

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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| 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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| 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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| 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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|----------------------------|----------------------------------|--------------|---|-----|
| 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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| 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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| 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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| 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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| 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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| 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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| 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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| 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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| 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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| 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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| 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 |

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

| 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 |

THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

| 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 | |