: 37
DOB: 17/08/1966
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia		Hyperglycaemia	Clozapine ceased. Treated with actrapid, metformin and amatyl

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	375.0 Milligram Daily Oral
Batch:	Started: 15/04/2004 Stopped: 03/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/05/2004	Other data				
17/05/2004	Serum glucose		01/05/2004	32 mmol/l	

Additional Information:

Other drug therapy ranitidine, valproate sodium.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197407

Seq: 1

Gender: F

Reported: 17/05/2004

Weight: 0.00

Hospitalisation:

Age: 32Y

Onset Date: 03/05/2004

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia (mild)	

Medicine Details:

CLOZAPINE (Suspected)	Reason: Schizophrenia		
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 02/05/2003	L TERM	Stopped: 03/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197443

Seq: 1

Gender: M

Reported: 18/05/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia		Thrombocytopenia	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/05/2004	Platelets				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197456	Seq: 1	Gender: M
Reported: 19/05/2004		Weight: 0.00
Hospitalisation:		Age: 25
Onset Date: 13/04/2004		DOB: 28/11/1978
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal Sinus tachycardia Leukocytosis White blood cell count increased		Blood albumin increased, ALT increased. Sinus tachycardia, elevated liver function tests, white blood cell count elevated.	Epilim and Lovan were ceased and Olanzapine was decreased to 20mg/day.

Medicine Details:

EPILIM (Suspected)	Reason:
Batch:	Started:
Batch:	Stopped:
OLANZAPINE (Suspected)	Reason:
Batch:	Started:
Batch:	Stopped:
LOVAN (Suspected)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	225.0 Milligram Daily Oral
Batch:	Started: 06/04/2004 Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/05/2004	Albumin	35-45	19/04/2004	51	
19/05/2004	Electrocardiograph		13/04/2004	Serial ECG's	
19/05/2004	GGT = SGGT =	7-64	19/04/2004	42	
19/05/2004	Haemoglobin	120-180	19/04/2004	170	
19/05/2004	Platelets	150-450	19/04/2004	251	
19/05/2004	SAP = ALP	30-120	19/04/2004	30	

Additional Information:

Medically significant.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197457
Reported: 19/05/2004
Hospitalisation:
Onset Date: 14/04/2004
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 45
DOB: 28/08/1958
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sedation		Patient complained of not being able to carry out his day to day activities due to sedation, and he spent long periods in his bed, nausea	Clozaril discontinued. Treated with maxolon
Nausea			

Medicine Details:

FLUPENTHIXOL DECANOATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 08/04/2004	Stopped: 22/04/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Involved persistent or significant disability or incapacity.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197458	Seq: 1	Gender: M
Reported: 19/05/2004		Weight: 0.00
Hospitalisation: Required a specialist consultation		Age: 25
Onset Date: 16/04/2004		DOB: 13/12/1978
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia	Severe	Patient developed severe thrombocytopenia.	No treatment was necessary and the patient had a haematology consult and continued blood count monitoring.

Medicine Details:

METHADONE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	450.0 Milligram Daily Oral
Batch:	Started: 25/03/2004 Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/05/2004	Platelets	150-400	15/12/2003	pre-treatment	
19/05/2004	Platelets	150-400	16/04/2004	31 x 10 ⁹ /L	
19/05/2004	Platelets	150-400	04/05/2004	66 x 10 ⁹ /L	

Additional Information:

Patient was an inpatient at a hospice.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197529	Seq: 1	Gender: F
Reported: 21/05/2004		Weight: 0.00
Hospitalisation:		Age: 51
Onset Date: 15/02/2004		DOB: 01/02/1953
Outcome: Recovered without treatment		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gait disturbance	Caused or prolonged inpatient hospitalisation	Gait disturbance, falls and lower limb weakness.	No treatment necessary.
Fall	Caused or prolonged inpatient hospitalisation		
Muscular weakness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 28/02/2003	Stopped: 26/03/2004	393 days

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197584	Seq: 1	Gender: M
Reported: 26/05/2004		Weight: 0.00
Hospitalisation:		Age: 30
Onset Date: 15/05/2004		DOB: 30/06/1973
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Viral infection Chest pain Ejection fraction decreased Electrocardiogram ST segment ele Fatigue Influenza Myocarditis	Caused or prolonged inpatient hospitalisation	Patient experienced a viral infection prior to developing symptoms of suspected myocarditis, pyrexia, fatigue, troponin increased, ECG ST elevated, ejection fraction decreased, chest pain, palpitations, tachycardia, influenza.	Clozaril ceased. Treated with aspirin and metoprolol.

Medicine Details:

SOLIAN (Other drug)	Reason:
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	125.0 Milligram Daily Oral
Batch:	Started: 28/04/2004 S TERM Stopped: 15/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/05/2004	Electrocardiograph				
26/05/2004	Troponin		16/05/2004	>50	
26/05/2004	Troponin		15/05/2004	11	
26/05/2004	Troponin		10/05/2004	not detected	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197584
Reported: 26/05/2004
Hospitalisation:
Onset Date: 15/05/2004
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 30
DOB: 30/06/1973
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Palpitations Pyrexia Tachycardia Troponin increased			

Medicine Details:

SOLIAN (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 28/04/2004	S TERM	Stopped: 15/05/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197699 **Seq:** 1 **Gender:** M
Reported: 28/05/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 24
Onset Date: 17/05/2004 **DOB:** 14/02/1980
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Haematemesis	Caused or prolonged inpatient hospitalisation	Haematemesis.	IV Fluids.

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)	Reason:
Tablet 40.0 Milligram Daily Oral	
Batch:	Started: Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral	
Batch:	Started: 01/01/2001 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/05/2004	Other data				No ulcers were present on gastroscopy.

Additional Information:

Patient had suspected ulcers and a gastroscopy has been scheduled.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197704

Seq: 1

Gender: F

Reported: 28/05/2004

Weight: 126.00

Hospitalisation:

Age: 44

Onset Date: 21/05/2004

DOB: 03/01/1960

Outcome: Death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		The patient weighed 126 kg with a body mass index (BMI) of 45, considered morbidly obese.	
Sudden death			

Medicine Details:

SOLIAN (Suspected)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason:		
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 11/01/1996	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died 21/05/04.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197741 **Seq:** 1 **Gender:** M
Reported: 31/05/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 22
Onset Date: **DOB:** 24/01/1982
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 06/05/2004 Stopped: 19/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
31/05/2004	Other data				LV dysfunction, Ejection fraction 35 - 40%

Additional Information:

He had never been previously treated with Clozapine. Other drug therapy: haloperidol, clonazepam, cogentin. Report 198063 is a duplicate.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197765	Seq: 1	Gender: F
Reported: 31/05/2004		Weight: 62.00
Hospitalisation:		Age: 53
Onset Date: 01/03/2004		DOB: 21/05/1950
Outcome: Recovered	19/03/2004	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Required Specialist Consultation	Clozapine induced fever. Low grade temperature abdominal pain and dysuria 1/3/04 - Rx stat dose gentamicin. 2/3/04 Temp 40.2, pulse 126. Troponin, U&Es, FBP all normal. 3/3/04 Temp 36-38.7, diarrhoea. 4/3/04 trimethoprim taken. Temp 39.7. MSU no growth. Temp 41. Patient sent to teaching hospital ED where reviewed by cardiology. Clozapine induced myocarditis excluded and patient discharged. 5/4/04 Temp 40.9 Patient transferred back to ED. ...	Cessation of clozapine. Haloperidol depot and aripiprazole started.

Medicine Details:

HALOPERIDOL (Other drug)	Reason:
150.0 Milligram	Fortnightly Intramuscular
Batch:	Started: Stopped:
SODIUM VALPROATE (Other drug)	Reason:
1500.0 Milligram	Daily Oral
Batch:	Started: Stopped:
CLOZAPINE (Suspected)	Reason: Schizophrenia
Tablet 175.0 Milligram	Daily Oral
Batch:	Started: 16/02/2004 Stopped: 19/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197765	Seq: 1	Gender: F
Reported: 31/05/2004		Weight: 62.00
Hospitalisation:		
Onset Date: 01/03/2004		Age: 53
Outcome: Recovered	19/03/2004	DOB: 21/05/1950
		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain	Required Specialist Consultation	... Diagnosis- pyrexia of unknown origin due to clozapine? Temp responded to cessation of clozapine. Rx Augmentin DF. 16/3/04 Clozapine restarted. 18/3/04 Temp 39.8. 19/3/04 Clozapine ceased. Temp 37.4.	
Diarrhoea	Required Specialist Consultation		

Medicine Details:

HALOPERIDOL (Other drug)		Reason:	
150.0	Milligram	Fortnightly	Intramuscular
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Other drug)		Reason:	
1500.0	Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CLOZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	175.0	Milligram	Daily
Batch:	Started: 16/02/2004	Oral	Stopped: 19/03/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197765	Seq: 1	Gender: F
Reported: 31/05/2004		Weight: 62.00
Hospitalisation:		
Onset Date: 01/03/2004		Age: 53
Outcome: Recovered	19/03/2004	DOB: 21/05/1950
		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysuria	Required Specialist Consultation		
Tachycardia	Required Specialist Consultation		

Medicine Details:

HALOPERIDOL (Other drug)	Reason:
150.0 Milligram	Fortnightly Intramuscular
Batch:	Started: Stopped:
SODIUM VALPROATE (Other drug)	Reason:
1500.0 Milligram	Daily Oral
Batch:	Started: Stopped:
CLOZAPINE (Suspected)	Reason: Schizophrenia
Tablet 175.0 Milligram	Daily Oral
Batch:	Started: 16/02/2004 Stopped: 19/03/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197805 **Seq:** 1 **Gender:** U
Reported: 02/06/2004 **Weight:** 77.00
Hospitalisation: **Age:** 41Y
Onset Date: 01/11/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cataract		Left dense cataract and tardive dyskinesia.	
Tardive dyskinesia			

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	200.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped:
MODECATE (Suspected)	Reason:
Injection	12.5 Milligram Daily
Batch:	Started: L TERM Stopped: 1982-1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197894 **Seq:** 1 **Gender:** M
Reported: 04/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 46
Onset Date: **DOB:** 02/07/1957
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Mild asymptomatic Cardiomyopathy.	Treated with Antifailure medication (Dilatrend and Tritace).

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason: Unspecifid affective psychosis
Tablet 500.0 Milligram Daily Oral	
Batch:	Started: 01/08/1999 L TERM Stopped: Contin
CLOPINE (Suspected)	Reason: Unspecifid affective psychosis
Tablet 400.0 Milligram Daily Oral	
Batch:	Started: 01/06/2001 L TERM Stopped: 27/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/06/2004	Echocardiogram				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197903
Reported: 04/06/2004
Hospitalisation:
Onset Date: 13/04/2004
Outcome: Recovered

Seq: 1

Gender: F
Weight: 0.00
Age: 42
DOB: 09/04/1962
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nephritis interstitial	Caused or prolonged inpatient hospitalisation	Drug-induced interstitial nephritis, renal impairment, pericarditis, pericardial effusion, pyrexia, malaise, slurred speech and ataxia.	
Coordination abnormal	Caused or prolonged inpatient hospitalisation		
Dysarthria	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 08/04/2004	Stopped: 24/04/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Drug abuser, previous IV drug user and hepatitis C.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197903
Reported: 04/06/2004
Hospitalisation:
Onset Date: 13/04/2004
Outcome: Recovered

Seq: 1

Gender: F
Weight: 0.00
Age: 42
DOB: 09/04/1962
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Malaise	Caused or prolonged inpatient hospitalisation		
Pericardial effusion	Caused or prolonged inpatient hospitalisation		
Pericarditis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 08/04/2004	Stopped: 24/04/2004	

Laboratory Investigations:

Additional Information:

History: Drug abuser, previous IV drug user and hepatitis C.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197903
Reported: 04/06/2004
Hospitalisation:
Onset Date: 13/04/2004
Outcome: Recovered

Seq: 1

Gender: F
Weight: 0.00
Age: 42
DOB: 09/04/1962
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation		
Renal impairment	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 08/04/2004	Stopped: 24/04/2004	

Laboratory Investigations:

Additional Information:

History: Drug abuser, previous IV drug user and hepatitis C.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197904

Seq: 1

Gender: M

Reported: 04/06/2004

Weight: 0.00

Hospitalisation:

Onset Date: 15/05/2004

Age: 23

Outcome: Unknown

DOB: 24/05/1980

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Acute myocarditis, dilatation ventricular, electrocardiogram abnormal, troponin increased, fever of 38.5 degrees celcius, vomiting and blood pressure fluctuation.	
Blood pressure fluctuation			
Electrocardiogram abnormal			
Pyrexia			
Troponin increased			
Vomiting			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 04/05/2004 Stopped: 24/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/06/2004	Echocardiogram				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197994 **Seq:** 1 **Gender:** M
Reported: 09/06/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 37
Onset Date: 08/04/2004 **DOB:** 04/01/1967
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Schizophrenia	Caused or prolonged inpatient hospitalisation	Schizophrenia aggravated.	
Drug ineffective	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	800.0 Milligram Daily Oral
Batch:	Started: 23/02/2004 Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/06/2004	Serum drug level		20/06/2003	490	Clozapine levels
09/06/2004	Serum drug level		04/05/2004	330	Clozapine levels

Additional Information:

Other drug therapy ibuprofen, chlorpromazine, flupentixol



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 197995

Seq: 1

Gender: M

Reported: 09/06/2004

Weight: 0.00

Hospitalisation:

Age: 47

Onset Date:

DOB: 10/08/1956

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Palpitations Constipation Salivary hypersecretion		Heart palpitations, constipation and hypersalivation.	Clopine ceased

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	150.0 Milligram Daily Oral
Batch:	Started: 14/05/2004 Stopped: 02/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198159
Reported: 15/06/2004

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 34

DOB: 14/02/1970

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Dyspnoea exertional Ventricular failure		Cardiomyopathy, ventricular dysfunction and dyspnoea exertional.	Clozaril ceased.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 27/05/1996	Stopped: 27/05/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/06/2004	Echocardiogram				

Additional Information:

The patient had a history of non-insulin dependent diabetes mellitus and obesity. The final diagnosis was stated as subclinical, dilated, drug induced cardiomyopathy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198160	Seq: 1	Gender: M
Reported: 15/06/2004		Weight: 0.00
Hospitalisation:		Age: 30
Onset Date: 01/06/2004		DOB: 25/11/1973
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis Nasopharyngitis		Agranulocytosis and nasopharyngitis.	Clozaril ceased.

Medicine Details:

BENZTROPINE MESYLATE (Other drug)	Reason:
Batch:	Started: Stopped:
THYROXINE SODIUM (Other drug)	Reason:
Batch:	Started: Stopped:
AMISULPRIDE (Other drug)	Reason:
Batch:	Started: Stopped:
CARBAMAZEPINE (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/06/2004	Neutrophils		02/06/2004	0.07	
15/06/2004	Neutrophils		01/06/2004	0.10	
15/06/2004	Neutrophils		15/10/2001	Pre-treatment	
15/06/2004	White blood cells		02/06/2004	2.20	
15/06/2004	White blood cells		01/06/2004	1.50	
15/06/2004	White blood cells		15/10/2001	Pre-treatment	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198160

Seq: 1

Gender: M

Reported: 15/06/2004

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date: 01/06/2004

DOB: 25/11/1973

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 15/10/2001	Stopped: 01/06/2004	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198222 **Seq:** 1 **Gender:** M
Reported: 17/06/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 38
Onset Date: 15/09/2003 **DOB:** 17/05/1965
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Sweating and constipation.	Treated with stool softeners, laxatives and an enema.
Constipation			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 26/08/2003 Stopped: 23/11/2004 Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/06/2004	Neutrophils		26/08/2003	5.65	
17/06/2004	Neutrophils		23/11/2004	1.38	
17/06/2004	Neutrophils		24/11/2004	2.14	
17/06/2004	Neutrophils		26/11/2004	2.21	
17/06/2004	Neutrophils		25/11/2004	1.93	
17/06/2004	White blood cells		26/08/2003	8.5	
17/06/2004	White blood cells		23/11/2004	3.00	

Additional Information:

Patient was also taking Valproate Sodium, Diazepam, Olanzapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198222 **Seq:** 1

Reported: 17/06/2004

Hospitalisation: Admitted to hospital

Onset Date: 15/09/2003

Outcome: Not yet recovered

Gender: M

Weight: 0.00

Age: 38

DOB: 17/05/1965

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 26/08/2003 Stopped: 23/11/2004 Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/06/2004	White blood cells		24/11/2004	3.50	
17/06/2004	White blood cells		25/11/2004	3.50	
17/06/2004	White blood cells		26/11/2004	4.30	

Additional Information:

Patient was also taking Valproate Sodium, Diazepam, Olanzapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198243

Seq: 1

Gender: F

Reported: 18/06/2004

Weight: 0.00

Hospitalisation:

Age: 48

Onset Date:

DOB: 26/03/1956

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		Orthostatic hypotension.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 29/11/2002 L TERM Stopped: 21/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose of Clopine varied from 300mg to 600 mg/daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198285	Seq: 1	Gender: M
Reported: 18/06/2004		Weight: 0.00
Hospitalisation:		Age: 27
Onset Date: 02/06/2004		DOB: 02/09/1976
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejection fraction decreased	Required Specialist Consultation	Moderate cardiac dysfunction with ejection fraction 44%, fever of 38.5 degrees, tachycardia and platelet count dropped from 156 to 124.	
Myocarditis	Required Specialist Consultation		
Platelet count decreased	Required Specialist Consultation		

Medicine Details:

OLANZAPINE (Other drug)	Reason:
	Dose Unspecified
Batch:	Started: Stopped:
SODIUM VALPROATE (Suspected)	Reason:
	4.0 Gram Oral
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 20/05/2004 Stopped: 07/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/06/2004	Echocardiogram				
18/06/2004	Other data				
18/06/2004	Platelets				
18/06/2004	Troponin		07/06/2004	0.06	

Additional Information:

History of drug and alcohol abuse but had been free from drugs for 2 years and free from alcohol for the last 6 months.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198285

Seq: 1

Gender: M

Reported: 18/06/2004

Weight: 0.00

Hospitalisation:

Onset Date: 02/06/2004

Age: 27

DOB: 02/09/1976

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Required Specialist Consultation		
Tachycardia	Required Specialist Consultation		
Troponin increased	Required Specialist Consultation		

Medicine Details:

OLANZAPINE (Other drug)	Reason:		
	Dose Unspecified		
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Suspected)	Reason:		
	4.0 Gram	Oral	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 20/05/2004	Stopped: 07/06/2004	

Laboratory Investigations:

Additional Information:

History of drug and alcohol abuse but had been free from drugs for 2 years and free from alcohol for the last 6 months.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198361 **Seq:** 1 **Gender:** F
Reported: 21/06/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 37
Onset Date: 09/06/2004 **DOB:** 07/09/1966
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation Heart rate increased Heart rate irregular Influenza Tachycardia		Patient complained of the flu, had an irregular pulse and showed atrial fibrillation and heart rate of 126 bpm on ECG.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet 350.0 Milligram Daily Oral	
Batch:	Started: 10/03/2004 Stopped: 13/09/2004 Contin
SEROQUEL (Suspected)	Reason:
Tablet 100.0 Milligram Daily Oral	
Batch:	Started: Stopped: 09/06/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/06/2004	Electrocardiograph				

Additional Information:

Family history: myocardial infarction. Father died of myocardial infarction at the age of 55 years. Brother had myocardial infarction at the age of 40 years.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198362

Seq: 1

Gender: M

Reported: 21/06/2004

Weight: 0.00

Hospitalisation:

Onset Date: 14/04/2004

Age: 45

Outcome: Not yet recovered

DOB: 12/12/1958

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Patient developed high fever, hypotension, basal lobe pneumonia, mycoplasma infection and hypoxia.	
Hypotension	Caused or prolonged inpatient hospitalisation		
Hypoxia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 17/03/2004	Stopped:	13/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198362

Seq: 1

Gender: M

Reported: 21/06/2004

Weight: 0.00

Hospitalisation:

Age: 45

Onset Date: 14/04/2004

DOB: 12/12/1958

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mycoplasma infection	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 17/03/2004	Stopped: 13/04/2004	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198377

Seq: 1

Gender: M

Reported: 22/06/2004

Weight: 0.00

Hospitalisation:

Onset Date: 09/06/2004

Age: 34

Outcome: Unknown

DOB: 11/05/1970

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension		(150 mm Hg (systolic and supine)Hypertension and tachycardia (130 bpm).	
Tachycardia			

Medicine Details:

COVERSYL (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason:		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 09/06/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/06/2004	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198403

Seq: 1

Gender: F

Reported: 23/06/2004

Weight: 0.00

Hospitalisation:

Age: 61

Onset Date: 10/06/2004

DOB: 15/02/1943

Outcome: Recovered

05/07/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin I increased		Increased troponin.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 04/06/2004 Stopped: 10/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198405
Reported: 23/06/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 21/05/2004
Outcome: Unknown

Age: 41
DOB: 28/01/1963
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Epilepsy	Treated in outpatient department only	Epileptic fit resulting in a fractured arm.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason: Schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 11/03/2004	Stopped:	16/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Tegretol for Epilepsy and Lipitor for Hyperlipidaemia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198496
Reported: 25/06/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 15/06/2004
Outcome: Unknown

Age: 28
DOB: 28/11/1975
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anxiety		Blood pressure increased, anxiety, heart rate increased, nausea, chest pain.	
Blood pressure increased		Blood pressure increased, anxiety, heart rate increased, nausea, chest pain.	
Chest pain		Blood pressure increased, anxiety, heart rate increased, nausea, chest pain.	
Heart rate increased		Blood pressure increased, anxiety, heart rate increased, nausea, chest pain.	
Nausea		Blood pressure increased, anxiety, heart rate increased, nausea, chest pain.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 03/08/2002	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/06/2004	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198511

Seq: 1

Gender: M

Reported: 25/06/2004

Weight: 0.00

Hospitalisation:

Age: 28

Onset Date: 15/04/2004

DOB: 20/01/1976

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Schizophrenia		Moderate to severe schizophrenia nos aggravated, drug ineffective and drug therapy changed.	Solian (50mg po nocte) was commenced on 28/04/2004 for the positive symptoms, but with no effect. It was ceased on 11/05/2004. The dose of Clopine was not increased.
Drug ineffective Drug therapy changed			

Medicine Details:

CLOPINE (Suspected)	Reason: Schizophrenia		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 24/02/2004	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/06/2004	Serum drug level				

Additional Information:

Patient has been on Clozaril (since 06/2003), and had good symptoms control. When he changed to Clopine on (24/02/04), an exacerbation of symptoms resulted.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198541	Seq: 1	Gender: M
Reported: 28/06/2004		Weight: 0.00
Hospitalisation:		Age: 30
Onset Date: 15/05/2004		DOB: 20/03/1974
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis Neutrophil count increased White blood cell count increased		Myocarditis, WBC increased and neutrophils increased.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 07/05/2004 Stopped: 02/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/06/2004	Neutrophils		06/05/2004	pre-treatment	
28/06/2004	Neutrophils		17/05/2004	9.81	
28/06/2004	Neutrophils		26/05/2004	11.20 x 10 ⁹ /L	
28/06/2004	White blood cells		06/05/2004	pre-treatment	
28/06/2004	White blood cells		17/05/2004	13.00	
28/06/2004	White blood cells		26/05/2004	15.80 x 10 ⁹ /L	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198589
Reported: 29/06/2004
Hospitalisation:
Onset Date: 14/06/2004
Outcome: Unknown

Seq: 1

Gender: M
Weight: 0.00
Age: 52
DOB: 13/08/1951
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebral infarction Coordination abnormal Fall Neutropenia Pancytopenia White blood cell count decreased		Cerebral infarction, fall, ataxia, pancytopenia, neutropenia and white blood cell count decreased.	Ceased Clozaril

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	700.0 Milligram Daily Oral
Batch:	Started: 17/02/1994 Stopped: 21/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/06/2004	Neutrophils		23/06/2004	2.30	
29/06/2004	Neutrophils		22/06/2004	1.50	
29/06/2004	Neutrophils		21/06/2004	1.20	
29/06/2004	Neutrophils		17/02/1994	4.80	
29/06/2004	Neutrophils		17/05/2004	3.30	
29/06/2004	Neutrophils		14/06/2004	2.10	
29/06/2004	White blood cells		23/06/2004	4.60	

Additional Information:

The patient had a previous medical history of stroke.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198589

Seq: 1

Gender: M

Reported: 29/06/2004

Weight: 0.00

Hospitalisation:

Age: 52

Onset Date: 14/06/2004

DOB: 13/08/1951

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 17/02/1994	Stopped: 21/06/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/06/2004	White blood cells		22/06/2004	4.00	
29/06/2004	White blood cells		21/06/2004	3.30	
29/06/2004	White blood cells		14/06/2004	3.20	
29/06/2004	White blood cells		17/05/2004	5.30	
29/06/2004	White blood cells		17/02/1994	7.40	

Additional Information:

The patient had a previous medical history of stroke.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198611 **Seq:** 1 **Gender:** M
Reported: 30/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 58
Onset Date: 14/04/2004 **DOB:** 12/12/1945
Outcome: Death 30/05/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Atrial flutter		Paroxysmal atrial flutter.	Required cardioversion.

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
	Dose Unspecified Oral
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 17/03/2004 Stopped: 13/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/06/2004	Other data				

Additional Information:

An autopsy was to be performed. Patient history: Major depression/psychotic depression and Bipolar disorder.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198706
Reported: 05/07/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 47
DOB: 24/09/1956

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis		Hepatitis, GGT increased, blood alkaline phosphatase increased, blood cholesterol increased, blood glucose increased, slight anaemia, slight thrombocytosis and white blood cell count increased, neutrophilia.	Ceased Sodium Valproate and Clozaril, commenced on Solian and Lithium.
Anaemia			
Blood alkaline phosphatase increased			
Blood glucose increased			
Liver function test abnormal			
Neutrophilia			
Thrombocythaemia			

Medicine Details:

AMISULPRIDE (Other drug)	Reason:
Batch:	Started: 08/06/2004 Stopped:
LITHIUM CARBONATE (Other drug)	Reason:
Batch:	Started: 17/06/2004 Stopped:
THYROXINE SODIUM (Other drug)	Reason:
Batch:	Started: Stopped:
LOGYNON ED (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/07/2004	Cholesterol	(0.0-5.4)	27/04/2004	6.3	
05/07/2004	Cholesterol	(0.0-5.4)	20/04/2004	6.3	
05/07/2004	Cholesterol	(0.0-5.4)	11/05/2004	6.8	
05/07/2004	GGT = SGGT =	(0-60)	21/06/2004	715	
05/07/2004	GGT = SGGT =	(0-60)	20/04/2004	886	
05/07/2004	GGT = SGGT =	(0-60)	11/03/2004	723	
05/07/2004	Haemoglobin	(115-155)	21/06/2004	111	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198706
Reported: 05/07/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 47
DOB: 24/09/1956
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
White blood cell count increased			

Medicine Details:

SODIUM VALPROATE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 03/06/1994	Stopped: 28/05/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/07/2004	Haemoglobin	(115-155)	01/04/2004	105	
05/07/2004	Liver biopsy				
05/07/2004	Neutrophils		01/04/2004	7.90	
05/07/2004	Neutrophils		03/06/1994	5.60	
05/07/2004	Platelets	(150-400)	21/06/2004	390	
05/07/2004	Platelets	(150-400)	01/04/2004	570	
05/07/2004	SAP = ALP	(30-110)	21/06/2004	775	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198706
Reported: 05/07/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 47
DOB: 24/09/1956
Causality: Causality possible

Reaction Details:

Medicine Details:

AMISULPRIDE (Other drug)	Reason:
Batch:	Started: 08/06/2004 Stopped:
LITHIUM CARBONATE (Other drug)	Reason:
Batch:	Started: 17/06/2004 Stopped:
THYROXINE SODIUM (Other drug)	Reason:
Batch:	Started: Stopped:
LOGYNON ED (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/07/2004	SAP = ALP	(30-110)	20/04/2004	1354	
05/07/2004	SAP = ALP	(30-110)	11/03/2004	902	
05/07/2004	Serum glucose	(3.8-5.5)	27/04/2004	5.4	
05/07/2004	Serum glucose	(3.8-5.5)	20/04/2004	7.4	
05/07/2004	Serum glucose	(3.8-5.5)	11/03/2004	8.6	
05/07/2004	White blood cells	(4.0-11.0)	21/06/2004	13.60	
05/07/2004	White blood cells	(4.0-11.0)	01/04/2004	12.70	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198706
Reported: 05/07/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 47
DOB: 24/09/1956
Causality: Causality possible

Reaction Details:

Medicine Details:

SODIUM VALPROATE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 03/06/1994	Stopped: 28/05/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/07/2004	White blood cells	(4.0-11.0)	03/06/1994	10.40	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198814	Seq: 1	Gender: M
Reported: 08/07/2004		Weight: 0.00
Hospitalisation:		Age: 25
Onset Date:		DOB: 11/04/1979
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Patient developed diabetes, bifocal vision, weight increased, still psychotic, migraine, nausea and salivary hypersecretion.	
Migraine			
Nausea			
Psychotic disorder			
Salivary hypersecretion			
Visual disturbance			
Weight increased			

Medicine Details:

CIPRAMIL (Other drug)		Reason:	
Tablet	Dose Unspecified	Oral	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified psychosis	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 12/02/1998	Stopped: 01/01/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozaril therapy was commenced on 12/02/1998. Therapy was switched to Clopine 350mg/daily. History: Diabetes mellitus NOS and hypertension NOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198815	Seq: 1	Gender: M
Reported: 08/07/2004		Weight: 0.00
Hospitalisation:		Age: 38
Onset Date: 15/04/2000		DOB: 03/03/1962
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinson's disease		Patient developed Parkinson's disease, salivary hypersecretion, speech disorder, dysarthria and high clozapine levels. High clozapine serum levelm had been due to patient giving up smoking overnight leading to an excessive clozapine level. It was then that the patient developed severe Parkinson's disease	Parlodel
Drug level increased			
Hyperhidrosis			
Salivary hypersecretion			
Speech disorder			

Medicine Details:

PARLODEL (Other drug)		Reason: Paralysis agitans	
Tablet	4.0 Dose Unspecified Daily	Oral	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Schizophrenia	
Tablet	700.0 Milligram Daily	Oral	
Batch:	Started: 16/01/1997	Stopped: Ongoing.	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/07/2004	Other data				Aug 2001: Clozapine plasma level 2059 ng/ml.

Additional Information:

The patient's mother believed her son was on Clopine at the time of the high plasma Clozapine levels. Clozaril was reduced from 700mg/daily to 300mg/daily. Patient was currently on 300mg - 350mg/daily. History: Smoker, approximately 60-100 cigarettes per day. Patient stopped smoking all of a sudden in April 2000. Patient was diagnosed with cerebral atrophy on MRI scan.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198840	Seq: 1	Gender: M
Reported: 09/07/2004		Weight: 0.00
Hospitalisation:		Age: 33
Onset Date: 14/06/2004		DOB: 12/04/1971
Outcome: Recovered	30/06/2004	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Colitis	Caused or prolonged inpatient hospitalisation	Patient developed severe colitis, diarrhoea, abdominal pain, increased white cell count and peritonism.	Treated with Salazopyrin for Colitis.
Abdominal pain	Caused or prolonged inpatient hospitalisation		
Diarrhoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)		Reason: Schizophrenia	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 29/03/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/07/2004	Neutrophils		29/03/2004	4.9	
09/07/2004	Neutrophils		13/05/2004	9.9	
09/07/2004	Neutrophils		24/06/2004	7.3	
09/07/2004	Neutrophils		17/06/2004	14.2	
09/07/2004	White blood cells		29/03/2004	8.3	
09/07/2004	White blood cells		13/05/2004	13.5	
09/07/2004	White blood cells		17/06/2004	17.7	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198840

Seq: 1

Gender: M

Reported: 09/07/2004

Weight: 0.00

Hospitalisation:

Age: 33

Onset Date: 14/06/2004

DOB: 12/04/1971

Outcome: Recovered

30/06/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Peritonitis	Caused or prolonged inpatient hospitalisation		
White blood cell count increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason: Schizophrenia		
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 29/03/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/07/2004	White blood cells		24/06/2004	10.5	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 198959 **Seq:** 1 **Gender:** F
Reported: 15/07/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 20
Onset Date: 20/06/2004 **DOB:** 27/12/1983
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation	Tachycardia, pharyngitis, sweating increased, hypotension.	Clopine ceased.
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Hypotension			
Pharyngitis			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet 300.0 Milligram Daily Oral	
Batch:	Started: 02/06/2004 Stopped: 22/07/2004
OLANZAPINE (Suspected)	Reason: Unspecified psychosis
Tablet 5.0 Milligram Daily Oral	
Batch:	Started: 07/05/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/07/2004	Echocardiogram				Echocardiogram on 26 May and 16 July 2004 showed sinus rhythm, normal cardiac chamber and valves
15/07/2004	Electrocardiograph				ECG noted a sinus tachycardia of 130
15/07/2004	Other data				

Additional Information:

Other drug therapy: valproate, clonazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199105	Seq: 1	Gender: M
Reported: 19/07/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 29
Onset Date:		DOB: 24/09/1974
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ileus paralytic	Life threatening	Patient experienced paralytic ileus, bowel obstruction with nausea and vomiting. An SSRI interaction suspected and fluvoxamine ceased	Clozaril ceased.
Drug interaction	Life threatening		
Drug level increased	Life threatening		
Intestinal obstruction	Life threatening		
Nausea	Life threatening		

Medicine Details:

CLOZARIL (Interaction)	Reason: Unspecified schizophrenia
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 14/01/2003 Stopped: 10/05/2004
CITALOPRAM HYDROBROMIDE (Interaction)	Reason:
	80.0 Milligram Daily
Batch:	Started: Stopped:
SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
GEMFIBROZIL (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/07/2004	Abdomen X-ray				X-Ray: small bowel dilatation with air-fluid levels present on the erect x-ray.
19/07/2004	Serum drug level				Clozapine blood level: 800ug/L, Norclozapine blood level: 300ug/L

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199105 **Seq:** 1 **Gender:** M
Reported: 19/07/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: **DOB:** 24/09/1974
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting	Life threatening		

Medicine Details:

PANTOPRAZOLE (Other drug)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199107 **Seq:** 1 **Gender:** M
Reported: 19/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 48
Onset Date: **DOB:** 28/05/1956
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Enuresis		Nocturnal enuresis	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	700.0 Milligram Daily Oral
Batch:	Started: 12/05/2000 Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/07/2004	Sodium				

Additional Information:

199107 is seq 01 of 199334 seq 02.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199108

Seq: 1

Gender: M

Reported: 19/07/2004

Weight: 0.00

Hospitalisation:

Age: 59

Onset Date: 18/06/2004

DOB: 22/01/1945

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood pressure fluctuation Myocarditis Anaemia Drug ineffective Thrombocytopenia		Haemodynamic instability Patient experienced myocarditis, anaemia, thrombocytopenia and drug ineffective.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 17/06/2004 Stopped: 05/07/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199134

Seq: 1

Gender: F

Reported: 19/07/2004

Weight: 0.00

Hospitalisation:

Onset Date: 08/07/2004

Age: 20

DOB: 10/06/1984

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin I increased Chills Hypotension Neutrophil count increased Pleuritic pain Pyrexia Tachycardia Tonsillar disorder		Elevated Troponin I levels, febrile, high neutrophil count, high white blood cell count, hypotension, tachycardia, chills/rigors and bilateral tonsillar enlargement.	

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	150.0 Milligram
	Daily
	Oral
Batch: 16064, 15938	Started: 28/06/2004
	Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinically, there was no cardiac abnormality and there were no changes in her ECG (from baseline). History: cannabis and amphetamine drug dependence.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199134

Seq: 1

Gender: F

Reported: 19/07/2004

Weight: 0.00

Hospitalisation:

Age: 20

Onset Date: 08/07/2004

DOB: 10/06/1984

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
White blood cell count increased			

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	150.0 Milligram
	Daily
	Oral
Batch: 16064, 15938	Started: 28/06/2004
	Stopped: Contin

Laboratory Investigations:

Additional Information:

Clinically, there was no cardiac abnormality and there were no changes in her ECG (from baseline). History: cannabis and amphetamine drug dependence.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199135	Seq: 1	Gender: M
Reported: 19/07/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 29
Onset Date: 08/07/2004		DOB: 29/09/1974
Outcome: Recovered	15/07/2004	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Seizure, nausea, vomiting and gamma GT slightly elevated, appetite decreased.	Clopine dose was reduced to 400mg.
Decreased appetite	Caused or prolonged inpatient hospitalisation		
Gamma-glutamyltransferase increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM (Other drug)		Reason:	
Batch:	Started:	Stopped:	15/06/2004
CLOPINE (Suspected)		Reason:	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 27/04/2004	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Epilim was ceased on 15/06/2004 as it was thought not to be needed. He had been on epilim for many years for schizoaffective disorder. He has no past history of epilepsy.



Therapeutic Goods Administration Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199135 **Seq:** 1 **Gender:** M
Reported: 19/07/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 08/07/2004 **DOB:** 29/09/1974
Outcome: Recovered 15/07/2004 **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

EPILIM (Other drug)	Reason:		
Batch:	Started:	Stopped: 15/06/2004	
CLOPINE (Suspected)	Reason:		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 27/04/2004	Stopped:	Contin

Laboratory Investigations:

Additional Information:

Epilim was ceased on 15/06/2004 as it was thought not to be needed.
He had been on epilim for many years for schizoaffective disorder. He has no past history of epilepsy.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199136
Reported: 19/07/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 15/07/2004
Outcome: Recovered

Age: 42
DOB: 18/10/1961
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse Pruritus Balance disorder Dizziness Restlessness Syncope		Collapsed/fainted and dizzy spells. itchy legs unsteady on feet	Clopine reduced to 450mg.

Medicine Details:

ACETYL CYSTEINE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	550.0 Milligram	Daily	Oral
Batch:	Started: 01/03/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Events lasted for 1 month and resolved with the reduction of dose



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199247 **Seq:** 1 **Gender:** F
Reported: 20/07/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 27
Onset Date: **DOB:** 18/03/1977
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation Abdominal pain Diarrhoea Vomiting		Constipation, vomiting, diarrhoea and adominal pain	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	375.0 Milligram Daily Oral
Batch:	Started: 05/03/2001 Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199304

Seq: 1

Gender: F

Reported: 22/07/2004

Weight: 0.00

Hospitalisation:

Age: 23

Onset Date: 09/07/2004

DOB: 08/12/1980

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Required Specialist Consultation	Patient experienced tachycardia 115-120 beats per minute.	Patient is continuing Clopine treatment.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 02/06/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199384	Seq: 1	Gender: F
Reported: 23/07/2004		Weight: 0.00
Hospitalisation:		Age: 51
Onset Date: 29/06/2004		DOB: 18/09/1952
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Increased liver enzymes, WBC increased, Neutrophils increased.	Clozaril discontinued.
Neutrophil count increased			
White blood cell count increased			

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
PAROXETINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 12/06/2004 Stopped: 12/07/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/07/2004	Neutrophils		05/07/2004	6.01	
23/07/2004	Neutrophils		13/07/2004	13.00	
23/07/2004	Neutrophils		12/06/2004	Pre-treatment	
23/07/2004	White blood cells		05/07/2004	9.05	
23/07/2004	White blood cells		13/07/2004	16.80	
23/07/2004	White blood cells		12/06/2004	Pre-treatment	

Additional Information:

Medical history of lupus, left lower lobectomy, rheumatoid arthritis, and chronic sinusitis, all of which were confirmed predating Clozaril.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199409 **Seq:** 1 **Gender:** M
Reported: 26/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 04/05/2004 **DOB:**
Outcome: Recovered 10/05/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ileus paralytic		Paralytic ileus.	Exploratory laparotomy.

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 550.0 Milligram Daily Oral	
Batch: Started: Stopped:	
CITALOPRAM HYDROBROMIDE (Suspected)	Reason: Unspecified schizophrenia
Tablet 20.0 Milligram Daily Oral	
Batch: Started: Stopped:	
SODIUM VALPROATE (Suspected)	Reason: Unspecified schizophrenia
Tablet 500.0 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 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199437

Seq: 1

Gender: M

Reported: 27/07/2004

Weight: 0.00

Hospitalisation:

Age: 21

Onset Date: 04/06/2004

DOB: 16/05/1983

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension Tachycardia		Tachycardia and postural hypotension.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 02/06/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/07/2004	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199452

Seq: 1

Gender: M

Reported: 28/07/2004

Weight: 0.00

Hospitalisation:

Age: 19

Onset Date: 09/06/2004

DOB: 05/02/1985

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		Intermittent episodes of postural hypotension, negative symptoms of schizophrenia, flat affect and reclusive behaviour.	
Abnormal behaviour			
Drug ineffective			

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 09/06/2004	S TERM	Stopped: Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient already in hospital. He was very guarded in his comments about his experience of positive symptoms which he may still be experiencing. The patient had a history of non-compliance.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199453	Seq: 1	Gender: M
Reported: 28/07/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 23
Onset Date: 08/06/2004		DOB: 09/03/1981
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pericarditis	Caused or prolonged inpatient hospitalisation	Respiratory infection, pericardial effusion and pericarditis.	Treatment included anti-inflammatory medication, Augmentin forte, brufen. Ceased Clozaril
Cardiac tamponade	Caused or prolonged inpatient hospitalisation		
Cardiomegaly	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANADEINE FORTE (Other drug)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	
DOXEPIN HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
EPILIM (Other drug)		Reason:	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 31/05/2004	Stopped: 21/07/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/07/2004	Chest X-ray				On 24 June 2004, the patient's chest X-ray showed borderline heart size with a cardiothoracic ratio of 18/36
28/07/2004	Serum drug level				Clozapine level decreased. Plasma valproate level slightly low.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199453	Seq: 1	Gender: M
Reported: 28/07/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 23
Onset Date: 08/06/2004		DOB: 09/03/1981
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level decreased	Caused or prolonged inpatient hospitalisation		
Electrocardiogram ST-T segment a	Caused or prolonged inpatient hospitalisation		
Musculoskeletal chest pain	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANADEINE FORTE (Other drug)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	
DOXEPIN HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
EPILIM (Other drug)		Reason:	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 31/05/2004	Stopped: 21/07/2004	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199453 **Seq:** 1 **Gender:** M
Reported: 28/07/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 23
Onset Date: 08/06/2004 **DOB:** 09/03/1981
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation		
Viral infection	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANADEINE FORTE (Other drug)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
DOXEPIN HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
EPILIM (Other drug)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: Stopped: 0
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 31/05/2004 Stopped: 21/07/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199460
Reported: 28/07/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 16/07/2004
Outcome: Recovered

Age: 31
DOB: 03/02/1973
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia Leukopenia		Neutropenia and leukopenia.	Ceased Clozaril.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 02/04/2003	Stopped: 19/07/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/07/2004	White blood cells		20/07/2004	4.40	
28/07/2004	White blood cells		16/07/2004	2.40	
28/07/2004	White blood cells		18/06/2004	5.60	
28/07/2004	White blood cells		20/07/2004	2.90	
28/07/2004	White blood cells		16/07/2004	1.20	
28/07/2004	White blood cells		18/06/2004	3.80	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199465
Reported: 28/07/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 15/08/2000
Outcome: Recovered

Age: 19
DOB: 23/03/1981
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension Abdominal pain Muscle spasms Nausea Neutropenia Night sweats Pharyngolaryngeal pain Pyrexia		Hypertension, neutropenia, pyrexia, pharyngolaryngeal pain, nausea, abdominal pain, night sweats and crampy.	Ceased Clozaril

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 14/05/1999 Stopped: 22/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/07/2004	Neutrophils		25/08/2000	1.09	
28/07/2004	Neutrophils		21/08/2000	2.40	
28/07/2004	Neutrophils		14/05/1999	6.8	
28/07/2004	White blood cells		25/08/2000	3.69	
28/07/2004	White blood cells		21/08/2000	4.50	
28/07/2004	White blood cells		14/05/1999	9.4	

Additional Information:

Patient was also taking Omeprazole and Sodium Valproate.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199523	Seq: 1	Gender: M
Reported: 30/07/2004		Weight: 0.00
Hospitalisation:		Age: 52
Onset Date: 15/01/2004		DOB: 11/11/1951
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Anaemia Angina pectoris Chest pain Echocardiogram abnormal Weight decreased		Cardiac complications such as chest pain and decreased ESF, anaemia and weight loss.	

Medicine Details:

RAMIPRIL (Other drug)	Reason:
Batch:	Started: Stopped: 0
CLONAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped: 0
OMEPRAZOLE (Other drug)	Reason:
Batch:	Started: Stopped: 0
LACTULOSE (Other drug)	Reason:
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/07/2004	Echocardiogram				07/05/2004 - Transthoracic Echo Report: Mildly enlarged left atrial. Conclusion: Moderate global left ventricular systolic dysfunction.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199523

Seq: 1

Gender: M

Reported: 30/07/2004

Weight: 0.00

Hospitalisation:

Age: 52

Onset Date: 15/01/2004

DOB: 11/11/1951

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

COLOXYL WITH SENNA (Other drug)		Reason:	
Batch:	Started:	Stopped:	0
LAMOTRIGINE (Other drug)		Reason:	
Batch:	Started:	Stopped:	0
CLOZARIL (Suspected)		Reason:	
Tablet	12.0 Milligram	Daily	Oral
Batch:	Started: 29/07/2003	Stopped: 22/06/2004	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199532

Seq: 1

Gender: M

Reported: 30/07/2004

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date:

DOB: 31/05/1962

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		Orthostatic hypotension.	Ceased Clopine

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	150.0 Milligram Daily Oral
Batch:	Started: 16/06/2004 Stopped: 17/07/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199533	Seq: 1	Gender: M
Reported: 30/07/2004		Weight: 0.00
Hospitalisation:		Age: 26
Onset Date: 19/07/2004		DOB: 28/06/1978
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis		Leukocytosis, tachycardia, fever, extreme sedation and postural dizziness.	Erythromycin, paracetamol. Clozapine was discontinued
Dizziness postural			
Eosinophilia			
Neutrophilia			
Pyrexia			
Sedation			
Tachycardia			

Medicine Details:

OLANZAPINE (Other drug)	Reason:
Batch:	Started: Stopped: 0
LITHIUM CARBONATE (Other drug)	Reason:
	1500.0 Milligram Daily
Batch:	Started: Stopped: 0
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	225.0 Milligram Daily Oral
Batch:	Started: 09/04/2000 Stopped: 27/07/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199534 **Seq:** 1 **Gender:** M
Reported: 30/07/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 37
Onset Date: 07/07/2004 **DOB:** 19/10/1966
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intentional overdose		Overdose.	

Medicine Details:

OMEPRAZOLE (Other drug)	Reason:		
40.0 Milligram	Oral		
Batch:	Started:	Stopped:	
AMISULPRIDE (Suspected)	Reason:		
Batch:	Started:	Stopped:	
CLOPINE (Suspected)	Reason: Schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 24/12/2002	Stopped: 07/07/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199536

Seq: 1

Gender: F

Reported: 30/07/2004

Weight: 0.00

Hospitalisation:

Age: 55

Onset Date: 19/07/2004

DOB: 23/02/1949

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutrophil count decreased		Very low neutrophil and white blood cell counts.	
White blood cell count decreased			

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 29/08/1995	Stopped: 20/07/2004	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/07/2004	Neutrophils	10 ⁹ L	19/07/2004	0.7	
30/07/2004	White blood cells	x 10 ⁹ L	19/07/2004	2.2	

Additional Information:

several weeks ago, patient had an operation for ovarian cancer, and was given chemotherapy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199593 **Seq:** 1 **Gender:** M
Reported: 02/08/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 42
Onset Date: **DOB:** 11/11/1961
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary retention	Caused or prolonged inpatient hospitalisation	Patient developed urinary retention and acute renal failure.	Patient required a Nephrostomy. Clopine ceased now on Haloperidol.
Renal failure acute	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 01/01/2003 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199624

Seq: 1

Gender: M

Reported: 03/08/2004

Weight: 0.00

Hospitalisation:

Age: 27

Onset Date: 11/03/2004

DOB: 06/08/1976

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Early cardiomyopathy.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)		Reason:		
Tablet	500.0 Milligram	Daily	Oral	
Batch:	Started: 21/05/1996	Stopped: 22/07/2004	0	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/08/2004	Echocardiogram				11 March 2004: Mild left atrial enlargement. Trivial mitral regurgitation. Right ventricular wall looked hypokinetic.. 20 July 2004: LV systolic function was mildly depressed.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199629 **Seq:** 1 **Gender:** M
Reported: 04/08/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 39
Onset Date: 15/07/2004 **DOB:** 30/01/1965
Outcome: Not yet 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:

SODIUM VALPROATE (Other drug)	Reason:	
Batch:	Started:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily
Batch:	Started: 05/07/2004	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199630	Seq: 1	Gender: M
Reported: 04/08/2004		Weight: 0.00
Hospitalisation:		Age: 46
Onset Date: 15/11/2002		DOB: 22/08/1956
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocardial ischaemia	Required Visit to Doctor	Ischaemic heart disease - myocardial ischaemia, tachycardia, angina pectoris and elevated serum lipids.	Ceased Gemfibrozil, commenced on metoprolol and atorvastatin.
Angina pectoris	Required Visit to Doctor		
Lipids increased	Required Visit to Doctor		
Tachycardia	Required Visit to Doctor		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)		Reason:	
Tablet	Dose Unspecified	Oral	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Oral	
Batch:	Started: 23/11/1994 L TERM	Stopped: Ongoing	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This report is a seq to 199657. History: diabetic patient with cardiovascular diseases, cardioavascular problems due to poor diet and lack of exercise.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199759	Seq: 1	Gender: M
Reported: 06/08/2004		Weight: 0.00
Hospitalisation:		Age: 66
Onset Date: 11/03/2004		DOB: 28/10/1937
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged		Patient experienced QT Prolonged and ventricular fibrillation paroxysm, dyspnoea, cardiac arrest and unconscious collapse.	Required resuscitation by MET-CPR + defibrillated, Adrenaline, intubated retrieved to ICU, Magnesium infusion, Noradrenaline, Lignocaine infusion. Ceased Clozapine and Amiodarone commenced.
Cardiac arrest			
Circulatory collapse			
Dyspnoea			
Ventricular fibrillation			

Medicine Details:

PREDNISOLONE (Other drug)	Reason:
Batch:	Started: Stopped:
LORAZEPAM (Other drug)	Reason:
Tablet	3.0 Dose Unspecified As necessary Oral
Batch:	Started: L TERM Stopped:
SPIRONOLACTONE (Other drug)	Reason:
Tablet	25.0 Milligram Daily
Batch:	Started: Stopped:
SIMVASTATIN (Other drug)	Reason:
	40.0 Milligram Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/08/2004	Other data				QTc 480-520

Additional Information:

Other drugs taken: Omega 3 fatty acids, Salbutamol/Atrovent and Isosorbide Mononitrate.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199759
Reported: 06/08/2004
Hospitalisation:
Onset Date: 11/03/2004
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 66
DOB: 28/10/1937
Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Other drug)	Reason:		
4.0 Milligram	Daily		
Batch:	Started:	Stopped:	
ASPIRIN (Other drug)	Reason:		
100.0 Milligram	Daily		
Batch:	Started:	Stopped:	
CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	550.0 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped:	0

Laboratory Investigations:

Additional Information:

Other drugs taken: Omega 3 fatty acids, Salbutamol/Atrovent and Isosorbide Mononitrate.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199780	Seq: 1	Gender: F
Reported: 09/08/2004		Weight: 0.00
Hospitalisation:		Age: 63
Onset Date: 31/05/2004		DOB: 20/04/1941
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state		Confusion, ongoing urinary tract infections, white blood cell count decreased, neutrophil count decreased, urinary incontinence, slumped posture, hypersalivation and amber blood test results.	
Neutrophil count decreased			
Posture abnormal			
Salivary hypersecretion			
Thrombocytopenia			
Urinary incontinence			
Urinary tract infection			

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
TRIPRIM (Other drug)	Reason:
	Oral
Batch:	Started: Stopped:
SENOKOT (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	75.0 Milligram Daily Oral
Batch:	Started: 15/03/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/08/2004	Neutrophils		28/07/2004	4.64	
09/08/2004	Neutrophils		26/07/2004	2.22	
09/08/2004	Neutrophils		04/02/2004	1.75	
09/08/2004	Neutrophils		11/03/2002	Pre treatment	
09/08/2004	White blood cells		28/07/2004	6.60	
09/08/2004	White blood cells		26/07/2004	3.50	
09/08/2004	White blood cells		04/02/2004	3.30	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199780	Seq: 1	Gender: F
Reported: 09/08/2004		Weight: 0.00
Hospitalisation:		Age: 63
Onset Date: 31/05/2004		DOB: 20/04/1941
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased			

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Tablet	Oral
Batch:	Started:
	Stopped:
TRIPRIM (Other drug)	Reason:
	Oral
Batch:	Started:
	Stopped:
SENOKOT (Other drug)	Reason:
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	75.0 Milligram Daily Oral
Batch:	Started: 15/03/2002
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/08/2004	White blood cells		11/03/2002	Pre treatment	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199801
Reported: 09/08/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 28/05/2002
Outcome: Recovered

Age: 61
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Heart rate increased		Heart rate increased.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet 100.0 Milligram Batch:	Daily Oral Started: 02/05/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/08/2004	Other data		29/04/2002	86.9 (24 hour	Pulse rate.
09/08/2004	Other data		28/05/2002	125.8 (24 hour	Pulse rate.
09/08/2004	Other data		29/04/2002	100.9 (AM	Pulse rate.
09/08/2004	Other data		28/05/2002	134.5 (AM	Pulse rate.
09/08/2004	Other data		29/05/2002	93.5 (PM	Pulse rate.
09/08/2004	Other data		28/05/2002	128.2 (PM	Pulse rate.
09/08/2004	Other data		29/04/2002	77.4 (During	Pulse rate.

Additional Information:

The report stated that the parameters measured over the 24 hour period demonstrated 'significant and concerning deviations'. Changes persisted throughout the 24 hour period. They are most pronounced during the sleep period.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199801
Reported: 09/08/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 28/05/2002
Outcome: Recovered

Age: 61
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 02/05/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/08/2004	Other data		28/05/2002	120.1 (During	Pulse rate.

Additional Information:

The report stated that the parameters measured over the 24 hour period demonstrated 'significant and concerning deviations'. Changes persisted throughout the 24 hour period. They are most pronounced during the sleep period.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199858	Seq: 1	Gender: M
Reported: 10/08/2004		Weight: 0.00
Hospitalisation:		Age: 23
Onset Date: 17/05/2004		DOB: 24/05/1980
Outcome: Not yet recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin increased	Required Visit to Doctor	Nausea, fever, tachycardia - suspected Myocarditis.	Clozapine ceased.
Nausea	Required Visit to Doctor		
Pyrexia	Required Visit to Doctor		
Tachycardia	Required Visit to Doctor		

Medicine Details:

DIAZEPAM (Other drug)	15.0 Milligram	Reason: Otr spec symp psychopathol nec	As necessary
Batch:	Started: 23/02/2004	S TERM	Stopped:
SOLIAN (Other drug)	600.0 Milligram	Reason: Unspecified psychosis	Daily Oral
Batch:	Started: 15/11/2003	S TERM	Stopped:
SERTRALINE HYDROCHLORIDE (Other drug)	50.0 Milligram	Reason: Depression	Daily Oral
Batch:	Started: 15/12/2003	S TERM	Stopped:
CLOZAPINE (Suspected)	300.0 Milligram	Reason: Unspecified psychosis	Daily Oral
Batch:	Started: 04/05/2004		Stopped: 18/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/08/2004	Echocardiogram				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199901
Reported: 11/08/2004
Hospitalisation:
Onset Date: 15/06/2004
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 24
DOB: 25/04/1980
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonism Dysphagia Salivary hypersecretion		Patient developed pseudo-parkinsonism, dysphagia and hypersalivation.	Clozaril ceased.

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:		
Batch:	Started:	Stopped:	Oral
CLOZARIL (Suspected)	Reason:		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 04/06/2004	Stopped: 16/06/2004	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199902 **Seq:** 1 **Gender:** M
Reported: 11/08/2004 **Weight:** 0.00
Hospitalisation: **Age:** 39
Onset Date: 15/06/2002 **DOB:** 05/12/1962
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation	Severe	Severe constipation, anorectal disorder and drug ineffective.	Bulking agents, lactulose and microenemas. Clozaril ceased.
Drug ineffective	Severe		
Proctitis	Severe		

Medicine Details:

RISPERIDONE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	12.0 Milligram	Daily	Oral
Batch:	Started: 27/05/2002	Stopped:	31/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs taken: Antidepressants. Medical history: Pilonidal Sinus repeated anus infections.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 199907

Seq: 1

Gender: F

Reported: 11/08/2004

Weight: 0.00

Hospitalisation:

Age: 41

Onset Date: 22/10/2002

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Heart rate increased		Heart rate elevated and pulse rate variability reduction.	
Pulse abnormal			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	1.0 Gram Daily
Batch:	Started: 11/09/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient showed a 24 hour mean pre-Clozaril treatment pulse rate of 77.7 beats/min and a PRV of 2.5 beats/min on 10 September 2002. 41 days after treatment, the same measurements over 24 hours were performed which showed a mean PR of 102.5 beats/min and a mean PRV of 2.00 beats/min.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200033

Seq: 1

Gender: M

Reported: 16/08/2004

Weight: 0.00

Hospitalisation:

Onset Date: 15/09/2002

Age: 22

Outcome: Not yet recovered

DOB: 08/09/1980

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal Hallucination, auditory Hepatomegaly Nausea Pruritus Splenomegaly Vomiting		Elevated LFT's, vomiting, pruritis, hepatomegaly, nausea, enlarged spleen, hearing voices intermittently.	Clozaril decreased to 300mg/day.

Medicine Details:

CLOZARIL (Suspected)	Reason: Schizophrenia		
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 03/06/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/08/2004	Biochemistry				Jul 2004 - GGT 112; ALT 158; AST 66; Urate 0.54mmol/L
16/08/2004	Other data				26 Jul 2004 - Ultrasound showed enlarged liver and spleen.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200035

Seq: 1

Gender: F

Reported: 16/08/2004

Weight: 0.00

Hospitalisation:

Age: 21

Onset Date: 15/12/1999

DOB: 24/11/1978

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sleep apnoea syndrome		Patient experienced sleep apnoea, weight gain of 30kg, diabetes and hypersalivation.	Clozaril ceased. Positive airway pressure (CPAP) treatment, oral tab for diabetes (unspecified), exercising and improving his diet.
Diabetes mellitus			
Salivary hypersecretion			
Weight increased			

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 10/12/1999	Stopped: 03/08/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/08/2004	Other data				(Dec 1999) Weight gain since commencing Clozaril = approx. 30kg

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200080	Seq: 1	Gender: M
Reported: 17/08/2004		Weight: 0.00
Hospitalisation:		Age: 25
Onset Date: 16/06/2004		DOB: 03/03/1979
Outcome: Recovered	03/08/2004	Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis, monocyte count increased, eosinophil count increased, white blood cell count increased, neutrophil count increased, troponin increased.	Clozaril ceased.
Eosinophil count increased			
Monocyte count increased			
Neutrophil count increased			
Troponin I increased			
White blood cell count increased			

Medicine Details:

EFEXOR-XR (Other drug)		Reason:	
Capsule	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started: 03/05/2004	Stopped: 07/07/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/08/2004	Eosinophils	0.-0.5	16/06/2003	0.7	
17/08/2004	Eosinophils	0.-0.5	23/06/2004	0.5	
17/08/2004	Eosinophils	0.-0.5	12/07/2004	0.4	
17/08/2004	Monocytes	0.1-1.0	16/06/2003	1.2	
17/08/2004	Monocytes	0.1-1.0	23/06/2004	1.6	
17/08/2004	Monocytes	0.1-1.0	12/07/2004	1.9	
17/08/2004	Neutrophils		16/06/2003	6.6	2.0-8.0

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200080
Reported: 17/08/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 16/06/2004
Outcome: Recovered

03/08/2004

Age: 25
DOB: 03/03/1979
Causality: Causality probable

Reaction Details:

Medicine Details:

EFEXOR-XR (Other drug)	Reason:		
Capsule	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started: 03/05/2004	Stopped: 07/07/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/08/2004	Neutrophils		23/06/2004	9.6	2.0-8.0
17/08/2004	Neutrophils		12/07/2004	8.9	2.0-8.0
17/08/2004	Neutrophils		26/07/2004	3.9	2.0-8.0
17/08/2004	Troponin	>0.10	05/07/2004	0.13	
17/08/2004	Troponin	>0.10	06/07/2004	0.14	
17/08/2004	Troponin	>0.10	07/07/2004	>0.10	
17/08/2004	White blood cells		16/06/2003	11.0	4.0-11.0

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200080
Reported: 17/08/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 16/06/2004
Outcome: Recovered

03/08/2004

Age: 25
DOB: 03/03/1979
Causality: Causality probable

Reaction Details:

Medicine Details:

EFEXOR-XR (Other drug)	Reason:		
Capsule	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started: 03/05/2004	Stopped: 07/07/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/08/2004	White blood cells		23/06/2004	13.8	4.0-11.0
17/08/2004	White blood cells		12/07/2004	14.4	4.0-11.0
17/08/2004	White blood cells		26/07/2004	7.3	4.0-11.0

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200114 **Seq:** 1 **Gender:** M
Reported: 18/08/2004 **Weight:** 0.00
Hospitalisation: **Age:** 19
Onset Date: 16/07/2004 **DOB:** 30/11/1984
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient developed Neutropenia.	Ceased Clozapine and continued to monitor blood neutrophil levels.

Medicine Details:

SOLIAN (Other drug)	Reason:
Tablet 800.0 Milligram Daily Oral	
Batch:	Started: 20/05/2004 S TERM Stopped:
CLOPINE (Suspected)	Reason: Agranulocytosis
Tablet 25.0 Milligram Daily Oral	
Batch:	Started: 05/07/2004 Stopped: 16/07/2004
CLOPINE (Suspected)	Reason: Agranulocytosis
Tablet 200.0 Milligram Daily Oral	
Batch:	Started: 05/07/2004 Stopped: 16/07/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Neutrophil count still below normal level at 28/7/2004.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200133
Reported: 18/08/2004

Seq: 1

Gender: M
Weight: 130.00

Hospitalisation:

Onset Date: 15/07/2004
Outcome: Unknown

Age: 32
DOB: 27/06/1972
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Required Visit to Doctor	Patient developed neutrophilia.	Quetiapine introduced.

Medicine Details:

QUETIAPINE (Other drug)	Reason:	
Tablet	Oral	
Batch:	Started:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia	
Tablet	125.0 Milligram	Oral
Batch:	Started: 27/07/1998	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/08/2004	Neutrophils		22/07/2004	14.30 x10 ⁹ /L	
18/08/2004	Neutrophils		30/07/2004	4.10 x 10 ⁹ /L	
18/08/2004	Neutrophils		05/08/2004	14.10 x 10 ⁹ /L	
18/08/2004	White blood cells		22/07/2004	18.80 x 10 ⁹ /L	
18/08/2004	White blood cells		30/07/2004	60.80 x 10 ⁹ /L	
18/08/2004	White blood cells		05/08/2004	17.80 x 10 ⁹ /L	

Additional Information:

The patient's physician mentioned that he was a tall erson (6 foot eight) and was 150 kg, however since his maintenance dose was stabilised at 200mg/daily and the doctor introduced Quetiapine, the patient had lost 20 kg. The patient's weight before starting Clozaril treatment was not mentioned. It was also stated that he currently had a flu like illness and sinus problems. Weight was initially at 130 kg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200171 **Seq:** 1 **Gender:** M
Reported: 20/08/2004 **Weight:** 100.00
Hospitalisation: **Age:** 44
Onset Date: 06/08/2004 **DOB:** 16/11/1959
Outcome: Recovered 09/08/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetic ketoacidosis	Life threatening	Diabetic Ketoacidosis.	

Medicine Details:

GEMFIBROZIL (Other drug)	Reason: Xanthomatosis
1.0 Gram	Daily Oral
Batch:	Started: Stopped:
CITALOPRAM HYDROBROMIDE (Other drug)	Reason:
Tablet 20.0 Milligram	Daily Oral
Batch:	Started: Stopped:
SODIUM VALPROATE (Other drug)	Reason: Other&unspecified epilepsy
Tablet 1.0 Gram	Daily Oral
Batch:	Started: Stopped:
CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 75.0 Milligram	Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/08/2004	Serum glucose				BSL - 40.
20/08/2004	pH				pH - 7.2.

Additional Information:

Likely background metabolic syndrome and possibly unrecognised T2DM.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200294
Reported: 25/08/2004
Hospitalisation:
Onset Date: 04/07/2004
Outcome: Recovered

Seq: 1

Gender: F
Weight: 0.00
Age: 19
DOB: 12/04/1985
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Patient experienced agranulocytosis, leucopenia and fever.	Clopine ceased.
Leukopenia			
Lymphopenia			
Pyrexia			
Syncope			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	175.0 Milligram Daily Oral
Batch:	Started: 24/06/2004 Stopped: 07/07/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/08/2004	Neutrophils		01/07/2004	2.4	
25/08/2004	Neutrophils		06/07/2004	2.1	
25/08/2004	Neutrophils		21/07/2004	4.0	
25/08/2004	White blood cells		01/07/2004	5.0	
25/08/2004	White blood cells		06/07/2004	2.9	
25/08/2004	White blood cells		21/07/2004	6.4	

Additional Information:

History of hypothyroidism (2 years ago).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200296	Seq: 1	Gender: M
Reported: 25/08/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 59
Onset Date: 15/07/2004		DOB: 30/05/1945
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mental disorder	Caused or prolonged inpatient hospitalisation	Florid psychotic symptoms, extremely drowsy.	Received zuclopenthixol 100mg/depot.
Confusional state	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
Benzodiazepine NOS (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	175.0 Milligram Daily Oral
Batch:	Started: 23/04/2003 Stopped: 28/10/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozaril was discontinued on 20 Sep 2004. Clozaril was reintroduced on 14 Oct 2004, with a new dose of zuclopenthixol decanoate 300mg/depot given to the patient on 18/10/2004. Patient recieved his last dose of Clozaril (50mg) and the medication was formally ceased on 28 Oct 2004.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200296 **Seq:** 1 **Gender:** M
Reported: 25/08/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 59
Onset Date: 15/07/2004 **DOB:** 30/05/1945
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
Benzodiazepine NOS (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	175.0 Milligram	Daily	Oral
Batch:	Started: 23/04/2003	Stopped: 28/10/2004	0

Laboratory Investigations:

Additional Information:

Clozaril was discontinued on 20 Sep 2004. Clozaril was reintroduced on 14 Oct 2004, with a new dose of zuclopenthixol decanoate 300mg/depot given to the patient on 18/10/2004. Patient recieved his last dose of Clozaril (50mg) and the medication was formally ceased on 28 Oct 2004.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200302	Seq: 1	Gender: M
Reported: 25/08/2004		Weight: 0.00
Hospitalisation:		Age: 22
Onset Date: 04/05/2004		DOB: 19/03/1982
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged		Patient developed tachycardia of 129 bpm and prolonged QTc interval on ECG.	Seen in emergency department. Clozaril ceased and Olanzapine commenced.
Tachycardia			

Medicine Details:

DIAZEPAM (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Schizophrenia
Tablet	175.0 Milligram Daily Oral
Batch:	Started: 14/04/2004 Stopped: 04/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/08/2004	Electrocardiograph				2004 - Pre-Clozaril treatment ECG normal. 04-May-2004 ECG showed prolonged QTc interval; heart rate 129 bpm. 2004 - post Clozaril cessation ECG normal.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200304

Seq: 1

Gender: U

Reported: 25/08/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Patient developed agranulocytosis.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The reporter was unable to provide any further information.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200305	Seq: 1	Gender: F
Reported: 25/08/2004		Weight: 0.00
Hospitalisation:		Age: 76
Onset Date: 05/08/2004		DOB: 11/04/1928
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sedation		Patient was over-sedated and often unarouseable post-surgery for 1-2 days.	
Drug interaction			

Medicine Details:

ANAESTHETIC NOS (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 27/05/1996	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200349	Seq: 1	Gender: M
Reported: 27/08/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 43
Onset Date: 17/08/2004		DOB: 14/06/1961
Outcome: Recovered	19/08/2004	Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Patient developed neutropenia, low neutrophil count.	Undergoing daily monitoring of FBC and ESR.

Medicine Details:

PARACETAMOL (Other drug)	Reason: Pain
Batch:	Stopped: Oral
Started:	
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	Oral
125.0 Milligram	Daily
Batch:	Stopped: 17/08/2004 0
Started: 21/04/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Cert:rechall. Patient has been previously exposed to Clozapine and has a history of seizures following administration of Clozapine and Sertraline last month (case 8671). Clopine was re-started and stopped again due to neutropenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200352

Seq: 1

Gender: F

Reported: 27/08/2004

Weight: 0.00

Hospitalisation:

Age: 33

Onset Date:

DOB: 26/02/1971

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal impairment		Poor renal function.	Clopine ceased

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	150.0 Milligram Daily Oral
Batch:	Started: 24/05/2004 Stopped: 17/08/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200361 **Seq:** 1 **Gender:** M
Reported: 27/08/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 30
Onset Date: 18/07/2004 **DOB:** 02/12/1973
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder Pericardial effusion Pericarditis		Cardiac complications.	Clopine ceased

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason:
2.0 Gram	Oral
Batch:	Started: 18/05/2004 Stopped: 28/08/2004
SODIUM VALPROATE (Other drug)	Reason:
2.0 Gram	
Batch:	Started: 18/05/2004 Stopped: 01/09/2004
RISPERIDONE (Other drug)	Reason:
6.0 Milligram	
Batch:	Started: 10/06/2004 Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 13/07/2004 Stopped: 31/07/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

200953 is a duplicate of this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200361 **Seq:** 1

Reported: 27/08/2004

Hospitalisation: Admitted to hospital

Onset Date: 18/07/2004

Outcome: Recovered

Gender: M

Weight: 0.00

Age: 30

DOB: 02/12/1973

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason:
	300.0 Milligram Daily
Batch:	Started: 18/06/2004 Stopped: 13/07/2004

Laboratory Investigations:

Additional Information:

200953 is a duplicate of this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200362	Seq: 1	Gender: M
Reported: 27/08/2004		Weight: 0.00
Hospitalisation:		Age: 48
Onset Date: 15/08/2003		DOB: 03/04/1955
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Tachycardia Echography abnormal Tachycardia		Cardiomyopathy. Tachyarrhythmia	Ceased Clozaril.

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
DIAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
BENZHEXOL HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 28/06/2002 Stopped: 20/08/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/08/2004	Electrocardiograph				ECG 18 Aug 2003: ECG normal 18 Aug 2003: Echocardiography abnormal: 40% left ventricular (LV) ejection fraction, no LV hypertrophy, LV dilation, LV end dimension 6.5 cm (diastole), LV end dimension 5.3 cm (systole), abnormal valves specified as systolic anterior motion of mitral, normal pericardium and normal localised/segmental function.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200363
Reported: 27/08/2004

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 53

DOB: 02/02/1951

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal necrosis	Severe	Large bowel necrosis with associated severe constipation.	Clopine ceased.
Constipation	Severe		

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	Daily Oral
Batch:	Started: 26/08/2002 Stopped: 09/08/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200366

Seq: 1

Gender: M

Reported: 27/08/2004

Weight: 0.00

Hospitalisation:

Age: 43

Onset Date:

DOB: 14/06/1961

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizures	Clopine and Sertraline ceased.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Interaction)	Reason:	
Batch:	Started:	Stopped:
CLOPINE (Interaction)	Reason: Schizophrenia	
Tablet	400.0 Milligram	Daily
Batch:	Started: 21/04/2004	Stopped: 14/07/2004
PARACETAMOL (Other drug)	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 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200428	Seq: 1	Gender: M
Reported: 30/08/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 24
Onset Date: 30/06/2004		DOB: 09/12/1979
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Accidental overdose	Caused or prolonged inpatient hospitalisation	Patient unintentionally overdosed on Clozapine and Lithium. Patient also experienced dribbling, sedation and accidental overdose.	
Salivary hypersecretion	Caused or prolonged inpatient hospitalisation		
Sedation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLONAZEPAM (Other drug)	Reason:
2.0 Milligram	Daily
Batch:	Started:
Batch:	Stopped:
CLOZAPINE (Suspected)	Reason:
Tablet	Oral
Batch:	Started: 01/01/2002
Batch:	Stopped: contin
LITHIUM CARBONATE (Suspected)	Reason:
Batch:	Started:
Batch:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200506	Seq: 1	Gender: M
Reported: 02/09/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 30
Onset Date: 27/07/2004		DOB: 24/02/1974
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome, sweating, headache, stiff joints, atrial flutter, fever, fine tremor, rash.	Ceased Clozaril.
Atrial flutter	Caused or prolonged inpatient hospitalisation		
Headache	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM (Other drug)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 02/06/2004	Stopped:	
ANAFRANIL (Other drug)		Reason:	
Tablet	100.0 Milligram	Daily	
Batch:	Started: 11/02/2004	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	550.0 Milligram	Daily	Oral
Batch:	Started: 06/12/2002	Stopped: 27/07/2004	
SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 17/07/2004	Stopped: 27/07/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/09/2004	Creatine	0-195	27/07/2004	655	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200506	Seq: 1	Gender: M
Reported: 02/09/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 30
Onset Date: 27/07/2004		DOB: 24/02/1974
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Joint stiffness	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM (Other drug)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 02/06/2004	Stopped:	
ANAFRANIL (Other drug)		Reason:	
Tablet	100.0 Milligram	Daily	
Batch:	Started: 11/02/2004	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	550.0 Milligram	Daily	Oral
Batch:	Started: 06/12/2002	Stopped: 27/07/2004	
SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 17/07/2004	Stopped: 27/07/2004	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200506	Seq: 1	Gender: M
Reported: 02/09/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 30
Onset Date: 27/07/2004		DOB: 24/02/1974
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM (Other drug)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 02/06/2004	Stopped:	
ANAFRANIL (Other drug)		Reason:	
Tablet	100.0 Milligram	Daily	
Batch:	Started: 11/02/2004	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	550.0 Milligram	Daily	Oral
Batch:	Started: 06/12/2002	Stopped: 27/07/2004	
SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 17/07/2004	Stopped: 27/07/2004	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200599	Seq: 1	Gender: M
Reported: 07/09/2004		Weight: 0.00
Hospitalisation:		Age: 26
Onset Date: 27/08/2004		DOB: 21/03/1978
Outcome: Recovered with sequelae		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	Patient was found with tonic-clonic seizures on the floor, biting through his top lip (mucosal surface only) and hitting the left side of his forehead on a skirting board.	Haloperidol was immediately ceased, following that, Sertraline was ceased. He was commenced on Diazepam 5mg and had his nightly Clozaril dose withheld. Clozaril continued as per usual the following day.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
CHLORPROMAZINE HYDROCHLORIDE (Suspected)	Reason:
Batch:	Started: Stopped:
HALOPERIDOL (Suspected)	Reason:
	As necessary
Batch:	Started: Stopped: 27/08/2004
CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 19/08/2004 Stopped: Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200617

Seq: 1

Gender: M

Reported: 07/09/2004

Weight: 0.00

Hospitalisation:

Age: 38

Onset Date:

DOB: 14/06/1966

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		The patient developed seizures.	

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	550.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical history of post head injury psychosis and epilepsy. The patient experienced an increase in seizures after the dose of clopine was increased from 450mg to 550mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200623	Seq: 1	Gender: F
Reported: 07/09/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 33
Onset Date: 28/05/2004		DOB: 03/03/1971
Outcome: Recovered	08/06/2004	Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperpyrexia	Caused or prolonged inpatient hospitalisation	The patient experienced hyperthermia, sustained pyrexia, rigors, sweats and tachycardia to 160/min.	Clopine ceased, Paracetamol given.
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		
Chills	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
	1.0 Gram	Daily	Oral
Batch:	Started: 15/01/2004	S TERM	Stopped: Continuing
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
	200.0 Milligram	Daily	Oral
Batch:	Started: 15/04/2004	Stopped: 05/06/2004	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/09/2004	C-Reactive Protein		28/05/2004	200	
07/09/2004	Electrocardiograph		28/05/2004	Sinus	

Additional Information:

The patient has a history of cannabis abuse.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200623 **Seq:** 1 **Gender:** F
Reported: 07/09/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 33
Onset Date: 28/05/2004 **DOB:** 03/03/1971
Outcome: Recovered 08/06/2004 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
	1.0 Gram	Daily	Oral
Batch:	Started: 15/01/2004	S TERM	Stopped: Continuing
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 15/04/2004	Stopped: 05/06/2004	0

Laboratory Investigations:

Additional Information:

The patient has a history of cannabis abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200831 **Seq:** 1 **Gender:** F
Reported: 14/09/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 28
Onset Date: 01/09/2004 **DOB:** 13/11/1975
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder	Caused or prolonged inpatient hospitalisation	The patient experienced florid psychosis as a withdrawal reaction.	Clozaril to be restarted at a reduced dose.
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.0 Milligram Daily Oral
Batch:	Started: 27/10/2003 Stopped: 26/08/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

At the time of the event, she was also taking drugs of abuse (not specified). Clozaril was recommenced on 25 September at a daily dose of 12.5 mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200955
Reported: 20/09/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 29/08/2004
Outcome: Recovered

Age: 26
DOB: 20/10/1977
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder Tachycardia Troponin increased		Cardiac disorder nos.	Ceased Clopine.

Medicine Details:

SODIUM VALPROATE (Other drug) 2.0 Gram Batch: Started: Stopped:	Reason: Unspecified schizophrenia
FLUPENTHIXOL DECANOATE (Other drug) Injection 40.0 Milligram Batch: Started: Stopped:	Reason: Intramuscular
MIRTAZAPINE (Other drug) 30.0 Milligram Batch: Started: Stopped:	Reason: Unspecified schizophrenia
CLOPINE (Suspected) Tablet 325.0 Milligram Daily Batch: Started: 20/08/2004 Stopped: 08/09/2004 0	Reason: Unspecified schizophrenia

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had a history of asthma, treatment-resistant schizophrenia/schizoaffective disorder and developmental delay.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 200976
Reported: 20/09/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 31/08/2004
Outcome: Recovered

Age: 44
DOB: 17/05/1960
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrasystoles	Life threatening	Patient experienced multiple ectopic beats.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 11/02/2004 Stopped: 06/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201097	Seq: 1	Gender: M
Reported: 23/09/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 22
Onset Date: 11/09/2004		DOB: 02/04/1982
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis, tachycardia, dyspnoea, influenza like illness, Troponin I increased, leukocytosis, neutrophilia, monocytosis.	Clozaril ceased.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 30/08/2004	Stopped: 14/09/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/09/2004	Creatine		15/09/2004	85	
23/09/2004	Monocytes		14/09/2004	1.18	
23/09/2004	Monocytes		27/08/2004	1.0	
23/09/2004	Monocytes		12/09/2004	1.81	
23/09/2004	Neutrophils		14/09/2004	11.6	
23/09/2004	Neutrophils		12/09/2004	7.91	
23/09/2004	Neutrophils		27/08/2004	3.59	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201097	Seq: 1	Gender: M
Reported: 23/09/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 22
Onset Date: 11/09/2004		DOB: 02/04/1982
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Influenza like illness	Caused or prolonged inpatient hospitalisation		
Leukocytosis	Caused or prolonged inpatient hospitalisation		
Monocytosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 30/08/2004	Stopped:	14/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/09/2004	Troponin		14/09/2004	1.6	
23/09/2004	Troponin		12/09/2004	4.3	
23/09/2004	Troponin		07/09/2004	Not detected	
23/09/2004	White blood cells		14/09/2004	11.2	
23/09/2004	White blood cells		12/09/2004	11.6	
23/09/2004	White blood cells		27/08/2004	7.9	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201097 **Seq:** 1 **Gender:** M
Reported: 23/09/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 22
Onset Date: 11/09/2004 **DOB:** 02/04/1982
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutrophilia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		
Troponin I increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 30/08/2004 Stopped: 14/09/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201289	Seq: 1	Gender: M
Reported: 27/09/2004		Weight: 0.00
Hospitalisation:		Age: 33
Onset Date: 13/09/2004		DOB: 30/12/1970
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis Blood cholesterol increased Blood glucose increased Blood triglycerides increased Chest pain Somnolence Troponin increased White blood cell count increased		Patient experienced myocarditis, drowsiness, raised Troponin level and pain in the chest.	Clozaril ceased.

Medicine Details:

HALOPERIDOL (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
RISPERIDONE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLONAZEPAM (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 02/09/2004 Stopped: 20/09/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/09/2004	Troponin		20/09/2004	1.1	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201305
Reported: 27/09/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 15/08/2004
Outcome: Recovered

Age: 45
DOB: 12/04/1959
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Required Visit to Doctor	The patient developed tachycardia of up to 130 bpm.	

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 25/06/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201306

Seq: 1

Gender: M

Reported: 27/09/2004

Weight: 0.00

Hospitalisation:

Onset Date: 24/08/2004

Age: 51

DOB: 04/03/1953

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Required Visit to Doctor	The first dose of Clozapine resulted in tachycardia of 130 bpm.	

Medicine Details:

LORAZEPAM (Other drug)	Reason: Otr spec symp psychopathol nec		
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	12.0 Milligram	Daily	Oral
Batch:	Started: 24/08/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201307 **Seq:** 1 **Gender:** M
Reported: 27/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 52
Onset Date: 15/08/2004 **DOB:** 22/06/1952
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Required Visit to Doctor	Developed raised neutrophil and WCC, temp increased, tachycardia up to 125 bpm and increased blood pressure.	Treated with Antibiotics and Ramipril 5mg/daily given.
Blood pressure increased	Required Visit to Doctor		
Body temperature increased	Required Visit to Doctor		
Neutrophil count increased	Required Visit to Doctor		
White blood cell count increased	Required Visit to Doctor		

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 16/07/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction continued even in the changes of dose of Clozapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201308
Reported: 27/09/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 15/08/2004
Outcome: Recovered

Age: 23
DOB: 08/12/1980
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Tachycardia up to 125 bpm-lasting for approximately 1 month.	Required a visit by doctor. Treated with Atenolol 50mg total till stopped currently on 25mg/daily.

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason: Manic-depression psycho,manic		
Tablet	1.0 Gram	Daily	Oral
Batch:	Started:	Stopped:	Continuing
CLOPIXOL DEPOT (Suspected)	Reason: Unspecified schizophrenia		
Injection			
Batch:	Started:	Stopped: 31/07/2004	
CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 02/07/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Recovery date: 09/2004



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201309	Seq: 1	Gender: M
Reported: 27/09/2004		Weight: 0.00
Hospitalisation:		Age: 23
Onset Date: 15/08/2004		DOB: 10/12/1980
Outcome: Not yet recovered		Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Hypertension Neutrophil count increased Pyrexia White blood cell count increased		The patient developed increased white cell count and neutrophil count, temperature and increased pulse and hypertension. Tachycardia of up to 130 bpm. Required a visit by doctor.	

Medicine Details:

AMISULPRIDE (Other drug)		Reason: Unspecified schizophrenia
Tablet	400.0 Milligram	Daily Oral
Batch:	Started: 15/07/2004	Stopped:
SODIUM VALPROATE (Other drug)		Reason: Manic-depression psycho,manic
	2.0 Gram	Daily Oral
Batch:	Started:	Stopped:
Aripiprazole (Other drug)		Reason: Unspecified schizophrenia
Tablet	15.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 15/06/2004
CLOPINE (Suspected)		Reason: Unspecified schizophrenia
Tablet	150.0 Milligram	Daily Oral
Batch:	Started: 11/07/2003	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug is cert/rechallenge.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201310

Seq: 1

Gender: F

Reported: 27/09/2004

Weight: 0.00

Hospitalisation:

Age: 41

Onset Date: 15/08/2004

DOB: 05/07/1963

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Severe	Patient experienced severe tachycardia up to 130 bpm.	Required a visit by doctor

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 02/08/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Once dose reached 200mg/day, severe tachycardia developed. Resolved slowly with time.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201311	Seq: 1	Gender: M
Reported: 27/09/2004		Weight: 0.00
Hospitalisation: Hospitalisation prolonged		Age: 43
Onset Date:		DOB: 01/10/1960
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion	Caused or prolonged inpatient hospitalisation	Patients complaining of feeling weak, having shortness of breath and a choking feeling (dysphagia?) due to excessive salivation which he attributes to clozapine (Clopine).	Clopine was slowly reduced then ceased and increased the dose of another antipsychotic that was being taken concurrently.
Asthenia	Caused or prolonged inpatient hospitalisation		
Choking sensation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Probitor (Other drug)	Reason:
20.0 Milligram	Daily Oral
Batch:	Started: Stopped:
ZYPREXA (Other drug)	Reason:
10.0 Milligram	Daily Oral
Batch:	Started: Stopped:
ENDEP (Other drug)	Reason:
25.0 Milligram	Daily Oral
Batch:	Started: Stopped:
CLOPINE (Suspected)	Reason:
800.0 Milligram	Oral
Batch:	Started: 29/04/2003 Stopped: 25/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201311	Seq: 1	Gender: M
Reported: 27/09/2004		Weight: 0.00
Hospitalisation: Hospitalisation prolonged		Age: 43
Onset Date:		DOB: 01/10/1960
Outcome: Unknown		Causality: Causality possible

Reaction Details:

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

Medicine Details:

Probitor (Other drug)	Reason:
20.0 Milligram	Daily Oral
Batch:	Started: Stopped:
ZYPREXA (Other drug)	Reason:
10.0 Milligram	Daily Oral
Batch:	Started: Stopped:
ENDEP (Other drug)	Reason:
25.0 Milligram	Daily Oral
Batch:	Started: Stopped:
CLOPINE (Suspected)	Reason:
800.0 Milligram	Oral
Batch:	Started: 29/04/2003 Stopped: 25/09/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201435

Seq: 1

Gender: F

Reported: 05/10/2004

Weight: 0.00

Hospitalisation:

Age: 35

Onset Date:

DOB: 16/04/1969

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced seizures.	Clozaril discontinued.

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 29/06/2004 Stopped: 01/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201437 **Seq:** 1 **Gender:** F
Reported: 05/10/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 32
Onset Date: 19/09/2004 **DOB:** 28/10/1971
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Patient experienced seizure.	Sodium Valproate 50mg bd.

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 23/06/2004 Stopped:
OXAZEPAM (Suspected)	Reason:
	30.0 Milligram Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201471 **Seq:** 1 **Gender:** F
Reported: 05/10/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 50
Onset Date: 15/09/2004 **DOB:** 28/08/1954
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Life threatening	The patient experienced seizure and became unconscious. She also experienced increased white blood cell and neutrophils count, however, at that time Clozaril had been interrupted.	Transferred to ICU.
Loss of consciousness	Life threatening		

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	12.0 Milligram	Daily	Oral
Batch:	Started: 25/11/1998	Stopped:	21/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201507
Reported: 07/10/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 37
DOB: 06/06/1967
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		The patient, who has been on Clozapine for approximately 4 years, is now suffering from tachycardia His heart rate is in the range of 130.	Clozapine dosage reduced from 600mg daily to 50mg daily.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	600.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/10/2004	Echocardiogram				Normal echocardiogram on 5 Sep 2002.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201509 **Seq:** 1 **Gender:** M
Reported: 07/10/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 53
Onset Date: 13/09/2004 **DOB:** 03/05/1951
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	The patient experienced neutropenia, leucopenia, hyperglycaemia and glycosuria.	Hospitalised. Clopine ceased.
Glycosuria	Caused or prolonged inpatient hospitalisation		
Hyperglycaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 04/08/2004 Stopped: 14/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/10/2004	Neutrophils		13/09/2004	1.4 x 10 ⁹ L	
07/10/2004	White blood cells		13/09/2004	3.2 x 10 ⁹ L	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201509 **Seq:** 1 **Gender:** M
Reported: 07/10/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 53
Onset Date: 13/09/2004 **DOB:** 03/05/1951
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Details:

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

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 04/08/2004 Stopped: 14/09/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201553 **Seq:** 1 **Gender:** M
Reported: 08/10/2004 **Weight:** 138.00
Hospitalisation: Admitted to hospital **Age:** 17
Onset Date: 15/12/1999 **DOB:** 21/01/1982
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sedation	Caused or prolonged inpatient hospitalisation	Sedation, weight increased.	Ceased Clopine and change of treatment to aripiprazole.
Weight increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason: Paranoid type schizophrenia
Tablet	450.0 Milligram Daily Oral
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201564	Seq: 1	Gender: M
Reported: 08/10/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 35
Onset Date: 20/08/2004		DOB: 04/12/1968
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased	Caused or prolonged inpatient hospitalisation	Weight gain, inadequate response, hypersomnolence.	Cease Clopine
Drug ineffective	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EFEXOR-XR (Other drug)		Reason:	
Capsule	150.0 Milligram		Oral
Batch:	Started:	L TERM	Stopped:
DIAZEPAM (Other drug)		Reason:	
	5.0 Milligram	As necessary	Oral
Batch:	Started: 20/08/2004		Stopped: 07/09/2004 0
CLONAZEPAM (Other drug)		Reason: Otr spec symp psychopathol nec	
Injection	2.0 Milligram	As necessary	Intramuscular
Batch:	Started: 20/08/2004		Stopped: 07/09/2004 0
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	275.0 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 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201753	Seq: 1	Gender: F
Reported: 15/10/2004		Weight: 0.00
Hospitalisation:		Age: 40
Onset Date: 01/10/2004		DOB: 06/09/1964
Outcome: Recovered	08/10/2004	Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased		White cell count decreased, neutrophil count decreased.	
Neutrophil count decreased			

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason:
500.0 Milligram	
Batch:	Started: 08/04/2004 Stopped: 01/10/2004
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	550.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/10/2004	Neutrophils	x 10^9/L	01/09/2004	2.3	
15/10/2004	Neutrophils	x 10^9/L	29/09/2004	1.7	
15/10/2004	Neutrophils	x 10^9/L	01/10/2004	1.5	
15/10/2004	Neutrophils	x 10^9/L	08/10/2004	3.1	
15/10/2004	Neutrophils	x 10^9/L	04/10/2004	2.3	
15/10/2004	White blood cells	x 10^9/L	01/09/2004	3.7	
15/10/2004	White blood cells	x 10^9/L	29/09/2004	2.8	

Additional Information:

Clopine therapy was re-commenced on 1 Oct 2004 and the patient developed low white cell count and neutrophil count again on 22 October 2004 after recovery from the event on 8 October 2004.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201753
Reported: 15/10/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 01/10/2004
Outcome: Recovered

08/10/2004

Age: 40
DOB: 06/09/1964
Causality: Causality certain

Reaction Details:

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason:
500.0 Milligram	
Batch:	Started: 08/04/2004 Stopped: 01/10/2004
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	550.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/10/2004	White blood cells	x 10 ⁹ /L	01/10/2004	2.8	
15/10/2004	White blood cells	x 10 ⁹ /L	04/10/2004	3.7	
15/10/2004	White blood cells	x 10 ⁹ /L	08/10/2004	4.6	

Additional Information:

Clopine therapy was re-commenced on 1 Oct 2004 and the patient developed low white cell count and neutrophil count again on 22 October 2004 after recovery from the event on 8 October 2004.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201768
Reported: 15/10/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 02/10/2004

Age: 32

Outcome: Unknown

DOB: 01/12/1971

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Treated in outpatient department only	Patient experienced neutropenia, flu-like symptoms, cough, pyrexia and pharyngolaryngeal pain.	
Cough	Treated in outpatient department only		
Influenza like illness	Treated in outpatient department only		

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	275.0 Milligram Daily Oral
Batch:	Started: 02/06/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/10/2004	Neutrophils		28/05/2004	5.05	
15/10/2004	Neutrophils		02/10/2004	2.3	
15/10/2004	Neutrophils		04/10/2004	3.5 x 10 ⁹ /L	
15/10/2004	Neutrophils		03/10/2004	1.97	
15/10/2004	White blood cells		28/05/2004	8	
15/10/2004	White blood cells		02/10/2004	3.6	
15/10/2004	White blood cells		03/10/2004	4.7	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201768
Reported: 15/10/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 02/10/2004
Outcome: Unknown

Age: 32
DOB: 01/12/1971
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pharyngolaryngeal abscess	Treated in outpatient department only		
Pyrexia	Treated in outpatient department only		

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	275.0 Milligram Daily Oral
Batch:	Started: 02/06/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/10/2004	White blood cells		04/10/2004	6.6 x 10 ⁹ /L	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201800
Reported: 18/10/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 01/10/2004
Outcome: Unknown

Age: 24
DOB: 02/06/1980
Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased		Patient developed high serum Clozapine levels.	Clopine ceased.

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
QUETIAPINE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOPINE (Suspected)	Reason:		
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/10/2004	Serum drug level	1.1 mmol/L			Serum Clozapine level of 4.36 mmol/L

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201828	Seq: 1	Gender: M
Reported: 19/10/2004		Weight: 0.00
Hospitalisation:		Age: 22
Onset Date: 25/08/2004		DOB: 07/12/1981
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome Blood creatine phosphokinase incr Disorientation Leukocytosis Liver function test abnormal Tremor		Neuroleptic malignant syndrome, leukocytosis, elevated liver enzymes, elevated CPK levels.	Clopine ceased

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)		Reason: Depression
300.0 Milligram	Daily	Oral
Batch:	Started: 24/08/2004	Stopped:
CLOPINE (Suspected)		Reason: Unspecified psychosis
Tablet	350.0 Milligram	Daily Oral
Batch:	Started: 22/07/2004	Stopped: 16/09/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/10/2004	ALT = SGPT		21/10/2004	90	
19/10/2004	AST = SGOT		21/10/2004	58	
19/10/2004	Creatine	0 - 270	21/10/2004	746	
19/10/2004	GGT = SGGT =		21/10/2004	113	
19/10/2004	LDH		21/10/2004	22	
19/10/2004	Neutrophils		21/10/2004	8.85 x 10 ⁹ /L	
19/10/2004	SAP = ALP		21/10/2004	123	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201828
Reported: 19/10/2004

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 25/08/2004

Age: 22

Outcome: Recovered

DOB: 07/12/1981

Causality: Causality possible

Reaction Details:

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)	Reason: Depression
300.0 Milligram	Daily Oral
Batch:	Started: 24/08/2004 Stopped:
CLOPINE (Suspected)	Reason: Unspecified psychosis
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 22/07/2004 Stopped: 16/09/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/10/2004	White blood cells		21/10/2004	12x10 ⁹ /L	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201864	Seq: 1	Gender: M
Reported: 20/10/2004		Weight: 0.00
Hospitalisation:		Age: 15
Onset Date: 13/10/2004		DOB: 01/04/1989
Outcome: Unknown		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		Patient experienced postural hypotension, bradycardia and severe sedation.	
Bradycardia			
Sedation	Severe		

Medicine Details:

CENTRUM TABLETS (Other drug)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
BENZTROPINE MESYLATE (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason:
Tablet	12.0 Milligram Daily Oral
Batch:	Started: 13/10/2004 Stopped: 14/10/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201888

Seq: 1

Gender: F

Reported: 21/10/2004

Weight: 0.00

Hospitalisation:

Onset Date: 09/09/2004

Age: 38

Outcome: Unknown

DOB: 03/03/1966

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus Fatigue Glucose tolerance impaired Hyperglycaemia Lethargy Low density lipoprotein increased Weight increased		Patient developed diabetes, hyperglycaemia, blocose tolerance test was abnormal, lethargy, fatigue, weight gain and low density lipoprotein level increased.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	550.0 Milligram Daily Oral
Batch:	Started: 11/04/2003 L TERM Stopped: 31/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/10/2004	Serum glucose				11/10/04: fasting blood glucose 5.5 mmol/L; 9/9/04: Fasting blood glucose 6.4 mmol/L; 11/10/04: Glucose 1 hour: 11.1 mmol/L 11/10/04: Glucose 2 hour: 11.0 mmol/L 11/10/04: Oral Glucose Tolerance Test: The findings indicate impaired glucose tolerance. 9/9/04: High-density lipoprotein: 1.27 9/9/04: Low-density lipoprotein: 4.1

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201969
Reported: 22/10/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 51
DOB: 20/10/1953
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Patient experienced tachycardia, elevated temperature and episode of atrial fibrillation.	Clopine ceased.
Atrial fibrillation			
Pyrexia			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 14/09/2004 Stopped: 05/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/10/2004	Other data				At the time of event, her white cell count an neutrophil count were withi the normal range whilst on 200mg PO Clopine daily.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 201976 **Seq:** 1 **Gender:** F
Reported: 25/10/2004 **Weight:** 0.00
Hospitalisation: Treated in Accident/Emergency Department **Age:** 44
Onset Date: 04/10/2004 **DOB:** 12/05/1960
Outcome: Recovered 28/10/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia	Caused or prolonged inpatient hospitalisation	Patient experienced pneumonia during Clopine treatment.	Clopine treatment ceased. Treated in ICU and was intubated.
Respiratory failure	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM (Other drug)	Reason: Unspecified schizophrenia		
Tablet	1.0 Gram	Daily	Oral
Batch:	Started:	Stopped:	
CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 04/02/2004	Stopped: 03/10/2004	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/10/2004	Other data				At the time event, patient had white cell count and neutrophil count within the normal range and was on 600mg PO Clopine.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202019

Seq: 1

Gender: M

Reported: 26/10/2004

Weight: 0.00

Hospitalisation:

Age: 28

Onset Date:

DOB: 05/12/1975

Outcome: Unknown

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Congestive cardiomyopathy		The patient experienced tachycardia and dilated cardiomyopathy.	Clopine ceased
Tachycardia			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	550.0 Milligram Daily Oral
Batch:	Started: 15/12/2003 Stopped: 18/10/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

CERTAIN - Rechallenge; Also taking benztropine, aspirin and omeprazole



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202097 **Seq:** 1 **Gender:** M
Reported: 27/10/2004 **Weight:** 0.00
Hospitalisation: **Age:** 31
Onset Date: **DOB:** 16/07/1973
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
White blood cell count increased		White blood cell count increased, suspected interaction between Clozaril and Luvox and drug level increased.	
Drug interaction			
Drug level increased			

Medicine Details:

LUVOX (Interaction)	Reason:		
Tablet	Oral		
Batch:	Started:	Stopped:	
CLOZARIL (Interaction)	Reason:		
Tablet	12.0 Milligram	Daily	Oral
Batch:	Started: 05/08/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/10/2004	Serum drug level				05/10/04: High plasma Clozapine level of 1090ng/ml (reference range unspecified).

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202134

Seq: 1

Gender: M

Reported: 28/10/2004

Weight: 0.00

Hospitalisation:

Onset Date: 13/10/2004

Age: 23

Outcome: Recovered

DOB: 04/10/1981

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Tachycardia, 130-138 beats per minute.	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 08/10/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202171
Reported: 29/10/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 15/03/2002
Outcome: Recovered

Age: 34
DOB: 02/02/1968
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Movement disorder Akathisia Tremor		The patient experienced movement disorder, akathisia and head tremor.	

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 19/12/2001 Stopped: 22/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202213 **Seq:** 1

Gender: F

Reported: 01/11/2004

Weight: 0.00

Hospitalisation:

Age: 26

Onset Date: 09/06/2004

DOB: 23/05/1978

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Severe	Patient experienced chest pain, tachycardia, hypotension, hypersalivation, treatment non-compliance, headaches and couldn't swallow.	Sublingual Nitroglycerin, beta-blocker (not specified), Desmopressin nasal spray.
Dysgeusia	Severe		
Dysphagia	Severe		
Headache	Severe		
Hypotension	Severe		
Salivary hypersecretion	Severe		
Tachycardia	Severe		
Treatment noncompliance	Severe		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 09/06/2004 Stopped: 15/09/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202229	Seq: 1	Gender: F
Reported: 01/11/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 49
Onset Date: 17/08/2004		DOB: 26/08/1954
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Convulsion, pneumonia aspiration, leukaemia, disseminated intravascular coagulation.	Admitted to ICU, chemotherapy was to be commenced that week. Clozaril was ceased.
Disseminated intravascular coagul	Caused or prolonged inpatient hospitalisation		
Leukaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Other drug)	Reason:
Batch:	Started: Stopped:
EFEXOR (Other drug)	Reason:
Batch:	Started: Stopped:
CLONAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
DITROPAN (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Developed leukaemia in Aug 2004, 5.75 years after commencing Clozaril for schizophrenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202229 **Seq:** 1 **Gender:** F
Reported: 01/11/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 49
Onset Date: 17/08/2004 **DOB:** 26/08/1954
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia aspiration	Caused or prolonged inpatient hospitalisation		

Medicine Details:

COGENTIN (Other drug)	Reason:	
Batch:	Started:	Stopped:
AGAROL (Other drug)	Reason:	
Batch:	Started:	Stopped:
COLOXYL (Other drug)	Reason:	
Batch:	Started:	Stopped:
NAPROSYN (Other drug)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

Developed leukaemia in Aug 2004, 5.75 years after commencing Clozaril for schizophrenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202229	Seq: 1	Gender: F
Reported: 01/11/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 49
Onset Date: 17/08/2004		DOB: 26/08/1954
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 25/11/1988	Stopped:	

Laboratory Investigations:

Additional Information:

Developed leukaemia in Aug 2004, 5.75 years after commencing Clozaril for schizophrenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202265	Seq: 1	Gender: F
Reported: 03/11/2004		Weight: 0.00
Hospitalisation:		Age: 50
Onset Date: 13/09/2004		DOB: 05/02/1954
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia Eosinophil count decreased Infection Leukopenia Malaise		Neutropenia, malaise, leukopenia, infection and eosinophil count decreased.	Clozaril ceased.

Medicine Details:

AMISULPRIDE (Other drug)	Reason:
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason:
Tablet	Oral
Batch:	Started: 30/10/1995
	Stopped: 13/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/11/2004	Eosinophils				20-22 Sep 2004: Zero eosinophil count.
03/11/2004	Neutrophils		30/10/1995	4.2	
03/11/2004	Neutrophils		13/06/2004	0.70	
03/11/2004	White blood cells		30/10/1995	5.3	
03/11/2004	White blood cells		13/06/2004	2.0	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202269 **Seq:** 1 **Gender:** F
Reported: 03/11/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 53
Onset Date: 20/10/2004 **DOB:** 21/05/1951
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Neutropenia, c-reactive protein increased, feeling hot and cold and rhinorrhoea.	Ceased Clozaril.
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		
Feeling hot and cold	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:
Suspension	300.0 Milligram Daily Oral
Batch:	Started: 25/01/2001 Stopped: 20/10/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/11/2004	C-Reactive Protein	<6.0	08/11/2004	61.2	
03/11/2004	C-Reactive Protein	<6.0	09/11/2004	52.6	
03/11/2004	C-Reactive Protein	<6.0	10/11/2004	27.4	
03/11/2004	C-Reactive Protein	<6.0	12/11/2004	10.9	
03/11/2004	Neutrophils		25/01/2001	5.6	
03/11/2004	Neutrophils		01/11/2004	0.88	
03/11/2004	Neutrophils		20/10/2004	1.43	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202269 **Seq:** 1 **Gender:** F
Reported: 03/11/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 53
Onset Date: 20/10/2004 **DOB:** 21/05/1951
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason:
Suspension	300.0 Milligram Daily Oral
Batch:	Started: 25/01/2001 Stopped: 20/10/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/11/2004	White blood cells		25/01/2001	9.6	
03/11/2004	White blood cells		20/10/2004	3.89	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202389	Seq: 1	Gender: M
Reported: 09/11/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 31
Onset Date: 26/10/2004		DOB: 07/10/1973
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Patient experienced myocardis, chest pain and elevated CK level	Clopine ceased.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Chest pain	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	225.0 Milligram Daily Oral
Batch:	Started: 08/10/2004 Stopped: 29/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/11/2004	Creatine		26/10/2004	697	echocardiogram showed mild global left ventricular dysfunction
09/11/2004	Creatine		01/11/2004	2558	
09/11/2004	Echocardiogram				
09/11/2004	Neutrophils		26/10/2004	9.09	Clozapine levels mg/day
09/11/2004	Neutrophils		01/11/2004	10.41	
09/11/2004	Serum drug level		26/10/2004	225	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202389 **Seq:** 1 **Gender:** M
Reported: 09/11/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 31
Onset Date: 26/10/2004 **DOB:** 07/10/1973
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	225.0 Milligram Daily Oral
Batch:	Started: 08/10/2004 Stopped: 29/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/11/2004	Serum drug level		01/11/2004	0	Clozapine levels mg/day
09/11/2004	Troponin		26/10/2004	1.77	
09/11/2004	Troponin		01/11/2004	0.02	
09/11/2004	White blood cells		26/10/2004	13.2	
09/11/2004	White blood cells		01/11/2004	13.2	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202406	Seq: 1	Gender: M
Reported: 09/11/2004		Weight: 105.00
Hospitalisation: Admitted to hospital		Age: 29
Onset Date: 06/10/2004		DOB: 21/07/1975
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Patient experienced neuroleptic malignant syndrome, loss of consciousness, hyperhidrosis, body temperature increased, psychotic rebound and sweating.	Treated with Cabergoline. Patient had discontinued all the neuroleptic medications and was taking one of the new anti-parkinsonian drug.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Blood pressure increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VALIUM (Other drug)	Reason:
Batch:	Started:
	Stopped:
Abilify (Suspected)	Reason:
Tablet	45.0 Milligram
	Oral
Batch:	Started: 06/10/2004
	Stopped: 06/10/2004 0
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram
	Daily
Batch:	Started: 06/09/2004
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/11/2004	Creatine		06/10/2004	3770	
09/11/2004	Creatine		07/10/2004	9840	
09/11/2004	Creatine		08/10/2004	8000	
09/11/2004	Creatine		09/10/2004	3160	
09/11/2004	Creatine		14/10/2004	1650	

Additional Information:

Clozaril was commenced on 2 October 2001 and the daily dose was being progressively decreased from 550mg on 27 January 2004, to 200mg. He was rechallenged on an unspecified date, and he was tolerating 75mg of Clozaril. The first reaction was a psychotic rebound on 4 October after dose reduction of clozapine followed by NMS on 6 October.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202406	Seq: 1	Gender: M
Reported: 09/11/2004		Weight: 105.00
Hospitalisation: Admitted to hospital		Age: 29
Onset Date: 06/10/2004		DOB: 21/07/1975
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Body temperature increased	Caused or prolonged inpatient hospitalisation		
Delirium	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VALIUM (Other drug)	Reason:
Batch:	Started:
	Stopped:
Abilify (Suspected)	Reason:
Tablet	45.0 Milligram
	Oral
Batch:	Started: 06/10/2004
	Stopped: 06/10/2004 0
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram
	Daily
	Oral
Batch:	Started: 06/09/2004
	Stopped:

Laboratory Investigations:

Additional Information:

Clozaril was commenced on 2 October 2001 and the daily dose was being progressively decreased from 550mg on 27 January 2004, to 200mg. He was rechallenged on an unspecified date, and he was tolerating 75mg of Clozaril. The first reaction was a psychotic rebound on 4 October after dose reduction of clozapine followed by NMS on 6 October.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202406 **Seq:** 1 **Gender:** M
Reported: 09/11/2004 **Weight:** 105.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 06/10/2004 **DOB:** 21/07/1975
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal	Caused or prolonged inpatient hospitalisation		
Loss of consciousness	Caused or prolonged inpatient hospitalisation		
Rebound effect	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VALIUM (Other drug)	Reason:	
Batch:	Started:	Stopped:
Abilify (Suspected)	Reason:	
Tablet	45.0 Milligram	Oral
Batch:	Started: 06/10/2004	Stopped: 06/10/2004 0
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily Oral
Batch:	Started: 06/09/2004	Stopped:

Laboratory Investigations:

Additional Information:

Clozaril was commenced on 2 October 2001 and the daily dose was being progressively decreased from 550mg on 27 January 2004, to 200mg.
He was rechallenged on an unspecified date, and he was tolerating 75mg of Clozaril. The first reaction was a psychotic rebound on 4 October after dose reduction of clozapine followed by NMS on 6 October.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202406 **Seq:** 1 **Gender:** M
Reported: 09/11/2004 **Weight:** 105.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 06/10/2004 **DOB:** 21/07/1975
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VALIUM (Other drug)	Reason:	
Batch:	Started:	Stopped:
Abilify (Suspected)	Reason:	
Tablet	45.0 Milligram	Oral
Batch:	Started: 06/10/2004	Stopped: 06/10/2004 0
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily Oral
Batch:	Started: 06/09/2004	Stopped:

Laboratory Investigations:

Additional Information:

Clozaril was commenced on 2 October 2001 and the daily dose was being progressively decreased from 550mg on 27 January 2004, to 200mg.
He was rechallenged on an unspecified date, and he was tolerating 75mg of Clozaril. The first reaction was a psychotic rebound on 4 October after dose reduction of clozapine followed by NMS on 6 October.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202489 **Seq:** 1 **Gender:** M
Reported: 12/11/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 38
Onset Date: 28/10/2004 **DOB:** 22/11/1965
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Patient experienced myocarditis, troponin increased, electrocardiogram abnormal, influenza like illness and productive cough.	
Electrocardiogram abnormal	Caused or prolonged inpatient hospitalisation		
Influenza like illness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Otr spec symp psychopathol nec
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 18/10/2004 Stopped: 28/10/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/11/2004	Electrocardiograph				Abnormal ECG.
12/11/2004	Troponin		28/10/2004	0.37	

Additional Information:

Reaction occurred approximately 2 weeks after commencing Clozaril (Clozapine).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202489 **Seq:** 1 **Gender:** M
Reported: 12/11/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 38
Onset Date: 28/10/2004 **DOB:** 22/11/1965
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Productive cough	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Otr spec symp psychopathol nec
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 18/10/2004 Stopped: 28/10/2004 0

Laboratory Investigations:

Additional Information:

Reaction occurred approximately 2 weeks after commencing Clozaril (Clozapine).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202490	Seq: 1	Gender: M
Reported: 11/11/2004		Weight: 0.00
Hospitalisation:		Age: 34
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia Drug level increased		Neutropenia and drug level increased.	Clozapine ceased.

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Batch:	Oral
Started:	Stopped:
SERTRALINE HYDROCHLORIDE (Other drug)	Reason:
Tablet	Oral
Batch:	Started:
Started:	Stopped:
CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	Oral
	300.0 Milligram Daily
Batch:	Started: 15/06/1996
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/11/2004	Neutrophils				Dec 1999: Mild neutropenia 1.86. Aug 2001: neutrophil count remained below 1.5.
11/11/2004	Serum drug level				Clozapine blood levels 916mcg/l before stopping Clozapine. Norclozapine levels 214mcg/l before stopping Clozapine.

Additional Information:

Journal: The Canadian Journal of Psychiatry
 Author: Thompson A, Castle D, Orr K
 Title: Late onset neutropenia with Clozapine
 Year: 2004.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202546

Seq: 1

Gender: M

Reported: 15/11/2004

Weight: 0.00

Hospitalisation:

Age: 65

Onset Date:

DOB: 09/07/1939

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced myocarditis during Clopine treatment.	Clopine was ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	175.0 Milligram Daily Oral
Batch:	Started: 21/09/2004 Stopped: 20/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202588

Seq: 1

Gender: M

Reported: 16/11/2004

Weight: 0.00

Hospitalisation:

Age: 26

Onset Date:

DOB: 17/02/1978

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		The patient developed a creatine kinase level of over 4500 and shortness of breath.	Rehydration fluid replacement given and Clozaril ceased.
Dyspnoea			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	12.0 Milligram Daily Oral
Batch:	Started: 27/09/2004 Stopped: 27/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/11/2004	Creatine			CK = 4500	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202591
Reported: 16/11/2004

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 26

DOB: 17/02/1978

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		The patient experienced psychotic symptoms shortly after ceasing Clozaril.	
Drug withdrawal syndrome			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	12.0 Milligram Daily Oral
Batch:	Started: 27/09/2004 Stopped: 27/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202594	Seq: 1	Gender: M
Reported: 16/11/2004		Weight: 0.00
Hospitalisation: Required a specialist consultation		Age: 33
Onset Date: 29/05/2004		DOB: 24/11/1970
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope	Caused or prolonged inpatient hospitalisation	In May 2004, he developed hypotension and suffered syncope from sep 2004 to Nove 2004.	Clozaril was discontinued.
Dizziness	Caused or prolonged inpatient hospitalisation	Oct 2004- When patient recommenced on Clozaril, he complained of dizziness and postural drop 125/80-100/60	
Cardiomyopathy	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DIAZEPAM (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
PAROXETINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 18/05/2004 Stopped: 02/11/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/11/2004	Echocardiogram		12/08/2004	Normal	
16/11/2004	Echocardiogram		29/10/2004	Echocardiogra	
16/11/2004	Echocardiogram		15/12/2004	Normal left	
16/11/2004	Electrocardiograph		03/05/2004	Normal	
16/11/2004	Electrocardiograph		15/10/2004	showed non	
16/11/2004	Erythrocyte	0 - 15			
16/11/2004	Neutrophils	0.01-0.4	17/05/2004	3.8	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202594	Seq: 1	Gender: M
Reported: 16/11/2004		Weight: 0.00
Hospitalisation: Required a specialist consultation		Age: 33
Onset Date: 29/05/2004		DOB: 24/11/1970
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Echocardiogram abnormal Ejection fraction decreased Electrocardiogram abnormal Neutrophil count increased Red blood cell sedimentation rate i White blood cell count increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DIAZEPAM (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
PAROXETINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 18/05/2004 Stopped: 02/11/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/11/2004	Neutrophils	0.01-0.4	22/11/2004	3.56	
16/11/2004	Neutrophils	0.01-0.4	05/11/2004	10.1	
16/11/2004	Neutrophils	0.01-0.4	20/10/2004	5.19	
16/11/2004	White blood cells	4-11	17/05/2004	5.1	
16/11/2004	White blood cells	4-11	20/10/2004	6.7	
16/11/2004	White blood cells	4-11	05/11/2004	11.3	
16/11/2004	White blood cells	4-11	22/11/2004	5.6	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202854

Seq: 1

Gender: U

Reported: 19/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Suicide attempt.	

Medicine Details:

EFEXOR (Suspected)	Reason:		
Batch:	Started:	Stopped:	Oral
CLOZAPINE (Suspected)	Reason:		
Tablet	Started:	Stopped:	Oral

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202914

Seq: 1

Gender: F

Reported: 22/11/2004

Weight: 0.00

Hospitalisation:

Onset Date: 14/11/2004

Age: 31

Outcome: Unknown

DOB: 04/03/1973

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		The patient experienced hypotension two hours after commencing Clozaril. Her pre-treatment test showed a blood pressure of 106/70. Two hours later her blood pressure had dropped to 79/52.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	12.0 Milligram Daily Oral
Batch:	Started: 14/11/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 202936	Seq: 1	Gender: M
Reported: 22/11/2004		Weight: 0.00
Hospitalisation:		Age: 23
Onset Date: 06/08/2004		DOB: 06/06/1981
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejection fraction decreased		The patient experienced suspected myocarditis and cardiac complications, mild dilated cardiomyopathy.	Clozapine ceased
Cardiomyopathy			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Batch:	Started: 07/06/2001 Stopped:
CLOPINE (Suspected)	Reason: Unspecified psychosis
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 12/12/2002 L TERM Stopped: 10/11/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/11/2004	Echocardiogram				Transthoracic echocardiogram revealed decrease in left ventricular ejection fraction. Echocardiogram investigations showed decreased left ventricular systolic function, decreased left ventricular ejection fraction 40-45% and lateral T-wave changes on ECG.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203022	Seq: 1	Gender: F
Reported: 24/11/2004		Weight: 0.00
Hospitalisation:		Age: 40
Onset Date: 15/03/2003		DOB: 08/12/1962
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced seizures, metabolic disorder, incontinence and thrombocytopenia.	
Thrombocytopenia			
Urinary incontinence			

Medicine Details:

TOPAMAX (Other drug)	Reason:
Batch:	Started: Stopped:
EFEXOR-XR (Other drug)	Reason:
Batch:	Started: Stopped:
CEPHALEXIN (Other drug)	Reason:
Batch:	Started: Stopped:
EPILIM (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/11/2004	Creatinine	0.04 - 0.11	17/12/2004	0.23	
24/11/2004	Creatinine	0.04 - 0.11	09/11/2004	0.23	
24/11/2004	Creatinine	0.04 - 0.11	21/09/2004	0.22	
24/11/2004	Haemoglobin	115 - 160	21/12/2004	107	
24/11/2004	Haemoglobin	115 - 160	08/12/2004	106	
24/11/2004	Haemoglobin	115 - 160	14/12/2004	102	
24/11/2004	Haemoglobin	115 - 160	17/12/2004	93	

Additional Information:

Current medical history: renal insufficiency.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203022

Seq: 1

Gender: F

Reported: 24/11/2004

Weight: 0.00

Hospitalisation:

Age: 40

Onset Date: 15/03/2003

DOB: 08/12/1962

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	475.0 Milligram	Daily	Oral
Batch:	Started: 06/06/1996	Stopped: 04/10/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/11/2004	Platelets	150 - 450	17/12/2004	130	
24/11/2004	Platelets	150 - 450	14/12/2004	112	
24/11/2004	Platelets	150 - 450	08/12/2004	163	
24/11/2004	Serum glucose	3.0 - 7.7	17/12/2004	2.3	
24/11/2004	Serum glucose	3.0 - 7.7	09/11/2004	8.2	
24/11/2004	Serum glucose	3.0 - 7.7	21/09/2004	10.3	
24/11/2004	Urea	2.0 - 7.0	17/12/2004	10.7	

Additional Information:

Current medical history: renal insufficiency.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203022

Seq: 1

Gender: F

Reported: 24/11/2004

Weight: 0.00

Hospitalisation:

Onset Date: 15/03/2003

Age: 40

Outcome: Unknown

DOB: 08/12/1962

Causality: Causality possible

Reaction Details:

Medicine Details:

TOPAMAX (Other drug)	Reason:	
Batch:	Started:	Stopped:
EFEXOR-XR (Other drug)	Reason:	
Batch:	Started:	Stopped:
CEPHALEXIN (Other drug)	Reason:	
Batch:	Started:	Stopped:
EPILIM (Suspected)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/11/2004	Urea	2.0 - 7.0	09/11/2004	10.4	
24/11/2004	Urea	2.0 - 7.0	21/09/2004	11.7	

Additional Information:

Current medical history: renal insufficiency.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203022

Seq: 1

Gender: F

Reported: 24/11/2004

Weight: 0.00

Hospitalisation:

Age: 40

Onset Date: 15/03/2003

DOB: 08/12/1962

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Unspecified schizophrenia

Tablet

475.0 Milligram

Daily

Oral

Batch:

Started: 06/06/1996

Stopped: 04/10/2000

Laboratory Investigations:

Additional Information:

Current medical history: renal insufficiency.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203113	Seq: 1	Gender: U
Reported: 29/11/2004		Weight: 0.00
Hospitalisation:		Age: 99u
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abnormal behaviour		The patient experienced dribble, tongue in and out, speech mangled and incoherent, unable to watch TV or listen to the radio, no feeling around mouth, disabled socially and unwilling to venture out.	
Dysarthria			
Hypoaesthesia			
Salivary hypersecretion			
Tardive dyskinesia			

Medicine Details:

MODECATE (Suspected)	Reason:
Injection	
Batch:	Started: Stopped:
CLOZAPINE (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
RISPERDAL (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 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203115

Seq: 1

Gender: M

Reported: 29/11/2004

Weight: 0.00

Hospitalisation:

Age: 47

Onset Date: 28/09/2004

DOB: 25/08/1957

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomegaly		The patient developed mild cardiac enlargement.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 17/11/1999	Stopped: 01/11/2004	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203160	Seq: 1	Gender: F
Reported: 01/12/2004		Weight:
Hospitalisation:		Age: 67
Onset Date: 12/11/2004		DOB: 16/09/1937
Outcome: Recovered	16/11/2004	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Diagnosed as NMS	Clopine ceased.
Cellulitis		The patient developed cellulitis and associated elevated temperatures.	Clopine ceased.
Pyrexia			

Medicine Details:

CLOPINE (Suspected)		Reason: Unspecified psychosis
Tablet	150.0 Milligram	Daily Oral
Batch:	Started: 25/10/2004	Stopped: 12/11/2004
AMISULPRIDE (Suspected)		Reason: Unspecified psychosis
Tablet	200.0 Milligram	Daily Oral
Batch:	Started: 27/08/2004	Stopped: 12/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/12/2004	Creatine				2879 Serum myoglobin: 1146 Temperature: 40
01/12/2004	Neutrophils		08/11/2004	4.6	
01/12/2004	Other data				
01/12/2004	Other data				
01/12/2004	White blood cells		08/11/2004	6.14	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203166	Seq: 1	Gender: M
Reported: 01/12/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 41
Onset Date: 09/11/2004		DOB: 03/06/1963
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder	Caused or prolonged inpatient hospitalisation	The patient experienced delirium, exacerbation of psychotic symptoms, tachycardia, hypertension, raised CK levels, leucocytosis and neutrophilia.	Clozaril ceased.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Delirium	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLONAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
DIAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
SOMAC (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 16/12/1994 Stopped: 14/11/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/12/2004	Creatine	<200	09/11/2004	665	
01/12/2004	Creatine	<200	10/11/2004	1920	
01/12/2004	White blood cells		16/02/1994	11.2	
01/12/2004	White blood cells		09/11/2004	18.40	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203166 **Seq:** 1 **Gender:** M
Reported: 01/12/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 41
Onset Date: 09/11/2004 **DOB:** 03/06/1963
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension	Caused or prolonged inpatient hospitalisation		
Leukocytosis	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AMISULPRIDE (Suspected)	Reason:
	600.0 Milligram Daily
Batch:	Started: 01/09/2004 Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203185 **Seq:** 1 **Gender:** M
Reported: 01/12/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 49
Onset Date: 02/10/2004 **DOB:** 14/06/1955
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Varices oesophageal	Caused or prolonged inpatient hospitalisation	Oesophageal varices nos, oesophageal varices were ruptured. Ceased Clopine	Admitted to ICU and was intubated.
Oesophageal varices haemorrhage	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 01/01/2002 Stopped: 21/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203189	Seq: 1	Gender: M
Reported: 01/12/2004		Weight: 0.00
Hospitalisation:		Age: 37
Onset Date: 20/11/2004		DOB: 22/12/1966
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Developed tachycardia, hypertension and first degree AV block.	Consultant cardiologist has been contacted for advise, Clopine has been withheld since 20/11/04.
Atrioventricular block first degree			
Hypertension			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 30/10/2004 Stopped: 20/11/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203228

Seq: 1

Gender: M

Reported: 02/12/2004

Weight: 0.00

Hospitalisation:

Age: 29

Onset Date: 30/10/2004

DOB: 28/02/1975

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		The patient experienced seizures and electroencephalogram showed that seizures were from Clozaril.	
Electrocardiogram abnormal			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	12.0 Milligram Daily Oral
Batch:	Started: 25/02/2003 Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/12/2004	Electroencephalogram				The reporter commented that the patient's electroencephalogram (date unspecified) showed that the seizures were from Clozaril.

Additional Information:

Past history of epileptic fits, before commencing Clozaril.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203231 **Seq:** 1 **Gender:** M
Reported: 02/12/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 46
Onset Date: 19/08/2004 **DOB:** 29/07/1958
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus	Caused or prolonged inpatient hospitalisation	The patient presented at hospital with sweating, thirst and dizziness and was diagnosed with diabetes.	Admitted to hospital, commenced on Actraphane insulin 10IU in the morning and 6IU at night. Clozaril was decreased to 300mg daily.
Dizziness	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	5000.0 Milligram Daily Oral
Batch:	Started: 16/04/1996 Stopped: 19/08/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/12/2004	Serum glucose				Blood glucose level was 440 mg/dL (reference range 60-110 mg/dL). November 2004 6 and 12 mmol/L (reference range 3.6-6.0 mmol/L)

Additional Information:

The patient had NIDDM as well as a family history of diabetes.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203231 **Seq:** 1 **Gender:** M
Reported: 02/12/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 46
Onset Date: 19/08/2004 **DOB:** 29/07/1958
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	5000.0 Milligram Daily Oral
Batch:	Started: 16/04/1996 Stopped: 19/08/2004

Laboratory Investigations:

Additional Information:

The patient had NIDDM as well as a family history of diabetes.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203236	Seq: 1	Gender: F
Reported: 02/12/2004		Weight:
Hospitalisation: Admitted to hospital		Age: 45
Onset Date: 18/11/2004		DOB: 29/06/1959
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis C-reactive protein increased Dyspnoea Tachycardia Troponin increased White blood cell count increased		Patient experienced myocarditis, shortness of breath, tachycardia and increased white cell count. Also had C-reactive protein, fever and troponin levels.	Clopine ceased.

Medicine Details:

COLOXYL WITH SENNA (Other drug)	Reason: Constipation
Batch:	Started: 05/10/2004 Stopped: Oral
IRON (Other drug)	Reason: Iron deficiency anemias
Batch:	325.0 Milligram Daily Oral Started: 05/10/2004 Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Batch:	Tablet 250.0 Milligram Daily Oral Started: 03/11/2004 Stopped: 18/11/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/12/2004	C-Reactive Protein		17/11/2004	96	<5 mg/L
02/12/2004	C-Reactive Protein		18/11/2004	232	<5 mg/L
02/12/2004	C-Reactive Protein		19/11/2004	-	<5 mg/L
02/12/2004	C-Reactive Protein		26/11/2004	-	<5 mg/L
02/12/2004	C-Reactive Protein		23/11/2004	187	<5 mg/L
02/12/2004	C-Reactive Protein		22/11/2004	154	<5 mg/L
02/12/2004	Neutrophils		17/11/2004	10.4	<0.4 x 10 ⁹ /L

Additional Information:

Patient was obese and was a heavy smoker.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203236 **Seq:** 1 **Gender:** F
Reported: 02/12/2004 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 45
Onset Date: 18/11/2004 **DOB:** 29/06/1959
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

COLOXYL WITH SENNA (Other drug)	Reason: Constipation
Batch:	Started: 05/10/2004 Stopped:
IRON (Other drug)	Reason: Iron deficiency anemias
325.0 Milligram Daily Oral	Batch: Started: 05/10/2004 Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 250.0 Milligram Daily Oral	Batch: Started: 03/11/2004 Stopped: 18/11/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/12/2004	Neutrophils		26/11/2004	13.1	<0.4 x 10 ⁹ /L
02/12/2004	Neutrophils		23/11/2004	14.6	<0.4 x 10 ⁹ /L
02/12/2004	Neutrophils		18/11/2004	12.5	<0.4 x 10 ⁹ /L
02/12/2004	Neutrophils		19/11/2004	12.7	<0.4 x 10 ⁹ /L
02/12/2004	Neutrophils		22/11/2004	14.3	<0.4 x 10 ⁹ /L
02/12/2004	Troponin	<0.16 ug/L	17/11/2004	<0.16	
02/12/2004	Troponin	<0.16 ug/L	18/11/2004	0.33	

Additional Information:

Patient was obese and was a heavy smoker.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203236 **Seq:** 1 **Gender:** F
Reported: 02/12/2004 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 45
Onset Date: 18/11/2004 **DOB:** 29/06/1959
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

COLOXYL WITH SENNA (Other drug)	Reason: Constipation
Batch:	Started: 05/10/2004 Stopped:
Oral	
IRON (Other drug)	Reason: Iron deficiency anemias
325.0 Milligram	Daily Oral
Batch:	Started: 05/10/2004 Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 03/11/2004 Stopped: 18/11/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/12/2004	Troponin	<0.16 ug/L	19/11/2004	14.89	
02/12/2004	Troponin	<0.16 ug/L	22/11/2004	1.32	
02/12/2004	Troponin	<0.16 ug/L	23/11/2004	0.46	
02/12/2004	Troponin	<0.16 ug/L	26/11/2004	<0.16	
02/12/2004	White blood cells		17/11/2004	12.5	4.0 - 11.0 x 10 ⁹ /L
02/12/2004	White blood cells		18/11/2004	14.5	4.0 - 11.0 x 10 ⁹ /L
02/12/2004	White blood cells		19/11/2004	14.5	4.0 - 11.0 x 10 ⁹ /L

Additional Information:

Patient was obese and was a heavy smoker.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203236 **Seq:** 1 **Gender:** F
Reported: 02/12/2004 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 45
Onset Date: 18/11/2004 **DOB:** 29/06/1959
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

COLOXYL WITH SENNA (Other drug)	Reason: Constipation
Batch:	Started: 05/10/2004 Stopped: Oral
IRON (Other drug)	Reason: Iron deficiency anemias
Batch:	325.0 Milligram Daily Oral Started: 05/10/2004 Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 03/11/2004 Stopped: 18/11/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/12/2004	White blood cells		22/11/2004	17.0	4.0 - 11.0 x 10 ⁹ /L
02/12/2004	White blood cells		23/11/2004	17.2	4.0 - 11.0 x 10 ⁹ /L
02/12/2004	White blood cells		26/11/2004	16.7	4.0 - 11.0 x 10 ⁹ /L

Additional Information:

Patient was obese and was a heavy smoker.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203246 **Seq:** 1 **Gender:** M
Reported: 02/12/2004 **Weight:** 0.00
Hospitalisation: **Age:** 17
Onset Date: **DOB:** 13/10/1987
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizures	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	800.0 Milligram Daily Oral
Batch:	Started: 06/11/2001 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was severely compromised with intellectual disability, ? autism and vaguely a history of fits.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203250	Seq: 1	Gender: F
Reported: 02/12/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 40
Onset Date: 10/10/2004		DOB: 23/06/1964
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Feeling hot and cold	Caused or prolonged inpatient hospitalisation	Feeling hot and cold.	
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation	Muscle stiffness, myalgia, arthralgia, tongue biting, headache, lethargy	Patient decided to cease Clozaril and was admitted to hospital. Clozaril was recommenced at a dose of 600mg and was ongoing on this dose.

Medicine Details:

ANTIDEPRESSANT NOS (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	650.0 Milligram Daily Oral
Batch:	Started: 31/08/2001 Stopped: 18/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/12/2004	Creatine				CK levels taken on 20 Oct 2004 were normal.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203250	Seq: 1	Gender: F
Reported: 02/12/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 40
Onset Date: 10/10/2004		DOB: 23/06/1964
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion	Caused or prolonged inpatient hospitalisation	Salivary hypersecretion,	
Arthralgia	Caused or prolonged inpatient hospitalisation		
Headache	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ANTIDEPRESSANT NOS (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	650.0 Milligram Daily Oral
Batch:	Started: 31/08/2001 Stopped: 18/10/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203250 **Seq:** 1 **Gender:** F
Reported: 02/12/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 40
Onset Date: 10/10/2004 **DOB:** 23/06/1964
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lethargy	Caused or prolonged inpatient hospitalisation		
Myalgia	Caused or prolonged inpatient hospitalisation		
Tongue biting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ANTIDEPRESSANT NOS (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	650.0 Milligram	Daily	Oral
Batch:	Started: 31/08/2001	Stopped: 18/10/2004	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203374

Seq: 1

Gender: F

Reported: 08/12/2004

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date: 18/11/2004

DOB: 12/12/1957

Outcome: Death

18/11/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death		Patient died.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 03/05/2002 Stopped: 18/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203380	Seq: 1	Gender: M
Reported: 09/12/2004		Weight: 0.00
Hospitalisation:		Age: 25
Onset Date: 13/05/2003		DOB: 14/09/1977
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Blood cholesterol increased Blood triglycerides increased Dilatation ventricular Ejection fraction decreased Gastrooesophageal reflux disease Tachycardia		Cardiomyopathy, ejection fraction decreased, tachycardia, gastrooesophageal reflux disease, blood cholesterol increased, dilatation ventricular and blood triglycerides increased.	

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 13/05/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/12/2004	Electrocardiograph				? Nov 2004 - ECG: Borderline dilated cardiomyopathy. ? Nov 2004 - ECG: Ejection fraction of 50%.
09/12/2004	Low density				Low density lipoprotein: 7.9mmol/L.
09/12/2004	Other data				? Nov 2004 - Heart rate: 112bpm.
09/12/2004	Serum drug level				? Oct 2004 - Serum Clozapine: 530ng/mL.
09/12/2004	Triglyceride				Triglycerides: 4.5.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203403	Seq: 1	Gender: M
Reported: 10/12/2004		Weight:
Hospitalisation:		Age: 36
Onset Date: 15/11/2004		DOB: 19/03/1968
Outcome: Death, maybe drug	25/11/2004	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction		Myocardial infarction, diabetes mellitus non-insulin dependent, blood cholesterol increased and obesity.	
Blood cholesterol increased			
Diabetes mellitus non-insulin-depe			
Obesity			

Medicine Details:

DESMOPRESSIN (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
DIAFORMIN (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
JEZIL (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	700.0 Milligram Daily Oral
Batch:	Started: 11/06/2004 Stopped: 17/11/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: High cholesterol, very obese and non-insulin-dependent diabetes mellitus.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203528

Seq: 1

Gender: F

Reported: 14/12/2004

Weight: 0.00

Hospitalisation:

Age: 23

Onset Date: 25/11/2004

DOB: 21/09/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		The patient experienced a seizure approximately 19 months after commencing Clozaril.	

Medicine Details:

RISPERIDONE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 07/04/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203529 **Seq:** 1 **Gender:** M
Reported: 14/12/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 50
Onset Date: 26/11/2004 **DOB:** 02/10/1954
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	The patient developed neutropenia approximately 7 weeks after commencing Clozaril.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	12.0 Milligram	Daily	Oral
Batch:	Started: 06/10/2004	Stopped:	26/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203553
Reported: 14/12/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 30/11/2004
Outcome: Recovered

Age: 51
DOB: 24/01/1953
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dry throat			
Dysuria			
Headache			
Hyperglycaemia			
Hyperhidrosis			
Nausea			
Palpitations			
Tremor			
Weight increased			

Medicine Details:

GLICLAZIDE (Other drug)	Reason: Diabetes mellitus		
Tablet	160.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
THYROXINE SODIUM (Other drug)	Reason: Myxedema		
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
Escitalopram (Other drug)	Reason: Depression		
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 09/11/2004	Stopped: 30/11/2004	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203566	Seq: 1	Gender: F
Reported: 15/12/2004		Weight: 80.00
Hospitalisation: Admitted to hospital		Age: 49
Onset Date: 23/11/2004		DOB: 25/05/1955
Outcome: Recovered	27/11/2004	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Febrile up to 40.1, tachycardic, hypotensive, widespread aches in limbs / stomach / back, 3 days incontinence, dehydrated and some peripheral oedema.	
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Dehydration	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia
Tablet	225.0 Milligram	Daily Oral
Batch:	Started: 08/11/2004	Stopped: 23/11/2004
ATORVASTATIN (Suspected)		Reason: Othr&unspec metabolic diseases
Tablet	40.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 23/11/2004
FLUOXETINE HYDROCHLORIDE (Suspected)		Reason: Depression
Capsule	20.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 23/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/12/2004	Creatine kinase				CK rise to 902
15/12/2004	Other data				serum myoglobin 128
15/12/2004	Troponin				TnI 1.8

Additional Information:

Deranged LFT's for over a year prior to this event --> secondary to statin therapy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203566 **Seq:** 1 **Gender:** F
Reported: 15/12/2004 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 49
Onset Date: 23/11/2004 **DOB:** 25/05/1955
Outcome: Recovered 27/11/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal	Caused or prolonged inpatient hospitalisation		
Hypotension	Caused or prolonged inpatient hospitalisation		
Myalgia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 225.0 Milligram Daily Oral	
Batch:	Started: 08/11/2004 Stopped: 23/11/2004
ATORVASTATIN (Suspected)	Reason: Othr&unspec metabolic diseases
Tablet 40.0 Milligram Daily Oral	
Batch:	Started: Stopped: 23/11/2004
FLUOXETINE HYDROCHLORIDE (Suspected)	Reason: Depression
Capsule 20.0 Milligram Daily Oral	
Batch:	Started: Stopped: 23/11/2004

Laboratory Investigations:

Additional Information:

Deranged LFT's for over a year prior to this event --> secondary to statin therapy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203566	Seq: 1	Gender: F
Reported: 15/12/2004		Weight: 80.00
Hospitalisation: Admitted to hospital		Age: 49
Onset Date: 23/11/2004		DOB: 25/05/1955
Outcome: Recovered	27/11/2004	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia
Tablet	225.0 Milligram	Daily Oral
Batch:	Started: 08/11/2004	Stopped: 23/11/2004
ATORVASTATIN (Suspected)		Reason: Othr&unspec metabolic diseases
Tablet	40.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 23/11/2004
FLUOXETINE HYDROCHLORIDE (Suspected)		Reason: Depression
Capsule	20.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 23/11/2004

Laboratory Investigations:

Additional Information:

Deranged LFT's for over a year prior to this event --> secondary to statin therapy.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203566 **Seq:** 1 **Gender:** F
Reported: 15/12/2004 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 49
Onset Date: 23/11/2004 **DOB:** 25/05/1955
Outcome: Recovered 27/11/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 225.0 Milligram Daily Oral	
Batch:	Started: 08/11/2004 Stopped: 23/11/2004
ATORVASTATIN (Suspected)	Reason: Othr&unspec metabolic diseases
Tablet 40.0 Milligram Daily Oral	
Batch:	Started: Stopped: 23/11/2004
FLUOXETINE HYDROCHLORIDE (Suspected)	Reason: Depression
Capsule 20.0 Milligram Daily Oral	
Batch:	Started: Stopped: 23/11/2004

Laboratory Investigations:

Additional Information:

Deranged LFT's for over a year prior to this event --> secondary to statin therapy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203643	Seq: 1	Gender: M
Reported: 17/12/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 39
Onset Date: 16/07/2004		DOB: 30/01/1965
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia	Life threatening	MRSA pneumonia	
Pitting oedema	Life threatening	Pitting oedema associated with dyspnoea, tachycardia on the 16/07, followed by flu-like symptoms, ongoing shortness of breath, fever, worsening renal function. Admitted to ICU on 25/07/2004. Provisional diagnosis of clozapine induced endocarditis, complicated by acute renal failure, cardiogenic shock, pulmonary oedema	Haemofiltration, inotropes, antibiotics
Cardiogenic shock	Life threatening		

Medicine Details:

AMISULPRIDE (Other drug)		Reason:	
Tablet	400.0 Milligram	2 times	Oral
Batch:	Started:	Stopped: 23/07/2004	
QUETIAPINE (Other drug)		Reason:	
Tablet	300.0 Milligram	2 times	Oral
Batch:	Started:	Stopped:	
EPILIM (Other drug)		Reason:	
Oral Liquid	1000.0 Milligram	2 times	Oral
Batch:	Started:	Stopped:	
AMLODIPINE (Other drug)		Reason:	
Tablet	10.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2004	Creatinine				On admission : Cr 0.14, peaking at 0.49 on 26/07
17/12/2004	Other data				Fever up to 40 degrees
17/12/2004	Troponin				On admission; Troponin T 0.32 peaking at 0.48

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203643 **Seq:** 1 **Gender:** M
Reported: 17/12/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 39
Onset Date: 16/07/2004 **DOB:** 30/01/1965
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea	Life threatening		
Endocarditis	Life threatening		
Influenza like illness	Life threatening		
Pulmonary oedema	Life threatening		
Pyrexia	Life threatening		
Renal failure acute	Life threatening		

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	225.0 Milligram 1 time Oral
Batch:	Started: 05/07/2004 Stopped: 23/07/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203643 **Seq:** 1 **Gender:** M
Reported: 17/12/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 39
Onset Date: 16/07/2004 **DOB:** 30/01/1965
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Life threatening		

Medicine Details:

AMISULPRIDE (Other drug)	Reason:
Tablet 400.0 Milligram 2 times Oral	
Batch:	Started: Stopped: 23/07/2004
QUETIAPINE (Other drug)	Reason:
Tablet 300.0 Milligram 2 times Oral	
Batch:	Started: Stopped:
EPILIM (Other drug)	Reason:
Oral Liquid 1000.0 Milligram 2 times Oral	
Batch:	Started: Stopped:
AMLODIPINE (Other drug)	Reason:
Tablet 10.0 Milligram 1 time Oral	
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203643 **Seq:** 1

Reported: 17/12/2004

Hospitalisation: Admitted to hospital

Onset Date: 16/07/2004

Outcome: Not yet recovered

Gender: M

Weight: 0.00

Age: 39

DOB: 30/01/1965

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	225.0 Milligram 1 time Oral
Batch:	Started: 05/07/2004 Stopped: 23/07/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203666	Seq: 1	Gender: F
Reported: 14/12/2004		Weight: 0.00
Hospitalisation:		Age: 37
Onset Date: 15/11/2000		DOB: 04/06/1963
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		The patient experienced diabetes, high cholesterol and weight gain since starting Clozaril. She also had swollen legs, shakes, stiff and aching joints, breast soreness two weeks prior to menstruation, anxiety, perspiration, flu-like symptoms, swollen tongue, excessive thirst, urinary frequency, bloatedness and headache.	Simvastatin.
Abdominal distension			
Anxiety			
Arthralgia			
Blood cholesterol increased			

Medicine Details:

TERBUTALINE SULPHATE (Other drug)	Reason:
Inhalation	Inhalation
Batch:	Started: Stopped:
SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	325.0 Milligram Daily Oral
Batch:	Started: 01/03/2000 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Pentacid.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203666
Reported: 14/12/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 15/11/2000
Outcome: Unknown

Age: 37
DOB: 04/06/1963
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Headache			
Influenza like illness			
Oedema peripheral			
Pollakiuria			
Swollen tongue			
Thirst			
Tremor			
Weight increased			

Medicine Details:

TERBUTALINE SULPHATE (Other drug)	Reason:
Inhalation	Inhalation
Batch:	Started: Stopped:
SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	325.0 Milligram Daily Oral
Batch:	Started: 01/03/2000 Stopped:

Laboratory Investigations:

Additional Information:

Patient was also taking Pentacid.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203676 **Seq:** 1 **Gender:** F
Reported: 20/12/2004 **Weight:**
Hospitalisation: **Age:** 26
Onset Date: 30/11/2004 **DOB:** 01/06/1978
Outcome: Recovered 11/12/2004 **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Experienced tachycardia and ECG changes.	Clopine ceased.
Electrocardiogram abnormal			

Medicine Details:

CLOPINE (Suspected)	Reason: Schizophrenia
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 29/11/2004 Stopped: 03/12/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/12/2004	Electrocardiograph				ECG right axis deviation and a posterior fascular block.

Additional Information:

Rechallenge. Previous episode on 10 October. Also taking orlistat, Seretide and Microgynon 20 ED and haloperidol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203716

Seq: 1

Gender: F

Reported: 21/12/2004

Weight: 0.00

Hospitalisation:

Age: 65

Onset Date: 28/11/2004

DOB: 18/02/1939

Outcome: Death

11/12/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident		Patient died due to a stroke.	
Cerebrovascular accident			
Death			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	325.0 Milligram Daily Oral
Batch:	Started: 12/11/2003 Stopped: 11/12/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Long history of arrhythmia. Was also taking Lanoxin PG, Coversyl, benztropine, aspirin and doxepin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203754	Seq: 1	Gender: M
Reported: 22/12/2004		Weight: 0.00
Hospitalisation:		Age: 55
Onset Date: 20/11/2004		DOB: 31/01/1949
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delusion Tachycardia C-reactive protein increased Dyspnoea Hallucination, auditory Infection Red blood cell sedimentation rate i		Delusions of grandeur. Patient experienced tachycardia, erythrocyte sedimentation rate was raised, shortness of breath, auditory hallucinations	

Medicine Details:

THIAMINE (Other drug)	Reason:
Batch:	Started: Stopped:
MULTIVITAMINS (Other drug)	Reason:
Batch:	Started: Stopped:
SODIUM VALPROATE (Suspected)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.0 Milligram Daily Oral
Batch:	Started: 20/11/2004 Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/12/2004	Erythrocyte sedimentation rate				(?Dec 2004) Erythrocyte Sedimentation rate:raised
22/12/2004	Other data				(03 Dec 2004) Heart rate:125bpm, (??2004) heart rate: 100 bpm, (20 Dec 2004) heart rate: 120 bpm, (date unspecified-baseline) heart rate:96 bpm.
22/12/2004	Troponin				(? Dec 2004) Troponin levels: normal.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203774

Seq: 1

Gender: M

Reported: 22/12/2004

Weight:

Hospitalisation:

Age: 34

Onset Date: 01/12/2004

DOB: 16/03/1970

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood cholesterol increased		Patient experienced increased total cholesterol levels >8.0 and random blood glucose levels of 8.3.	Clozaril dose was being titrated down.
Blood glucose increased			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 06/09/2001	Stopped: 06/12/2004	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozaril dose was reduced to 100mg/daily, while continuing to reduce Clozaril dose until its discontinuation.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203781 **Seq:** 1 **Gender:** M
Reported: 23/12/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 38
Onset Date: 15/09/2003 **DOB:** 17/05/1965
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		Patient had become very manic as a withdrawal effect of Clozaril.	A rechallengd of the medication was being considered.
Mania			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	550.0 Milligram Daily Oral
Batch:	Started: 26/08/2003 Stopped: 23/11/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203803

Seq: 1

Gender: F

Reported: 23/12/2004

Weight: 0.00

Hospitalisation:

Age: 54

Onset Date: 01/12/2004

DOB: 09/12/1949

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension		Hypertension 180/115 mm Hg, tachycardia 124 bpm, dizziness.	Clozaril was increased to 550mg/day, followed by treatment with Tritace.
Dizziness			
Tachycardia			

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 29/01/2004	Stopped:	01/12/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203806

Seq: 1

Gender: M

Reported: 23/12/2004

Weight: 0.00

Hospitalisation:

Age: 71

Onset Date: 07/12/2004

DOB: 25/10/1933

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Suspected myocarditis, troponin increased.	Clozaril ceased.
Troponin increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 17/11/2004	Stopped:	01/12/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203808	Seq: 1	Gender: M
Reported: 23/12/2004		Weight:
Hospitalisation:		Age: 43
Onset Date: 04/12/2004		DOB: 10/01/1961
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Suspected myocarditis, Troponin increased, pericardial effusion.	Clozaril ceased.
Pericardial effusion	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 17/11/2004	Stopped: 01/12/2004	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203820
Reported: 24/12/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 45
DOB: 14/10/1959
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain of 125kg for a duration of 6 years.	Ceased Clopine, was prescribed 300mg/day PO clozapine.

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2004 To 31 Dec 2004 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 203828

Seq: 1

Gender: M

Reported: 24/12/2004

Weight: 0.00

Hospitalisation:

Age: 29Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Cardiomyopathy.	Ceased Clozaril

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information: