



THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

CLOZAPINE		Layer 1 of 1		
		ALL REPORT DATES		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
- Cases Including Medicine		3902	248	3388
- Occurrences of Medicine		3930	254	3388
- Reactions Related to Medicine		9823	575	8304
Blood and lymphatic system disorders	Agranulocytosis	112	2	97
	Anaemia	33	2	30
	Anaemia macrocytic	1	0	1
	Anaemia neonatal	1	0	1
	Anisocytosis	3	0	3
	Basophilia	1	0	1
	Bone marrow failure	2	0	2
	Coagulopathy	2	2	1
	Disseminated intravascular coagulation	2	0	2
	Eosinopenia	4	0	4
	Eosinophilia	145	0	129
	Granulocytosis	3	0	3
	Haemolysis	1	0	1
	Haemolytic anaemia	1	0	1
	Hypochromic anaemia	1	0	1
	Leukocytosis	132	5	117
	Leukopenia	272	1	249
	Lymphadenopathy	4	0	3
	Lymphocytosis	8	0	6
	Lymphopenia	21	2	18
	Microcytic anaemia	2	0	2
	Microcytosis	1	0	1
	Monocytopenia	1	0	1
	Monocytosis	1	0	1
	Neutropenia	578	3	530
	Neutrophilia	22	0	18
	Normochromic normocytic anaemia	1	0	0
	Pancytopenia	14	0	8

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CLOZAPINE		Layer 1 of 1		
Blood and lymphatic system disorders	Poikilocytosis	3	0	3
	Splenomegaly	5	1	3
	Thrombocythaemia	10	0	8
	Thrombocytopenia	54	1	45
Cardiac disorders	Acute myocardial infarction	1	0	1
	Angina pectoris	7	0	7
	Aortic valve disease	1	0	1
	Arrhythmia	18	3	13
	Atrial fibrillation	24	2	20
	Atrial flutter	3	1	1
	Atrial hypertrophy	2	0	1
	Atrioventricular block	3	0	3
	Atrioventricular block first degree	2	0	2
	Atrioventricular block second degree	1	0	1
	Bradycardia	12	0	12
	Bundle branch block	7	0	6
	Bundle branch block left	2	0	1
	Bundle branch block right	7	0	7
	Cardiac arrest	22	18	15
	Cardiac disorder	67	1	62
	Cardiac failure	42	7	33
	Cardiac failure congestive	3	0	3
	Cardiac tamponade	3	0	3
	Cardiogenic shock	1	0	1
	Cardiomegaly	35	3	27
	Cardiomyopathy	166	6	148
	Cardio-respiratory arrest	3	3	3
	Congestive cardiomyopathy	5	0	5
	Coronary artery occlusion	1	1	1
	Cyanosis	8	2	4
	Diastolic dysfunction	3	0	3
	Dilatation atrial	7	0	7
	Dilatation ventricular	11	0	9
	Extrasystoles	11	0	11
	Hypertensive cardiomyopathy	1	0	1

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CLOZAPINE		Layer 1 of 1		
Cardiac disorders	Hypertrophic cardiomyopathy	3	0	3
	Left ventricular dysfunction	14	0	14
	Left ventricular failure	15	1	13
	Left ventricular hypertrophy	3	1	3
	Mitral valve disease	1	0	1
	Mitral valve incompetence	6	0	5
	Myocardial infarction	33	20	29
	Myocardial ischaemia	12	3	12
	Myocarditis	227	12	201
	Nodal arrhythmia	1	0	1
	Palpitations	37	0	35
	Pericardial effusion	23	1	20
	Pericarditis	30	1	26
	Right atrial dilatation	1	0	1
	Right ventricular failure	2	0	1
	Right ventricular hypertrophy	1	0	1
	Sinus tachycardia	30	0	27
	Supraventricular tachycardia	6	0	3
	Tachyarrhythmia	2	0	2
	Tachycardia	426	6	367
	Tricuspid valve incompetence	3	0	3
	Ventricular dysfunction	10	0	9
	Ventricular extrasystoles	1	0	1
	Ventricular failure	4	0	4
	Ventricular fibrillation	2	1	2
	Ventricular hyperkinesia	2	0	2
	Ventricular hypertrophy	10	0	10
Ventricular hypokinesia	7	0	7	
Ventricular tachycardia	2	0	2	
Congenital, familial and genetic disorders	Cleft palate	1	0	0
	Congenital foot malformation	1	0	0
	Deafness congenital	1	0	1
Ear and labyrinth disorders	Deafness	1	0	1
	Vertigo	1	0	1
Endocrine disorders	Diabetes insipidus	1	0	1

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CLOZAPINE		Layer 1 of 1		
Endocrine disorders	Hyperadrenocorticism	1	0	1
	Hyperparathyroidism	1	0	1
	Hyperprolactinaemia	2	0	1
	Hypoparathyroidism	1	0	1
	Hypothyroidism	1	0	1
	Thyroiditis	1	0	1
Eye disorders	Blepharospasm	1	0	1
	Cataract	3	0	2
	Conjunctivitis	1	0	1
	Diplopia	1	0	1
	Eyelid ptosis	1	0	1
	Glaucoma	1	0	0
	Miosis	1	0	1
	Mydriasis	1	0	1
	Night blindness	1	0	1
	Oculogyration	3	0	3
	Optic neuropathy	1	0	0
	Photophobia	1	0	1
	Pupillary reflex impaired	1	0	0
	Retinal detachment	1	0	1
	Retinal disorder	1	0	0
	Vision blurred	2	0	2
Visual disturbance	6	0	6	
Gastrointestinal disorders	Abdominal discomfort	2	0	2
	Abdominal distension	5	0	4
	Abdominal pain	40	1	31
	Abdominal pain upper	7	0	6
	Abdominal rigidity	1	0	1
	Anorectal disorder	1	0	1
	Bowel sounds abnormal	1	0	1
	Coeliac disease	1	0	0
	Colitis	7	0	6
	Colitis ulcerative	1	0	0
	Constipation	63	6	53
	Crohn's disease	1	0	1

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CLOZAPINE		Layer 1 of 1		
Gastrointestinal disorders	Diarrhoea	73	0	64
	Duodenitis	1	0	1
	Dyspepsia	15	1	14
	Dysphagia	21	0	19
	Enteritis	2	0	2
	Faecal incontinence	5	0	4
	Flatulence	2	1	2
	Gastritis	3	0	3
	Gastrointestinal disorder	4	1	3
	Gastrointestinal haemorrhage	3	2	3
	Gastrointestinal necrosis	3	2	2
	Gastrooesophageal reflux disease	7	0	7
	Haematemesis	6	0	6
	Hiatus hernia	1	0	1
	Ileus	2	1	2
	Ileus paralytic	8	1	5
	Inflammatory bowel disease	1	0	1
	Intestinal ischaemia	1	1	1
	Intestinal obstruction	20	4	19
	Intestinal perforation	4	2	3
	Large intestine perforation	1	0	1
	Megacolon	1	0	1
	Melaena	2	0	2
	Mouth ulceration	3	0	3
	Nausea	119	2	100
	Odynophagia	1	0	1
	Oesophageal varices haemorrhage	1	0	1
	Oesophagitis	5	0	5
	Oesophagitis ulcerative	3	0	3
	Pancreatitis	12	0	8
	Pancreatitis acute	2	0	1
	Peptic ulcer	2	0	2
	Peritonitis	2	0	2
	Proctitis	1	0	1
Rectal haemorrhage	2	0	2	

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CLOZAPINE		Layer 1 of 1		
Gastrointestinal disorders	Reflux oesophagitis	1	0	1
	Salivary gland enlargement	15	0	12
	Salivary hypersecretion	110	1	94
	Small intestinal obstruction	2	0	2
	Swollen tongue	1	0	1
	Tongue oedema	3	0	1
	Varices oesophageal	1	0	1
	Vomiting	141	7	112
General disorders and administration site conditions	Abasia	1	0	1
	Asthenia	29	0	25
	Chest discomfort	6	1	4
	Chest pain	151	1	135
	Chills	17	0	15
	Condition aggravated	3	0	3
	Crepitations	1	1	1
	Death	48	48	40
	Disease progression	1	0	1
	Drug ineffective	63	2	58
	Drug interaction	13	0	0
	Drug withdrawal syndrome	35	1	28
	Exercise tolerance decreased	1	0	1
	Face oedema	5	0	5
	Fatigue	72	2	67
	Feeling abnormal	4	0	4
	Feeling cold	1	0	1
	Feeling hot	1	0	1
	Feeling hot and cold	4	0	4
	Foaming at mouth	1	0	0
	Gait disturbance	11	2	8
	General physical health deterioration	1	0	1
	Generalised oedema	1	1	1
	Gravitational oedema	5	1	4
	Hunger	1	0	1
	Hyperpyrexia	3	0	3
	Hyperthermia	1	0	1

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CLOZAPINE		Layer 1 of 1		
General disorders and administration site conditions	Hypothermia	4	0	3
	Influenza like illness	65	4	60
	Irritability	1	0	0
	Malaise	103	3	91
	Mucosal inflammation	1	0	1
	Multi-organ failure	2	1	1
	Oedema	3	0	2
	Oedema peripheral	16	0	13
	Pain	16	0	15
	Pitting oedema	1	0	1
	Pyrexia	397	8	337
	Rebound effect	1	0	0
	Sluggishness	1	0	1
	Sudden death	111	111	89
	Swelling	1	0	1
	Therapeutic response decreased	13	0	9
	Therapeutic response increased	1	0	0
	Therapeutic response unexpected with drug	1	0	1
	Thirst	3	0	3
	Hepatobiliary disorders	Cholangitis	1	0
Cholecystitis		1	0	1
Cholelithiasis		2	0	2
Cholestasis		3	0	2
Gallbladder disorder		1	0	1
Hepatic cirrhosis		1	1	0
Hepatic failure		1	1	1
Hepatic function abnormal		85	1	68
Hepatic steatosis		8	0	5
Hepatitis		18	1	16
Hepatitis cholestatic		3	0	3
Hepatomegaly		7	0	3
Hepatosplenomegaly		2	0	1
Hepatosplenomegaly neonatal		1	0	0
Hyperbilirubinaemia		1	0	0
Jaundice		5	1	4



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CLOZAPINE		Layer 1 of 1		
Hepatobiliary disorders	Jaundice cholestatic	1	0	1
Immune system disorders	Drug hypersensitivity	1	0	1
	Hypersensitivity	3	0	3
Infections and infestations	Abscess	1	0	1
	Appendicitis	2	0	2
	Bacterial infection	6	0	6
	Bronchiectasis	1	0	1
	Bronchitis	6	1	5
	Bronchopneumonia	3	3	3
	Candidiasis	2	0	2
	Cellulitis	3	0	2
	Clostridial infection	1	0	1
	Cytomegalovirus infection	1	0	1
	Endocarditis	3	0	3
	Gastroenteritis	8	2	7
	Haemophilus infection	1	0	1
	Helicobacter infection	5	0	5
	Hepatitis C	1	1	1
	Hepatitis viral	1	0	0
	Herpes zoster	3	0	2
	Infection	15	0	13
	Infection in an immunocompromised host	1	0	1
	Infectious mononucleosis	1	0	1
	Influenza	6	0	5
	Lower respiratory tract infection	4	0	4
	Lung infection	1	1	1
	Measles	1	0	1
	Meningitis	2	1	2
	Mycoplasma infection	1	0	1
	Nasopharyngitis	3	0	1
	Necrotising fasciitis	1	0	1
	Otitis media	1	0	1
	Parotitis	1	0	1
	Perianal abscess	1	0	1
	Pharyngitis	29	0	25

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CLOZAPINE		Layer 1 of 1		
Infections and infestations	Pharyngolaryngeal abscess	1	0	1
	Pneumonia	100	16	89
	Pneumonia primary atypical	3	0	2
	Pyelonephritis	2	0	1
	Pyothorax	1	0	1
	Rash pustular	5	0	5
	Respiratory tract infection	3	0	3
	Respiratory tract infection viral	1	1	1
	Rhinitis	4	0	4
	Sepsis	18	6	13
	Sinusitis	2	0	2
	Streptococcal infection	1	0	1
	Streptococcal sepsis	2	1	2
	Subcutaneous abscess	1	1	1
	Tooth abscess	2	0	2
	Upper respiratory tract infection	11	1	10
	Urinary tract infection	8	1	7
	Varicella	3	0	2
	Viral infection	16	0	16
Injury, poisoning and procedural complications	Accidental exposure	2	0	2
	Accidental overdose	7	1	6
	Cardiac function disturbance postoperative	2	0	2
	Drug exposure during pregnancy	1	0	1
	Drug toxicity	4	0	2
	Fall	12	2	9
	Heat stroke	1	1	0
	Incorrect dose administered	2	0	2
	Intentional overdose	8	1	7
	Medication error	6	0	5
	Overdose	10	0	8
	Therapeutic agent toxicity	1	0	0
	Wrong drug administered	1	0	1
Investigations	Alanine aminotransferase increased	10	0	8
	Ammonia increased	1	0	0
	Antinuclear antibody positive	1	0	1

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CLOZAPINE		Layer 1 of 1		
Investigations	Antipsychotic drug level below therapeutic	1	0	1
	Antipsychotic drug level increased	6	0	3
	Aspartate aminotransferase increased	10	0	8
	Blood albumin increased	1	0	1
	Blood alkaline phosphatase increased	8	0	5
	Blood amylase increased	2	0	1
	Blood bilirubin increased	2	0	2
	Blood calcium decreased	1	0	0
	Blood cholesterol increased	11	1	11
	Blood creatine increased	2	0	2
	Blood creatine phosphokinase increased	164	4	138
	Blood creatine phosphokinase MB increase	2	0	2
	Blood creatinine decreased	1	0	1
	Blood creatinine increased	4	0	3
	Blood glucose increased	21	1	18
	Blood homocysteine increased	1	0	1
	Blood insulin abnormal	1	0	1
	Blood lactate dehydrogenase increased	3	0	2
	Blood lactic acid increased	1	0	1
	Blood osmolarity decreased	2	0	2
	Blood osmolarity increased	1	0	1
	Blood phosphorus decreased	1	0	1
	Blood potassium abnormal	1	0	1
	Blood pressure decreased	6	0	5
	Blood pressure diastolic increased	2	0	2
	Blood pressure increased	13	0	11
	Blood prolactin increased	4	0	3
	Blood sodium abnormal	1	0	1
	Blood sodium decreased	1	0	1
	Blood test abnormal	1	0	1
	Blood triglycerides increased	12	0	12
	Blood urea decreased	1	0	1
	Blood urea increased	1	0	0
	Blood urea nitrogen/creatinine ratio decreases	1	0	1
	Blood uric acid increased	2	0	2

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CLOZAPINE		Layer 1 of 1		
Investigations	Body temperature increased	19	0	17
	Cardiac enzymes increased	6	0	5
	Cardiac murmur	2	0	2
	Cardiac output decreased	1	0	1
	C-reactive protein increased	59	0	51
	Creatinine urine increased	1	0	0
	Drug level above therapeutic	7	0	3
	Drug level below therapeutic	2	0	2
	Drug level changed	4	0	4
	Drug level decreased	23	0	17
	Drug level fluctuating	2	0	0
	Drug level increased	84	4	51
	ECG signs of ventricular hypertrophy	1	0	1
	Echocardiogram abnormal	49	0	49
	Echography abnormal	1	0	1
	Ejection fraction	1	0	1
	Ejection fraction abnormal	2	0	2
	Ejection fraction decreased	57	1	51
	Electrocardiogram abnormal	120	1	108
	Electrocardiogram change	1	0	1
	Electrocardiogram normal	1	0	1
	Electrocardiogram P wave biphasic	1	0	1
	Electrocardiogram QT prolonged	18	0	16
	Electrocardiogram QT shortened	1	0	1
	Electrocardiogram repolarisation abnormality	1	0	1
	Electrocardiogram ST segment abnormal	2	0	2
	Electrocardiogram ST segment depression	1	0	0
	Electrocardiogram ST segment elevation	4	0	4
	Electrocardiogram ST-T change	2	0	2
	Electrocardiogram ST-T segment abnormal	1	0	1
	Electrocardiogram T wave abnormal	5	0	5
	Electrocardiogram T wave amplitude decreased	2	0	2
	Electrocardiogram T wave inversion	24	0	20
	Electroencephalogram abnormal	7	0	5
	Eosinophil count decreased	1	0	1

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CLOZAPINE		Layer 1 of 1		
Investigations	Eosinophil count increased	28	1	25
	Exercise electrocardiogram abnormal	1	0	1
	Gamma-glutamyltransferase increased	15	0	13
	Glasgow coma scale abnormal	1	0	0
	Globulins increased	1	0	1
	Glucose tolerance test abnormal	1	0	1
	Haematocrit decreased	2	0	2
	Haemoglobin decreased	9	1	7
	Heart rate increased	13	0	12
	Heart rate irregular	3	0	2
	Hepatic enzyme abnormal	1	0	0
	Hepatic enzyme increased	6	0	5
	High density lipoprotein decreased	3	0	3
	Lipase increased	4	0	3
	Lipids abnormal	1	0	1
	Lipids increased	1	0	1
	Liver function test abnormal	34	0	28
	Low density lipoprotein increased	1	0	1
	Lymphocyte count decreased	6	0	4
	Lymphocyte count increased	1	0	1
	Lymphocyte morphology abnormal	2	0	2
	Mean cell volume decreased	2	0	2
	Monocyte count decreased	1	0	1
	Monocyte count increased	3	0	3
	Myoglobin blood increased	1	0	1
	Myoglobin urine present	1	0	1
	Neutrophil count decreased	30	0	29
	Neutrophil count increased	35	0	33
	Oxygen saturation decreased	4	0	1
	Platelet count decreased	13	0	9
	Platelet count increased	6	0	4
	Protein total increased	1	0	1
	Prothrombin level decreased	1	0	1
	Prothrombin time prolonged	1	0	0
	Pulse abnormal	1	0	1

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CLOZAPINE		Layer 1 of 1		
Investigations	QRS axis abnormal	2	0	1
	Red blood cell count decreased	2	0	2
	Red blood cell count increased	2	0	1
	Red blood cell elliptocytes present	1	0	1
	Red blood cell sedimentation rate abnormal	1	0	1
	Red blood cell sedimentation rate increased	35	1	23
	Red cell distribution width increased	1	0	0
	Respiratory rate increased	1	0	0
	Scan myocardial perfusion abnormal	1	0	1
	Thyroid function test abnormal	1	0	1
	Transaminases increased	1	0	0
	Troponin I increased	22	0	20
	Troponin increased	119	1	111
	Troponin T increased	1	0	1
	Ultrasound liver abnormal	1	0	1
	Urine osmolarity decreased	1	0	1
	Weight decreased	18	0	17
	Weight increased	94	2	81
	White blood cell count decreased	31	0	29
	White blood cell count increased	46	1	38
Metabolism and nutrition disorders	Acidosis	2	2	1
	Anorexia	23	2	17
	Decreased appetite	1	0	1
	Dehydration	16	0	13
	Diabetes mellitus	93	2	86
	Diabetes mellitus inadequate control	2	0	1
	Diabetes mellitus insulin-dependent	5	1	5
	Diabetes mellitus non-insulin-dependent	8	2	7
	Diabetic ketoacidosis	4	0	3
	Electrolyte imbalance	2	1	2
	Glucose tolerance impaired	4	0	3
	Hyperammonaemia	1	0	0
	Hypercalcaemia	4	0	3
	Hypercholesterolaemia	3	0	3
	Hyperglycaemia	64	1	61

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CLOZAPINE		Layer 1 of 1		
Metabolism and nutrition disorders	Hyperkalaemia	2	2	0
	Hyperlipidaemia	7	1	6
	Hypernatraemia	2	0	2
	Hyperphosphataemia	2	0	2
	Hypertriglyceridaemia	2	0	2
	Hyperuricaemia	1	0	1
	Hypocalcaemia	3	1	1
	Hypochloraemia	1	0	1
	Hypoglycaemia	3	1	3
	Hypokalaemia	6	1	5
	Hyponatraemia	21	4	15
	Hypophosphataemia	1	0	1
	Hypoproteinaemia	1	0	1
	Increased appetite	2	0	2
	Insulin resistance	2	0	1
	Ketoacidosis	1	0	1
	Ketosis	11	2	11
	Metabolic syndrome	1	0	1
	Obesity	3	2	3
	Polydipsia	15	0	12
Vitamin B12 deficiency	1	0	1	
Musculoskeletal and connective tissue disorders	Arthralgia	14	0	12
	Back pain	2	0	1
	Joint stiffness	2	0	1
	Mobility decreased	2	0	2
	Muscle atrophy	1	0	1
	Muscle disorder	1	0	1
	Muscle rigidity	3	0	2
	Muscle spasms	3	0	3
	Muscle twitching	8	0	7
	Muscular weakness	3	0	2
	Musculoskeletal chest pain	1	0	1
	Musculoskeletal stiffness	2	0	2
	Myalgia	26	0	21
	Myopathy	4	0	4

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CLOZAPINE		Layer 1 of 1		
Musculoskeletal and connective tissue disorders	Myositis	4	0	4
	Neck mass	1	0	1
	Pathological fracture	1	0	1
	Posture abnormal	2	0	2
	Rhabdomyolysis	6	1	5
	Tendonitis	1	0	1
	Torticollis	1	0	1
	Trismus	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adrenal carcinoma	1	0	1
	Angiocentric lymphoma	1	1	0
	Basal cell carcinoma	1	0	1
	Brain neoplasm malignant	2	2	2
	Breast cancer female	3	1	1
	Chronic lymphocytic leukaemia	1	0	1
	Hepatic neoplasm malignant	2	0	2
	Leukaemia	4	2	3
	Lung neoplasm malignant	1	0	1
	Lymphocytic leukaemia	1	0	1
	Lymphoma	5	0	3
	Malignant melanoma	1	0	1
	Metastatic neoplasm	1	1	1
	Multiple myeloma	3	0	2
	Neoplasm malignant	2	2	2
	Pituitary tumour	1	0	0
	Pituitary tumour benign	1	0	1
	Pseudolymphoma	4	1	3
	Testis cancer	1	0	1
	Nervous system disorders	Akathisia	4	0
Amnesia		3	0	2
Anticholinergic syndrome		2	0	2
Aphasia		5	0	4
Aura		1	0	0
Balance disorder		5	0	5
Cataplexy		1	0	1
Cerebral atrophy		1	0	0

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CLOZAPINE		Layer 1 of 1		
Nervous system disorders	Cerebral haemorrhage	1	0	1
	Cerebral haemorrhage neonatal	1	0	0
	Cerebral infarction	2	1	2
	Cerebrovascular accident	2	2	2
	Cerebrovascular disorder	7	3	6
	Cholinergic syndrome	2	0	2
	Choreoathetosis	2	0	2
	Circadian rhythm sleep disorder	1	0	1
	Cogwheel rigidity	2	0	2
	Coma	19	4	12
	Consciousness fluctuating	9	0	7
	Convulsion	206	8	155
	Coordination abnormal	25	0	20
	Cranial nerve disorder	1	0	1
	Dementia	1	0	1
	Depressed level of consciousness	7	1	4
	Disturbance in attention	1	0	1
	Dizziness	86	1	81
	Dizziness postural	1	0	1
	Drooling	6	0	6
	Dysarthria	19	0	15
	Dysgeusia	3	0	3
	Dyskinesia	10	0	6
	Dysstasia	1	0	1
	Dystonia	19	0	13
	Encephalopathy	4	0	3
	Epilepsy	4	0	3
	Extrapyramidal disorder	7	0	4
	Facial palsy	1	0	1
	Grand mal convulsion	51	0	35
	Haemorrhage intracranial	1	0	1
	Headache	46	1	38
	Hemiparesis	2	0	1
	Hemiplegia	1	0	1
	Hyperkinesia	3	0	2

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CLOZAPINE		Layer 1 of 1		
Nervous system disorders	Hyperreflexia	2	0	0
	Hypersomnia	1	0	1
	Hypertonia	15	0	10
	Hypoaesthesia	5	0	4
	Hypokinesia	6	0	5
	Hyporeflexia	1	0	0
	Hypotonia	2	0	2
	Incoherent	1	0	0
	Lethargy	15	0	13
	Loss of consciousness	14	1	11
	Memory impairment	4	0	3
	Meningism	1	0	1
	Mental impairment	2	0	2
	Migraine	1	0	1
	Movement disorder	3	0	3
	Muscle contractions involuntary	3	0	3
	Myoclonic epilepsy	1	0	1
	Myoclonus	16	0	11
	Neuroleptic malignant syndrome	87	2	60
	Neuropathy	1	0	1
	Neuropathy peripheral	1	0	1
	Nystagmus	1	0	1
	Opisthotonus	2	0	2
	Paraesthesia	6	0	5
	Paresis	1	0	1
	Parkinsonian gait	1	0	1
	Parkinsonism	4	0	2
	Parkinson's disease	2	0	2
	Partial seizures	1	0	1
	Petit mal epilepsy	1	0	1
	Reflexes abnormal	1	0	1
	Restless legs syndrome	1	0	1
	Sedation	38	1	31
	Sensory disturbance	1	0	1
Serotonin syndrome	1	0	0	

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

CLOZAPINE		Layer 1 of 1		
Nervous system disorders	Somnolence	106	3	84
	Speech disorder	15	0	14
	Stupor	3	0	1
	Syncope	69	8	51
	Syncope vasovagal	1	0	1
	Tardive dyskinesia	12	0	4
	Tongue biting	1	0	1
	Transient ischaemic attack	2	0	2
	Tremor	35	0	29
	Upper motor neurone lesion	1	0	0
	Visual field defect	2	0	2
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	1	0	1
	Foetal distress syndrome	2	0	1
	Intra-uterine death	1	0	1
	Weight decrease neonatal	1	0	0
Psychiatric disorders	Abnormal behaviour	6	1	2
	Acute psychosis	1	0	1
	Affect lability	1	0	1
	Aggression	8	0	7
	Agitation	24	1	14
	Alcohol withdrawal syndrome	1	0	1
	Anxiety	20	1	17
	Apathy	4	0	4
	Catatonia	6	0	4
	Completed suicide	9	9	8
	Confusional state	74	2	60
	Crying	1	0	0
	Delirium	35	2	23
	Delusion	5	0	4
	Delusional disorder, mixed type	1	0	1
	Depersonalisation	2	0	2
	Depression	8	1	5
	Disorientation	4	1	2
	Disturbance in social behaviour	1	0	1
	Elevated mood	1	0	1

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

CLOZAPINE		Layer 1 of 1		
Psychiatric disorders	Emotional distress	2	0	2
	Hallucination	12	1	11
	Hallucination, auditory	6	0	4
	Hallucination, visual	2	0	2
	Illusion	1	0	1
	Impulsive behaviour	1	0	0
	Inappropriate affect	1	0	1
	Insomnia	4	1	4
	Libido increased	1	0	1
	Mania	4	0	4
	Mental disorder	6	0	6
	Neurosis	15	0	14
	Nightmare	1	0	1
	Obsessive-compulsive disorder	7	0	5
	Panic attack	1	1	1
	Paranoia	3	0	2
	Polydipsia psychogenic	1	0	0
	Psychotic disorder	41	0	31
	Restlessness	4	0	4
	Schizophrenia	3	0	3
	Schizophreniform disorder	2	0	2
	Sleep disorder	2	0	2
	Social avoidant behaviour	1	0	1
	Suicidal ideation	2	0	1
Suicide attempt	55	18	50	
Tension	1	0	0	
Thinking abnormal	5	1	4	
Violent ideation	1	0	0	
Renal and urinary disorders	Albuminuria	2	1	0
	Dysuria	4	0	3
	Enuresis	8	0	7
	Glycosuria	2	0	2
	Haematuria	2	1	0
	Hydronephrosis	1	0	1
	Myoglobinuria	2	0	1

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

CLOZAPINE		Layer 1 of 1		
Renal and urinary disorders	Nephritis	1	0	0
	Nephritis interstitial	5	0	5
	Nephrolithiasis	1	0	1
	Nocturia	4	0	4
	Oliguria	1	0	1
	Pollakiuria	5	0	5
	Polyuria	11	0	9
	Renal failure	7	0	6
	Renal failure acute	19	3	15
	Renal impairment	19	1	16
	Tubulointerstitial nephritis	1	0	1
	Urinary incontinence	59	0	49
	Urinary retention	6	0	5
	Reproductive system and breast disorders	Amenorrhoea	2	0
Benign prostatic hyperplasia		1	0	1
Breast tenderness		1	0	1
Dysmenorrhoea		1	0	0
Ejaculation disorder		2	0	2
Ejaculation failure		16	0	13
Erectile dysfunction		6	0	5
Galactorrhoea		3	0	1
Gynaecomastia		1	0	1
Menorrhagia		1	0	0
Oligomenorrhoea		1	0	0
Ovarian cyst		2	0	2
Penis disorder		1	0	1
Polycystic ovaries		1	0	1
Priapism		6	0	6
Prostatism		1	0	1
Sexual dysfunction		2	0	2
Testicular disorder		2	0	2
Respiratory, thoracic and mediastinal disorders	Alveolitis	1	0	1
	Alveolitis allergic	3	0	2
	Apnoea	6	1	6
	Asphyxia	4	4	4

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

CLOZAPINE		Layer 1 of 1		
Respiratory, thoracic and mediastinal disorders	Aspiration	5	4	5
	Asthma	6	2	6
	Bronchospasm	14	1	13
	Choking	7	0	6
	Choking sensation	1	0	1
	Chronic obstructive pulmonary disease	1	1	1
	Cough	29	1	24
	Dry throat	1	0	1
	Dyspnoea	137	4	114
	Dyspnoea exertional	2	0	2
	Eosinophilic pneumonia	1	0	1
	Epistaxis	2	0	2
	Haemoptysis	1	0	1
	Hiccups	1	0	1
	Hyperventilation	5	0	2
	Hypoventilation	2	0	2
	Hypoxia	17	2	10
	Infantile apnoeic attack	1	0	0
	Interstitial lung disease	1	0	1
	Lung consolidation	1	0	1
	Lung infiltration	2	0	2
	Obstructive airways disorder	1	0	1
	Orthopnoea	2	0	2
	Pharyngeal oedema	1	0	1
	Pharyngolaryngeal pain	7	0	7
	Pleural effusion	11	0	9
	Pleurisy	2	0	1
	Pleuritic pain	13	0	10
	Pneumonia aspiration	4	2	4
	Pneumonitis	2	0	2
	Productive cough	5	0	4
	Pulmonary embolism	17	3	13
	Pulmonary fibrosis	2	0	2
	Pulmonary hypertension	2	0	1
	Pulmonary oedema	13	5	9

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

CLOZAPINE		Layer 1 of 1		
Respiratory, thoracic and mediastinal disorders	Respiratory arrest	1	1	1
	Respiratory depression	7	1	5
	Respiratory disorder	10	1	7
	Respiratory distress	1	0	0
	Respiratory failure	9	7	8
	Rhinorrhoea	1	0	1
	Sinus disorder	1	0	1
	Sleep apnoea syndrome	2	0	2
	Tachypnoea	1	0	1
	Tonsillar disorder	1	0	1
	Wheezing	5	0	4
Skin and subcutaneous tissue disorders	Acne	3	0	2
	Alopecia	6	0	5
	Angioedema	1	0	0
	Cold sweat	4	0	3
	Dermatitis exfoliative generalised	1	0	1
	Drug eruption	1	0	1
	Eczema	2	0	2
	Erythema	2	0	0
	Erythema nodosum	1	0	1
	Hyperhidrosis	86	1	69
	Lichenoid keratosis	1	0	1
	Night sweats	2	0	2
	Periorbital oedema	4	0	3
	Photosensitivity reaction	2	0	1
	Pruritus	14	0	14
	Psoriasis	1	0	1
	Purpura	2	0	2
	Rash	32	0	26
	Rash erythematous	6	0	6
	Rash generalised	1	1	0
	Rash maculo-papular	17	0	13
	Rash morbilliform	1	0	0
Rash papular	1	0	1	
Rash vesicular	1	0	1	



THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

CLOZAPINE		Layer 1 of 1		
Skin and subcutaneous tissue disorders	Skin discolouration	1	0	1
	Skin disorder	1	0	0
	Skin odour abnormal	2	0	2
	Sweat gland disorder	1	0	1
	Swelling face	3	0	2
	Systemic lupus erythematosus rash	1	0	1
	Urticaria	6	0	4
Social circumstances	Activities of daily living impaired	1	0	1
	Treatment noncompliance	8	0	8
Surgical and medical procedures	Drug therapy changed	2	0	2
	Therapy regimen changed	6	0	4
Vascular disorders	Aortic stenosis	2	0	2
	Arteritis	1	0	0
	Blood pressure fluctuation	12	0	12
	Circulatory collapse	13	2	11
	Deep vein thrombosis	6	4	4
	Embolism	6	1	5
	Flushing	5	0	5
	Haemorrhage	3	1	2
	Hypertension	81	1	74
	Hypotension	109	4	88
	Necrosis ischaemic	2	1	2
	Orthostatic hypotension	61	0	52
	Pallor	17	0	15
	Peripheral ischaemia	2	0	2
	Shock	7	3	4
	Thrombophlebitis	3	0	2
	Thrombosis	1	0	1
	Venous thrombosis	1	1	1