



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 214519 **Seq:** 1 **Gender:** M
Reported: 03/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 80
Onset Date: 06/12/2005 **DOB:** 10/04/1925
Outcome: Death, maybe drug 10/12/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypoxia		84%	
Pneumonia		Patient experienced pneumonia.	Clopine ceased.
Headache			
Pulmonary oedema			
Vomiting			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 08/06/2004 Stopped: 05/12/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Date Range: 1 Jan 2006 To 31 Dec 2005 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 214559 **Seq:** 1 **Gender:** M
Reported: 04/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 34
Onset Date: 30/11/2005 **DOB:** 09/04/1971
Outcome: Death, maybe drug 30/11/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient died while on Clopine.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 01/09/2004 Stopped: 30/11/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 214584	Seq: 1	Gender: M
Reported: 04/01/2006		Weight: 77.10
Hospitalisation: Admitted to hospital		Age: 23
Onset Date: 15/08/1999		DOB: 07/08/1976
Outcome: Death, maybe drug	22/08/2005	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gait disturbance	Death	The patient was diagnosed with a febrile illness (sudden onset fever and spiking temperatures, headache, sore throat, cough, nasal congestion and generally unwell). He had a respiratory tract infection, chest discomfort or chest tightness, felt disorientated, suffered nausea and vomiting, felt dizzy and had a generalised rash. He developed a viral infection, temperature, high fever and was very sedated. His CK and Clozapine levels increased. He was sedated and drowsy, not able to walk properly (droopy and ungainly), seemingly having ...	

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason:
Batch:	Started: Stopped:
VENTOLIN (Other drug)	Reason:
Batch:	Started: Stopped:
EPILIM (Suspected)	Reason:
Batch:	Started: Stopped:
VALIUM (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This report is a duplicate of 215449. Patient history: Schizophrenia and depression. Was receiving generic clozapine at time of death.



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Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 214584 **Seq:** 1 **Gender:** M
Reported: 04/01/2006 **Weight:** 77.10
Hospitalisation: Admitted to hospital **Age:** 23
Onset Date: 15/08/1999 **DOB:** 07/08/1976
Outcome: Death, maybe drug 22/08/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest discomfort	Death	... lost muscular control. He had an increase in psychotic symptoms. On 22 August 2005 he was found dead in his hospital room.	
Disorientation	Death		
Rash generalised	Death		
Somnolence	Death		
Vomiting	Death		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 02/04/1998	Stopped: 15/03/2000	

Laboratory Investigations:

Additional Information:

This report is a duplicate of 215449. Patient history: Schizophrenia and depression. Was receiving generic clozapine at time of death.



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Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 214607	Seq: 1	Gender: M
Reported: 05/01/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 32
Onset Date: 15/12/2005		DOB: 01/09/1973
Outcome: Death, maybe drug		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Deep vein thrombosis	Death	The patient developed bilateral deep vein thrombosis in the ileo-femoral vein in both legs going up to the inferior vena cava while receiving Clozaril. He ceased Clozaril treatment on 19 December 2005 due to coagulation disorder, but died on an unknown date.	Clozaril ceased.
Coagulopathy	Death		

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 29/11/1999	Stopped:	19/12/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 214748	Seq: 1	Gender: M
Reported: 10/01/2006		Weight: 0.00
Hospitalisation:		Age: 24
Onset Date:		DOB: 21/11/1981
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sedation		The patient became very sedated and experienced hypersalivation.	Clozaril dose reduced to 425mg daily.
Salivary hypersecretion			

Medicine Details:

LUVOX (Interaction)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	
CLOZARIL (Interaction)		Reason: Unspecified schizophrenia	
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 11/01/2005	Stopped: 0	
NALTREXONE HYDROCHLORIDE (Interaction)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 214750
Reported: 10/01/2006

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 37

DOB: 05/05/1968

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Caused or prolonged inpatient hospitalisation	The patient overdosed on Clozapine and may have ingested other medications as well.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2001	Stopped:	15/12/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 214774	Seq: 1	Gender: M
Reported: 10/01/2006		Weight: 0.00
Hospitalisation:		Age: 46
Onset Date: 28/04/2000		DOB: 21/01/1954
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Circulatory collapse Diastolic dysfunction Dilatation atrial		Patient was known to have a cardiac disorder, electrocardiogram changes, an episode of collapse (due to postural hypotension, dilatation ventricular, scan myocardial perfusion abnormal, ventricular dysfunction, ejection fraction abnormal, ventricular hypertrophy, diastolic dysfunction, dilatation atrial, mitral valve incompetence and drug ineffective.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 03/01/1995	Stopped: 22/11/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/01/2006	Echocardiogram				26 Jun 2003: Echocardiogram - mild dilated LV with normal systolic function. Conclusion: borderline LV hypertrophy; impaired LV distolic function. 5 Jul 2004: mildly dilated LV with normal LV systolic function; mild/moderate concentric LVH. 14 Apr 2004: mildly dilated LV with mild global systolic dysfunction. Conclusion: mild global LV systolic dysfunction. 21 Nov 2005: Moderately dilated left ventricle (LV) with mild ...

Additional Information:



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Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 214774	Seq: 1	Gender: M
Reported: 10/01/2006		Weight: 0.00
Hospitalisation:		Age: 46
Onset Date: 28/04/2000		DOB: 21/01/1954
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dilatation ventricular Drug ineffective Echocardiogram abnormal Ejection fraction abnormal Exercise electrocardiogram abnormal Mitral valve incompetence Orthostatic hypotension Scan myocardial perfusion abnormal Ventricular dysfunction Ventricular hypertrophy			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	800.0 Milligram Daily Oral
Batch:	Started: 03/01/1995 Stopped: 22/11/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
					... to moderte global dysfunction with segmental variation. Conclusion: moderate dilation of LV; mild to moderate global reduction in LV function; mildly dilated right atrium, trivial mitral regergitation.

Additional Information:



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Report Details:

Case Number: 214774
Reported: 10/01/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 28/04/2000
Outcome: Unknown

Age: 46
DOB: 21/01/1954
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	800.0 Milligram
	Daily
	Oral
Batch:	Started: 03/01/1995
	Stopped: 22/11/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/01/2006	Electrocardiograph				28 Apr 2000: Exercise ECG - poor R wave progression and diffuse secondary ST segment changes; accentuated during exercise (up to 1.4 mm ST segment depression in leads 2, 3 and AVF and 1 mm ST segment depression in leads V4 to V6). Myocardial perfusion scan: mildly dilated LV with mild apparent reduction of thallium uptake within the inferior wall. Post-exercise gated images showed mild global LV systolic dysfunction with LV ejection fraction of 48%. Conclusion: ...

Additional Information:



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Report Details:

Case Number: 214774

Seq: 1

Gender: M

Reported: 10/01/2006

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date: 28/04/2000

DOB: 21/01/1954

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Unspecified schizophrenia

Tablet

800.0 Milligram

Daily

Oral

Batch:

Started: 03/01/1995

Stopped: 22/11/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
					... Fixed apparent basal inferior wall defect (best explained by diaphragmatic attenuation artefact in the supine position); mild global LV systolic dysfunction with LV ejection fraction of 48%.

Additional Information:



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Date Range: 1 Jan 2006 To 31 Dec 2005 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 214800 **Seq:** 1 **Gender:** M
Reported: 10/01/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 37Y
Onset Date: 22/09/2005 **DOB:**
Outcome: Recovered 30/09/2005 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Odynophagia	Caused or prolonged inpatient hospitalisation	Patient developed odynophagia.	Clozapine was temporarily stopped.

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)	Reason:
Tablet 20.0 Milligram Oral	
Batch:	Started: 19/05/2005 Stopped:
CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 350.0 Milligram Daily Oral	
Batch:	Started: 28/08/2005 Stopped: 22/09/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 214814	Seq: 1	Gender: M
Reported: 11/01/2006		Weight: 0.00
Hospitalisation:		Age: 25
Onset Date:		DOB: 30/05/1980
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Left ventricular dysfunction		echocardiogram showed mild to moderate left ventricular systolic function The patient was diagnosed with suspected myocarditis approximately 10 years after commencing Clozaril.	
Left ventricular dysfunction			
Myocarditis			
Cardiomyopathy			

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 16/09/1996	Stopped: 28/12/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 214815

Seq: 1

Gender: M

Reported: 11/01/2006

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date:

DOB: 11/06/1971

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		The patient was diagnosed with diabetes while receiving Clozaril.	Clozaril ceased and later recommenced. Treated with two hypoglycaemic agents.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 214857	Seq: 1	Gender: M
Reported: 11/01/2006		Weight: 108.00
Hospitalisation: Required a visit to the doctor		Age: 19
Onset Date: 20/12/2005		DOB: 09/04/1986
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Congestive cardiomyopathy		The patient experienced dilated cardiomyopathy 8 weeks after starting Clozapine.	
Tachycardia			

Medicine Details:

CAMPRAL (Other drug)	Reason:
Batch:	Started:
	Stopped:
Abilify (Other drug)	Reason:
Batch:	Started:
	Stopped:
COGENTIN (Other drug)	Reason:
Batch:	Started:
	Stopped:
OROXINE (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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 214857 **Seq:** 1

Gender: M

Reported: 11/01/2006

Weight: 108.00

Hospitalisation: Required a visit to the doctor

Age: 19

Onset Date: 20/12/2005

DOB: 09/04/1986

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 214891

Seq: 1

Gender: M

Reported: 12/01/2006

Weight: 0.00

Hospitalisation:

Age: 38

Onset Date:

DOB: 31/10/1967

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		The patient's WBC and neutrophil counts were above the normal ranges on quite a number of occasions.	Clozapine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	700.0 Milligram Daily Oral
Batch:	Started: 28/07/2004 Stopped: 15/12/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 214893

Seq: 1

Gender: M

Reported: 12/01/2006

Weight: 0.00

Hospitalisation:

Age: 19

Onset Date:

DOB: 09/04/1986

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		The patient experienced cardiac complications.	Clopine titrated down to 300mg, then ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 01/08/2005 Stopped: 16/12/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 214912	Seq: 1	Gender: F
Reported: 12/01/2006		Weight: 0.00
Hospitalisation:		Age: 39
Onset Date: 05/11/2005		DOB: 16/09/1966
Outcome: Recovered	17/11/2005	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Patient experienced myocarditis and patient's WBC and neutrophil counts are above the normal ranges. Also experienced tachycardia, breathlessness, postural hypotension, raised troponin, increased cardiac markings on chest X-ray.	Clopine ceased.
Leukocytosis			

Medicine Details:

CLOZAPINE (Suspected)		Reason:	
Batch:	Started: 12/10/2005	Stopped: 30/11/2005	
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 01/11/2005	Stopped: 10/11/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/01/2006	Neutrophils		09/11/2005	12.4	
12/01/2006	Neutrophils		07/11/2005	15.3	
12/01/2006	White blood cells		09/11/2005	16.1	
12/01/2006	White blood cells		07/11/2005	18.9	

Additional Information:

Patient has a history of morbid obesity.



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Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215058 **Seq:** 1 **Gender:** M
Reported: 18/01/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 35
Onset Date: 15/12/2005 **DOB:** 23/04/1970
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged	Caused or prolonged inpatient hospitalisation	Patient presented to hospital with chest pain and was admitted and found to have a prolonged QTc interval.	Clozaril was ceased.
Chest pain	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 14/12/2005	Stopped: 28/12/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215090	Seq: 1	Gender: M
Reported: 19/01/2006		Weight: 0.00
Hospitalisation:		Age: 20
Onset Date: 01/01/2006		DOB: 30/03/1985
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder	Caused or prolonged inpatient hospitalisation	The patient experienced acute myocarditis	Ceased Clopine.
Myocarditis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Other drug)		Reason:	
20.0 Milligram		Oral	
Batch:	Started: 24/11/2005	Stopped:	
CLOPINE (Suspected)		Reason:	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 05/12/2005	Stopped: 02/01/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/01/2006	Electrocardiograph				The patient underwent an ECG which revealed that the inferior and lateral leads showed ischemic change which is continuing to resolve.

Additional Information:



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Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215108	Seq: 1	Gender: M
Reported: 20/01/2006		Weight: 0.00
Hospitalisation:		Age: 41
Onset Date: 12/12/2005		DOB: 28/07/1964
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperthermia	Caused or prolonged inpatient hospitalisation	The patient experienced an unexplained high fever, elevated temperature and diarrhoea 12 days after commencing Clozaril. He had a suspected neuroleptic malignant syndrome-type illness. The working diagnosis at this stage was a benign hyperthermia.	Clozaril ceased.
Diarrhoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 30/11/2005	Stopped: 11/12/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215108

Seq: 1

Gender: M

Reported: 20/01/2006

Weight: 0.00

Hospitalisation:

Age: 41

Onset Date: 12/12/2005

DOB: 28/07/1964

Outcome: Recovered

Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 30/11/2005	Stopped: 11/12/2005	

Laboratory Investigations:

Additional Information:



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Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2005 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215209
Reported: 24/01/2006

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 22/11/2005
Outcome: Recovered

Age: 19
DOB: 18/03/1986

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ventricular hypertrophy	Caused or prolonged inpatient hospitalisation	The patient experienced right ventricular hypertrophy, sinus tachycardia (119) and right axis deviation after commencing Clozaril. She had a mildly elevated troponin, increased white cell and neutrophil count and increased C-reactive protein. She also experienced a little weight gain, drooling and flu-like symptoms, especially a sore throat.	
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 19/10/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2006	C-Reactive Protein	<8.0	28/11/2005	31	06 Dec 2005: Echocardiogram - normal ventricular systolic function with no evidence of Clozapine cardiotoxicity.
24/01/2006	Echocardiogram				
24/01/2006	Electrocardiograph				9 Jan 2006: ECG - sinus tachy cardia ventricular premature complex(es), bigeminy, rightward axis considered right ventricular hypertrphy.
24/01/2006	Eosinophils	<0.04.	28/11/2005	0.5	

Additional Information:



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Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215209	Seq: 1	Gender: F
Reported: 24/01/2006		Weight: 0.00
Hospitalisation:		Age: 19
Onset Date: 22/11/2005		DOB: 18/03/1986
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drooling	Caused or prolonged inpatient hospitalisation		
Extrasystoles	Caused or prolonged inpatient hospitalisation		
Infection	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 19/10/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2006	Troponin	<0.15.	28/11/2005	0.18	Serum Troponin I.
24/01/2006	Troponin	<0.15.	22/11/2005	0.18	Serum Troponin I.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215209	Seq: 1	Gender: F
Reported: 24/01/2006		Weight: 0.00
Hospitalisation:		Age: 19
Onset Date: 22/11/2005		DOB: 18/03/1986
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Influenza like illness	Caused or prolonged inpatient hospitalisation		
Neutrophil count increased	Caused or prolonged inpatient hospitalisation		
Pharyngolaryngeal pain	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 19/10/2005	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215209
Reported: 24/01/2006

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 22/11/2005
Outcome: Recovered

Age: 19
DOB: 18/03/1986
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
QRS axis abnormal	Caused or prolonged inpatient hospitalisation		
Sinus tachycardia	Caused or prolonged inpatient hospitalisation		
Troponin I increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 19/10/2005	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215209

Seq: 1

Gender: F

Reported: 24/01/2006

Weight: 0.00

Hospitalisation:

Onset Date: 22/11/2005

Age: 19

Outcome: Recovered

DOB: 18/03/1986

Causality: Causality possible

Reaction Details:

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

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 19/10/2005	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215232	Seq: 1	Gender: M
Reported: 24/01/2006		Weight: 94.00
Hospitalisation:		Age: 36
Onset Date: 10/01/2006		DOB: 13/02/1969
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder	Caused or prolonged inpatient hospitalisation	The patient experienced cardiac complications, fever, tachycardia, restlessness and sweating. Lab results revealed mild neutrophilia and markedly raised creatine kinase levels. Patient diagnosed with neuroleptic malignant syndrome..	Ceased Clopine.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 29/11/2005 Stopped: 11/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2006	C-Reactive Protein		11/01/2006	13	
24/01/2006	Creatine		11/01/2006	75075	
24/01/2006	Creatine		16/01/2006	2855	
24/01/2006	Other data		11/01/2006	49697	Urine myoglobin
24/01/2006	Troponin		11/01/2006	0.06	
24/01/2006	White blood cells		11/01/2006	13.2	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215232
Reported: 24/01/2006

Seq: 1

Gender: M
Weight: 94.00
Age: 36
DOB: 13/02/1969
Causality: Causality possible

Hospitalisation:

Onset Date: 10/01/2006
Outcome: Recovered

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation		
Neutrophilia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 29/11/2005 Stopped: 11/01/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215232
Reported: 24/01/2006
Hospitalisation:
Onset Date: 10/01/2006
Outcome: Recovered

Seq: 1

Gender: M
Weight: 94.00
Age: 36
DOB: 13/02/1969
Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 29/11/2005 Stopped: 11/01/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2005 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215236 **Seq:** 1 **Gender:** M
Reported: 24/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 22
Onset Date: 10/12/2005 **DOB:** 12/12/1982
Outcome: Recovered 25/12/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Patient experienced fever with highest recorded temperatures of 39.9 and 38.2 degrees celcius.	Clopine was ceased and treated with Paracetamol.

Medicine Details:

ZOLOFT (Other drug)	Reason: Obsessive compulsive neurosis
Tablet 100.0 Milligram Oral	
Batch:	Started: Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 125.0 Milligram Daily Oral	
Batch:	Started: 28/11/2005 Stopped: 24/12/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2006	C-Reactive Protein				125 mg/L.
24/01/2006	Creatine kinase				59 U/L.
24/01/2006	Neutrophils				10.08 x 10 ⁹ /L
24/01/2006	Other data				Liver function test within normal range.
24/01/2006	Troponin				Negative.
24/01/2006	White blood cells				12.2 x 10 ⁹ /L.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215242	Seq: 1	Gender: M
Reported: 24/01/2006		Weight: 0.00
Hospitalisation:		Age: 36
Onset Date: 23/01/2006		DOB: 12/01/1970
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Obsessive-compulsive disorder		The patient developed depression and obsessional behaviour since commencing Clozaril and he developed elevated Clozapine and Norclozapine levels. Also developed possible right atrial hypertrophy and sinus tachycardia.	Clozaril dose reduced and Fluvoxamine dose reduced.
Atrial hypertrophy			
Depression			
Drug interaction			
Drug level increased			
Sinus tachycardia			

Medicine Details:

CLOZARIL (Interaction)		Reason:	
Tablet	475.0 Milligram	Daily	Oral
Batch:	Started: 08/08/1994	L TERM	Stopped:
FLUVOXAMINE MALEATE (Interaction)		Reason: Depression	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2006	Electrocardiograph				5 january 2006: Electrocardiogram: sinus tachycardia, possible right atrial hypertrophy, compatible with a bundle branch block.
24/01/2006	Other data		11/01/2006	844	Norclozapine level.
24/01/2006	Other data		19/01/2005	-	Norclozapine level.
24/01/2006	Other data		11/01/2006	-	Norclozapine level.
24/01/2006	Other data		26/04/2005	-	Norclozapine level.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215242

Seq: 1

Gender: M

Reported: 24/01/2006

Weight: 0.00

Hospitalisation:

Age: 36

Onset Date: 23/01/2006

DOB: 12/01/1970

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Interaction)	Reason:
Tablet	475.0 Milligram Daily Oral
Batch:	Started: 08/08/1994 L TERM Stopped:
FLUVOXAMINE MALEATE (Interaction)	Reason: Depression
Tablet	150.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2006	Serum drug level		23/07/2001	320	Clozapine level.
24/01/2006	Serum drug level		19/01/2005	1102	Clozapine level.
24/01/2006	Serum drug level		26/04/2005	1950	Clozapine level.
24/01/2006	Serum drug level		11/01/2006	3486	Clozapine level.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215279 **Seq:** 1 **Gender:** M
Reported: 25/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 28
Onset Date: **DOB:** 06/12/1977
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Patient experienced raised CK and cardiac disorder.	Clopine ceased.
Cardiac disorder			

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 08/12/2005	Stopped:	23/12/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215298
Reported: 25/01/2006

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 03/12/2005

Age: 23

DOB: 15/05/1982

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sinus tachycardia		Patient experienced sinus tachycardia, ventricular hypertrophy, protein total increased, platelet count increased and white blood cell count increased.	
Platelet count increased			
Protein total increased			
Ventricular hypertrophy			
White blood cell count increased			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
OMEPRAZOLE (Other drug)	Reason:
Batch:	Started: Stopped:
THIAMINE (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	900.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/01/2006	Echocardiogram				15/12/05 Echocardiogram: Mild concentric left ventricular hypertrophy. Echocardiogram: Abnormal (pre-treatment baseline).
25/01/2006	Electrocardiograph				29/12/05 Electrocardiogram: Sinus tachycardia.

Additional Information:

History: Gastric ulcer, haematemesis, joint arthroplasty and alcoholism.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215348	Seq: 1	Gender: M
Reported: 30/01/2006		Weight: 0.00
Hospitalisation:		
Onset Date: 11/01/2006		Age: 46
Outcome: Recovered	17/01/2006	DOB: 05/06/1959
		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient developed neutropenia.	

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Other drug)	Reason:
300.0 Milligram	
Batch:	Started:
Batch:	Stopped:
BENZTROPINE MESYLATE (Other drug)	Reason:
2.0 Milligram	
Batch:	Started:
Batch:	Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram
	Daily
	Oral
Batch:	Started: 22/11/2005
	Stopped: 12/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/01/2006	Neutrophils		11/01/2006	1.4	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215391	Seq: 1	Gender: F
Reported: 30/01/2006		Weight: 0.00
Hospitalisation:		Age: 16
Onset Date: 06/01/2006		DOB: 20/07/1989
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Palpitations	Caused or prolonged inpatient hospitalisation	Within days of commencing Clozaril patient experienced tachycardia heart rate of 120-130 beats per minutes, developed low grade fever (37.5-37.9), palpitations (but no chest pain), dizziness and flu-like symptoms, C-reactive protein increased, white blood cell count increased.	
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Other drug)	Reason:
Batch:	Started:
	Stopped:
AMISULPRIDE (Other drug)	Reason:
Batch:	Oral
	Started:
	Stopped:
LORAZEPAM (Other drug)	Reason:
Tablet	Oral
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	275.0 Milligram Daily Oral
Batch:	Started: 28/12/2005 S TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/01/2006	Troponin				troponin I = 0.09 (NR < 0.04)

Additional Information:

Note that a viral infection was concurrently diagnosed by the hospital. At an unknown stage an overdose may have been taken.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215391	Seq: 1	Gender: F
Reported: 30/01/2006		Weight: 0.00
Hospitalisation:		
Onset Date: 06/01/2006		Age: 16
Outcome: Unknown		DOB: 20/07/1989
		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Influenza like illness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Other drug)	Reason:
Batch:	Started:
	Stopped:
AMISULPRIDE (Other drug)	Reason:
	Oral
Batch:	Started:
	Stopped:
LORAZEPAM (Other drug)	Reason:
Tablet	Oral
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	275.0 Milligram
	Daily
Batch:	Started: 28/12/2005 S TERM
	Stopped:

Laboratory Investigations:

Additional Information:

Note that a viral infection was concurrently diagnosed by the hospital.
At an unknown stage an overdose may have been taken.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215391	Seq: 1	Gender: F
Reported: 30/01/2006		Weight: 0.00
Hospitalisation:		Age: 16
Onset Date: 06/01/2006		DOB: 20/07/1989
Outcome: Unknown		Causality: Causality possible

Reaction Details:

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

Medicine Details:

OLANZAPINE (Other drug)	Reason:
Batch:	Started: Stopped:
AMISULPRIDE (Other drug)	Reason:
Batch:	Started: Stopped: Oral
LORAZEPAM (Other drug)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	275.0 Milligram Daily Oral
Batch:	Started: 28/12/2005 S TERM Stopped:

Laboratory Investigations:

Additional Information:

Note that a viral infection was concurrently diagnosed by the hospital.
At an unknown stage an overdose may have been taken.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215407

Seq: 1

Gender: M

Reported: 30/01/2006

Weight: 0.00

Hospitalisation:

Onset Date: 18/01/2006

Age: 54

Outcome: Recovered

DOB: 23/06/1951

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient developed neutropenia.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 24/09/2001 L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/01/2006	Neutrophils		11/01/2006	3.1	
30/01/2006	Neutrophils		18/01/2006	0.7	
30/01/2006	Neutrophils		15/02/2006	2.6	
30/01/2006	Neutrophils		28/06/2006	4.1	
30/01/2006	Neutrophils		19/07/2006	1.5	
30/01/2006	Neutrophils		16/08/2006	2.1	

Additional Information:

Currently receiving chemotherapy providing an alternative explanation for decreased neutrophils and white cells.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215421	Seq: 1	Gender: M
Reported: 31/01/2006		Weight: 0.00
Hospitalisation:		Age: 26
Onset Date: 24/12/2005		DOB: 11/09/1979
Outcome: Recovered	04/01/2006	Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash papular		Patient erythematous, papular rash over extensor aspect of left arm, several small pustules on arm and chest.	
Rash pustular			

Medicine Details:

EPILIM (Other drug)	Reason:
1.6 Gram	
Batch:	Started: 14/10/2005 Stopped:
ATEHEXAL (Other drug)	Reason: Essential benign hypertension
50.0 Milligram	
Batch:	Started: 14/10/2005 Stopped:
SEROQUEL (Other drug)	Reason: Unspecified psychosis
1.1 Gram	
Batch:	Started: 15/01/2005 Stopped:
CLOPINE (Suspected)	Reason: Unspecified psychosis
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 18/12/2005 Stopped: 28/12/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous allergic dermatitis to Clopine.
Suspect drug certain rechallenge.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215461 **Seq:** 1 **Gender:** M
Reported: 01/02/2006 **Weight:** 95.00
Hospitalisation: Admitted to hospital **Age:** 43
Onset Date: 19/01/2006 **DOB:** 29/10/1962
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Arthralgia Liver function test abnormal Urticaria Wheezing		Patient developed fever 40 degrees, wheezes, urticarial like rash, liver dysfunction, arthralgia.	Ceased Clozapine.

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	175.0 Milligram Daily Oral
Batch:	Started: 10/01/2006 Stopped: 22/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mainly cholestatic - increased GGT, ALP and AST.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215484 **Seq:** 1 **Gender:** F
Reported: 01/02/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 63
Onset Date: 17/01/2006 **DOB:** 03/12/1942
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin I increased	Life threatening	Patient developed raised troponin levels.	Clozaril discontinued.

Medicine Details:

AMITRIPTYLINE HYDROCHLORIDE (Other drug)	Reason:	
Batch:	Started:	Stopped:
AUGMENTIN (Other drug)	Reason:	
Batch:	Started:	Stopped:
DILTIAZEM HYDROCHLORIDE (Other drug)	Reason:	
Batch:	Started:	Stopped:
IRBESARTAN (Other drug)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/02/2006	Troponin	0.06ug/L	17/01/2006	0.23ug/L	Result = 0.2ug/L pre-treatment.
01/02/2006	Troponin	0.06ug/L	18/01/2006	0.14ug/L	Result = 0.2ug/L pre-treatment.

Additional Information:

Carcinoma of the bile duct, blood alkaline phosphatase increased, eosinophil count increased, neoplasm malignant, terminal state, oral intake reduced, anorexia, diarrhoea, faeces discoloured, jaundice, abdominal distension, obstruction of small bowel, collapse intestinal obstruction, blood work consistent with sepsis, neutropenia, leukopenia, neutrophil toxic granulation present. The reporter considered that the carcinoma of the bile duct was not related to Clozaril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215484 **Seq:** 1

Gender: F

Reported: 01/02/2006

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 63

Onset Date: 17/01/2006

DOB: 03/12/1942

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

MAXOLON (Other drug)	Reason:		
Batch:	Started:	Stopped:	
MORPHINE NOS (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 15/08/2001	L TERM	Stopped: 17/01/2006 0

Laboratory Investigations:

Additional Information:

Carcinoma of the bile duct, blood alkaline phosphatase increased, eosinophil count increased, neoplasm malignant, terminal state, oral intake reduced, anorexia, diarrhoea, faeces discoloured, jaundice, abdominal distension, obstruction of small bowel, collapse intestinal obstruction, blood work consistent with sepsis, neutropenia, leukopenia, neutrophil toxic granulation present. The reporter considered that the carcinoma of the bile duct was not related to Clozaril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215485	Seq: 1	Gender: M
Reported: 02/02/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 43
Onset Date: 19/01/2006		DOB: 29/10/1962
Outcome: Not yet recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation	The patient experienced tachycardia, fever with shivers and rigors, abnormal liver function tests, urticarial-like rash, wheeze, cough, possible pneumonitis and arthralgia after Clopine dose was increased from 125mg to 175mg.	Clopine ceased.
Arthralgia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DIAZEPAM (Other drug)	Reason: Otr spec symp psychopathol nec
Tablet	10.0 Milligram Oral
Batch:	Started: Stopped:
OLANZAPINE (Other drug)	Reason: Otr spec symp psychopathol nec
	10.0 Milligram Oral
Batch:	Started: Stopped: 22/01/2006
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	175.0 Milligram Daily Oral
Batch:	Started: 10/01/2006 Stopped: 23/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/02/2006	AST = SGOT				AST - 65.
02/02/2006	C-Reactive Protein				C-reactive Protein - 143.
02/02/2006	Creatine				Ceartine Kinase - 262.
02/02/2006	Echocardiogram				Transthoracic echocardiogram showed LV to be at the lower end of noraml function wise, mildly dilated LA, and small pericardial effusion.
02/02/2006	GGT = SGGT =				Gamma GT - 233

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215485	Seq: 1	Gender: M
Reported: 02/02/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 43
Onset Date: 19/01/2006		DOB: 29/10/1962
Outcome: Not yet recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chills	Caused or prolonged inpatient hospitalisation		
Cough	Caused or prolonged inpatient hospitalisation		
Hepatitis cholestatic	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DIAZEPAM (Other drug)	Reason: Otr spec symp psychopathol nec
Tablet	10.0 Milligram Oral
Batch:	Started:
Batch:	Started:
OLANZAPINE (Other drug)	Reason: Otr spec symp psychopathol nec
	10.0 Milligram Oral
Batch:	Started:
	Stopped: 22/01/2006
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	175.0 Milligram Daily Oral
Batch:	Started: 10/01/2006
	Stopped: 23/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/02/2006	SAP = ALP				Alkaline Phosphatase - 145.
02/02/2006	Troponin				Troponin - <0.04.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215485 **Seq:** 1 **Gender:** M
Reported: 02/02/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 43
Onset Date: 19/01/2006 **DOB:** 29/10/1962
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Details:

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

Medicine Details:

DIAZEPAM (Other drug)	Reason: Otr spec symp psychopathol nec
Tablet 10.0 Milligram Oral	
Batch:	Started: Stopped:
OLANZAPINE (Other drug)	Reason: Otr spec symp psychopathol nec
10.0 Milligram Oral	
Batch:	Started: Stopped: 22/01/2006
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 175.0 Milligram Daily Oral	
Batch:	Started: 10/01/2006 Stopped: 23/01/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215485 **Seq:** 1 **Gender:** M
Reported: 02/02/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 43
Onset Date: 19/01/2006 **DOB:** 29/10/1962
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urticaria	Caused or prolonged inpatient hospitalisation		
Wheezing	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DIAZEPAM (Other drug)	Reason: Otr spec symp psychopathol nec
Tablet 10.0 Milligram Oral	
Batch:	Started: Stopped:
OLANZAPINE (Other drug)	Reason: Otr spec symp psychopathol nec
Tablet 10.0 Milligram Oral	
Batch:	Started: Stopped: 22/01/2006
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 175.0 Milligram Daily Oral	
Batch:	Started: 10/01/2006 Stopped: 23/01/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215487
Reported: 01/02/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 20/01/2006
Outcome: Unknown

Age: 25
DOB: 12/01/1981
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Caused or prolonged inpatient hospitalisation	Patient experienced agranulocytosis (neutrophil count 0.4), diarrhoea, vomiting and anxiety. He also had increased platelet levels and red cell count and decreased levels of mean cell volume and lymphocytes.	Olanazapine was prescribed. Clozaril was ceased.
Agranulocytosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 13/03/2001 Stopped: 15/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215487

Seq: 1

Gender: M

Reported: 01/02/2006

Weight: 0.00

Hospitalisation:

Onset Date: 20/01/2006

Age: 25

Outcome: Unknown

DOB: 12/01/1981

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anxiety	Caused or prolonged inpatient hospitalisation		
Lymphocyte count decreased	Caused or prolonged inpatient hospitalisation		
Mean cell volume decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 13/03/2001 Stopped: 15/01/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215487
Reported: 01/02/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 20/01/2006
Outcome: Unknown

Age: 25
DOB: 12/01/1981
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Platelet count increased	Caused or prolonged inpatient hospitalisation		
Red blood cell count increased	Caused or prolonged inpatient hospitalisation		
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 13/03/2001 Stopped: 15/01/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215520	Seq: 1	Gender: M
Reported: 02/02/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 28
Onset Date: 15/01/2006		DOB: 12/12/1977
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased Chest pain Gamma-glutamyltransferase increased Neutrophil count increased Rhabdomyolysis		Patient experienced blood creatine phosphokinase increased, rhabdomyolysis, non-cardiac chest pain, neutrophil count increased, gamma-glutamyltransferase increased.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 30/10/2002 Stopped: 22/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/02/2006	Creatine		22/01/2006	2030	Jan 2006: CK - 1960.
02/02/2006	Creatinine				(Date not specified) Creatinine - 38.
02/02/2006	Neutrophils		22/01/2006	12.69	28 Oct 2002: Pre-treatment NC - 3.37.
02/02/2006	White blood cells		22/01/2006	15.4	28 Oct 2002: Pre-treatment WCC - 6.6.
02/02/2006	White blood cells		23/01/2006	10.1	28 Oct 2002: Pre-treatment WCC - 6.6.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215602 **Seq:** 1 **Gender:** F
Reported: 07/02/2006 **Weight:** 0.00
Hospitalisation: **Age:** 52
Onset Date: 11/01/2006 **DOB:** 11/07/1953
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia Leukopenia Pharyngolaryngeal pain Pyrexia		The patient experienced low neutrophil and white blood cell counts, sore throat and fever.	Clopine ceased.

Medicine Details:

OMEPRAZOLE (Other drug) Tablet Batch:	20.0 Milligram Started:	Reason: Other diseases of esophagus Stopped:	Oral
SIMVASTATIN (Other drug) Tablet Batch:	40.0 Milligram Started:	Reason: Othr&unspec metabolic diseases Stopped:	Oral
CLOPINE (Suspected) Tablet Batch:	250.0 Milligram Started: 24/12/2003	Reason: Unspecified schizophrenia Stopped: 11/01/2006	Daily Oral

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/02/2006	Neutrophils		13/01/2006	1.2	
07/02/2006	White blood cells		13/01/2006	2.8	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215616

Seq: 1

Gender: M

Reported: 07/02/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		The patient experienced somnolence (groggy) and possible overdose following treatment with Clopine. He was taking 350mg Clopine and ceased for 6 days. He was admitted to Emergency Department and given 350mg of Clopine without retitrating the dose.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	350.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Possilbe overdose.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215635	Seq: 1	Gender: M
Reported: 07/02/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 22
Onset Date: 22/01/2006		DOB: 31/12/1983
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Red blood cell sedimentation rate i	Caused or prolonged inpatient hospitalisation	102	
C-reactive protein increased	Caused or prolonged inpatient hospitalisation	194	
Troponin I increased	Caused or prolonged inpatient hospitalisation	3.95 mg/L	

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 05/01/2006	Stopped: 23/01/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/02/2006	Other data				Cardiac echo - trial post cardial effusion, low/normal level. Cardiac MRI - evidence of myocarditis. CXR - LLL pneumonial

Additional Information:

Also taking quetiapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215635 **Seq:** 1 **Gender:** M
Reported: 07/02/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 22
Onset Date: 22/01/2006 **DOB:** 31/12/1983
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	The patient experienced myocarditis on MRI, arthralgia and pneumonia whilst on Clozaril.	Supportive therapy, IV fluids, O2 and Antibiotics. Clozapine ceased.
Myocarditis		The patient experienced myocarditis whilst on Clozaril.	
Arthralgia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 05/01/2006	Stopped: 23/01/2006	0

Laboratory Investigations:

Additional Information:

Also taking quetiapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215635 **Seq:** 1 **Gender:** M
Reported: 07/02/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 22
Onset Date: 22/01/2006 **DOB:** 31/12/1983
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Pneumonia	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	250.0 Milligram
	Daily
	Oral
Batch:	Started: 05/01/2006
	Stopped: 23/01/2006 0

Laboratory Investigations:

Additional Information:

Also taking quetiapine.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215662 **Seq:** 1
Reported: 08/02/2006

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 01/02/2006
Outcome: Recovered with sequelae

Age: 27
DOB: 12/01/1979
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus non-insulin-depe	Caused or prolonged inpatient hospitalisation	non insulin dependent diabetes	cease clopine

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 01/06/2001 Stopped: 07/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215679

Seq: 1

Gender: F

Reported: 09/02/2006

Weight: 0.00

Hospitalisation:

Age: 28

Onset Date:

DOB: 16/05/1977

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		The patient experienced an increase in CK and troponin levels.	Clopine ceased.
Troponin increased			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	150.0 Milligram Daily Oral
Batch:	Started: 16/01/2006 Stopped: 31/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215680

Seq: 1

Gender: F

Reported: 09/02/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Heart rate increased		The patient experienced increased heart rate.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215681 **Seq:** 1 **Gender:** M
Reported: 09/02/2006 **Weight:** 0.00
Hospitalisation: **Age:** 59
Onset Date: 30/01/2006 **DOB:** 20/05/1946
Outcome: Recovered 28/02/2006 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia		The patient experienced leukopenia and a low neutrophil count.	Ceased Clopine.
Neutropenia			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	40.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/02/2006	Neutrophils		30/01/2006	1.3	
09/02/2006	Neutrophils		03/02/2006	2.2	
09/02/2006	Neutrophils		28/02/2006	3.9	
09/02/2006	Neutrophils		20/02/2006	1.3	
09/02/2006	White blood cells		30/01/2006	2.3	
09/02/2006	White blood cells		03/02/2006	3.4	
09/02/2006	White blood cells		20/02/2006	2.3	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215681

Seq: 1

Gender: M

Reported: 09/02/2006

Weight: 0.00

Hospitalisation:

Age: 59

Onset Date: 30/01/2006

DOB: 20/05/1946

Outcome: Recovered

28/02/2006

Causality: Causality probable

Reaction Details:

Medicine Details:

CLOPINE (Suspected)

Reason:

Tablet

40.0 Milligram

Daily

Oral

Batch:

Started:

Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/02/2006	White blood cells		28/02/2006	3.9	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215808

Seq: 1

Gender: M

Reported: 13/02/2006

Weight: 0.00

Hospitalisation:

Onset Date: 12/08/2003

Age: 28

Outcome: Unknown

DOB: 26/02/1975

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	The patient experienced a grand mal fit and suffered a "head gash" five weeks after commencing Clozaril. Clozaril was ceased, then restarted on 2 September 2005. The patient experienced seizures, weight gain and lack of efficacy.	Clozaril ceased.
Drug ineffective	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 07/07/2003	Stopped:	15/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspect drug certain rechallenge.

This patient was restarted on Clozaril on 2 Sep 2005 and experienced seizures.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215808

Seq: 1

Gender: M

Reported: 13/02/2006

Weight: 0.00

Hospitalisation:

Onset Date: 12/08/2003

Age: 28

Outcome: Unknown

DOB: 26/02/1975

Causality: Causality certain

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 07/07/2003 Stopped: 15/08/2003

Laboratory Investigations:

Additional Information:

Suspect drug certain rechallenge.

This patient was restarted on Clozaril on 2 Sep 2005 and experienced seizures.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215810 **Seq:** 1 **Gender:** M
Reported: 13/02/2006 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 99U
Onset Date: 11/01/2006 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Life threatening	Neutropenia suspected.	

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 02/01/2006 Stopped: 17/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215884	Seq: 1	Gender: F
Reported: 16/02/2006		Weight: 0.00
Hospitalisation:		Age: 45
Onset Date: 25/05/2005		DOB: 15/06/1959
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		FI that the patient experienced "subclinical cardiomyopathy" whilst on Clozaril.	Clozaril ceased.
Myocarditis		The patient experienced suspected myocarditis whilst on Clozaril.	Clozaril ceased.
Aortic stenosis			
C-reactive protein increased			
Dilatation ventricular			
Hypotension			
Malaise			
Mitral valve disease			
Pericarditis			

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 09/10/1995	Stopped:	20/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/02/2006	Erythrocyte			65 mm	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215884

Seq: 1

Gender: F

Reported: 16/02/2006

Weight: 0.00

Hospitalisation:

Age: 45

Onset Date: 25/05/2005

DOB: 15/06/1959

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia			
Red blood cell sedimentation rate i			
Tachycardia			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 09/10/1995 Stopped: 20/01/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215888 **Seq:** 1 **Gender:** M
Reported: 16/02/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 34
Onset Date: 31/01/2006 **DOB:** 07/05/1971
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Platelet count increased	Caused or prolonged inpatient hospitalisation	The patient experienced very elevated platelet levels (969) after commencing Clozaril.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 03/04/2005 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/02/2006	Platelets		31/01/2006	969	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215948	Seq: 1	Gender: M
Reported: 16/02/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 65
Onset Date: 14/10/2004		DOB: 09/07/1939
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Patient developed myocarditis, fever, hypotension, tachycardia, decreased oxygen saturation, increased troponin, increased LFT's, urine positive for myoglobin. ECHO global LV dysfunction.	Treated with Prednisone, Tritace, Carvedilol, Aldactone, Warfarin, Digoxin and reduced Risperidone gradually to 1.5mg/daily and Frusemide.
Ejection fraction decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 29/09/2004	Stopped: 30/09/2004	
CHLORPROMAZINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 10/09/2004	Stopped: 26/09/2004 0	
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 10/09/2004	Stopped: 27/09/2004 0	
CLOZAPINE (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 27/09/2004	Stopped: 28/09/2004 0	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/02/2006	Echocardiogram				Echo: global LV dysfunction. EF about 25%.
16/02/2006	Electrocardiograph				ECG: nil conduction deficits.
16/02/2006	Troponin				Troponin - 0.38.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215948	Seq: 1	Gender: M
Reported: 16/02/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 65
Onset Date: 14/10/2004		DOB: 09/07/1939
Outcome: Not yet recovered		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		
Myoglobinuria	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 27/09/2004	Stopped: 06/10/2004	0
RISPERIDONE (Suspected)		Reason:	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 10/09/2004	Stopped: 29/09/2004	0
CLOZAPINE (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/10/2004	Stopped: 04/10/2004	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215948	Seq: 1	Gender: M
Reported: 16/02/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 65
Onset Date: 14/10/2004		DOB: 09/07/1939
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 29/09/2004	Stopped: 30/09/2004	
CHLORPROMAZINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 10/09/2004	Stopped: 26/09/2004 0	
RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 10/09/2004	Stopped: 27/09/2004 0	
CLOZAPINE (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 27/09/2004	Stopped: 28/09/2004 0	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215948 **Seq:** 1 **Gender:** M
Reported: 16/02/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 65
Onset Date: 14/10/2004 **DOB:** 09/07/1939
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

RISPERIDONE (Suspected)	Reason:
Tablet 4.0 Milligram Daily Oral	
Batch:	Started: 27/09/2004 Stopped: 06/10/2004 0
RISPERIDONE (Suspected)	Reason:
Tablet 3.0 Milligram Daily Oral	
Batch:	Started: 10/09/2004 Stopped: 29/09/2004 0
CLOZAPINE (Suspected)	Reason:
Tablet 50.0 Milligram Daily Oral	
Batch:	Started: 01/10/2004 Stopped: 04/10/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215959	Seq: 1	Gender: M
Reported: 17/02/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 39
Onset Date: 14/02/2005		DOB: 14/02/1966
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea	Caused or prolonged inpatient hospitalisation	Patient experienced dyspnoea, fever, chest pain, drowsiness and depressed myocardial function decreased.	Treated with Bisoprolol, Tritace and Clonazepam.
Chest pain	Caused or prolonged inpatient hospitalisation		
Ejection fraction decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
OMEPRAZOLE (Other drug)	Reason:
Batch:	Started: Stopped:
RISPERIDONE (Other drug)	Reason: Unspecified schizophrenia
Batch:	Started: Stopped:
CLONAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/02/2006	Other data				EF about 35%.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215959 **Seq:** 1 **Gender:** M
Reported: 17/02/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 39
Onset Date: 14/02/2005 **DOB:** 14/02/1966
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram
	Daily
	Oral
Batch:	Started: 21/01/2005
	Stopped: 15/02/2005

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 215986	Seq: 1	Gender: M
Reported: 20/02/2006		Weight: 0.00
Hospitalisation:		Age: 38
Onset Date: 19/01/2006		DOB: 29/05/1967
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		The patient's routine echocardiogram showed mild global left ventricular systolic dysfunction approximately 7 weeks after commencing Clozaril, which raised the possibility that the patient could have Clozapine induced cardiomyopathy.	
Echocardiogram abnormal Ventricular dysfunction			

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 22/11/2005	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/02/2006	Echocardiogram				09 Nov 2006 - Echocardiogram: Conclusion - Normal LV and RV systolic function, mildly enlarged LA, normal valve function. 19 Jan 2006: Conclusion - Mild global LV systolic dysfunction, mildly enlarged LA, normal RV function, normal valve function.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216032

Seq: 1

Gender: M

Reported: 21/02/2006

Weight: 0.00

Hospitalisation:

Onset Date: 09/02/2006

Age: 27

Outcome: Unknown

DOB: 07/11/1978

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutrophilia		Lab tests revealed a 'high WBC' and neutrophilia.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 07/10/2005 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216040	Seq: 1	Gender: M
Reported: 21/02/2006		Weight: 0.00
Hospitalisation:		Age: 41
Onset Date: 15/05/2003		DOB: 03/09/1961
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		The patient has experienced elevated LFTs since May 2003.	
Dizziness		patient treated with pravastatin in Dec 2005 for high cholesterol and has been experiencing dizziness since that time. He stopped pravastatin briefly with no change to dizzy symptoms. He stopped clopine for a couple of days and felt better. Dizziness is mostly nocturnal but soemtimes during day	

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	250.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/02/2006	ALT = SGPT				ALT - 112.
21/02/2006	AST = SGOT				AST - 42.
21/02/2006	Bilirubin				Bili - 19.
21/02/2006	GGT = SGGT =				GGT - 348.
21/02/2006	SAP = ALP				ALP - 117.

Additional Information:

PMHx, Heavy drinker with poor liver function.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216116

Seq: 1

Gender: M

Reported: 23/02/2006

Weight: 0.00

Hospitalisation:

Age: 44

Onset Date: 28/02/2006

DOB: 01/05/1961

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Patient developed cardiac disorder.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 13/01/2006 Stopped: 28/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216159	Seq: 1	Gender: M
Reported: 27/02/2006		Weight: 0.00
Hospitalisation:		Age: 37
Onset Date: 07/02/2006		DOB: 16/07/1968
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejection fraction decreased	Incapacity/disability	Left ventricular ejection fraction decreased with 35-40%. Ventricular hypokinesia.	
Echocardiogram abnormal			

Medicine Details:

MIRTAZAPINE (Other drug)	Reason:
Batch:	Started:
	Stopped:
RISPERIDONE (Other drug)	Reason:
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram
	Daily
	Oral
Batch:	Started: 15/02/2004
	Stopped: 15/12/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/02/2006	Echocardiogram				Echocardiogram was performed showing a global reduction in left ventricular ejection fraction with 35-40%, (no ref range provided). Moreover, a global hypokinesia of the left ventricle was mentioned.

Additional Information:

PRE CLOZAPINE ECHO WAS NORMAL



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216160
Reported: 27/02/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 10/02/2006
Outcome: Unknown

Age: 99u
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		The patient developed a "large postural drop" of 36 mmHg systolic. Later on, the postural drop had reduced to 15 mmHg systolic.	Reduction in Clozaril dosage was planned.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	12.5 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 2006 To 31 Dec 2005 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216161

Seq: 1

Gender: F

Reported: 27/02/2006

Weight: 0.00

Hospitalisation:

Onset Date: 25/01/2005

Age: 50

DOB: 22/05/1954

Outcome: Recovered

13/02/2006

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Life threatening	The patient experienced low neutrophil and white blood cell counts.	Ceased Clozapine.
White blood cell count decreased	Life threatening		

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	250.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/02/2006	Neutrophils		29/12/2005	1.3	
27/02/2006	Neutrophils		25/01/2006	1.4	
27/02/2006	Neutrophils		27/01/2006	1.2	
27/02/2006	Neutrophils		28/01/2006	1.1	
27/02/2006	Neutrophils		13/02/2006	1.5	
27/02/2006	Neutrophils		08/02/2006	0.9	
27/02/2006	Neutrophils		30/01/2006	3.2	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216161
Reported: 27/02/2006

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 25/01/2005

Age: 50

Outcome: Recovered

13/02/2006

DOB: 22/05/1954

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)

Reason:

Tablet

250.0 Milligram

Daily

Oral

Batch:

Started:

Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/02/2006	Neutrophils		29/01/2006	1.1	
27/02/2006	White blood cells		29/12/2005	5.1	
27/02/2006	White blood cells		25/01/2006	3.2	
27/02/2006	White blood cells		27/01/2006	3.6	
27/02/2006	White blood cells		28/01/2006	4.0	
27/02/2006	White blood cells		29/01/2006	3.9	
27/02/2006	White blood cells		30/01/2006	3.4	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216161

Seq: 1

Gender: F

Reported: 27/02/2006

Weight: 0.00

Hospitalisation:

Age: 50

Onset Date: 25/01/2005

DOB: 22/05/1954

Outcome: Recovered

13/02/2006

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)

Reason:

Tablet

250.0 Milligram

Daily

Oral

Batch:

Started:

Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/02/2006	White blood cells		08/02/2006	3.1	
27/02/2006	White blood cells		13/02/2006	4.5	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216189

Seq: 1

Gender: M

Reported: 28/02/2006

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date:

DOB: 25/08/1980

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		The patient experienced tachycardia.	

Medicine Details:

AMOXYCILLIN-POTASSIUM CLAVULANATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOPINE (Suspected)		Reason:	
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 03/01/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216206	Seq: 1	Gender: M
Reported: 28/02/2006		Weight: 0.00
Hospitalisation:		Age: 35
Onset Date: 13/02/2006		DOB: 25/05/1970
Outcome: Unknown		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancytopenia	Caused or prolonged inpatient hospitalisation	Patient developed agranulocytosis which later amended to pancytopenia.	Clozaril was discontinued.

Medicine Details:

INTERFERON ALFA-2B (Suspected)		Reason: Other diseases of liver	
Batch:	Started:	Stopped:	0
CLOZARIL (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 29/12/1994	Stopped:	14/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/02/2006	Haemoglobin		01/05/2006	120	
28/02/2006	Lymphocytes		01/05/2006	700	
28/02/2006	Neutrophils		03/02/2006	400	
28/02/2006	Neutrophils		14/02/2006	680	
28/02/2006	Neutrophils		01/05/2006	900	
28/02/2006	Platelets		01/05/2006	116	
28/02/2006	White blood cells		03/02/2006	1000	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216206
Reported: 28/02/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 13/02/2006
Outcome: Unknown

Age: 35
DOB: 25/05/1970
Causality: Causality probable

Reaction Details:

Medicine Details:

INTERFERON ALFA-2B (Suspected)		Reason: Other diseases of liver	
Batch:	Started:	Stopped:	0
CLOZARIL (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 29/12/1994	Stopped:	14/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/02/2006	White blood cells		14/02/2006	1550	
28/02/2006	White blood cells		01/05/2006	1700	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216240 **Seq:** 1 **Gender:** M
Reported: 02/03/2006 **Weight:** 0.00
Hospitalisation: **Age:** 51
Onset Date: 04/02/2006 **DOB:** 04/03/1954
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Unexplained death.	

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216241 **Seq:** 1

Gender: M

Reported: 02/03/2006

Weight: 0.00

Hospitalisation:

Age: 41

Onset Date: 06/02/2006

DOB: 12/08/1964

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient suicide while on Clopine.	

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216287 **Seq:** 1 **Gender:** F
Reported: 07/03/2006 **Weight:** 0.00
Hospitalisation: **Age:** 34Y
Onset Date: **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient was found dead.	

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
CLOZAPINE (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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216308 **Seq:** 1 **Gender:** F
Reported: 08/03/2006 **Weight:** 0.00
Hospitalisation: **Age:** 38
Onset Date: 25/02/2006 **DOB:** 05/10/1967
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient died on the weekend of 25-Feb-2006 to 26-Feb-2006.	
Confusional state	Death		was hospitalised, died in hospital

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 30/11/2005 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216364	Seq: 1	Gender: M
Reported: 09/03/2006		Weight: 0.00
Hospitalisation:		Age: 41
Onset Date: 09/11/2005		DOB: 09/09/1964
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertrophic cardiomyopathy		Hypertrophic cardiomyopathy, ventricular hypertrophy, echocardiogram abnormal, urea/creatinine ratio low, urate increased, ggt/alt/CK increased and phosphate decreased.	
Alanine aminotransferase increase			
Blood creatine phosphokinase incr			
Blood phosphorus decreased			
Blood urea nitrogen/creatinine rati			
Blood uric acid increased			
Echocardiogram abnormal			
Gamma-glutamyltransferase increa			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
600.0 Milligram	Daily Oral
Batch:	Started: 16/03/2004 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/03/2006	Electrocardiograph				9/11/2005: Echocardiography report conclusion: Again no evidence of dilated cardiomyopathy. Normal left ventricular size and function - 67%. Asymmetrical left ventricular hypertrophy maximally involving the apex and a hypertrophic cardiomyopathy still requiring consideration.

Additional Information:

Also taking venlafaxine. No cardiac ischaemia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216405 **Seq:** 1 **Gender:** M
Reported: 10/03/2006 **Weight:** 0.00
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 09/05/1967
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Completed suicide Death		Patient committed suicide.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	550.0 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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216430	Seq: 1	Gender: M
Reported: 10/03/2006		Weight: 0.00
Hospitalisation:		
Onset Date: 21/02/2006		Age: 39
Outcome: Recovered		DOB: 08/06/1966
		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Patient experienced neutropenia 0.6 and white blood cell count decreased.	
White blood cell count decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 13/03/2002	Stopped:	15/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/03/2006	Neutrophils		13/03/2002	10.61	
10/03/2006	Neutrophils		21/02/2006	0.6	
10/03/2006	Neutrophils		13/03/2006	5.78	
10/03/2006	Neutrophils		28/02/2006	0.76	
10/03/2006	White blood cells		13/03/2002	17.3	
10/03/2006	White blood cells		21/02/2006	2.7	
10/03/2006	White blood cells		28/02/2006	4.1	

Additional Information:

Also taking folate



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216430
Reported: 10/03/2006

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date: 21/02/2006

DOB: 08/06/1966

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason:

Tablet

400.0 Milligram

Daily

Oral

Batch:

Started: 13/03/2002

Stopped: 15/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/03/2006	White blood cells		13/03/2006	12.1	

Additional Information:

Also taking folate



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216431	Seq: 1	Gender: M
Reported: 10/03/2006		Weight: 0.00
Hospitalisation:		Age: 31
Onset Date:		DOB: 21/01/1975
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Patient experienced suspected myocarditis, pyrexia, tachycardia, troponin increased, blood creatine phosphokinase increased, atrial fibrillation.	Antibiotics were administered intravenously. Clozaril was discontinued.
Atrial fibrillation	Caused or prolonged inpatient hospitalisation		
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Aripiprazole (Other drug)	Reason:
Batch:	Started: Stopped:
LOSEC (Other drug)	Reason:
Batch:	Started: Stopped:
COGENTIN (Other drug)	Reason:
Batch:	Started: Stopped:
DIAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/03/2006	Creatine		25/02/2006	99	21 Feb 2006: Fever up to 39 degrees C.
10/03/2006	Creatine		27/02/2006	280	
10/03/2006	Neutrophils		24/02/2006	11.4	
10/03/2006	Other data				
10/03/2006	Troponin		27/02/2006	0.6	
10/03/2006	White blood cells		24/02/2006	13/4	

Additional Information:

Current condition: Diabetes mellitus non-insulin dependent.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216431	Seq: 1	Gender: M
Reported: 10/03/2006		Weight: 0.00
Hospitalisation:		Age: 31
Onset Date:		DOB: 21/01/1975
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		
Leukocytosis	Caused or prolonged inpatient hospitalisation		
Neutrophilia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ATORVASTATIN (Other drug)	Reason:
Batch:	Started: Stopped:
METFORMIN HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
GLIMEPIRIDE (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 09/02/2006 Stopped: 15/02/2006 0

Laboratory Investigations:

Additional Information:

Current condition: Diabetes mellitus non-insulin dependent.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216431
Reported: 10/03/2006

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 31

DOB: 21/01/1975

Causality: Causality possible

Reaction Details:

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

Medicine Details:

Aripiprazole (Other drug)	Reason:	
Batch:	Started:	Stopped:
LOSEC (Other drug)	Reason:	
Batch:	Started:	Stopped:
COGENTIN (Other drug)	Reason:	
Batch:	Started:	Stopped:
DIAZEPAM (Other drug)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

Current condition: Diabetes mellitus non-insulin dependent.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216431
Reported: 10/03/2006

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 31

DOB: 21/01/1975

Causality: Causality possible

Reaction Details:

Medicine Details:

ATORVASTATIN (Other drug)	Reason:		
Batch:	Started:	Stopped:	
METFORMIN HYDROCHLORIDE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
GLIMEPIRIDE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 09/02/2006	Stopped: 15/02/2006	0

Laboratory Investigations:

Additional Information:

Current condition: Diabetes mellitus non-insulin dependent.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216517
Reported: 15/03/2006

Seq: 1

Gender: M
Weight: 115.00

Hospitalisation:

Onset Date: 15/02/2006
Outcome: Unknown

Age: 34
DOB: 24/04/1971
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Tachycardia of 106-115bph and echocardiogram abnormal.	
Echocardiogram abnormal			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 13/02/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/03/2006	Electrocardiograph				Feb 2006: Echocardiography showed "mildly enlarged left atrium".
15/03/2006	Other data				Feb 2006: Tachycardia of 106 - 116bpm.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216561
Reported: 16/03/2006

Seq: 1

Gender: M
Weight: 115.00

Hospitalisation:

Onset Date: 01/02/2006
Outcome: Unknown

Age: 34
DOB: 24/04/1971
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dilatation atrial		Patient developed a persistent tachycardia of 106-115 bpm, moreover, an echocardiography showed a mildly enlarged left atrium.	
Echocardiogram abnormal			
Tachycardia			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 13/02/2006	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/03/2006	Electrocardiograph				Feb 2006: Echocardiography showed "mildly enlarged left atrium".
16/03/2006	Other data				Feb 2006: Tachycardia of 106-115 bpm.

Additional Information:

ECG and bloods all normal



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216590 **Seq:** 1 **Gender:** F
Reported: 21/03/2006 **Weight:** 0.00
Hospitalisation: **Age:** 47
Onset Date: 04/02/2006 **DOB:** 27/02/1958
Outcome: Death, maybe drug 04/02/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest	Death	Cardiac arrest.	Full resuscitation treatment
Convulsion	Death		
Respiratory arrest	Death		

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 01/02/1999 Stopped: 04/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216613 **Seq:** 1 **Gender:** M
Reported: 22/03/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 53
Onset Date: **DOB:** 09/05/1952
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective	Caused or prolonged inpatient hospitalisation	Patient's psychosis exacerbated.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 17/09/2001 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216727

Seq: 1

Gender: M

Reported: 28/03/2006

Weight: 0.00

Hospitalisation:

Age: 35

Onset Date:

DOB: 13/02/1971

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Patient had been diagnosed with an enlarged heart which was confirmed by echocardiography. Also patient had been breathless	
Cardiomegaly			
Dyspnoea			
Echocardiogram abnormal			

Medicine Details:

CLOZARIL (Suspected)	Reason:
	625.0 Milligram Daily Oral
Batch:	Started: 01/09/1997 Stopped: 08/03/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216728

Seq: 1

Gender: M

Reported: 28/03/2006

Weight: 0.00

Hospitalisation:

Age: 26

Onset Date:

DOB: 01/02/1980

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Priapism	Required Visit to Doctor	Patient experienced priapism	

Medicine Details:

CLOZARIL (Suspected)	Reason:
	500.0 Milligram Daily
Batch:	Started: 06/12/2001 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

priapism was not the cause of hospitalisation



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216731	Seq: 1	Gender: M
Reported: 28/03/2006		Weight: 0.00
Hospitalisation:		Age: 50
Onset Date: 11/03/2006		DOB: 09/04/1955
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Body temperature increased	Caused or prolonged inpatient hospitalisation	Patient had been found non-responsive, unconscious, sedated and with frothing at mouth, increased body temperature and an increased CK.	
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Loss of consciousness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 30/08/1995	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/03/2006	Creatine		11/03/2006	63000	

Additional Information:

No muscle rigidity.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216787	Seq: 1	Gender: M
Reported: 29/03/2006		Weight: 90.00
Hospitalisation:		Age: 50
Onset Date: 12/03/2006		DOB: 09/04/1955
Outcome: Recovered	23/03/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life threatening	Patient in hostel was observed to slump from chair- no obvious fitting but described as frothing from the mouth. Lost consciousness for 5 mins. When he awoke- agitated, aggressive. Intubated for airway protection and admitted to ICU. In ICU, elevated CK, acute renal failure, febrile. Neuroleptic malignancy syndrome diagnosed. No muscle rigidity.	Intubation, Fluids and mannitol to maintain urine output; dantrolene and bromocriptine
Aggression	Life threatening		
Agitation	Life threatening		

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
PAROXETINE HYDROCHLORIDE (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
CLOZAPINE (Suspected)		Reason:	
Tablet	600.0 Milligram	1 time	Oral
Batch:	Started: 31/03/2005	Stopped: 12/03/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/03/2006	Creatine				CK on admission 606 IU/L and peaked at 63328 on the 13/03/2006. Gradually decreased to normal (< 200 IU/L) on 24/03/2006. U&Es, FBE all normal. Micro: blood, urine, sputum, CSF- no growth

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216787 **Seq:** 1 **Gender:** M
Reported: 29/03/2006 **Weight:** 90.00
Hospitalisation: **Age:** 50
Onset Date: 12/03/2006 **DOB:** 09/04/1955
Outcome: Recovered 23/03/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Life threatening		

Medicine Details:

OLANZAPINE (Suspected)	Reason:		
Batch:	Started:	Stopped:	0
PAROXETINE HYDROCHLORIDE (Suspected)	Reason:		
Batch:	Started:	Stopped:	0
CLOZAPINE (Suspected)	Reason:		
Tablet	600.0 Milligram	1 time	Oral
Batch:	Started: 31/03/2005	Stopped:	12/03/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216860

Seq: 1

Gender: M

Reported: 31/03/2006

Weight: 0.00

Hospitalisation:

Onset Date: 28/02/2006

Age: 24

DOB: 22/07/1981

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis		Patient experienced myocarditis, hepatitis	Clopine was ceased.
Hyperhidrosis			Clopine was ceased.
Myocarditis			
Vomiting			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	150.0 Milligram Daily Oral
Batch:	Started: 13/02/2006 Stopped: 01/03/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
31/03/2006	Troponin			0.16	

Additional Information:

ECG normal



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216905

Seq: 1

Gender: M

Reported: 03/04/2006

Weight: 0.00

Hospitalisation:

Onset Date: 15/05/2000

Age: 31

Outcome: Unknown

DOB: 25/08/1968

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Caused or prolonged inpatient hospitalisation	Patient experienced cardiomyopathy	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
750.0 Milligram	Daily
Oral	
Batch:	Started: 29/01/1995
	Stopped: 05/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/04/2006	Other data				Global left ventricular systolic dysfunction.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216918	Seq: 1	Gender: F
Reported: 03/04/2006		Weight: 0.00
Hospitalisation:		Age: 38
Onset Date: 15/03/2006		DOB: 09/03/1968
Outcome: Recovered	23/05/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced leucopenia and low neutrophil count.	
Leukopenia			

Medicine Details:

PREDNISONE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
HALOPERIDOL (Other drug)	Reason: Unspecified schizophrenia
50.0 Milligram	Monthly Intramuscular
Batch:	Started:
Batch:	Stopped:
DOXORUBICIN HYDROCHLORIDE (Suspected)	Reason: Otr prim malign lymphoid tissu
Batch:	Started:
Batch:	Stopped:
VINCRIStINE SULPHATE (Suspected)	Reason: Otr prim malign lymphoid tissu
Batch:	Started:
Batch:	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/04/2006	Neutrophils		02/03/2006	4.7	
03/04/2006	Neutrophils		13/03/2006	11.1	
03/04/2006	Neutrophils		15/03/2006	1.1	
03/04/2006	Neutrophils		17/03/2006	0.1	
03/04/2006	Neutrophils		20/03/2006	2.3	
03/04/2006	White blood cells		02/03/2006	6.6	
03/04/2006	White blood cells		13/03/2006	12.2	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216918
Reported: 03/04/2006

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 15/03/2006
Outcome: Recovered

23/05/2006

Age: 38
DOB: 09/03/1968
Causality: Causality possible

Reaction Details:

Medicine Details:

RITUXIMAB (Suspected)	Reason: Otr prim malig n lymphoid tissu		
Batch:	Started:	Stopped: 0	
CYCLOPHOSPHAMIDE (Suspected)	Reason: Otr prim malig n lymphoid tissu		
Batch:	Started:	Stopped:	
CLOPINE (Suspected)	Reason:		
	700.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/04/2006	White blood cells		15/03/2006	2.0	
03/04/2006	White blood cells		17/03/2006	1.8	
03/04/2006	White blood cells		20/03/2006	6.2	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216948 **Seq:** 1 **Gender:** M
Reported: 04/04/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 34
Onset Date: **DOB:** 09/06/1971
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Patient was non-compliant with his therapy for 1 week and his fther then gave him the full dose of 700mg for two days at which point the patient experienced tachycardis. He then jumped off a bridge and was admitted to hospital (not a suicide attempt).	
Incorrect dose administered			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	700.0 Milligram 2 times Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 216949 is the second sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 216998	Seq: 1	Gender: M
Reported: 04/04/2006		Weight: 0.00
Hospitalisation:		Age: 49
Onset Date:		DOB: 01/11/1956
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation	Increased CK levels.	
Hyperhidrosis			
Malaise	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/04/2006	Creatine			CK:4000+	

Additional Information:

Report 208878 is the first sequence to this report and 212094 is the second sequence.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217017 **Seq:** 1 **Gender:** M
Reported: 04/04/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 39
Onset Date: 06/03/2006 **DOB:** 03/11/1966
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217027	Seq: 1	Gender: M
Reported: 05/04/2006		Weight: 0.00
Hospitalisation:		
Onset Date: 07/08/1999		Age: 19
Outcome: Recovered		DOB: 21/01/1980
		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation	Patient experienced tachycardia up to 160 bpm	Clozaril ceased, beta blockers.

Medicine Details:

RISPERIDONE (Other drug)	Reason:
Batch:	Started:
	Stopped:
THIORIDAZINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram
	Daily
	Oral
Batch:	Started: 27/07/1999
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217030

Seq: 1

Gender: M

Reported: 05/04/2006

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date: 06/03/2006

DOB: 19/07/1971

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pericarditis		Patient vomited once and experienced pericarditis and a pulse rate of 107	
Tachycardia			
Vomiting			

Medicine Details:

CLOZARIL (Suspected)	Reason:
	300.0 Milligram Daily Oral
Batch:	Started: 24/01/2006 Stopped: 08/03/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pulse rate of 107.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217031	Seq: 1	Gender: M
Reported: 05/04/2006		Weight: 0.00
Hospitalisation:		Age: 25
Onset Date:		DOB: 09/04/1980
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis Aortic valve disease C-reactive protein increased Electrocardiogram T wave inversio Eosinophilia Myocarditis Pyrexia Tachycardia		An ECG showed a T wave inversion, a tachycardia. The reporter also mentioned leukocytosis, an increased CRP and fever of unkown origin.	Clozaril ceased

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 23/02/2006	Stopped: 04/04/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217052 **Seq:** 1 **Gender:** M
Reported: 05/04/2006 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: 14/02/2006 **DOB:** 25/03/1970
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient developed neutropenia.	Withheld Pegatron and Clozapine.

Medicine Details:

PANTOPRAZOLE (Other drug)	Reason:
20.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
Pegatron Combination Therapy (Suspected)	Reason: Other diseases of liver
1.2 Gram Daily	
Batch:	Started: 27/01/2006 Stopped: 14/02/2006 0
CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 600.0 Milligram Daily Oral	
Batch:	Started: Stopped: 14/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/04/2006	Neutrophils				Neutrophils - 0.6.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217115	Seq: 1	Gender: F
Reported: 07/04/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 54
Onset Date: 15/09/2005		DOB: 03/02/1951
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased	Caused or prolonged inpatient hospitalisation	Drug level increased and Gamma-glutamyltransferase increased.	reduced dose
Constipation	Caused or prolonged inpatient hospitalisation		
Gamma-glutamyltransferase increa	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLONAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
PANTOPRAZOLE (Other drug)	Reason:
Batch:	Started: Stopped:
BENZTROPINE MESYLATE (Other drug)	Reason:
Batch:	Started: Stopped:
LACTULOSE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/04/2006	GGT = SGGT =		23/03/2006	62	Clozapine level. Mar 2006: 1320, Nov 2005: 770, Oct 2005: 750, Sep 2005: 770 and Sep 2005: 1100.
07/04/2006	COTP Serum drug level		21/03/2006	1520	
07/04/2006	Serum drug level		28/03/2006	1180	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217115 **Seq:** 1

Gender: F

Reported: 07/04/2006

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 54

Onset Date: 15/09/2005

DOB: 03/02/1951

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason:

Tablet

12.0 Milligram

Daily

Oral

Batch:

Started: 08/02/2000

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217145	Seq: 1	Gender: M
Reported: 07/04/2006		Weight: 0.00
Hospitalisation:		Age: 41
Onset Date: 16/03/2006		DOB: 03/03/1965
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
C-reactive protein increased Troponin increased		105 mg/L (NR 2-10) Patient experienced cardiac complications with increased troponin and rising inflammatory markers. Echo normal.	Clozaril discontinued.

Medicine Details:

QUETIAPINE (Other drug)	Reason:
Batch:	Started:
	Stopped:
CITALOPRAM HYDROBROMIDE (Other drug)	Reason:
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason:
Tablet	175.0 Milligram
	Daily
	Oral
Batch:	Started: 10/03/2006
	Stopped: 17/03/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/04/2006	C-Reactive Protein		16/03/2006	51	<2-10 mg/L
07/04/2006	C-Reactive Protein		19/03/2006	105	<2-10 mg/L
07/04/2006	C-Reactive Protein		20/03/2006	76	<2-10 mg/L
07/04/2006	Neutrophils		10/03/2006	4.96	
07/04/2006	Troponin	<0.03ng/mL	16/03/2006	0.03	
07/04/2006	Troponin	<0.03ng/mL	17/03/2006	0.05	
07/04/2006	Troponin	<0.03ng/mL	19/03/2006	0.01	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217145
Reported: 07/04/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 16/03/2006
Outcome: Unknown

Age: 41
DOB: 03/03/1965
Causality: Causality possible

Reaction Details:

Medicine Details:

QUETIAPINE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CITALOPRAM HYDROBROMIDE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason:		
Tablet	175.0 Milligram	Daily	Oral
Batch:	Started: 10/03/2006	Stopped: 17/03/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/04/2006	Troponin	<0.03ng/mL	18/03/2006	0.09	
07/04/2006	White blood cells		10/03/2006	7.1	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217189

Seq: 1

Gender: M

Reported: 10/04/2006

Weight: 0.00

Hospitalisation:

Age: 21

Onset Date: 23/03/2006

DOB: 24/12/1984

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejection fraction decreased		An echocardiogram showed a decrease in ejection fraction from 60% to 40-45%.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)		Reason:		
Tablet	450.0 Milligram	Daily	Oral	
Batch:	Started: 27/01/2005	Stopped:	23/03/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217315

Seq: 1

Gender: F

Reported: 11/04/2006

Weight: 0.00

Hospitalisation:

Age: 65

Onset Date: 04/02/2006

DOB: 04/08/1940

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizures, white blood cell count decreased and neutrophil count decreased.	Valproate for seizures. Clozaril ceased.
Neutrophil count decreased			
White blood cell count decreased			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 21/11/2005	Stopped: 24/02/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217347 **Seq:** 1

Gender: U

Reported: 12/04/2006

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date: 15/06/2004

DOB: 06/03/1962

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonism		Parkinson's syndrome.	

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Other drug)	Reason:		
75.0 Milligram	Oral		
Batch:	Started:	Stopped:	
CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	400.0 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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217435
Reported: 18/04/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 22/03/2006
Outcome: Unknown

Age: 45
DOB: 18/12/1960
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Cardiomyopathy and ejection fraction decreased.	Reduced dose of Clozaril from 350mg to 300mg
Ejection fraction decreased			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 05/04/2001	Stopped: 18/07/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/04/2006	Electrocardiograph				22 Mar 2006: Echocardiography - Moderate global left ventricular systolic dysfunction, ejection fraction of 33%, probable Clozapine-related cardiomyopathy, mild left atrial dilatation, sclerotic aortic valve with mild aortic stenosis.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217437 **Seq:** 1 **Gender:** U
Reported: 18/04/2006 **Weight:** 0.00
Hospitalisation: **Age:** 20
Onset Date: **DOB:** 26/11/1985
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting	Incapacity/disability	Patient had been taking Clozaril for approximately 1 year and had experienced persistent vomiting over the past few months to the point of noticable weight loss.	

Medicine Details:

SOLIAN (Other drug)	Reason:		
Batch:	Started:	Stopped:	
EFEXOR (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLONAZEPAM (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason:		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 17/03/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217443 **Seq:** 1 **Gender:** F
Reported: 18/04/2006 **Weight:** 0.00
Hospitalisation: **Age:** 50
Onset Date: 15/03/2006 **DOB:** 02/08/1955
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Patient experienced involuntary movement in her throat and increased clozaril leves. Possible drug interaction.	
Drug interaction			
Drug level above therapeutic			

Medicine Details:

CLOZARIL (Interaction)	Reason:
Tablet	13.0 Milligram Daily Oral
Batch:	Started: 11/02/1998 Stopped: 0
PREMARIN (Interaction)	Reason:
	2.5 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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217450	Seq: 1	Gender: M
Reported: 18/04/2006		Weight: 0.00
Hospitalisation:		Age: 43
Onset Date: 24/03/2006		DOB: 08/11/1962
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Patient experienced cardiac complications after commencing Clozaril.	
Echocardiogram abnormal	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
VITAMIN NOS (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 07/03/2006 Stopped: 24/03/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/04/2006	Electrocardiograph				27 March 2006 - Echocardiography showed a moderate biventricular failure.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217483	Seq: 1	Gender: F
Reported: 19/04/2006		Weight: 165.40
Hospitalisation:		Age: 36
Onset Date:		DOB: 14/08/1969
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Patient experienced weight gain of 75.4kg, poor control of diabetes	
Blood glucose increased	Incapacity/disability	blood sugar level 7.9	
Diabetes mellitus inadequate contr			

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
PANADEINE FORTE (Other drug)	Reason:
Batch:	Started: Stopped:
OGEN (Suspected)	Reason:
Batch:	Started: Stopped: 0
LUVOX (Suspected)	Reason:
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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217483
Reported: 19/04/2006

Seq: 1

Gender: F
Weight: 165.40
Age: 36
DOB: 14/08/1969
Causality: Causality possible

Hospitalisation:

Onset Date:
Outcome: Unknown

Reaction Details:

Medicine Details:

GABAPENTIN (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 22/01/2002	Stopped: 27/03/2006	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217489
Reported: 19/04/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 27/03/2006
Outcome: Recovered

Age: 52
DOB: 06/11/1953
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Leucopenia and Neutropenia.	Clopine ceased.
Neutropenia			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 16/02/2006 Stopped: 26/03/2006
MIRTAZAPINE (Suspected)	Reason: Depression
	45.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/04/2006	Neutrophils		26/03/2006	0.5	
19/04/2006	Neutrophils		20/03/2006	3.3	
19/04/2006	Neutrophils		03/04/2006	2.2	
19/04/2006	Neutrophils		01/04/2006	1.8	
19/04/2006	White blood cells		26/03/2006	1.7	
19/04/2006	White blood cells		20/03/2006	4.4	
19/04/2006	White blood cells		01/04/2006	3.6	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217489

Seq: 1

Gender: M

Reported: 19/04/2006

Weight: 0.00

Hospitalisation:

Age: 52

Onset Date: 27/03/2006

DOB: 06/11/1953

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 16/02/2006 Stopped: 26/03/2006
MIRTAZAPINE (Suspected)	Reason: Depression
	45.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/04/2006	White blood cells		03/04/2006	3.8	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217543

Seq: 1

Gender: F

Reported: 20/04/2006

Weight: 0.00

Hospitalisation:

Age: 54

Onset Date:

DOB: 24/02/1952

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intestinal obstruction		Patient developed a recurrent bowel obstruction.	Ceased Clopine.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217545

Seq: 1

Gender: F

Reported: 20/04/2006

Weight: 0.00

Hospitalisation:

Age: 36

Onset Date:

DOB: 07/05/1969

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Patient experienced tachycardia.	Ceased Clopine

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 17/03/2006 Stopped: 29/03/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217563	Seq: 1	Gender: M
Reported: 20/04/2006		Weight: 0.00
Hospitalisation:		Age: 33
Onset Date: 20/03/2006		DOB: 10/04/1972
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin T increased	Caused or prolonged inpatient hospitalisation	Increased troponin level, fever, flu-like symptoms, nausea, vomiting, diarrhoea, shivering, feeling sick, pain in knee joint and sore throat.	Clopine ceased
Arthralgia	Caused or prolonged inpatient hospitalisation		
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Other drug)	Reason:
20.0 Milligram	
Batch:	Started: 15/03/2006 Stopped:
RISPERIDONE (Other drug)	Reason:
50.0 Milligram	
Batch:	Started: 15/03/2006 Stopped:
CLOPINE (Suspected)	Reason:
Tablet 300.0 Milligram	Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/04/2006	C-Reactive Protein		22/03/2006	200	
20/04/2006	Creatine		22/03/2006	123	
20/04/2006	Creatine		24/03/2006	280	
20/04/2006	Erythrocyte		22/03/2006	75	
20/04/2006	Erythrocyte		24/03/2006	75	
20/04/2006	Troponin		22/03/2006	0.01	Troponin T.
20/04/2006	Troponin		24/03/2006	0.09	Troponin T.

Additional Information:



Therapeutic Goods Administration Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217563
Reported: 20/04/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 20/03/2006
Outcome: Recovered

Age: 33
DOB: 10/04/1972
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		
Diarrhoea	Caused or prolonged inpatient hospitalisation		
Influenza like illness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Other drug)	Reason:
20.0 Milligram	
Batch:	Started: 15/03/2006 Stopped:
RISPERIDONE (Other drug)	Reason:
50.0 Milligram	
Batch:	Started: 15/03/2006 Stopped:
CLOPINE (Suspected)	Reason:
Tablet 300.0 Milligram	Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217563
Reported: 20/04/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 20/03/2006
Outcome: Recovered

Age: 33
DOB: 10/04/1972
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Red blood cell sedimentation rate i	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Other drug)	Reason:
20.0 Milligram	
Batch:	Started: 15/03/2006 Stopped:
RISPERIDONE (Other drug)	Reason:
50.0 Milligram	
Batch:	Started: 15/03/2006 Stopped:
CLOPINE (Suspected)	Reason:
Tablet 300.0 Milligram	Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217563
Reported: 20/04/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 20/03/2006
Outcome: Recovered

Age: 33
DOB: 10/04/1972
Causality: Causality possible

Reaction Details:

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

Medicine Details:

OLANZAPINE (Other drug)	Reason:
20.0 Milligram	
Batch:	Started: 15/03/2006 Stopped:
RISPERIDONE (Other drug)	Reason:
50.0 Milligram	
Batch:	Started: 15/03/2006 Stopped:
CLOPINE (Suspected)	Reason:
Tablet 300.0 Milligram	Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2005 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217639 **Seq:** 1 **Gender:** F
Reported: 24/04/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 15/01/2005 **DOB:** 07/08/1975
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Obsessive-compulsive disorder	Incapacity/disability	Obsessive compulsive syndrome	Clozaril was withheld for the night of 04 Apr 2006. Treated with Zolof.
Tachycardia	Incapacity/disability		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 15/11/2002 Stopped: 15/04/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217649	Seq: 1	Gender: F
Reported: 24/04/2006		Weight: 0.00
Hospitalisation:		Age: 99u
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective	Caused or prolonged inpatient hospitalisation	Patient experienced a lack of effect while being treated with Abilify.	5 months in an acute psychiatric unit.

Medicine Details:

ZOLOFT (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
CLOZAPINE (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
Abilify (Suspected)	Reason: Unspecified schizophrenia
Tablet	30.0 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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217699	Seq: 1	Gender: F
Reported: 26/04/2006		Weight: 0.00
Hospitalisation:		Age: 23
Onset Date: 04/04/2006		DOB: 28/06/1982
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sinus tachycardia		Patient suffered from tiredness, headache, sinus tachycardia, electrocardiogram abnormal.	
Constipation			
Electrocardiogram abnormal			
Fatigue			
Headache			

Medicine Details:

LACTULOSE (Other drug)	Reason:
Batch:	Started: Stopped:
PARACETAMOL (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	112.5 Milligram Daily Oral
Batch:	Started: 25/03/2006 Stopped: 04/04/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/04/2006	Electrocardiograph				4/4/06: ECG abnormal ECG revealed a sinus tachycardia of 130 bpm 10/04/06: ECG abnormal: ECG revealed a sinus tachycardia of 124 bpm.
26/04/2006	Other data		25/03/2006	110	Pulse rate between 86 - 105 (pre-commencement pulse rate).
26/04/2006	Other data		04/04/2006	130	Pulse rate between 86 - 105 (pre-commencement pulse rate).
26/04/2006	Other data		10/04/2006	124	Pulse rate between 86 - 105 (pre-commencement pulse rate).

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217769 **Seq:** 1 **Gender:** F
Reported: 28/04/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 34
Onset Date: 15/02/2006 **DOB:** 13/08/1971
Outcome: Recovered 15/03/2006 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Patient developed a fever and high CRP levels.	Clopine ceased.
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 29/12/2005 Stopped: 20/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217800	Seq: 1	Gender: M
Reported: 01/05/2006		Weight: 0.00
Hospitalisation:		Age: 20
Onset Date: 03/03/2006		DOB: 08/04/1985
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Blood pressure increased C-reactive protein increased Dilatation atrial Weight increased		Patient experienced mild left atrial dilatation, mild impairment of systolic function, weight gain of approximately 6kg, tachycardia and increased blood pressure.	Antihypertensive therapy and is trying to lose weight.

Medicine Details:

COVERSYL (Other drug)	Reason:
Batch:	Started:
	Stopped:
ATENOLOL (Other drug)	Reason:
Batch:	Started:
	Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram
	Daily
	Oral
Batch:	Started: 18/07/2005
	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217818 **Seq:** 1 **Gender:** F
Reported: 01/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 25
Onset Date: 25/02/2006 **DOB:** 24/07/1980
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation	Patient experiencing persistant tachycardia whilst being treated with Clopine therapy.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	325.0 Milligram Daily Oral
Batch:	Started: 18/10/2004 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/05/2006	Neutrophils	high			
01/05/2006	White blood cells	high			

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217819

Seq: 1

Gender: M

Reported: 01/05/2006

Weight: 0.00

Hospitalisation:

Onset Date:

Age: 56

Outcome: Unknown

DOB: 04/10/1949

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dilatation atrial		Patient experienced mild left atrial dilatation whilst being treated with Clopine therapy.	

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason: Unspecified schizophrenia
1.5 Gram	Daily Oral
Batch:	Started: Stopped:
CLOPINE (Suspected)	Reason:
Tablet	625.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

A cardiologist has reviewed the result, and states the dilation is either 'secondary to increased blood pressure or mild diastolic dysfunction'.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217891
Reported: 02/05/2006

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 23/12/1999
Outcome: Unknown

Age: 42
DOB: 15/11/1957
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lymphocytosis		Patient was noted to have lymphocytosis (risen from 2.1 to 4.9).	
Convulsion			
Diabetes mellitus			

Medicine Details:

MIPRAMINE HYDROCHLORIDE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
RISPERIDONE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
EFEXOR (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	12.0 Milligram	Daily	Oral
Batch:	Started: 04/02/1999	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217910

Seq: 1

Gender: F

Reported: 02/05/2006

Weight: 0.00

Hospitalisation:

Age: 83

Onset Date: 15/03/2006

DOB: 27/12/1922

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cholestasis		Patient experienced abnormal liver function tests in a cholestatic pattern.	
Liver function test abnormal			

Medicine Details:

EPILIM (Other drug)	Reason:	
Batch:	Started:	Stopped:
PARACETAMOL (Other drug)	Reason:	
Batch:	Started:	Stopped:
OMEPRAZOLE (Other drug)	Reason:	
Batch:	Started:	Stopped:
MELOXICAM (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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217910 **Seq:** 1

Gender: F

Reported: 02/05/2006

Weight: 0.00

Hospitalisation:

Age: 83

Onset Date: 15/03/2006

DOB: 27/12/1922

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RAMIPRIL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 217960

Seq: 1

Gender: M

Reported: 04/05/2006

Weight: 0.00

Hospitalisation:

Onset Date:

Age: 60

Outcome: Not yet recovered

DOB: 21/01/1946

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Left ventricular dysfunction		Patient experiencing left ventricular dysfunction.	Cardiology follow-up.

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason: Other&unspecified epilepsy				
Batch:	Started:	Stopped:	Oral		
CARBIMAZOLE (Other drug)	Reason: Thyrotoxicosis w/o ment goiter				
Tablet	2.5 Milligram	Started:	Stopped:	Oral	
ATENOLOL (Other drug)	Reason:				
Tablet	25.0 Milligram	Started:	Stopped:	Oral	
CLOPINE (Suspected)	Reason: Unspecified schizophrenia				
Tablet	350.0 Milligram	Daily	Started:	Stopped:	Oral
Batch:	Started: 29/04/2005	Stopped:			

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/05/2006	Echocardiogram				Left ventricular dysfunction was detected on a routine echocardiogram. The patient had a normal reading in 2005.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218010
Reported: 05/05/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 20/03/2006
Outcome: Unknown

Age: 28
DOB: 08/08/1977
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Patient experienced increased liver function tests, neutropenia and leucopenia.	Clozaril discontinued.
Liver function test abnormal			
Neutropenia			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 20/02/2006 Stopped: 15/04/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/05/2006	ALT = SGPT		11/04/2006	362	
05/05/2006	GGT = SGGT = GOTP		11/04/2006	1.5	
05/05/2006	Neutrophils		20/03/2006	1.1	
05/05/2006	Neutrophils		14/02/2006	1.76	
05/05/2006	Neutrophils		13/04/2006	3.06	
05/05/2006	Neutrophils		21/04/2006	1.33	
05/05/2006	Neutrophils		30/03/2006	1.13	

Additional Information:

Report 204233 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218010
Reported: 05/05/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 20/03/2006
Outcome: Unknown

Age: 28
DOB: 08/08/1977
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 20/02/2006 Stopped: 15/04/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/05/2006	Neutrophils		24/04/2006	2.05	
05/05/2006	White blood cells		14/02/2006	3.8	
05/05/2006	White blood cells		20/03/2006	4.4	
05/05/2006	White blood cells		30/03/2006	3.9	
05/05/2006	White blood cells		13/04/2006	6.4	

Additional Information:

Report 204233 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218017

Seq: 1

Gender: M

Reported: 05/05/2006

Weight: 0.00

Hospitalisation:

Age: 48

Onset Date:

DOB: 17/01/1958

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation		Patient experienced shortness of breath, confused thoughts, stomach pain and constipation.	
Abdominal pain upper			
Confusional state			
Dyspnoea			

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 06/05/2004 Stopped: Continuing.

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218060	Seq: 1	Gender: M
Reported: 05/05/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 19Y
Onset Date: 25/04/2006		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Patient experienced neuroleptic malignancy syndrome, CK(approx 6000), troponin 1 normal, ecg tachycardia, flu symptoms (incl fever, hot/cold).	Ceased Clozapine (antibiotics for concomitant bacteremia).
Influenza like illness	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 11/04/2006	Stopped: 26/04/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218060 **Seq:** 1 **Gender:** M
Reported: 05/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 19Y
Onset Date: 25/04/2006 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 11/04/2006 Stopped: 26/04/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218097

Seq: 1

Gender: M

Reported: 08/05/2006

Weight: 0.00

Hospitalisation:

Onset Date: 23/02/2006

Age: 24

DOB: 23/02/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation		Severe constipation.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	750.0 Milligram	Daily	Oral
Batch:	Started: 25/11/2005	Stopped:	
BENZTROPINE MESYLATE (Suspected)	Reason:		
	4.0 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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218143	Seq: 1	Gender: F
Reported: 09/05/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 45
Onset Date: 20/01/2006		DOB: 20/08/1960
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutrophil count decreased	Caused or prolonged inpatient hospitalisation	Patient experienced neutrophil count decreased, white blood cell count decreased, anisocytosis and monocyte count decreased.	Clozaril discontinued. Granulocyte colony stimulating factor (GCSF) and close monitoring of temperature, blood pressure and daily blood tests.
Anisocytosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

INSULIN NOS (Other drug)	Reason:
Batch:	Started: Stopped:
ATENOLOL (Other drug)	Reason:
Batch:	Started: Stopped:
F.G.F. (Other drug)	Reason:
Batch:	Started: Stopped:
SEROQUEL (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/05/2006	Neutrophils	2.0-8.0	20/01/2006	0.8	
09/05/2006	Neutrophils	2.0-8.0	23/01/2006	0.3	
09/05/2006	Neutrophils	2.0-8.0	24/01/2006	0.10	
09/05/2006	Neutrophils	2.0-8.0	26/01/2006	0.00	
09/05/2006	Neutrophils	2.0-8.0	29/01/2006	0.00	
09/05/2006	Neutrophils	2.0-8.0	27/01/2006	0.00	
09/05/2006	Neutrophils	2.0-8.0	25/01/2006	0.10	

Additional Information:

Report 208364 is the first sequence to this report.
Patient also taking B Complex.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218143 **Seq:** 1 **Gender:** F
Reported: 09/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 45
Onset Date: 20/01/2006 **DOB:** 20/08/1960
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

ORDINE (Other drug)	Reason:	
Batch:	Started:	Stopped:

CLOZARIL (Suspected)	Reason:		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 20/04/2005	Stopped: 20/01/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/05/2006	White blood cells	4.0-11.0	20/01/2006	2.70	
09/05/2006	White blood cells	4.0-11.0	23/01/2006	2.20	
09/05/2006	White blood cells	4.0-11.0	24/01/2006	1.70	
09/05/2006	White blood cells	4.0-11.0	25/01/2006	2.20	
09/05/2006	White blood cells	4.0-11.0	26/01/2006	0.90	
09/05/2006	White blood cells	4.0-11.0	27/01/2006	1.00	
09/05/2006	White blood cells	4.0-11.0	29/01/2006	1.10	

Additional Information:

Report 208364 is the first sequence to this report.
Patient also taking B Complex.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218225

Seq: 1

Gender: M

Reported: 10/05/2006

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date: 15/03/2006

DOB: 06/06/1963

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic enzyme abnormal		Patient experienced increased liver enzymes.	Clozaril and Alcohol were ceased.

Medicine Details:

ALCOHOL (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	12.0 Milligram	Daily	Oral
Batch:	Started: 19/06/1995	Stopped: 19/04/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Current condition Alcoholism and Hepatis C.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218277	Seq: 1	Gender: F
Reported: 12/05/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 16
Onset Date: 12/04/2006		DOB: 22/07/1989
Outcome: Recovered	28/04/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged	Caused or prolonged inpatient hospitalisation	Patient experienced QT prolonged, postural hypotension, weight gain, sedation and diaphoresis.	Clopine ceased.
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)	Reason: Depression
20.0 Milligram	Oral
Batch:	Started: 20/02/2006 Stopped:
LAMOTRIGINE (Other drug)	Reason:
Tablet 150.0 Milligram	Oral
Batch:	Started: 24/02/2006 Stopped:
TRIFLUOPERAZINE HYDROCHLORIDE (Other drug)	Reason: Unspecified psychosis
10.0 Milligram	Oral
Batch:	Started: 20/02/2006 Stopped:
LITHIUM CARBONATE (Other drug)	Reason:
2.0 Gram	Oral
Batch:	Started: 13/02/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/05/2006	Serum drug level	>350	19/04/2006	358	Clozapine level

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218277	Seq: 1	Gender: F
Reported: 12/05/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 16
Onset Date: 12/04/2006		DOB: 22/07/1989
Outcome: Recovered	28/04/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lipids abnormal	Incapacity/disability		
Orthostatic hypotension	Caused or prolonged inpatient hospitalisation		
Sedation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

THYROXINE SODIUM (Other drug)	Reason:
100.0 Microgram	Oral
Batch:	Started: 15/03/2006 Stopped:
DIANE-35 ED (Other drug)	Reason: Contraception
Tablet 1.0 Dose Unspecified Daily	Oral
Batch:	Started: 13/02/2006 Stopped: Contin
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 100.0 Milligram Daily	Oral
Batch:	Started: Stopped: 27/04/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218277 **Seq:** 1 **Gender:** F
Reported: 12/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 16
Onset Date: 12/04/2006 **DOB:** 22/07/1989
Outcome: Recovered 28/04/2006 **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)	Reason: Depression
20.0 Milligram	Oral
Batch:	Started: 20/02/2006 Stopped:
LAMOTRIGINE (Other drug)	Reason:
Tablet 150.0 Milligram	Oral
Batch:	Started: 24/02/2006 Stopped:
TRIFLUOPERAZINE HYDROCHLORIDE (Other drug)	Reason: Unspecified psychosis
10.0 Milligram	Oral
Batch:	Started: 20/02/2006 Stopped:
LITHIUM CARBONATE (Other drug)	Reason:
2.0 Gram	Oral
Batch:	Started: 13/02/2006 Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218277 **Seq:** 1 **Gender:** F
Reported: 12/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 16
Onset Date: 12/04/2006 **DOB:** 22/07/1989
Outcome: Recovered 28/04/2006 **Causality:** Causality possible

Reaction Details:

Medicine Details:

THYROXINE SODIUM (Other drug)	Reason:
100.0 Microgram	Oral
Batch:	Started: 15/03/2006 Stopped:
DIANE-35 ED (Other drug)	Reason: Contraception
Tablet 1.0 Dose Unspecified Daily	Oral
Batch:	Started: 13/02/2006 Stopped: Contin
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 100.0 Milligram Daily	Oral
Batch:	Started: Stopped: 27/04/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218292

Seq: 1

Gender: F

Reported: 12/05/2006

Weight: 0.00

Hospitalisation:

Age: 55

Onset Date:

DOB: 27/09/1950

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death		Death unexplained.	

Medicine Details:

CLOPINE (Suspected)	Reason:
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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218295 **Seq:** 1 **Gender:** M
Reported: 12/05/2006 **Weight:** 79.00
Hospitalisation: **Age:** 33
Onset Date: 28/04/2006 **DOB:** 10/06/1972
Outcome: Recovered 29/04/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Body temperature increased		Patient experienced a slight increase in temperature, hypertension and moderate tachycardia.	
Blood pressure increased			
Tachycardia			

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 07/04/2006 Stopped: Continuing.

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218336	Seq: 1	Gender: F
Reported: 15/05/2006		Weight: 0.00
Hospitalisation:		Age: 36
Onset Date: 21/03/2006		DOB: 26/10/1969
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis C-reactive protein increased Chest pain Constipation Cough Dizziness		Patient experienced myocarditis, electrocardiogram abnormal, tachycardia, C-reactive protein increased, oedema peripheral, ventricular hypokinesia, chest pain, pyrexia, dizziness, cough and constipation.	Clozaril discontinued, treatment with Thiamine 100mg daily.

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
STILNOX (Other drug)	Reason:
Batch:	Started: Stopped:
MULTIVITAMINS (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 06/03/2006 Stopped: 21/03/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/05/2006	C-Reactive Protein				Increased CRP of 182u/l (no ref range provided).
15/05/2006	Electrocardiograph				Echocardiography revealed "evidence of grade II left ventricule hypokinesia of basal to mid anteroseptal regions" and an estimated ejection fraction of 50% (no ref range provided).

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218336	Seq: 1	Gender: F
Reported: 15/05/2006		Weight: 0.00
Hospitalisation:		Age: 36
Onset Date: 21/03/2006		DOB: 26/10/1969
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal Oedema peripheral Pyrexia Tachycardia Ventricular hypokinesia			

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
STILNOX (Other drug)	Reason:
Batch:	Started: Stopped:
MULTIVITAMINS (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 06/03/2006 Stopped: 21/03/2006 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218392	Seq: 1	Gender: M
Reported: 16/05/2006		Weight: 0.00
Hospitalisation:		Age: 57
Onset Date: 06/04/2006		DOB: 08/12/1948
Outcome: Death, maybe drug	20/04/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia aspiration	Death	Patient died due to complications related to pneumonia whilst on Clopine.	
Cough	Death		
Malaise	Death		
Pyrexia	Death		

Medicine Details:

CHLORAMPHENICOL (Other drug)	Reason:
12.0 Dose Unspecified	
Batch:	Started: Stopped:
PERGOLIDE (Other drug)	Reason:
3.0 Milligram	
Batch:	Started: Stopped:
ENTACAPONE (Other drug)	Reason:
600.0 Milligram	Oral
Batch:	Started: Stopped:
SINEMET (Other drug)	Reason:
6.0 Dose Unspecified	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/05/2006	Echocardiogram				27 March 2006 - Normal left ventricular size and systolic function. No haemodynamically significant valvular dysfunction.
16/05/2006	Neutrophils		17/04/2006	13.1	
16/05/2006	White blood cells		17/04/2006	16.5	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218392 **Seq:** 1

Gender: M

Reported: 16/05/2006

Weight: 0.00

Hospitalisation:

Age: 57

Onset Date: 06/04/2006

DOB: 08/12/1948

Outcome: Death, maybe drug 20/04/2006

Causality: Causality possible

Reaction Details:

Medicine Details:

OMEPRAZOLE (Other drug)	Reason:
40.0 Milligram	Oral
Batch:	Started: Stopped:
COLOXYL (Other drug)	Reason: Constipation
Tablet 2.0 Dose Unspecified Daily	Oral
Batch:	Started: Stopped:
CLOPINE (Suspected)	Reason:
Tablet 150.0 Milligram Daily	Oral
Batch:	Started: 29/03/2006 Stopped: 17/04/2006 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218416 **Seq:** 1 **Gender:** M
Reported: 16/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 22
Onset Date: **DOB:** 05/04/1984
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia		A recent ECG showed an errhythmia.	Clozaril withheld.

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	Oral
Batch:	Started: 20/08/2005 Stopped: 01/06/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218417

Seq: 1

Gender: F

Reported: 16/05/2006

Weight: 0.00

Hospitalisation:

Onset Date: 02/05/2006

Age: 26

Outcome: Unknown

DOB: 17/11/1979

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient developed fluctuating Clozapine plasma levels with a maximum of 1040ng/ml.	
Drug level increased			

Medicine Details:

RISPERDAL (Other drug)	Reason:	
Batch:	Started:	Stopped:
SEROQUEL (Other drug)	Reason:	
Batch:	Started:	Stopped:
LAMOTRIGINE (Other drug)	Reason:	
Batch:	Started:	Stopped:
CIPRAMIL (Other drug)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/05/2006	Serum drug level				Plasma clozapine: 1040 ng/mL

Additional Information:

History of alcohol abuse, event possibly secondary to alcohol intoxication



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218417

Seq: 1

Gender: F

Reported: 16/05/2006

Weight: 0.00

Hospitalisation:

Age: 26

Onset Date: 02/05/2006

DOB: 17/11/1979

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Unspecified schizophrenia

Tablet

850.0 Milligram

Daily

Oral

Batch:

Started: 12/11/2002

Stopped:

Laboratory Investigations:

Additional Information:

History of alcohol abuse, event possibly secondary to alcohol intoxication



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218460	Seq: 1	Gender: M
Reported: 18/05/2006		Weight: 0.00
Hospitalisation:		Age: 31
Onset Date: 27/04/2006		DOB: 12/11/1974
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myopathy	Life threatening	Patient commenced having joint aches 27/4. This gradually worsened. It was associated with sweats, tachycardia, fever and a neutrophillia. This was reveiewed by 3 medical officers with the thought it could be a reaction to clozapine however, it was diagnosed as a viral illness. His ECG showed a sinus tachycardia. His CK and troponin were normal. As he did not improve, the clozapine was ceased 29/4. On 1/5, he woke up in the early hours of the morning with retrosternal crushing chest pain, pleuritic in nature. He was transferred ...	Clozapine induced Myocarditis

Medicine Details:

CLOZAPINE (Suspected)	Reason:
200.0 Milligram	Daily
Oral	
Batch:	Started: 29/04/2006 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218460 **Seq:** 1 **Gender:** M
Reported: 18/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 31
Onset Date: 27/04/2006 **DOB:** 12/11/1974
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arthralgia	Life threatening	... to JHH where he was managed in CCU on telemetry for the next two days. His troponin reached 4.12. An angiogram showed patent coronary arteries and echocardiography showed preserved ventricular function. Unfortunately a biopsy was not performed. Since his discharge from JHH, he had no further ill effects and his follow up troponin was normal. He is to be reviewed by the cardiologist in the next few days.	

Medicine Details:

CLOZAPINE (Suspected)	Reason:
200.0 Milligram	Daily
Oral	
Batch:	Started:
	Stopped: 29/04/2006 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218460
Reported: 18/05/2006
Hospitalisation:
Onset Date: 27/04/2006
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 31
DOB: 12/11/1974
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Life threatening		
Hyperhidrosis	Life threatening		
Neutrophilia	Life threatening		
Pyrexia	Life threatening		
Tachycardia	Life threatening		
Troponin increased	Life threatening		

Medicine Details:

CLOZAPINE (Suspected)	Reason:
200.0 Milligram	Daily
Oral	
Batch:	Started:
	Stopped: 29/04/2006 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218469 **Seq:** 1 **Gender:** M
Reported: 18/05/2006 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 28
Onset Date: **DOB:** 06/10/1977
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal impairment		Patient developed deterioration in renal function- chronic tubulointerstitial nephritis (biopsy).	
Renal failure			
Tubulointerstitial nephritis			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Family history of systemic lupus erythematosus. Nil relevant past health.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218489

Seq: 1

Gender: M

Reported: 18/05/2006

Weight: 0.00

Hospitalisation:

Age: 35

Onset Date:

DOB: 11/07/1970

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Retinal detachment		The patient has experienced retinal detachment in one eye, and the retina in the second eye is starting to detach. Patient is having preventative laser treatment for the second eye.	

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	600.0 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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218490	Seq: 1	Gender: F
Reported: 18/05/2006		Weight: 0.00
Hospitalisation:		Age: 18
Onset Date:		DOB: 25/03/1988
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypoparathyroidism		Patient experienced hypocalcaemia (severe), hyperphosphataemia, increased CK levels, lethargy, weakness, vomiting, diarrhoea, muscle cramps, blepharospasm and hypotension.	Calcium replacement.
Asthenia			
Blepharospasm			
Blood creatine phosphokinase incr			
Diarrhoea			
Hyperphosphataemia			
Hypocalcaemia			
Hypotension			

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason: Other&unspecified epilepsy	
1.0 Gram	Oral		
Batch:	Started:	Stopped:	
CLOPINE (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 15/03/2006	Stopped: 20/04/2006 0	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/05/2006	Magnetic Resonance				MRI showed non-specific changes in white matter which "could be due to vasculitis or demyelination".

Additional Information:

The patient's condition may have been pre-existing, but has become more pronounced during treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218490 **Seq:** 1 **Gender:** F
Reported: 18/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 18
Onset Date: **DOB:** 25/03/1988
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting			

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason: Other&unspecified epilepsy		
1.0 Gram	Oral		
Batch:	Started:	Stopped:	
CLOPINE (Suspected)	Reason:		
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 15/03/2006	Stopped: 20/04/2006	0

Laboratory Investigations:

Additional Information:

The patient's condition may have been pre-existing, but has become more pronounced during treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218503
Reported: 19/05/2006

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 02/05/2006
Outcome: Recovered

Age: 14
DOB: 17/12/1991
Causality: Causality possible

Reaction Details:

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

Medicine Details:

CABERGOLINE (Other drug)	Reason:
Batch:	Started: Stopped:
TRIFLUOPERAZINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
Aripiprazole (Other drug)	Reason: Unspecified psychosis
Batch:	Started: Stopped:
SEROQUEL (Other drug)	Reason: Unspecified psychosis
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 218502 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218503
Reported: 19/05/2006

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 02/05/2006
Outcome: Recovered

Age: 14
DOB: 17/12/1991
Causality: Causality possible

Reaction Details:

Medicine Details:

QUETIAPINE (Other drug)	Reason: Unspecified psychosis		
Batch:	Started:	Stopped:	
FLUTICASONE PROPIONATE (Other drug)	Reason: Asthma		
Batch:	Started:	Stopped:	
CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 01/05/2006	Stopped: 04/05/2006	

Laboratory Investigations:

Additional Information:

Report 218502 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218504 **Seq:** 1 **Gender:** M
Reported: 19/05/2006 **Weight:** 65.00
Hospitalisation: **Age:** 34
Onset Date: 10/08/2004 **DOB:** 17/11/1969
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejection fraction decreased		Patient experienced a decrease in ejection fraction from 65% to 48%, left ventricular dysfunction and chest pain.	Clozapine ceased.
Chest pain			
Left ventricular dysfunction			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	475.0 Milligram Daily Oral
Batch:	Started: 03/12/2002 Stopped: 20/03/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/05/2006	Echocardiogram				10 Aug 2004: EF - 51%. 4 Oct 2005: EF - 46%. 27 Mar 2006: EF - 57%.,

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218505 **Seq:** 1 **Gender:** F
Reported: 19/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 39
Onset Date: 04/05/2006 **DOB:** 20/10/1966
Outcome: Recovered 05/05/2006 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Patient experienced leucopenia and low neutrophil count.	
Neutropenia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/05/2006	Neutrophils		05/05/2006	2.9	
19/05/2006	Neutrophils		04/05/2006	1.4	
19/05/2006	Neutrophils		02/05/2006	1.7	
19/05/2006	White blood cells		05/05/2006	5.0	
19/05/2006	White blood cells		04/05/2006	2.9	
19/05/2006	White blood cells		02/05/2006	3.4	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218511

Seq: 1

Gender: M

Reported: 19/05/2006

Weight: 0.00

Hospitalisation:

Age: 59

Onset Date: 04/05/2006

DOB: 20/10/1946

Outcome: Unknown

Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	350.0 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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218512

Seq: 1

Gender: F

Reported: 19/05/2006

Weight: 0.00

Hospitalisation:

Age: 28

Onset Date: 30/04/2006

DOB: 07/04/1978

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain		Chest pain and abnormal T waves.	Ceased Clopine then recommenced on 08/05/06 following approval from the cardiologist.
Electrocardiogram abnormal			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218581 **Seq:** 1 **Gender:** F
Reported: 23/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 58
Onset Date: 05/05/2006 **DOB:** 21/02/1948
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased		On 05 May 2006, lab tests revealed an agranulocytosis with a WBC of 3500 and neutrphils of 100.	Clozaril ceased.
Neutrophil count decreased	Caused or prolonged inpatient hospitalisation		Antibiotics
Pneumonia			

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
LITHIUM CARBONATE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason:		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 22/02/2006	Stopped: 07/05/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/05/2006	Neutrophils		05/05/2006	100	
23/05/2006	Neutrophils		07/05/2006	20	
23/05/2006	Neutrophils		10/05/2006	4280	
23/05/2006	White blood cells		05/05/2006	3500	
23/05/2006	White blood cells		07/05/2006	3200	
23/05/2006	White blood cells		10/05/2006	18600	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218657 **Seq:** 1 **Gender:** F
Reported: 24/05/2006 **Weight:** 80.00
Hospitalisation: Required a specialist consultation **Age:** 0
Onset Date: 07/07/1955 **DOB:** 07/07/1955
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Echocardiogram abnormal		mild septal hypertrophy, mildly dilated right ventricle and mildly dilated right atrium,	
Cardiomyopathy			Ceased Clozaril

Medicine Details:

RISPERIDONE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/05/2006	Echocardiogram				On 4 May 2006, an echocardiogram revealed mild septal hypertrophy, mildly dilated right ventricle and mildly dilated right atrium.

Additional Information:

Was previously on higher dose- reaching maximum 500mg a year ago before tapering to lower dose



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218658

Seq: 1

Gender: F

Reported: 24/05/2006

Weight: 0.00

Hospitalisation:

Onset Date: 21/04/2006

Age: 42

Outcome: Unknown

DOB: 14/12/1963

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Patient developed leucopenia and low neutrophil count.	Ceased Clopine
Neutropenia			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	650.0 Milligram Daily Oral
Batch:	Started: 03/01/2003 Stopped: 26/05/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/05/2006	Neutrophils		12/05/2006	1.4	
24/05/2006	Neutrophils		21/04/2006	1.9	
24/05/2006	Neutrophils		21/03/2006	3.2	
24/05/2006	White blood cells		12/05/2006	2.4	
24/05/2006	White blood cells		21/04/2006	3.1	
24/05/2006	White blood cells		21/03/2006	5.0	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218659

Seq: 1

Gender: M

Reported: 24/05/2006

Weight: 0.00

Hospitalisation:

Age: 23

Onset Date:

DOB: 03/07/1982

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Patient Patient experienced increased CK increased and left ventricular ejection fraction decreased.	
Ejection fraction decreased			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218662 **Seq:** 1 **Gender:** M
Reported: 24/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 42
Onset Date: **DOB:** 28/05/1963
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death		Sudden death unexplained.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	800.0 Milligram Daily Oral
Batch:	Started: 15/07/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218680

Seq: 1

Gender: M

Reported: 25/05/2006

Weight: 0.00

Hospitalisation:

Onset Date: 11/01/2006

Age: 34

Outcome: Unknown

DOB: 11/06/1971

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		The symptoms included eosinophilia, neutrophilia, sinus tachycardia and T-wave abnormalities on the electrocardiogram. The patient also experienced anisocytosis, polkilocytosis and rouleaux. The patient remained asymptomatic. The cardiologist indicated that it was unlikely that the T-wave changes reflected myocarditis.	
Anisocytosis			
Electrocardiogram T wave abnorm			
Eosinophilia			
Neutrophilia			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 15/12/2005 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Troponin was normal.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218680

Seq: 1

Gender: M

Reported: 25/05/2006

Weight: 0.00

Hospitalisation:

Onset Date: 11/01/2006

Age: 34

Outcome: Unknown

DOB: 11/06/1971

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Poikilocytosis			
Sinus tachycardia			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 15/12/2005 Stopped:

Laboratory Investigations:

Additional Information:

Troponin was normal.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218704

Seq: 1

Gender: M

Reported: 26/05/2006

Weight: 0.00

Hospitalisation:

Onset Date: 05/05/2006

Age: 64

Outcome: Unknown

DOB: 04/04/1942

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac murmur Endocarditis Urinary retention		Patient experienced pansystolic murmur, urinary retention, infective endocarditis.	Ceased Clopine

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	75.0 Milligram Daily Oral
Batch:	Started: 01/05/2006 Stopped: 08/05/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

White blood cell and neutrophil counts were elevated on 01 May 2006. Patient reportedly was already very unwell with MRSA sepsis originating from necrotic/infected diabetic foot ulcer. Patient was noted to have murmur on 8 May 2006. Clozapine was ceased as a precautionary measure. Murmur is believed to be secondary infective endocarditis. The symptoms were moderate in severity.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218711 **Seq:** 1 **Gender:** M
Reported: 26/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 50
Onset Date: 19/04/2006 **DOB:** 04/05/1955
Outcome: Death, maybe drug 19/04/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death	Death	Sudden death unexplained, patient died whilst on Clopine.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 11/08/2004 Stopped: 19/04/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218761

Seq: 1

Gender: M

Reported: 29/05/2006

Weight: 0.00

Hospitalisation:

Age: 48

Onset Date: 09/05/2006

DOB: 17/01/1958

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Patient experienced cardiomyopathy	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 06/05/2004 Stopped: 23/04/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient has a previously experienced adverse events while on Clopine. This involved shortness of breath, confusion, constipation and stomach pain.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218766	Seq: 1	Gender: F
Reported: 29/05/2006		Weight: 0.00
Hospitalisation:		Age: 84
Onset Date: 15/11/2005		DOB: 21/09/1921
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Cardiac failure congestive Cardiomegaly Dyspnoea Echocardiogram abnormal Ejection fraction decreased Hypotension		Patient experienced cardiomyopathy, left pleural effusion, shortness of breath, congestive cardiac failure, echocardiogram abnormal, severe left ventricular hypertrophy, hypotension, ejection fraction reduced.	Reduced Clozapine then stopped. Frusemide, Slow K, Ramipril and Risperidone.

Medicine Details:

SPIRIVA (Other drug)	Reason:
18.0 Microgram	
Batch:	Started: Stopped:
CELESTONE (Other drug)	Reason:
Batch:	Started: Stopped:
OXAZEPAM (Other drug)	Reason:
7.5 Milligram	
Batch:	Started: Stopped:
ASPIRIN (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/05/2006	Chest X-ray				20/10/05: Cardiomegaly and left pleural effusion. Has had several echocardiograms. 16/2/2001: (Pre-commencement of Clozapine) - mild LV hypertrophy and normal systolic function. 15/05/2002: (follow-up echo after started on Clozapine) - normal LV size and suystolic function and mild LV hypertrophy. 16/10/2005: Mild LVH, severe LV systolic dysfunction, dilated LA and pleural effusion.
29/05/2006	Echocardiogram				

Additional Information:

Clozapine changed, has been on for 5 years.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218766

Seq: 1

Gender: F

Reported: 29/05/2006

Weight: 0.00

Hospitalisation:

Onset Date: 15/11/2005

Age: 84

Outcome: Not yet recovered

DOB: 21/09/1921

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Left ventricular hypertrophy			
Pleural effusion			

Medicine Details:

Seretide 250/50 Accuhaler (Other drug)	Reason:	
Batch:	Started:	Stopped:
LACTULOSE (Other drug)	Reason: Constipation	
Batch:	Started:	Stopped:
COLOXYL WITH SENNA (Other drug)	Reason: Constipation	
Batch:	Started:	Stopped:
ASCORBIC ACID (Other drug)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

Clozapine changed, has been on for 5 years.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218766 **Seq:** 1
Reported: 29/05/2006

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 15/11/2005
Outcome: Not yet recovered

Age: 84
DOB: 21/09/1921
Causality: Causality possible

Reaction Details:

Medicine Details:

ZINC (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	07/11/2005 0

Laboratory Investigations:

Additional Information:

Clozapine changed, has been on for 5 years.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218778	Seq: 1	Gender: M
Reported: 29/05/2006		Weight: 0.00
Hospitalisation:		Age: 38Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain		Patient troubled with chest pain associated with a cough, sputum, febrile with a temperature of 37.7 degrees celsius. Troponin I increased, platelets decreased and blood eosinophils increased.	Clozapine ceased.
Cough			
Eosinophil count increased			
Platelet count decreased			
Productive cough			
Pyrexia			
Troponin I increased			

Medicine Details:

CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/05/2006	Eosinophils	(<0.4)			Eosinophils: 0.50x10 ⁹ /L
29/05/2006	Other data				After 24 hours of ceasing Clozapine treatment Troponin-1 reduced to 0.5ug/L, eosinophil count increased to 0.7x10 ⁹ /L and platelets were within normal reference range at 208x10 ⁹ /L. Four days after ceasing Clozapine treatment troponin-1 reduced to <0.3ug/L and the eosinophil count rose to 1.4x10 ⁹ /L. After 10 days of ceasing treatment, troponin-1 remained at <0.3 and eosinophil count reduced to 0.5x10 ⁹ /L

Additional Information:

History: 11 year history of DSM-IV diagnosis of paranoid schizophrenia. Prasad S, Bell Dr. Myocarditis and cardiomyopathy linked with Clozapine treatment. Ir J Psych Med 2005; 22 (4): 147-150.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218778
Reported: 29/05/2006

Seq: 1

Gender: M
Weight: 0.00
Age: 38Y

Hospitalisation:

Onset Date:
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	225.0 Milligram
	Daily
	Oral
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/05/2006	Platelets	(150-400)			Platelets: $14 \times 10^9/L$
29/05/2006	Troponin	(<0.6)			Increase of Troponin: -1 at 0.6ug/L

Additional Information:

History: 11 year history of DSM-IV diagnosis of paranoid schizophrenia. Prasad S, Bell Dr. Myocarditis and cardiomyopathy linked with Clozapine treatment. Ir J Psych Med 2005; 22 (4): 147-150.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218836

Seq: 1

Gender: M

Reported: 01/06/2006

Weight: 0.00

Hospitalisation:

Age: 38

Onset Date:

DOB: 20/12/1967

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism		Pateint experienced a pulmonary embolus whilst on Clopine.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	225.0 Milligram Daily Oral
Batch:	Started: 08/08/2005 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218837
Reported: 01/06/2006
Hospitalisation:
Onset Date: 21/05/2006
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 28
DOB: 07/10/1977
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Life threatening	Patient experienced chest pains, tachycardia and hypotension.	
Electrocardiogram abnormal	Life threatening	non-specific T-wave change and right bundle branch block	
C-reactive protein increased	Life threatening		
Hypotension			
Tachycardia			

Medicine Details:

OLANZAPINE (Other drug)	Reason:		
7.5 Milligram	Oral		
Batch:	Started:	Stopped:	
CLOPINE (Suspected)	Reason:		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 28/04/2006	Stopped: 22/05/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218840 **Seq:** 1 **Gender:** F
Reported: 31/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 43Y
Onset Date: 10/01/2006 **DOB:**
Outcome: Recovered 11/01/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oxygen saturation decreased		On 10 Jan 2006 the patient received a dose of Clozapine 400mg. Twenty minutes later, the patient was found in his room semi-conscious, with a decreased oxygen saturation level.	Clozapine and Zuclopenthixol ceased.
Depressed level of consciousness			

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet 400.0 Milligram Daily Oral	
Batch:	Started: 10/01/2006 Stopped:
ZUCLOPENTHIXOL ACETATE (Suspected)	Reason:
Tablet 20.0 Milligram Daily Oral	
Batch:	Started: 10/01/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218897 **Seq:** 1 **Gender:** M
Reported: 05/06/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 58
Onset Date: **DOB:** 22/04/1948
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain	Caused or prolonged inpatient hospitalisation	Patient experienced abdominal pain.	Clozaril ceased on 21/04/06.

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 11/12/2001 L TERM Stopped: 21/04/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218903 **Seq:** 1 **Gender:** M
Reported: 05/06/2006 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: 15/05/2006 **DOB:** 01/03/1971
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myalgia		Patient developed back pain, abdominal pain and finally pleuric chest pain. On the evening of the 18/05/06 patient had an 8 minute episode of central chest pain with associated shortness of breath.	Clopine discontinued.
Chest pain			
Dyspnoea			

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 05/05/2006 Stopped: 19/05/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Schizophrenia and THC use.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 218977

Seq: 1

Gender: M

Reported: 06/06/2006

Weight: 0.00

Hospitalisation:

Age: 26

Onset Date:

DOB: 08/08/1979

Outcome: Unknown

Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 10/05/2006 Stopped: 25/05/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219063	Seq: 1	Gender: M
Reported: 08/06/2006		Weight: 0.00
Hospitalisation:		Age: 44
Onset Date: 30/03/2006		DOB: 25/04/1961
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertensive cardiomyopathy Electrocardiogram P wave biphasic Electrocardiogram QT prolonged Electrocardiogram abnormal Ventricular hypertrophy		Patient experienced hypertensive cardiomyopathy, ventricular hypertrophy, electrocardiogram abnormal, electrocardiogram QT corrected interval prolonged and electrocardiogram P wave biphasic.	

Medicine Details:

QUETIAPINE (Other drug)	Reason:
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	450.0 Milligram Daily Oral
Batch:	Started: 27/03/2006 Stopped: 16/05/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/06/2006	Echocardiogram				30 Mar 2006: Echocardiogram showed concentric left ventricular hypertrophy with normal left ventricular cavity size and systolic function. Right ventricular cavity size was at the upper limit of normal with normal systolic function. As a conclusion, the sonographer stated that the diagnosis was of hypertensive cardiomyopathy.

Additional Information:

No previous history or family history of heart disease.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219063
Reported: 08/06/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 30/03/2006
Outcome: Unknown

Age: 44
DOB: 25/04/1961
Causality: Causality possible

Reaction Details:

Medicine Details:

QUETIAPINE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 27/03/2006	Stopped: 16/05/2006 0	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/06/2006	Electrocardiograph				ECG on 09 Apr 2006 showed "wide or notched" P waves, T wave flattening or inversion in leads I, aVL and V2 to V3. QTc was borderline prolonged with 465 msec. Heart rate in this ECG was 94/min.

Additional Information:

No previous history or family history of heart disease.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219109

Seq: 1

Gender: M

Reported: 13/06/2006

Weight: 0.00

Hospitalisation:

Age: 19

Onset Date:

DOB: 15/05/1987

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Epilepsy		Patient developed mildly elevated liver function tests and a "recent" onset of epilepsy.	Anticonvulsant.
Liver function test abnormal			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 15/12/2003 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/06/2006	Other data				(Date unspecified) Liver Function Tests: mildly elevated.
13/06/2006	Serum drug level				(Date unspecified) Clozapine level: greater than 100ng/mL.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219181 **Seq:** 1 **Gender:** M
Reported: 15/06/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 35
Onset Date: 10/05/2006 **DOB:** 22/06/1970
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intentional overdose	Caused or prolonged inpatient hospitalisation	Patient attempted suicide by overdosing on approximately 1400mg of Clopine.	Admitted to emergency, Clopine was ceased.
Suicide attempt	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	1.4 Gram Total Oral
Batch:	Started: 10/05/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219187
Reported: 15/06/2006

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 46
DOB: 11/06/1960
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Patient developed an increased body temperature of 37.5 degrees C, a tachycardia of 130-135 bpm, increased blood pressure of 140/90 mmHg, baseline BP was mentioned with 110/70 mmHg.	
Blood pressure increased Body temperature increased			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 22/05/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219298

Seq: 1

Gender: M

Reported: 20/06/2006

Weight: 0.00

Hospitalisation:

Onset Date: 30/05/2006

Age: 37

Outcome: Unknown

DOB: 11/02/1969

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cellulitis Haematocrit decreased Influenza like illness Neutrophil count decreased Pneumonia Red blood cell count decreased Sepsis		Patient experienced cellulitis, fever, decreased red cell count, decreased haematocrit, decreased neutrophil count and leucopenia.	Ceased Clopine

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 18/05/2006 Stopped: 01/06/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/06/2006	Chest X-ray				Small area of consolidation towards the right lung base consistent with early basal pneumonia
20/06/2006	White blood cells		31/05/2006	3.02	

Additional Information:

Report 219975 is the second sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219301	Seq: 1	Gender: M
Reported: 20/06/2006		Weight: 0.00
Hospitalisation:		Age: 52
Onset Date: 15/03/2006		DOB: 29/01/1954
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alanine aminotransferase increase Blood bilirubin increased Hepatic function abnormal White blood cell count increased		Patient experienced ALT increased, Bilirubin total increased, white blood cell count increased.	Clozaril ceased.

Medicine Details:

OLANZAPINE (Other drug)	Reason:
Batch:	Started:
	Stopped: 0
RISPERIDONE (Other drug)	Reason:
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219302

Seq: 1

Gender: M

Reported: 20/06/2006

Weight: 0.00

Hospitalisation:

Age: 19

Onset Date: 02/06/2006

DOB: 16/04/1987

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal		After one and a half weeks of treatment, patient showed an abnormal ECG.	

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 22/05/2006	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219393 **Seq:** 1 **Gender:** M
Reported: 21/06/2006 **Weight:** 0.00
Hospitalisation: **Age:** 51
Onset Date: 11/06/2006 **DOB:** 01/05/1955
Outcome: Death, maybe drug 11/06/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest	Death	Patient died of cardiac complications whilst on Clopine.	
Atrial fibrillation	Death		
Hyperlipidaemia	Death		
Left ventricular failure	Death		

Medicine Details:

GLYCERYL TRINITRATE (Other drug)	Reason:
2.0 Dose Unspecified	
Batch:	Started: 22/06/2005 Stopped:
CHLORPROMAZINE HYDROCHLORIDE (Other drug)	Reason:
100.0 Milligram	Oral
Batch:	Started: 15/06/2005 Stopped:
COVERSYL (Other drug)	Reason:
Batch:	Started: Stopped:
TRANSIDERM-NITRO (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/06/2006	Echocardiogram				23 Jan 2006: Transthoracic echocardiogram; mitral regurgitation, LV dysfunction.

Additional Information:

History: alcohol abuse; smoker; NIDDM; gout; anaemia; intellectual disability (unable to read or write).
Patient had underlying dilated cardiomyopathy which was probably due to alcohol abuse. Patient also had a history of moderate mitral regurgitation (MR), myxomatous mitral and tricuspid valves.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219393 **Seq:** 1

Gender: M

Reported: 21/06/2006

Weight: 0.00

Hospitalisation:

Age: 51

Onset Date: 11/06/2006

DOB: 01/05/1955

Outcome: Death, maybe drug 11/06/2006

Causality: Causality possible

Reaction Details:

Medicine Details:

LARGACTIL (Other drug)	Reason:	
Batch:	Started:	Stopped:
ZOTON (Other drug)	Reason:	
Batch:	Started:	Stopped:
Simvar (Other drug)	Reason:	
Batch:	Started:	Stopped:
Benztrop (Other drug)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

History: alcohol abuse; smoker; NIDDM; gout; anaemia; intellectual disability (unable to read or write).
Patient had underlying dilated cardiomyopathy which was probably due to alcohol abuse. Patient also had a history of moderate mitral regurgitation (MR), myxomatous mitral and tricuspid valves.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219393 **Seq:** 1

Gender: M

Reported: 21/06/2006

Weight: 0.00

Hospitalisation:

Age: 51

Onset Date: 11/06/2006

DOB: 01/05/1955

Outcome: Death, maybe drug 11/06/2006

Causality: Causality possible

Reaction Details:

Medicine Details:

DILATREND (Other drug)	Reason:
Batch:	Started: Stopped:
DIAMICRON (Other drug)	Reason:
Batch:	Started: Stopped:
UREMIDE (Other drug)	Reason:
Batch:	Started: Stopped:
ARTHREXIN (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

History: alcohol abuse; smoker; NIDDM; gout; anaemia; intellectual disability (unable to read or write).
Patient had underlying dilated cardiomyopathy which was probably due to alcohol abuse. Patient also had a history of moderate mitral regurgitation (MR), myxomatous mitral and tricuspid valves.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219393 **Seq:** 1

Gender: M

Reported: 21/06/2006

Weight: 0.00

Hospitalisation:

Age: 51

Onset Date: 11/06/2006

DOB: 01/05/1955

Outcome: Death, maybe drug 11/06/2006

Causality: Causality possible

Reaction Details:

Medicine Details:

SPAN-K (Other drug)	Reason:
Batch:	Started: Stopped:
VALPRO (Other drug)	Reason:
Batch:	Started: Stopped:
SPIRACTIN (Other drug)	Reason:
Batch:	Started: Stopped:
UREX FORTE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

History: alcohol abuse; smoker; NIDDM; gout; anaemia; intellectual disability (unable to read or write). Patient had underlying dilated cardiomyopathy which was probably due to alcohol abuse. Patient also had a history of moderate mitral regurgitation (MR), myxomatous mitral and tricuspid valves.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219393 **Seq:** 1

Gender: M

Reported: 21/06/2006

Weight: 0.00

Hospitalisation:

Age: 51

Onset Date: 11/06/2006

DOB: 01/05/1955

Outcome: Death, maybe drug 11/06/2006

Causality: Causality possible

Reaction Details:

Medicine Details:

MAREVAN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
PERINDOPRIL (Other drug)		Reason:	
	4.0 Milligram	Daily	Oral
Batch:	Started: 13/07/2005	Stopped:	0
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 27/11/2002	Stopped: 11/06/2006	0

Laboratory Investigations:

Additional Information:

History: alcohol abuse; smoker; NIDDM; gout; anaemia; intellectual disability (unable to read or write).
Patient had underlying dilated cardiomyopathy which was probably due to alcohol abuse. Patient also had a history of moderate mitral regurgitation (MR), myxomatous mitral and tricuspid valves.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219504

Seq: 1

Gender: M

Reported: 26/06/2006

Weight: 0.00

Hospitalisation:

Onset Date: 08/11/2005

Age: 19

DOB: 01/08/1986

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Assymptomatic rise in CK secondary to Clozapine.	Patient given IV fluids and Hydralite for rehydration.

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	275.0 Milligram	Daily	Oral
Batch:	Started: 24/10/2005	Stopped: 08/11/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/06/2006	Creatine		08/11/2005	1042	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219552 **Seq:** 1 **Gender:** M
Reported: 28/06/2006 **Weight:** 0.00
Hospitalisation: **Age:** 30
Onset Date: **DOB:** 10/09/1975
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Suspected cardiomyopathy.	Clozaril discontinued.

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	Oral
Batch:	Started: 20/10/2004 Stopped: 02/06/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219555	Seq: 1	Gender: F
Reported: 28/06/2006		Weight: 85.00
Hospitalisation:		Age: 34
Onset Date: 26/05/2006		DOB: 17/03/1972
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Patient developed leucopenia and low neutropenia count.	Clopine discontinued.
Neutropenia			

Medicine Details:

INTERFERON ALFA-2A (Suspected)	Reason: Other diseases of liver
Injection	135.0 Microgram Weekly Intramuscular
Batch:	Started: Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 16/12/2004 L TERM Stopped: 26/05/2006
RIBAVIRIN (Suspected)	Reason: Other diseases of liver
	1.0 Gram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/06/2006	Neutrophils		26/05/2006	1.10	
28/06/2006	Neutrophils		28/05/2006	1.40	
28/06/2006	Neutrophils		13/06/2006	1.00	
28/06/2006	Neutrophils		06/06/2006	4.40	
28/06/2006	Neutrophils		23/06/2006	0.80	
28/06/2006	Neutrophils		04/07/2006	2.20	
28/06/2006	Neutrophils		18/07/2006	0.90	

Additional Information:

History: Resistant schizophrenia, allergy to Penicillin, history of abusing marijuana use. Currently abstinent, history of abusing nicotine. Currently abstinent. Further drop in WBCs on 13 June.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219555 **Seq:** 1 **Gender:** F
Reported: 28/06/2006 **Weight:** 85.00
Hospitalisation: **Age:** 34
Onset Date: 26/05/2006 **DOB:** 17/03/1972
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

INTERFERON ALFA-2A (Suspected)	Reason: Other diseases of liver
Injection 135.0 Microgram Weekly Intramuscular	
Batch: Started: Stopped:	
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 600.0 Milligram Daily Oral	
Batch: Started: 16/12/2004 L TERM Stopped: 26/05/2006	
RIBAVIRIN (Suspected)	Reason: Other diseases of liver
1.0 Gram Daily Oral	
Batch: Started: Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/06/2006	Neutrophils		11/07/2006	0.90	
28/06/2006	Neutrophils		27/06/2006	1.20	
28/06/2006	Neutrophils		19/06/2006	1.40	
28/06/2006	White blood cells		26/05/2006	4.10	
28/06/2006	White blood cells		28/05/2006	3.90	
28/06/2006	White blood cells		06/06/2006	6.40	
28/06/2006	White blood cells		13/06/2006	3.00	

Additional Information:

History: Resistant schizophrenia, allergy to Penicillin, history of abusing marijuana use. Currently abstinent, history of abusing nicotine. Currently abstinent. Further drop in WBCs on 13 June.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219555	Seq: 1	Gender: F
Reported: 28/06/2006		Weight: 85.00
Hospitalisation:		Age: 34
Onset Date: 26/05/2006		DOB: 17/03/1972
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Medicine Details:

INTERFERON ALFA-2A (Suspected)		Reason: Other diseases of liver	
Injection	135.0 Microgram	Weekly	Intramuscular
Batch:	Started:	Stopped:	
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 16/12/2004 L TERM	Stopped: 26/05/2006	
RIBAVIRIN (Suspected)		Reason: Other diseases of liver	
	1.0 Gram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/06/2006	White blood cells		19/06/2006	3.00	
28/06/2006	White blood cells		23/06/2006	2.20	
28/06/2006	White blood cells		27/06/2006	3.30	
28/06/2006	White blood cells		04/07/2006	3.90	
28/06/2006	White blood cells		11/07/2006	2.70	
28/06/2006	White blood cells		18/07/2006	2.70	

Additional Information:

History: Resistant schizophrenia, allergy to Penicillin, history of abusing marijuana use. Currently abstinent, history of abusing nicotine. Currently abstinent. Further drop in WBCs on 13 June.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219602 **Seq:** 1 **Gender:** M
Reported: 03/07/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 59
Onset Date: **DOB:** 27/12/1946
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delirium	Caused or prolonged inpatient hospitalisation	The patient was admitted with an overdose of an unknown quantity of Clozaril and was delirious and confused. The patient may have taken up to 40 x 400mg tablets.	
Confusional state	Caused or prolonged inpatient hospitalisation		
Overdose	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	700.0 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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219682

Seq: 1

Gender: M

Reported: 04/07/2006

Weight: 0.00

Hospitalisation:

Age: 59

Onset Date:

DOB: 26/09/1946

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life threatening	Suspected neuroleptic malignant syndrome.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	800.0 Milligram Daily Oral
Batch:	Started: 30/06/1999 Stopped: 20/05/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219686	Seq: 1	Gender: F
Reported: 04/07/2006		Weight: 0.00
Hospitalisation:		Age: 27
Onset Date:		DOB: 07/10/1978
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Patient developed left ventricular cardiomyopathy, ventricular dysfunction and ejection fraction decreased.	Clozaril discontinued.
Ejection fraction decreased			
Ventricular dysfunction			

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 25/11/2005	Stopped:	12/05/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219688 **Seq:** 1 **Gender:** M
Reported: 04/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 43
Onset Date: 05/06/2006 **DOB:** 07/01/1963
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Patient developed myocarditis and suspected cardiomyopathy.	

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:		
1.5 Gram	Oral		
Batch:	Started:	Stopped:	
OLANZAPINE (Other drug)	Reason:		
15.0 Milligram	Oral		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 11/05/2006	Stopped: 05/06/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/07/2006	Troponin		05/06/2006	0.26	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219731 **Seq:** 1
Reported: 05/07/2006

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 14/11/2001
Outcome: Not yet recovered

Age: 42
DOB: 24/09/1959
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus	Incapacity/disability	Pateint developed diabetes.	Metformin

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet 275.0 Milligram	Daily Oral
Batch:	Started: 19/04/1995 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219736
Reported: 06/07/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 10/06/2006
Outcome: Unknown

Age: 22
DOB: 07/11/1983
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal Tachycardia		ECG changes Patient experienced tachycardia, was showing a heart rate of 130 bpm, it was also noted that he had two febrile episodes.	
Pyrexia			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 06/06/2006 Stopped: 28/06/2006 Continuing.

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219773

Seq: 1

Gender: M

Reported: 06/07/2006

Weight: 0.00

Hospitalisation:

Age: 28

Onset Date:

DOB: 30/01/1978

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced suspected myocarditis and eosinophilia.	
Eosinophilia			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 09/06/2006 Stopped: 26/06/2006 Continuing.

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219844	Seq: 1	Gender: M
Reported: 10/07/2006		Weight: 0.00
Hospitalisation:		Age: 34Y
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dilatation ventricular		Patient had shown a dilated left ventricle with mild to moderate left ventricular systolic dysfunction.	Abilify discontinued
Ventricular dysfunction			

Medicine Details:

Abilify (Suspected)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	650.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Chronic paranoid shizophrenia, anxiety, depression, smoker and overweight.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219900 **Seq:** 1 **Gender:** M
Reported: 11/07/2006 **Weight:** 80.00
Hospitalisation: **Age:** 30
Onset Date: 30/05/2006 **DOB:** 26/09/1975
Outcome: Recovered 30/05/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Right ventricular hypertrophy Neutrophil count increased White blood cell count increased		130 bpm, lasted 6 hours Patient experienced right ventricular hypertrophy and tachycardia. White blood cell and neutrophil counts were frequently elevated throughout the treatment period.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 23/08/2005 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/07/2006	Electrocardiograph				ECG - right ventricular hypertrophy.
11/07/2006	Neutrophils				NC - 15.0.
11/07/2006	Other data				Pulse rate - 120-130bpm.
11/07/2006	White blood cells				WBC - 19.60.

Additional Information:

The patient is asymptomatic. Smoker



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219970	Seq: 1	Gender: M
Reported: 13/07/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 19
Onset Date: 25/04/2006		DOB: 14/07/1986
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myositis	Caused or prolonged inpatient hospitalisation	Patient developed skeletal myositis and CPK increased.	Clozaril discontinued.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DIAZEPAM (Other drug)	Reason:
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	Oral
Batch:	Started: 15/04/2006
	Stopped: 01/05/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/07/2006	Creatine	(20-200)	25/04/2006	>628	Pre-treatment CK 74.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219975
Reported: 13/07/2006

Seq: 1

Gender: M
Weight: 152.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 37
DOB: 11/02/1969
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal		Patient had an ECG which revealed an underlying heart disease.	Ceased Clopine.
Eosinophil count increased			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 13/06/2006 Stopped: 29/06/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/07/2006	Electrocardiograph				ECG shows underlying heart disease.
13/07/2006	Eosinophils	0.00 - 0.05	19/06/2006	1.32	
13/07/2006	Eosinophils	0.00 - 0.05	22/06/2006	1.80	
13/07/2006	Eosinophils	0.00 - 0.05	26/06/2006	1.40	
13/07/2006	Troponin	0.00 - 0.05	19/06/2006	0.12	
13/07/2006	Troponin	0.00 - 0.05	26/06/2006	0.01	

Additional Information:

Report 219298 is the first sequence to this report.
Patient is a heavy smoke (50 per day) and is obese.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 219991 **Seq:** 1 **Gender:** M
Reported: 13/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 34
Onset Date: 12/05/2005 **DOB:** 29/09/1970
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ventricular dysfunction Echocardiogram abnormal		Echocardiogram showed ventricular dysfunction.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 07/02/2000 Stopped: 30/05/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/07/2006	Echocardiogram	28-44%.			12 Nov 2002: Fractional shortening 31%. 4 May 2006: Fractional shortening 24%. 9 May 2006: Left ventricular systolic function reduced - mild global dyskinesia. Pre-treatment level with normal limits.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220011

Seq: 1

Gender: M

Reported: 14/07/2006

Weight: 60.00

Hospitalisation:

Age: 22

Onset Date: 26/06/2006

DOB: 07/11/1983

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Life threatening	Clozapine induced - tachycardia, fever of 39c and myocarditis.	Clozapine discontinued.
Myocarditis	Life threatening		
Pyrexia	Life threatening		

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 10/06/2006	Stopped: 27/06/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/07/2006	Echocardiogram				Second echo conformed myopericarditis.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220017

Seq: 1

Gender: F

Reported: 14/07/2006

Weight: 0.00

Hospitalisation:

Onset Date: 23/06/2006

Age: 26

Outcome: Unknown

DOB: 16/03/1980

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Patient experienced tachycardia between 120-130bpm. Patient's heart rate was still at 100bpm despite bed rest.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 23/06/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220052 **Seq:** 1 **Gender:** F
Reported: 14/07/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 54
Onset Date: 26/06/2006 **DOB:** 09/03/1952
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	The patient had had 3 occurrences of neutropenia and leukopenia.	G-CSF.
Leukopenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 21/02/2006 Stopped: 26/06/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/07/2006	Neutrophils		30/06/2006	0.96	
14/07/2006	Neutrophils		29/06/2006	0.90	
14/07/2006	Neutrophils		26/06/2006	1.60	
14/07/2006	Neutrophils		21/06/2006	2.10	
14/07/2006	Neutrophils		22/06/2006	2.30	
14/07/2006	Neutrophils		26/06/2006	1.30	
14/07/2006	White blood cells		30/06/2006	2.20	

Additional Information:

Not yet recovered but improving



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220052 **Seq:** 1

Gender: F

Reported: 14/07/2006

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 54

Onset Date: 26/06/2006

DOB: 09/03/1952

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 21/02/2006 Stopped: 26/06/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/07/2006	White blood cells		29/06/2006	2.00	
14/07/2006	White blood cells		26/06/2006	3.00	
14/07/2006	White blood cells		26/06/2006	2.40	
14/07/2006	White blood cells		22/06/2006	3.50	
14/07/2006	White blood cells		21/06/2006	3..30	

Additional Information:

Not yet recovered but improving



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220101

Seq: 1

Gender: M

Reported: 17/07/2006

Weight: 0.00

Hospitalisation:

Age: 31

Onset Date: 28/05/2006

DOB: 21/12/1974

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension	Incapacity/disability	Patient experienced orthostatic hypotension.	Clopine ceased. Fludrocortisone was used but was not ineffective.

Medicine Details:

Aripiprazole (Other drug)	Reason: Unspecified schizophrenia		
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 16/03/2006	Stopped: 25/06/2006	
CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 26/05/2006	Stopped: 22/06/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Patient previously on Risperidone and Olanzapine (weight gain). Stevens-Johnson Syndrome after receiving Phenytoin treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220217 **Seq:** 1 **Gender:** F
Reported: 20/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 49
Onset Date: 07/07/2006 **DOB:** 25/07/1956
Outcome: Recovered 25/07/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Patient experienced low white blood cell and neutrophil counts whilst on Clopine treatment.	Clopine ceased.
Neutropenia			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 23/05/2006 Stopped: 07/07/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/07/2006	Neutrophils		07/07/2006	1.30	
20/07/2006	Neutrophils		08/07/2006	1.40	
20/07/2006	Neutrophils		10/07/2006	0.60	
20/07/2006	Other data		07/07/2006	300.0	Dose mg/day
20/07/2006	Other data		08/07/2006	0.0	Dose mg/day
20/07/2006	Other data		10/07/2006	0.0	Dose mg/day
20/07/2006	White blood cells		07/07/2006	2.80	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220217

Seq: 1

Gender: F

Reported: 20/07/2006

Weight: 0.00

Hospitalisation:

Age: 49

Onset Date: 07/07/2006

DOB: 25/07/1956

Outcome: Recovered

25/07/2006

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)

Reason:

Tablet

300.0 Milligram

Daily

Oral

Batch:

Started: 23/05/2006

Stopped: 07/07/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/07/2006	White blood cells		08/07/2006	2.60	
20/07/2006	White blood cells		10/07/2006	2.10	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220222

Seq: 1

Gender: F

Reported: 20/07/2006

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date:

DOB: 01/02/1972

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombosis		Patient experienced partial thrombosis, shortness of breath and tachycardia whilst on Clopine treatment.	
Dyspnoea			
Tachycardia			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 13/04/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220223	Seq: 1	Gender: M
Reported: 20/07/2006		Weight: 0.00
Hospitalisation: Required a specialist consultation		Age: 34
Onset Date:		DOB: 29/05/1972
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram change Hypertension		ECG now reported as normal Patient experienced ECG changes, decreased sodium, creatinine decreased and hypertension whilst on Clopine treatment. Baseling blood pressure was measured at around 120/70. After commencing treatment blood pressure increased to around 170/98 and spiked at 181/108.	Propranolol, clozapine dose reduced
Blood creatinine decreased Blood sodium decreased			

Medicine Details:

CLOPINE (Suspected)		Reason:	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 23/06/2006	Stopped:	Continuing.

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220244 **Seq:** 1 **Gender:** F
Reported: 20/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 57
Onset Date: 16/06/2006 **DOB:** 11/02/1949
Outcome: Death, maybe drug 16/06/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction	Death	Patient died from a heart attack whilst on Clopine.	

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	650.0 Milligram	Daily	Oral
Batch:	Started: 21/01/2002	Stopped:	16/06/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220249

Seq: 1

Gender: M

Reported: 20/07/2006

Weight: 0.00

Hospitalisation:

Age: 56

Onset Date:

DOB: 02/08/1949

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin increased		Patient experienced increased troponin levels.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 29/06/2006 Stopped: 04/07/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220254 **Seq:** 1 **Gender:** M
Reported: 20/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 61
Onset Date: 25/06/2006 **DOB:** 02/02/1945
Outcome: Unrelated death 25/12/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sepsis		Patient experienced sepsis whilst on Clopine	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	325.0 Milligram Daily Oral
Batch:	Started: 05/04/2005 Stopped: 25/06/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/07/2006	Neutrophils		25/06/2006	19.65	
20/07/2006	White blood cells		25/06/2006	28.90	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220276 **Seq:** 1 **Gender:** M
Reported: 21/07/2006 **Weight:** 83.00
Hospitalisation: **Age:** 29
Onset Date: 27/06/2006 **DOB:** 02/02/1977
Outcome: Recovered 05/07/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bundle branch block right		Patient experienced an incomplete right bundle branch block.	

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 23/05/2006 Stopped: Continuing.

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Substantial amount of cannabis and alcohol before the event.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220286	Seq: 1	Gender: M
Reported: 21/07/2006		Weight: 0.00
Hospitalisation:		Age: 28
Onset Date: 06/05/1994		DOB: 28/09/1965
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Patient experienced agranulocytosis, tachycardia and malaise.	Clozaril ceased.
Malaise			
Tachycardia			

Medicine Details:

HALOPERIDOL (Other drug)	Reason:
Batch:	Started: Stopped:
RIVOTRIL (Other drug)	Reason:
Batch:	Started: Stopped:
TEMAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped: Oral
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 25/03/1994 Stopped: 07/05/1994 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/07/2006	Neutrophils		06/05/1994	1.10 x 11^9/L	
21/07/2006	Neutrophils		07/05/1994	0.6 x 10^9/L	
21/07/2006	Neutrophils		08/05/1994	1.5 x 10^9/L	
21/07/2006	White blood cells		06/05/1994	3.82 x 10^9/L	
21/07/2006	White blood cells		07/05/1994	3.7 x 10^9/L	
21/07/2006	White blood cells		08/05/1994	4.9 x 10^9/L	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220341 **Seq:** 1 **Gender:** M
Reported: 25/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 49
Onset Date: 05/07/2006 **DOB:** 21/08/1956
Outcome: Death, maybe drug 05/07/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient suffered an unexplained death while on Clopine treatment.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 08/06/2006 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220343 **Seq:** 1 **Gender:** F
Reported: 25/07/2006 **Weight:** 86.00
Hospitalisation: **Age:** 44
Onset Date: 08/07/2006 **DOB:** 10/08/1961
Outcome: Death, maybe drug 08/07/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction	Death	Patient was found deceased at home after suffering a heart attack whilst on Clopine treatment.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/07/2006	Other data				TTE: Normal LV systolic function (29/03/06). ECG RBBB (29/03/06).

Additional Information:

History: Schizophrenia and cigarette smoker.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220351

Seq: 1

Gender: M

Reported: 25/07/2006

Weight: 0.00

Hospitalisation:

Age: 18

Onset Date: 05/07/2006

DOB: 18/03/1988

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pericarditis		Patient experienced mild pericarditis and troponin increased (0 to 4.4).	Clopine ceased.
Troponin increased			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	150.0 Milligram Daily Oral
Batch:	Started: 17/05/2006 Stopped: 29/05/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220370	Seq: 1	Gender: M
Reported: 25/07/2006		Weight: 0.00
Hospitalisation:		Age: 26
Onset Date: 01/07/2006		DOB: 28/03/1980
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pericardial effusion		Patient was admitted to intensive care with chest pain, pericarditis, raised eosinophils, raised C-reactive protein, echocardiogram abnormal, neutrophilia, leukocytosis.	Ceased Clozaril
Myocarditis		The final diagnosis was myocarditis with the complication of pericardial effusion	
C-reactive protein increased			
Cardiac tamponade			
Chest pain			
Echocardiogram abnormal			
Electrocardiogram abnormal			

Medicine Details:

RISPERIDONE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 09/05/2006 Stopped: 07/07/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220370	Seq: 1	Gender: M
Reported: 25/07/2006		Weight: 0.00
Hospitalisation:		Age: 26
Onset Date: 01/07/2006		DOB: 28/03/1980
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophil count increased			
Leukocytosis			
Neutrophilia			
Pyrexia			
Sinus tachycardia			
Ventricular hypertrophy			

Medicine Details:

RISPERIDONE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 09/05/2006 Stopped: 07/07/2006 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220371	Seq: 1	Gender: M
Reported: 25/07/2006		Weight: 0.00
Hospitalisation:		Age: 28
Onset Date:		DOB: 04/02/1978
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Patient developed dilated cardiomyopathy with an ejection fraction of 35-40% with increased CTR and tachycardia.	Ceased Clozaril.
Echocardiogram abnormal			
Ejection fraction decreased			
Tachycardia			

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started:
Stopped:	
SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started:
Stopped:	
NEXIUM (Other drug)	Reason:
Batch:	Started:
Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 30/07/2003 Stopped: 08/07/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/07/2006	Chest X-ray				08/07/06: Increased CFTR
25/07/2006	Echocardiogram				08/07/06: Dilated cardiomyopathy
25/07/2006	Ejection fraction		08/07/2006	35-40%	35-40%

Additional Information:

Not yet recovered but improving



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220374	Seq: 1	Gender: F
Reported: 25/07/2006		Weight: 0.00
Hospitalisation:		Age: 99u
Onset Date: 15/07/2006		DOB:
Outcome: Recovered	25/07/2006	Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Life threatening	Severe neutopenia following clozapine therapy	Cessation of clozapine and administration of a single dose of filgrastim 300mcg.
Leukopenia	Life threatening		

Medicine Details:

CLOZARIL (Suspected)	Reason:
300.0 Milligram	1 time Oral
Batch:	Started: 15/02/2006 Stopped: 15/07/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/07/2006	Neutrophils		10/02/2006	3.18	
25/07/2006	Neutrophils		14/02/2006	5.21	
25/07/2006	Neutrophils		15/07/2006	0.17	
25/07/2006	Neutrophils		20/07/2006	0.01	
25/07/2006	Neutrophils		19/07/2006	0.01	
25/07/2006	Neutrophils		17/07/2006	0.02	
25/07/2006	White blood cells	4.0-11	10/02/2006	5.8	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220374

Seq: 1

Gender: F

Reported: 25/07/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date: 15/07/2006

DOB:

Outcome: Recovered

25/07/2006

Causality: Causality probable

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason:

300.0 Milligram

1 time

Oral

Batch:

Started: 15/02/2006

Stopped: 15/07/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/07/2006	White blood cells	4.0-11	14/02/2006	7.5	
25/07/2006	White blood cells	4.0-11	15/07/2006	1.2	
25/07/2006	White blood cells	4.0-11	17/07/2006	1.7	
25/07/2006	White blood cells	4.0-11	19/07/2006	1.2	
25/07/2006	White blood cells	4.0-11	20/07/2006	1.7	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220404	Seq: 1	Gender: M
Reported: 28/07/2006		Weight: 0.00
Hospitalisation:		Age: 67
Onset Date: 11/07/2006		DOB: 04/12/1938
Outcome: Recovered	14/07/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia		Patient developed pneumonia, platelets decreased and decreased haemoglobin whilst on Clopine therapy.	
Haemoglobin decreased			
Platelet count decreased			

Medicine Details:

CLOPINE (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 04/07/2006	Stopped:	
AMOXYCILLIN TRIHYDRATE (Suspected)		Reason: Otr respiratory systm diseases	
	1.5 Gram	Daily	Oral
Batch:	Started: 05/07/2006	Stopped: 15/07/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220422	Seq: 1	Gender: M
Reported: 28/07/2006		Weight: 0.00
Hospitalisation:		Age: 27
Onset Date: 29/06/2006		DOB: 13/09/1978
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Respiratory depression	Life threatening	Patient had a reaction and went into a coma had respiratory depression and exacerbation of psychosis.	Clozaril discontinued. Treated with Antibiotics.
Coma	Life threatening		
Psychotic disorder	Life threatening		

Medicine Details:

CLONAZEPAM (Suspected)		Reason:	
Injection	2.0 Milligram	1 time	Intramuscular
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 18/03/1998	Stopped: 29/06/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220445 **Seq:** 1 **Gender:** M
Reported: 31/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 50
Onset Date: 15/07/2006 **DOB:** 24/06/1956
Outcome: Death, maybe drug 15/07/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient died whilst on Clopine.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 03/05/2005 Stopped: 15/07/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220464	Seq: 1	Gender: M
Reported: 31/07/2006		Weight: 96.00
Hospitalisation:		Age: 20
Onset Date: 16/03/2006		DOB: 14/04/1985
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		An echocardiogram revealed borderline left ventricular dilatation with mild global hypokinesis, left ventricular ejection fraction 50%. Patient was a little breathless on exertion and have occasional palpitations, significant weight gain. Patient had a mild cardiomyopathy of unknown aetiology.	
Dyspnoea		Mild exteriorial dyspnoea.	
Dilatation ventricular			
Echocardiogram abnormal			
Ejection fraction decreased			

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 31/08/2005	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
31/07/2006	Electrocardiograph				16 Mar 2006 - Echocardiography: Normal left ventricular dimensions with mild global hypokinesia. No evidence of left ventricular hypertrophy. Normal right ventricle. Normal left atrium. Normal right atrium. Normal (20mm) ascending aorta. Normal aortic valve morphology (velocity 0.8m/sec). Normal mitral valve (E 0.5m/sec, A 0.4m/sec, physiological regurgitation). Normal tricuspid valve. Normal pulmonary valve. Conclusion: Borderline left ventricular dilatation ...

Additional Information:

Specialist recommended continuation of clozapine as ventricular dysfunction was mild and may have been present prior to clozapine commencement. An ACEI was recommended to prevent progressive ventricular remodelling and a beta blocker if necessary.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220464	Seq: 1	Gender: M
Reported: 31/07/2006		Weight: 96.00
Hospitalisation:		Age: 20
Onset Date: 16/03/2006		DOB: 14/04/1985
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Palpitations Ventricular hypokinesia Weight increased			

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 31/08/2005	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
					... with mild global hypoknesis. Ejection fraction 50%. No valvular abnormality. 25 May 2006 - Echocardiography: Normal left ventricular dimensions with mild global hypokinesia. Mildly depressed left systolic function. No evidence of left ventricular hypertrophy. Normal right ventricle. Normal left atrium. Normal right atrium. Normal (30mm) ascending aorta. Normal ...

Additional Information:

Specialist recommended continuation of clozapine as ventricular dysfunction was mild and may have been present prior to clozapine commencement. An ACEI was recommended to prevent progressive ventricular remodelling and a beta blocker if necessary.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220464 **Seq:** 1
Reported: 31/07/2006

Gender: M
Weight: 96.00
Age: 20
DOB: 14/04/1985
Causality: Causality possible

Hospitalisation:

Onset Date: 16/03/2006
Outcome: Not yet recovered

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	250.0 Milligram
	Daily
	Oral
Batch:	Started: 31/08/2005
	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
					... asortic valve morphology (velocity 1.0m/sec, LVOT 0.8 m/sec). Normal mitral valve (E 0.5 m/sec, A 0.6m/sec, physiological regurgitation). Normal tricuspid valve, physiological regurgitation. Normal pulmonary valve. Conclusion: Normal left ventricular dilatation with mildly depressed systolic function - global hypokinesia.

Additional Information:

Specialist recommended continuation of clozapine as ventricular dysfunction was mild and may have been present prior to clozapine commencement. An ACEI was recommended to prevent progressive ventricular remodelling and a beta blocker if necessary.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220473 **Seq:** 1 **Gender:** M
Reported: 31/07/2006 **Weight:** 74.00
Hospitalisation: **Age:** 17
Onset Date: 08/07/2006 **DOB:** 03/01/1989
Outcome: Recovered 17/07/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Encephalopathy Constipation Convulsion Delirium Extrapyramidal disorder Hypotension Myoclonus		Toxic encephalopathy, hypotonia, myoclonic jerks, hypotension, delirium and extrapyramidal symptoms, seizures and severely constipated.	Ceased Clopine

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Tablet 150.0 Milligram Oral	
Batch:	Started: 05/10/2005 Stopped:
DOXYCYCLINE HYDROCHLORIDE (Other drug)	Reason:
Tablet 100.0 Milligram Oral	
Batch:	Started: 29/06/2006 Stopped: 17/07/2006
FISH OIL NOS (Other drug)	Reason:
Batch:	Started: Stopped:
CLOPINE (Suspected)	Reason: Unspecified psychosis
Tablet 800.0 Milligram Daily Oral	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
31/07/2006	Serum drug level				Clozapine levels (normal range 350-900): 07/07/06 - 947 and 07/07/06 - 620. Lithium levels (normal range 0.6-1.2): 07/07/06 - 0.77.

Additional Information:

History: Alcohol and cannabis abuse since 12 years of age.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220473

Seq: 1

Gender: M

Reported: 31/07/2006

Weight: 74.00

Hospitalisation:

Age: 17

Onset Date: 08/07/2006

DOB: 03/01/1989

Outcome: Recovered

17/07/2006

Causality: Causality possible

Reaction Details:

Medicine Details:

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected)

Reason: Unspecified psychosis

20.0 Milligram

Daily

Oral

Batch:

Started:

Stopped:

0

Laboratory Investigations:

Additional Information:

History: Alcohol and cannabis abuse since 12 years of age.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220499 **Seq:** 1 **Gender:** M
Reported: 01/08/2006 **Weight:** 0.00
Hospitalisation: **Age:** 31
Onset Date: 16/07/2006 **DOB:** 29/06/1975
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		CK increased.	Ceased Clopine.

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified psychosis
Tablet	125.0 Milligram Daily Oral
Batch:	Started: 27/10/2004 Stopped: 15/07/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/08/2006	Creatine	<171	16/07/2006	10044	
01/08/2006	Creatine	<171	18/07/2006	3939	
01/08/2006	Creatine	<171	19/07/2006	1638	
01/08/2006	Creatine	<171	21/07/2006	302	
01/08/2006	Creatine	<171	25/07/2006	126	
01/08/2006	Creatine	<171	01/08/2006	262	

Additional Information:

Rechallenged with clozapine on 25/07/06 and CK levels increased --> certain (rechallenge)



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220523	Seq: 1	Gender: F
Reported: 01/08/2006		Weight: 0.00
Hospitalisation:		Age: 25
Onset Date: 03/07/2006		DOB: 20/11/1980
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia C-reactive protein increased Eosinophilia Extrasystoles Hypokinesia Monocyte count increased Pyrexia Rash Red blood cell sedimentation rate i		Arrhythmia, hypokinesia, bigeminy, drug fever, eosinophilia, rash.	Ceased Clozaril 5/7/2006.

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 19/06/2006	Stopped: 05/07/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/08/2006	C-Reactive Protein	<7	05/07/2006	119	
01/08/2006	Echocardiogram				Echo: hypokinesia.
01/08/2006	Electrocardiograph				ECG changes: bigeminy.
01/08/2006	Eosinophils	0.0 - 0.4	04/07/2006	0.4	Pretreatment: 0.4
01/08/2006	Erythrocyte	1 - 19	05/07/2006	75	
01/08/2006	Monocytes	0.2 - 0.8	04/07/2006	1.5	Pretreatment: 0.5

Additional Information:

Recovered from arrhythmia, fever and rash; blood indicators still resolving.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220596	Seq: 1	Gender: F
Reported: 04/08/2006		Weight: 0.00
Hospitalisation:		Age: 26
Onset Date: 23/09/1997		DOB: 05/11/1970
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Liver function test abnormal, respiratory tract infection, jaundice cholestatic.	Ceased Clozaril and Rulide given.
Jaundice cholestatic			
Respiratory tract infection			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)	Reason:		
Batch:	Started:		
Batch:	Stopped:		
FLUPENTHIXOL DECANOATE (Other drug)	Reason:		
Batch:	Started:		
Batch:	Stopped:		
CLONAZEPAM (Other drug)	Reason:		
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started: 11/09/1997	Stopped: 08/10/1997	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/08/2006	GGT = SGGT =		08/10/1997	48	
04/08/2006	GGT = SAP = ALP		08/10/1997	309	

Additional Information:

Recovered with clozapine withdrawal, fever, sore throat, abdominal tenderness, sweats and rash on re-challenge



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220612	Seq: 1	Gender: M
Reported: 07/08/2006		Weight: 0.00
Hospitalisation:		Age: 53
Onset Date: 14/07/2006		DOB: 26/08/1952
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Querying neuromuscular malignant syndrome, neuroleptic malignant syndrome, blood creatine phosphokinase increased, platelet count decreased, eosinophil count increased.	
Blood creatine phosphokinase incr			
Eosinophil count increased			
Neuroleptic malignant syndrome			
Platelet count decreased			

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 29/06/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/08/2006	Creatine		14/07/2006	588	
07/08/2006	Creatine		17/07/2006	203	
07/08/2006	Eosinophils		14/07/2006	0.2	
07/08/2006	Eosinophils		17/07/2006	0.6	
07/08/2006	Platelets		14/07/2006	115	
07/08/2006	Platelets		17/07/2006	223	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220644	Seq: 1	Gender: M
Reported: 08/08/2006		Weight: 0.00
Hospitalisation:		Age: 40
Onset Date: 22/07/2006		DOB: 25/05/1966
Outcome: Death, maybe drug	22/07/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gastroenteritis	Death	Initially thought to be a major bowel obstruction but later found to be gastroenteritis.	
Convulsion	Death	Observed to have a number of seizures	
Vomiting	Death	Vomiting from his mouth and nose	
Aspiration	Death		
Cardio-respiratory arrest	Death		
Respiratory tract infection viral	Death		

Medicine Details:

CLOZAPINE (Other drug)		Reason:	
Batch:	Started: 02/02/1996	Stopped: 21/06/2004	
CLOPINE (Suspected)		Reason:	
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 22/06/2004	Stopped: 22/07/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/08/2006	Autopsy report				Cause of death cardio-respiratory arrest and acute aspiration as a direct cause with vomiting, gastroenteritis and a recent respiratory viral infection as antecedent causes.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220659

Seq: 1

Gender: M

Reported: 08/08/2006

Weight: 0.00

Hospitalisation:

Age: 19

Onset Date: 23/07/2006

DOB: 23/10/1986

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myoclonus		Uncontrolled twitching, later described as myoclonic jerks and urinary incontinence.	Clopine dose to be reduced to 200mg.

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 03/07/2006	Stopped:	Continuing.

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220666 **Seq:** 1 **Gender:** M
Reported: 08/08/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 22
Onset Date: 16/09/2002 **DOB:** 17/07/1980
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Suspected myocarditis.	Clozaril discontinued and the patient was monitored and given supportive care.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 04/09/2002 Stopped: 24/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220684 **Seq:** 1 **Gender:** M
Reported: 09/08/2006 **Weight:** 0.00
Hospitalisation: **Age:** 41
Onset Date: 11/05/2006 **DOB:** 16/01/1965
Outcome: Death, maybe drug 11/05/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Unexplained Death	

Medicine Details:

CLOPINE (Suspected)	Reason:
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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220704	Seq: 1	Gender: M
Reported: 09/08/2006		Weight: 113.00
Hospitalisation:		Age: 26
Onset Date: 19/07/2006		DOB: 25/07/1979
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Life threatening	Probable cardiomyopathy.	
Ejection fraction decreased	Life threatening		

Medicine Details:

RISPERIDONE (Other drug)	Reason:
Batch:	Started: Stopped:
COGENTIN (Other drug)	Reason:
Batch:	Started: Stopped:
EPILIM (Other drug)	Reason:
Batch:	Started: Stopped:
RABEPRAZOLE SODIUM (Other drug)	Reason: Other diseases of esophagus
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/08/2006	Ejection fraction				19/05/06: LVEF - 50%. 14/06/06: LVEF - 45-50%. 19/07/06: LVEF - 30-35%.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220704 **Seq:** 1

Gender: M

Reported: 09/08/2006

Weight: 113.00

Hospitalisation:

Age: 26

Onset Date: 19/07/2006

DOB: 25/07/1979

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Other drug)	Reason: Otr spec symp psychopathol nec		
Batch:	Started:	Stopped:	
CLOZAPINE (Suspected)	Reason:		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 05/05/2006	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220746	Seq: 1	Gender: F
Reported: 11/08/2006		Weight: 0.00
Hospitalisation:		Age: 46
Onset Date: 17/07/2006		DOB: 11/06/1960
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Patient developed shingles, agranulocytosis and tooth abscess.	Treated with amoxicillin and metronidazole for one week. Both medications ceased. Clozaril ceased.
Herpes zoster			
Tooth abscess			

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 22/05/2006	Stopped:	17/07/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/08/2006	Neutrophils		17/07/2006	1.40x10 ⁹ /L	
11/08/2006	Neutrophils		18/07/2006	1.50x10 ⁹ /L	
11/08/2006	Neutrophils		19/07/2006	1.40x10 ⁹ /L	
11/08/2006	Neutrophils		20/07/2006	1.10x10 ⁹ /L	
11/08/2006	Neutrophils		24/07/2006	0.40x10 ⁹ /L	
11/08/2006	White blood cells		17/07/2006	2.50	x10 ⁹ /L
11/08/2006	White blood cells		18/07/2006	2.80	x10 ⁹ /L

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220746

Seq: 1

Gender: F

Reported: 11/08/2006

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date: 17/07/2006

DOB: 11/06/1960

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason:

Tablet

12.5 Milligram

Daily

Oral

Batch:

Started: 22/05/2006

Stopped: 17/07/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/08/2006	White blood cells		19/07/2006	2.50	x10 ⁹ /L
11/08/2006	White blood cells		20/07/2006	2.50	x10 ⁹ /L
11/08/2006	White blood cells		24/07/2006	1.00	x10 ⁹ /L
11/08/2006	White blood cells		26/07/2006	2.30	x10 ⁹ /L
11/08/2006	White blood cells		27/07/2006	3.10	x10 ⁹ /L
11/08/2006	White blood cells		01/08/2006	5.60	x10 ⁹ /L

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220827	Seq: 1	Gender: F
Reported: 16/08/2006		Weight: 0.00
Hospitalisation:		Age: 27
Onset Date: 19/06/2006		DOB: 27/03/1979
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin increased	Caused or prolonged inpatient hospitalisation	0.41	
Blood creatinine increased	Caused or prolonged inpatient hospitalisation	CK 269	
Blood glucose increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Other drug)		Reason:	
Tablet	30.0 Milligram		Oral
Batch:	Started:	Stopped:	0
MIXTARD 30/70 (Other drug)		Reason: Diabetes mellitus	
Injection	60.0 Unit	Daily	Subcutaneous
Batch:	Started:	Stopped:	0
CLOZARIL (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 31/05/2006	Stopped:	0
CLOZARIL (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 12/06/2006	Stopped:	19/06/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/08/2006	Creatine kinase			269	
16/08/2006	Troponin			0.41	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220827	Seq: 1	Gender: F
Reported: 16/08/2006		Weight: 0.00
Hospitalisation:		Age: 27
Onset Date: 19/06/2006		DOB: 27/03/1979
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation		
Myocarditis	Caused or prolonged inpatient hospitalisation		Ceased Clozaril. Start risperidone
Wheezing	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Other drug)		Reason:	
Tablet	30.0 Milligram		Oral
Batch:	Started:	Stopped:	0
MIXTARD 30/70 (Other drug)		Reason: Diabetes mellitus	
Injection	60.0 Unit	Daily	Subcutaneous
Batch:	Started:	Stopped:	0
CLOZARIL (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 31/05/2006	Stopped:	0
CLOZARIL (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 12/06/2006	Stopped:	19/06/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220828 **Seq:** 1 **Gender:** M
Reported: 16/08/2006 **Weight:** 178.00
Hospitalisation: **Age:** 33
Onset Date: 28/07/2006 **DOB:** 04/02/1973
Outcome: Death, maybe drug 28/07/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Death unexplained.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 01/05/2002 Stopped: 28/07/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/08/2006	Neutrophils		17/07/2006	7.3	(X10 ⁹ L) 400mg/Day
16/08/2006	Neutrophils		19/07/2006	13.4	(X10 ⁹ L) 400mg/Day
16/08/2006	White blood cells		17/07/2006	11.3	(X10 ⁹ L) 400mg/day
16/08/2006	White blood cells		19/07/2006	16.7	(X10 ⁹ L) 400mg/day

Additional Information:

Morbidly obese (178 kg), history of diabetes and schizophrenia, CPAP machine near bed suggestive of sleep apnoea, cannabis noted at the scene and syringes suggestive of heroin use.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220866

Seq: 1

Gender: M

Reported: 17/08/2006

Weight: 0.00

Hospitalisation:

Age: 45

Onset Date:

DOB: 12/07/1961

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Left ventricular dysfunction		Left ventricular dysfunction.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	287.5 Milligram Daily Oral
Batch:	Started: 18/07/2006 Stopped: 01/08/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

A report received via Clopine Connect on 1/8/2006 describes a 45 year old male patient (DB/1761F) who developed left ventricular dysfunction while on Clopine (clozapine) treatment.

The patient had not received clozapine treatment previously. The patient commenced Clopine on 18/7/2006 for an unknown indication. He ceased Clopine treatment on 1/8/2006 due to the event. Dose at time of ceasing was 287.5mg PO daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 220980	Seq: 1	Gender: M
Reported: 23/08/2006		Weight: 0.00
Hospitalisation:		Age: 26
Onset Date: 14/06/2006		DOB: 25/06/1979
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Decrease in ejection fraction and cardiomyopathy.	Clopine ceased. Tritace 1.25mg PO daily and carvedilol 3.125mg PO bd.
Ejection fraction decreased			

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
Tablet	1.5 Gram		Oral
Batch:	Started:	Stopped:	
RABEPRAZOLE SODIUM (Other drug)		Reason: Other diseases of esophagus	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
BENZTROPINE MESYLATE (Other drug)		Reason:	
	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0
CLOPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 05/05/2006	Stopped: 27/07/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/08/2006	Echocardiogram	(>50%)	19/05/2006	LVEF 50%	
23/08/2006	Echocardiogram	(>50%)	14/06/2006	LVEF 45-50%	
23/08/2006	Echocardiogram	(>50%)	19/07/2006	LVEF 30-35%	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221035	Seq: 1	Gender: M
Reported: 25/08/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 47Y
Onset Date: 22/05/2006		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation	Patient experienced chest pain, troponin increased and echocardiogram abnormal (St depression/T wave incersion).	CCU admission.
Electrocardiogram abnormal	Caused or prolonged inpatient hospitalisation		
Myocarditis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 15/04/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/08/2006	Coronary				Angio (30/5):moderate diffuse 50% stenosis mid LAD.
25/08/2006	Echocardiogram				Normal LV systolicm fn

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221035 **Seq:** 1 **Gender:** M
Reported: 25/08/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 47Y
Onset Date: 22/05/2006 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 15/04/2006 Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221181	Seq: 1	Gender: M
Reported: 29/08/2006		Weight: 0.00
Hospitalisation:		Age: 42
Onset Date: 27/07/2006		DOB: 23/05/1964
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin I increased	Caused or prolonged inpatient hospitalisation	2 day history of chest pain, febrile and hypertension and increased Troponin levels.	Perindopril, erbumin and biosprolol. Clozaril discontinued on 27 July 2006.
Chest pain	Caused or prolonged inpatient hospitalisation		
Hypertension	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Other drug)		Reason:	
Injection	400.0 Milligram		
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Other drug)		Reason:	
	2.4 Gram		
Batch:	Started:	Stopped:	
ATORVASTATIN (Other drug)		Reason:	
	2.0 Gram		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 13/07/2006	Stopped: 27/07/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/08/2006	Troponin	<0.4ug/L	12/07/2006	ND	
29/08/2006	Troponin	<0.4ug/L	27/07/2006	5.1	
29/08/2006	Troponin	<0.4ug/L	27/07/2006	7.2	
29/08/2006	Troponin	<0.4ug/L	28/07/2006	5.1	
29/08/2006	Troponin	<0.4ug/L	29/07/2006	1.7	

Additional Information:

Not yet recovered but improving



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221181	Seq: 1	Gender: M
Reported: 29/08/2006		Weight: 0.00
Hospitalisation:		
Onset Date: 27/07/2006		Age: 42
Outcome: Not yet recovered		DOB: 23/05/1964
		Causality: Causality possible

Reaction Details:

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

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Other drug)		Reason:
Injection	400.0 Milligram	
Batch:	Started:	Stopped:
SODIUM VALPROATE (Other drug)		Reason:
	2.4 Gram	
Batch:	Started:	Stopped:
ATORVASTATIN (Other drug)		Reason:
	2.0 Gram	
Batch:	Started:	Stopped:
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia
Tablet	250.0 Milligram	Daily Oral
Batch:	Started: 13/07/2006	Stopped: 27/07/2006

Laboratory Investigations:

Additional Information:

Not yet recovered but improving



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221182	Seq: 1	Gender: M
Reported: 29/08/2006		Weight: 70.00
Hospitalisation:		Age: 33
Onset Date:		DOB: 26/11/1972
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Echocardiogram abnormal		Abnormal echo result with increased density within the ductal septum and distal anterior wall, possibly early cardiomyopathy. Also elevated white blood cell and neutrophil counts.	
Leukocytosis			
White blood cell count increased			

Medicine Details:

EPILIM EC 500 (Other drug)	Reason:
500.0 Milligram	
Batch:	Started: Stopped:
HALOPERIDOL (Other drug)	Reason: Unspecified schizophrenia
2.5 Milligram	Daily Oral
Batch:	Started: Stopped:
CLOZAPINE (Suspected)	Reason:
Tablet 600.0 Milligram	Daily Oral
Batch:	Started: 14/03/2000 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/08/2006	White blood cells		18/10/2004	32.80	

Additional Information:

Not yet recovered but improving



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221189	Seq: 1	Gender: M
Reported: 29/08/2006		Weight: 71.00
Hospitalisation:		Age: 52
Onset Date:		DOB: 15/12/1953
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizures and bowel obstruction	
Intestinal obstruction			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)	Reason:
50.0 Milligram	
Batch:	Started:
Batch:	Stopped:
AMISULPRIDE (Other drug)	Reason: Unspecified schizophrenia
800.0 Milligram	Daily Oral
Batch:	Started:
Batch:	Stopped:
PHENYTOIN SODIUM (Other drug)	Reason: Convulsions
360.0 Milligram	Daily Oral
Batch:	Started:
Batch:	Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram
Batch:	Daily Oral
Batch:	Started: 16/03/2006
Batch:	Stopped: 04/08/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Partially recovered, no more seizures. Patient has a history of epilepsy, paraplegia and limited activity of upper limbs and severe constipation.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221191
Reported: 29/08/2006

Seq: 1

Gender: M
Weight: 90.00
Age: 48
DOB: 18/09/1957
Causality: Causality possible

Hospitalisation:

Onset Date:
Outcome: Unknown

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Experienced cardiomyopathy (mild) with breathlessness, pulmonary congestion, fevers and chest discomfort	

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 17/07/2006 Stopped: 03/08/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/08/2006	Echocardiogram				Mild (non-dilated) global left ventricular dysfunction

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221223
Reported: 30/08/2006

Seq: 1

Gender: M
Weight: 160.00

Hospitalisation:

Onset Date: 05/09/2006
Outcome: Unknown

Age: 18
DOB: 01/04/1988
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased Diabetes mellitus Glucose tolerance impaired Hyperglycaemia		Weight gain of 20-30 kilos and impaired glucose tolerance.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 04/07/2006 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/08/2006	Serum glucose	<5.5	05/09/2006	7.2	pretreatment: 5.1

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221241 **Seq:** 1 **Gender:** F
Reported: 31/08/2006 **Weight:** 0.00
Hospitalisation: **Age:** 53
Onset Date: 01/08/2006 **DOB:** 29/12/1952
Outcome: Death 01/08/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Unexplained death.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 23/09/2004 Stopped: 01/08/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221270
Reported: 01/09/2006

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 40
DOB: 17/11/1965
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nephritis interstitial	Caused or prolonged inpatient hospitalisation	Acute interstitial nephritis.	Ceased Clopine

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 01/09/2004 Stopped: 03/08/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking levothyroxine sodium.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221323	Seq: 1	Gender: F
Reported: 04/09/2006		Weight: 0.00
Hospitalisation:		Age: 43
Onset Date: 15/05/2006		DOB: 16/04/1963
Outcome: Recovered		Causality: Causality possible

Reaction Details:

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

Medicine Details:

MULTIVITAMINS (Other drug)	Reason:
1.0 Dose Unspecified	
Batch:	Started: Stopped:
RISPERIDONE (Suspected)	Reason: Unspecified schizophrenia
Tablet 6.0 Milligram Daily Oral	
Batch:	Started: Stopped:
CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 900.0 Milligram Daily Oral	
Batch:	Started: 28/04/2006 Stopped:
CLOMIPRAMINE HYDROCHLORIDE (Suspected)	Reason: Depression
Tablet 150.0 Milligram Daily Oral	
Batch:	Started: Stopped:

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221475	Seq: 1	Gender: M
Reported: 07/09/2006		Weight: 0.00
Hospitalisation:		Age: 21
Onset Date: 06/07/2006		DOB: 24/08/1984
Outcome: Recovered	31/08/2006	Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis Blood creatine phosphokinase incr Drug ineffective Ejection fraction decreased Electrocardiogram ST segment ele Pyrexia Tachycardia		Recommenced on Clozaril on 28 June 2006 and developed mild myocarditis.	Clozaril discontinued.

Medicine Details:

CLOZARIL (Other drug)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 06/10/2004	Stopped: 07/02/2006	0
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
	12.5 Milligram	Daily	Oral
Batch:	Started: 05/07/2006	Stopped: 15/07/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/09/2006	Creatine		21/07/2006	131	
07/09/2006	Creatine		25/07/2006	256	
07/09/2006	Creatine		31/08/2006	192	
07/09/2006	Echocardiogram				Showned LV ejection fraction of 49%
07/09/2006	Electrocardiograph				showed sinus tachycardia and ST elevation

Additional Information:

History of drug abuse, cannabis and caffeine and on multiple drug therapy



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221514	Seq: 1	Gender: M
Reported: 08/09/2006		Weight: 0.00
Hospitalisation:		Age: 48
Onset Date: 07/08/2006		DOB: 25/08/1957
Outcome: Recovered	11/08/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ileus paralytic Abdominal pain Bowel sounds abnormal Constipation Vomiting		The patient became increasingly constipated, had abdominal pain, vomiting and no bowel sounds. Diagnosed with paralytic ileus.	

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Other drug)	Reason:
Batch:	Started:
	Stopped: 0
RANITIDINE (Other drug)	Reason:
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 10/07/2006 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221523 **Seq:** 1 **Gender:** M
Reported: 08/09/2006 **Weight:** 77.00
Hospitalisation: **Age:** 23
Onset Date: 10/08/2006 **DOB:** 31/12/1982
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		An increase in heart rate from 90 bpm to 120-140 bpm	

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	150.0 Milligram Daily Oral
Batch:	Started: 08/08/2006 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221621
Reported: 14/09/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 99u
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		Psychosis following a one-off accidental administration of 125mg of Clozaril instead of risperidone.	
Medication error			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	125.0 Milligram 1 time 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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221639
Reported: 15/09/2006

Seq: 1

Gender: F
Weight: 110.00

Hospitalisation:

Onset Date: 01/07/2005
Outcome: Recovered

Age: 42
DOB: 24/01/1963
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion		Wakes with intermittent swelling of right parotid gland, hypersalivation.	None.
Salivary gland enlargement			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 15/01/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221648

Seq: 1

Gender: F

Reported: 15/09/2006

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date:

DOB: 03/09/1967

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Severe seizures such that no one was able to get near her to give treatment	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	450.0 Milligram Daily Oral
Batch:	Started: 05/06/2006 Stopped: 17/08/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221710	Seq: 1	Gender: F
Reported: 19/09/2006		Weight: 0.00
Hospitalisation:		Age: 39
Onset Date: 28/07/2006		DOB: 10/10/1966
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal	Caused or prolonged inpatient hospitalisation	Patient experienced electrocardiogram abnormal, sedation, suicide attempt, intentional overdose, and T wave inversion.	Clozaril ceased. Recommended on 21/08/06.
Intentional overdose	Caused or prolonged inpatient hospitalisation		
Sedation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Other drug)	Reason:
Batch:	Started: 28/07/2006 Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 04/09/2002 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Alcohol abuse.



Therapeutic Goods Administration Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221710 **Seq:** 1 **Gender:** F
Reported: 19/09/2006 **Weight:** 0.00
Hospitalisation: **Age:** 39
Onset Date: 28/07/2006 **DOB:** 10/10/1966
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Other drug)	Reason:
Batch:	Started: 28/07/2006 Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 04/09/2002 Stopped: 0

Laboratory Investigations:

Additional Information:

Alcohol abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221725	Seq: 1	Gender: M
Reported: 19/09/2006		Weight: 0.00
Hospitalisation:		Age: 23
Onset Date:		DOB: 14/02/1983
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Patient experienced blood creatine phosphokinase increased and aspartate aminotransferase increased.	
Aspartate aminotransferase increa			

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 15/08/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/09/2006	AST = SGOT				AST: 2 times upper limit of normal.
19/09/2006	Creatine				CK increased to 6800u/L, tested on same day CK: 7300 u/L.

Additional Information:

No other signs or symptoms of NMS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221756	Seq: 1	Gender: F
Reported: 20/09/2006		Weight: 140.00
Hospitalisation:		Age: 26
Onset Date: 25/08/2006		DOB: 26/09/1979
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia	Caused or prolonged inpatient hospitalisation	Patient experienced pneumonia (presumed) with respiratory failure, which was though exacerbated by obesity hypoventilation while on Clopine treatment	Ceased Clopine, ventilated and treated with antibiotics
Hypoventilation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	150.0 Milligram Daily Oral
Batch:	Started: 04/05/2006 Stopped: 25/08/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Not yet recovered but improving



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221757	Seq: 1	Gender: M
Reported: 20/09/2006		Weight: 62.00
Hospitalisation:		
Onset Date: 17/08/2006		Age: 48
Outcome: Recovered	02/09/2006	DOB: 06/09/1957
		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Respiratory tract infection		The patient experienced a respiratory infection which was reported to be mild. The patient experienced high fever, nausea, cough and lab blood tests which showed mild neutrophilia and moderate thrombocytosis	Cefuroxime, roxithromycin

Medicine Details:

PIROXICAM (Other drug)	Reason:
20.0 Milligram	Oral
Batch:	Started: Stopped:
CLONAZEPAM (Other drug)	Reason:
3.0 Milligram	Oral
Batch:	Started: Stopped:
CARBAMAZEPINE (Other drug)	Reason: Other&unspecified epilepsy
400.0 Milligram	Daily Oral
Batch:	Started: 20/07/2006 Stopped:
Escitalopram (Other drug)	Reason: Depression
40.0 Milligram	Daily Oral
Batch:	Started: 20/07/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/09/2006	Neutrophils		14/08/2006	10.44 x 10 ⁹ /L	Neutrophil counts were elevated for most of the treatment period
20/09/2006	White blood cells		14/08/2006	14.50 x 10 ⁹ /L	White blood cell counts were elevated for mos tof the treatment period.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221757

Seq: 1

Gender: M

Reported: 20/09/2006

Weight: 62.00

Hospitalisation:

Age: 48

Onset Date: 17/08/2006

DOB: 06/09/1957

Outcome: Recovered

02/09/2006

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram
	Daily
	Oral
Batch:	Started: 07/08/2006
	Stopped: 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221758
Reported: 20/09/2006

Seq: 1

Gender: M
Weight: 88.00
Age: 36
DOB: 14/11/1969
Causality: Causality possible

Hospitalisation:

Onset Date:
Outcome: Unknown

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Increase in blood glucose levels	Ceased Clopine, dose of oral hypoglycaemics increased, insulin given
Hyperglycaemia			

Medicine Details:

RISPERIDONE (Other drug)	Reason: Unspecified schizophrenia
2.0 Milligram	Daily Oral
Batch:	Started: Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	150.0 Milligram Daily Oral
Batch:	Started: 10/06/2006 Stopped: 14/08/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/09/2006	Serum glucose	3.5 - 5.5 mmol/L	20/07/2006	16.6	
20/09/2006	Serum glucose	3.5 - 5.5 mmol/L	01/08/2006	9.6	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221759

Seq: 1

Gender: F

Reported: 20/09/2006

Weight: 0.00

Hospitalisation:

Age: 50

Onset Date:

DOB: 25/03/1956

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonian gait		Parkinsonian shuffling gait and increasing stiffness	Ceased Clopine
Musculoskeletal stiffness			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 08/12/2002 Stopped: 04/07/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221760

Seq: 1

Gender: F

Reported: 20/09/2006

Weight: 0.00

Hospitalisation:

Age: 45

Onset Date:

DOB: 06/12/1960

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Neuroleptic malignant syndrome	Ceased Clopine

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 28/07/2006 Stopped: 18/08/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221778	Seq: 1	Gender: M
Reported: 20/09/2006		Weight: 0.00
Hospitalisation:		Age: 38
Onset Date: 08/08/2006		DOB: 30/01/1968
Outcome: Recovered	16/08/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Life threatening	Patient developed myocarditis, troponin increased, electrocardiogram abnormal, ejection fraction decreased and electrocardiogram T wave abnormal.	Patient treated with Antibiotics and ACE inhibitor. Clozaril discontinued.
Ejection fraction decreased	Life threatening		
Electrocardiogram T wave abnormal	Life threatening		
Electrocardiogram abnormal	Life threatening		
Troponin increased	Life threatening		

Medicine Details:

RISPERIDONE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 22/07/2006 Stopped: 09/08/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/09/2006	Echocardiogram				10/08/2006 Echocardiogram: Dilated right ventricle, moderately hypokinetic, EF 40%, (no pre-treatment echocardiogram was done.
20/09/2006	Electrocardiograph				09/08/2006 ECG: Lateral T and ST wave changes, (pre-treatment:normal)
20/09/2006	Troponin	<0.15ug/L	09/08/2006	0.49	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221821	Seq: 1	Gender: F
Reported: 22/09/2006		Weight: 0.00
Hospitalisation:		
Onset Date: 25/08/2006		Age: 48
Outcome: Recovered	03/10/2006	DOB: 28/02/1958
		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancreatitis	Caused or prolonged inpatient hospitalisation	Patient developed acute pancreatitis.	Admitted to the intensive care unit and intubated.

Medicine Details:

ALCOHOL (Other drug)	Reason:
Batch:	Started:
	Stopped:
SERTRALINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	12.0 Milligram Daily Oral
Batch:	Started: 06/03/1995 Stopped: 25/08/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/09/2006	lipase	<70	25/08/2006	2510	

Additional Information:

History of alcohol abuse



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221884

Seq: 1

Gender: M

Reported: 25/09/2006

Weight: 0.00

Hospitalisation:

Age: 45

Onset Date:

DOB: 18/11/1960

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased		Increasing plasma clozapine levels.	

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 06/07/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/09/2006	Serum drug level		21/12/2005	991/1047	Plasma Clozapine levels/Plasma Norclozapine levels.
25/09/2006	Serum drug level		28/08/2006	2565/1292	Plasma Clozapine levels/Plasma Norclozapine levels.
25/09/2006	Serum drug level		29/08/2006	2632/1198	Plasma Clozapine levels/Plasma Norclozapine levels.
25/09/2006	White blood cells				The Patient's last three white blood cell and neutrophil counts were within normal ranges.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221894	Seq: 1	Gender: F
Reported: 26/09/2006		Weight: 0.00
Hospitalisation:		Age: 21
Onset Date: 29/06/2006		DOB: 01/08/1984
Outcome: Recovered	07/07/2006	Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Possibly - Clozapine induced neutropenia.	

Medicine Details:

BENZTROPINE MESYLATE (Other drug)	Reason:
2.0 Milligram	
Batch:	Started:
	Stopped:
DIAZEPAM (Other drug)	Reason: Otr spec symp psychopathol nec
10.0 Milligram	As necessary
Batch:	Started:
	Stopped:
SODIUM VALPROATE (Other drug)	Reason: Unspecifid affective psychosis
Tablet 1.6 Gram	Daily Oral
Batch:	Started:
	Stopped:
CLOZAPINE (Suspected)	Reason:
Tablet 1.0 Dose Unspecified	Daily Oral
Batch:	Started: 22/06/2006
	Stopped: 29/06/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/09/2006	Neutrophils	(2.00 - 8.00)	29/06/2006	1.62 x 10 ⁹ /L	
26/09/2006	Neutrophils	(2.00 - 8.00)	29/06/2006	1.75 x 10 ⁹ /L	
26/09/2006	Neutrophils	(2.00 - 8.00)	30/06/2006	3.36 x 10 ⁹ /L	
26/09/2006	Neutrophils	(2.00 - 8.00)	01/07/2006	2.31 x 10 ⁹ /L	
26/09/2006	Neutrophils	(2.00 - 8.00)	02/07/2006	2.48 x 10 ⁹ /L	
26/09/2006	Neutrophils	(2.00 - 8.00)	03/07/2006	1.96 x 10 ⁹ /L	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221945 **Seq:** 1 **Gender:** M
Reported: 26/09/2006 **Weight:** 0.00
Hospitalisation: **Age:** 31
Onset Date: 23/08/2006 **DOB:** 18/03/1975
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Cardiomyopathy	Ceased Clopine

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 10/04/2006 Stopped: 24/08/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/09/2006	Echocardiogram				18 July 2006 - echocardiogram showed hypokinesis
26/09/2006	Other data				11 August 2006 Thallium scan - ejection fraction of 41%.

Additional Information:

Current tobacco smoker.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 221985 **Seq:** 1 **Gender:** M
Reported: 27/09/2006 **Weight:** 0.00
Hospitalisation: **Age:** 21
Onset Date: 04/07/2006 **DOB:** 04/08/1984
Outcome: Recovered 27/07/2006 **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gastroenteritis Abdominal pain Diarrhoea Nausea Vomiting Weight decreased		Gastroenteritis, nausea, vomiting, weight loss of 10 kilos, abdominal pain and diarrhoea.	Clozaril discontinued. Conservative measures, fluids and close monitoring.

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason:		
Tablet	Oral		
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Other drug)	Reason:		
Tablet	Oral		
Batch:	Started:	Stopped:	
ZUCLOPENTHIXOL ACETATE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason:		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 03/07/2006	Stopped: 20/07/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug is cert/rechallenge. History: Schizophrenia and intellectual impairment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222022 **Seq:** 1 **Gender:** M
Reported: 28/09/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 24
Onset Date: **DOB:** 25/06/1982
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Seizures.	Overnight observation.

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 31/01/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222023	Seq: 1	Gender: F
Reported: 28/09/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 48
Onset Date: 31/07/2006		DOB: 04/12/1957
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomegaly	Caused or prolonged inpatient hospitalisation	Admitted with atrial flutter and arrhythmia's.	Clozaril discontinued. Warfarin for one month then Aspirin thereafter.
Arrhythmia	Caused or prolonged inpatient hospitalisation		
Atrial flutter	Caused or prolonged inpatient hospitalisation		

Medicine Details:

METOPROLOL TARTRATE (Other drug)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
DIABEX (Other drug)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
AMARYL (Other drug)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
COVERSYL (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/09/2006	Other data				Full blood count: raised eosinophils, gated heart pool scan (GHP): mildly dilated right atrium ventricle but normal contractility, no regional wall abnormality and the left ventricular ejection fraction was 54%. Also increased Troponin of x 2 normal.

Additional Information:

History: Schizophrenia and hypertension.



Therapeutic Goods Administration Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222023 **Seq:** 1 **Gender:** F
Reported: 28/09/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 48
Onset Date: 31/07/2006 **DOB:** 04/12/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 05/07/2006	Stopped: 01/08/2006	

Laboratory Investigations:

Additional Information:

History: Schizophrenia and hypertension.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222046	Seq: 1	Gender: F
Reported: 28/09/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 55
Onset Date: 31/08/2006		DOB: 18/05/1951
Outcome: Death, maybe drug	24/11/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Life threatening	Seizure, delirium, pneumonia aspiration and sedation.	Clozaril discontinued. Treated with aciclovir and Phenytoin.
Delirium	Life threatening		
Pneumonia aspiration	Life threatening		
Sedation	Life threatening		

Medicine Details:

ASPIRIN (Other drug)	Reason:
Batch:	Oral
Started:	Stopped:
PANTOPRAZOLE (Other drug)	Reason:
Batch:	
Started:	Stopped:
ELOCON (Other drug)	Reason:
Batch:	
Started:	Stopped:
TIOTROPIUM (Other drug)	Reason:
Inhalation, powder for	Inhalation
Batch:	
Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical condition: Obstructive airways disorder.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222046 **Seq:** 1 **Gender:** F
Reported: 28/09/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 55
Onset Date: 31/08/2006 **DOB:** 18/05/1951
Outcome: Death, maybe drug 24/11/2006 **Causality:** Causality possible

Reaction Details:

Medicine Details:

Symbicort Turbuhaler (Other drug) Inhalation, powder for Batch: Started: Stopped:	Reason: Inhalation
METAMUCIL (Other drug) Batch: Started: Stopped:	Reason:
SENOKOT (Other drug) Batch: Started: Stopped:	Reason:
CLOZARIL (Suspected) Tablet 600.0 Milligram Daily Oral Batch: Started: 03/07/2001 Stopped: 0	Reason: Unspecified schizophrenia

Laboratory Investigations:

Additional Information:

Medical condition: Obstructive airways disorder.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222088

Seq: 1

Gender: M

Reported: 29/09/2006

Weight: 0.00

Hospitalisation:

Age: 23

Onset Date:

DOB: 12/08/1983

Outcome: Unknown

Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	125.0 Milligram Daily Oral
Batch:	Started: 07/08/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222091

Seq: 1

Gender: F

Reported: 29/09/2006

Weight: 0.00

Hospitalisation:

Onset Date: 15/08/2006

Age: 48

DOB: 24/11/1957

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia Neutrophil count decreased		Leucopenia and neutrophil count low.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 20/12/2004 L TERM Stopped: 16/08/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/09/2006	Neutrophils		16/08/2006	1.2 x 10 ⁹ /L	Dose (mg/day) 300.0
29/09/2006	Neutrophils		18/08/2006	1.2	Dose (mg/day) 300.0
29/09/2006	Neutrophils		22/08/2006	1.0	Dose (mg/day) 300.0
29/09/2006	Neutrophils		28/08/2006	1.8	Dose (mg/day) 300.0
29/09/2006	Neutrophils		26/08/2006	1.4	Dose (mg/day) 300.0
29/09/2006	Neutrophils		24/08/2006	1.0	Dose (mg/day) 300.0
29/09/2006	White blood cells		16/08/2006	2.8	Dose (mg/day) 300.0

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222091 **Seq:** 1
Reported: 29/09/2006

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 15/08/2006
Outcome: Not yet recovered

Age: 48
DOB: 24/11/1957
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 20/12/2004 L TERM Stopped: 16/08/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/09/2006	White blood cells		18/08/2006	2.7 x 10 ⁹ /L	Dose (mg/day) 300.0
29/09/2006	White blood cells		22/08/2006	2.4	Dose (mg/day) 300.0
29/09/2006	White blood cells		24/08/2006	2.6	Dose (mg/day) 300.0
29/09/2006	White blood cells		26/08/2006	3.2	Dose (mg/day) 300.0
29/09/2006	White blood cells		28/08/2006	3.8	Dose (mg/day) 300.0

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222142 **Seq:** 1 **Gender:** F
Reported: 04/10/2006 **Weight:** 0.00
Hospitalisation: **Age:** 29
Onset Date: 29/08/2006 **DOB:** 10/07/1977
Outcome: Death, maybe drug 29/08/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Completed suicide	Death	Died as a result of suicide.	

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 26/07/2004 Stopped: 29/08/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of schizophrenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222148 **Seq:** 1 **Gender:** M
Reported: 04/10/2006 **Weight:** 0.00
Hospitalisation: **Age:** 46
Onset Date: 12/08/2006 **DOB:** 21/01/1960
Outcome: Death 12/08/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Unexplained death.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 10/03/2003 Stopped: 12/08/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Methadone user, substance abuser, smoker, COD unknown



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222150 **Seq:** 1 **Gender:** F
Reported: 04/10/2006 **Weight:** 65.00
Hospitalisation: **Age:** 71
Onset Date: 02/09/2006 **DOB:** 02/09/1935
Outcome: Recovered 07/09/2006 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		60/27	
Sedation		Renal failure, chest infection and sedation.	Clopine ceased.
Renal impairment			

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 15/08/2006 Stopped: 06/09/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222179 **Seq:** 1 **Gender:** M
Reported: 05/10/2006 **Weight:** 0.00
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 13/04/1968
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Tachycardia, tachypnea and shallow breathing.	Clopine ceased.
Hypoventilation			
Tachypnoea			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 24/08/2006 Stopped: 07/09/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222180

Seq: 1

Gender: M

Reported: 05/10/2006

Weight: 0.00

Hospitalisation:

Age: 49

Onset Date:

DOB: 15/07/1957

Outcome: Unknown

Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	550.0 Milligram Daily Oral
Batch:	Started: 03/09/2001 Stopped: 01/08/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222233	Seq: 1	Gender: F
Reported: 06/10/2006		Weight: 0.00
Hospitalisation:		
Onset Date: 31/08/2006		Age: 57
Outcome: Recovered	04/09/2006	DOB: 22/03/1949
		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia and leucopenia.	Clopine temporarily discontinued for 1 day.
Leukopenia			

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
Tablet	400.0 Milligram	Oral	
Batch:	Started: 15/07/2006	Stopped:	
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 25/10/2004	Stopped: 31/08/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/10/2006	Neutrophils		28/08/2006	1.9 x 10 ⁹ /L	
06/10/2006	Neutrophils		31/08/2006	1.2	
06/10/2006	Neutrophils		04/09/2006	2.4	
06/10/2006	Neutrophils		01/09/2006	1.7	
06/10/2006	Other data		28/08/2006	100.0 mg/day	
06/10/2006	Other data		31/08/2006	100.0	
06/10/2006	Other data		04/09/2006	100.0	

Additional Information:

History: Schizophrenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222233

Seq: 1

Gender: F

Reported: 06/10/2006

Weight: 0.00

Hospitalisation:

Onset Date: 31/08/2006

Age: 57

DOB: 22/03/1949

Outcome: Recovered

04/09/2006

Causality: Causality possible

Reaction Details:

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason:		
Tablet	400.0 Milligram	Oral	
Batch:	Started: 15/07/2006	Stopped:	
CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 25/10/2004	Stopped: 31/08/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/10/2006	Other data		01/09/2006	0.0	
06/10/2006	White blood cells		28/08/2006	3.4 x 10 ⁹ /L	
06/10/2006	White blood cells		31/08/2006	2.5	
06/10/2006	White blood cells		01/09/2006	3.4	
06/10/2006	White blood cells		04/09/2006	4.0	

Additional Information:

History: Schizophrenia.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222251 **Seq:** 1 **Gender:** M
Reported: 09/10/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 23
Onset Date: **DOB:** 07/01/1983
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life threatening	Suicide attempt, overdose intentional.	
Intentional overdose	Life threatening		

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 10/05/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Historical drug: Clopine. Patient on generic clozapine previous to starting Clozaril treatment. Patient could have taken up to 80 Clozaril tablets.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222318 **Seq:** 1 **Gender:** M
Reported: 10/10/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 28
Onset Date: **DOB:** 03/08/1978
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder	Caused or prolonged inpatient hospitalisation	Cardiac complications, elevated troponin, increased temperature and flu-like symptoms.	Coronary care unit for 3-4 days observation. Clozaril ceased.
Body temperature increased	Caused or prolonged inpatient hospitalisation		
Influenza like illness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:		
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 16/08/2006	Stopped: 04/09/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/10/2006	Troponin				Troponin rose from 0.3 to 0.9

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222318 **Seq:** 1 **Gender:** M
Reported: 10/10/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 28
Onset Date: **DOB:** 03/08/1978
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 16/08/2006 Stopped: 04/09/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222326

Seq: 1

Gender: M

Reported: 10/10/2006

Weight: 0.00

Hospitalisation:

Age: 27

Onset Date:

DOB: 07/11/1978

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Acutely unwell with no specific symptoms. Suspected Neuroleptic Malignant Syndrome.	Clopine ceased.
Malaise			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	800.0 Milligram Daily Oral
Batch:	Started: 09/04/2003 Stopped: 09/09/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222329

Seq: 1

Gender: M

Reported: 10/10/2006

Weight: 0.00

Hospitalisation:

Age: 33

Onset Date:

DOB: 17/11/1972

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Tachycardia.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 26/07/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222410

Seq: 1

Gender: M

Reported: 12/10/2006

Weight: 84.00

Hospitalisation:

Age: 33

Onset Date: 14/09/2006

DOB: 15/09/1972

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis suspected.	Clopine ceased.
Angina pectoris Troponin increased			

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started: 28/08/2006	Stopped: 14/09/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/10/2006	Echocardiogram				Cardiomyopathy, ejection fraction = 30%
12/10/2006	Troponin	0.0 - 0.3	14/09/2006	0.31	

Additional Information:

Smoker



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222418

Seq: 1

Gender: F

Reported: 12/10/2006

Weight: 0.00

Hospitalisation:

Onset Date: 27/09/2006

Age: 51

DOB: 04/03/1955

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes	Commenced on Diaformin.

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	100.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped:
AMISULPRIDE (Suspected)	Reason:
Tablet	150.0 Milligram Daily Oral
Batch:	Started: 15/03/2004 Stopped: 0
LITHIUM CARBONATE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 15/09/2001 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222540

Seq: 1

Gender: M

Reported: 18/10/2006

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date:

DOB: 13/05/1981

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Obsessive-compulsive disorder		Obsessive-compulsive disorder.	Ceased Clozaril.

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	12.5 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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222552	Seq: 1	Gender: M
Reported: 18/10/2006		Weight: 0.00
Hospitalisation:		Age: 51
Onset Date: 19/04/2006		DOB: 27/05/1954
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Life threatening	Borderline cardiomyopathy.	

Medicine Details:

SOMAC (Other drug)	Reason:
40.0 Milligram	
Batch:	Started: Stopped: 0
LITHICARB (Other drug)	Reason:
Tablet 1.0 Gram Oral	
Batch:	Started: Stopped: 0
ASTRIX 100 (Other drug)	Reason:
Capsule 100.0 Milligram Oral	
Batch:	Started: Stopped: 0
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet 900.0 Milligram Daily Oral	
Batch:	Started: 09/05/2005 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/10/2006	C-Reactive Protein	(0-6)	15/07/2006	+9mg/L	CRP
18/10/2006	Erythrocyte	(1-20)	15/07/2006	24mm/hr	
18/10/2006	Haemoglobin	(135-180)	15/07/2006	131g/L	
18/10/2006	Other data				Features of developing dilated cardiomyopathy. Mild left ventricular dilatation with mildly reduced global systolic function - EF 45-50% Global features.
18/10/2006	Other data	(30-115)	15/07/2006	131U/L	Alk, Phos

Additional Information:

History of smoking.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222552

Seq: 1

Gender: M

Reported: 18/10/2006

Weight: 0.00

Hospitalisation:

Onset Date: 19/04/2006

Age: 51

Outcome: Unknown

DOB: 27/05/1954

Causality: Causality possible

Reaction Details:

Medicine Details:

SOMAC (Other drug)			Reason:
	40.0	Milligram	
Batch:	Started:	Stopped:	0
LITHICARB (Other drug)			Reason:
Tablet	1.0	Gram	Oral
Batch:	Started:	Stopped:	0
ASTRIX 100 (Other drug)			Reason:
Capsule	100.0	Milligram	Oral
Batch:	Started:	Stopped:	0
CLOZARIL (Suspected)			Reason: Unspecified schizophrenia
Tablet	900.0	Milligram	Daily Oral
Batch:	Started: 09/05/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/10/2006	Other data	(10-33)	15/07/2006	7umol/L	Iron
18/10/2006	Serum glucose	Fasting (3.0-6.0)	15/07/2006	7.4 mmol/L	

Additional Information:

History of smoking.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222616 **Seq:** 1 **Gender:** M
Reported: 20/10/2006 **Weight:** 0.00
Hospitalisation: **Age:** 39
Onset Date: 02/09/2006 **DOB:** 26/10/1966
Outcome: Death, maybe drug 02/09/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Unexplained death.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 15/06/2005 Stopped: 02/09/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222628	Seq: 1	Gender: M
Reported: 23/10/2006		Weight: 0.00
Hospitalisation:		Age: 27
Onset Date: 22/08/2006		DOB: 23/02/1979
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal Antipsychotic drug level below therapeutic Electrocardiogram T wave abnormality Eosinopenia Neutrophil count increased Red blood cell count decreased		Abnormal ECG with sinus tachycardia and non specific T wave abnormality. Also experienced low clozapine levels, low norclozapine levels, increased white blood cell count, low red cell count, increased neutrophil count, increased platelets and marked eosinophilia.	Clozaril withheld.

Medicine Details:

RISPERIDONE (Other drug)	Reason:
Batch:	Started: 16/08/2006 Stopped:
SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: 16/08/2006 Stopped:
TEMAZEPAM (Other drug)	Reason:
Batch:	Started: 16/08/2006 Stopped: 17/08/2006
BENZTROPINE MESYLATE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/10/2006	Electrocardiograph				07/07/2006, 28/07/2006, 14/08/2006, 18/08/2006, 01/09/2006, ECG: normal sinus rhythm, normal ECG. 31/08/2006, ECG: Sinus tachycardia, non specific T wave abnormality, abnormal ECG. 18/09/2006, ECG: Sinus tachycardia, non specific ST abnormality, abnormal ECG. 19/09/2006, ECG: normal sinus rhythm, normal ECG normal ECG QT normalize with cessation of clozapine.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222628	Seq: 1	Gender: M
Reported: 23/10/2006		Weight: 0.00
Hospitalisation:		Age: 27
Onset Date: 22/08/2006		DOB: 23/02/1979
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sinus tachycardia			
White blood cell count increased			

Medicine Details:

EFEXOR-XR (Other drug)	Reason:
Batch:	Started: Stopped:
ERYTHROMYCIN (Other drug)	Reason:
Batch:	Started: Stopped:
PSEUDOEPHEDRINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 14/08/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/10/2006	Neutrophils	(2.0-8.0)	04/09/2006	10.69	
23/10/2006	Other data	>400	22/08/2006	77	Clozapine level:
23/10/2006	Other data	>400	29/08/2006	100	Clozapine level:
23/10/2006	Other data	>400	12/09/2006	83	Clozapine level:
23/10/2006	Other data		22/08/2006	31	Norclozapine level:
23/10/2006	Other data		29/08/2006	24	Norclozapine level:
23/10/2006	Other data		12/09/2006	>20	Norclozapine level:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222628
Reported: 23/10/2006

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 22/08/2006

Age: 27

DOB: 23/02/1979

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Other drug)	Reason:
Batch:	Started: 16/08/2006 Stopped:
SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: 16/08/2006 Stopped:
TEMAZEPAM (Other drug)	Reason:
Batch:	Started: 16/08/2006 Stopped: 17/08/2006
BENZTROPINE MESYLATE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/10/2006	Platelets	(140-400)	04/09/2006	10	
23/10/2006	Red blood cells	(4.5-6.0)	18/09/2006	4.39	
23/10/2006	White blood cells	(4.0-11.0)	04/09/2006	16.4	
23/10/2006	White blood cells	(4.0-11.0)	12/09/2006	25.3	
23/10/2006	White blood cells	(4.0-11.0)	18/09/2006	14.8	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222628

Seq: 1

Gender: M

Reported: 23/10/2006

Weight: 0.00

Hospitalisation:

Age: 27

Onset Date: 22/08/2006

DOB: 23/02/1979

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

EFEXOR-XR (Other drug)	Reason:		
Batch:	Started:	Stopped:	
ERYTHROMYCIN (Other drug)	Reason:		
Batch:	Started:	Stopped:	
PSEUDOEPHEDRINE HYDROCHLORIDE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason:		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 14/08/2006	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222972

Seq: 1

Gender: M

Reported: 08/11/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged		Prolonged QT interval.	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZAPINE (Suspected)		Reason:	
Tablet	175.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical history was not provided.
More information has been requested from the treating centre.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222984	Seq: 1	Gender: F
Reported: 09/11/2006		Weight: 0.00
Hospitalisation:		Age: 21
Onset Date: 28/09/2006		DOB: 22/11/1984
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutrophil count decreased	Caused or prolonged inpatient hospitalisation	Patient had decreased Neutrophil count, diarrhoea, gastroenteritis and drug withdrawal syndrome.	Clozaril was discontinued and patient was treated with fluids.
Diarrhoea	Caused or prolonged inpatient hospitalisation		
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LAMOTRIGINE (Other drug)		Reason:	
Batch:	Started: 25/09/2006	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 24/07/2003	Stopped: 0	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/11/2006	Neutrophils		28/09/2006	1.21	
09/11/2006	Neutrophils		29/09/2006	0.82	
09/11/2006	Neutrophils		30/09/2006	0.88	
09/11/2006	Neutrophils		02/10/2006	3.84	
09/11/2006	Neutrophils		01/10/2006	1.31	
09/11/2006	White blood cells		28/09/2006	3.91	
09/11/2006	White blood cells		29/09/2006	4.56	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222984	Seq: 1	Gender: F
Reported: 09/11/2006		Weight: 0.00
Hospitalisation:		Age: 21
Onset Date: 28/09/2006		DOB: 22/11/1984
Outcome: Recovered		Causality: Causality possible

Reaction Details:

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

Medicine Details:

LAMOTRIGINE (Other drug)		Reason:	
Batch:	Started: 25/09/2006	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 24/07/2003	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/11/2006	White blood cells		30/09/2006	3.93	
09/11/2006	White blood cells		01/10/2006	3.93	
09/11/2006	White blood cells		02/10/2006	6.44	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222989

Seq: 1

Gender: M

Reported: 09/11/2006

Weight: 0.00

Hospitalisation:

Age: 29

Onset Date:

DOB: 29/07/1977

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Suspected Myocarditis which on echocardiogram was shown to be cardiomyopathy.	Clopine withdrawn, pain relief
Chest pain			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 08/03/2005 Stopped: 29/09/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/11/2006	Echocardiogram				Focal cardiomyopathy

Additional Information:

History of smoking and cannabis use.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 222990 **Seq:** 1 **Gender:** M
Reported: 09/11/2006 **Weight:** 98.00
Hospitalisation: **Age:** 42
Onset Date: 03/10/2006 **DOB:** 19/01/1964
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Unexplained death	

Medicine Details:

OLANZAPINE (Other drug)	Reason: Unspecified schizophrenia
20.0 Milligram Daily Oral	
Batch: Started: Stopped: 0	
SERTRALINE HYDROCHLORIDE (Other drug)	Reason: Depression
50.0 Milligram Daily Oral	
Batch: Started: Stopped:	
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 250.0 Milligram Daily Oral	
Batch: Started: 12/09/2006 Stopped: 03/10/2006 0	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of paranoid schizophrenia, opioid dependence, amphetamine and THC abuse, smoking (25/day), hypercholesterolaemia, mild liver function impairment and mildly elevated blood glucose levels.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223001	Seq: 1	Gender: F
Reported: 09/11/2006		Weight: 0.00
Hospitalisation:		Age: 22
Onset Date: 29/09/2006		DOB: 17/05/1984
Outcome: Recovered	05/10/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Life threatening	Myocarditis	
Hypotension			
Palpitations			
Pyrexia			
Tachycardia			

Medicine Details:

QUETIAPINE (Other drug)	Reason:
Batch:	Started: Stopped:
DIAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 11/09/2006 Stopped: 29/09/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient was on Clozaril (clozapine) for an unpecifed indication sine 11 Sep 2006 when she experienced myocarditis. The date of onset of myocarditis was not provided. The patient discontinued Clozaril on 28 Sep 2006.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223003	Seq: 1	Gender: F
Reported: 09/11/2006		Weight: 0.00
Hospitalisation:		Age: 51
Onset Date: 05/10/2006		DOB: 18/11/1954
Outcome: Recovered	08/10/2006	Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Cardiac complications - small pericardial effusion and elevated cardiac enzymes suggestive of likely myocarditis and neutropenia. Also became acutely confused, had a fever and CK and troponin were mildly elevated.	Symptoms ceased with Clozaril cessation.
Tachycardia Blood creatine phosphokinase incr Cardiac enzymes increased Confusional state Echocardiogram abnormal Neutropenia		HR: 120 bpm	

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
AMISULPRIDE (Other drug)	Reason:
Batch:	Started: Stopped:
KEFLEX (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 26/09/2006 Stopped: 02/10/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/11/2006	Neutrophils		01/10/2006	1.25	
09/11/2006	Neutrophils		02/10/2006	1.33	
09/11/2006	Neutrophils		03/10/2006	4.01	

Additional Information:

This patient was taking Clozaril (clozapine) since 26 Sep 2006 (according to the patient's CPMS blood history) for an unspecified indication. The patient discontinued Clozaril on the 2nd Oct 2006 due to cardiac complications-small pericardial effusion an elevated cardiac enzymes suggestive of likely myocarditis.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223003	Seq: 1	Gender: F
Reported: 09/11/2006		Weight: 0.00
Hospitalisation:		
Onset Date: 05/10/2006		Age: 51
Outcome: Recovered	08/10/2006	DOB: 18/11/1954
		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pericardial effusion			
Pyrexia			
Troponin increased			

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
AMISULPRIDE (Other drug)	Reason:
Batch:	Started: Stopped:
KEFLEX (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 26/09/2006 Stopped: 02/10/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/11/2006	Other data				(date not specified) Caridac enzymes CK and troponin; mildly elevated. (date not specified) Echocardiogram: small pericardial effeusion in the region of the right ventricle. (date not specified) Septic screen: negative.

Additional Information:

This patient was taking Clozaril (clozapine) since 26 Sep 2006 (according to the patient's CPMS blood history) for an unspecified indication. The patient discontinued Clozaril on the 2nd Oct 2006 due to cardiac complications-small pericardial effusion an elevated cardiac enzymes suggestive of likely myocarditis.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223009

Seq: 1

Gender: M

Reported: 09/11/2006

Weight: 0.00

Hospitalisation:

Age: 38

Onset Date:

DOB: 01/02/1968

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Tachycardia (130 bpm) and chest pain probably from a viral infection.	The patient had no changes to the dose of his medications.
Chest pain			
Viral infection			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram
	Daily
	Oral
Batch:	Started: 16/05/2006
	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/11/2006	Electrocardiograph				(date unknown) ECG: no cardiac abnormalities detected, tachycardia:130bpm.

Additional Information:

The patient was on antibiotics for an infection recently (no further details specified)



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223019 **Seq:** 1 **Gender:** M
Reported: 10/11/2006 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 34
Onset Date: 18/08/2006 **DOB:** 30/01/1972
Outcome: Unknown **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Caused or prolonged inpatient hospitalisation	Clozapine induced suspected cardiomyopathy	Cessation of clozapine

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	600.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/11/2006	Echocardiogram				Routine echocardiogram shows decreased liver function with global hypokinesia.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223080

Seq: 1

Gender: M

Reported: 13/11/2006

Weight: 0.00

Hospitalisation:

Onset Date: 14/10/2006

Age: 21

Outcome: Unknown

DOB: 22/05/1985

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain Blood creatine phosphokinase incr Myocarditis Troponin increased		Patient experienced chest pain, Troponin was 0.15, creatine kinase was 305 - suspected myocarditis.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 19/09/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/11/2006	Creatine		14/10/2006	305	
13/11/2006	Echocardiogram		14/10/2006	Normal	
13/11/2006	Troponin		14/10/2006	0.15	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223086

Seq: 1

Gender: M

Reported: 14/11/2006

Weight: 70.00

Hospitalisation:

Onset Date: 16/10/2006

Age: 29

DOB: 01/10/1977

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation	Chest pain - patient diagnosed with myocarditis	
Myocarditis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

HALOPERIDOL (Other drug)	Reason:	
Batch:	Started:	Stopped:
ZYPREXA (Other drug)	Reason:	
Batch:	Started:	Stopped:
DIAZEPAM (Other drug)	Reason:	
Batch:	Started:	Stopped:
THIAMINE (Other drug)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous cardiac problems.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223086

Seq: 1

Gender: M

Reported: 14/11/2006

Weight: 70.00

Hospitalisation:

Age: 29

Onset Date: 16/10/2006

DOB: 01/10/1977

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZAPINE (Suspected)

Reason: Unspecified psychosis

Tablet

250.0 Milligram

Daily

Oral

Batch:

Started: 03/10/2006

Stopped: 16/10/2006

Laboratory Investigations:

Additional Information:

No previous cardiac problems.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223110

Seq: 1

Gender: M

Reported: 14/11/2006

Weight: 0.00

Hospitalisation:

Age: 33

Onset Date:

DOB: 21/09/1973

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Echocardiogram abnormal			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	700.0 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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223116

Seq: 1

Gender: M

Reported: 14/11/2006

Weight: 0.00

Hospitalisation:

Onset Date: 18/08/2006

Age: 34

Outcome: Unknown

DOB: 30/01/1972

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			

Medicine Details:

OMEPRAZOLE (Other drug)	Reason:		
20.0 Milligram			
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 30/11/2000	L TERM	Stopped: 20/09/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/11/2006	Echocardiogram				18 Aug 2006: Global hypokinesia

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223184 **Seq:** 1 **Gender:** F
Reported: 15/11/2006 **Weight:** 0.00
Hospitalisation: **Age:** 27
Onset Date: 28/09/2006 **DOB:** 29/06/1979
Outcome: Recovered 07/10/2006 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia	Ceased Clopine, CSF

Medicine Details:

DEXAMPHETAMINE SULPHATE (Other drug)	Reason: Behavior disorders of childhood
10.0 Milligram Daily	
Batch:	Started: Stopped:
DIAZEPAM (Other drug)	Reason: Anxiety neurosis
30.0 Milligram Daily	
Batch:	Started: Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 275.0 Milligram Daily Oral	
Batch:	Started: 20/07/2006 Stopped: 28/09/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/11/2006	Neutrophils		28/09/2006	0.6	
15/11/2006	Neutrophils		02/10/2006	0.2	
15/11/2006	Neutrophils		07/10/2006	2.1	
15/11/2006	White blood cells		28/09/2006	3.2	
15/11/2006	White blood cells		29/09/2006	3.4	
15/11/2006	White blood cells		02/10/2006	2.0	
15/11/2006	White blood cells		07/10/2006	4.2	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223213	Seq: 1	Gender: M
Reported: 15/11/2006		Weight: 0.00
Hospitalisation:		Age: 36
Onset Date: 20/04/2006		DOB: 06/08/1969
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alanine aminotransferase increase		Alanine aminotransferase increased, aspartate aminotransferase increased.	
Aspartate aminotransferase increase			
Gamma-glutamyltransferase increase			

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 19/01/0200	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/11/2006	ALT = SGPT	<41	03/10/2006	543	Pre-treatment level = 22
15/11/2006	ALT = SGPT	<41	26/04/2006	53	Pre-treatment level = 22
15/11/2006	ALT = SGPT	<41	28/08/2006	256	Pre-treatment level = 22
15/11/2006	ALT = SGPT	<41	05/09/2006	485	Pre-treatment level = 22
15/11/2006	ALT = SGPT	<41	22/09/2006	583	Pre-treatment level = 22
15/11/2006	GGT = SGGT =	<71	03/10/2006	1517	Pretreatment: 18
15/11/2006	GGT = SGGT =	<71	26/04/2006	25	Pretreatment: 18

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223213 **Seq:** 1
Reported: 15/11/2006

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 20/04/2006
Outcome: Not yet recovered

Age: 36
DOB: 06/08/1969
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 19/01/0200 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/11/2006	GGT = SGGT =	<71	28/08/2006	47	Pretreatment: 18
15/11/2006	GGT = SGGT =	<71	05/09/2006	78	Pretreatment: 18
15/11/2006	GGT = SGGT =	<71	22/09/2006	119	Pretreatment: 18
15/11/2006	SAP = ALP	<129	26/04/2006	105	Pretreatment: 125
15/11/2006	SAP = ALP	<129	28/08/2006	128	Pretreatment: 125
15/11/2006	SAP = ALP	<129	05/09/2006	140	Pretreatment: 125
15/11/2006	SAP = ALP	<129	22/09/2006	133	Pretreatment: 125

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223267	Seq: 1	Gender: F
Reported: 16/11/2006		Weight: 0.00
Hospitalisation:		Age: 43
Onset Date: 29/09/2006		DOB: 26/04/1963
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Leucopenia	

Medicine Details:

Interferon NOS (Suspected)	Reason: Unspecified cirrhosis of liver
180.0 Microgram	Weekly
Batch:	Started:
	Stopped: 0
CLOPINE (Suspected)	Reason:
Tablet	500.0 Milligram
	Daily
	Oral
Batch:	Started: 28/02/2001
	Stopped: Continuing.

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/11/2006	Neutrophils		06/10/2006	1.6 x10^9/L	Dose 500.0
16/11/2006	Neutrophils		29/09/2006	1.8 x10^9/L	Dose 500.0
16/11/2006	Neutrophils		04/09/2006	2.7 x10^9/L	Dose 500.0
16/11/2006	Neutrophils		30/10/2006	2.4 x10^9/L	Dose 500.0
16/11/2006	Neutrophils		16/10/2006	2.4 x10^9/L	Dose 500.0
16/11/2006	White blood cells		06/10/2006	2.3 x10^9/L	Dose 500.0
16/11/2006	White blood cells		29/09/2006	2.8 x10^9/L	Dose 500.0

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223267
Reported: 16/11/2006

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 29/09/2006
Outcome: Unknown

Age: 43
DOB: 26/04/1963
Causality: Causality possible

Reaction Details:

Medicine Details:

Interferon NOS (Suspected)	Reason: Unspecified cirrhosis of liver		
180.0 Microgram	Weekly		
Batch:	Started:	Stopped: 0	
CLOPINE (Suspected)	Reason:		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 28/02/2001	Stopped:	Continuing.

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/11/2006	White blood cells		04/09/2006	4.1 x10 ⁹ L	Dose 500.0
16/11/2006	White blood cells		16/10/2006	3.1 x10 ⁹ L	Dose 500.0
16/11/2006	White blood cells		30/10/2006	3.3 x10 ⁹ L	Dose 500.0

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223269

Seq: 1

Gender: F

Reported: 16/11/2006

Weight: 0.00

Hospitalisation:

Age: 59

Onset Date:

DOB: 19/01/1947

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Experienced leukopenia whilst on Clopine.	Ceased Clopine

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	75.0 Milligram Daily Oral
Batch:	Started: 15/09/2006 Stopped: 26/09/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223302	Seq: 1	Gender: M
Reported: 17/11/2006		Weight: 0.00
Hospitalisation:		Age: 40
Onset Date: 19/10/2006		DOB: 27/05/1966
Outcome: Death, maybe drug		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	No previous medical history or concomitant medications were provided. Patient had taken clozapine from 1995 and switched to Clopine (unknown date) patient died due to unknown causes. Prior to the event the patient was taking PO Clopine 800mg daily.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	900.0 Milligram Daily Oral
Batch:	Started: Stopped: 19/10/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/11/2006	Haemoglobin				White blood cell and neutrophil counts were within the normal limits throughout the treatment period.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223420

Seq: 1

Gender: U

Reported: 22/11/2006

Weight: 0.00

Hospitalisation:

Age: 27

Onset Date: 04/10/2006

DOB: 31/10/1978

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sinus tachycardia		Patient experienced tachycardia and a pulse of 140.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/11/2006	Electrocardiograph				An electrocariogram ECG was performed and it was reported that the patient had sinus tachycardia.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223451 **Seq:** 1 **Gender:** M
Reported: 23/11/2006 **Weight:** 0.00
Hospitalisation: **Age:** 55
Onset Date: 10/10/2006 **DOB:** 04/07/1951
Outcome: Death, maybe drug 01/11/2006 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Caused or prolonged inpatient hospitalisation	Patient developed severe leucopenia and neutropenia due to Clopine treatment. Reassessed as agranulocytosis	Observation given. Clopine ceased.
Pneumonia	Caused or prolonged inpatient hospitalisation	later developed pneumonia which was the cause of death	

Medicine Details:

OMEPRAZOLE (Other drug)		Reason:	
Tablet	25.0 Milligram	Oral	
Batch:	Started:	Stopped:	
SERETIDE ACCUHALER NOS (Other drug)		Reason: Asthma	
Batch:	Started:	Stopped:	
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 27/08/2006	Stopped: 10/10/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/11/2006	Neutrophils		10/10/2005	0.1	
23/11/2006	Neutrophils		11/10/2005	0.01	
23/11/2006	Neutrophils		13/10/2005	0.1	
23/11/2006	Neutrophils		12/10/2006	0.1	
23/11/2006	Neutrophils		16/10/2005	0.1	
23/11/2006	Neutrophils		24/10/2006	0.01	
23/11/2006	Neutrophils		20/10/2006	0.01	

Additional Information:

Hiistory of schizophrenia, asthma, hepatitis C and chronic smoking.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223451 **Seq:** 1 **Gender:** M
Reported: 23/11/2006 **Weight:** 0.00
Hospitalisation: **Age:** 55
Onset Date: 10/10/2006 **DOB:** 04/07/1951
Outcome: Death, maybe drug 01/11/2006 **Causality:** Causality probable

Reaction Details:

Medicine Details:

OMEPRAZOLE (Other drug)	Reason:
Tablet 25.0 Milligram Oral	
Batch:	Started: Stopped:
SERETIDE ACCUHALER NOS (Other drug)	Reason: Asthma
Batch:	Started: Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral	
Batch:	Started: 27/08/2006 Stopped: 10/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/11/2006	Neutrophils		15/10/2005	0.1	
23/11/2006	Neutrophils		14/10/2005	0.1	
23/11/2006	White blood cells		10/10/2005	1.4	
23/11/2006	White blood cells		11/10/2005	0.7	
23/11/2006	White blood cells		12/10/2006	0.8	
23/11/2006	White blood cells		13/10/2005	0.7	
23/11/2006	White blood cells		14/10/2005	0.5	

Additional Information:

Hiistory of schizophrenia, asthma, hepatitis C and chronic smoking.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223451 **Seq:** 1 **Gender:** M
Reported: 23/11/2006 **Weight:** 0.00
Hospitalisation: **Age:** 55
Onset Date: 10/10/2006 **DOB:** 04/07/1951
Outcome: Death, maybe drug 01/11/2006 **Causality:** Causality probable

Reaction Details:

Medicine Details:

OMEPRAZOLE (Other drug)	Reason:
Tablet 25.0 Milligram Oral	
Batch:	Started: Stopped:
SERETIDE ACCUHALER NOS (Other drug)	Reason: Asthma
Batch:	Started: Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral	
Batch:	Started: 27/08/2006 Stopped: 10/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/11/2006	White blood cells		15/10/2005	0.6	
23/11/2006	White blood cells		16/10/2005	0.6	
23/11/2006	White blood cells		20/10/2006	0.5	
23/11/2006	White blood cells		24/10/2006	0.3	

Additional Information:

Hiistory of schizophrenia, asthma, hepatitis C and chronic smoking.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223493	Seq: 1	Gender: F
Reported: 27/11/2006		Weight: 62.00
Hospitalisation:		Age: 17
Onset Date: 10/10/2006		DOB: 30/09/1989
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia	Life threatening	Leucopenia, neutropenia.	Ceased clopine.
Neutropenia	Life threatening		

Medicine Details:

LORAZEPAM (Other drug)		Reason: Anxiety neurosis
6.0 Milligram	Daily	Oral
Batch:	Started: 10/08/2006	Stopped:
CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia
Tablet	350.0 Milligram	Daily Oral
Batch:	Started: 07/08/2006	Stopped: 11/10/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/11/2006	Neutrophils		10/10/2006	1.35	
27/11/2006	Neutrophils		11/10/2006	1.65	
27/11/2006	Neutrophils		13/10/2006	1.74	
27/11/2006	Neutrophils		12/10/2006	1.97	
27/11/2006	White blood cells		10/10/2006	3.2	
27/11/2006	White blood cells		11/10/2006	3.93	
27/11/2006	White blood cells		12/10/2006	4.12	

Additional Information:

Patients medical history included previous leucopenia prior to commencement of clozapine, probably due to valproate. Valproate treatment was ceased prior to the introduction of clozapine.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223493 **Seq:** 1
Reported: 27/11/2006

Gender: F
Weight: 62.00
Age: 17
DOB: 30/09/1989
Causality: Causality possible

Hospitalisation:

Onset Date: 10/10/2006
Outcome: Not yet recovered

Reaction Details:

Medicine Details:

LORAZEPAM (Other drug)	Reason: Anxiety neurosis
6.0 Milligram Daily Oral	
Batch:	Started: 10/08/2006 Stopped:
CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 350.0 Milligram Daily Oral	
Batch:	Started: 07/08/2006 Stopped: 11/10/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/11/2006	White blood cells		13/10/2006	4.15	

Additional Information:

Patients medical history included previous leucopenia prior to commencement of clozapine, probably due to valproate. Valproate treatment was ceased prior to the introduction of clozapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223566	Seq: 1	Gender: M
Reported: 28/11/2006		Weight: 0.00
Hospitalisation:		Age: 36
Onset Date: 09/05/2005		DOB: 20/06/1968
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient's neutrophil count dropped to 1.30, liver function tests were mildly abnormal.	Clozaril ceased.
Liver function test abnormal			

Medicine Details:

SODIUM VALPROATE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 11/06/1994 L TERM	Stopped: 29/09/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/11/2006	Liver function tests				LFT's were mildly abnormal, alanine aminotransferase 104, aspartate aminotransferase 62.
28/11/2006	Neutrophils		09/05/2005	1.30 x 10 ⁹ /L	
28/11/2006	Neutrophils		17/10/2006	1.30 x 10 ⁹ /L	
28/11/2006	Neutrophils		18/10/2006	1.80 x 10 ⁹ /L	
28/11/2006	Neutrophils		20/10/2006	1.80 x 10 ⁹ /L	
28/11/2006	Neutrophils		23/10/2006	2.10 x 10 ⁹ /L	

Additional Information:

History: Heavy x-smoker and diabetes.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223568	Seq: 1	Gender: M
Reported: 28/11/2006		Weight: 0.00
Hospitalisation:		Age: 38
Onset Date:		DOB: 20/06/1968
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes mellitus.	

Medicine Details:

METFORMIN HYDROCHLORIDE (Suspected)		Reason:	
Batch:	Started:	Oral	
CLOZARIL (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 11/06/1994	Stopped: 29/09/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Heavy x-smoker and diabetes.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223606	Seq: 1	Gender: M
Reported: 29/11/2006		Weight: 0.00
Hospitalisation:		Age: 28
Onset Date: 04/09/2006		DOB: 12/07/1978
Outcome: Unknown		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain		The patient was receiving Clozaril for an unspecified indication. The patient experienced tachycardia and atypical chest apin.	Treatment discontinued.
Tachycardia			

Medicine Details:

RISPERDAL (Other drug)	Reason:
Batch:	Started:
	Stopped:
MIRTAZAPINE (Other drug)	Reason:
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 11/04/2006 L TERM Stopped: 14/09/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/11/2006	Chest X-ray		07/09/0906	normal	Frequent full blood count demonstrated normal white blood cell count and neutrophil count.
29/11/2006	Echocardiogram		20/09/2006	normal	
29/11/2006	Haematology				

Additional Information:

Treatment resistant schizophrenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223705	Seq: 1	Gender: M
Reported: 01/12/2006		Weight: 0.00
Hospitalisation:		Age: 25
Onset Date: 24/10/2006		DOB: 12/10/1981
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alanine aminotransferase increase		Patient had increased Alanine aminotransferase, aspartate amino-transferase and gamma glutamyltransferase.	Olanzapine was stopped and clozapine withheld, Recommended next day and increased slowly with improvement of liver function
Aspartate aminotransferase increase			
Gamma-glutamyltransferase increase			

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 10/10/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/12/2006	ALT = SGPT	<55	23/10/2006	354	baseline: 90
01/12/2006	ALT = SGPT	<55	24/10/2006	306	baseline: 90
01/12/2006	ALT = SGPT	<55	26/10/2006	239	baseline: 90
01/12/2006	ALT = SGPT	<55	29/10/2006	143	baseline: 90
01/12/2006	ALT = SGPT	<55	03/10/2006	105	baseline: 90
01/12/2006	ALT = SGPT	<55	31/10/2006	90	baseline: 90
01/12/2006	AST = SGOT	<50	23/10/2006	153	Baseline: normal

Additional Information:

Patient has hepatitis B.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223705
Reported: 01/12/2006

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 24/10/2006

Age: 25

DOB: 12/10/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 10/10/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/12/2006	AST = SGOT	<50	24/10/2006	85	Baseline: normal
01/12/2006	AST = SGOT	<50	26/10/2006	66	Baseline: normal
01/12/2006	Bilirubin	<19	03/10/2006	20	
01/12/2006	Bilirubin	<19	26/10/2006	19	
01/12/2006	GGT = SGGT =	<50	23/10/2006	192	baseline: 90
01/12/2006	GGT = SGGT =	<50	24/10/2006	181	baseline: 90
01/12/2006	GGT = SGGT =	<50	26/10/2006	161	baseline: 90

Additional Information:

Patient has hepatitis B.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223705
Reported: 01/12/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 24/10/2006
Outcome: Unknown

Age: 25
DOB: 12/10/1981
Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 10/10/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/12/2006	GGT = SGGT = COTP	<50	31/10/2006	132	baseline: 90
01/12/2006	GGT = SGGT = COTP	<50	03/10/2006	119	baseline: 90
01/12/2006	Ultrasound				24 Oct: fatty liver

Additional Information:

Patient has hepatitis B.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223738

Seq: 1

Gender: M

Reported: 04/12/2006

Weight: 0.00

Hospitalisation:

Onset Date: 19/10/2006

Age: 31

DOB: 14/01/1975

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Patient had agranulocytosis.	Ceased drug.

Medicine Details:

CLOPINE (Suspected)	Reason:
	700.0 Milligram Daily Oral
Batch:	Started: 02/12/2003 Stopped: 19/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/12/2006	Neutrophils		19/10/2006	1.20	
04/12/2006	Neutrophils		20/10/2006	2.10	
04/12/2006	Neutrophils		21/10/2006	2.60	
04/12/2006	Neutrophils		23/10/2006	4.80	
04/12/2006	Neutrophils		22/10/2006	6.50	
04/12/2006	White blood cells		19/10/2006	2.4	
04/12/2006	White blood cells		20/10/2006	3.90	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223738

Seq: 1

Gender: M

Reported: 04/12/2006

Weight: 0.00

Hospitalisation:

Age: 31

Onset Date: 19/10/2006

DOB: 14/01/1975

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)

Reason:

700.0 Milligram

Daily

Oral

Batch:

Started: 02/12/2003

Stopped: 19/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/12/2006	White blood cells		21/10/2006	4.90	
04/12/2006	White blood cells		22/10/2006	10.30	
04/12/2006	White blood cells		23/10/2006	7.40	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223752

Seq: 1

Gender: M

Reported: 04/12/2006

Weight: 0.00

Hospitalisation:

Onset Date: 25/10/2006

Age: 41

Outcome: Unknown

DOB: 02/08/1965

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope vasovagal Blood pressure decreased Dizziness Pallor		Patient complained of dizziness and was pale and vasovagal. Blood pressure was 90/70 mmHg and the pulse was 60 bpm.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	175.0 Milligram Daily Oral
Batch:	Started: 13/10/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223864 **Seq:** 1 **Gender:** M
Reported: 06/12/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 53
Onset Date: **DOB:** 02/03/1953
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia	Caused or prolonged inpatient hospitalisation	Patient experienced elevated glucose levels (41) after starting Clopine.	Ceased Clopine, treated with Insulin.

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 31/08/2006 Stopped: 20/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/12/2006	White blood cells	(Lab normal: 4-11)			White blood cell counts and neutrophil counts were within acceptable limits with the exception of a few raised WBC counts. White glucose level = 41.

Additional Information:

History: Obesity and schizophrenia. History of obesity caused partly by other antipsychotics. Previous substantial raised blood sugar levels. Previously treated with Zprexa and experienced weight gain.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223866	Seq: 1	Gender: M
Reported: 06/12/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 29
Onset Date: 16/10/2006		DOB: 01/10/1977
Outcome: Recovered	23/10/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Patient experienced chest pain, increased white cell count, increased troponin and ST elevation.	Discontinuation of Clopine.
Chest pain	Caused or prolonged inpatient hospitalisation		
Electrocardiogram ST segment ele	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DIAZEPAM (Other drug)		Reason: Otr spec symp psychopathol nec
Tablet	10.0 Milligram	Daily Oral
Batch:	Started: 29/08/2006	Stopped: 0
HALOPERIDOL (Other drug)		Reason: Unspecified psychosis
Tablet	10.0 Milligram	Daily Oral
Batch:	Started: 16/10/2006	Stopped:
THIAMINE (Other drug)		Reason: Alcoholism
Tablet	100.0 Milligram	Daily Oral
Batch:	Started: 29/08/2006	Stopped: Continuing.
CLOPINE (Suspected)		Reason: Unspecified schizophrenia
Tablet	250.0 Milligram	Daily Oral
Batch:	Started: 03/10/2006	Stopped: 19/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/12/2006	Echocardiogram	(Normal)	20/10/2006	Normal	
06/12/2006	Electrocardiograph		19/10/2006	ST elevation.	
06/12/2006	Troponin	(Normal)	19/10/2006	0.88	
06/12/2006	Troponin	(Normal)	23/10/2006	Normal	
06/12/2006	White blood cells	(High)	19/10/2006	Increased	

Additional Information:

History: Alcohol abuse, schizophrenia, psychosis and agitation.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223866	Seq: 1	Gender: M
Reported: 06/12/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 29
Onset Date: 16/10/2006		DOB: 01/10/1977
Outcome: Recovered	23/10/2006	Causality: Causality possible

Reaction Details:

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

Medicine Details:

DIAZEPAM (Other drug)		Reason: Otr spec symp psychopathol nec	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 29/08/2006	Stopped:	0
HALOPERIDOL (Other drug)		Reason: Unspecified psychosis	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 16/10/2006	Stopped:	
THIAMINE (Other drug)		Reason: Alcoholism	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 29/08/2006	Stopped:	Continuing.
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 03/10/2006	Stopped:	19/10/2006

Laboratory Investigations:

Additional Information:

History: Alcohol abuse, schizophrenia, psychosis and agitation.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223867	Seq: 1	Gender: M
Reported: 06/12/2006		Weight: 0.00
Hospitalisation:		Age: 22
Onset Date: 26/09/2006		DOB: 01/10/1983
Outcome: Recovered	02/10/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis, atypical chest pain, tachycardia, pleurtic chest pain, shortness of breath-worsening and dizziness on walking. Tachycardia wqas in sinus rythm.	
Chest pain	Caused or prolonged inpatient hospitalisation		
Dizziness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DIAZEPAM (Other drug)	Reason: Other acne of sebaceous glands
50.0 Milligram	
Batch:	Started: 12/09/2006 Stopped:
ERYTHROMYCIN (Other drug)	Reason: Other acne of sebaceous glands
Gel	Topical
Batch:	Started: Stopped:
QUETIAPINE (Other drug)	Reason: Unspecified schizophrenia
Batch:	Started: Stopped:
CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 08/09/2006 Stopped: 28/09/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/12/2006	Echocardiogram				Mild global systolic dysfunction and small amount of pericardial fluid. No segmental changes.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223867	Seq: 1	Gender: M
Reported: 06/12/2006		Weight: 0.00
Hospitalisation:		
Onset Date: 26/09/2006		Age: 22
Outcome: Recovered	02/10/2006	DOB: 01/10/1983
		Causality: Causality possible

Reaction Details:

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

Medicine Details:

DIAZEPAM (Other drug)	Reason: Other acne of sebaceous glands
50.0 Milligram	
Batch:	Started: 12/09/2006 Stopped:
ERYTHROMYCIN (Other drug)	Reason: Other acne of sebaceous glands
Gel	Topical
Batch:	Started: Stopped:
QUETIAPINE (Other drug)	Reason: Unspecified schizophrenia
Batch:	Started: Stopped:
CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 08/09/2006 Stopped: 28/09/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223896

Seq: 1

Gender: M

Reported: 07/12/2006

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date:

DOB: 07/06/1967

Outcome: Unknown

Causality: Causality certain

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/12/2006	Neutrophils		04/10/2006	12.68	
07/12/2006	Neutrophils		28/09/2006	22.38	
07/12/2006	Neutrophils		19/09/2006	14.53	
07/12/2006	Serum drug level		04/10/2006	0.0	Clozapine
07/12/2006	Serum drug level		28/09/2006	50.0	Clozapine
07/12/2006	Serum drug level		19/09/2006	100.0	Clozapine
07/12/2006	White blood cells		04/10/2006	13.9	

Additional Information:

+VE RECHALLENGE



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223896
Reported: 07/12/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 39
DOB: 07/06/1967
Causality: Causality certain

Reaction Details:

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/12/2006	White blood cells		28/09/2006	25.4	
07/12/2006	White blood cells		19/09/2006	17.4	

Additional Information:

+VE RECHALLENGE



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223897	Seq: 1	Gender: M
Reported: 07/12/2006		Weight: 0.00
Hospitalisation:		Age: 39
Onset Date: 13/09/2006		DOB: 07/06/1967
Outcome: Recovered	10/10/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nephritis		Renal failure initially suspected, later revised to nephritis	Clopine ceased, corticosteroids.
Pyrexia		increased temperature, decreased blood pressure, worsening creatinine and urea over a 10 day period	
Eosinophilia			
Renal impairment			

Medicine Details:

FOLIC ACID (Other drug)	Reason:
5.0 Milligram	Oral
Batch:	Started: Stopped:
OMEPRAZOLE (Other drug)	Reason: Gastritis&duodenitis
20.0 Milligram	Daily Oral
Batch:	Started: Stopped:
Abilify (Other drug)	Reason: Unspecified schizophrenia
30.0 Milligram	Daily Oral
Batch:	Started: Stopped:
RISPERIDONE (Other drug)	Reason: Unspecified schizophrenia
4.0 Milligram	Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/12/2006	Neutrophils		04/10/2006	12.68	
07/12/2006	Neutrophils		28/09/2006	22.38	
07/12/2006	Neutrophils		19/09/2006	14.53	
07/12/2006	Serum drug level		04/10/2006	0.0	Clozapine
07/12/2006	Serum drug level		28/09/2006	50.0	Clozapine
07/12/2006	Serum drug level		19/09/2006	100.0	Clozapine
07/12/2006	White blood cells		04/10/2006	13.9	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223897 **Seq:** 1 **Gender:** M
Reported: 07/12/2006 **Weight:** 0.00
Hospitalisation: **Age:** 39
Onset Date: 13/09/2006 **DOB:** 07/06/1967
Outcome: Recovered 10/10/2006 **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 13/09/2006 Stopped: 28/09/2006 0
LITHIUM CARBONATE (Suspected)	Reason: Unspecified psychosis
	1.2 Gram Daily Oral
Batch:	Started: Stopped: 01/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/12/2006	White blood cells		28/09/2006	25.4	
07/12/2006	White blood cells		19/09/2006	17.4	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223925	Seq: 1	Gender: M
Reported: 07/12/2006		Weight: 0.00
Hospitalisation: Hospitalisation prolonged		Age: 36
Onset Date:		DOB: 09/03/1970
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysstasia	Caused or prolonged inpatient hospitalisation	Patient experienced difficulty standing up, general mobility, it is suspected that patient had cut down dosage. Patient not feeling well and admitted to hosp. Patient also had diabetes and very obese.	Clozaril discontinued.
Malaise	Caused or prolonged inpatient hospitalisation		
Mobility decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 04/10/2006	Stopped: 23/10/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223970	Seq: 1	Gender: M
Reported: 11/12/2006		Weight: 0.00
Hospitalisation:		Age: 25
Onset Date:		DOB: 07/12/1981
Outcome: Recovered	05/10/2004	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Neuroleptic malignant syndrome, tachycardia, liver function test abnormal, white blood cell count increased, gamma-glutamyltransferase increased, blood alkaline phosphate increased, alanine aminotransferase increased, aspartate aminotransferase increased, blood lactate dehydrogenase increased.	Treatment was discontinued on 25/8/04 and rechallenged on 30/8/04. Rechallenge result was persistent tachycardia (non-serious). Treatment with Clozaril was ceased on 27/9/04.
Alanine aminotransferase increase			
Aspartate aminotransferase increa			
Blood alkaline phosphatase increa			
Blood lactate dehydrogenase incre			

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Suspected)		Reason:	
Batch:	Started:	Stopped: 25/08/2004	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 20/07/2004	Stopped: 25/08/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/12/2006	ALT = SGPT		24/08/2006	90 U/L	
11/12/2006	AST = SGOT		24/08/2006	58 U/L	
11/12/2006	GGT = SGGT =		24/08/2006	113U/L	
11/12/2006	LDH		24/08/2006	262 U/L	
11/12/2006	SAP = ALP		24/08/2004	123 U/L	

Additional Information:

+ve rechllenge



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 223970

Seq: 1

Gender: M

Reported: 11/12/2006

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date:

DOB: 07/12/1981

Outcome: Recovered

05/10/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gamma-glutamyltransferase increased Liver function test abnormal Tachycardia White blood cell count increased			

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Suspected)	Reason:		
Batch:	Started:	Stopped: 25/08/2004	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 20/07/2004	Stopped: 25/08/2004	

Laboratory Investigations:

Additional Information:

+ve rechllenge



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224009

Seq: 1

Gender: U

Reported: 12/12/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224016

Seq: 1

Gender: M

Reported: 12/12/2006

Weight: 0.00

Hospitalisation:

Onset Date: 17/07/2006

Age: 51

Outcome: Unknown

DOB: 23/06/1955

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Patient had gained 20kg since commencing Clozaril.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Obesity othr than endoc origin
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 26/07/2002 L TERM Stopped: 15/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was previously receiving Clozaril from 26/7/02 to 15/2/06 however patient experienced steady weight gain since July this year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224018

Seq: 1

Gender: U

Reported: 12/12/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Patient developed tachycardia.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	600.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was taking Clozaril for some time. Patient's dose recently increased to 600mg daily when developed tachycardia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224046

Seq: 1

Gender: F

Reported: 13/12/2006

Weight: 0.00

Hospitalisation:

Onset Date: 02/11/2006

Age: 42

DOB: 05/09/1964

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Patient experienced a seizure.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	725.0 Milligram Daily Oral
Batch:	Started: 26/04/2006 Stopped: 02/02/2007 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was a smoker; inpatient in hospital which banned smoking 30/10/06 - seizure occurred on 2/11/06.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224090

Seq: 1

Gender: M

Reported: 14/12/2006

Weight: 0.00

Hospitalisation:

Age: 47

Onset Date:

DOB: 17/01/1959

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Cardiac complications.	Clopine ceased

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 08/05/2006 Stopped: 07/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/12/2006	Other data				White blood cells and neutrophils counts were within acceptable limits for the treatment period.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224138	Seq: 1	Gender: M
Reported: 18/12/2006		Weight: 0.00
Hospitalisation:		
Onset Date: 06/11/2006		Age: 28
Outcome: Recovered	15/11/2006	DOB: 20/07/1978
		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Caused or prolonged inpatient hospitalisation	A diagnosis of myocarditis and cardiomyopathy was made. Also evidence of left heart failure	
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis with symptoms of chest pain, dyspnoea, palpitations, tachycardia, tachyarrhythmia, hypotension and fever.	Transferred to CCU and treated with dobutamine.

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
	10.0 Milligram		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	275.0 Milligram	Daily	Oral
Batch:	Started: 18/10/2006	Stopped: 06/11/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224142

Seq: 1

Gender: F

Reported: 18/12/2006

Weight: 0.00

Hospitalisation:

Onset Date: 05/10/2006

Age: 36

Outcome: Unknown

DOB: 12/09/1970

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis Neutrophil count increased White blood cell count increased		Myocarditis, neutrophil count increased, white blood count increased.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	175.0 Milligram Daily Oral
Batch:	Started: 05/10/2006 Stopped: 05/11/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/12/2006	Neutrophils		06/10/2006	9.8	
18/12/2006	Neutrophils		26/10/2006	9.8	
18/12/2006	Neutrophils		14/11/2006	9.7	
18/12/2006	Neutrophils		02/11/2006	11.2	
18/12/2006	White blood cells		05/10/2006	13.8	
18/12/2006	White blood cells		26/10/2006	12.6	
18/12/2006	White blood cells		02/11/2006	14.8	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224142

Seq: 1

Gender: F

Reported: 18/12/2006

Weight: 0.00

Hospitalisation:

Age: 36

Onset Date: 05/10/2006

DOB: 12/09/1970

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason:

Tablet

175.0 Milligram

Daily

Oral

Batch:

Started: 05/10/2006

Stopped: 05/11/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/12/2006	White blood cells		14/11/2006	14.4	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224189

Seq: 1

Gender: U

Reported: 19/12/2006

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Tachycardia, heart rate of 120 after 2 weeks.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224190
Reported: 19/12/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 06/11/2006
Outcome: Unknown

Age: 58
DOB: 05/05/1948
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Echocardiogram abnormal Ejection fraction abnormal Ventricular hypertrophy		Patient underwent an echocardiogram and the results showed cardiomyopathy, mild left ventricular hypertrophy, moderate to severe ventricular function and ejection fraction of 30%.	Clozaril discontinued.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 27/07/1998	Stopped: 06/11/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/12/2006	Echocardiogram				(06/11/2006) Echocardiogram: Mild left ventricular hypertrophy. Moderate to severe ventricular function. ejection fraction 30%. Valves ok.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224191	Seq: 1	Gender: F
Reported: 19/12/2006		Weight: 0.00
Hospitalisation:		
Onset Date: 12/08/2006		Age: 34
Outcome: Recovered	15/09/2006	DOB: 30/09/1971
		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Life threatening	Patient experienced diarrhoea, pneumonia, fever, hypotensive, tachycardia, anorexia, vomiting and lethargy.	Patient treated with loperamide, IV rehydration and potassium supplementation. Clopine stopped.
Anorexia	Life threatening		
Hypotension	Life threatening		
Lethargy	Life threatening		

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
RISPERIDONE (Other drug)	Reason: Unspecified schizophrenia
Batch:	Started:
Batch:	Stopped:
QUETIAPINE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	500.0 Milligram
	Daily
	Oral
Batch:	Started: 28/07/2006
	Stopped: 28/08/2006
	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of schizophrenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224191
Reported: 19/12/2006

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 12/08/2006

Age: 34

Outcome: Recovered

15/09/2006

DOB: 30/09/1971

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia	Life threatening		
Pyrexia	Life threatening		
Tachycardia	Life threatening		
Vomiting	Life threatening		

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
RISPERIDONE (Other drug)	Reason: Unspecified schizophrenia		
Batch:	Started:	Stopped:	
QUETIAPINE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 28/07/2006	Stopped: 28/08/2006	0

Laboratory Investigations:

Additional Information:

History of schizophrenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224208

Seq: 1

Gender: M

Reported: 19/12/2006

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date:

DOB: 18/04/1960

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis, tachycardia, increased troponin.	Ceased Clopine
Tachycardia			
Troponin increased			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	175.0 Milligram Daily Oral
Batch:	Started: 20/09/2006 Stopped: 17/11/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224215	Seq: 1	Gender: M
Reported: 20/12/2006		Weight: 0.00
Hospitalisation: Hospitalisation prolonged		Age: 56
Onset Date: 30/10/2006		DOB: 16/05/1950
Outcome: Recovered	09/11/2006	Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Life threatening	Acute myocarditis, fever, increased troponin.	Transferred to the cardiovascular unit, Clopine was ceased and metoprolol 25mg bid and aspirin 150mg were commenced.
Pyrexia	Life threatening		
Troponin increased	Life threatening		

Medicine Details:

METOCLOPRAMIDE HYDROCHLORIDE (Other drug)	Reason:
20.0 Milligram	Oral
Batch:	Started: Stopped:
TEMAZEPAM (Other drug)	Reason:
20.0 Milligram	Oral
Batch:	Started: Stopped:
ASPIRIN (Other drug)	Reason:
150.0 Milligram	Oral
Batch:	Started: Stopped:
Aripiprazole (Other drug)	Reason:
5.0 Milligram	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/12/2006	Troponin			0.18, 0.25	

Additional Information:

History of anaemia, depression, fever of unknown origin, mitral valve prolapse, esophageal stricture, pneumonia, suicide attempts, reflux and elevated lipids. No allergies and no history of smoking or drug abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224215 **Seq:** 1 **Gender:** M
Reported: 20/12/2006 **Weight:** 0.00
Hospitalisation: Hospitalisation prolonged **Age:** 56
Onset Date: 30/10/2006 **DOB:** 16/05/1950
Outcome: Recovered 09/11/2006 **Causality:** Causality probable

Reaction Details:

Medicine Details:

METOPROLOL TARTRATE (Other drug)	Reason:
25.0 Milligram	Oral
Batch:	Started: Stopped:
ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug)	Reason: Heartburn
40.0 Milligram	Daily Oral
Batch:	Started: Stopped:
QUETIAPINE (Other drug)	Reason: Unspecified psychosis
200.0 Milligram	Daily Oral
Batch:	Started: Stopped:
MIRTAZAPINE (Other drug)	Reason: Depression
30.0 Milligram	Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

History of anaemia, depression, fever of unknown origin, mitral valve prolapse, esophageal stricture, pneumonia, suicide attempts, reflux and elevated lipids. No allergies and no history of smoking or drug abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224215	Seq: 1	Gender: M
Reported: 20/12/2006		Weight: 0.00
Hospitalisation: Hospitalisation prolonged		Age: 56
Onset Date: 30/10/2006		DOB: 16/05/1950
Outcome: Recovered	09/11/2006	Causality: Causality probable

Reaction Details:

Medicine Details:

FERROUS SULPHATE (Other drug)	Reason: Unspecified anemia
10.0 Millilitre	Daily Oral
Batch:	Started: Stopped:
ATORVASTATIN (Other drug)	Reason: Othr&unspec metabolic diseases
10.0 Milligram	Daily Oral
Batch:	Started: Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 18/10/2006 Stopped: 31/10/2006

Laboratory Investigations:

Additional Information:

History of anaemia, depression, fever of unknown origin, mitral valve prolapse, esophageal stricture, pneumonia, suicide attempts, reflux and elevated lipids. No allergies and no history of smoking or drug abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224225 **Seq:** 1 **Gender:** M
Reported: 20/12/2006 **Weight:** 75.00
Hospitalisation: **Age:** 44
Onset Date: 09/11/2006 **DOB:** 24/05/1962
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis Chest pain Heart rate increased Pyrexia Red blood cell sedimentation rate i Troponin increased		Patient had mild myocarditis, pyrexia, increased troponin, chest pain, increased ESR and increased heart rate.	Clozapine ceased.

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 17/10/2006	Stopped: 09/11/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224251

Seq: 1

Gender: M

Reported: 20/12/2006

Weight: 95.00

Hospitalisation:

Age: 34

Onset Date: 10/11/2006

DOB: 09/06/1972

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Cardiomyopathy.	Ceased drug.

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 04/02/2004	Stopped: 20/11/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224257

Seq: 1

Gender: F

Reported: 20/12/2006

Weight: 0.00

Hospitalisation:

Age: 29

Onset Date:

DOB: 22/04/1977

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Creatine Kinase increased.	Ceased clopine.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 07/01/2005 Stopped: 28/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224258 **Seq:** 1 **Gender:** M
Reported: 21/12/2006 **Weight:** 0.00
Hospitalisation: Hospitalisation prolonged **Age:** 47
Onset Date: 07/10/2006 **DOB:** 17/01/1959
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Life threatening	Cardiomyopathy.	Drug ceased.

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 08/05/2006 Stopped: 07/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/12/2006	Echocardiogram				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224259 **Seq:** 1 **Gender:** M
Reported: 21/12/2006 **Weight:** 138.00
Hospitalisation: Hospitalisation prolonged **Age:** 56
Onset Date: 15/12/2005 **DOB:** 30/07/1949
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting	Incapacity/disability	Patient had vomiting, sedation and hypersalivation.	Ceased Clopine, was treated with Pariet.
Salivary hypersecretion	Incapacity/disability		
Sedation	Incapacity/disability		

Medicine Details:

RABEPRAZOLE SODIUM (Other drug)	Reason:
20.0 Milligram	Oral
Batch:	Started: 17/06/2005 Stopped:
METFORMIN HYDROCHLORIDE (Other drug)	Reason:
1.0 Gram	
Batch:	Started: 30/05/2005 Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 17/05/2001 Stopped: 15/11/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient commenced Clozaril, switched to Clopine in 2001. Clopine ceased 15/11/06 due to the events. He was taking clopine 50mg po daily at the time of ceasing however for the duration of his treatment was on significantly higher doses of upto 500mg which was maintained for approx 4 yrs.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224261 **Seq:** 1 **Gender:** F
Reported: 21/12/2006 **Weight:** 0.00
Hospitalisation: Hospitalisation prolonged **Age:** 35
Onset Date: 13/11/2006 **DOB:** 09/01/1971
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Respiratory depression	Life threatening	Patient had necrotizing fasciitis after a peri-anal abscess. Then developed spiking fevers and tachycardia, also neutrophilia and leucocytosis. The patient "coded" with respiratory depression and had to be resuscitated.	Fluconazole and hyperbaric treatment.
Leukocytosis	Life threatening		
Necrotising fasciitis	Life threatening		
Neutrophilia	Life threatening		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 25/07/2000	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/12/2006	Neutrophils		25/07/2000	5.2	
21/12/2006	Neutrophils		25/10/2006	7.9	
21/12/2006	Neutrophils		13/11/2006	20.1	
21/12/2006	White blood cells		25/07/2000	10.1	
21/12/2006	White blood cells		25/10/2006	11.5	
21/12/2006	White blood cells		13/11/2006	24.0	

Additional Information:

Not yet recovered but improving



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224261 **Seq:** 1 **Gender:** F
Reported: 21/12/2006 **Weight:** 0.00
Hospitalisation: Hospitalisation prolonged **Age:** 35
Onset Date: 13/11/2006 **DOB:** 09/01/1971
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Perianal abscess	Life threatening		
Pyrexia	Life threatening		
Tachycardia	Life threatening		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 25/07/2000 Stopped: 0

Laboratory Investigations:

Additional Information:

Not yet recovered but improving



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224360	Seq: 1	Gender: M
Reported: 03/01/2007		Weight: 0.00
Hospitalisation:		Age: 19
Onset Date: 26/09/2006		DOB: 02/12/1986
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Cardiac side effects - mild global left ventricular systolic dysfunction, mildly overweight with sedation and hypersalivation.	Buscopan.
Bundle branch block right			
Chest pain			
Echocardiogram abnormal			
Ejection fraction			
Electrocardiogram abnormal			
Salivary hypersecretion			
Sedation			
Ventricular dysfunction			

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 12/07/2005	Stopped: 14/11/2006	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/01/2007	Echocardiogram		29/09/2005	normal	
03/01/2007	Echocardiogram		15/01/2006	normal	
03/01/2007	Echocardiogram		26/09/2006	mild global left	
03/01/2007	Electrocardiograph		18/07/2005	normal,	
03/01/2007	Electrocardiograph		25/07/2005	normal,	
03/01/2007	Electrocardiograph		05/10/2006	Incomplete	

Additional Information:

The patient had comorbid amphetamine and marijuana abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224360

Seq: 1

Gender: M

Reported: 03/01/2007

Weight: 0.00

Hospitalisation:

Age: 19

Onset Date: 26/09/2006

DOB: 02/12/1986

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ventricular hypokinesia			
Weight increased			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 12/07/2005	Stopped: 14/11/2006	Contin

Laboratory Investigations:

Additional Information:

The patient had comorbid amphetamine and marijuana abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224362	Seq: 1	Gender: F
Reported: 03/01/2007		Weight: 0.00
Hospitalisation:		Age: 39
Onset Date: 10/11/2006		DOB: 20/02/1967
Outcome: Recovered	23/11/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced myocarditis. Other symptoms included chest pain/discomfort, myalgia, tachycardia, tachyarrhythmia, fever (40 degrees), hypotension and fluctuation blood pressure. Also had increase in troponin level and increased C-reactive protein level.	Ceased using drug. Treated with paracetamol, haloperidol and diazepam.
Back pain	Caused or prolonged inpatient hospitalisation		
Blood pressure fluctuation			

Medicine Details:

NICABATE (Other drug)		Reason:	
Lozenge			Oral
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 30/10/2006	Stopped: 10/11/2006 0	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/01/2007	ALT = SGPT		13/11/2006	79	
03/01/2007	AST = SGOT		13/11/2006	53	
03/01/2007	C-Reactive Protein		14/11/2006	250	
03/01/2007	C-Reactive Protein		15/11/2006	250	
03/01/2007	Erythrocyte		13/11/2006	31	
03/01/2007	GGT = SGGT =		13/11/2006	122	
03/01/2007	SAP = ALP		13/11/2006	150	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224362	Seq: 1	Gender: F
Reported: 03/01/2007		Weight: 0.00
Hospitalisation:		Age: 39
Onset Date: 10/11/2006		DOB: 20/02/1967
Outcome: Recovered	23/11/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
C-reactive protein increased Chest pain Chills	Caused or prolonged inpatient hospitalisation		
Diarrhoea	Caused or prolonged inpatient hospitalisation		
Hypotension Myalgia			

Medicine Details:

NICABATE (Other drug)		Reason:	
Lozenge		Oral	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 30/10/2006	Stopped: 10/11/2006 0	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/01/2007	Troponin		11/11/2006	<0.01	
03/01/2007	Troponin		13/11/2006	0.47	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224362 **Seq:** 1 **Gender:** F
Reported: 03/01/2007 **Weight:** 0.00
Hospitalisation: **Age:** 39
Onset Date: 10/11/2006 **DOB:** 20/02/1967
Outcome: Recovered 23/11/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Tachyarrhythmia Tachycardia Troponin increased Vertigo	Caused or prolonged inpatient hospitalisation		

Medicine Details:

NICABATE (Other drug)	Reason:
Lozenge	Oral
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 30/10/2006 Stopped: 10/11/2006 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224371
Reported: 04/01/2007

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 12/10/2004
Outcome: Recovered

Age: 38
DOB: 07/06/1966
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		The patient experienced agranulocytosis.	

Medicine Details:

CLOPINE (Other drug)	Reason:		
Tablet	Oral		
Batch:	Started:	Stopped:	0
Interferon NOS (Suspected)	Reason:		
Batch:	Started: 01/10/2004	Stopped:	15/10/2005
CLOZARIL (Suspected)	Reason:		
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 02/11/2003	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/01/2007	Neutrophils		02/11/1993	4.6	
04/01/2007	Neutrophils		15/09/2004	3.10	
04/01/2007	Neutrophils		12/10/2004	1.10	
04/01/2007	Neutrophils		24/05/2005	0.46	
04/01/2007	Neutrophils		13/11/2006	2.30	
04/01/2007	Neutrophils		05/12/2005	2.00	
04/01/2007	Neutrophils		10/10/2005	2.70	

Additional Information:

Patient previously been on the generic brand of clozapine, Clopine. Clozapine therapy was started in Nov 1993. Also on Interferon.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224371
Reported: 04/01/2007

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 12/10/2004

Age: 38

Outcome: Recovered

DOB: 07/06/1966

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Other drug)	Reason:		
Tablet	Oral		
Batch:	Started:	Stopped:	0
Interferon NOS (Suspected)	Reason:		
Batch:	Started: 01/10/2004	Stopped:	15/10/2005
CLOZARIL (Suspected)	Reason:		
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 02/11/2003	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/01/2007	Neutrophils		06/06/2005	0.40	
04/01/2007	White blood cells		02/11/1993	8.1	
04/01/2007	White blood cells		15/09/2004	5.0	
04/01/2007	White blood cells		12/10/2004	2.20	
04/01/2007	White blood cells		24/05/2005	1.10	
04/01/2007	White blood cells		06/06/2005	1.10	
04/01/2007	White blood cells		10/10/2005	4.00	

Additional Information:

Patient previously been on the generic brand of clozapine, Clopine. Clozapine therapy was started in Nov 1993. Also on Interferon.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224371
Reported: 04/01/2007

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 12/10/2004

Age: 38

Outcome: Recovered

DOB: 07/06/1966

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Other drug)	Reason:		
Tablet	Oral		
Batch:	Started:	Stopped:	0
Interferon NOS (Suspected)	Reason:		
Batch:	Started: 01/10/2004	Stopped:	15/10/2005
CLOZARIL (Suspected)	Reason:		
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 02/11/2003	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/01/2007	White blood cells		05/12/2005	3.20	
04/01/2007	White blood cells		13/11/2006	3.70	

Additional Information:

Patient previously been on the generic brand of clozapine, Clopine. Clozapine therapy was started in Nov 1993. Also on Interferon.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224380

Seq: 1

Gender: M

Reported: 04/01/2007

Weight: 100.00

Hospitalisation:

Age: 89

Onset Date: 20/10/2006

DOB: 05/10/1917

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Peptic ulcer	Caused or prolonged inpatient hospitalisation	Peptic ulcer causing melaena.	Transfusion
Melaena	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	350.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224398

Seq: 1

Gender: F

Reported: 05/01/2007

Weight: 0.00

Hospitalisation:

Age: 52

Onset Date:

DOB: 04/03/1954

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Left ventricular dysfunction Echocardiogram abnormal		Patient had decreased LV function and cardiac symptoms.	Drug ceased.

Medicine Details:

CLOZAPINE (Suspected)	Reason:	
Batch:	Started: 15/01/1996	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/01/2007	Echocardiogram				Abnormal ECHO results

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224412

Seq: 1

Gender: F

Reported: 08/01/2007

Weight: 0.00

Hospitalisation:

Onset Date: 23/11/2006

Age: 35

DOB: 18/04/1971

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope		Experienced fainting and tachycardia after first dose of Clozaril.and other problems which appeared on day 3	Ceased Clozaril
Dizziness		Lightheadedness	
Sedation		Sleeping 13-14 hours a day	
Tachycardia		from 90 bpm pre-clozapine to 100-110 bpm	
Agitation			
Anxiety			
Asthenia			
Muscular weakness			
Restlessness			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 23/11/2006 Stopped: 30/11/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/01/2007	Other data				Blood Tests
08/01/2007	Other data				Heart Rate

Additional Information:

Blood tests normal. History of tachycardia, especially when anxious or with exercise but never more then 90 bpm.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224414

Seq: 1

Gender: M

Reported: 08/01/2007

Weight: 0.00

Hospitalisation:

Onset Date: 24/11/2006

Age: 30

Outcome: Not yet recovered

DOB: 27/05/1976

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Ten weeks after starting Clozaril the patine experienced cardiomyopathy, disastolic dysfunction, echocardiogram abnormal.	
Diastolic dysfunction			
Echocardiogram abnormal			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	75.0 Milligram Daily Oral
Batch:	Started: 15/09/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/01/2007	Echocardiogram		24/11/2006	mild	

Additional Information:

Medical history; hypertension; suicidal ideation.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224420

Seq: 1

Gender: F

Reported: 08/01/2007

Weight: 0.00

Hospitalisation:

Onset Date: 15/04/1999

Age: 54

DOB: 01/06/1944

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Heart rate irregular		Tachycardia and irregular pulse	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 27/10/1993 Stopped: 20/04/1999 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/01/2007	Albumin		20/05/2004	51 g/L	
08/01/2007	Albumin		13/09/2004	47 g/L	
08/01/2007	Albumin		28/09/2004	49 g/L	
08/01/2007	Chloride		17/12/2004	96 mmol/L	
08/01/2007	Creatine kinase		13/09/2004	26 U/L	
08/01/2007	Creatine kinase		13/09/2004	54% (reference	
08/01/2007	Creatine kinase		03/11/2006	6%	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224420
Reported: 08/01/2007

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 15/04/1999
Outcome: Unknown

Age: 54
DOB: 01/06/1944
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 27/10/1993 Stopped: 20/04/1999 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/01/2007	Creatine		03/11/2006	268 U/L	
08/01/2007	Echocardiogram		02/11/2006	Heart rate of 44 bpm	
08/01/2007	Electrocardiograph		02/11/2006	Sinus	
08/01/2007	Serum glucose		03/11/2006	6.6 mmol/L	Glucose Fast
08/01/2007	Serum glucose		13/09/2004	7.5 mmol/L	Glucose Rand
08/01/2007	Serum glucose		17/12/2004	8.3 mmol/L	Glucose Rand

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224475

Seq: 1

Gender: M

Reported: 09/01/2007

Weight: 0.00

Hospitalisation:

Onset Date: 21/09/2006

Age: 24

Outcome: Unknown

DOB: 07/12/1981

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Patient was receiving Clozaril for an unspecified indication then experienced probable neuroleptic malignant syndrome and Clozaril treatment was ceased.	Treatment was ceased.

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 20/07/2004 Stopped: 20/07/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224478

Seq: 1

Gender: F

Reported: 09/01/2007

Weight: 0.00

Hospitalisation:

Onset Date: 09/11/2006

Age: 51

Outcome: Unknown

DOB: 15/02/1955

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocythaemia		Thrombocytosis,nausea, vomiting, unwell. Suspected infection or inflammation and iron deficiency.	
Malaise			
Nausea			
Vomiting			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 07/06/1995 L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/01/2007	Platelets		09/11/2006	800 x 10 ⁹ /L	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224482

Seq: 1

Gender: M

Reported: 09/01/2007

Weight: 0.00

Hospitalisation:

Onset Date:

Age: 20

Outcome: Unknown

DOB: 11/10/1986

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Choking Dysphagia		Couldn't breath and thought he was going to die,Dysphagia/Severe swallowing difficulties. Also choking on food and water.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224527 **Seq:** 1 **Gender:** M
Reported: 10/01/2007 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: **DOB:** 15/09/1971
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism		Pulmonary embolism	Ceased drug.

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	150.0 Milligram Daily Oral
Batch:	Started: 10/11/2006 Stopped: 29/11/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/01/2007	Neutrophils				
10/01/2007	White blood cells				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224532	Seq: 1	Gender: F
Reported: 10/01/2007		Weight: 0.00
Hospitalisation:		Age: 27
Onset Date: 04/10/2006		DOB: 30/04/1979
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Low neutrophil count.	Hytrin withdrawn, sodium valproate reduced

Medicine Details:

SOLIAN (Other drug)		Reason:	
Tablet	200.0 Milligram		Oral
Batch:	Started:	Stopped:	
CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	650.0 Milligram	Daily	Oral
Batch:	Started: 06/06/1998	Stopped:	
EPILIM (Suspected)		Reason:	
	1.7 Gram	Daily	Oral
Batch:	Started:	Stopped:	
HYTRIN (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 26/09/2006	Stopped: 06/10/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/01/2007	Neutrophils		06/10/2006	1.53	<1.5
10/01/2007	Neutrophils		08/10/2006	2.05	<1.5
10/01/2007	White blood cells		06/10/2006	4.8	
10/01/2007	White blood cells		08/10/2006	6.1	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224547 **Seq:** 1 **Gender:** F
Reported: 10/01/2007 **Weight:** 0.00
Hospitalisation: **Age:** 39
Onset Date: 11/12/2006 **DOB:** 08/11/1967
Outcome: Death 11/12/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Unexplained death.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	550.0 Milligram Daily Oral
Batch:	Started: 21/07/2004 Stopped: 11/12/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

An autopsy was performed with no unusual findings. No inquest will be undertaken.
The patient's white cell and neutrophil counts were generally within normal ranges throughout treatment with Clopine, with occasionally elevated counts.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224556

Seq: 1

Gender: M

Reported: 11/01/2007

Weight: 0.00

Hospitalisation:

Age: 33

Onset Date:

DOB: 27/02/1973

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		The patient experienced convulsions in 2001 not long after starting Clozaril treatment.	Patient commenced Epilim (sodium valporate)

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 08/03/2001 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient commenced Epilim (sodium valproate) treatment and had no seizures since.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224582

Seq: 1

Gender: M

Reported: 11/01/2007

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date: 01/03/2005

DOB: 25/01/1980

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Enuresis		nocturnal enuresis - occured when clozapine increased from 600mg to 650mg	reduction of clozapine dose back to 600mg. symptoms improved since then

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified psychosis		
Tablet	650.0 Milligram	Daily	Oral
Batch:	Started: 10/02/2005	Stopped: 20/05/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Not yet recovered but improved.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224622

Seq: 1

Gender: M

Reported: 12/01/2007

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date: 15/09/2006

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Patient experince episodic tachycardia since commencing on Clozaril for the treatment of Schizophrenia.	
Electrocardiogram normal			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/01/2007	Electrocardiograph				
12/01/2007	Other data		14/11/2006	140 beats per	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224645

Seq: 1

Gender: M

Reported: 15/01/2007

Weight: 0.00

Hospitalisation:

Age: 37

Onset Date:

DOB: 10/10/1969

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Diarrhoea, high temperature while on clozaril.	Clozaril was ceased.
Pyrexia			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 24/10/2006 Stopped: 14/11/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/01/2007	Temperature				Temperature high

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224652

Seq: 1

Gender: M

Reported: 15/01/2007

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date:

DOB: 23/09/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Patient experienced a high heart rate whilst on Clopine.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	800.0 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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224731

Seq: 1

Gender: F

Reported: 16/01/2007

Weight: 0.00

Hospitalisation:

Onset Date: 17/11/2006

Age: 38

DOB: 23/08/1968

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Low neutrophil count.	Ceased Clopine.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	675.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/01/2007	Neutrophils		17/11/2006	1.1	
16/01/2007	Neutrophils		18/11/2006	1.1	
16/01/2007	Neutrophils		19/11/2006	1.9	
16/01/2007	Neutrophils		22/11/2006	2.0	
16/01/2007	Neutrophils		21/11/2006	1.7	
16/01/2007	Neutrophils		20/11/2006	1.4	
16/01/2007	White blood cells		17/11/2006	2.3	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224731

Seq: 1

Gender: F

Reported: 16/01/2007

Weight: 0.00

Hospitalisation:

Age: 38

Onset Date: 17/11/2006

DOB: 23/08/1968

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)

Reason:

Tablet

675.0 Milligram

Daily

Oral

Batch:

Started:

Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/01/2007	White blood cells		18/11/2006	2.5	
16/01/2007	White blood cells		19/11/2006	3.2	
16/01/2007	White blood cells		20/11/2006	2.9	
16/01/2007	White blood cells		21/11/2006	3.1	
16/01/2007	White blood cells		22/11/2006	3.6	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224737
Reported: 16/01/2007

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 19

Onset Date:

DOB: 18/01/1987

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Blood creatine increased C-reactive protein increased Eosinophil count increased Lipase increased Malaise		High pulse rate, raised creatine, CRP, lipase, eosinophils and generally unwell.	Drug ceased

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	225.0 Milligram Daily Oral
Batch:	Started: 10/11/2006 Stopped: 22/11/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224752

Seq: 1

Gender: M

Reported: 17/01/2007

Weight: 0.00

Hospitalisation:

Onset Date: 09/10/2006

Age: 55

Outcome: Unknown

DOB: 24/07/1951

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Low neutrophil and low white blood cell count.	
Leukopenia			

Medicine Details:

INTERFERON ALFA-2B (Other drug)	Reason:		
Batch:	Started:	Stopped:	
RIBAVIRIN (Other drug)	Reason:		
Batch:	Started: 15/08/2006	Stopped:	
SERTRALINE HYDROCHLORIDE (Other drug)	Reason: Depression		
	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CLOPINE (Suspected)	Reason:		
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/01/2007	Neutrophils		09/10/2006	1.3	
17/01/2007	Neutrophils		12/10/2006	1.2	
17/01/2007	Neutrophils		16/10/2006	1.8	
17/01/2007	Neutrophils		26/10/2006	1.3	
17/01/2007	Neutrophils		30/10/2006	2.1	
17/01/2007	Neutrophils		23/10/2006	1.8	
17/01/2007	Neutrophils		19/10/2006	1.6	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224752

Seq: 1

Gender: M

Reported: 17/01/2007

Weight: 0.00

Hospitalisation:

Onset Date: 09/10/2006

Age: 55

Outcome: Unknown

DOB: 24/07/1951

Causality: Causality possible

Reaction Details:

Medicine Details:

INTERFERON ALFA-2B (Other drug)	Reason:		
Batch:	Started:	Stopped:	
RIBAVIRIN (Other drug)	Reason:		
Batch:	Started: 15/08/2006	Stopped:	
SERTRALINE HYDROCHLORIDE (Other drug)	Reason: Depression		
Batch:	100.0 Milligram	Daily	Oral
Started:	Stopped:		
CLOPINE (Suspected)	Reason:		
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/01/2007	Neutrophils		14/11/2006	1.2	
17/01/2007	Neutrophils		20/11/2006	1.4	
17/01/2007	Neutrophils		11/12/2006	4.5	
17/01/2007	Neutrophils		04/12/2006	0.9	
17/01/2007	Neutrophils		30/11/2006	1.5	
17/01/2007	Neutrophils		24/11/2006	0.7	
17/01/2007	Neutrophils		17/11/2006	0.7	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224752
Reported: 17/01/2007

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 09/10/2006
Outcome: Unknown

Age: 55
DOB: 24/07/1951
Causality: Causality possible

Reaction Details:

Medicine Details:

INTERFERON ALFA-2B (Other drug)	Reason:		
Batch:	Started:	Stopped:	
RIBAVIRIN (Other drug)	Reason:		
Batch:	Started: 15/08/2006	Stopped:	
SERTRALINE HYDROCHLORIDE (Other drug)	Reason: Depression		
Batch:	100.0 Milligram	Daily	Oral
Started:	Stopped:		
CLOPINE (Suspected)	Reason:		
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/01/2007	White blood cells		09/10/2006	3.6	
17/01/2007	White blood cells		12/10/2006	3.7	
17/01/2007	White blood cells		16/10/2006	3.3	
17/01/2007	White blood cells		19/10/2006	3.6	
17/01/2007	White blood cells		23/10/2006	4.2	
17/01/2007	White blood cells		26/10/2006	3.0	
17/01/2007	White blood cells		30/10/2006	4.2	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224752

Seq: 1

Gender: M

Reported: 17/01/2007

Weight: 0.00

Hospitalisation:

Onset Date: 09/10/2006

Age: 55

Outcome: Unknown

DOB: 24/07/1951

Causality: Causality possible

Reaction Details:

Medicine Details:

INTERFERON ALFA-2B (Other drug)	Reason:		
Batch:	Started:	Stopped:	
RIBAVIRIN (Other drug)	Reason:		
Batch:	Started: 15/08/2006	Stopped:	
SERTRALINE HYDROCHLORIDE (Other drug)	Reason: Depression		
	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CLOPINE (Suspected)	Reason:		
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/01/2007	White blood cells		14/11/2006	2.8	
17/01/2007	White blood cells		17/11/2006	2.0	
17/01/2007	White blood cells		20/11/2006	2.9	
17/01/2007	White blood cells		24/11/2006	2.6	
17/01/2007	White blood cells		30/11/2006	3.1	
17/01/2007	White blood cells		04/12/2006	2.2	
17/01/2007	White blood cells		11/12/2006	6.5	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224758

Seq: 1

Gender: F

Reported: 17/01/2007

Weight: 0.00

Hospitalisation:

Age: 49

Onset Date:

DOB: 14/04/1957

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes mellitus	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 05/04/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224764

Seq: 1

Gender: M

Reported: 17/01/2007

Weight: 0.00

Hospitalisation:

Onset Date: 18/11/2006

Age: 24

DOB: 18/03/1982

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient commenced treatment with Clopine when he died from unknown reasons.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	450.0 Milligram Daily Oral
Batch:	Started: 20/03/2006 Stopped: 18/11/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224829

Seq: 1

Gender: M

Reported: 18/01/2007

Weight: 0.00

Hospitalisation:

Age: 33

Onset Date:

DOB: 25/04/1973

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic steatosis Blood glucose increased Liver function test abnormal Ultrasound liver abnormal		Patient developed elevated LFTs and blood glucose and fatty liver.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 15/10/2001	Stopped: 13/02/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/01/2007	Ultrasound				

Additional Information:

Patient's alcohol consumption may also be contributing to the increased LFTs and fatty liver.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224830

Seq: 1

Gender: M

Reported: 18/01/2007

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date:

DOB: 09/01/1973

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia		Experienced cardiac arrhythmia.	Ceased Clozaril

Medicine Details:

CLOZARIL (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 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224849

Seq: 1

Gender: M

Reported: 18/01/2007

Weight: 87.90

Hospitalisation:

Onset Date: 29/11/2006

Age: 35

DOB: 15/09/1971

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism		Developed chest pain and shortness of breath. Pulmonary embolism.	Clexane and Warfarin
Chest pain			
Dyspnoea			

Medicine Details:

CLOZAPINE (Other drug)	Reason:	
Batch:	Started:	Stopped:
RABEPRAZOLE SODIUM (Other drug)	Reason:	
Batch:	Started:	Stopped:
LAMOTRIGINE (Other drug)	Reason:	
Batch:	Started:	Stopped:
OLANZAPINE (Other drug)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/01/2007	Other data				VQ Scan

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224849 **Seq:** 1
Reported: 18/01/2007

Gender: M
Weight: 87.90

Hospitalisation:

Onset Date: 29/11/2006
Outcome: Not yet recovered

Age: 35
DOB: 15/09/1971
Causality: Causality possible

Reaction Details:

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZAPINE (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 13/11/2006	Stopped: 29/11/2006	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224866	Seq: 1	Gender: M
Reported: 19/01/2007		Weight: 0.00
Hospitalisation:		Age: 50
Onset Date: 20/12/2006		DOB: 11/01/1956
Outcome: Recovered	12/01/2007	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation		When dose was increased to 200mg patient developed severe constipation, ankle oedema, hypersalivation, lethargy, nausea, and collapsed once. Also developed recurrent pyrexias of varying duration. Drug was stopped for two days when patient became more alert and physically more settled. Restarted again at 25mg d, then 50mg d but physical symptoms commenced to recur again. Clozapine was ceased on 10/01/07.	Clozapine withdrawn, Lactulose
Circulatory collapse			
Lethargy			

Medicine Details:

RAMIPRIL (Other drug)	Reason: Essential benign hypertension
5.0 Milligram	Daily Oral
Batch:	Started: 01/11/2006 Stopped:
SODIUM VALPROATE (Other drug)	Reason:
1.5 Gram	Daily
Batch:	Started: L TERM Stopped:
CLOZAPINE (Suspected)	Reason: Unspecified psychosis
200.0 Milligram	Daily Oral
Batch:	Started: 11/12/2006 Stopped: 10/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224866 **Seq:** 1 **Gender:** M
Reported: 19/01/2007 **Weight:** 0.00
Hospitalisation: **Age:** 50
Onset Date: 20/12/2006 **DOB:** 11/01/1956
Outcome: Recovered 12/01/2007 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea			
Oedema peripheral			
Pyrexia			
Salivary hypersecretion			

Medicine Details:

RAMIPRIL (Other drug)	Reason: Essential benign hypertension
5.0 Milligram Daily Oral	
Batch:	Started: 01/11/2006 Stopped:
SODIUM VALPROATE (Other drug)	Reason:
1.5 Gram Daily	
Batch:	Started: L TERM Stopped:
CLOZAPINE (Suspected)	Reason: Unspecified psychosis
200.0 Milligram Daily Oral	
Batch:	Started: 11/12/2006 Stopped: 10/01/2007

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224881

Seq: 1

Gender: M

Reported: 19/01/2007

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date:

DOB: 30/11/1964

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Took Clopine and experienced Tachycardia. Heart was reaching very high.	

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 28/11/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/01/2007	Other data		01/01/2006	145 beats per	Heart Rate
19/01/2007	Other data		01/12/2006	90-120 beats	Heart Rate

Additional Information:

White cell count and neutrophil counts were within normal range during treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224893

Seq: 1

Gender: M

Reported: 22/01/2007

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date:

DOB: 30/12/1964

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Took Clopine and experienced Tachycardia,	

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 28/11/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224910

Seq: 1

Gender: F

Reported: 22/01/2007

Weight: 0.00

Hospitalisation:

Age: 35

Onset Date:

DOB: 19/07/1971

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pericardial effusion		Patient was taking Clozaril and experienced pericardial effusion. Clozaril was discontinued.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 24/11/2006 Stopped: 18/12/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224915

Seq: 1

Gender: F

Reported: 22/01/2007

Weight: 0.00

Hospitalisation:

Onset Date: 07/12/2006

Age: 29

DOB: 06/02/1977

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased		Remarkable rise in the serum level of clozapine.	Clozaril dose reduced.

Medicine Details:

FLUVOXAMINE MALEATE (Interaction)	Reason:		
Tablet	Oral		
Batch:	Started:	Stopped: 15/11/2006	
CLOZARIL (Interaction)	Reason: Unspecified schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 23/04/1999	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient suffered from treatment-resistant schizophrenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224922

Seq: 1

Gender: F

Reported: 22/01/2007

Weight: 0.00

Hospitalisation:

Onset Date: 07/12/2006

Age: 29

DOB: 06/02/1977

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis, tachycardia, white blood cell count decreased, neutrophil decreased.	
Tachycardia			
White blood cell count decreased			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 23/04/1999	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/01/2007	Electrocardiograph				(07 Dec 2006) ECG: normal sinus rhythm. (07 Dec 2006) ECG: normal ECG.
22/01/2007	Neutrophils		23/04/1999	3.5	
22/01/2007	Neutrophils		27/11/2006	2.01	
22/01/2007	Neutrophils		07/12/2006	1.83	
22/01/2007	Neutrophils		05/12/2006	1.74	
22/01/2007	Other data				07 Dec 2006 Pulse rate:118/minute

Additional Information:

The consultant psychiatrist was seeking advice of the consultant haematologist regarding the possibility of early stage of myocarditis in this patient.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224922

Seq: 1

Gender: F

Reported: 22/01/2007

Weight: 0.00

Hospitalisation:

Onset Date: 07/12/2006

Age: 29

Outcome: Unknown

DOB: 06/02/1977

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram
	Daily
	Oral
Batch:	Started: 23/04/1999
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/01/2007	Serum drug level				(Date not specified) clozapine level: 2800 (Date not specified) clozapine level: 2970 (Date not specified) clozapine level: 1300 (1 week after 1480 result), (3 weeks after 2970).
22/01/2007	White blood cells		23/04/1999	5.4	
22/01/2007	White blood cells		27/11/2006	3.90	
22/01/2007	White blood cells		05/12/2006	3.30	

Additional Information:

The consultant psychiatrist was seeking advice of the consultant haematologist regarding the possibility of early stage of myocarditis in this patient.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224922

Seq: 1

Gender: F

Reported: 22/01/2007

Weight: 0.00

Hospitalisation:

Age: 29

Onset Date: 07/12/2006

DOB: 06/02/1977

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Unspecified schizophrenia

Tablet

400.0 Milligram

Daily

Oral

Batch:

Started: 23/04/1999

Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/01/2007	White blood cells		07/12/2006	3.20	

Additional Information:

The consultant psychiatrist was seeking advice of the consultant haematologist regarding the possibility of early stage of myocarditis in this patient.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224924	Seq: 1	Gender: M
Reported: 22/01/2007		Weight: 113.60
Hospitalisation:		
Onset Date: 23/11/2006		Age: 25
Outcome: Recovered	02/12/2006	DOB: 11/02/1981
		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Patient experienced Lucopenia and Neutropenia.	Clozapine ceased.
Neutropenia			

Medicine Details:

FERROUS SULPHATE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
GEMFIBROZIL (Other drug)	Reason: Othr&unspec metabolic diseases
	1.2 Gram Daily Oral
Batch:	Started:
Batch:	Stopped:
HALOPERIDOL (Other drug)	Reason: Othr&unspec metabolic diseases
	15.0 Milligram Daily Oral
Batch:	Started:
Batch:	Stopped:
METOPROLOL TARTRATE (Other drug)	Reason: Essential benign hypertension
Tablet	50.0 Milligram Daily Oral
Batch:	Started:
Batch:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/01/2007	Neutrophils		16/11/2006	2.91	
22/01/2007	Neutrophils		21/11/2006	3.01	
22/01/2007	Neutrophils		23/11/2006	2.91	
22/01/2007	Neutrophils		30/11/2006	1.5	
22/01/2007	Neutrophils		01/12/2006	1.2	
22/01/2007	Neutrophils		27/11/2006	3.8	
22/01/2007	Neutrophils		24/11/2006	2.0	

Additional Information:

The patient had previously experienced leucopenia and neutropenia in June 2005 and Clopine (clozapine) was withheld during this period until patient recovered.
 History: previous history of drug abuse (amphetamine/THC), smoking 15 cigarettes/day, no known drug allergy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224924

Seq: 1

Gender: M

Reported: 22/01/2007

Weight: 113.60

Hospitalisation:

Onset Date: 23/11/2006

Age: 25

DOB: 11/02/1981

Outcome: Recovered

02/12/2006

Causality: Causality probable

Reaction Details:

Medicine Details:

CLOPINE (Suspected)

Reason: Unspecified schizophrenia

Tablet

550.0 Milligram

Daily

Oral

Batch:

Started: 09/12/2002

Stopped: 01/12/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/01/2007	Neutrophils		02/12/2006	2.5	
22/01/2007	Neutrophils		04/12/2006	5.44	
22/01/2007	Neutrophils		03/12/2006	3.7	
22/01/2007	White blood cells		24/11/2006	3.2	
22/01/2007	White blood cells		27/11/2006	4.6	
22/01/2007	White blood cells		30/11/2006	2.5	
22/01/2007	White blood cells		01/12/2006	2.0	

Additional Information:

The patient had previously experienced leucopenia and neutropenia in June 2005 and Clopine (clozapine) was withheld during this period until patient recovered.

History: previous history of drug abuse (amphetamine/THC), smoking 15 cigarettes/day, no known drug allergy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224924

Seq: 1

Gender: M

Reported: 22/01/2007

Weight: 113.60

Hospitalisation:

Onset Date: 23/11/2006

Age: 25

DOB: 11/02/1981

Outcome: Recovered

02/12/2006

Causality: Causality probable

Reaction Details:

Medicine Details:

Medicine Name	Reason
FERROUS SULPHATE (Other drug)	
Batch:	Started:
Stopped:	
GEMFIBROZIL (Other drug)	Reason: Othr&unspec metabolic diseases
Batch:	Started: 1.2 Gram Daily
Stopped: Oral	
HALOPERIDOL (Other drug)	Reason: Othr&unspec metabolic diseases
Batch:	Started: 15.0 Milligram Daily
Stopped: Oral	
METOPROLOL TARTRATE (Other drug)	Reason: Essential benign hypertension
Tablet	Started: 50.0 Milligram Daily
Batch:	Stopped: Oral

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/01/2007	White blood cells		02/12/2006	3.7	
22/01/2007	White blood cells		03/12/2006	4.7	

Additional Information:

The patient had previously experienced leucopenia and neutropenia in June 2005 and Clopine (clozapine) was withheld during this period until patient recovered.

History: previous history of drug abuse (amphetamine/THC), smoking 15 cigarettes/day, no known drug allergy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224924

Seq: 1

Gender: M

Reported: 22/01/2007

Weight: 113.60

Hospitalisation:

Age: 25

Onset Date: 23/11/2006

DOB: 11/02/1981

Outcome: Recovered

02/12/2006

Causality: Causality probable

Reaction Details:

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	550.0 Milligram
	Daily
	Oral
Batch:	Started: 09/12/2002
	Stopped: 01/12/2006 0

Laboratory Investigations:

Additional Information:

The patient had previously experienced leucopenia and neutropenia in June 2005 and Clopine (clozapine) was withheld during this period until patient recovered.

History: previous history of drug abuse (amphetamine/THC), smoking 15 cigarettes/day, no known drug allergy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 224931

Seq: 1

Gender: M

Reported: 22/01/2007

Weight: 0.00

Hospitalisation:

Age: 48

Onset Date: 15/11/2006

DOB: 16/09/1958

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension		Developed a sudden onset of hypertension, whilst on Clozaril.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Batch:	Started: 14/11/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225000

Seq: 1

Gender: F

Reported: 24/01/2007

Weight: 0.00

Hospitalisation:

Onset Date:

Age: 39

Outcome: Unknown

DOB: 31/07/1967

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Blood pressure decreased Confusional state Malaise		Tachycardia, Blood pressure decreased, confusion, feeling unwell.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 16/11/2006 Stopped: 04/12/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2007	Neutrophils				Neutrophils count was within the normal ranges during Clopine treatment.
24/01/2007	White blood cells				White cell count was within the normal ranges during Clopine treatment.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225037 **Seq:** 1 **Gender:** F
Reported: 24/01/2007 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 28
Onset Date: 09/12/2006 **DOB:** 23/05/1978
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Accidental overdose	Caused or prolonged inpatient hospitalisation	Patient was receiving Clozaril and took 1600mg. Patient was admitted hospital and monitored. Patient was not showing much drowsiness	
Antipsychotic drug level increased	Caused or prolonged inpatient hospitalisation		
Incorrect dose administered	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 29/09/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2007	Serum drug level		10/12/2006	clozapine leve	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225037 **Seq:** 1 **Gender:** F
Reported: 24/01/2007 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 28
Onset Date: 09/12/2006 **DOB:** 23/05/1978
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 29/09/2006 Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225051	Seq: 1	Gender: F
Reported: 24/01/2007		Weight: 0.00
Hospitalisation:		Age: 48
Onset Date:		DOB: 03/02/1958
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anaemia		Patient was receiving Clozaril for the treatment of Schizophrenia and experinced anaemia and discontinued Clozaril treatment. Patient was also taking sodium valproate, banzodiazepine and panadol.	

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram Daily
Batch:	Started: 24/11/2006
	Stopped: 16/12/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225054

Seq: 1

Gender: M

Reported: 24/01/2007

Weight: 0.00

Hospitalisation:

Onset Date: 14/12/2006

Age: 44

Outcome: Unknown

DOB: 01/01/1962

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose		Overdose of Clozaril.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	450.0 Milligram Daily
Batch:	Started: 24/12/2005 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225060	Seq: 1	Gender: F
Reported: 24/01/2007		Weight: 0.00
Hospitalisation:		Age: 63
Onset Date:		DOB: 25/05/1943
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dehydration		Dehydration, confusion, alcohol withdrawal. Patient was receiving multiple therapy.	
Alcohol withdrawal syndrome			
Antipsychotic drug level increased			
Confusional state			
Sedation			

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)	Reason:
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason:
Tablet	250.0 Milligram Daily
Batch:	Started: 24/04/2004
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2007	Serum drug level				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225068

Seq: 1

Gender: F

Reported: 24/01/2007

Weight: 0.00

Hospitalisation:

Age: 0

Onset Date:

DOB: 04/01/2007

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient developed increased troponin levels, fever	
Pyrexia			
Troponin increased			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	225.0 Milligram Daily
Batch:	Started: 16/11/2006 Stopped: 03/12/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2007	Troponin				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225071	Seq: 1	Gender: M
Reported: 24/01/2007		Weight: 0.00
Hospitalisation:		Age: 22
Onset Date:		DOB: 26/02/1984
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation	Blood creatine phosphokinase increased, myoglobin blood increased, blood prolactin increased, increased drowsiness and non compliance with treatment.	Clozaril ceased.
Blood prolactin increased	Caused or prolonged inpatient hospitalisation		
Myoglobin blood increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUPENTHIXOL DECANOATE (Other drug)	Reason:
Batch:	Started: Stopped:
RISPERIDONE (Other drug)	Reason:
Batch:	Started: Stopped:
BENZTROPINE MESYLATE (Other drug)	Reason:
Batch:	Started: Stopped:
DIAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2007	Other data	<200 U/L	10/04/2006	31400 U/L	Creatine Kinase (CK)
24/01/2007	Other data	<200 U/L	26/10/2006	418 U/L	Creatine Kinase (CK)
24/01/2007	Other data	<200 U/L	02/11/2006	906 U/L	Creatine Kinase (CK)
24/01/2007	Other data	<200 U/L	07/11/2006	1180 U/L	Creatine Kinase (CK)
24/01/2007	Other data	<200 U/L	07/11/2006	1030 U/L	Creatine Kinase (CK)

Additional Information:

HISTORY OF LARGACTIL AND BENZTROPINE OVERDOSE; RHABDOMYOLYSIS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225071
Reported: 24/01/2007

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 22

Onset Date:

DOB: 26/02/1984

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		
Treatment noncompliance	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	125.0 Milligram
	Daily
	Oral
Batch:	Started: 14/08/2002
	Stopped: 18/08/2004

Laboratory Investigations:

Additional Information:

HISTORY OF LARGACTIL AND BENZTROPINE OVERDOSE; RHABDOMYOLYSIS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225073

Seq: 1

Gender: F

Reported: 24/01/2007

Weight: 0.00

Hospitalisation:

Age: 27

Onset Date: 07/08/2006

DOB: 28/04/1979

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 04/06/1999	Stopped: 09/08/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2007	Neutrophils		09/08/2006	1.50 x 10 ⁹ /L	
24/01/2007	Neutrophils		07/07/2006	3.10 x 10 ⁹ /L	
24/01/2007	White blood cells		11/08/2006	3.90 x 10 ⁹ /L	
24/01/2007	White blood cells		09/08/2006	2.90 x 10 ⁹ /L	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225085

Seq: 1

Gender: M

Reported: 25/01/2007

Weight: 100.00

Hospitalisation:

Onset Date: 09/11/2006

Age: 33

Outcome: Unknown

DOB: 07/02/1973

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ventricular dysfunction		Low normal left ventricular function. Taking Clozaril for schizophrenia.	
Electrocardiogram abnormal			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 28/11/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/01/2007	Echocardiogram		06/03/2006	normal left	
25/01/2007	Echocardiogram		09/11/2006	normal LV size	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225179

Seq: 1

Gender: M

Reported: 30/01/2007

Weight: 0.00

Hospitalisation:

Age: 37

Onset Date:

DOB: 15/12/1969

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia		Patient commenced Clozaril and was diagnosed with hyperglycaemia.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 19/09/2001 Stopped: 10/12/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225182

Seq: 1

Gender: F

Reported: 30/01/2007

Weight: 0.00

Hospitalisation:

Onset Date: 12/12/2006

Age: 46

Outcome: Unknown

DOB: 18/11/1960

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain		Chest pain.	

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 24/07/2001	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225211
Reported: 30/01/2007

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 13/12/2006
Outcome: Unknown

Age: 41
DOB: 11/11/1965
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Was receiving Clopine and experinced, Neutropenia and Leucopenia.	
Leukopenia			

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 26/10/2006 L TERM Stopped: 14/12/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/01/2007	Neutrophils		15/11/2006	5.5	300mg Dose at 15/11/06
30/01/2007	Neutrophils		13/12/2006	1.0	300mg Dose at 15/11/06
30/01/2007	Neutrophils		15/12/2006	1.1	300mg Dose at 15/11/06
30/01/2007	Neutrophils		14/12/2006	0.9	300mg Dose at 15/11/06
30/01/2007	White blood cells	X 10 ⁹ /L	15/11/2006	7.7	300mg Dose at 15/11/06
30/01/2007	White blood cells	X 10 ⁹ /L	13/12/2006	2.9	300mg Dose at 15/11/06
30/01/2007	White blood cells	X 10 ⁹ /L	14/12/2006	3.0	300mg Dose at 15/11/06

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225211
Reported: 30/01/2007

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 13/12/2006
Outcome: Unknown

Age: 41
DOB: 11/11/1965
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 26/10/2006 L TERM Stopped: 14/12/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/01/2007	White blood cells	X 10 ⁹ /L	15/12/2006	3.2	300mg Dose at 15/11/06

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225246
Reported: 31/01/2007

Seq: 1

Gender: F
Weight: 87.00

Hospitalisation:

Onset Date: 20/12/2006
Outcome: Unknown

Age: 78
DOB: 19/12/1928
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation	Patient presented with tachycardia (130 bpm), dyspnoea (described as moderate in severity) when walking, orthopnea, chest pain.	Clopine ceased.
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Orthopnoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug)	Reason:
Tablet 1.5 Gram	Oral
Batch:	Started: Stopped:
METOPROLOL TARTRATE (Other drug)	Reason:
Batch:	Started: Stopped:
CHLORPROMAZINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
SODIUM VALPROATE (Other drug)	Reason: Unspecified schizophrenia
1.0 Gram	Daily Oral
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
31/01/2007	C-Reactive Protein		28/12/2006	<9	
31/01/2007	Calcium		28/12/2006	Normal	
31/01/2007	Cholesterol		29/12/2006	5.3	
31/01/2007	Creatinine		29/12/2006	Normal	
31/01/2007	Echocardiogram		15/12/2006	Normal	
31/01/2007	Haematology				FBC 28/12/2006 Normal.
31/01/2007	High density		29/12/2006	1	

Additional Information:

History: diabetes mellitus type 11, polycystic ovaries, obesity, newly diagnosed hypertension, high cholesterol and is a current smoker of approximately 15 cigarettes per day. Clopine use approx. 1 year with no problems.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225246	Seq: 1	Gender: F
Reported: 31/01/2007		Weight: 87.00
Hospitalisation:		Age: 78
Onset Date: 20/12/2006		DOB: 19/12/1928
Outcome: Unknown		Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 16/11/2005 Stopped: 28/12/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
31/01/2007	International		28/12/2006	1.1	Neutrophil counts have been slightly elevated on occasions throughout the treatment period reaching a maximum 10.1 x 10 ⁹ /L.
31/01/2007	LDH		29/12/2006	1.8	
31/01/2007	Liver function tests		28/12/2006	Normal	
31/01/2007	Neutrophils				
31/01/2007	Other data				
					UEC 29/12/2006 Normal.

Additional Information:

History: diabetes mellitus type 11, polycystic ovaries, obesity, newly diagnosed hypertension, high cholesterol and is a current smoker of approximatley 15 cigarettes per day. Clopine use approx. 1 year with no problems.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225246

Seq: 1

Gender: F

Reported: 31/01/2007

Weight: 87.00

Hospitalisation:

Onset Date: 20/12/2006

Age: 78

Outcome: Unknown

DOB: 19/12/1928

Causality: Causality possible

Reaction Details:

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug)	Reason:
Tablet 1.5 Gram	Oral
Batch:	Started: Stopped:
METOPROLOL TARTRATE (Other drug)	Reason:
Batch:	Started: Stopped:
CHLORPROMAZINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
SODIUM VALPROATE (Other drug)	Reason: Unspecified schizophrenia
1.0 Gram	Daily Oral
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
31/01/2007	Triglyceride		29/12/2006	5.4	
31/01/2007	White blood cells				White blood cells have been slightly elevated on occasions throughout the treatment period reaching a maximum 16.2 x 10 ⁹ /L.

Additional Information:

History: diabetes mellitus type 11, polycystic ovaries, obesity, newly diagnosed hypertension, high cholesterol and is a current smoker of approximately 15 cigarettes per day. Clopine use approx. 1 year with no problems.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225246

Seq: 1

Gender: F

Reported: 31/01/2007

Weight: 87.00

Hospitalisation:

Age: 78

Onset Date: 20/12/2006

DOB: 19/12/1928

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 16/11/2005	Stopped: 28/12/2006	

Laboratory Investigations:

Additional Information:

History: diabetes mellitus type 11, polycystic ovaries, obesity, newly diagnosed hypertension, high cholesterol and is a current smoker of approximatley 15 cigarettes per day. Clopine use approx. 1 year with no problems.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225247

Seq: 1

Gender: F

Reported: 31/01/2007

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		- Agranulocytosis	

Medicine Details:

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

SEROQUEL (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
31/01/2007	Neutrophils		28/12/2006	1.3	Baseline with clozapine and before Seroquel: 2.9
31/01/2007	Neutrophils		09/01/2007	1.3	Baseline with clozapine and before Seroquel: 2.9
31/01/2007	Neutrophils		19/01/2007	1.2	Baseline with clozapine and before Seroquel: 2.9

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225267

Seq: 1

Gender: M

Reported: 01/02/2007

Weight: 0.00

Hospitalisation:

Age: 53

Onset Date:

DOB: 21/04/1953

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine increased		Blood creatine increased	Ceased Clopine

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient's white cell and neutrophil counts were within normal ranges throughout treatment with Clopine (clozapine), with only a single elevated white count reported.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225270	Seq: 1	Gender: M
Reported: 01/02/2007		Weight: 0.00
Hospitalisation:		Age: 40
Onset Date:		DOB: 23/02/1966
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Blood creatine phosphokinase incr Bundle branch block right Dilatation atrial Echocardiogram abnormal		Cardiomyopathy, ventricular hypertrophy, dilatation atrial, sinus tachycardia, incomplete bundle branch block right, blood creatine phosphokinase increased, electrocardiogram abnormal, electrocardiogram repolarisation abnormality, echocardiogram abnormal, hypertension.	

Medicine Details:

Aripiprazole (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason:
Tablet	950.0 Milligram Daily Oral
Batch:	Started: 09/09/1996
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/02/2007	Creatinine	(40-200)	27/12/2006	204	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225270
Reported: 01/02/2007

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 40

Onset Date:

DOB: 23/02/1966

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal Electrocardiogram repolarisation a Sinus tachycardia Ventricular hypertrophy			

Medicine Details:

Aripiprazole (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	950.0 Milligram	Daily	Oral
Batch:	Started: 09/09/1996	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/02/2007	Echocardiogram				22 Nov 2004 Echocardiogram left ventricle of normal size with mild hypertrophy. Overall systolic function is normal with no regional wall motion abnormalities detected. The left atrium is moderately dilated. The right heart is of normal size and function. The aortic valve is trileaflet. 05 Oct 2006 Echocardiogram: Normal left ventricular size and ...

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225270
Reported: 01/02/2007

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 40

DOB: 23/02/1966

Causality: Causality possible

Reaction Details:

Medicine Details:

Aripiprazole (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	950.0 Milligram	Daily	Oral
Batch:	Started: 09/09/1996	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
					... systolic function. Borderline left ventricular hypertrophy. Normal right ventricular size and function. Moderate enlarged left atrium. Normal size right atrium. Normal right ventricular size and function. Morphologically normal trileaflet aortic valve. Morphologically normal mitral and tricuspid valves. Estimated pulmonary artery pressure 19mmHg + right atrium pressure. Normal pulmonary ...

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225270	Seq: 1	Gender: M
Reported: 01/02/2007		Weight: 0.00
Hospitalisation:		Age: 40
Onset Date:		DOB: 23/02/1966
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Medicine Details:

Aripiprazole (Other drug)	Reason:
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason:
Tablet	950.0 Milligram
	Daily
	Oral
Batch:	Started: 09/09/1996
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/02/2007	Electrocardiograph				... Doppler profile. 19 Dec 2006 Echocardiogram: Left ventricular hypertrophy. 27 Dec 2006 Electrocardiogram: Sinus tachycardia. left atrial abnormality, R-Transition zone in ventricle leads displaced to the right incomplete right bundle block. Left ventricular hypertrophy repolarisation abnormality. Ischaemia cannot be excluded.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225270

Seq: 1

Gender: M

Reported: 01/02/2007

Weight: 0.00

Hospitalisation:

Age: 40

Onset Date:

DOB: 23/02/1966

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

Aripiprazole (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	950.0 Milligram	Daily	Oral
Batch:	Started: 09/09/1996	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/02/2007	Troponin	(<0.03)	27/12/2006	<0.03	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225272	Seq: 1	Gender: M
Reported: 01/02/2007		Weight: 0.00
Hospitalisation:		Age: 60
Onset Date:		DOB: 09/05/1946
Outcome: Death	03/01/2007	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis C	Death	Hepatitis C, Type II Diabetes Mellitus.	
Diabetes mellitus non-insulin-depe	Death		

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	275.0 Milligram Daily Oral
Batch:	Started: 10/07/2006 Stopped: 03/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225275 **Seq:** 1 **Gender:** M
Reported: 01/02/2007 **Weight:** 0.00
Hospitalisation: **Age:** 44
Onset Date: 19/12/2006 **DOB:** 10/03/1962
Outcome: Death 19/12/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Unexplained death.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 17/04/2006 Stopped: 19/12/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225291

Seq: 1

Gender: M

Reported: 01/02/2007

Weight: 0.00

Hospitalisation:

Age: 63

Onset Date:

DOB: 17/07/1943

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Fever of 37.9.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	475.0 Milligram Daily Oral
Batch:	Started: 01/11/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225342 **Seq:** 1 **Gender:** F
Reported: 02/02/2007 **Weight:** 0.00
Hospitalisation: **Age:** 49
Onset Date: **DOB:** 07/07/1957
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis	Drug ceased

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 29/09/2006	Stopped:	05/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225383

Seq: 1

Gender: F

Reported: 05/02/2007

Weight: 0.00

Hospitalisation:

Age: 23

Onset Date:

DOB: 09/11/1983

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis Eosinophilia		Myocarditis and Eosinophilia	Ceased drug

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 19/10/2004 Stopped: 02/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225393	Seq: 1	Gender: F
Reported: 05/02/2007		Weight: 0.00
Hospitalisation:		Age: 99u
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Developed agranulocytosis and redness while taking clozapine. Switched to Seroquel - neutrophil count still low but better than with clozapine	
Erythema			

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Batch:	Started:
	Stopped:
SEROQUEL (Suspected)	Reason:
Tablet	Oral
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225629

Seq: 1

Gender: M

Reported: 09/02/2007

Weight: 0.00

Hospitalisation:

Age: 57

Onset Date:

DOB: 11/08/1949

Outcome: Unknown

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug interaction Antipsychotic drug level increased Convulsion		Seizures after several years without any seizures, increase in clozapine levels.	

Medicine Details:

EFEXOR (Suspected)	Reason:		
225.0 Milligram			
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 22/02/1995	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/02/2007	Serum drug level				Clozapine level:600 (dose and reference range not provided). (unknown date) clozapine level:400.

Additional Information:

Therapeutic threshold for clozapine plasma, through levels are 350-400ng/L.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225655 **Seq:** 1 **Gender:** M
Reported: 12/02/2007 **Weight:** 0.00
Hospitalisation: **Age:** 50
Onset Date: **DOB:** 06/08/1956
Outcome: Unknown **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia		Akathisia.	Ceased Clopine.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	75.0 Milligram Daily Oral
Batch:	Started: 10/11/2006 Stopped: 18/11/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/02/2007	Neutrophils				Neutrophil counts were all within normal ranges.
12/02/2007	White blood cells				White blood cell counts were all within normal ranges.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225662	Seq: 1	Gender: M
Reported: 12/02/2007		Weight: 129.00
Hospitalisation:		Age: 41
Onset Date: 17/01/2007		DOB: 13/12/1965
Outcome: Death		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	The patient commenced treatment with clozapine on 01/07/2000 and switched to Clopine in 14/10/05. The patient died on 17/01/07. The cause of death is suspected as being due to natural causes.	

Medicine Details:

DIAMICRON (Other drug)	Reason:
30.0 Milligram	
Batch:	Started: Stopped:
METFORMIN HYDROCHLORIDE (Other drug)	Reason: Diabetes mellitus
1.0 Gram	Daily
Batch:	Started: Stopped:
LIPITOR (Other drug)	Reason: Othr&unspec metabolic diseases
10.0 Milligram	Daily Oral
Batch:	Started: 27/11/2006 Stopped: 0
CLOPINE (Suspected)	Reason:
Tablet 350.0 Milligram	Daily Oral
Batch:	Started: 14/10/2005 Stopped: 17/01/2007 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/02/2007	Neutrophils				Neutrophils counts were within normal range.
12/02/2007	White blood cells				White cell counts were within normal range.

Additional Information:

History of diabetes mellitus and high cholesterol for which the patient was non-compliant with medications.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225665	Seq: 1	Gender: M
Reported: 12/02/2007		Weight: 0.00
Hospitalisation:		Age: 42
Onset Date: 12/12/2006		DOB: 17/07/1964
Outcome: Unknown		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pericardial effusion	Life threatening	Patient experienced preicardial effusion, chest pain and difficulty breathing.	Patient ceased Clozaril, started Olanzapine.
Chest pain	Life threatening		
Dyspnoea	Life threatening		
Neutrophil count increased	Life threatening		
White blood cell count increased	Life threatening		

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 13/11/2006	Stopped: 04/01/2007	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/02/2007	Neutrophils		19/01/2007	10.5	
12/02/2007	White blood cells		19/01/2007	14.2	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225688

Seq: 1

Gender: M

Reported: 12/02/2007

Weight: 0.00

Hospitalisation:

Age: 40

Onset Date:

DOB: 04/08/1966

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Cardiac disorder	Ceased Clopine.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 28/11/2006 Stopped: 18/12/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225724

Seq: 1

Gender: F

Reported: 12/02/2007

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date: 15/12/2006

DOB: 14/09/1972

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Antipsychotic drug level increased		Patient was found to have elevated Clozaril levels of 1760.	

Medicine Details:

CAFFEINE (Interaction)		Reason:	
Batch:	Started:	Stopped:	Oral 0
CLOZARIL (Interaction)		Reason: Unspecified schizophrenia	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 30/10/1996	Stopped:	22/09/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225725	Seq: 1	Gender: M
Reported: 12/02/2007		Weight: 0.00
Hospitalisation:		Age: 22
Onset Date: 04/12/2006		DOB: 31/08/1984
Outcome: Recovered	08/12/2006	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased	Caused or prolonged inpatient hospitalisation	Patient experienced weight gain and severe sedation.	Clopine withdrawn. Patient intubated and remained in ICU.
Sedation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Escitalopram (Other drug)	Reason:
20.0 Milligram	
Batch:	Started: Stopped:
FLUOXETINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
Metoprolol Succinate (Other drug)	Reason:
Batch:	Started: Stopped:
ALPRAZOLAM (Suspected)	Reason: Anxiety neurosis
Tablet	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient has a history of obesity, alcohol abuse, benzodiazepine abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225725

Seq: 1

Gender: M

Reported: 12/02/2007

Weight: 0.00

Hospitalisation:

Age: 22

Onset Date: 04/12/2006

DOB: 31/08/1984

Outcome: Recovered

08/12/2006

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified psychosis		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 05/10/2006	Stopped: 12/12/2006	
OLANZAPINE (Suspected)	Reason: Unspecified psychosis		
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

The patient has a history of obesity, alcohol abuse, benzodiazepine abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225728

Seq: 1

Gender: M

Reported: 13/02/2007

Weight: 0.00

Hospitalisation:

Age: 48

Onset Date:

DOB: 15/06/1958

Outcome: Unknown

Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 30/12/2006 Stopped: 19/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225750

Seq: 1

Gender: M

Reported: 13/02/2007

Weight: 0.00

Hospitalisation:

Age: 21Y

Onset Date: 19/11/2006

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Grand mal siezure lasting 4 minutes.	Clozapine dose reduced, commenced sodium valproate.
Drug level increased			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
800.0 Milligram	Daily
Batch:	Started: 08/02/2006
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225758

Seq: 1

Gender: M

Reported: 13/02/2007

Weight: 0.00

Hospitalisation:

Onset Date: 21/08/2006

Age: 29

DOB: 05/11/1976

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia Leukopenia		Neutropenia and Leucopenia.	Ceased Clopine

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	225.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/02/2007	Neutrophils		21/08/2006	0.40 (Dose 225mg/dose)	x10^9L
13/02/2007	White blood cells		21/08/2006	1.50 (dose 225mg/dose)	x10^9L

Additional Information:

The patient commenced clozapine on 17/7/98 and switched to Clopine 12/10/05.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225767

Seq: 1

Gender: U

Reported: 13/02/2007

Weight: 0.00

Hospitalisation:

Onset Date: 09/01/2007

Age: 69

Outcome: Unknown

DOB: 02/11/1937

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinson's disease		Parkinson's Disease, Antipsychotic drug level increased.	
Drug level above therapeutic			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/02/2007	Liver function tests				
13/02/2007	Serum drug level		07/01/2007	2170ng/mL	

Additional Information:

Serious Criteria: Medically significant.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225777	Seq: 1	Gender: M
Reported: 13/02/2007		Weight: 0.00
Hospitalisation:		Age: 99u
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ventricular dysfunction Blood pressure diastolic increased Echocardiogram abnormal Electrocardiogram abnormal Hypertension Myocardial ischaemia		Patient taking Clozaril for severe psychiatric disease was found to have impaired left ventricular function. A myocardial perfusion scan suggested that there was a small amount of myocardial ischaemia, diastolic blood pressure was consistently elevated.	Clozaril ceased.

Medicine Details:

QUETIAPINE (Other drug)	Reason:
Batch:	Started: Stopped:
BENZTROPINE MESYLATE (Other drug)	Reason:
Batch:	Started: Stopped:
ATENOLOL (Other drug)	Reason:
Batch:	Started: Stopped:
THIAMINE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/02/2007	Echocardiogram		01/01/2006	Left ventricular dysfunction	
13/02/2007	Eosinophils		09/08/2006	0.97 (no units)	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225777 **Seq:** 1
Reported: 13/02/2007

Gender: M
Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram
	Daily
	Oral
Batch:	Started: 15/11/2005
	Stopped: 15/06/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225787

Seq: 1

Gender: M

Reported: 13/02/2007

Weight: 0.00

Hospitalisation:

Onset Date: 15/11/2006

Age: 28

Outcome: Unknown

DOB: 20/06/1978

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Platelet count decreased		Platelet count decreased, lower respiratory tract infection.	
Lower respiratory tract infection			
Thrombocytopenia			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	12.0 Milligram	Daily	Oral
Batch:	Started: 25/06/1998	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/02/2007	Platelets				Platelet count (32x10 ⁹ /L (References ranges not provided).

Additional Information:

History of ITP (Splenectomy)
WBC (LRT current infection)



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225832

Seq: 1

Gender: F

Reported: 14/02/2007

Weight: 0.00

Hospitalisation:

Age: 50

Onset Date:

DOB: 13/03/1956

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ventricular dysfunction		Patient experienced small pericardial effusion and left ventricular abnormalities.	
Pericardial effusion			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	700.0 Milligram Daily Oral
Batch:	Started: 28/07/1997 Stopped: 15/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225852

Seq: 1

Gender: F

Reported: 14/02/2007

Weight: 0.00

Hospitalisation:

Onset Date: 25/01/2007

Age: 37

Outcome: Unknown

DOB: 31/05/1969

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Dyspnoea Eosinophilia		Tachycardia, dyspnoea and high eosinophilia.	

Medicine Details:

RISPERIDONE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason:		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 20/12/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/02/2007	Creatine				CK 181
14/02/2007	Electrocardiograph				ECG normal
14/02/2007	Eosinophils		25/01/2007	2.5	
14/02/2007	Neutrophils		29/01/2007	7.80	
14/02/2007	Troponin				Troponin normal
14/02/2007	White blood cells		23/01/2007	12.00	
14/02/2007	White blood cells		29/01/2007	11.50	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225892

Seq: 1

Gender: M

Reported: 16/02/2007

Weight: 0.00

Hospitalisation:

Age: 54

Onset Date:

DOB: 28/09/1952

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Constipation Lethargy		Patient experienced shortness of breath, lethargy and constipation.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 26/09/2006 Stopped: 27/12/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225893

Seq: 1

Gender: F

Reported: 16/02/2007

Weight: 0.00

Hospitalisation:

Age: 55

Onset Date:

DOB: 10/06/1951

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced myocarditis.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 10/01/2007 Stopped: 24/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225894

Seq: 1

Gender: M

Reported: 16/02/2007

Weight: 0.00

Hospitalisation:

Age: 36

Onset Date:

DOB: 03/07/1970

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain		Patient experienced intermittent chest pain.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: 27/08/2001 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225896

Seq: 1

Gender: M

Reported: 16/02/2007

Weight: 0.00

Hospitalisation:

Age: 43

Onset Date:

DOB: 11/10/1963

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Hypotension Malaise		Patient experienced tachycardia, hypotension and generally feeling unwell.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 03/01/2007 Stopped: 10/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225902

Seq: 1

Gender: M

Reported: 16/02/2007

Weight: 0.00

Hospitalisation:

Age: 39

Onset Date:

DOB: 17/04/1967

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased		Thrombocytopenia. White blood cell count decreased, Neutrophil count decreased, Alanine aminotransferase increased.	
Neutrophil count decreased			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	Milligram Daily Oral
Batch:	Started: 19/10/1993 Stopped: 23/11/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 225929

Seq: 1

Gender: F

Reported: 19/02/2007

Weight: 0.00

Hospitalisation:

Age: 45

Onset Date: 18/01/2007

DOB: 11/02/1961

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure		Patient experienced heart failure, fever and increased serum creatinine.	Clozaril ceased.
Blood creatinine increased			
Pyrexia			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 05/05/2003 Stopped: 18/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226045	Seq: 1	Gender: U
Reported: 22/02/2007		Weight: 116.00
Hospitalisation: Admitted to hospital		Age: 22
Onset Date: 29/01/2007		DOB: 06/02/1984
Outcome: Death		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Heat stroke	Life threatening	Heat stroke:Severe Heat stroke,leading to multi-organ failure with rhabdomyolysis, coagulopathy and hepatic dysfunction.	
Blood creatine phosphokinase incr	Life threatening		
Circulatory collapse	Life threatening		
Coagulopathy	Life threatening		
Hepatic function abnormal	Life threatening		

Medicine Details:

CLOZAPINE (Other drug)		Reason: No reason given
Batch:	Started: 11/12/2001	Stopped: 10/01/2007 0
CLOPINE (Suspected)		Reason: No reason given
Tablet	500.0 Milligram	Daily Oral
Batch:	Started: 10/01/2007	Stopped: 30/01/2007 0
EFEXOR-XR (Suspected)		Reason: No reason given
Capsule	225.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 0
SOLIAN (Suspected)		Reason: Unspecified schizophrenia
Tablet	200.0 Milligram	Daily Oral
Batch:	Started: 01/01/2006	Stopped: 08/02/2007 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/02/2007	Creatine kinase				CK "very high"

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226045	Seq: 1	Gender: U
Reported: 22/02/2007		Weight: 116.00
Hospitalisation: Admitted to hospital		Age: 22
Onset Date: 29/01/2007		DOB: 06/02/1984
Outcome: Death		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Life threatening		
Loss of consciousness	Life threatening		
Multi-organ failure	Life threatening		
Rhabdomyolysis	Life threatening		
Sepsis	Life threatening		

Medicine Details:

CLOZAPINE (Other drug)		Reason: No reason given	
Batch:	Started: 11/12/2001	Stopped: 10/01/2007	0
CLOPINE (Suspected)		Reason: No reason given	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 10/01/2007	Stopped: 30/01/2007	0
EFEXOR-XR (Suspected)		Reason: No reason given	
Capsule	225.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0
SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2006	Stopped: 08/02/2007	0

Laboratory Investigations:

Additional Information:



Therapeutic Goods Administration Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226089

Seq: 1

Gender: M

Reported: 26/02/2007

Weight: 0.00

Hospitalisation:

Onset Date: 08/01/2007

Age: 42

DOB: 18/08/1964

Outcome: Death

08/01/2007

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Unexplained death.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 06/12/2006 Stopped: 08/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient commenced treatment with clozapine on 27-Feb-1996 and was switched to Clopine (clozapine) on 06-Dec-2006. The patient died on 8-Jan-2007.

An inquest into the death is being conducted.

Follow-up information has been sought from the prescriber.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226090 **Seq:** 1 **Gender:** M
Reported: 26/02/2007 **Weight:** 0.00
Hospitalisation: **Age:** 47
Onset Date: 03/02/2007 **DOB:** 27/03/1959
Outcome: Death 03/02/2007 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Unexplained death.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 12/12/2001 Stopped: 03/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Follow-up information has been sought from the prescriber.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226094

Seq: 1

Gender: M

Reported: 26/02/2007

Weight: 0.00

Hospitalisation:

Onset Date: 24/01/2007

Age: 24

Outcome: Unknown

DOB: 22/06/1982

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder Hypotension Tachycardia		Patient had cardiac complications, tachycardia and hypotension.	Ceased Clopine.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 24/01/2007 Stopped: 25/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/02/2007	Neutrophils				Neutrophil I counts were within normal ranges.
26/02/2007	White blood cells				White blood cell count were within normal ranges.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226096

Seq: 1

Gender: M

Reported: 26/02/2007

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date:

DOB: 14/06/1972

Outcome: Unknown

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Patient experienced cardiac complications.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	225.0 Milligram Daily Oral
Batch:	Started: 11/01/2007 Stopped: 26/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/02/2007	Neutrophils				Neutrophil counts were within normal ranges.
26/02/2007	White blood cells				White blood cell counts were within normal ranges.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226097

Seq: 1

Gender: M

Reported: 26/02/2007

Weight: 0.00

Hospitalisation:

Age: 58

Onset Date:

DOB: 31/01/1949

Outcome: Unknown

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Patient experienced neuroleptic malignant syndrome.	Ceased clopine.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 29/08/2006 Stopped: 02/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/02/2007	Neutrophils				Neutrophil counts were within normal ranges throughout treatment period.
26/02/2007	White blood cells				WCC cell counts were within normal ranges throughout treatment.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226120

Seq: 1

Gender: F

Reported: 26/02/2007

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date:

DOB: 05/01/1961

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intestinal obstruction Constipation		Constipation, Bowel obstruction.	Ceased Clopine

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: Stopped: 22/11/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/02/2007	Neutrophils				The neutrophil counts were generally within the normal ranges, with occasional counts noted.
26/02/2007	White blood cells				The white cell counts were generally within normal ranges, with occasional high counts noted.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226182

Seq: 1

Gender: M

Reported: 28/02/2007

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date:

DOB: 17/05/1972

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	Milligram
	Daily
	Oral
Batch:	Started: 15/01/2007
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/02/2007	Neutrophils		30/01/2006	3.60	
28/02/2007	White blood cells		30/01/2006	6.0	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226190
Reported: 28/02/2007

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 28/09/2006

Age: 46

Outcome: Unknown

DOB: 02/05/1960

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tooth abscess	Caused or prolonged inpatient hospitalisation	Dental abscess, swollen cheek, elevated temperature, breathing heavily, shaking, leucopenia and neutropenia.	Taken off Clozaril and patient was then prescribed Zyprexa.
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Leukopenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	125.0 Milligram Daily Oral
Batch:	Started: 06/09/1993 Stopped: 28/09/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/02/2007	Neutrophils	(2.0-7.7)	28/09/2006	2.0	
28/02/2007	Neutrophils	(2.0-7.7)	29/09/2006	1.57	
28/02/2007	Neutrophils	(2.0-7.7)	30/09/2006	1.76	
28/02/2007	Neutrophils	(2.0-7.7)	02/10/2006	1.79	
28/02/2007	Neutrophils	(2.0-7.7)	01/10/2006	1.40	
28/02/2007	White blood cells	(4.5-11.0)	28/09/2006	2.9	
28/02/2007	White blood cells	(4.5-11.0)	29/09/2006	2.8	

Additional Information:

The patient had a history of dental abscess.
The reporter was suspicious tha the Clozaril induced neutropenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226190
Reported: 28/02/2007

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 28/09/2006
Outcome: Unknown

Age: 46
DOB: 02/05/1960
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Swelling face	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	125.0 Milligram Daily Oral
Batch:	Started: 06/09/1993 Stopped: 28/09/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/02/2007	White blood cells	(4.5-11.0)	30/09/2006	2.7	
28/02/2007	White blood cells	(4.5-11.0)	01/10/2006	2.5	
28/02/2007	White blood cells	(4.5-11.0)	02/10/2006	3.3	

Additional Information:

The patient had a history of dental abscess.
The reporter was suspicious tha the Clozaril induced neutropenia.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226190

Seq: 1

Gender: M

Reported: 28/02/2007

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date: 28/09/2006

DOB: 02/05/1960

Outcome: Unknown

Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	125.0 Milligram Daily Oral
Batch:	Started: 06/09/1993 Stopped: 28/09/2006

Laboratory Investigations:

Additional Information:

The patient had a history of dental abscess.
The reporter was suspicious tha the Clozaril induced neutropenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226239

Seq: 1

Gender: M

Reported: 01/03/2007

Weight: 55.00

Hospitalisation:

Age: 19

Onset Date: 26/02/2007

DOB: 13/12/1987

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin increased	Caused or prolonged inpatient hospitalisation	Raised triponin levels	Discontinuation of treatment, until clinically cleared for recommencement

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	500.0 Milligram	Daily	Oral
Batch: unknown	Started: 01/06/2006	Stopped: 20/02/2007	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226305

Seq: 1

Gender: F

Reported: 05/03/2007

Weight: 0.00

Hospitalisation:

Age: 20

Onset Date:

DOB: 20/05/1986

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion		Weight gain, hypersalivation.	
Weight increased			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	375.0 Milligram	Daily	Oral
Batch:	Started: 13/07/2006	Stopped: 03/01/2007	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226312

Seq: 1

Gender: M

Reported: 05/03/2007

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date:

DOB: 13/05/1976

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Cardiac complications.	Ceased Clopine.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226313

Seq: 1

Gender: F

Reported: 05/03/2007

Weight: 0.00

Hospitalisation:

Onset Date: 31/01/2007

Age: 38

Outcome: Unknown

DOB: 08/07/1968

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia.	Ceased treatment.

Medicine Details:

CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 19/08/2006	Stopped: 31/01/2007	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/03/2007	Neutrophils		08/02/2007	1.7	
05/03/2007	Neutrophils		04/02/2007	0.9	
05/03/2007	Neutrophils		30/01/2007	1.9	
05/03/2007	White blood cells		08/02/2007	5.1	
05/03/2007	White blood cells		04/02/2007	3.5	
05/03/2007	White blood cells		30/01/2007	3.7	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226317

Seq: 1

Gender: F

Reported: 05/03/2007

Weight: 0.00

Hospitalisation:

Age: 33

Onset Date:

DOB: 22/09/1973

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Antipsychotic drug level increased		Seizure, high clopine levels.	

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet 700.0 Milligram Batch:	Daily Oral Started: 23/06/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226344

Seq: 1

Gender: M

Reported: 06/03/2007

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date: 09/01/2007

DOB: 29/12/1964

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Caused or prolonged inpatient hospitalisation	Patient admitted to intensive care with cardiomyopathy.	Clozaril treatment ceased.

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 29/08/2006	Stopped: 09/01/2007	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226394

Seq: 1

Gender: M

Reported: 06/03/2007

Weight: 0.00

Hospitalisation:

Age: 37

Onset Date:

DOB: 19/02/1970

Outcome: Death

05/02/2007

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Embolism	Death	Patient had thromboembolism.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 06/04/2006 Stopped: 05/02/2007 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Overweight, smoker, sedentary lifestyle



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226412 **Seq:** 1 **Gender:** M
Reported: 07/03/2007 **Weight:** 102.00
Hospitalisation: Required a visit to the doctor **Age:** 44
Onset Date: 30/11/2007 **DOB:** 01/06/1963
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction		Generalised dermatits now has developed into exfoliation dermatits.	
Dermatitis exfoliative generalised			

Medicine Details:

COLOXYL WITH SENNA (Other drug)	Reason: Constipation
Tablet	2.0 Dose Unspecified As necessary Oral
Batch:	Started: Stopped:
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Diabetes.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226422	Seq: 1	Gender: M
Reported: 07/03/2007		Weight: 0.00
Hospitalisation:		Age: 47
Onset Date: 12/02/2007		DOB: 26/08/1959
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation	Patient presented with chest pain and shortness of breath. Patient had raised WCC, NC, troponin levels, diagnosed with myocarditis.	Ceased clopine.
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Leukocytosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 12/02/2007	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



Therapeutic Goods Administration Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226422

Seq: 1

Gender: M

Reported: 07/03/2007

Weight: 0.00

Hospitalisation:

Onset Date: 12/02/2007

Age: 47

DOB: 26/08/1959

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation		
Neutrophil count increased	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:
	Stopped: 12/02/2007

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226449	Seq: 1	Gender: M
Reported: 07/03/2007		Weight: 60.00
Hospitalisation:		
Onset Date: 12/02/2007		Age: 32
Outcome: Recovered	12/02/2007	DOB: 20/05/1974
		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Patient experienced tachycardia, pyrexia and pronounced diaphoresis and abnormal ECG results.	Clopine ceased.
Electrocardiogram abnormal			
Hyperhidrosis			
Pyrexia			

Medicine Details:

CLOPINE (Suspected)		Reason: Unspecified schizophrenia
Tablet	275.0 Milligram	Daily Oral
Batch:	Started:	Stopped:
CIPRAMIL (Suspected)		Reason: Depression
Tablet	20.0 Milligram	Daily Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/03/2007	Other data				Intermittent incomplete RBBB/or NSR.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226458

Seq: 1

Gender: M

Reported: 07/03/2007

Weight: 0.00

Hospitalisation:

Age: 23

Onset Date:

DOB: 29/03/1983

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Patient had cardiac complications and cardiomyopathy.	Ceased Clozapine.

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 07/01/2005	Stopped:	23/12/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226503 **Seq:** 1 **Gender:** M
Reported: 09/03/2007 **Weight:** 0.00
Hospitalisation: **Age:** 41
Onset Date: 15/01/2007 **DOB:** 05/04/1965
Outcome: Death 15/01/2007 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction	Death	Patient experienced a myocardial infarction.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 16/11/2004 Stopped: 15/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226545

Seq: 1

Gender: M

Reported: 12/03/2007

Weight: 0.00

Hospitalisation:

Age: 44

Onset Date:

DOB: 30/01/1963

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis Cardiac disorder Dizziness Tachycardia		Patient experienced cardiac complications, tachycardia and dizziness.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 27/10/2004 Stopped: 26/12/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226586	Seq: 1	Gender: M
Reported: 13/03/2007		Weight: 0.00
Hospitalisation:		Age: 28
Onset Date:		DOB: 01/06/1978
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pericarditis		Patient experienced suspected pericarditis, chest pain, abnormal ECG results, dizziness, hypotension, nausea, drowsiness and accidental overdose.	Ceased Clozapine.
Accidental overdose			
Chest pain			
Dizziness			
Electrocardiogram abnormal			
Hypotension			
Medication error			
Nausea			
Somnolence			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	125.0 Milligram Total Oral
Batch:	Started: 12/02/2007 Stopped: 12/02/2007 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226612

Seq: 1

Gender: M

Reported: 14/03/2007

Weight: 0.00

Hospitalisation:

Age: 35

Onset Date: 16/02/2007

DOB: 18/07/1971

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Discontinuation of treatment due to non compliance and weight gain.	

Medicine Details:

CLOZARIL (Suspected)	Reason:	
Tablet	100.0 Milligram	Oral
Batch:	Started: 24/05/2006	Stopped: 16/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226738	Seq: 1	Gender: F
Reported: 20/03/2007		Weight: 80.00
Hospitalisation: Admitted to hospital		Age: 41
Onset Date: 15/02/2007		DOB: 05/12/1965
Outcome: Recovered	15/02/2007	Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradycardia	Caused or prolonged inpatient hospitalisation	Patient became bradycardic but asymptomatic, no shortness of breath, no chest pain. No further clozapine given. Bradycardia and ECG resolved after two hours.	Drug ceased.

Medicine Details:

MIRTAZAPINE (Other drug)	Reason:
45.0 Milligram	
Batch:	Started: 12/02/2007 Stopped:
THYROXINE SODIUM (Other drug)	Reason:
Tablet 100.0 Microgram	
Batch:	Started: Stopped:
Risperdal Consta (Other drug)	Reason:
25.0 Milligram Daily	
Batch:	Started: 09/02/2007 Stopped: 0
CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 12.5 Milligram Daily	Oral
Batch:	Started: 15/02/2007 Stopped: 15/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/03/2007	Electrocardiograph				

Additional Information:

Much concern was presence of bradycardia 30 minutes after starting first dose of clozapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226775

Seq: 1

Gender: M

Reported: 20/03/2007

Weight: 0.00

Hospitalisation:

Onset Date:

Age: 26

Outcome: Unknown

DOB: 20/07/1980

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Patient is experiencing persistent tachycardia.	

Medicine Details:

QUETIAPINE (Other drug)		Reason:	
Batch:	Started:	Stopped: 15/02/2007	
CLOPINE (Suspected)		Reason:	
Tablet	350.0 Milligram	Daily	Oral
Batch:	Started: 23/01/2007	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: stopped clopine previously due to weight gain.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226809

Seq: 1

Gender: F

Reported: 21/03/2007

Weight: 0.00

Hospitalisation:

Age: 15Y

Onset Date: 14/01/2007

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Patient experienced hyperthermia and was febrile. The patient's white cells had not dropped and there was a slight neutrophilia.	
Neutrophilia			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	62.5 Milligram Daily Oral
Batch:	Started: 14/01/2007 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226914

Seq: 1

Gender: F

Reported: 22/03/2007

Weight: 0.00

Hospitalisation:

Age: 36

Onset Date:

DOB: 14/01/1971

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced seizures.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	125.0 Milligram Daily Oral
Batch:	Started: 13/02/2007 Stopped: 17/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 226937

Seq: 1

Gender: M

Reported: 23/03/2007

Weight: 0.00

Hospitalisation:

Age: 76

Onset Date:

DOB: 16/03/1931

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia Lymphopenia		Patient had leucopenia and lymphopenia	Ceased clopine.

Medicine Details:

CLOPINE (Suspected)	Reason:
	50.0 Milligram Daily
Batch:	Started: 25/10/2006 Stopped: 05/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose of Clopine (clozapine) was titrated up to 125 mg daily but immediately prior to the event, the dose of Clopine was po 50mg daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227033

Seq: 1

Gender: F

Reported: 27/03/2007

Weight: 0.00

Hospitalisation:

Age: 35

Onset Date:

DOB: 06/11/1971

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Patient developed cardiac complications and sinus tachycardia.	Patient ceased Clozapine.
Sinus tachycardia			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 03/01/2007 Stopped: 22/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

White blood cell and neutrophil counts were within normal ranges for the treatment period.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227090	Seq: 1	Gender: M
Reported: 28/03/2007		Weight: 0.00
Hospitalisation:		Age: 32
Onset Date: 11/02/2007		DOB: 18/07/1974
Outcome: Recovered	15/02/2007	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bundle branch block right	Caused or prolonged inpatient hospitalisation	Patient experienced cardiac complications, new right bundle branch block, shortness of breath, fever and sweating.	Ceased clopine, oxygen, intubated.
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 25/01/2007	Stopped: 11/02/2007	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/03/2007	Temperature				On 11-Feb-2007, the patient developed fever of ~38.9 to 41 degrees celcius.

Additional Information:

The patient has a history of asthma, obstructive sleep apnoea, and previous ethanol abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227090 **Seq:** 1 **Gender:** M
Reported: 28/03/2007 **Weight:** 0.00
Hospitalisation: **Age:** 32
Onset Date: 11/02/2007 **DOB:** 18/07/1974
Outcome: Recovered 15/02/2007 **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 25/01/2007 Stopped: 11/02/2007

Laboratory Investigations:

Additional Information:

The patient has a history of asthma, obstructive sleep apnoea, and previous ethanol abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227091	Seq: 1	Gender: M
Reported: 28/03/2007		Weight: 0.00
Hospitalisation:		Age: 47
Onset Date: 08/02/2007		DOB: 26/08/1959
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation	Patient experienced chest pain, exertional dyspnoea, orthopnea, flu-like symptoms, malaise and restlessness.	Ceased Clozapine, quetiapine 50 mg every 6 hours, enoxaparin 100 mg subcutaneously twice a day, aspirin 100 mg daily, ceftriaxone 2 g intravenously daily, azithromycin 500 mg IV daily, perindopril 2.5 mg daily, eplerenone 12.5 mg daily, metoclopramide 10 mg 3 times a day as required and paracetamol 1 g four times a day.

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	225.0 Milligram Daily Oral
Batch:	Started: 22/01/2007 Stopped: 12/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/03/2007	C-Reactive Protein		12/02/2007	200	Echocardiogram (date unknown) showed mild left enlargement and mild ascending aorta enlargement.
28/03/2007	Creatine		12/02/2007	195	
28/03/2007	Creatine		15/02/2007	87	
28/03/2007	Echocardiogram				
28/03/2007	Troponin	(<0.03)	12/02/2007	0.21	
28/03/2007	Troponin	(<0.03)	15/02/2007	0.04	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227091

Seq: 1

Gender: M

Reported: 28/03/2007

Weight: 0.00

Hospitalisation:

Onset Date: 08/02/2007

Age: 47

DOB: 26/08/1959

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Dyspnoea exertional	Caused or prolonged inpatient hospitalisation		
Electrocardiogram abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started: 22/01/2007	Stopped: 12/02/2007	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227091

Seq: 1

Gender: M

Reported: 28/03/2007

Weight: 0.00

Hospitalisation:

Onset Date: 08/02/2007

Age: 47

DOB: 26/08/1959

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Influenza like illness	Caused or prolonged inpatient hospitalisation		
Malaise	Caused or prolonged inpatient hospitalisation		
Orthopnoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	225.0 Milligram
	Daily
	Oral
Batch:	Started: 22/01/2007
	Stopped: 12/02/2007

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227091

Seq: 1

Gender: M

Reported: 28/03/2007

Weight: 0.00

Hospitalisation:

Age: 47

Onset Date: 08/02/2007

DOB: 26/08/1959

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia		
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started: 22/01/2007	Stopped: 12/02/2007	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227096	Seq: 1	Gender: M
Reported: 28/03/2007		Weight: 0.00
Hospitalisation:		Age: 31
Onset Date: 26/02/2007		DOB: 19/02/1976
Outcome: Recovered	06/03/2007	Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Patient experienced myocarditis, chest pain, troponin rise, ECG changes, normal echocardiogram.	Cessation of clozapine, supportive conservative care.
Chest pain	Caused or prolonged inpatient hospitalisation		
Electrocardiogram abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
350.0 Milligram	Daily
Batch:	Started: 14/02/2007 Stopped: 04/03/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227096

Seq: 1

Gender: M

Reported: 28/03/2007

Weight: 0.00

Hospitalisation:

Age: 31

Onset Date: 26/02/2007

DOB: 19/02/1976

Outcome: Recovered

06/03/2007

Causality: Causality probable

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
350.0 Milligram	Daily
Batch:	Started: 14/02/2007
	Stopped: 04/03/2007

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227148

Seq: 1

Gender: F

Reported: 30/03/2007

Weight: 0.00

Hospitalisation:

Age: 24

Onset Date:

DOB: 01/04/1982

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure		Patient ceased treatment due to cardiac complications, weakening of the heart, potential for cardiomyopathy.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 07/12/2005 Stopped: 13/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227162	Seq: 1	Gender: M
Reported: 30/03/2007		Weight: 0.00
Hospitalisation:		Age: 56
Onset Date:		DOB: 28/07/1950
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction		Myocardial infarction, chest pain, creatine kinase increased, abnormal LFTs.	
Blood creatine phosphokinase incr			
Chest pain			
Liver function test abnormal			

Medicine Details:

OLANZAPINE (Other drug)	Reason:
Batch:	Started: Stopped:
Aripiprazole (Other drug)	Reason:
Batch:	Started: Stopped:
SERTRALINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
CLOPINE (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 15/02/2007 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227211	Seq: 1	Gender: M
Reported: 02/04/2007		Weight: 103.00
Hospitalisation:		Age: 24
Onset Date: 25/02/2007		DOB: 08/08/1982
Outcome: Not yet recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced chest pain and an increase in troponin, red blood cell sedimentation rate increased, C-reactive protein increased.	Clopine ceased.

Medicine Details:

CARBIMAZOLE (Other drug)	Reason:
5.0 Milligram	Daily
Batch:	Started: L TERM Stopped:
AMISULPRIDE (Other drug)	Reason:
600.0 Milligram	Daily
Batch:	Started: S TERM Stopped:
CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram
	Daily
	Oral
Batch:	Started: 13/02/2007 Stopped: 26/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/04/2007	Other data		27/02/2007	ECG - no abnormalities	patient commenced treatment with clozapine on 13/2/07, on 25/2/07 experienced chest pain, increase in troponin ESR and C-reactive protein levels.
02/04/2007	Other data		28/02/2007	Troponin 0.81	

Additional Information:

weight = 103kg, height = 180cm. History of treatment-resistant schizophrenia and Grave's disease.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227211 **Seq:** 1
Reported: 02/04/2007

Gender: M
Weight: 103.00

Hospitalisation:

Onset Date: 25/02/2007
Outcome: Not yet recovered

Age: 24
DOB: 08/08/1982
Causality: Causality probable

Reaction Details:

Medicine Details:

CARBIMAZOLE (Other drug)	Reason:
5.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
AMISULPRIDE (Other drug)	Reason:
600.0 Milligram Daily	
Batch:	Started: S TERM Stopped:
CLOZAPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral	
Batch:	Started: 13/02/2007 Stopped: 26/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/04/2007	Other data		01/03/2007	Troponin 0.47	patient commenced treatment with clozapine on 13/2/07, on 25/2/07 experienced chest pain, increase in troponin ESR and C-reactive protein levels.
02/04/2007	Other data		01/03/2007	ESR 49	patient commenced treatment with clozapine on 13/2/07, on 25/2/07 experienced chest pain, increase in troponin ESR and C-reactive protein levels.

Additional Information:

weight = 103kg, height = 180cm. History of treatment-resistant schizophrenia and Grave's disease.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227211 **Seq:** 1
Reported: 02/04/2007

Gender: M
Weight: 103.00

Hospitalisation:

Onset Date: 25/02/2007
Outcome: Not yet recovered

Age: 24
DOB: 08/08/1982
Causality: Causality probable

Reaction Details:

Medicine Details:

CARBIMAZOLE (Other drug)	Reason:	
5.0 Milligram	Daily	
Batch:	Started:	Stopped:
	L TERM	
AMISULPRIDE (Other drug)	Reason:	
600.0 Milligram	Daily	
Batch:	Started:	Stopped:
	S TERM	
CLOZAPINE (Suspected)	Reason:	Unspecified schizophrenia
Tablet	200.0 Milligram	Daily
Batch:	Started: 13/02/2007	Stopped: 26/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/04/2007	Other data		01/03/2007	CRP 70.3	patient commenced treatment with clozapine on 13/2/07, on 25/2/07 experienced chest pain, increase in troponin ESR and C-reactive protein levels.
02/04/2007	Other data		01/04/2007	ECHO Normal	patient commenced treatment with clozapine on 13/2/07, on 25/2/07 experienced chest pain, increase in troponin ESR and C-reactive protein levels.

Additional Information:

weight = 103kg, height = 180cm. History of treatment-resistant schizophrenia and Grave's disease.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227244
Reported: 03/04/2007

Seq: 1

Gender: M
Weight: 36.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 36
DOB: 17/05/1970
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Palpitations Neutrophil count increased White blood cell count increased		Heart palpitations, Increased white blood cell count,	Ceased Clopine

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 22/01/2007 Stopped: 20/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/04/2007	Neutrophils		17/01/2007	4.86	
03/04/2007	Neutrophils		29/01/2007	8.15	
03/04/2007	Neutrophils		14/02/2007	10.16	
03/04/2007	Neutrophils		05/02/2007	8.10	
03/04/2007	White blood cells		17/01/2007	16.90	
03/04/2007	White blood cells		29/01/2007	11.80	
03/04/2007	White blood cells		05/02/2007	12.40	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227244

Seq: 1

Gender: M

Reported: 03/04/2007

Weight: 36.00

Hospitalisation:

Age: 36

Onset Date:

DOB: 17/05/1970

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 22/01/2007 Stopped: 20/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/04/2007	White blood cells		14/02/2007	16.90	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227245

Seq: 1

Gender: M

Reported: 03/04/2007

Weight: 0.00

Hospitalisation:

Age: 45

Onset Date:

DOB: 12/10/1961

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia.	Ceased Clopine

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 28/05/2003 Stopped: 11/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient has hepatitis and is taking medication.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227246

Seq: 1

Gender: M

Reported: 03/04/2007

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date:

DOB: 24/09/1972

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vision blurred		Blurred vision and increased glucose levels.	Ceased Clopine.
Blood glucose increased			

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	50.0 Milligram Daily Oral
Batch:	Started: S TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/04/2007	Serum glucose				Patient's blood glucose rose to 21mmol/L.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227519	Seq: 1	Gender: M
Reported: 12/04/2007		Weight: 0.00
Hospitalisation:		Age: 45
Onset Date: 15/07/2005		DOB: 20/05/1960
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Activities of daily living impaired	Caused or prolonged inpatient hospitalisation	Patient experienced increased sedation, inability to function in day-to-day situations and deteriorated general health (weight gain and lack of energy and motivation).	Dosage of Clozaril decreased, then ceased.
Asthenia	Caused or prolonged inpatient hospitalisation		
Delusion	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 15/07/2005	Stopped: 18/12/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Current condition intellectual impairment
Not on any other medications at the time.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227519

Seq: 1

Gender: M

Reported: 12/04/2007

Weight: 0.00

Hospitalisation:

Onset Date: 15/07/2005

Age: 45

Outcome: Recovered

DOB: 20/05/1960

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective	Caused or prolonged inpatient hospitalisation		
General physical health deterioration	Caused or prolonged inpatient hospitalisation		
Sedation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram
	Daily
	Oral
Batch:	Started: 15/07/2005
	Stopped: 18/12/2006 0

Laboratory Investigations:

Additional Information:

Current condition intellectual impairment
Not on any other medications at the time.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227519

Seq: 1

Gender: M

Reported: 12/04/2007

Weight: 0.00

Hospitalisation:

Age: 45

Onset Date: 15/07/2005

DOB: 20/05/1960

Outcome: Recovered

Causality: Causality probable

Reaction Details:

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

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 15/07/2005	Stopped: 18/12/2006	0

Laboratory Investigations:

Additional Information:

Current condition intellectual impairment
Not on any other medications at the time.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227585

Seq: 1

Gender: M

Reported: 13/04/2007

Weight: 0.00

Hospitalisation:

Age: 60

Onset Date:

DOB: 26/06/1946

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Loss of consciousness		Episode of lost consciousness, patient commenced clozapine on 8/10/1996 and switched to the Clopine brand.	Ceased Clopine
Therapeutic response unexpected			

Medicine Details:

CLOPINE (Suspected)		Reason:		
Tablet	200.0 Milligram	Daily	Oral	
Batch:	Started:	L TERM	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/04/2007	White blood cells				Patient's white blood cells were within normal ranges for the treatment period.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227613

Seq: 1

Gender: F

Reported: 16/04/2007

Weight: 0.00

Hospitalisation:

Age: 54

Onset Date:

DOB: 19/07/1952

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Drug induced pyrexia.	Ceased Clopine

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 13/02/2007 Stopped: 26/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/04/2007	Neutrophils				Neutrophil counts were within normal ranges for the treatment period.
16/04/2007	White blood cells				White blood cell counts were within normal ranges for the treatment period.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227715

Seq: 1

Gender: M

Reported: 18/04/2007

Weight: 0.00

Hospitalisation:

Age: 26Y

Onset Date: 21/02/2007

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Neutrophil count increased White blood cell count increased		Tachycardia since taking Clopine commencement fluctuating between 80 and 120 bpm, white blood cell count increased, neutrophil count increased.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 21/02/2007 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/04/2007	Neutrophils		21/02/2007	7.32	Neutrophil counts have been elevated throughout his treatment period reaching a maximum of 14.36 on 28/02/2007.
18/04/2007	Neutrophils		28/02/2007	14.36	Neutrophil counts have been elevated throughout his treatment period reaching a maximum of 14.36 on 28/02/2007.
18/04/2007	Neutrophils		07/03/2007	9.21	Neutrophil counts have been elevated throughout his treatment period reaching a maximum of 14.36 on 28/02/2007.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227715
Reported: 18/04/2007

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 21/02/2007
Outcome: Unknown

Age: 26Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 21/02/2007 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/04/2007	Neutrophils		14/03/2007	9.68	Neutrophil counts have been elevated throughout his treatment period reaching a maximum of 14.36 on 28/02/2007.
18/04/2007	Other data				Heart rate has been persistently over 100 bpm since 10/03/2007.
18/04/2007	White blood cells		21/02/2007	11.30	White blood cell counts have been elevated throughout his treatment period reaching a maximum of $19.2 \times 10^9/L$ on 28/02/2007.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227715
Reported: 18/04/2007

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 21/02/2007
Outcome: Unknown

Age: 26Y

DOB:

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	350.0 Milligram Daily Oral
Batch:	Started: 21/02/2007 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/04/2007	White blood cells		28/02/2007	19.20	White blood cell counts have been elevated throughout his treatment period reaching a maximum of $19.2 \times 10^9/L$ on 28/02/2007.
18/04/2007	White blood cells		07/03/2007	14.10	White blood cell counts have been elevated throughout his treatment period reaching a maximum of $19.2 \times 10^9/L$ on 28/02/2007.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227715

Seq: 1

Gender: M

Reported: 18/04/2007

Weight: 0.00

Hospitalisation:

Age: 26Y

Onset Date: 21/02/2007

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)

Reason:

Tablet

350.0 Milligram

Daily

Oral

Batch:

Started: 21/02/2007

Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/04/2007	White blood cells		14/03/2007	14.90	White blood cell counts have been elevated throughout his treatment period reaching a maximum of $19.2 \times 10^9/L$ on 28/02/2007.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227724
Reported: 19/04/2007

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 13/03/2007
Outcome: Unknown

Age: 50
DOB: 26/10/1956
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal		Abnormal Echocardiogram, rightward axis and T-wave abnormalities in the anterolateral lead.	

Medicine Details:

FERROUS SULPHATE (Other drug)	Reason:	
Batch:	Started:	Stopped:
THYROXINE SODIUM (Other drug)	Reason:	
Batch:	Started:	Stopped:
INFLUENZA VACCINE (Other drug)	Reason:	
Batch:	Started:	Stopped:
LOPERAMIDE HYDROCHLORIDE (Other drug)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/04/2007	Creatine		19/03/2007	77	13 March 2007: ECG abnormal
19/04/2007	Electrocardiograph				
19/04/2007	Full Blood Count		19/03/2007	Normal	Normal
19/04/2007	Low density		19/03/2007	1.6	
19/04/2007	Neutrophils				
19/04/2007	Triglyceride		19/03/2007	2.8	Troponin T
19/04/2007	Troponin		19/03/2007	<0.03	

Additional Information:

The patient has a medical history of hepatitis B, hypercholesterolaemia, schizophrenia and had a hysterectomy in 2000.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227724

Seq: 1

Gender: F

Reported: 19/04/2007

Weight: 0.00

Hospitalisation:

Onset Date: 13/03/2007

Age: 50

Outcome: Unknown

DOB: 26/10/1956

Causality: Causality possible

Reaction Details:

Medicine Details:

CEPHALEXIN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
LACTULOSE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZAPINE (Suspected)		Reason:	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 12/02/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/04/2007	White blood cells				Normal

Additional Information:

The patient has a medical history of hepatitis B, hypercholesterolaemia, schizophrenia and had a hysterectomy in 2000.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227732

Seq: 1

Gender: F

Reported: 19/04/2007

Weight: 0.00

Hospitalisation:

Onset Date: 04/03/2007

Age: 24

Outcome: Unknown

DOB: 02/10/1982

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Caused or prolonged inpatient hospitalisation	Agranulocytosis and Pyrexia.	
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 08/11/2006 Stopped: 06/11/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/04/2007	Neutrophils	1.8 - 7.7	27/02/2007	2.90	
19/04/2007	Neutrophils	1.8 - 7.7	06/03/2007	0.00	
19/04/2007	Neutrophils	1.8 - 7.7	09/03/2007	0.10	
19/04/2007	Neutrophils	1.8 - 7.7	08/03/2007	0.00	
19/04/2007	White blood cells	4.5 - 11	27/02/2007	5.2	
19/04/2007	White blood cells	4.5 - 11	06/03/2007	0.6	
19/04/2007	White blood cells	4.5 - 11	08/03/2007	1.4	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227732

Seq: 1

Gender: F

Reported: 19/04/2007

Weight: 0.00

Hospitalisation:

Age: 24

Onset Date: 04/03/2007

DOB: 02/10/1982

Outcome: Unknown

Causality: Causality probable

Reaction Details:

Medicine Details:

CLOZAPINE (Suspected)

Reason:

Tablet

12.5 Milligram

Daily

Oral

Batch:

Started: 08/11/2006

Stopped: 06/11/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/04/2007	White blood cells	4.5 - 11	09/03/2007	1.10	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227733

Seq: 1

Gender: M

Reported: 19/04/2007

Weight: 0.00

Hospitalisation:

Age: 34Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure, hypersalivation	Treatment discontinued.
Salivary hypersecretion			

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 22/01/2007 Stopped: 19/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

It was noted that the patient also objected to regular blood tests. No further details were provided.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227735 **Seq:** 1 **Gender:** M
Reported: 19/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 31
Onset Date: **DOB:** 19/02/1976
Outcome: Unknown **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis.	

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 12/02/2007 Stopped: 04/03/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227736

Seq: 1

Gender: M

Reported: 19/04/2007

Weight: 0.00

Hospitalisation:

Age: 26

Onset Date:

DOB: 08/05/1980

Outcome: Unknown

Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	125.0 Milligram Daily Oral
Batch:	Started: 16/11/2005 Stopped: 28/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient experienced an ADE in 2005 involving Clopine and eosinophilia. The patients white blood cell and neutrophil counts were within normal ranges for the treatment period with the exception of a few slightly raised results.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227739

Seq: 1

Gender: M

Reported: 19/04/2007

Weight: 0.00

Hospitalisation:

Age: 56

Onset Date:

DOB: 28/07/1950

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Angina pectoris		Angina Pectoris.	Clopine ceased.

Medicine Details:

CLOZAPINE (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 08/02/2007 Stopped: 01/03/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient's white blood cell and neutrophil counts were within normal ranges for the treatment period.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227755 **Seq:** 1 **Gender:** M
Reported: 19/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 24
Onset Date: 14/03/2007 **DOB:** 03/11/1982
Outcome: Unknown **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient commenced treatment with Clopine on 22/02/07 and ceased treatment due to myocarditis on 14/03/07. At the time of the event the dose was PO 200mg daily.	Ceased drug.

Medicine Details:

CLOPINE (Suspected)	Reason:		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 22/02/2007	Stopped:	14/03/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227828	Seq: 1	Gender: M
Reported: 23/04/2007		Weight: 0.00
Hospitalisation:		Age: 42
Onset Date: 26/02/2007		DOB: 14/03/1964
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia		Eosinophilia, chest discomfort, nausea, anorexia, diarrhoea. Whilst on a dose of 137.5mg daily, he experienced 2 or 3 episodes of chest discomfort on 27 and 28 Feb 2007. He also had some episodes of mild nausea and anorexia.	
Anorexia			
Chest discomfort			
Diarrhoea			
Nausea			
Neutrophil count increased			
White blood cell count increased			

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	Milligram	Daily	Oral
Batch:	Started: 07/02/2007	Stopped: 08/03/2007	0
CAFFEINE (Suspected)		Reason:	
	1.0 Dose Unspecified	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/04/2007	Electrocardiograph		22/02/2007	Normal	
23/04/2007	Electrocardiograph		08/03/2007	Normal	
23/04/2007	Eosinophils		28/02/2007	1.7	
23/04/2007	Eosinophils		14/03/2007	0.3	
23/04/2007	Eosinophils		07/03/2007	3.2	
23/04/2007	Neutrophils		28/02/2007	12.8	
23/04/2007	Neutrophils		14/03/2007	8.4	

Additional Information:

It was noted that he drank two "Red Bull" (caffeine) drinks per day (co-suspect) and refused to cease intake.
 Historical condition alcoholism.
 Mild developmental delay/intellectual disability.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 227828
Reported: 23/04/2007

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 26/02/2007

Age: 42

DOB: 14/03/1964

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	Milligram Daily Oral
Batch:	Started: 07/02/2007 Stopped: 08/03/2007 0
CAFFEINE (Suspected)	Reason:
	1.0 Dose Unspecified Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/04/2007	Troponin		07/03/2007	0.04	
23/04/2007	White blood cells		28/02/2007	17.0	
23/04/2007	White blood cells		07/03/2007	14.4	
23/04/2007	White blood cells		14/03/2007	8.4	

Additional Information:

It was noted that he drank two "Red Bull" (caffeine) drinks per day (co-suspect) and refused to cease intake.
Historical condition alcoholism.
Mild developmental delay/intellectual disability.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 228056 **Seq:** 1 **Gender:** M
Reported: 30/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: 24/03/2007 **DOB:** 24/01/1972
Outcome: Death, maybe drug 24/03/2007 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Death unexplained.	

Medicine Details:

CLOPINE (Suspected)	Reason:
Tablet	125.0 Milligram Daily Oral
Batch:	Started: 31/05/2006 Stopped: 24/03/2007 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/04/2007	Neutrophils				
30/04/2007	White blood cells				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 228120	Seq: 1	Gender: M
Reported: 02/05/2007		Weight: 110.00
Hospitalisation:		Age: 36
Onset Date: 23/04/2007		DOB: 08/07/1970
Outcome: Recovered	01/05/2007	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia	Caused or prolonged inpatient hospitalisation	mild	
Abdominal pain	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 13/04/2007 Stopped: 26/04/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/05/2007	C-Reactive Protein		26/04/2007	165	
02/05/2007	C-Reactive Protein		28/04/2007	208	
02/05/2007	C-Reactive Protein		30/04/2007	105	
02/05/2007	lipase	110-290	26/04/2007	705	
02/05/2007	lipase	110-290	28/04/2007	1141	
02/05/2007	lipase	110-290	30/04/2007	512	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 228120 **Seq:** 1 **Gender:** M
Reported: 02/05/2007 **Weight:** 110.00
Hospitalisation: **Age:** 36
Onset Date: 23/04/2007 **DOB:** 08/07/1970
Outcome: Recovered 01/05/2007 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lipase increased	Caused or prolonged inpatient hospitalisation		
Malaise	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Suspected)	Reason: Unspecified schizophrenia
Tablet	400.0 Milligram Daily Oral
Batch:	Started: 13/04/2007 Stopped: 26/04/2007

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 228142	Seq: 1	Gender: M
Reported: 02/05/2007		Weight: 0.00
Hospitalisation:		Age: 50
Onset Date: 02/02/2007		DOB: 03/09/1956
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Reflux oesophagitis	Caused or prolonged inpatient hospitalisation	Patient experienced tachyarrhythmia, reflux oesophagitis, duodinitis, hiatus hernia, had troponin rise, was tachycardic, febrile, had "marked liver shift", "possible bacterial infection", vomited blood.	Clozaril discontinued, pantoprazole 40mg bid and flucloxacillin 2g qid.
Bacterial infection	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LORAZEPAM (Other drug)	Reason:
Batch:	Started: 16/12/2006 Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 12/01/2007 Stopped: 05/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/05/2007	Endoscopy				6 Feb 2007 Upper endoscopy: Oesophagus: Moderate to severe reflux oesophagitis. Stomach : normal. Duodenum: Moderate diffuse erythematous bulbar post bulbar duodenitis.
02/05/2007	Other data				12 Feb 2007 Angiogram: Official report not available but reporter was informed verbally: No abnormality detected.

Additional Information:



Therapeutic Goods Administration Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 228142

Seq: 1

Gender: M

Reported: 02/05/2007

Weight: 0.00

Hospitalisation:

Age: 50

Onset Date: 02/02/2007

DOB: 03/09/1956

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Duodenitis	Caused or prolonged inpatient hospitalisation		
Haematemesis	Caused or prolonged inpatient hospitalisation		
Hiatus hernia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LORAZEPAM (Other drug)	Reason:		
Batch:	Started: 16/12/2006	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 12/01/2007	Stopped: 05/02/2007	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 228142
Reported: 02/05/2007

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 02/02/2007
Outcome: Recovered

Age: 50
DOB: 03/09/1956
Causality: Causality possible

Reaction Details:

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

Medicine Details:

LORAZEPAM (Other drug)	Reason:		
Batch:	Started: 16/12/2006	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 12/01/2007	Stopped: 05/02/2007	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2006 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 228142

Seq: 1

Gender: M

Reported: 02/05/2007

Weight: 0.00

Hospitalisation:

Onset Date: 02/02/2007

Age: 50

Outcome: Recovered

DOB: 03/09/1956

Causality: Causality possible

Reaction Details:

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

Medicine Details:

LORAZEPAM (Other drug)	Reason:		
Batch:	Started: 16/12/2006	Stopped:	
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 12/01/2007	Stopped: 05/02/2007	

Laboratory Investigations:

Additional Information: