

COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Data Lock Date: 23-Nov-2022 18:30:06

All UK spontaneous reports received up to and including 23/11/22 for COVID-19 Vaccine AstraZeneca.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Blood disorders | | |
| <i>Anaemia deficiencies</i> | | |
| Anaemia folate deficiency | 3 | 0 |
| Anaemia vitamin B12 deficiency | 16 | 0 |
| Deficiency anaemia | 2 | 0 |
| Iron deficiency anaemia | 17 | 0 |
| Pernicious anaemia | 6 | 0 |
| <i>Anaemias NEC</i> | | |
| Anaemia | 203 | 0 |
| Autoimmune anaemia | 2 | 0 |
| Blood loss anaemia | 4 | 0 |
| Hypochromic anaemia | 3 | 0 |
| Microcytic anaemia | 1 | 0 |
| Normocytic anaemia | 4 | 0 |
| <i>Anaemias haemolytic NEC</i> | | |
| Haemolytic anaemia | 10 | 0 |
| <i>Anaemias haemolytic immune</i> | | |
| Autoimmune haemolytic anaemia | 10 | 0 |
| Cold type haemolytic anaemia | 1 | 0 |
| Evans syndrome | 1 | 0 |
| <i>Anaemias haemolytic mechanical factor</i> | | |
| Atypical haemolytic uraemic syndrome | 1 | 0 |
| Microangiopathic haemolytic anaemia | 1 | 0 |
| Red cell fragmentation syndrome | 1 | 0 |
| <i>Bleeding tendencies</i> | | |
| Increased tendency to bruise | 145 | 0 |
| Spontaneous haematoma | 8 | 0 |
| Spontaneous haemorrhage | 2 | 0 |
| <i>Coagulation factor deficiencies</i> | | |
| Acquired haemophilia | 1 | 0 |
| Hypofibrinogenaemia | 4 | 0 |
| <i>Coagulopathies</i> | | |
| Abnormal clotting factor | 12 | 0 |
| Antiphospholipid syndrome | 33 | 0 |
| Coagulopathy | 93 | 0 |
| Disseminated intravascular coagulation | 19 | 2 |
| Hypercoagulation | 30 | 1 |
| Hyperfibrinogenaemia | 1 | 0 |
| Hypocoagulable state | 1 | 0 |
| <i>Eosinophilic disorders</i> | | |
| Eosinophilia | 22 | 0 |
| Hypereosinophilic syndrome | 1 | 0 |
| <i>Haematological cysts and polyps</i> | | |
| Splenic cyst | 1 | 0 |
| <i>Haematological disorders</i> | | |
| Blood disorder | 16 | 1 |
| Bone marrow disorder | 3 | 0 |
| Bone marrow oedema | 1 | 0 |
| Mast cell activation syndrome | 22 | 0 |
| Mastocytosis | 4 | 0 |
| Methaemoglobinaemia | 1 | 0 |
| <i>Haemolyses NEC</i> | | |
| Haemolysis | 11 | 0 |
| <i>Leukocytoses NEC</i> | | |

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|---|-------|-------|
| Blood disorders Blood disorders cont'd | | |
| Leukocytosis | 5 | 0 |
| Lymphocytosis | 11 | 0 |
| Monocytosis | 2 | 0 |
| Neutrophilia | 14 | 0 |
| Leukopenias NEC | | |
| B-cell aplasia | 1 | 0 |
| Leukopenia | 15 | 0 |
| Lymphopenia | 9 | 0 |
| Lymphatic system disorders NEC | | |
| Abdominal lymphadenopathy | 1 | 0 |
| Hilar lymphadenopathy | 1 | 0 |
| Lymph node fibrosis | 1 | 0 |
| Lymph node pain | 600 | 0 |
| Lymphadenitis | 36 | 0 |
| Lymphadenopathy | 5062 | 0 |
| Lymphadenopathy mediastinal | 1 | 0 |
| Lymphatic disorder | 2 | 0 |
| Lymphatic insufficiency | 1 | 0 |
| Lymphoid tissue hyperplasia | 1 | 0 |
| Pseudolymphoma | 4 | 0 |
| Marrow depression and hypoplastic anaemias | | |
| Aplastic anaemia | 7 | 0 |
| Cytopenia | 1 | 0 |
| Myelosuppression | 5 | 0 |
| Pancytopenia | 21 | 1 |
| Neutropenias | | |
| Agranulocytosis | 4 | 0 |
| Autoimmune neutropenia | 2 | 0 |
| Febrile neutropenia | 1 | 0 |
| Neutropenia | 85 | 0 |
| Platelet disorders NEC | | |
| Platelet anisocytosis | 4 | 0 |
| Platelet disorder | 9 | 0 |
| Polycythaemia (excl rubra vera) | | |
| Polycythaemia | 7 | 0 |
| Stress polycythaemia | 3 | 0 |
| Purpuras (excl thrombocytopenic) | | |
| Purpura non-thrombocytopenic | 4 | 0 |
| Red blood cell abnormal findings NEC | | |
| Anisocytosis | 3 | 0 |
| Macrocytosis | 3 | 0 |
| Poikilocytosis | 1 | 0 |
| Polychromasia | 4 | 0 |
| Red blood cell abnormality | 1 | 0 |
| Rouleaux formation | 1 | 0 |
| Sickle cell trait and disorders | | |
| Sickle cell anaemia with crisis | 7 | 0 |
| Spleen disorders | | |
| Spleen disorder | 2 | 0 |
| Splenic artery thrombosis | 3 | 0 |
| Splenic haemorrhage | 2 | 0 |
| Splenic infarction | 20 | 0 |
| Splenic thrombosis | 1 | 0 |

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| Blood disorders Blood disorders cont'd | | |
| Splenic varices | 1 | 0 |
| Splenic vein thrombosis | 13 | 0 |
| Splenomegaly | 8 | 0 |
| Spleno renal shunt | 1 | 0 |
| <i>Thrombocytopenias</i> | | |
| Autoimmune heparin-induced thrombocytopenia | 1 | 0 |
| Heparin-induced thrombocytopenia | 17 | 0 |
| Immune thrombocytopenia | 228 | 1 |
| Thrombocytopenia | 892 | 9 |
| Thrombocytopenic purpura | 11 | 0 |
| Thrombosis with thrombocytopenia syndrome | 51 | 1 |
| Thrombotic thrombocytopenic purpura | 12 | 0 |
| <i>Thrombocytoses</i> | | |
| Thrombocytosis | 14 | 0 |
| <i>White blood cell abnormal findings NEC</i> | | |
| White blood cell disorder | 4 | 0 |
| Blood disorders SOC TOTAL | 7938 | 16 |

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|--|-------|-------|
| Cardiac disorders | | |
| <i>Aortic valvular disorders</i> | | |
| Aortic valve incompetence | 5 | 0 |
| Aortic valve sclerosis | 1 | 0 |
| Aortic valve stenosis | 1 | 0 |
| <i>Cardiac conduction disorders</i> | | |
| Adams-Stokes syndrome | 1 | 0 |
| Atrioventricular block | 36 | 2 |
| Atrioventricular block complete | 3 | 0 |
| Atrioventricular block first degree | 6 | 0 |
| Atrioventricular block second degree | 7 | 0 |
| Bundle branch block | 2 | 0 |
| Bundle branch block left | 11 | 0 |
| Bundle branch block right | 7 | 0 |
| Long QT syndrome | 2 | 0 |
| Trifascicular block | 2 | 0 |
| <i>Cardiac disorders NEC</i> | | |
| Acute cardiac event | 4 | 2 |
| Atrial thrombosis | 5 | 0 |
| Cardiac disorder | 115 | 3 |
| Cardiac dysfunction | 2 | 0 |
| Cardiac ventricular thrombosis | 15 | 2 |
| Cardiovascular disorder | 10 | 0 |
| Cardiovascular insufficiency | 10 | 0 |
| Intracardiac thrombus | 21 | 3 |
| <i>Cardiac hypertensive complications</i> | | |
| Hypertensive heart disease | 2 | 0 |
| <i>Cardiac infections and inflammations NEC</i> | | |
| Carditis | 3 | 0 |
| <i>Cardiac signs and symptoms NEC</i> | | |
| Cardiac discomfort | 20 | 0 |
| Cardiovascular symptom | 3 | 0 |
| Palpitations | 6093 | 0 |
| <i>Cardiac valve disorders NEC</i> | | |
| Cardiac valve disease | 4 | 1 |
| Heart valve incompetence | 4 | 0 |
| <i>Cardiomyopathies</i> | | |
| Cardiomyopathy | 20 | 1 |
| Cardiomyopathy acute | 1 | 0 |
| Cardiomyopathy neonatal | 1 | 0 |
| Congestive cardiomyopathy | 16 | 1 |
| Stress cardiomyopathy | 6 | 0 |
| <i>Coronary artery disorders NEC</i> | | |
| Arteriosclerosis coronary artery | 10 | 1 |
| Coronary artery disease | 15 | 0 |
| Coronary artery dissection | 5 | 1 |
| Coronary artery embolism | 1 | 0 |
| Coronary artery occlusion | 5 | 0 |
| Coronary artery stenosis | 1 | 0 |
| Coronary artery thrombosis | 29 | 4 |
| <i>Heart failure signs and symptoms</i> | | |
| Cardiac asthma | 1 | 0 |
| <i>Heart failures NEC</i> | | |
| Cardiac failure | 127 | 16 |

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| Cardiac disorders Cardiac disorders cont'd | | |
| Cardiac failure acute | 14 | 5 |
| Cardiac failure chronic | 4 | 1 |
| Cardiac failure congestive | 9 | 4 |
| Cardiogenic shock | 11 | 2 |
| Cardiopulmonary failure | 3 | 2 |
| Ventricular failure | 1 | 0 |
| Ischaemic coronary artery disorders | | |
| Acute coronary syndrome | 9 | 0 |
| Acute myocardial infarction | 92 | 14 |
| Angina pectoris | 272 | 0 |
| Angina unstable | 20 | 0 |
| Arteriospasm coronary | 7 | 0 |
| Microvascular coronary artery disease | 2 | 0 |
| Myocardial infarction | 535 | 69 |
| Myocardial ischaemia | 37 | 14 |
| Prinzmetal angina | 2 | 0 |
| Left ventricular failures | | |
| Acute left ventricular failure | 2 | 0 |
| Left ventricular failure | 10 | 1 |
| Mitral valvular disorders | | |
| Ischaemic mitral regurgitation | 1 | 0 |
| Mitral valve disease | 2 | 0 |
| Mitral valve incompetence | 11 | 0 |
| Mitral valve prolapse | 6 | 0 |
| Myocardial disorders NEC | | |
| Cardiac aneurysm | 1 | 0 |
| Cardiac sarcoidosis | 1 | 0 |
| Cardiac septal hypertrophy | 1 | 1 |
| Cardiac ventricular scarring | 1 | 0 |
| Cardiomegaly | 39 | 1 |
| Diastolic dysfunction | 3 | 0 |
| Dilatation ventricular | 1 | 0 |
| Left atrial dilatation | 1 | 0 |
| Left ventricular dilatation | 2 | 0 |
| Left ventricular dysfunction | 24 | 0 |
| Left ventricular hypertrophy | 5 | 0 |
| Myocardial fibrosis | 3 | 0 |
| Myocardial injury | 22 | 0 |
| Myocardial oedema | 1 | 0 |
| Myocardial rupture | 2 | 0 |
| Right atrial dilatation | 2 | 0 |
| Right ventricular dilatation | 3 | 0 |
| Right ventricular dysfunction | 5 | 0 |
| Systolic dysfunction | 1 | 0 |
| Ventricular dyskinesia | 1 | 0 |
| Ventricular hypertrophy | 5 | 1 |
| Ventricular hypokinesia | 3 | 0 |
| Noninfectious myocarditis | | |
| Autoimmune myocarditis | 1 | 0 |
| Myocarditis | 210 | 6 |
| Myocarditis post infection | 1 | 0 |
| Myopericarditis | 31 | 0 |
| Noninfectious pericarditis | | |

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| Cardiac disorders Cardiac disorders cont'd | | |
| Autoimmune pericarditis | 1 | 0 |
| Pericarditis | 226 | 0 |
| <i>Pericardial disorders NEC</i> | | |
| Cardiac tamponade | 2 | 2 |
| Pericardial disease | 1 | 0 |
| Pericardial effusion | 45 | 0 |
| Pericardial haemorrhage | 9 | 4 |
| Pericardial rub | 3 | 0 |
| <i>Rate and rhythm disorders NEC</i> | | |
| Arrhythmia | 168 | 4 |
| Arrhythmia neonatal | 1 | 0 |
| Bradyarrhythmia | 1 | 0 |
| Bradycardia | 95 | 1 |
| Cardiac fibrillation | 9 | 0 |
| Cardiac flutter | 327 | 0 |
| Extrasystoles | 176 | 0 |
| Heart alternation | 4 | 0 |
| Paroxysmal arrhythmia | 2 | 0 |
| Postural orthostatic tachycardia syndrome | 45 | 0 |
| Tachyarrhythmia | 11 | 0 |
| Tachycardia | 1749 | 0 |
| <i>Right ventricular failures</i> | | |
| Right ventricular failure | 5 | 1 |
| <i>Supraventricular arrhythmias</i> | | |
| Arrhythmia supraventricular | 21 | 0 |
| Atrial fibrillation | 381 | 1 |
| Atrial flutter | 56 | 0 |
| Atrial tachycardia | 4 | 0 |
| Sinus arrest | 1 | 0 |
| Sinus arrhythmia | 3 | 0 |
| Sinus bradycardia | 7 | 0 |
| Sinus node dysfunction | 2 | 0 |
| Sinus tachycardia | 76 | 0 |
| Supraventricular extrasystoles | 2 | 0 |
| Supraventricular tachycardia | 47 | 0 |
| <i>Tricuspid valvular disorders</i> | | |
| Tricuspid valve incompetence | 10 | 0 |
| <i>Ventricular arrhythmias and cardiac arrest</i> | | |
| Cardiac arrest | 203 | 44 |
| Cardio-respiratory arrest | 2 | 1 |
| Pulseless electrical activity | 7 | 0 |
| Ventricular arrhythmia | 2 | 0 |
| Ventricular extrasystoles | 25 | 0 |
| Ventricular fibrillation | 10 | 1 |
| Ventricular tachycardia | 21 | 0 |
| Cardiac disorders SOC TOTAL | 11813 | 217 |

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| Congenital disorders | | |
| <i>Autosomal chromosomal abnormalities</i> | | |
| Trisomy 18 | 1 | 0 |
| Trisomy 21 | 1 | 0 |
| <i>Cardiac disorders congenital NEC</i> | | |
| Brugada syndrome | 1 | 0 |
| Heart disease congenital | 12 | 0 |
| <i>Cardiac septal defects congenital</i> | | |
| Atrial septal defect | 2 | 0 |
| Hypertrophic cardiomyopathy | 3 | 0 |
| <i>Cardiac valve disorders congenital</i> | | |
| Bicuspid aortic valve | 1 | 0 |
| <i>Central nervous system disorders congenital NEC</i> | | |
| Brain malformation | 2 | 0 |
| Neural tube defect | 1 | 1 |
| Spina bifida | 2 | 0 |
| Syringomyelia | 1 | 0 |
| <i>Cerebellar disorders congenital</i> | | |
| Arnold-Chiari malformation | 2 | 0 |
| <i>Cerebral disorders congenital</i> | | |
| Anencephaly | 1 | 0 |
| Cerebral palsy | 2 | 0 |
| <i>Coagulation disorders congenital</i> | | |
| Factor VII deficiency | 1 | 0 |
| <i>Congenital disorders NEC</i> | | |
| Congenital anomaly | 5 | 0 |
| Congenital midline defect | 1 | 0 |
| Heterotaxia | 1 | 0 |
| Young's syndrome | 1 | 0 |
| <i>Connective tissue disorders congenital</i> | | |
| Ehlers-Danlos syndrome | 6 | 0 |
| Hypermobility syndrome | 3 | 0 |
| <i>Diaphragmatic disorders congenital</i> | | |
| Congenital diaphragmatic hernia | 2 | 0 |
| <i>Gastrointestinal tract disorders congenital NEC</i> | | |
| Gastrointestinal malformation | 1 | 0 |
| <i>Gene mutations and other alterations NEC</i> | | |
| Tuberous sclerosis complex | 1 | 0 |
| <i>Great vessel disorders congenital</i> | | |
| Coarctation of the aorta | 1 | 0 |
| Double outlet right ventricle | 1 | 0 |
| Transposition of the great vessels | 1 | 0 |
| <i>Immune system abnormalities congenital</i> | | |
| Combined immunodeficiency | 1 | 0 |
| <i>Inborn errors of lipid metabolism</i> | | |
| Type IIa hyperlipidaemia | 1 | 0 |
| <i>Inborn errors of porphyrin metabolism</i> | | |
| Porphyria acute | 1 | 0 |
| <i>Lacrimal system disorders congenital</i> | | |
| Dacryostenosis congenital | 1 | 0 |
| <i>Lysosomal storage disorders</i> | | |
| Mucopolipidosis | 1 | 0 |
| <i>Male reproductive tract disorders congenital</i> | | |
| Hydrocele | 3 | 0 |

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| Congenital disorders Congenital disorders cont'd | | |
| Micropenis | 2 | 0 |
| Penoscrotal fusion | 3 | 0 |
| Multiple cardiac abnormalities congenital | | |
| Multiple cardiac defects | 1 | 0 |
| Musculoskeletal and connective tissue disorders of face, neck and jaw congenital | | |
| Branchial cyst | 3 | 0 |
| Opitz-G/BBB syndrome | 1 | 0 |
| Musculoskeletal and connective tissue disorders of limbs congenital | | |
| Limb reduction defect | 3 | 0 |
| Os trigonum | 1 | 0 |
| Musculoskeletal disorders congenital NEC | | |
| Congenital multiplex arthrogryposis | 1 | 0 |
| Dysmorphism | 2 | 0 |
| Neurological disorders congenital NEC | | |
| Epilepsy with myoclonic-atonic seizures | 1 | 0 |
| Familial hemiplegic migraine | 1 | 0 |
| Huntington's disease | 1 | 1 |
| Neurofibromatosis | 1 | 0 |
| Spinal muscular atrophy | 1 | 0 |
| Tourette's disorder | 3 | 0 |
| Ocular disorders congenital NEC | | |
| Colour blindness | 9 | 0 |
| Palate disorders congenital | | |
| Cleft lip and palate | 1 | 0 |
| Pancreatic disorders congenital | | |
| Hereditary pancreatitis | 1 | 0 |
| Peripheral nervous system disorders congenital NEC | | |
| Paroxysmal extreme pain disorder | 14 | 0 |
| Pulmonary and bronchial disorders congenital | | |
| Cystic fibrosis | 2 | 0 |
| Sex chromosomal abnormalities | | |
| Klinefelter's syndrome | 1 | 0 |
| Skin and subcutaneous tissue disorders congenital NEC | | |
| Benign familial pemphigus | 1 | 0 |
| Tongue disorders congenital | | |
| Ankyloglossia congenital | 1 | 0 |
| Macroglossia | 1 | 0 |
| Vascular anomalies congenital NEC | | |
| Arteriovenous malformation | 1 | 0 |
| Congenital disorders SOC TOTAL | 122 | 2 |

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|---|-------|-------|
| Ear disorders | | |
| <i>Ear disorders NEC</i> | | |
| Aural polyp | 1 | 0 |
| Ear canal erythema | 1 | 0 |
| Ear congestion | 34 | 0 |
| Ear discomfort | 129 | 0 |
| Ear disorder | 24 | 0 |
| Ear haemorrhage | 20 | 0 |
| Ear inflammation | 2 | 0 |
| Ear pain | 2130 | 0 |
| Ear pruritus | 7 | 0 |
| Ear swelling | 79 | 0 |
| Otorrhoea | 8 | 0 |
| Paraesthesia ear | 1 | 0 |
| <i>Eustachian tube disorders</i> | | |
| Eustachian tube disorder | 7 | 0 |
| Eustachian tube dysfunction | 6 | 0 |
| Eustachian tube obstruction | 9 | 0 |
| <i>External ear disorders NEC</i> | | |
| Excessive cerumen production | 42 | 0 |
| External ear pain | 14 | 0 |
| Juvenile spring eruption | 1 | 0 |
| Red ear syndrome | 5 | 0 |
| <i>External ear infections and inflammations</i> | | |
| External ear inflammation | 4 | 0 |
| <i>Hearing disorders NEC</i> | | |
| Auditory disorder | 8 | 0 |
| Dysacusis | 1 | 0 |
| <i>Hearing losses</i> | | |
| Conductive deafness | 1 | 0 |
| Deafness | 447 | 1 |
| Deafness bilateral | 21 | 0 |
| Deafness neurosensory | 43 | 0 |
| Deafness transitory | 4 | 0 |
| Deafness unilateral | 61 | 0 |
| Hypoacusis | 256 | 0 |
| Mixed deafness | 3 | 0 |
| Neurosensory hypoacusis | 2 | 0 |
| Sudden hearing loss | 86 | 0 |
| <i>Hyperacusia</i> | | |
| Hyperacusis | 183 | 0 |
| <i>Inner ear disorders NEC</i> | | |
| Endolymphatic hydrops | 1 | 0 |
| Inner ear disorder | 9 | 0 |
| Meniere's disease | 30 | 0 |
| Vestibular disorder | 11 | 0 |
| <i>Inner ear infections and inflammations</i> | | |
| Autoimmune inner ear disease | 1 | 0 |
| Inner ear inflammation | 5 | 0 |
| <i>Inner ear signs and symptoms</i> | | |
| Motion sickness | 131 | 0 |
| Phobic postural vertigo | 2 | 0 |
| Tinnitus | 4572 | 0 |
| Vertigo | 2363 | 0 |

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| Ear disorders Ear disorders cont'd | | |
| Vertigo labyrinthine | 18 | 0 |
| Vertigo positional | 165 | 0 |
| Vestibular ataxia | 1 | 0 |
| <i>Middle ear disorders NEC</i> | | |
| Middle ear disorder | 1 | 0 |
| Middle ear effusion | 6 | 0 |
| <i>Tympanic membrane disorders (excl infections)</i> | | |
| Tympanic membrane perforation | 7 | 0 |
| Ear disorders SOC TOTAL | 10963 | 1 |

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| Endocrine disorders | | |
| <i>Acute and chronic thyroiditis</i> | | |
| Autoimmune thyroiditis | 12 | 0 |
| Thyroiditis | 24 | 0 |
| Thyroiditis acute | 9 | 0 |
| Thyroiditis chronic | 2 | 0 |
| Thyroiditis subacute | 9 | 0 |
| <i>Adrenal cortical hyperfunctions</i> | | |
| Cushing's syndrome | 2 | 0 |
| Cushingoid | 5 | 0 |
| <i>Adrenal cortical hypofunctions</i> | | |
| Addison's disease | 5 | 0 |
| Adrenal insufficiency | 24 | 0 |
| Adrenocortical insufficiency acute | 31 | 0 |
| Glucocorticoid deficiency | 1 | 0 |
| <i>Adrenal gland disorders NEC</i> | | |
| Adrenal disorder | 3 | 0 |
| Adrenal haematoma | 1 | 0 |
| Adrenal haemorrhage | 7 | 0 |
| Adrenal mass | 2 | 0 |
| Adrenal thrombosis | 2 | 0 |
| Adrenomegaly | 2 | 0 |
| Haemorrhagic adrenal infarction | 5 | 0 |
| <i>Anterior pituitary hyperfunction</i> | | |
| Hyperprolactinaemia | 2 | 0 |
| <i>Anterior pituitary hypofunction</i> | | |
| Hypopituitarism | 3 | 0 |
| Luteal phase deficiency | 2 | 0 |
| <i>Ectopic endocrine disorders</i> | | |
| Carcinoid syndrome | 1 | 0 |
| <i>Endocrine abnormalities of gonadal function NEC</i> | | |
| Oestrogenic effect | 1 | 0 |
| <i>Endocrine abnormalities of puberty</i> | | |
| Delayed menarche | 2 | 0 |
| Premature menarche | 17 | 0 |
| <i>Endocrine disorders NEC</i> | | |
| Endocrine disorder | 1 | 0 |
| <i>Female gonadal function disorders</i> | | |
| Anovulatory cycle | 23 | 0 |
| Ovulation delayed | 18 | 0 |
| <i>Hyperparathyroid disorders</i> | | |
| Hyperparathyroidism | 2 | 0 |
| <i>Hypoparathyroid disorders</i> | | |
| Hypoparathyroidism | 2 | 0 |
| Primary hypoparathyroidism | 1 | 0 |
| <i>Hypothalamic and pituitary disorders NEC</i> | | |
| Empty sella syndrome | 1 | 0 |
| Hypothalamo-pituitary disorder | 2 | 0 |
| Pituitary apoplexy | 2 | 0 |
| Pituitary haemorrhage | 1 | 0 |
| Secondary adrenocortical insufficiency | 1 | 0 |
| <i>Posterior pituitary disorders</i> | | |
| Diabetes insipidus | 9 | 0 |
| Inappropriate antidiuretic hormone secretion | 1 | 0 |

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| Endocrine disorders Endocrine disorders cont'd | | |
| <i>Thyroid disorders NEC</i> | | |
| Autoimmune thyroid disorder | 1 | 0 |
| Euthyroid sick syndrome | 1 | 0 |
| Goitre | 28 | 0 |
| Thyroid disorder | 29 | 0 |
| Thyroid mass | 9 | 0 |
| Thyroid pain | 20 | 0 |
| <i>Thyroid hyperfunction disorders</i> | | |
| Basedow's disease | 28 | 0 |
| Hyperthyroidism | 72 | 0 |
| Thyrotoxic crisis | 6 | 0 |
| <i>Thyroid hypofunction disorders</i> | | |
| Hypothyroidism | 77 | 0 |
| Immune-mediated hypothyroidism | 1 | 0 |
| <i>Thyroid neoplasms</i> | | |
| Thyroid cyst | 1 | 0 |
| Endocrine disorders SOC TOTAL | 511 | 0 |

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Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Eye disorders | | |
| <i>Amblyopic vision impairment</i> | | |
| Amblyopia | 13 | 0 |
| <i>Cataract conditions</i> | | |
| Cataract | 29 | 0 |
| Cataract cortical | 2 | 0 |
| Cataract subcapsular | 4 | 0 |
| <i>Choroid and vitreous haemorrhages and vascular disorders</i> | | |
| Vitreous haematoma | 1 | 0 |
| Vitreous haemorrhage | 10 | 0 |
| <i>Choroid and vitreous structural change, deposit and degeneration</i> | | |
| Chorioretinopathy | 1 | 0 |
| Vitreous detachment | 62 | 0 |
| Vitreous floaters | 218 | 0 |
| Vitreous opacities | 1 | 0 |
| <i>Colour blindness (incl acquired)</i> | | |
| Dyschromatopsia | 21 | 0 |
| <i>Conjunctival and corneal bleeding and vascular disorders</i> | | |
| Conjunctival haemorrhage | 131 | 0 |
| Corneal neovascularisation | 1 | 0 |
| Scleral haemorrhage | 1 | 0 |
| <i>Conjunctival infections, irritations and inflammations</i> | | |
| Conjunctival hyperaemia | 2 | 0 |
| Conjunctivitis allergic | 2 | 0 |
| <i>Conjunctival structural change, deposit and degeneration</i> | | |
| Conjunctival bleb | 1 | 0 |
| Conjunctival disorder | 1 | 0 |
| <i>Corneal disorders NEC</i> | | |
| Corneal defect | 1 | 0 |
| <i>Corneal infections, oedemas and inflammations</i> | | |
| Keratitis | 5 | 0 |
| Ulcerative keratitis | 4 | 0 |
| <i>Corneal structural change, deposit and degeneration</i> | | |
| Arcus lipoides | 1 | 0 |
| Corneal perforation | 1 | 0 |
| Corneal scar | 1 | 0 |
| <i>Eyelid movement disorders</i> | | |
| Blepharospasm | 164 | 0 |
| Excessive eye blinking | 9 | 0 |
| Eyelid function disorder | 1 | 0 |
| Eyelid myokymia | 3 | 0 |
| Eyelid ptosis | 65 | 0 |
| Paralytic lagophthalmos | 1 | 0 |
| <i>Glaucomas (excl congenital)</i> | | |
| Angle closure glaucoma | 6 | 0 |
| Glaucoma | 18 | 0 |
| <i>Iris and ciliary body structural change, deposit and degeneration</i> | | |
| Eye colour change | 9 | 0 |
| <i>Iris and uveal tract infections, irritations and inflammations</i> | | |
| Autoimmune uveitis | 1 | 0 |
| Iridocyclitis | 27 | 0 |
| Iritis | 15 | 0 |
| Uveitis | 55 | 0 |
| <i>Lacrimation disorders</i> | | |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Eye disorders Eye disorders cont'd | | |
| Dry eye | 334 | 0 |
| Lacrimal disorder | 1 | 0 |
| Lacrimation increased | 269 | 0 |
| <i>Lens structural change, deposit and degeneration (excl cataracts)</i> | | |
| Anterior capsule contraction | 2 | 0 |
| <i>Lid bleeding and vascular disorders</i> | | |
| Eyelid bleeding | 3 | 0 |
| Eyelid haematoma | 3 | 0 |
| <i>Lid, lash and lacrimal infections, irritations and inflammations</i> | | |
| Blepharitis | 33 | 0 |
| Chalazion | 2 | 0 |
| Eczema eyelids | 9 | 0 |
| Erythema of eyelid | 9 | 0 |
| Eyelid cyst | 20 | 0 |
| Eyelid irritation | 5 | 0 |
| Eyelid margin crusting | 1 | 0 |
| Eyelid oedema | 14 | 0 |
| Eyelid rash | 15 | 0 |
| Meibomianitis | 1 | 0 |
| Swelling of eyelid | 144 | 0 |
| <i>Lid, lash and lacrimal structural disorders</i> | | |
| Blepharal pigmentation | 1 | 0 |
| Dermatochalasis | 1 | 0 |
| Ectropion | 1 | 0 |
| Eyelid exfoliation | 3 | 0 |
| Eyelid skin dryness | 6 | 0 |
| Eyelid thickening | 4 | 0 |
| Growth of eyelashes | 10 | 0 |
| Lagophthalmos | 5 | 0 |
| <i>Ocular bleeding and vascular disorders NEC</i> | | |
| Eye haematoma | 4 | 0 |
| Eye haemorrhage | 118 | 0 |
| Ocular retrobulbar haemorrhage | 1 | 0 |
| Ocular vascular disorder | 2 | 0 |
| Ophthalmic vein thrombosis | 4 | 0 |
| <i>Ocular cysts and polyps</i> | | |
| Vitreous cyst | 1 | 0 |
| <i>Ocular disorders NEC</i> | | |
| Dark circles under eyes | 12 | 0 |
| Eye disorder | 52 | 0 |
| Eye oedema | 20 | 0 |
| Eye pain | 3433 | 0 |
| Eye swelling | 657 | 0 |
| Eye symptom | 11 | 0 |
| Eye ulcer | 11 | 0 |
| Eyelid disorder | 18 | 0 |
| Eyelid pain | 21 | 0 |
| Eyelids pruritus | 14 | 0 |
| Ocular discomfort | 91 | 0 |
| Periorbital discomfort | 1 | 0 |
| Periorbital oedema | 18 | 0 |
| Periorbital pain | 4 | 0 |
| Periorbital swelling | 112 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Eye disorders Eye disorders cont'd | | |
| Retinal disorder | 2 | 0 |
| Retinal fovea disorder | 1 | 0 |
| <i>Ocular infections, inflammations and associated manifestations</i> | | |
| Autoimmune eye disorder | 1 | 0 |
| Eye allergy | 32 | 0 |
| Eye discharge | 31 | 0 |
| Eye inflammation | 37 | 0 |
| Eye irritation | 210 | 0 |
| Eye pruritus | 309 | 0 |
| Limbal swelling | 8 | 0 |
| Ocular hyperaemia | 480 | 0 |
| Ocular rosacea | 1 | 0 |
| <i>Ocular nerve and muscle disorders</i> | | |
| Eye movement disorder | 58 | 0 |
| Gaze palsy | 5 | 0 |
| Ocular myasthenia | 6 | 0 |
| Ophthalmoplegia | 15 | 0 |
| Parinaud syndrome | 1 | 0 |
| Strabismus | 5 | 0 |
| Tolosa-Hunt syndrome | 1 | 0 |
| <i>Ocular sensation disorders</i> | | |
| Abnormal sensation in eye | 29 | 0 |
| Asthenopia | 365 | 0 |
| Eye paraesthesia | 5 | 0 |
| Eyelid sensory disorder | 5 | 0 |
| Foreign body sensation in eyes | 37 | 0 |
| Hypoaesthesia eye | 30 | 0 |
| Photophobia | 1103 | 0 |
| <i>Optic disc abnormalities NEC</i> | | |
| Optic atrophy | 2 | 0 |
| Optic disc drusen | 1 | 0 |
| Optic discs blurred | 3 | 0 |
| Papilloedema | 17 | 0 |
| <i>Optic nerve bleeding and vascular disorders</i> | | |
| Optic disc haemorrhage | 2 | 0 |
| Optic ischaemic neuropathy | 11 | 0 |
| Optic nerve sheath haemorrhage | 1 | 0 |
| <i>Orbital infections, inflammations and irritations</i> | | |
| Orbital myositis | 1 | 0 |
| Parophthalmia | 1 | 0 |
| <i>Orbital structural change, deposit and degeneration</i> | | |
| Lid sulcus deepened | 3 | 0 |
| Orbital oedema | 2 | 0 |
| <i>Pupil disorders</i> | | |
| Anisocoria | 12 | 0 |
| Holmes-Adie pupil | 1 | 0 |
| Miosis | 16 | 0 |
| Mydriasis | 35 | 0 |
| Pupil fixed | 16 | 0 |
| Pupillary deformity | 1 | 0 |
| Pupillary reflex impaired | 4 | 0 |
| <i>Refractive and accommodative disorders</i> | | |
| Altered visual depth perception | 5 | 0 |

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Eye disorders Eye disorders cont'd | | |
| Hypermetropia | 3 | 0 |
| Myopia | 6 | 0 |
| Refraction disorder | 1 | 0 |
| <i>Retinal bleeding and vascular disorders (excl retinopathy)</i> | | |
| Retinal aneurysm | 2 | 0 |
| Retinal artery embolism | 5 | 0 |
| Retinal artery occlusion | 29 | 0 |
| Retinal haemorrhage | 23 | 0 |
| Retinal infarction | 1 | 0 |
| Retinal ischaemia | 2 | 0 |
| Retinal vascular occlusion | 3 | 0 |
| Retinal vascular thrombosis | 4 | 0 |
| Retinal vein occlusion | 107 | 0 |
| Retinal vein thrombosis | 8 | 0 |
| Retinal vein varices | 1 | 0 |
| Retinal vessel avulsion | 1 | 0 |
| <i>Retinal structural change, deposit and degeneration</i> | | |
| Epiretinal membrane | 2 | 0 |
| Macular cyst | 1 | 0 |
| Macular degeneration | 11 | 0 |
| Macular detachment | 1 | 0 |
| Macular hole | 2 | 0 |
| Macular rupture | 2 | 0 |
| Maculopathy | 4 | 0 |
| Neovascular age-related macular degeneration | 13 | 0 |
| Retinal degeneration | 1 | 0 |
| Retinal detachment | 31 | 0 |
| Retinal drusen | 1 | 0 |
| Retinal tear | 21 | 0 |
| Retinal toxicity | 5 | 0 |
| Vitreoretinal traction syndrome | 1 | 0 |
| <i>Retinal, choroid and vitreous infections and inflammations</i> | | |
| Cystoid macular oedema | 1 | 0 |
| Macular oedema | 8 | 0 |
| Retinal occlusive vasculitis | 1 | 0 |
| Retinal oedema | 3 | 0 |
| Retinal vasculitis | 1 | 0 |
| <i>Retinopathies NEC</i> | | |
| Acute macular neuroretinopathy | 6 | 0 |
| Central serous chorioretinopathy | 1 | 0 |
| Diabetic retinopathy | 3 | 0 |
| Retinal exudates | 17 | 0 |
| Retinal white dots syndrome | 1 | 0 |
| Retinopathy | 8 | 0 |
| Serous retinopathy | 1 | 0 |
| <i>Scleral infections, irritations and inflammations</i> | | |
| Episcleritis | 22 | 0 |
| Scleritis | 14 | 0 |
| <i>Scleral structural change, deposit and degeneration</i> | | |
| Scleral discolouration | 1 | 0 |
| <i>Structural change, deposit and degeneration of eye NEC</i> | | |
| Deposit eye | 1 | 0 |
| Endocrine ophthalmopathy | 6 | 0 |

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| Reaction Name | Total | Fatal |
|--|--------------|----------|
| Eye disorders Eye disorders cont'd | | |
| Exophthalmos | 8 | 0 |
| Eye opacity | 1 | 0 |
| Visual colour distortions | | |
| Chloropsia | 2 | 0 |
| Chromatopsia | 1 | 0 |
| Cyanopsia | 3 | 0 |
| Erythropsia | 7 | 0 |
| Xanthopsia | 9 | 0 |
| Visual disorders NEC | | |
| Charles Bonnet syndrome | 1 | 0 |
| Delayed dark adaptation | 1 | 0 |
| Diplopia | 377 | 0 |
| Dysmetropsia | 1 | 0 |
| Halo vision | 13 | 0 |
| Metamorphopsia | 42 | 0 |
| Oscillopsia | 1 | 0 |
| Photopsia | 349 | 0 |
| Scintillating scotoma | 10 | 0 |
| Vision blurred | 3178 | 0 |
| Visual brightness | 10 | 0 |
| Visual snow syndrome | 6 | 0 |
| Visual field disorders | | |
| Visual field defect | 48 | 0 |
| Visual impairment and blindness (excl colour blindness) | | |
| Amaurosis | 1 | 0 |
| Amaurosis fugax | 10 | 0 |
| Blindness | 330 | 0 |
| Blindness cortical | 1 | 0 |
| Blindness day | 1 | 0 |
| Blindness transient | 30 | 0 |
| Blindness unilateral | 52 | 0 |
| Central vision loss | 3 | 0 |
| Night blindness | 6 | 0 |
| Sudden visual loss | 5 | 0 |
| Visual acuity reduced | 40 | 0 |
| Visual acuity reduced transiently | 1 | 0 |
| Visual impairment | 854 | 0 |
| Visual pathway disorders | | |
| Optic nerve compression | 2 | 0 |
| Optic nerve disorder | 5 | 0 |
| Optic neuropathy | 11 | 0 |
| Eye disorders SOC TOTAL | 15107 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Abdominal findings abnormal</i> | | |
| Abdominal mass | 4 | 0 |
| Gastrointestinal sounds abnormal | 27 | 0 |
| <i>Abdominal hernias NEC</i> | | |
| Abdominal hernia | 1 | 0 |
| Internal hernia | 1 | 0 |
| <i>Acute and chronic pancreatitis</i> | | |
| Obstructive pancreatitis | 1 | 1 |
| Pancreatitis | 45 | 2 |
| Pancreatitis acute | 21 | 0 |
| Pancreatitis chronic | 2 | 0 |
| Pancreatitis necrotising | 2 | 0 |
| <i>Anal and rectal disorders NEC</i> | | |
| Anal fissure | 2 | 0 |
| <i>Anal and rectal pains</i> | | |
| Proctalgia | 29 | 0 |
| <i>Anal and rectal signs and symptoms</i> | | |
| Anal blister | 2 | 0 |
| Anal hypoaesthesia | 7 | 0 |
| Anal inflammation | 2 | 0 |
| Anal paraesthesia | 2 | 0 |
| Anal pruritus | 8 | 0 |
| Anal rash | 1 | 0 |
| Anal spasm | 1 | 0 |
| Anorectal discomfort | 12 | 0 |
| Anorectal swelling | 1 | 0 |
| Rectal discharge | 2 | 0 |
| Rectal spasm | 2 | 0 |
| Rectal tenesmus | 2 | 0 |
| <i>Anal and rectal ulcers and perforation</i> | | |
| Anal ulcer | 2 | 0 |
| <i>Benign oral cavity neoplasms</i> | | |
| Mouth cyst | 15 | 0 |
| Tongue cyst | 5 | 0 |
| Tongue polyp | 2 | 0 |
| <i>Colitis (excl infective)</i> | | |
| Autoimmune colitis | 5 | 0 |
| Colitis | 64 | 0 |
| Colitis ischaemic | 8 | 1 |
| Colitis microscopic | 6 | 0 |
| Colitis ulcerative | 118 | 0 |
| Crohn's disease | 109 | 0 |
| Inflammatory bowel disease | 16 | 0 |
| Terminal ileitis | 1 | 0 |
| <i>Cystic pancreatic disorders</i> | | |
| Pancreatic cyst | 1 | 0 |
| Pancreatic pseudocyst | 1 | 0 |
| <i>Dental and periodontal infections and inflammations</i> | | |
| Dental caries | 8 | 0 |
| <i>Dental developmental disorders and anomalies</i> | | |
| Tooth impacted | 1 | 0 |
| <i>Dental disorders NEC</i> | | |
| Diastema | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Loose tooth | 3 | 0 |
| Malpositioned teeth | 3 | 0 |
| Teething | 22 | 0 |
| Tooth disorder | 5 | 0 |
| Tooth erosion | 1 | 0 |
| Tooth socket haemorrhage | 2 | 0 |
| <i>Dental pain and sensation disorders</i> | | |
| Dental discomfort | 12 | 0 |
| Dental paraesthesia | 18 | 0 |
| Hyperaesthesia teeth | 68 | 0 |
| Hypoaesthesia teeth | 2 | 0 |
| Toothache | 349 | 0 |
| <i>Dental pulp disorders</i> | | |
| Dental pulp disorder | 2 | 0 |
| <i>Dental surface disorders</i> | | |
| Tooth discolouration | 19 | 0 |
| <i>Diaphragmatic hernias</i> | | |
| Hiatus hernia | 21 | 0 |
| <i>Diarrhoea (excl infective)</i> | | |
| Diarrhoea | 9062 | 0 |
| Diarrhoea haemorrhagic | 34 | 0 |
| <i>Diverticula</i> | | |
| Diverticulum | 12 | 0 |
| Diverticulum intestinal | 1 | 0 |
| <i>Duodenal and small intestinal stenosis and obstruction</i> | | |
| Small intestinal obstruction | 1 | 0 |
| Superior mesenteric artery syndrome | 1 | 0 |
| <i>Duodenal ulcers and perforation</i> | | |
| Duodenal ulcer | 2 | 0 |
| Duodenal ulcer haemorrhage | 2 | 1 |
| <i>Dyspeptic signs and symptoms</i> | | |
| Dyspepsia | 924 | 0 |
| Epigastric discomfort | 20 | 0 |
| Eructation | 112 | 0 |
| <i>Faecal abnormalities NEC</i> | | |
| Abnormal faeces | 27 | 0 |
| Faecaloma | 5 | 0 |
| Faeces discoloured | 57 | 0 |
| Faeces hard | 4 | 0 |
| Faeces pale | 8 | 0 |
| Faeces soft | 23 | 0 |
| Mucous stools | 16 | 0 |
| <i>Flatulence, bloating and distension</i> | | |
| Abdominal distension | 750 | 0 |
| Aerophagia | 2 | 0 |
| Flatulence | 414 | 0 |
| <i>Gastric and oesophageal haemorrhages</i> | | |
| Gastric haemorrhage | 16 | 1 |
| Portal hypertensive gastropathy | 1 | 0 |
| <i>Gastric ulcers and perforation</i> | | |
| Gastric ulcer | 14 | 0 |
| Gastric ulcer haemorrhage | 1 | 0 |
| Gastric ulcer perforation | 1 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| <i>Gastritis (excl infective)</i> | | |
| Chronic gastritis | 5 | 0 |
| Gastritis | 124 | 0 |
| Reflux gastritis | 20 | 0 |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> | | |
| Abdominal migraine | 3 | 0 |
| Abdominal pain | 4645 | 1 |
| Abdominal pain lower | 273 | 0 |
| Abdominal pain upper | 5383 | 0 |
| Abdominal rigidity | 64 | 0 |
| Abdominal tenderness | 25 | 0 |
| Gastrointestinal pain | 336 | 0 |
| Oesophageal pain | 11 | 0 |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i> | | |
| Constipation | 527 | 0 |
| Duodenogastric reflux | 5 | 0 |
| Gastric dilatation | 18 | 0 |
| Gastrooesophageal reflux disease | 253 | 0 |
| Impaired gastric emptying | 9 | 0 |
| Infrequent bowel movements | 3 | 0 |
| Intestinal dilatation | 4 | 0 |
| Oesophageal hypomotility | 1 | 0 |
| <i>Gastrointestinal disorders NEC</i> | | |
| Appendix disorder | 4 | 0 |
| Food poisoning | 13 | 0 |
| Functional gastrointestinal disorder | 25 | 0 |
| Gastric disorder | 21 | 0 |
| Gastrointestinal disorder | 54 | 0 |
| Gastrointestinal oedema | 3 | 0 |
| Gastroptosis | 1 | 0 |
| Neurogenic bowel | 3 | 0 |
| Stomach mass | 3 | 0 |
| <i>Gastrointestinal dyskinetic disorders</i> | | |
| Bowel movement irregularity | 10 | 0 |
| Change of bowel habit | 24 | 0 |
| Dyschezia | 14 | 0 |
| Gastrointestinal motility disorder | 7 | 0 |
| Oesophageal achalasia | 5 | 0 |
| <i>Gastrointestinal fistulae</i> | | |
| Anal fistula | 1 | 0 |
| <i>Gastrointestinal inflammatory disorders NEC</i> | | |
| Appendicitis noninfective | 2 | 0 |
| Duodenitis | 1 | 0 |
| Enteritis | 3 | 0 |
| Gastrointestinal inflammation | 4 | 0 |
| Gastrointestinal tract irritation | 4 | 0 |
| Intestinal angioedema | 1 | 0 |
| Ischaemic enteritis | 1 | 0 |
| <i>Gastrointestinal mucosal dystrophies and secretion disorders</i> | | |
| Achlorhydria | 1 | 0 |
| Barrett's oesophagus | 1 | 0 |
| Hyperchlorhydria | 4 | 0 |
| <i>Gastrointestinal necrosis and gangrene (excl gangrenous hernia)</i> | | |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Gastrointestinal necrosis | 2 | 0 |
| <i>Gastrointestinal signs and symptoms NEC</i> | | |
| Abdominal discomfort | 1630 | 0 |
| Abdominal symptom | 6 | 0 |
| Acute abdomen | 18 | 0 |
| Anal incontinence | 62 | 0 |
| Breath odour | 27 | 0 |
| Dysphagia | 313 | 0 |
| Intestinal congestion | 1 | 0 |
| Odynophagia | 35 | 0 |
| Oesophageal discomfort | 1 | 0 |
| <i>Gastrointestinal spastic and hypermotility disorders</i> | | |
| Cardiospasm | 2 | 1 |
| Defaecation urgency | 17 | 0 |
| Frequent bowel movements | 51 | 0 |
| Irritable bowel syndrome | 165 | 0 |
| Oesophageal spasm | 9 | 0 |
| <i>Gastrointestinal stenosis and obstruction NEC</i> | | |
| Intestinal obstruction | 9 | 0 |
| Intussusception | 1 | 0 |
| Volvulus | 1 | 1 |
| <i>Gastrointestinal ulcers and perforation, site unspecified</i> | | |
| Diverticular perforation | 2 | 0 |
| Gastrointestinal perforation | 1 | 0 |
| Gastrointestinal ulcer | 1 | 0 |
| <i>Gastrointestinal vascular malformations</i> | | |
| Gastric antral vascular ectasia | 12 | 0 |
| <i>Gastrointestinal vascular occlusion and infarction</i> | | |
| Intestinal infarction | 6 | 1 |
| Intestinal ischaemia | 40 | 1 |
| Mesenteric arterial occlusion | 1 | 0 |
| Mesenteric artery embolism | 1 | 0 |
| Mesenteric artery stenosis | 1 | 0 |
| Mesenteric artery thrombosis | 5 | 0 |
| Mesenteric vein thrombosis | 25 | 0 |
| Mesenteric venous occlusion | 1 | 0 |
| Thrombosis mesenteric vessel | 4 | 0 |
| Visceral venous thrombosis | 15 | 1 |
| <i>Gingival disorders, signs and symptoms NEC</i> | | |
| Amalgam tattoo | 1 | 0 |
| Epulis | 1 | 0 |
| Gingival atrophy | 1 | 0 |
| Gingival blister | 23 | 0 |
| Gingival discolouration | 1 | 0 |
| Gingival discomfort | 8 | 0 |
| Gingival disorder | 18 | 0 |
| Gingival hypertrophy | 1 | 0 |
| Gingival oedema | 2 | 0 |
| Gingival pain | 243 | 0 |
| Gingival pruritus | 1 | 0 |
| Gingival recession | 3 | 0 |
| Gingival swelling | 59 | 0 |
| Gingival ulceration | 10 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Gingivitis ulcerative | 2 | 0 |
| Noninfective gingivitis | 25 | 0 |
| <i>Gingival haemorrhages</i> | | |
| Gingival bleeding | 186 | 0 |
| <i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i> | | |
| Anorectal varices | 1 | 0 |
| Haemorrhoidal haemorrhage | 4 | 0 |
| Haemorrhoids | 72 | 0 |
| Haemorrhoids thrombosed | 15 | 0 |
| <i>Inguinal hernias</i> | | |
| Inguinal hernia | 7 | 0 |
| <i>Intestinal haemorrhages</i> | | |
| Anal haemorrhage | 53 | 0 |
| Intestinal haemorrhage | 1 | 0 |
| Lower gastrointestinal haemorrhage | 3 | 0 |
| Mesenteric haemorrhage | 5 | 0 |
| Rectal haemorrhage | 124 | 0 |
| Small intestinal haemorrhage | 27 | 0 |
| <i>Intestinal ulcers and perforation NEC</i> | | |
| Intestinal perforation | 5 | 0 |
| Large intestine perforation | 1 | 0 |
| <i>Large intestinal stenosis and obstruction</i> | | |
| Large intestinal obstruction | 1 | 0 |
| Large intestinal stenosis | 1 | 0 |
| <i>Malabsorption syndromes</i> | | |
| Bile acid malabsorption | 1 | 0 |
| Coeliac disease | 27 | 0 |
| Steatorrhoea | 2 | 0 |
| <i>Nausea and vomiting symptoms</i> | | |
| Acetonaemic vomiting | 1 | 0 |
| Cyclic vomiting syndrome | 2 | 0 |
| Discoloured vomit | 19 | 0 |
| Faecal vomiting | 3 | 0 |
| Infantile spitting up | 1 | 0 |
| Infantile vomiting | 6 | 0 |
| Nausea | 33719 | 0 |
| Regurgitation | 4 | 0 |
| Retching | 239 | 0 |
| Vomiting | 11528 | 0 |
| Vomiting projectile | 157 | 0 |
| <i>Non-site specific gastrointestinal haemorrhages</i> | | |
| Gastrointestinal haemorrhage | 41 | 2 |
| Haematemesis | 83 | 0 |
| Haematochezia | 113 | 0 |
| Intra-abdominal haematoma | 2 | 0 |
| Intra-abdominal haemorrhage | 2 | 0 |
| Melaena | 10 | 0 |
| Upper gastrointestinal haemorrhage | 10 | 0 |
| <i>Oesophageal disorders NEC</i> | | |
| Oesophageal disorder | 2 | 0 |
| <i>Oesophageal stenosis and obstruction</i> | | |
| Acquired oesophageal web | 1 | 0 |
| Oesophageal obstruction | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| <i>Oesophageal ulcers and perforation</i> | | |
| Oesophageal rupture | 1 | 1 |
| Oesophageal ulcer | 1 | 0 |
| <i>Oesophageal varices</i> | | |
| Varices oesophageal | 4 | 0 |
| <i>Oesophagitis (excl infective)</i> | | |
| Eosinophilic oesophagitis | 3 | 0 |
| Oesophagitis | 21 | 0 |
| <i>Oral dryness and saliva altered</i> | | |
| Aptyalism | 5 | 0 |
| Dry mouth | 1175 | 0 |
| Lip dry | 81 | 0 |
| Saliva altered | 9 | 0 |
| Saliva discolouration | 1 | 0 |
| Salivary hypersecretion | 96 | 0 |
| <i>Oral soft tissue disorders NEC</i> | | |
| Angina bullosa haemorrhagica | 4 | 0 |
| Chapped lips | 25 | 0 |
| Cheilitis | 42 | 0 |
| Chronic cheek biting | 1 | 0 |
| Enlarged uvula | 11 | 0 |
| Leukoplakia oral | 2 | 0 |
| Lip blister | 38 | 0 |
| Lip disorder | 6 | 0 |
| Oral disorder | 23 | 0 |
| Oral lichen planus | 20 | 0 |
| Oral papule | 2 | 0 |
| Palatal disorder | 2 | 0 |
| Uvulitis | 5 | 0 |
| <i>Oral soft tissue haemorrhages</i> | | |
| Lip haemorrhage | 4 | 0 |
| Mouth haemorrhage | 61 | 0 |
| Oral blood blister | 56 | 0 |
| Oral purpura | 2 | 0 |
| <i>Oral soft tissue infections</i> | | |
| Angular cheilitis | 12 | 0 |
| <i>Oral soft tissue signs and symptoms</i> | | |
| Anaesthesia oral | 9 | 0 |
| Burning mouth syndrome | 17 | 0 |
| Coating in mouth | 4 | 0 |
| Hypoaesthesia oral | 687 | 0 |
| Lip discolouration | 5 | 0 |
| Lip erythema | 4 | 0 |
| Lip exfoliation | 9 | 0 |
| Lip pain | 61 | 0 |
| Lip pruritus | 16 | 0 |
| Oral discharge | 1 | 0 |
| Oral discomfort | 115 | 0 |
| Oral dysaesthesia | 1 | 0 |
| Oral mucosal blistering | 35 | 0 |
| Oral mucosal discolouration | 1 | 0 |
| Oral mucosal eruption | 33 | 0 |
| Oral mucosal erythema | 3 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Oral mucosal exfoliation | 11 | 0 |
| Oral mucosal roughening | 3 | 0 |
| Oral pain | 374 | 0 |
| Oral pruritus | 21 | 0 |
| Paraesthesia oral | 883 | 0 |
| Oral soft tissue swelling and oedema | | |
| Lip oedema | 10 | 0 |
| Lip swelling | 1020 | 0 |
| Mouth swelling | 140 | 0 |
| Oedema mouth | 1 | 0 |
| Palatal oedema | 1 | 0 |
| Palatal swelling | 14 | 0 |
| Pancreatic disorders NEC | | |
| Pancreatic disorder | 1 | 0 |
| Pancreatic failure | 1 | 0 |
| Pancreatic mass | 1 | 0 |
| Pancreatic steatosis | 1 | 0 |
| Peptic ulcers and perforation | | |
| Peptic ulcer | 2 | 0 |
| Peptic ulcer haemorrhage | 9 | 0 |
| Peritoneal and retroperitoneal disorders | | |
| Ascites | 10 | 0 |
| Pneumoperitoneum | 1 | 0 |
| Peritoneal and retroperitoneal fibrosis and adhesions | | |
| Abdominal adhesions | 2 | 0 |
| Retroperitoneal fibrosis | 1 | 0 |
| Peritoneal and retroperitoneal haemorrhages | | |
| Haemoperitoneum | 2 | 0 |
| Retroperitoneal haematoma | 1 | 0 |
| Retroperitoneal haemorrhage | 1 | 0 |
| Rectal inflammations NEC | | |
| Proctitis | 5 | 0 |
| Salivary gland disorders NEC | | |
| Salivary gland calculus | 4 | 0 |
| Salivary gland cyst | 1 | 0 |
| Salivary gland disorder | 1 | 0 |
| Salivary gland mass | 2 | 0 |
| Salivary gland pain | 14 | 0 |
| Salivary gland enlargements | | |
| Parotid gland enlargement | 14 | 0 |
| Salivary gland enlargement | 6 | 0 |
| Salivary gland infections and inflammations | | |
| Noninfective sialoadenitis | 2 | 0 |
| Stomatitis and ulceration | | |
| Aphthous ulcer | 67 | 0 |
| Lip ulceration | 19 | 0 |
| Mouth ulceration | 781 | 0 |
| Stomatitis | 113 | 0 |
| Tongue disorders | | |
| Acquired macroglossia | 1 | 0 |
| Glossitis | 19 | 0 |
| Plicated tongue | 4 | 0 |
| Tongue disorder | 37 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
 Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
 MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|--------------|-----------|
| Gastrointestinal disorders | | |
| Gastrointestinal disorders cont'd | | |
| Tongue geographic | 6 | 0 |
| Tongue haemorrhage | 2 | 0 |
| Tongue ulceration | 33 | 0 |
| Trichoglossia | 7 | 0 |
| <i>Tongue signs and symptoms</i> | | |
| Glossodynia | 272 | 0 |
| Scalloped tongue | 4 | 0 |
| Stiff tongue | 6 | 0 |
| Strawberry tongue | 1 | 0 |
| Swollen tongue | 643 | 0 |
| Tongue blistering | 29 | 0 |
| Tongue coated | 38 | 0 |
| Tongue discolouration | 42 | 0 |
| Tongue discomfort | 59 | 0 |
| Tongue dry | 25 | 0 |
| Tongue eruption | 12 | 0 |
| Tongue erythema | 7 | 0 |
| Tongue exfoliation | 3 | 0 |
| Tongue movement disturbance | 9 | 0 |
| Tongue oedema | 18 | 0 |
| Tongue pruritus | 3 | 0 |
| Tongue rough | 4 | 0 |
| Tongue spasm | 6 | 0 |
| <i>Tooth missing</i> | | |
| Tooth loss | 12 | 0 |
| Gastrointestinal disorders SOC TOTAL | 81396 | 15 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders | | |
| <i>Administration site reactions NEC</i> | | |
| Administration site bruise | 18 | 0 |
| Administration site coldness | 1 | 0 |
| Administration site erythema | 6 | 0 |
| Administration site extravasation | 1 | 0 |
| Administration site haemorrhage | 1 | 0 |
| Administration site indentation | 1 | 0 |
| Administration site induration | 1 | 0 |
| Administration site injury | 1 | 0 |
| Administration site irritation | 1 | 0 |
| Administration site joint movement impairment | 1 | 0 |
| Administration site mass | 1 | 0 |
| Administration site movement impairment | 1 | 0 |
| Administration site pain | 45 | 0 |
| Administration site rash | 5 | 0 |
| Administration site reaction | 6 | 0 |
| Administration site swelling | 3 | 0 |
| Administration site urticaria | 5 | 0 |
| Administration site warmth | 2 | 0 |
| Puncture site bruise | 61 | 0 |
| Puncture site haemorrhage | 1 | 0 |
| Puncture site pain | 22 | 0 |
| Puncture site reaction | 3 | 0 |
| Puncture site swelling | 1 | 0 |
| Vessel puncture site bruise | 2 | 0 |
| <i>Adverse effect absent</i> | | |
| No adverse event | 3 | 0 |
| <i>Application and instillation site reactions</i> | | |
| Application site acne | 1 | 0 |
| Application site bruise | 25 | 0 |
| Application site burn | 4 | 0 |
| Application site coldness | 2 | 0 |
| Application site discharge | 1 | 0 |
| Application site discolouration | 2 | 0 |
| Application site erythema | 29 | 0 |
| Application site exfoliation | 1 | 0 |
| Application site haemorrhage | 1 | 0 |
| Application site hypersensitivity | 1 | 0 |
| Application site hypoaesthesia | 2 | 0 |
| Application site inflammation | 2 | 0 |
| Application site joint pain | 1 | 0 |
| Application site laceration | 1 | 0 |
| Application site movement impairment | 1 | 0 |
| Application site odour | 1 | 0 |
| Application site pain | 54 | 0 |
| Application site pruritus | 20 | 0 |
| Application site rash | 4 | 0 |
| Application site reaction | 1 | 0 |
| Application site scar | 1 | 0 |
| Application site swelling | 4 | 0 |
| Application site vesicles | 14 | 0 |
| Application site warmth | 2 | 0 |
| Application site wound | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Instillation site bruise | 1 | 0 |
| Instillation site discomfort | 1 | 0 |
| Instillation site pain | 5 | 0 |
| Instillation site pruritus | 1 | 0 |
| Instillation site warmth | 12 | 0 |
| <i>Asthenic conditions</i> | | |
| Asthenia | 5239 | 2 |
| Chronic fatigue syndrome | 186 | 0 |
| Decreased activity | 17 | 0 |
| Fatigue | 51627 | 0 |
| Malaise | 12915 | 0 |
| Sluggishness | 32 | 0 |
| <i>Body temperature altered</i> | | |
| Hyperthermia | 13 | 0 |
| Hypothermia | 59 | 0 |
| Temperature regulation disorder | 31 | 0 |
| <i>Breast complications associated with device</i> | | |
| Capsular contracture associated with breast implant | 1 | 0 |
| <i>Complications associated with device NEC</i> | | |
| Complication associated with device | 1 | 0 |
| Complication of device removal | 1 | 0 |
| Injury associated with device | 10 | 0 |
| Medical device site dysaesthesia | 1 | 0 |
| Medical device site joint pain | 1 | 0 |
| Medical device site papule | 1 | 0 |
| Phantom shocks | 4 | 0 |
| <i>Death and sudden death</i> | | |
| Brain death | 5 | 3 |
| Cardiac death | 8 | 7 |
| Death | 332 | 332 |
| Drowning | 1 | 0 |
| Hanging | 2 | 1 |
| Sudden cardiac death | 2 | 2 |
| Sudden death | 45 | 45 |
| Sudden unexplained death in epilepsy | 1 | 1 |
| <i>Febrile disorders</i> | | |
| Hyperpyrexia | 42 | 0 |
| Masked fever | 1 | 0 |
| PFAPA syndrome | 1 | 0 |
| Pyrexia | 55785 | 0 |
| <i>Feelings and sensations NEC</i> | | |
| Chills | 43295 | 0 |
| Early satiety | 1 | 0 |
| Feeling abnormal | 3487 | 0 |
| Feeling cold | 5316 | 0 |
| Feeling drunk | 133 | 0 |
| Feeling hot | 2510 | 0 |
| Feeling jittery | 50 | 0 |
| Feeling of body temperature change | 975 | 0 |
| Feeling of relaxation | 2 | 0 |
| Hangover | 201 | 0 |
| Humidity intolerance | 1 | 0 |
| Hunger | 85 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Sensation of blood flow | 17 | 0 |
| Sensation of foreign body | 60 | 0 |
| Temperature intolerance | 96 | 0 |
| Thirst | 1278 | 0 |
| Thirst decreased | 11 | 0 |
| Fibrosis NEC | | |
| Fibrosis | 8 | 0 |
| Gait disturbances | | |
| Decreased gait velocity | 3 | 0 |
| Gait disturbance | 541 | 0 |
| Gait inability | 257 | 0 |
| Loss of control of legs | 63 | 0 |
| General signs and symptoms NEC | | |
| Apparent death | 1 | 0 |
| Chronic disease | 1 | 0 |
| Condition aggravated | 369 | 0 |
| Crepitations | 10 | 0 |
| Crying | 308 | 0 |
| Deformity | 1 | 0 |
| Developmental delay | 3 | 0 |
| Discharge | 9 | 0 |
| Disease prodromal stage | 1 | 0 |
| Disease progression | 3 | 1 |
| Disease recurrence | 2 | 0 |
| Effusion | 2 | 0 |
| Energy increased | 26 | 0 |
| Exercise tolerance decreased | 50 | 0 |
| Foaming at mouth | 7 | 0 |
| General physical health deterioration | 41 | 2 |
| General symptom | 12 | 0 |
| Glassy eyes | 8 | 0 |
| High-pitched crying | 8 | 0 |
| Idiopathic environmental intolerance | 2 | 0 |
| Ill-defined disorder | 15 | 0 |
| Illness | 5192 | 1 |
| Impaired self-care | 2 | 0 |
| Induration | 23 | 0 |
| Influenza like illness | 9758 | 0 |
| Irritability postvaccinal | 3 | 0 |
| Local reaction | 157 | 0 |
| Moaning | 9 | 0 |
| Multiple organ dysfunction syndrome | 30 | 14 |
| Nonspecific reaction | 3 | 0 |
| Organ failure | 6 | 0 |
| Perforation | 2 | 0 |
| Performance status decreased | 1 | 0 |
| Peripheral swelling | 6116 | 0 |
| Pre-existing condition improved | 18 | 0 |
| Premature ageing | 3 | 0 |
| Prolapse | 2 | 0 |
| Screaming | 34 | 0 |
| Secretion discharge | 35 | 0 |
| Sensitivity to weather change | 3 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Stenosis | 3 | 0 |
| Swelling | 2879 | 0 |
| Swelling face | 1142 | 0 |
| Symptom masked | 1 | 0 |
| Symptom recurrence | 4 | 0 |
| Tissue discolouration | 1 | 0 |
| Tissue infiltration | 1 | 0 |
| Unevaluable event | 9 | 0 |
| Healing abnormal NEC | | |
| Impaired healing | 8 | 0 |
| Hernias NEC | | |
| Hernia | 6 | 0 |
| Implant and catheter site reactions | | |
| Catheter site urticaria | 1 | 0 |
| Implant site coldness | 1 | 0 |
| Implant site discharge | 1 | 0 |
| Implant site discolouration | 4 | 0 |
| Implant site hypoaesthesia | 2 | 0 |
| Implant site pain | 5 | 0 |
| Implant site rash | 1 | 0 |
| Implant site swelling | 3 | 0 |
| Implant site urticaria | 3 | 0 |
| Implant site vesicles | 1 | 0 |
| Implant site warmth | 7 | 0 |
| Inflammations | | |
| Granuloma | 2 | 0 |
| Inflammation | 928 | 0 |
| Papillitis | 1 | 0 |
| Scar inflammation | 1 | 0 |
| Serositis | 1 | 0 |
| Systemic inflammatory response syndrome | 10 | 0 |
| Infusion site reactions | | |
| Infusion site bruising | 1 | 0 |
| Infusion site discomfort | 1 | 0 |
| Infusion site erythema | 3 | 0 |
| Infusion site joint pain | 1 | 0 |
| Infusion site mass | 5 | 0 |
| Infusion site mobility decreased | 1 | 0 |
| Infusion site nodule | 2 | 0 |
| Infusion site pain | 14 | 0 |
| Infusion site urticaria | 2 | 0 |
| Infusion site warmth | 6 | 0 |
| Injection site reactions | | |
| Injected limb mobility decreased | 51 | 0 |
| Injection site atrophy | 9 | 0 |
| Injection site bruising | 126 | 0 |
| Injection site coldness | 6 | 0 |
| Injection site cyst | 6 | 0 |
| Injection site deformation | 1 | 0 |
| Injection site discharge | 3 | 0 |
| Injection site discolouration | 9 | 0 |
| Injection site discomfort | 24 | 0 |
| Injection site dryness | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
 Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
 MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Injection site erythema | 608 | 0 |
| Injection site exfoliation | 1 | 0 |
| Injection site haematoma | 3 | 0 |
| Injection site haemorrhage | 22 | 0 |
| Injection site hypersensitivity | 5 | 0 |
| Injection site hypoaesthesia | 16 | 0 |
| Injection site indentation | 22 | 0 |
| Injection site induration | 11 | 0 |
| Injection site inflammation | 67 | 0 |
| Injection site injury | 6 | 0 |
| Injection site irritation | 4 | 0 |
| Injection site joint discomfort | 1 | 0 |
| Injection site joint erythema | 8 | 0 |
| Injection site joint pain | 35 | 0 |
| Injection site joint swelling | 1 | 0 |
| Injection site mass | 1433 | 0 |
| Injection site movement impairment | 5 | 0 |
| Injection site muscle atrophy | 1 | 0 |
| Injection site muscle weakness | 3 | 0 |
| Injection site necrosis | 7 | 0 |
| Injection site nerve damage | 2 | 0 |
| Injection site nodule | 5 | 0 |
| Injection site oedema | 28 | 0 |
| Injection site pain | 4555 | 0 |
| Injection site papule | 2 | 0 |
| Injection site paraesthesia | 27 | 0 |
| Injection site pruritus | 303 | 0 |
| Injection site rash | 311 | 0 |
| Injection site reaction | 124 | 0 |
| Injection site scab | 4 | 0 |
| Injection site scar | 6 | 0 |
| Injection site swelling | 268 | 0 |
| Injection site thrombosis | 1 | 0 |
| Injection site ulcer | 1 | 0 |
| Injection site urticaria | 41 | 0 |
| Injection site vesicles | 16 | 0 |
| Injection site warmth | 356 | 0 |
| Interactions | | |
| Drug interaction | 39 | 0 |
| Drug-device interaction | 3 | 0 |
| Food interaction | 2 | 0 |
| Inhibitory drug interaction | 12 | 0 |
| Mass conditions NEC | | |
| Cyst | 40 | 0 |
| Cyst rupture | 1 | 0 |
| Mass | 101 | 0 |
| Nodule | 29 | 0 |
| Pelvic mass | 1 | 0 |
| Mucosal findings abnormal | | |
| Mucosa vesicle | 2 | 0 |
| Mucosal disorder | 2 | 0 |
| Mucosal dryness | 1 | 0 |
| Mucosal haemorrhage | 12 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Mucosal inflammation | 11 | 0 |
| Mucosal pain | 2 | 0 |
| Mucosal ulceration | 1 | 0 |
| Oedema mucosal | 3 | 0 |
| Polyp | 6 | 0 |
| Necrosis NEC | | |
| Fat necrosis | 5 | 0 |
| Necrosis | 8 | 0 |
| Oedema NEC | | |
| Face oedema | 38 | 0 |
| Generalised oedema | 1 | 0 |
| Localised oedema | 14 | 0 |
| Oedema | 99 | 0 |
| Oedema peripheral | 176 | 0 |
| Pain and discomfort NEC | | |
| Axillary pain | 786 | 0 |
| Chest discomfort | 2198 | 0 |
| Chest pain | 6304 | 0 |
| Discomfort | 672 | 0 |
| Facial discomfort | 24 | 0 |
| Facial pain | 306 | 0 |
| Hernia pain | 4 | 0 |
| Inflammatory pain | 40 | 0 |
| Non-cardiac chest pain | 50 | 0 |
| Pain | 18093 | 0 |
| Suprapubic pain | 1 | 0 |
| Tenderness | 1853 | 0 |
| Visceral pain | 4 | 0 |
| Therapeutic and nontherapeutic responses | | |
| Adverse drug reaction | 131 | 3 |
| Adverse event | 13 | 0 |
| Adverse food reaction | 2 | 0 |
| Adverse reaction | 12 | 0 |
| Diet failure | 1 | 0 |
| Drug effect less than expected | 1 | 0 |
| Drug ineffective | 265 | 1 |
| Drug intolerance | 9 | 0 |
| Idiosyncratic drug reaction | 1 | 0 |
| Immediate post-injection reaction | 4 | 0 |
| Inadequate analgesia | 32 | 0 |
| No reaction on previous exposure to drug | 11 | 0 |
| Remission not achieved | 1 | 0 |
| Similar reaction on previous exposure to drug | 1 | 0 |
| Therapeutic product effect decreased | 3 | 0 |
| Therapeutic product effect delayed | 1 | 0 |
| Therapeutic product effect incomplete | 2 | 0 |
| Therapeutic product effect prolonged | 1 | 0 |
| Therapeutic product ineffective | 9 | 0 |
| Therapeutic reaction time decreased | 1 | 0 |
| Therapeutic response changed | 1 | 0 |
| Therapeutic response decreased | 1 | 0 |
| Therapeutic response delayed | 1 | 0 |
| Therapeutic response shortened | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Therapeutic response unexpected | 192 | 0 |
| Therapy non-responder | 3 | 0 |
| Treatment failure | 20 | 0 |
| Treatment noncompliance | 1 | 0 |
| Vaccination failure | 46 | 0 |
| Vaccine positive rechallenge | 1 | 0 |
| Trophic disorders | | |
| Atrophy | 4 | 0 |
| Calcinosis | 2 | 0 |
| Dysplasia | 3 | 0 |
| Hyperplasia | 2 | 0 |
| Ulcers NEC | | |
| Ulcer | 49 | 0 |
| Ulcer haemorrhage | 4 | 0 |
| Vaccination site reactions | | |
| Extensive swelling of vaccinated limb | 20 | 0 |
| Shoulder injury related to vaccine administration | 121 | 0 |
| Vaccination site atrophy | 1 | 0 |
| Vaccination site bruising | 142 | 0 |
| Vaccination site coldness | 1 | 0 |
| Vaccination site cyst | 3 | 0 |
| Vaccination site discharge | 1 | 0 |
| Vaccination site discolouration | 18 | 0 |
| Vaccination site discomfort | 50 | 0 |
| Vaccination site dryness | 1 | 0 |
| Vaccination site erythema | 720 | 0 |
| Vaccination site extravasation | 1 | 0 |
| Vaccination site granuloma | 8 | 0 |
| Vaccination site haematoma | 1 | 0 |
| Vaccination site haemorrhage | 11 | 0 |
| Vaccination site hyperaesthesia | 1 | 0 |
| Vaccination site hypersensitivity | 4 | 0 |
| Vaccination site hypoaesthesia | 25 | 0 |
| Vaccination site induration | 71 | 0 |
| Vaccination site inflammation | 57 | 0 |
| Vaccination site injury | 4 | 0 |
| Vaccination site irritation | 14 | 0 |
| Vaccination site joint discomfort | 2 | 0 |
| Vaccination site joint erythema | 5 | 0 |
| Vaccination site joint inflammation | 1 | 0 |
| Vaccination site joint movement impairment | 18 | 0 |
| Vaccination site joint pain | 59 | 0 |
| Vaccination site joint swelling | 4 | 0 |
| Vaccination site joint warmth | 2 | 0 |
| Vaccination site lymphadenopathy | 2 | 0 |
| Vaccination site mass | 573 | 0 |
| Vaccination site movement impairment | 115 | 0 |
| Vaccination site nerve damage | 2 | 0 |
| Vaccination site nodule | 1 | 0 |
| Vaccination site oedema | 3 | 0 |
| Vaccination site pain | 2158 | 0 |
| Vaccination site papule | 4 | 0 |
| Vaccination site paraesthesia | 13 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|---------------|------------|
| General disorders General disorders cont'd | | |
| Vaccination site pruritus | 113 | 0 |
| Vaccination site rash | 195 | 0 |
| Vaccination site reaction | 26 | 0 |
| Vaccination site scab | 2 | 0 |
| Vaccination site scar | 8 | 0 |
| Vaccination site swelling | 519 | 0 |
| Vaccination site urticaria | 13 | 0 |
| Vaccination site vesicles | 11 | 0 |
| Vaccination site warmth | 386 | 0 |
| <i>Vascular complications associated with device</i> | | |
| Vascular stent occlusion | 1 | 0 |
| Vascular stent thrombosis | 1 | 0 |
| <i>Withdrawal and rebound effects</i> | | |
| Drug withdrawal syndrome | 8 | 0 |
| Rebound effect | 1 | 0 |
| Withdrawal syndrome | 104 | 0 |
| General disorders SOC TOTAL | 258428 | 415 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Hepatic disorders | | |
| <i>Bile duct infections and inflammations</i> | | |
| Biliary colic | 33 | 0 |
| Cholangitis | 4 | 0 |
| <i>Cholecystitis and cholelithiasis</i> | | |
| Cholecystitis | 16 | 0 |
| Cholecystitis acute | 3 | 0 |
| Cholelithiasis | 17 | 0 |
| <i>Cholestasis and jaundice</i> | | |
| Cholestasis | 7 | 0 |
| Cholestasis of pregnancy | 1 | 0 |
| Jaundice | 60 | 0 |
| Jaundice cholestatic | 12 | 0 |
| Ocular icterus | 1 | 0 |
| <i>Gallbladder disorders NEC</i> | | |
| Gallbladder disorder | 4 | 0 |
| Gallbladder oedema | 1 | 0 |
| Gallbladder polyp | 1 | 0 |
| <i>Hepatic and hepatobiliary disorders NEC</i> | | |
| Liver disorder | 21 | 0 |
| <i>Hepatic enzymes and function abnormalities</i> | | |
| Hepatic function abnormal | 14 | 0 |
| Hypertransaminasaemia | 10 | 0 |
| <i>Hepatic failure and associated disorders</i> | | |
| Acute hepatic failure | 2 | 0 |
| Hepatic failure | 14 | 1 |
| Hepatorenal syndrome | 1 | 0 |
| Subacute hepatic failure | 3 | 0 |
| <i>Hepatic fibrosis and cirrhosis</i> | | |
| Cirrhosis alcoholic | 1 | 0 |
| Hepatic cirrhosis | 10 | 1 |
| Hepatic fibrosis | 2 | 0 |
| <i>Hepatic vascular disorders</i> | | |
| Budd-Chiari syndrome | 2 | 1 |
| Hepatic artery thrombosis | 1 | 0 |
| Hepatic haemorrhage | 1 | 0 |
| Hepatic hypoperfusion | 1 | 0 |
| Hepatic infarction | 2 | 1 |
| Hepatic vascular thrombosis | 2 | 0 |
| Hepatic vein thrombosis | 17 | 0 |
| Portal hypertension | 4 | 0 |
| Portal vein phlebitis | 1 | 0 |
| Portal vein thrombosis | 78 | 3 |
| Portosplenomesenteric venous thrombosis | 2 | 0 |
| <i>Hepatobiliary signs and symptoms</i> | | |
| Hepatic pain | 81 | 0 |
| Hepatomegaly | 5 | 0 |
| Liver tenderness | 6 | 0 |
| <i>Hepatocellular damage and hepatitis NEC</i> | | |
| Acute yellow liver atrophy | 1 | 0 |
| Allergic hepatitis | 1 | 0 |
| Autoimmune hepatitis | 14 | 0 |
| Cholestatic liver injury | 1 | 0 |
| Drug-induced liver injury | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
 Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
 MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Hepatic disorders Hepatic disorders cont'd | | |
| Hepatic necrosis | 2 | 1 |
| Hepatic steatosis | 14 | 0 |
| Hepatitis | 35 | 0 |
| Hepatitis acute | 8 | 1 |
| Immune-mediated hepatitis | 1 | 0 |
| Ischaemic hepatitis | 1 | 0 |
| Liver injury | 31 | 0 |
| Non-alcoholic fatty liver | 1 | 0 |
| Reye's syndrome | 1 | 0 |
| <i>Obstructive bile duct disorders (excl neoplasms)</i> | | |
| Biliary obstruction | 1 | 0 |
| Sphincter of Oddi dysfunction | 3 | 0 |
| Hepatic disorders SOC TOTAL | 558 | 9 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Immune system disorders | | |
| <i>Acute and chronic sarcoidosis</i> | | |
| Sarcoidosis | 31 | 0 |
| <i>Allergic conditions NEC</i> | | |
| Allergic oedema | 22 | 0 |
| Allergy to animal | 1 | 0 |
| Allergy to arthropod bite | 1 | 0 |
| Allergy to arthropod sting | 4 | 0 |
| Allergy to metals | 1 | 0 |
| Allergy to sting | 1 | 0 |
| Allergy to venom | 1 | 0 |
| Dust allergy | 3 | 0 |
| Hypersensitivity | 1604 | 2 |
| Infusion related hypersensitivity reaction | 5 | 0 |
| Mite allergy | 2 | 0 |
| Multiple allergies | 29 | 0 |
| Serum sickness | 15 | 0 |
| Serum sickness-like reaction | 13 | 0 |
| Type I hypersensitivity | 1 | 0 |
| Type III immune complex mediated reaction | 9 | 0 |
| Type IV hypersensitivity reaction | 4 | 0 |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> | | |
| Allergic reaction to excipient | 3 | 0 |
| Allergy to chemicals | 10 | 0 |
| Allergy to vaccine | 62 | 0 |
| Contrast media reaction | 4 | 0 |
| Drug hypersensitivity | 74 | 0 |
| Food allergy | 64 | 0 |
| Milk allergy | 1 | 0 |
| Oral allergy syndrome | 5 | 0 |
| Polymers allergy | 1 | 0 |
| Reaction to colouring | 2 | 0 |
| Reaction to excipient | 14 | 0 |
| Reaction to flavouring | 1 | 0 |
| Reaction to preservatives | 16 | 0 |
| Rubber sensitivity | 3 | 0 |
| Smoke sensitivity | 3 | 0 |
| <i>Anaphylactic and anaphylactoid responses</i> | | |
| Anaphylactic reaction | 729 | 2 |
| Anaphylactic shock | 131 | 0 |
| Anaphylactoid reaction | 24 | 0 |
| Anaphylactoid shock | 4 | 0 |
| <i>Atopic disorders</i> | | |
| Atopy | 6 | 0 |
| Seasonal allergy | 149 | 0 |
| <i>Autoimmune disorders NEC</i> | | |
| Autoimmune disorder | 89 | 0 |
| <i>Autoinflammatory diseases</i> | | |
| Autoinflammatory disease | 1 | 0 |
| <i>Endocrine autoimmune disorders</i> | | |
| Hashitoxicosis | 1 | 0 |
| <i>Immune and associated conditions NEC</i> | | |
| Bacille Calmette-Guerin scar reactivation | 38 | 0 |
| Cytokine release syndrome | 2 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022
 Earliest Reaction Date: 03-Feb-1921

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 MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Immune system disorders | | |
| Immune system disorders cont'd | | |
| Cytokine storm | 6 | 0 |
| Decreased immune responsiveness | 3 | 0 |
| Haemophagocytic lymphohistiocytosis | 16 | 1 |
| Hypocomplementaemia | 1 | 0 |
| Immune system disorder | 70 | 0 |
| Immune-mediated adverse reaction | 11 | 0 |
| Immunisation reaction | 115 | 0 |
| Multisystem inflammatory syndrome | 2 | 0 |
| Pre-engraftment immune reaction | 1 | 0 |
| Sensitisation | 34 | 0 |
| Systemic immune activation | 1 | 0 |
| Immunodeficiency disorders NEC | | |
| Immunodeficiency | 18 | 0 |
| Immunosuppression | 8 | 0 |
| Transplant rejections | | |
| Corneal graft rejection | 3 | 0 |
| Transplant rejection | 7 | 0 |
| Vasculitides | | |
| Anti-neutrophil cytoplasmic antibody positive vasculitis | 5 | 1 |
| Eosinophilic granulomatosis with polyangiitis | 2 | 0 |
| Immune system disorders SOC TOTAL | 3487 | 6 |

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022
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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Infections | | |
| <i>Abdominal and gastrointestinal infections</i> | | |
| Abdominal infection | 1 | 0 |
| Abdominal wall infection | 1 | 0 |
| Anal abscess | 1 | 0 |
| Appendicitis | 45 | 0 |
| Appendicitis perforated | 5 | 0 |
| Diarrhoea infectious | 4 | 0 |
| Diverticulitis | 33 | 0 |
| Dysentery | 5 | 0 |
| Gastric infection | 1 | 0 |
| Gastroenteritis | 47 | 0 |
| Gastrointestinal infection | 6 | 0 |
| Large intestine infection | 2 | 0 |
| Peritonitis | 5 | 0 |
| <i>Adenoviral infections</i> | | |
| Adenovirus infection | 1 | 0 |
| <i>Bacillary infections</i> | | |
| Bacillus infection | 1 | 0 |
| Gastroenteritis bacillus | 1 | 0 |
| <i>Bacterial infections NEC</i> | | |
| Abscess bacterial | 1 | 0 |
| Administration site cellulitis | 1 | 0 |
| Arthritis bacterial | 11 | 0 |
| Bacterial infection | 38 | 1 |
| Bacterial sepsis | 1 | 0 |
| Bacterial vaginosis | 5 | 0 |
| Bacterial vulvovaginitis | 1 | 0 |
| Cellulitis | 552 | 0 |
| Cellulitis orbital | 4 | 0 |
| Ear infection bacterial | 2 | 0 |
| Endocarditis bacterial | 2 | 0 |
| Eye infection bacterial | 1 | 0 |
| Folliculitis | 13 | 0 |
| Gangrene | 3 | 0 |
| Injection site cellulitis | 8 | 0 |
| Janeway lesion | 1 | 0 |
| Meningitis bacterial | 1 | 0 |
| Perichondritis | 1 | 0 |
| Periorbital cellulitis | 5 | 0 |
| Pneumonia bacterial | 7 | 1 |
| Post procedural cellulitis | 1 | 0 |
| Skin bacterial infection | 6 | 0 |
| Urinary tract infection bacterial | 5 | 0 |
| Vaccination site cellulitis | 22 | 0 |
| <i>Bone and joint infections</i> | | |
| Abscess jaw | 1 | 0 |
| Arthritis infective | 4 | 0 |
| Bursitis infective | 3 | 0 |
| Intervertebral discitis | 3 | 0 |
| Osteomyelitis | 2 | 1 |
| <i>Bordetella infections</i> | | |
| Pertussis | 3 | 0 |
| <i>Borrelial infections</i> | | |

Case Series Drug Analysis Print

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Infections | | |
| Infections cont'd | | |
| Erythema migrans | 2 | 0 |
| Lyme disease | 9 | 0 |
| Relapsing fever | 1 | 0 |
| Breast infections | | |
| Breast abscess | 3 | 0 |
| Mastitis | 47 | 0 |
| Brucella infections | | |
| Brucellosis | 1 | 0 |
| Caliciviral infections | | |
| Gastroenteritis norovirus | 1 | 0 |
| Norovirus infection | 1 | 0 |
| Campylobacter infections | | |
| Campylobacter colitis | 1 | 0 |
| Campylobacter gastroenteritis | 1 | 0 |
| Campylobacter infection | 1 | 0 |
| Candida infections | | |
| Anal candidiasis | 2 | 0 |
| Balanitis candida | 1 | 0 |
| Candida infection | 83 | 0 |
| Oral candidiasis | 64 | 0 |
| Skin candida | 3 | 0 |
| Vulvovaginal candidiasis | 64 | 0 |
| Cardiac infections | | |
| Acute endocarditis | 2 | 0 |
| Cardiac infection | 1 | 0 |
| Endocarditis | 9 | 0 |
| Myocarditis infectious | 1 | 0 |
| Central nervous system and spinal infections | | |
| Brain abscess | 3 | 0 |
| Cavernous sinus thrombosis | 9 | 0 |
| Central nervous system infection | 2 | 0 |
| Encephalitis | 51 | 1 |
| Encephalomyelitis | 4 | 0 |
| Extradural abscess | 1 | 0 |
| Meningitis | 30 | 0 |
| Myelitis | 32 | 0 |
| Chlamydial infections | | |
| Chlamydial infection | 1 | 0 |
| Clostridia infections | | |
| Clostridium difficile colitis | 5 | 0 |
| Clostridium difficile infection | 3 | 0 |
| Tetanus | 5 | 0 |
| Coronavirus infections | | |
| Asymptomatic COVID-19 | 6 | 0 |
| Breakthrough COVID-19 | 1 | 0 |
| COVID-19 | 2238 | 32 |
| COVID-19 pneumonia | 76 | 13 |
| Coronavirus infection | 7 | 0 |
| Post-acute COVID-19 syndrome | 31 | 0 |
| SARS-CoV-2 sepsis | 1 | 0 |
| Severe acute respiratory syndrome | 5 | 0 |
| Suspected COVID-19 | 56 | 0 |
| Vaccine derived SARS-CoV-2 infection | 1 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections Infections cont'd | | |
| <i>Corynebacteria infections</i> | | |
| Diphtheria | 3 | 0 |
| <i>Coxiella infections</i> | | |
| Q fever | 114 | 0 |
| <i>Coxsackie viral infections</i> | | |
| Coxsackie bronchitis | 1 | 0 |
| <i>Cytomegaloviral infections</i> | | |
| Encephalitis cytomegalovirus | 1 | 0 |
| <i>Dental and oral soft tissue infections</i> | | |
| Abscess oral | 4 | 0 |
| Gingival abscess | 9 | 0 |
| Gingivitis | 31 | 0 |
| Lip infection | 1 | 0 |
| Oral infection | 1 | 0 |
| Oral pustule | 3 | 0 |
| Parotitis | 15 | 0 |
| Pericoronitis | 3 | 0 |
| Periodontitis | 2 | 0 |
| Pulpitis dental | 1 | 0 |
| Sialoadenitis | 3 | 0 |
| Tongue abscess | 5 | 0 |
| Tooth abscess | 17 | 0 |
| Tooth infection | 15 | 0 |
| <i>Ear infections</i> | | |
| Ear infection | 154 | 0 |
| Labyrinthitis | 195 | 0 |
| Mastoiditis | 5 | 0 |
| Otitis externa | 7 | 0 |
| Otitis media | 9 | 0 |
| Otitis media chronic | 15 | 0 |
| Otosalpingitis | 1 | 0 |
| <i>Ectoparasitic infestations</i> | | |
| Acarodermatitis | 10 | 0 |
| Infestation | 1 | 0 |
| Trombidiasis | 3 | 0 |
| <i>Enterococcal infections</i> | | |
| Enterococcal infection | 1 | 0 |
| <i>Epstein-Barr viral infections</i> | | |
| Epstein-Barr virus infection | 6 | 0 |
| Epstein-Barr virus infection reactivation | 3 | 0 |
| Infectious mononucleosis | 60 | 0 |
| <i>Escherichia infections</i> | | |
| Escherichia infection | 2 | 0 |
| Escherichia sepsis | 2 | 0 |
| Gastroenteritis Escherichia coli | 1 | 0 |
| <i>Eye and eyelid infections</i> | | |
| Conjunctivitis | 88 | 0 |
| Eye infection | 48 | 0 |
| Eyelid boil | 3 | 0 |
| Eyelid infection | 6 | 0 |
| Hordeolum | 43 | 0 |
| Keratouveitis | 1 | 0 |
| Retinitis | 4 | 0 |

Case Series Drug Analysis Print

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Infections | | |
| Infections cont'd | | |
| <i>Female reproductive tract infections</i> | | |
| Endometritis | 3 | 0 |
| Fallopian tube abscess | 1 | 0 |
| Genital infection female | 1 | 0 |
| Ovarian abscess | 1 | 0 |
| Pelvic inflammatory disease | 2 | 0 |
| Pyometra | 2 | 0 |
| Vaginal abscess | 3 | 0 |
| Vaginal infection | 6 | 0 |
| Vulval abscess | 1 | 0 |
| <i>Flaviviral infections</i> | | |
| Dengue fever | 1 | 0 |
| Yellow fever | 1 | 0 |
| Yellow fever vaccine-associated neurotropic disease | 1 | 0 |
| <i>Fungal infections NEC</i> | | |
| Ear infection fungal | 2 | 0 |
| Fungal infection | 34 | 0 |
| Fungal skin infection | 10 | 0 |
| Oral fungal infection | 1 | 0 |
| Overgrowth fungal | 1 | 0 |
| Pneumonia fungal | 1 | 0 |
| Severe asthma with fungal sensitisation | 5 | 0 |
| Tonsillitis fungal | 1 | 0 |
| Vulvovaginal mycotic infection | 4 | 0 |
| <i>Helicobacter infections</i> | | |
| Helicobacter infection | 1 | 0 |
| <i>Hepatitis virus infections</i> | | |
| Hepatitis E | 1 | 0 |
| <i>Hepatobiliary and spleen infections</i> | | |
| Biliary sepsis | 5 | 1 |
| Liver abscess | 1 | 0 |
| Splenic infection | 1 | 0 |
| <i>Herpes viral infections</i> | | |
| Eczema herpeticum | 4 | 0 |
| Genital herpes | 85 | 0 |
| Genital herpes simplex | 1 | 0 |
| Genital herpes zoster | 1 | 0 |
| Haemorrhagic varicella syndrome | 1 | 0 |
| Herpes dermatitis | 2 | 0 |
| Herpes ophthalmic | 16 | 0 |
| Herpes pharyngitis | 1 | 0 |
| Herpes simplex | 50 | 0 |
| Herpes simplex reactivation | 5 | 0 |
| Herpes virus infection | 17 | 0 |
| Herpes zoster | 1715 | 0 |
| Herpes zoster disseminated | 1 | 0 |
| Herpes zoster oticus | 17 | 0 |
| Herpes zoster reactivation | 2 | 0 |
| Meningoencephalitis herpetic | 2 | 0 |
| Nasal herpes | 16 | 0 |
| Ophthalmic herpes simplex | 2 | 0 |
| Ophthalmic herpes zoster | 10 | 0 |
| Oral herpes | 728 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Infections | | |
| Infections cont'd | | |
| Varicella | 45 | 0 |
| Varicella zoster virus infection | 4 | 0 |
| <i>Infections NEC</i> | | |
| Abscess | 55 | 0 |
| Abscess limb | 25 | 0 |
| Abscess soft tissue | 2 | 0 |
| Catheter site infection | 1 | 0 |
| Coinfection | 1 | 0 |
| Device related infection | 3 | 0 |
| Empyema | 1 | 0 |
| Genital abscess | 1 | 0 |
| Groin abscess | 2 | 0 |
| Groin infection | 1 | 0 |
| Infected bite | 5 | 0 |
| Infected cyst | 4 | 0 |
| Infection | 562 | 4 |
| Infection in an immunocompromised host | 3 | 0 |
| Infection susceptibility increased | 1 | 0 |
| Infectious thyroiditis | 1 | 0 |
| Injection site abscess | 3 | 0 |
| Injection site infection | 22 | 0 |
| Localised infection | 110 | 0 |
| Lymph gland infection | 9 | 0 |
| Lymph node abscess | 2 | 0 |
| Omphalitis | 1 | 0 |
| Pathogen resistance | 3 | 0 |
| Pelvic infection | 1 | 0 |
| Pyuria | 1 | 0 |
| Respiratory tract infection | 10 | 1 |
| Toxic shock syndrome | 2 | 0 |
| Vaccination site abscess | 7 | 0 |
| Vaccination site infection | 26 | 0 |
| Vaccine breakthrough infection | 3 | 0 |
| Vestibulitis | 4 | 0 |
| Wound abscess | 1 | 0 |
| <i>Infectious disorders carrier</i> | | |
| SARS-CoV-2 carrier | 1 | 0 |
| <i>Infectious transmissions</i> | | |
| Secondary transmission | 16 | 0 |
| Vaccine virus shedding | 1 | 0 |
| <i>Influenza viral infections</i> | | |
| H1N1 influenza | 1 | 0 |
| H2N2 influenza | 3 | 0 |
| Influenza | 6863 | 0 |
| <i>Klebsiella infections</i> | | |
| Cystitis klebsiella | 1 | 0 |
| Klebsiella infection | 1 | 0 |
| Pneumonia klebsiella | 1 | 0 |
| <i>Lower respiratory tract and lung infections</i> | | |
| Atypical pneumonia | 2 | 0 |
| Bronchitis | 30 | 0 |
| Infectious pleural effusion | 4 | 0 |
| Infective exacerbation of bronchiectasis | 1 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections | | |
| Infections cont'd | | |
| Infective pulmonary exacerbation of cystic fibrosis | 1 | 1 |
| Lower respiratory tract infection | 357 | 3 |
| Pleural infection | 1 | 0 |
| Pneumonia | 302 | 30 |
| Pneumonia aspiration | 32 | 7 |
| Sputum purulent | 3 | 0 |
| Male reproductive tract infections | | |
| Epididymitis | 10 | 0 |
| Orchitis | 7 | 0 |
| Molluscum contagiosum viral infections | | |
| Molluscum contagiosum | 1 | 0 |
| Mumps viral infections | | |
| Mumps | 13 | 0 |
| Muscle and soft tissue infections | | |
| Muscle abscess | 1 | 0 |
| Necrotising fasciitis | 1 | 0 |
| Soft tissue infection | 5 | 0 |
| Neisseria infections | | |
| Gonorrhoea | 1 | 0 |
| Prostatitis gonococcal | 1 | 0 |
| Orthopox viral infections | | |
| Cow pox | 1 | 0 |
| Vaccinia virus infection | 2 | 0 |
| Papilloma viral infections | | |
| Papilloma viral infection | 1 | 0 |
| Paravaccinia infections | | |
| Paravaccinia | 1 | 0 |
| Phleboviral infections | | |
| Severe fever with thrombocytopenia syndrome | 2 | 0 |
| Plasmodia infections | | |
| Malaria | 8 | 0 |
| Pneumocystis infections | | |
| Pneumocystis jirovecii pneumonia | 1 | 0 |
| Prion-associated disorders | | |
| Creutzfeldt-Jakob disease | 3 | 0 |
| Pseudomonal infections | | |
| Pseudomonas infection | 1 | 0 |
| Retroviral infections | | |
| Acquired immunodeficiency syndrome | 2 | 0 |
| HIV infection | 3 | 0 |
| HIV-associated neurocognitive disorder | 1 | 0 |
| Persistent generalised lymphadenopathy | 1 | 0 |
| Rotaviral infections | | |
| Gastroenteritis rotavirus | 1 | 0 |
| Rotavirus infection | 1 | 0 |
| Rubella viral infections | | |
| Rubella | 1 | 0 |
| Rubeola viral infections | | |
| Measles | 6 | 0 |
| Measles post vaccine | 1 | 0 |
| Salmonella infections | | |
| Typhoid fever | 2 | 0 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | | |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections | | |
| Infections cont'd | | |
| Abdominal sepsis | 2 | 0 |
| Bacteraemia | 1 | 0 |
| Haematological infection | 1 | 0 |
| Neutropenic sepsis | 10 | 0 |
| Pelvic sepsis | 1 | 0 |
| Pulmonary sepsis | 1 | 0 |
| Sepsis | 127 | 16 |
| Sepsis syndrome | 1 | 0 |
| Septic pulmonary embolism | 1 | 0 |
| Septic rash | 13 | 0 |
| Septic shock | 5 | 2 |
| Urosepsis | 11 | 1 |
| Viraemia | 4 | 0 |
| Wound sepsis | 1 | 0 |
| <i>Skin structures and soft tissue infections</i> | | |
| Blister infected | 2 | 0 |
| Carbuncle | 1 | 0 |
| Dermatitis infected | 10 | 0 |
| Dermo-hypodermatitis | 1 | 0 |
| Eczema infected | 3 | 0 |
| Impetigo | 13 | 0 |
| Infected dermal cyst | 3 | 0 |
| Pilonidal disease | 2 | 0 |
| Pustule | 27 | 0 |
| Pyoderma | 1 | 0 |
| Rash pustular | 19 | 0 |
| Skin infection | 75 | 0 |
| Subcutaneous abscess | 11 | 0 |
| Vaccination site pustule | 5 | 0 |
| <i>Staphylococcal infections</i> | | |
| Furuncle | 59 | 0 |
| Pneumonia staphylococcal | 1 | 0 |
| Staphylococcal bacteraemia | 2 | 0 |
| Staphylococcal infection | 3 | 0 |
| Staphylococcal scalded skin syndrome | 1 | 0 |
| Staphylococcal sepsis | 4 | 1 |
| Toxic shock syndrome staphylococcal | 1 | 0 |
| Vulvovaginitis staphylococcal | 1 | 0 |
| Wound infection staphylococcal | 1 | 0 |
| <i>Streptococcal infections</i> | | |
| Beta haemolytic streptococcal infection | 1 | 0 |
| Cellulitis streptococcal | 1 | 0 |
| Erysipelas | 1 | 0 |
| Meningitis pneumococcal | 2 | 1 |
| Pharyngitis streptococcal | 9 | 0 |
| Pneumonia pneumococcal | 1 | 0 |
| Scarlet fever | 1 | 0 |
| Streptococcal bacteraemia | 1 | 0 |
| Streptococcal infection | 5 | 0 |
| Streptococcal sepsis | 1 | 0 |
| Tonsillitis streptococcal | 1 | 0 |
| <i>Tinea infections</i> | | |
| Body tinea | 9 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections Infections cont'd | | |
| Tinea cruris | 3 | 0 |
| Tinea infection | 3 | 0 |
| Tinea pedis | 4 | 0 |
| Tinea versicolour | 2 | 0 |
| <i>Treponema infections</i> | | |
| Neurosyphilis | 1 | 0 |
| Pinta | 1 | 0 |
| Syphilis | 4 | 0 |
| <i>Trypanosomal infections</i> | | |
| African trypanosomiasis | 6 | 0 |
| <i>Tuberculous infections</i> | | |
| Disseminated Bacillus Calmette-Guerin infection | 1 | 0 |
| Erythema induratum | 1 | 0 |
| Lymph node tuberculosis | 3 | 0 |
| Meningitis tuberculous | 1 | 0 |
| Pulmonary tuberculosis | 2 | 0 |
| Tuberculosis | 6 | 2 |
| <i>Upper respiratory tract infections</i> | | |
| Acute sinusitis | 6 | 0 |
| Chronic sinusitis | 18 | 0 |
| Chronic tonsillitis | 1 | 0 |
| Croup infectious | 1 | 0 |
| Epiglottitis | 1 | 0 |
| Laryngitis | 42 | 0 |
| Nasal vestibulitis | 1 | 0 |
| Nasopharyngitis | 1957 | 0 |
| Peritonsillar abscess | 1 | 0 |
| Pharyngeal abscess | 1 | 0 |
| Pharyngitis | 44 | 0 |
| Rhinitis | 59 | 0 |
| Sinobronchitis | 1 | 0 |
| Sinusitis | 415 | 0 |
| Tonsillitis | 91 | 0 |
| Tracheitis | 2 | 0 |
| Upper respiratory tract infection | 12 | 0 |
| <i>Urinary tract infections</i> | | |
| Cystitis | 104 | 0 |
| Genitourinary tract infection | 1 | 0 |
| Kidney infection | 64 | 0 |
| Pyelonephritis | 9 | 0 |
| Pyelonephritis acute | 1 | 0 |
| Pyelonephritis chronic | 1 | 0 |
| Renal abscess | 2 | 0 |
| Urethritis | 1 | 0 |
| Urinary tract infection | 285 | 0 |
| <i>Vascular infections</i> | | |
| Haematoma infection | 2 | 0 |
| Infected lymphocele | 1 | 0 |
| Infected varicose vein | 1 | 0 |
| Lymphangitis | 6 | 0 |
| <i>Viral infections NEC</i> | | |
| Arthritis viral | 3 | 0 |
| Bronchitis viral | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|--------------|------------|
| Infections | | |
| Infections cont'd | | |
| Conjunctivitis viral | 1 | 0 |
| Ear infection viral | 2 | 0 |
| Encephalitis viral | 8 | 0 |
| Eye infection viral | 1 | 0 |
| Gastritis viral | 1 | 0 |
| Gastroenteritis viral | 72 | 0 |
| Gastrointestinal viral infection | 1 | 0 |
| Hepatitis viral | 3 | 0 |
| Meningitis viral | 23 | 0 |
| Pleurisy viral | 1 | 0 |
| Pneumonia viral | 13 | 1 |
| Post viral fatigue syndrome | 163 | 0 |
| Sweating fever | 742 | 0 |
| Vestibular neuronitis | 44 | 0 |
| Viral diarrhoea | 4 | 0 |
| Viral infection | 90 | 0 |
| Viral labyrinthitis | 7 | 0 |
| Viral myelitis | 1 | 0 |
| Viral myocarditis | 3 | 0 |
| Viral pericarditis | 5 | 0 |
| Viral pharyngitis | 31 | 0 |
| Viral rash | 81 | 0 |
| Viral sepsis | 1 | 0 |
| Viral sinusitis | 1 | 0 |
| Viral tonsillitis | 1 | 0 |
| Viral upper respiratory tract infection | 1 | 0 |
| Infections SOC TOTAL | 20951 | 120 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries | | |
| <i>Abdominal and gastrointestinal injuries NEC</i> | | |
| Abdomen crushing | 3 | 0 |
| Abdominal injury | 1 | 0 |
| Colon injury | 1 | 0 |
| Lip injury | 2 | 0 |
| Mouth injury | 3 | 0 |
| Oral contusion | 13 | 0 |
| Palate injury | 2 | 0 |
| Pelvic bone injury | 1 | 0 |
| Splenic rupture | 4 | 0 |
| Tongue injury | 3 | 0 |
| Tooth fracture | 2 | 0 |
| Tooth injury | 2 | 0 |
| <i>Accidental exposures to product</i> | | |
| Accidental exposure to product | 27 | 0 |
| Accidental exposure to product packaging | 1 | 0 |
| <i>Anaesthetic and allied procedural complications</i> | | |
| Airway complication of anaesthesia | 2 | 0 |
| Anaesthetic complication | 3 | 0 |
| Anaesthetic complication neurological | 1 | 0 |
| Delayed recovery from anaesthesia | 6 | 0 |
| Sedation complication | 4 | 0 |
| <i>Atmospheric pressure injuries</i> | | |
| Barotrauma | 1 | 0 |
| Decompression sickness | 2 | 0 |
| Hypobarism | 3 | 0 |
| <i>Bone and joint injuries NEC</i> | | |
| Bursa injury | 3 | 0 |
| Cartilage injury | 3 | 0 |
| Joint injury | 20 | 0 |
| Synovial rupture | 2 | 0 |
| <i>Cardiac and vascular procedural complications</i> | | |
| Deep vein thrombosis postoperative | 1 | 0 |
| Ischaemic contracture of the left ventricle | 1 | 0 |
| Vascular access site bruising | 1 | 0 |
| Vascular graft occlusion | 1 | 0 |
| Vascular graft thrombosis | 1 | 0 |
| Vascular pseudoaneurysm | 1 | 0 |
| Vasoplegia syndrome | 1 | 0 |
| <i>Cardiovascular injuries</i> | | |
| Arterial injury | 1 | 0 |
| Vascular injury | 14 | 0 |
| Venous injury | 1 | 0 |
| <i>Cerebral injuries NEC</i> | | |
| Brain contusion | 16 | 0 |
| Brain herniation | 7 | 0 |
| Concussion | 10 | 0 |
| Craniocerebral injury | 1 | 0 |
| Epidural haemorrhage | 1 | 0 |
| Extradural haematoma | 2 | 0 |
| Subarachnoid haematoma | 3 | 0 |
| Subdural haematoma | 21 | 1 |
| Subdural haemorrhage | 6 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Injuries Injuries cont'd | | |
| Traumatic intracranial haemorrhage | 1 | 0 |
| Chemical injuries | | |
| Chemical burn | 2 | 0 |
| Chemical burn of oral cavity | 2 | 0 |
| Chemical burn of skin | 7 | 0 |
| Chemical phlebitis | 2 | 0 |
| Chest and respiratory tract injuries NEC | | |
| Asbestosis | 1 | 0 |
| Chest crushing | 17 | 0 |
| Chest injury | 2 | 0 |
| Foreign body in throat | 2 | 0 |
| Traumatic haemothorax | 1 | 0 |
| Traumatic lung injury | 1 | 0 |
| Conditions caused by cold | | |
| Chillblains | 78 | 0 |
| Frostbite | 1 | 0 |
| Cranial nerve injuries | | |
| Cranial nerve injury | 1 | 0 |
| Optic nerve injury | 10 | 0 |
| VIIIth nerve injury | 1 | 0 |
| Vth nerve injury | 1 | 0 |
| Ear injuries NEC | | |
| Deafness traumatic | 1 | 0 |
| Exposures associated with pregnancy, delivery and lactation | | |
| Drug exposure before pregnancy | 1 | 0 |
| Exposure during pregnancy | 20 | 0 |
| Exposure via breast milk | 113 | 0 |
| Foetal exposure during pregnancy | 40 | 0 |
| Maternal exposure before pregnancy | 19 | 0 |
| Maternal exposure during breast feeding | 1398 | 0 |
| Maternal exposure during pregnancy | 407 | 0 |
| Maternal exposure timing unspecified | 3 | 0 |
| Paternal exposure during pregnancy | 2 | 0 |
| Exposures to agents or circumstances NEC | | |
| Exposure to SARS-CoV-2 | 8 | 0 |
| Exposure to household chemicals | 1 | 0 |
| Exposure to toxic agent | 1 | 0 |
| Exposure to vaccinated person | 4 | 0 |
| Eye injuries NEC | | |
| Cataract traumatic | 1 | 0 |
| Eye contusion | 59 | 0 |
| Eye injury | 58 | 0 |
| Eyelid contusion | 5 | 0 |
| Foreign body in eye | 2 | 0 |
| Hyphaema | 1 | 0 |
| Injury corneal | 1 | 0 |
| Periorbital haematoma | 1 | 0 |
| Periorbital haemorrhage | 2 | 0 |
| Retinal injury | 4 | 0 |
| Superficial injury of eye | 1 | 0 |
| Traumatic iritis | 1 | 0 |
| Foetal and neonatal conditions associated with product exposure | | |
| Intoxication by breast feeding | 1 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries Injuries cont'd | | |
| <i>Fractures and dislocations NEC</i> | | |
| Fracture | 2 | 0 |
| Joint dislocation | 16 | 1 |
| Multiple fractures | 2 | 0 |
| Stress fracture | 4 | 0 |
| Traumatic fracture | 1 | 0 |
| <i>Gastrointestinal and hepatobiliary procedural complications</i> | | |
| Anastomotic ulcer | 1 | 0 |
| Peripancreatic fluid collection | 1 | 0 |
| Procedural nausea | 27 | 0 |
| Procedural vomiting | 7 | 0 |
| <i>Heat injuries (excl thermal burns)</i> | | |
| Heat cramps | 2 | 0 |
| Heat exhaustion | 4 | 0 |
| Heat illness | 4 | 0 |
| Heat oedema | 13 | 0 |
| Heat stroke | 11 | 0 |
| <i>Intentional product misuses</i> | | |
| Intentional product misuse | 16 | 0 |
| <i>Intentional product use issues</i> | | |
| Intentional dose omission | 21 | 0 |
| Intentional product use issue | 2 | 0 |
| <i>Limb fractures and dislocations</i> | | |
| Ankle fracture | 3 | 0 |
| Atypical femur fracture | 1 | 0 |
| Clavicle fracture | 22 | 0 |
| Femoral neck fracture | 2 | 0 |
| Femur fracture | 2 | 0 |
| Foot fracture | 3 | 0 |
| Humerus fracture | 1 | 0 |
| Lower limb fracture | 4 | 0 |
| Osteochondral fracture | 1 | 0 |
| Patella fracture | 1 | 0 |
| Tibia fracture | 1 | 0 |
| Upper limb fracture | 4 | 0 |
| Wrist fracture | 4 | 0 |
| <i>Medication errors, product use errors and issues NEC</i> | | |
| Circumstance or information capable of leading to medication error | 16 | 0 |
| Device use issue | 1 | 0 |
| Dose calculation error | 3 | 0 |
| Drug titration error | 1 | 0 |
| Inadequate aseptic technique in use of product | 2 | 0 |
| Intercepted medication error | 6 | 0 |
| Medication error | 193 | 0 |
| Prescription drug used without a prescription | 2 | 0 |
| Product use in unapproved indication | 1 | 0 |
| Product use issue | 10 | 0 |
| Vaccination error | 11 | 0 |
| Wrong device used | 1 | 0 |
| Wrong drug | 5 | 0 |
| Wrong route | 1 | 0 |
| Wrong schedule | 2 | 0 |
| Wrong technique in product usage process | 12 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries | | |
| Injuries cont'd | | |
| <i>Muscle, tendon and ligament injuries</i> | | |
| Epicondylitis | 33 | 0 |
| Ligament injury | 4 | 0 |
| Ligament rupture | 2 | 0 |
| Ligament sprain | 25 | 0 |
| Muscle injury | 72 | 0 |
| Muscle rupture | 20 | 0 |
| Muscle strain | 61 | 0 |
| Post-traumatic neck syndrome | 4 | 0 |
| Repetitive strain injury | 3 | 0 |
| Tendon injury | 9 | 0 |
| Tendon rupture | 32 | 0 |
| <i>Nerve injuries NEC</i> | | |
| Nerve injury | 230 | 0 |
| <i>Neurological and psychiatric procedural complications</i> | | |
| Post lumbar puncture syndrome | 8 | 0 |
| Posterior fossa syndrome | 1 | 0 |
| Procedural dizziness | 37 | 0 |
| <i>Non-occupational environmental exposures</i> | | |
| Exposure to chemical pollution | 1 | 0 |
| Exposure to extreme temperature | 3 | 0 |
| Exposure to noise | 2 | 0 |
| <i>Non-site specific injuries NEC</i> | | |
| Animal bite | 1 | 0 |
| Arthropod bite | 7 | 0 |
| Arthropod sting | 13 | 0 |
| Bite | 1 | 0 |
| Child maltreatment syndrome | 1 | 0 |
| Electric shock | 38 | 0 |
| Extraskeletal ossification | 1 | 0 |
| Fall | 322 | 0 |
| Foreign body | 3 | 0 |
| Inflammation of wound | 5 | 0 |
| Injury | 27 | 0 |
| Internal injury | 1 | 0 |
| Musculoskeletal injury | 1 | 0 |
| Nervous system injury | 5 | 0 |
| Post concussion syndrome | 2 | 0 |
| Road traffic accident | 2 | 0 |
| Skeletal injury | 1 | 0 |
| Soft tissue injury | 6 | 0 |
| Sports injury | 1 | 0 |
| Struck by lightning | 1 | 0 |
| Tissue injury | 4 | 0 |
| Traumatic haematoma | 3 | 0 |
| Traumatic shock | 1 | 0 |
| Wound | 10 | 0 |
| Wound complication | 15 | 0 |
| Wound haemorrhage | 11 | 0 |
| Wound secretion | 4 | 0 |
| <i>Non-site specific procedural complications</i> | | |
| Administration related reaction | 2 | 0 |
| Incision site erythema | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Injuries Injuries cont'd | | |
| Incision site haemorrhage | 1 | 0 |
| Incision site oedema | 1 | 0 |
| Incision site pain | 10 | 0 |
| Infusion related reaction | 19 | 0 |
| Injection related reaction | 613 | 0 |
| Needle fatigue | 1 | 0 |
| Post procedural complication | 35 | 0 |
| Post procedural contusion | 2 | 0 |
| Post procedural discomfort | 2 | 0 |
| Post procedural haematoma | 1 | 0 |
| Post procedural haemorrhage | 1 | 0 |
| Procedural complication | 1 | 0 |
| Procedural hypertension | 1 | 0 |
| Procedural pain | 8 | 0 |
| Procedural site reaction | 1 | 0 |
| Suture related complication | 1 | 0 |
| Occupational exposures | | |
| Occupational exposure to product | 1 | 0 |
| Off label uses | | |
| Off label use | 151 | 0 |
| Overdoses NEC | | |
| Intentional overdose | 14 | 0 |
| Overdose | 58 | 0 |
| Prescribed overdose | 1 | 0 |
| Pathways and sources of exposure | | |
| Exposure via body fluid | 1 | 0 |
| Exposure via partner | 1 | 0 |
| Exposure via unknown route | 1 | 0 |
| Peripheral nerve injuries | | |
| Brachial plexus injury | 2 | 0 |
| Median nerve injury | 2 | 0 |
| Peripheral nerve injury | 1 | 0 |
| Radial nerve injury | 2 | 0 |
| Sciatic nerve injury | 1 | 0 |
| Ulnar nerve injury | 3 | 0 |
| Poisoning and toxicity | | |
| Alcohol poisoning | 3 | 0 |
| Chemical poisoning | 1 | 0 |
| Metal poisoning | 2 | 0 |
| Poisoning | 8 | 0 |
| Systemic toxicity | 2 | 0 |
| Toxicity to various agents | 10 | 0 |
| Product administration errors and issues | | |
| Accidental overdose | 4 | 0 |
| Accidental underdose | 2 | 0 |
| Booster dose missed | 1 | 0 |
| Contraindicated product administered | 5 | 0 |
| Drug administered in wrong device | 1 | 0 |
| Duplicate therapy error | 2 | 0 |
| Expired product administered | 27 | 0 |
| Extra dose administered | 10 | 0 |
| Inappropriate schedule of product administration | 155 | 0 |
| Incomplete course of vaccination | 80 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries | | |
| Injuries cont'd | | |
| Incorrect dose administered | 13 | 0 |
| Incorrect product administration duration | 2 | 0 |
| Incorrect product formulation administered | 1 | 0 |
| Incorrect route of product administration | 60 | 0 |
| Intercepted product administration error | 2 | 0 |
| Lack of vaccination site rotation | 1 | 0 |
| Poor quality product administered | 3 | 0 |
| Product administered at inappropriate site | 34 | 0 |
| Product administered to patient of inappropriate age | 31 | 0 |
| Product administration error | 31 | 0 |
| Product dose omission in error | 2 | 0 |
| Product dose omission issue | 46 | 0 |
| Wrong patient received product | 1 | 0 |
| Wrong product administered | 22 | 0 |
| Product confusion errors and issues | | |
| Product label confusion | 1 | 0 |
| Product name confusion | 2 | 0 |
| Product packaging confusion | 1 | 0 |
| Product dispensing errors and issues | | |
| Product dispensing error | 16 | 0 |
| Product monitoring errors and issues | | |
| Documented hypersensitivity to administered product | 1 | 0 |
| Labelled drug-drug interaction medication error | 1 | 0 |
| Product monitoring error | 1 | 0 |
| Product prescribing errors and issues | | |
| Contraindicated product prescribed | 10 | 0 |
| Product prescribing error | 6 | 0 |
| Product selection errors and issues | | |
| Product selection error | 3 | 0 |
| Product storage errors and issues in the product use system | | |
| Intercepted product storage error | 1 | 0 |
| Product storage error | 7 | 0 |
| Product transcribing errors and communication issues | | |
| Product communication issue | 2 | 0 |
| Radiation injuries | | |
| Sunburn | 57 | 0 |
| Renal and urinary tract injuries NEC | | |
| Bladder injury | 1 | 0 |
| Kidney rupture | 2 | 0 |
| Reproductive system and breast injuries | | |
| Penile contusion | 3 | 0 |
| Penis injury | 2 | 0 |
| Uterine rupture | 1 | 0 |
| Reproductive tract and breast procedural complications | | |
| Ovarian injury | 1 | 0 |
| Postmastectomy lymphoedema syndrome | 1 | 0 |
| Respiratory tract and thoracic cavity procedural complications | | |
| Pulmonary oil microembolism | 2 | 0 |
| Site specific injuries NEC | | |
| Back injury | 7 | 0 |
| Central nervous system injury | 1 | 0 |
| Face crushing | 1 | 0 |
| Face injury | 2 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Injuries | | |
| Injuries cont'd | | |
| Head injury | 45 | 0 |
| Limb crushing injury | 11 | 0 |
| Limb injury | 390 | 0 |
| Nasal injury | 2 | 0 |
| Neck crushing | 1 | 0 |
| Neck injury | 3 | 0 |
| Pharyngeal contusion | 3 | 0 |
| Site specific procedural complications NEC | | |
| Axillary web syndrome | 3 | 0 |
| Head and neck procedural complication | 1 | 0 |
| Skin injuries NEC | | |
| Contusion | 3438 | 0 |
| Hair injury | 4 | 0 |
| Nail injury | 1 | 0 |
| Scar | 50 | 0 |
| Scratch | 6 | 0 |
| Skin abrasion | 7 | 0 |
| Skin injury | 28 | 0 |
| Skin laceration | 7 | 0 |
| Skin pressure mark | 1 | 0 |
| Skin wound | 8 | 0 |
| Subcutaneous haematoma | 3 | 0 |
| Skin procedural complications | | |
| Dermal filler overcorrection | 1 | 0 |
| Recall phenomenon | 2 | 0 |
| Skin procedural complication | 1 | 0 |
| Skull fractures, facial bone fractures and dislocations | | |
| Skull fracture | 1 | 0 |
| Spinal cord injuries NEC | | |
| Prevertebral soft tissue swelling of cervical space | 1 | 0 |
| Spinal cord injury | 5 | 0 |
| Spinal cord injury sacral | 1 | 0 |
| Spinal cord injury thoracic | 1 | 0 |
| Spinal fractures and dislocations | | |
| Spinal compression fracture | 4 | 0 |
| Spinal fracture | 9 | 0 |
| Stoma complications | | |
| Gastrointestinal stoma complication | 2 | 0 |
| Stoma obstruction | 1 | 0 |
| Stoma site haemorrhage | 1 | 0 |
| Stoma site pain | 2 | 0 |
| Stoma site rash | 1 | 0 |
| Thermal burns | | |
| Airway burns | 1 | 0 |
| Burn oesophageal | 1 | 0 |
| Burn of internal organs | 4 | 0 |
| Burn oral cavity | 11 | 0 |
| Burns second degree | 3 | 0 |
| Cold burn | 3 | 0 |
| Thermal burn | 57 | 0 |
| Thermal burns of eye | 48 | 0 |
| Thoracic cage fractures and dislocations | | |
| Rib fracture | 1 | 0 |

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|---|-------------|----------|
| Injuries Injuries cont'd | | |
| <i>Transplantation complications</i> | | |
| Transplant failure | 1 | 0 |
| <i>Underdoses NEC</i> | | |
| Intentional underdose | 1 | 0 |
| Underdose | 11 | 0 |
| <i>Vaccination related complications</i> | | |
| Adverse event following immunisation | 5 | 0 |
| Post vaccination syndrome | 7 | 0 |
| Reaction to previous exposure to any vaccine | 1 | 0 |
| Vaccination complication | 3 | 0 |
| Injuries SOC TOTAL | 9812 | 2 |

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|--|-------|-------|
| Investigations | | |
| <i>Adrenal cortex tests</i> | | |
| Blood cortisol | 1 | 0 |
| Cortisol decreased | 3 | 0 |
| Cortisol increased | 2 | 0 |
| <i>Adrenal medulla tests</i> | | |
| Epinephrine increased | 1 | 0 |
| Norepinephrine increased | 2 | 0 |
| <i>Auditory and vestibular diagnostic procedures</i> | | |
| Acoustic stimulation tests | 8 | 0 |
| Audiogram | 1 | 0 |
| <i>Autoimmunity analyses</i> | | |
| Anti-sperm antibody | 1 | 0 |
| Antimitochondrial antibody positive | 2 | 0 |
| Antineutrophil cytoplasmic antibody positive | 1 | 0 |
| Antinuclear antibody | 2 | 0 |
| Antinuclear antibody increased | 2 | 0 |
| Antinuclear antibody positive | 3 | 0 |
| Antiphospholipid antibodies | 3 | 0 |
| Antiphospholipid antibodies positive | 5 | 0 |
| Cold agglutinins positive | 2 | 0 |
| DNA antibody negative | 1 | 0 |
| DNA antibody positive | 1 | 0 |
| Rheumatoid factor | 4 | 0 |
| Rheumatoid factor increased | 3 | 0 |
| Rheumatoid factor negative | 1 | 0 |
| Smooth muscle antibody | 1 | 0 |
| <i>Bacteria identification and serology (excl mycobacteria)</i> | | |
| Bacterial test | 1 | 0 |
| Staphylococcus test positive | 1 | 0 |
| Streptococcus test positive | 1 | 0 |
| Treponema test positive | 1 | 0 |
| <i>Blood counts NEC</i> | | |
| Full blood count | 21 | 0 |
| Full blood count abnormal | 15 | 0 |
| Full blood count decreased | 3 | 0 |
| Full blood count increased | 1 | 0 |
| Full blood count normal | 1 | 0 |
| <i>Blood gas and acid base analyses</i> | | |
| Blood gases | 1 | 0 |
| Blood gases abnormal | 1 | 0 |
| Blood lactic acid | 4 | 0 |
| Blood lactic acid increased | 6 | 0 |
| Blood pH | 18 | 0 |
| Blood pH increased | 15 | 0 |
| Carbon dioxide increased | 1 | 0 |
| Oxygen consumption | 2 | 0 |
| Oxygen saturation | 27 | 0 |
| Oxygen saturation abnormal | 3 | 0 |
| Oxygen saturation decreased | 204 | 0 |
| Oxygen saturation normal | 1 | 0 |
| Venous oxygen saturation decreased | 1 | 0 |
| <i>Blood grouping and cross-matching analyses</i> | | |
| Blood group O | 2 | 0 |

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|---|-------|-------|
| Investigations Investigations cont'd | | |
| Blood grouping | 1 | 0 |
| Rhesus antigen negative | 1 | 0 |
| <i>Bone marrow and immune tissue histopathology procedures</i> | | |
| Biopsy lymph gland | 1 | 0 |
| <i>Bone marrow and immune tissue imaging procedures</i> | | |
| Scan lymph nodes | 2 | 0 |
| <i>Carbohydrate tolerance analyses (incl diabetes)</i> | | |
| Blood glucose | 20 | 0 |
| Blood glucose abnormal | 23 | 0 |
| Blood glucose decreased | 46 | 0 |
| Blood glucose fluctuation | 35 | 0 |
| Blood glucose increased | 193 | 0 |
| Glycosylated haemoglobin increased | 2 | 0 |
| <i>Cardiac auscultatory investigations</i> | | |
| Cardiac murmur | 47 | 0 |
| Heart sounds | 19 | 0 |
| Heart sounds abnormal | 9 | 0 |
| <i>Cardiac function diagnostic procedures</i> | | |
| Cardiac monitoring | 1 | 0 |
| Central venous pressure | 1 | 0 |
| Echocardiogram | 3 | 0 |
| Ejection fraction decreased | 6 | 0 |
| Myocardial strain imaging | 21 | 0 |
| Stroke volume decreased | 2 | 0 |
| Stroke volume increased | 3 | 0 |
| Venous pressure jugular increased | 1 | 0 |
| <i>Cardiac imaging procedures</i> | | |
| Magnetic resonance imaging heart | 1 | 0 |
| <i>Cell marker analyses</i> | | |
| Carbohydrate antigen 15-3 | 1 | 0 |
| Carcinoembryonic antigen increased | 2 | 0 |
| Prostatic specific antigen decreased | 1 | 0 |
| Prostatic specific antigen increased | 5 | 0 |
| Tumour marker increased | 1 | 0 |
| <i>Central nervous system histopathology procedures</i> | | |
| Biopsy brain | 1 | 0 |
| <i>Central nervous system imaging procedures</i> | | |
| Brain scan abnormal | 2 | 0 |
| Computerised tomogram head | 28 | 0 |
| Magnetic resonance imaging head | 47 | 0 |
| Magnetic resonance imaging head abnormal | 1 | 0 |
| Scan brain | 1 | 0 |
| <i>Cerebrospinal fluid tests (excl microbiology)</i> | | |
| CSF cell count abnormal | 1 | 0 |
| CSF lymphocyte count abnormal | 1 | 0 |
| CSF oligoclonal band present | 1 | 0 |
| CSF pressure | 4 | 0 |
| CSF protein increased | 1 | 0 |
| CSF test abnormal | 1 | 0 |
| CSF white blood cell count increased | 1 | 0 |
| Xanthochromia | 1 | 0 |
| <i>Chemistry analyses NEC</i> | | |
| Histamine abnormal | 5 | 0 |

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|---|-------|-------|
| Investigations | | |
| Investigations cont'd | | |
| Histamine level | 4 | 0 |
| Histamine level increased | 1 | 0 |
| Inflammatory marker decreased | 1 | 0 |
| Inflammatory marker increased | 14 | 0 |
| Serum serotonin increased | 1 | 0 |
| Cholesterol analyses | | |
| Blood cholesterol increased | 23 | 0 |
| Low density lipoprotein | 1 | 0 |
| Low density lipoprotein increased | 1 | 0 |
| Very low density lipoprotein decreased | 1 | 0 |
| Coagulation and bleeding analyses | | |
| ADAMTS13 activity abnormal | 1 | 0 |
| ADAMTS13 activity decreased | 1 | 0 |
| Activated partial thromboplastin time | 1 | 0 |
| Activated partial thromboplastin time abnormal | 1 | 0 |
| Activated partial thromboplastin time prolonged | 123 | 0 |
| Anti factor VIII antibody positive | 1 | 0 |
| Anti-platelet factor 4 antibody positive | 1 | 0 |
| Bleeding time | 11 | 0 |
| Bleeding time abnormal | 3 | 0 |
| Bleeding time prolonged | 6 | 0 |
| Bleeding time shortened | 2 | 0 |
| Blood fibrinogen abnormal | 2 | 0 |
| Blood fibrinogen decreased | 7 | 0 |
| Blood fibrinogen increased | 2 | 0 |
| Blood thromboplastin | 1 | 0 |
| Blood thromboplastin abnormal | 1 | 0 |
| Clot retraction | 1 | 0 |
| Coagulation factor | 1 | 0 |
| Coagulation factor VIII level decreased | 6 | 0 |
| Coagulation test abnormal | 1 | 0 |
| Coagulation time | 10 | 0 |
| Coagulation time prolonged | 14 | 0 |
| Coagulation time shortened | 5 | 0 |
| Fibrin D dimer | 1 | 0 |
| Fibrin D dimer decreased | 1 | 0 |
| Fibrin D dimer increased | 69 | 0 |
| Heparin-induced thrombocytopenia test positive | 1 | 0 |
| International normalised ratio | 4 | 0 |
| International normalised ratio abnormal | 11 | 0 |
| International normalised ratio decreased | 44 | 0 |
| International normalised ratio fluctuation | 5 | 0 |
| International normalised ratio increased | 91 | 0 |
| Prothrombin level increased | 1 | 0 |
| Prothrombin time | 1 | 0 |
| Prothrombin time prolonged | 1 | 0 |
| Thrombin time | 1 | 0 |
| Thrombin time abnormal | 2 | 0 |
| Digestive enzymes | | |
| Amylase increased | 1 | 0 |
| Lipase increased | 1 | 0 |
| Pancreatic enzymes increased | 1 | 0 |
| ECG investigations | | |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations | | |
| Investigations cont'd | | |
| Cardiac telemetry | 1 | 0 |
| Electrocardiogram | 8 | 0 |
| Electrocardiogram P wave abnormal | 1 | 0 |
| Electrocardiogram QT prolonged | 5 | 0 |
| Electrocardiogram ST segment depression | 2 | 0 |
| Electrocardiogram ST segment elevation | 7 | 0 |
| Electrocardiogram ST-T segment abnormal | 6 | 0 |
| Electrocardiogram T wave inversion | 5 | 0 |
| Electrocardiogram abnormal | 22 | 0 |
| Electrocardiogram change | 2 | 0 |
| Electrocardiogram normal | 1 | 0 |
| Electrocardiogram pacemaker spike | 1 | 0 |
| Exercise electrocardiogram | 1 | 0 |
| QRS axis abnormal | 2 | 0 |
| Endocrine analyses and imaging NEC | | |
| Hormone level abnormal | 67 | 0 |
| Faecal analyses NEC | | |
| Faecal calprotectin | 1 | 0 |
| Faecal calprotectin increased | 9 | 0 |
| Occult blood | 1 | 0 |
| Stool analysis abnormal | 2 | 0 |
| Fertility analyses | | |
| Semen analysis abnormal | 1 | 0 |
| Semen volume decreased | 2 | 0 |
| Sperm concentration | 1 | 0 |
| Spermatozoa abnormal | 1 | 0 |
| Foetal and neonatal diagnostic procedures | | |
| Foetal heart rate | 1 | 0 |
| Foetal heart rate abnormal | 1 | 0 |
| Fungus identification and serology | | |
| Fungal test | 1 | 0 |
| Gastrointestinal and abdominal imaging procedures | | |
| Barium swallow | 2 | 0 |
| Computerised tomogram abdomen | 4 | 0 |
| Magnetic resonance imaging abdominal | 1 | 0 |
| Stomach scan | 1 | 0 |
| Gastrointestinal function diagnostic procedures | | |
| Gastric pH | 2 | 0 |
| Gastric pH decreased | 2 | 0 |
| Gastrointestinal stoma output increased | 1 | 0 |
| Swallow study | 3 | 0 |
| Gastrointestinal, pancreatic and APUD hormone analyses | | |
| Blood gastrin | 1 | 0 |
| Blood gastrin normal | 1 | 0 |
| Blood insulin | 4 | 0 |
| Blood insulin abnormal | 1 | 0 |
| Blood insulin decreased | 2 | 0 |
| Blood insulin increased | 3 | 0 |
| Haematological analyses NEC | | |
| Blood viscosity abnormal | 1 | 0 |
| Blood viscosity decreased | 1 | 0 |
| Blood viscosity increased | 5 | 0 |
| Haematology test abnormal | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations | | |
| Investigations cont'd | | |
| Plasma viscosity abnormal | 1 | 0 |
| Red blood cell sedimentation rate | 1 | 0 |
| Red blood cell sedimentation rate abnormal | 1 | 0 |
| Red blood cell sedimentation rate increased | 14 | 0 |
| Heart rate and pulse investigations | | |
| Brachial pulse decreased | 1 | 0 |
| Carotid pulse | 1 | 0 |
| Femoral pulse | 1 | 0 |
| Heart rate | 1157 | 0 |
| Heart rate abnormal | 75 | 0 |
| Heart rate decreased | 145 | 0 |
| Heart rate increased | 2205 | 0 |
| Heart rate irregular | 288 | 0 |
| Heart rate variability decreased | 1 | 0 |
| Heart rate variability increased | 3 | 0 |
| Maximum heart rate | 8 | 0 |
| Maximum heart rate decreased | 1 | 0 |
| Maximum heart rate increased | 2 | 0 |
| Orthostatic heart rate response increased | 1 | 0 |
| Popliteal pulse | 1 | 0 |
| Pulse abnormal | 33 | 0 |
| Pulse absent | 4 | 0 |
| Pulse pressure decreased | 1 | 0 |
| Pulse pressure increased | 3 | 0 |
| Pulse waveform abnormal | 1 | 0 |
| Radial pulse | 1 | 0 |
| Sinus rhythm | 11 | 0 |
| Hepatobiliary function diagnostic procedures | | |
| Alanine aminotransferase decreased | 1 | 0 |
| Alanine aminotransferase increased | 34 | 0 |
| Alanine aminotransferase normal | 1 | 0 |
| Aspartate aminotransferase | 1 | 0 |
| Aspartate aminotransferase increased | 4 | 0 |
| Bile output | 4 | 0 |
| Blood bilirubin | 1 | 0 |
| Blood bilirubin increased | 7 | 0 |
| Gamma-glutamyltransferase increased | 6 | 0 |
| Hepatic enzyme abnormal | 2 | 0 |
| Hepatic enzyme increased | 17 | 0 |
| Liver function test | 3 | 0 |
| Liver function test abnormal | 58 | 0 |
| Liver function test increased | 17 | 0 |
| Transaminases increased | 3 | 0 |
| Histopathology procedures NEC | | |
| Biopsy | 1 | 0 |
| Smear test | 1 | 0 |
| Imaging procedures NEC | | |
| Computerised tomogram | 7 | 0 |
| Computerised tomogram normal | 1 | 0 |
| Magnetic resonance imaging | 2 | 0 |
| Magnetic resonance imaging abnormal | 1 | 0 |
| Magnetic resonance imaging whole body | 1 | 0 |
| Scan | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| Ultrasound scan | 1 | 0 |
| X-ray | 1 | 0 |
| <i>Immune response protein analyses NEC</i> | | |
| Cytokine abnormal | 1 | 0 |
| Cytokine increased | 1 | 0 |
| <i>Immunoglobulin analyses</i> | | |
| Blood immunoglobulin A increased | 2 | 0 |
| Blood immunoglobulin E | 1 | 0 |
| Blood immunoglobulin E increased | 4 | 0 |
| Blood immunoglobulin G | 1 | 0 |
| Blood immunoglobulin M | 1 | 0 |
| Blood immunoglobulin M increased | 2 | 0 |
| Immunoglobulins decreased | 2 | 0 |
| <i>Immunology analyses NEC</i> | | |
| Antibody test | 6 | 0 |
| Antibody test abnormal | 9 | 0 |
| Antibody test negative | 19 | 0 |
| Antibody test positive | 3 | 0 |
| Immunology test | 14 | 1 |
| Immunology test normal | 1 | 0 |
| Mast cell degranulation present | 1 | 0 |
| Tryptase increased | 1 | 0 |
| <i>Immunology skin tests NEC</i> | | |
| Allergy alert test | 3 | 0 |
| Skin test | 1 | 0 |
| Skin test positive | 7 | 0 |
| <i>Investigations NEC</i> | | |
| APACHE II score | 1 | 0 |
| Blood test | 53 | 0 |
| Blood test abnormal | 96 | 0 |
| Blood test normal | 1 | 0 |
| Laboratory test | 1 | 0 |
| Laboratory test abnormal | 1 | 0 |
| Polymerase chain reaction positive | 3 | 0 |
| Quality of life decreased | 6 | 0 |
| <i>Metabolism tests NEC</i> | | |
| Blood ketone body | 10 | 0 |
| Blood ketone body increased | 1 | 0 |
| Blood ketone body present | 1 | 0 |
| Blood uric acid increased | 4 | 0 |
| Brain natriuretic peptide increased | 1 | 0 |
| N-terminal prohormone brain natriuretic peptide increased | 1 | 0 |
| Ubiquinone | 4 | 0 |
| Ubiquinone decreased | 2 | 0 |
| Urine ketone body present | 2 | 0 |
| <i>Microbiology and serology tests NEC</i> | | |
| Blood culture | 3 | 0 |
| Blood culture negative | 1 | 0 |
| Septic screen | 1 | 0 |
| Serology test | 1 | 0 |
| Vaccine induced antibody absent | 1 | 0 |
| <i>Mineral and electrolyte analyses</i> | | |
| Blood calcium | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations | | |
| Investigations cont'd | | |
| Blood calcium decreased | 1 | 0 |
| Blood calcium increased | 1 | 0 |
| Blood cyanide | 1 | 0 |
| Blood iron | 14 | 0 |
| Blood iron decreased | 40 | 0 |
| Blood iron increased | 6 | 0 |
| Blood magnesium decreased | 3 | 0 |
| Blood phosphorus abnormal | 1 | 0 |
| Blood phosphorus decreased | 7 | 0 |
| Blood phosphorus increased | 4 | 0 |
| Blood potassium decreased | 12 | 0 |
| Blood potassium increased | 9 | 0 |
| Blood sodium | 2 | 0 |
| Blood sodium decreased | 6 | 0 |
| Blood zinc increased | 1 | 0 |
| Iron binding capacity total decreased | 1 | 0 |
| Serum ferritin | 1 | 0 |
| Serum ferritin decreased | 7 | 0 |
| Serum ferritin increased | 9 | 0 |
| Sweat test | 3 | 0 |
| Transferrin decreased | 1 | 0 |
| Urine copper | 2 | 0 |
| <i>Musculoskeletal and soft tissue imaging procedures</i> | | |
| Bone densitometry | 1 | 0 |
| Bone density decreased | 1 | 0 |
| Discogram abnormal | 1 | 0 |
| Magnetic resonance imaging neck | 1 | 0 |
| Skull X-ray | 12 | 0 |
| X-ray limb | 2 | 0 |
| X-ray limb abnormal | 1 | 0 |
| X-ray of pelvis and hip | 2 | 0 |
| <i>Musculoskeletal and soft tissue tests NEC</i> | | |
| Muscle mass percentage | 1 | 0 |
| Swollen joint count | 2 | 0 |
| Swollen joint count increased | 5 | 0 |
| Tender joint count | 4 | 0 |
| <i>Mycobacteria identification and serology</i> | | |
| Interferon gamma release assay positive | 2 | 0 |
| <i>Neurologic diagnostic procedures</i> | | |
| Balance test | 1 | 0 |
| Coma scale abnormal | 19 | 0 |
| Electroencephalogram abnormal | 1 | 0 |
| Electromyogram abnormal | 3 | 0 |
| Hoover's sign of leg paresis | 1 | 0 |
| Joint position sense decreased | 2 | 0 |
| Lumbar puncture | 19 | 0 |
| Nerve conduction studies | 1 | 0 |
| Nerve conduction studies abnormal | 2 | 0 |
| Nerve stimulation test abnormal | 1 | 0 |
| Neurotransmitter level altered | 1 | 0 |
| Sensory level abnormal | 1 | 0 |
| Sleep study normal | 1 | 0 |
| <i>Ophthalmic function diagnostic procedures</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations | | |
| Investigations cont'd | | |
| Corneal reflex decreased | 2 | 0 |
| Intraocular pressure increased | 9 | 0 |
| Intraocular pressure test | 8 | 0 |
| Pupillary light reflex tests abnormal | 1 | 0 |
| Retinal function test abnormal | 1 | 0 |
| Visual tracking test | 1 | 0 |
| Parathyroid analyses | | |
| Blood parathyroid hormone decreased | 1 | 0 |
| Physical examination procedures and organ system status | | |
| Body height decreased | 1 | 0 |
| Body surface area | 3 | 0 |
| Body surface area decreased | 1 | 0 |
| Body temperature | 1045 | 0 |
| Body temperature abnormal | 93 | 0 |
| Body temperature decreased | 143 | 0 |
| Body temperature fluctuation | 198 | 0 |
| Body temperature increased | 1176 | 0 |
| Body temperature normal | 3 | 0 |
| Breath sounds | 3 | 0 |
| Breath sounds abnormal | 9 | 0 |
| Dermatologic examination abnormal | 1 | 0 |
| Emergency care examination | 1 | 0 |
| General physical condition abnormal | 4 | 0 |
| Grip strength | 16 | 0 |
| Grip strength decreased | 45 | 0 |
| Head lag | 19 | 0 |
| Lymph node palpable | 6 | 0 |
| Male genital examination abnormal | 2 | 0 |
| Menstruation normal | 7 | 0 |
| Muscle strength abnormal | 6 | 0 |
| Neurological examination | 1 | 0 |
| Neurological examination abnormal | 1 | 0 |
| Neurological examination normal | 1 | 0 |
| Ophthalmological examination | 5 | 0 |
| Ophthalmological examination abnormal | 1 | 0 |
| Palpatory finding abnormal | 1 | 0 |
| Product residue present | 3 | 0 |
| Psoriasis area severity index decreased | 1 | 0 |
| Psoriasis area severity index increased | 1 | 0 |
| Respiratory rate | 13 | 0 |
| Respiratory rate decreased | 33 | 0 |
| Respiratory rate increased | 86 | 0 |
| Skin temperature | 179 | 0 |
| Temperature difference of extremities | 9 | 0 |
| Urological examination | 1 | 0 |
| Vital signs measurement | 1 | 0 |
| Weight | 1 | 0 |
| Weight decreased | 267 | 0 |
| Weight increased | 86 | 0 |
| Pituitary analyses anterior | | |
| Blood corticotrophin | 1 | 0 |
| Blood corticotrophin abnormal | 1 | 0 |
| Blood follicle stimulating hormone increased | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations | | |
| Investigations cont'd | | |
| Blood growth hormone increased | 1 | 0 |
| Blood prolactin increased | 1 | 0 |
| Blood thyroid stimulating hormone | 1 | 0 |
| Blood thyroid stimulating hormone abnormal | 1 | 0 |
| Blood thyroid stimulating hormone decreased | 4 | 0 |
| Blood thyroid stimulating hormone increased | 7 | 0 |
| Platelet analyses | | |
| Platelet count | 4 | 0 |
| Platelet count abnormal | 2 | 0 |
| Platelet count decreased | 365 | 1 |
| Platelet count increased | 8 | 0 |
| Platelet count normal | 1 | 0 |
| Platelet morphology abnormal | 1 | 0 |
| Plateletcrit | 1 | 0 |
| Protein analyses NEC | | |
| Blood albumin abnormal | 1 | 0 |
| C-reactive protein | 1 | 0 |
| C-reactive protein abnormal | 3 | 0 |
| C-reactive protein decreased | 1 | 0 |
| C-reactive protein increased | 47 | 0 |
| Protein total | 2 | 0 |
| Protein total abnormal | 1 | 0 |
| Protein total increased | 2 | 0 |
| Zinc sulphate turbidity increased | 1 | 0 |
| Red blood cell analyses | | |
| Haematocrit | 10 | 0 |
| Haematocrit decreased | 1 | 0 |
| Haematocrit increased | 3 | 0 |
| Haemoglobin | 7 | 0 |
| Haemoglobin abnormal | 1 | 0 |
| Haemoglobin decreased | 22 | 0 |
| Haemoglobin increased | 2 | 0 |
| Mean cell haemoglobin concentration | 1 | 0 |
| Mean cell volume abnormal | 3 | 0 |
| Red blood cell count | 3 | 0 |
| Red blood cell count decreased | 2 | 0 |
| Red blood cell count increased | 1 | 0 |
| Red blood cell elliptocytes present | 1 | 0 |
| Red blood cell morphology abnormal | 1 | 0 |
| Red blood cell target cells present | 1 | 0 |
| Renal function analyses | | |
| Blood creatine increased | 1 | 0 |
| Blood creatinine abnormal | 1 | 0 |
| Blood creatinine decreased | 3 | 0 |
| Blood creatinine increased | 3 | 0 |
| Blood urea | 7 | 0 |
| Blood urea increased | 1 | 0 |
| Glomerular filtration rate decreased | 7 | 0 |
| Reproductive hormone analyses | | |
| 17 ketosteroids urine decreased | 1 | 0 |
| Anti-Muellerian hormone level decreased | 4 | 0 |
| Blood oestrogen | 2 | 0 |
| Blood oestrogen decreased | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations | | |
| Investigations cont'd | | |
| Blood oestrogen increased | 2 | 0 |
| Blood testosterone decreased | 3 | 0 |
| Blood testosterone increased | 1 | 0 |
| Dihydrotestosterone decreased | 1 | 0 |
| False negative pregnancy test | 5 | 0 |
| Female sex hormone level | 1 | 0 |
| Human chorionic gonadotropin decreased | 1 | 0 |
| Oestradiol | 2 | 0 |
| Oestradiol decreased | 1 | 0 |
| Oestriol | 1 | 0 |
| Pregnancy test | 17 | 0 |
| Pregnancy test false positive | 2 | 0 |
| Pregnancy test negative | 2 | 0 |
| Progesterone decreased | 1 | 0 |
| Reproductive hormone | 1 | 0 |
| <i>Reproductive organ and breast histopathology procedures</i> | | |
| Biopsy breast | 1 | 0 |
| Biopsy vagina | 1 | 0 |
| Smear cervix | 2 | 0 |
| <i>Reproductive organ and breast imaging procedures</i> | | |
| Mammogram | 1 | 0 |
| Ultrasound scan vagina normal | 1 | 0 |
| <i>Respiratory and pulmonary function diagnostic procedures</i> | | |
| Forced expiratory volume | 2 | 0 |
| Forced expiratory volume decreased | 1 | 0 |
| Forced expiratory volume increased | 14 | 0 |
| Forced expiratory volume normal | 1 | 0 |
| Forced vital capacity decreased | 2 | 0 |
| Fractional exhaled nitric oxide normal | 1 | 0 |
| Maximal voluntary ventilation | 2 | 0 |
| Peak expiratory flow rate | 1 | 0 |
| Peak expiratory flow rate abnormal | 1 | 0 |
| Peak expiratory flow rate decreased | 7 | 0 |
| Pulmonary function test | 5 | 0 |
| Pulmonary function test decreased | 7 | 0 |
| Slow vital capacity | 1 | 0 |
| Total lung capacity decreased | 6 | 0 |
| <i>Respiratory tract and thoracic histopathology procedures</i> | | |
| Sputum abnormal | 3 | 0 |
| <i>Respiratory tract and thoracic imaging procedures</i> | | |
| Chest X-ray | 21 | 0 |
| Computerised tomogram thorax | 4 | 0 |
| Laryngoscopy | 1 | 0 |
| Ventilation/perfusion scan | 1 | 0 |
| <i>Skeletal and cardiac muscle analyses</i> | | |
| Blood creatine phosphokinase increased | 8 | 0 |
| Muscle enzyme increased | 1 | 0 |
| Myocardial necrosis marker | 1 | 0 |
| Myocardial necrosis marker increased | 1 | 0 |
| Troponin | 2 | 0 |
| Troponin I increased | 3 | 0 |
| Troponin T | 1 | 0 |
| Troponin T increased | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| Troponin increased | 21 | 0 |
| <i>Skin histopathology and skin investigations NEC</i> | | |
| Biopsy skin | 2 | 0 |
| <i>Special sense investigations NEC</i> | | |
| Olfactory test | 1 | 0 |
| <i>Therapeutic drug monitoring analyses</i> | | |
| Analgesic drug level | 17 | 0 |
| Analgesic drug level increased | 1 | 0 |
| Analgesic drug level therapeutic | 1 | 0 |
| Anticoagulation drug level above therapeutic | 3 | 0 |
| Anticoagulation drug level below therapeutic | 4 | 0 |
| Anticoagulation drug level increased | 1 | 0 |
| Antidepressant drug level decreased | 1 | 0 |
| Drug level increased | 3 | 0 |
| <i>Thyroid analyses</i> | | |
| Anti-thyroid antibody | 1 | 0 |
| Thyroid function test abnormal | 4 | 0 |
| Thyroxine | 2 | 0 |
| Thyroxine abnormal | 1 | 0 |
| Thyroxine free decreased | 1 | 0 |
| Thyroxine increased | 2 | 0 |
| Tri-iodothyronine decreased | 7 | 0 |
| <i>Tissue enzyme analyses NEC</i> | | |
| Blood alkaline phosphatase | 1 | 0 |
| Blood alkaline phosphatase decreased | 1 | 0 |
| Blood alkaline phosphatase increased | 3 | 0 |
| Blood lactate dehydrogenase | 1 | 0 |
| Blood lactate dehydrogenase increased | 1 | 0 |
| Lactate dehydrogenase urine increased | 1 | 0 |
| <i>Toxicology laboratory analyses</i> | | |
| Blood aluminium | 1 | 0 |
| Blood arsenic normal | 1 | 0 |
| Blood cannabinoids | 1 | 0 |
| Blood carbon monoxide increased | 3 | 0 |
| Blood lead | 1 | 0 |
| Drug screen positive | 4 | 0 |
| Heavy metal test | 1 | 0 |
| <i>Triglyceride analyses</i> | | |
| Blood triglycerides | 1 | 0 |
| Blood triglycerides increased | 2 | 0 |
| <i>Urinalysis NEC</i> | | |
| Blood urine | 41 | 0 |
| Blood urine present | 98 | 0 |
| Cells in urine | 2 | 0 |
| Crystal urine | 4 | 0 |
| Glucose urine | 1 | 0 |
| Haemoglobin urine | 1 | 0 |
| Medication crystals in urine present | 1 | 0 |
| Protein urine | 3 | 0 |
| Protein urine present | 2 | 0 |
| Red blood cells urine | 1 | 0 |
| Urea urine increased | 1 | 0 |
| Urine analysis | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| Urine analysis abnormal | 17 | 0 |
| Urine analysis normal | 3 | 0 |
| White blood cells urine positive | 1 | 0 |
| pH urine | 11 | 0 |
| pH urine decreased | 2 | 0 |
| pH urine increased | 3 | 0 |
| Urinary tract function analyses NEC | | |
| Urine output | 51 | 0 |
| Urine output decreased | 18 | 0 |
| Urine output increased | 11 | 0 |
| Urinary tract histopathology procedures | | |
| Biopsy kidney | 1 | 0 |
| Urinary tract imaging procedures | | |
| Bladder scan | 1 | 0 |
| Cystoscopy | 3 | 0 |
| Ultrasound kidney | 1 | 0 |
| Vascular auscultatory investigations | | |
| Abdominal bruit | 1 | 0 |
| Aortic bruit | 1 | 0 |
| Carotid bruit | 1 | 0 |
| Vascular imaging procedures NEC | | |
| Arteriogram carotid | 1 | 0 |
| Venogram | 2 | 0 |
| Vascular tests NEC (incl blood pressure) | | |
| Blood pressure abnormal | 21 | 0 |
| Blood pressure decreased | 109 | 0 |
| Blood pressure diastolic | 1 | 0 |
| Blood pressure diastolic decreased | 1 | 0 |
| Blood pressure diastolic increased | 5 | 0 |
| Blood pressure difference of extremities | 2 | 0 |
| Blood pressure increased | 374 | 0 |
| Blood pressure measurement | 121 | 0 |
| Blood pressure normal | 6 | 0 |
| Blood pressure orthostatic decreased | 1 | 0 |
| Blood pressure systolic | 1 | 0 |
| Blood pressure systolic abnormal | 1 | 0 |
| Blood pressure systolic increased | 5 | 0 |
| Capillary nail refill test | 1 | 0 |
| Pulmonary arterial pressure abnormal | 1 | 0 |
| Venous pressure | 1 | 0 |
| Virus identification and serology | | |
| Blood HIV RNA increased | 1 | 0 |
| Coronavirus test | 43 | 0 |
| Cytomegalovirus test | 1 | 0 |
| Epstein-Barr virus antibody positive | 1 | 0 |
| HIV antibody negative | 2 | 0 |
| Hepatitis B core antibody positive | 1 | 0 |
| Hepatitis B surface antibody positive | 1 | 0 |
| Herpes virus test | 1 | 0 |
| Human papilloma virus test negative | 1 | 0 |
| Human papilloma virus test positive | 1 | 0 |
| SARS-CoV-1 test positive | 1 | 0 |
| SARS-CoV-2 RNA | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|--------------|----------|
| Investigations | | |
| Investigations cont'd | | |
| SARS-CoV-2 antibody test | 12 | 0 |
| SARS-CoV-2 antibody test negative | 39 | 0 |
| SARS-CoV-2 antibody test positive | 11 | 0 |
| SARS-CoV-2 test | 30 | 0 |
| SARS-CoV-2 test false negative | 5 | 0 |
| SARS-CoV-2 test false positive | 4 | 0 |
| SARS-CoV-2 test negative | 19 | 0 |
| SARS-CoV-2 test positive | 120 | 0 |
| Varicella virus test positive | 1 | 0 |
| Viral load | 1 | 0 |
| Viral test | 4 | 0 |
| Viral test positive | 1 | 0 |
| Vitamin analyses | | |
| Blood folate | 3 | 0 |
| Blood folate abnormal | 1 | 0 |
| Blood folate decreased | 19 | 0 |
| Vitamin B12 | 3 | 0 |
| Vitamin B12 abnormal | 3 | 0 |
| Vitamin B12 decreased | 8 | 0 |
| Vitamin B12 increased | 1 | 0 |
| Vitamin D | 4 | 0 |
| Vitamin D decreased | 7 | 0 |
| Vitamin D increased | 1 | 0 |
| Vitamin E decreased | 1 | 0 |
| Water and electrolyte analyses NEC | | |
| Blood electrolytes decreased | 2 | 0 |
| Blood osmolarity | 1 | 0 |
| Volume blood | 7 | 0 |
| White blood cell analyses | | |
| CD4 lymphocytes decreased | 1 | 0 |
| Eosinophil count | 1 | 0 |
| Eosinophil count abnormal | 2 | 0 |
| Eosinophil count decreased | 1 | 0 |
| Eosinophil count increased | 7 | 0 |
| Lymphocyte count | 3 | 0 |
| Lymphocyte count abnormal | 1 | 0 |
| Lymphocyte count decreased | 7 | 0 |
| Lymphocyte count increased | 4 | 0 |
| Monocyte count increased | 1 | 0 |
| Mononuclear cell count abnormal | 1 | 0 |
| Natural killer cell count increased | 1 | 0 |
| Neutrophil count | 4 | 0 |
| Neutrophil count abnormal | 1 | 0 |
| Neutrophil count decreased | 22 | 0 |
| Neutrophil count increased | 1 | 0 |
| Neutrophil toxic granulation present | 1 | 0 |
| White blood cell count | 21 | 0 |
| White blood cell count decreased | 38 | 0 |
| White blood cell count increased | 14 | 0 |
| White blood cell count normal | 1 | 0 |
| Investigations SOC TOTAL | 11953 | 2 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Appetite disorder | 38 | 0 |
| Decreased appetite | 6517 | 0 |
| Diet refusal | 2 | 0 |
| Eating disorder symptom | 1 | 0 |
| Food craving | 26 | 0 |
| Food refusal | 44 | 0 |
| Hyperphagia | 10 | 0 |
| Hypophagia | 41 | 0 |
| Increased appetite | 62 | 0 |
| Salt craving | 4 | 0 |
| <i>Calcium metabolism disorders</i> | | |
| Hypercalcaemia | 2 | 0 |
| Hypocalcaemia | 8 | 0 |
| Tetany | 1 | 0 |
| <i>Copper metabolism disorders</i> | | |
| Copper deficiency | 1 | 0 |
| <i>Diabetes mellitus (incl subtypes)</i> | | |
| Diabetes mellitus | 123 | 0 |
| Diabetes mellitus inadequate control | 29 | 0 |
| Fulminant type 1 diabetes mellitus | 1 | 0 |
| Increased insulin requirement | 1 | 0 |
| Insulin resistant diabetes | 1 | 0 |
| Steroid diabetes | 1 | 0 |
| Type 1 diabetes mellitus | 27 | 0 |
| Type 2 diabetes mellitus | 7 | 0 |
| <i>Diabetic complications NEC</i> | | |
| Diabetic complication | 1 | 0 |
| Diabetic ketoacidosis | 42 | 2 |
| Diabetic ketosis | 5 | 0 |
| Euglycaemic diabetic ketoacidosis | 1 | 0 |
| <i>Diabetic complications neurological</i> | | |
| Hyperglycaemic hyperosmolar nonketotic syndrome | 2 | 0 |
| <i>Disorders of purine metabolism</i> | | |
| Gout | 194 | 0 |
| <i>Electrolyte imbalance NEC</i> | | |
| Electrolyte imbalance | 4 | 0 |
| Fluid imbalance | 1 | 0 |
| Hyperosmolar state | 1 | 0 |
| <i>Elevated cholesterol</i> | | |
| Hypercholesterolaemia | 1 | 0 |
| <i>Fat soluble vitamin deficiencies and disorders</i> | | |
| Vitamin D deficiency | 22 | 0 |
| <i>Fluid intake decreased</i> | | |
| Fluid intake reduced | 11 | 0 |
| <i>Fluid intake increased</i> | | |
| Polydipsia | 17 | 0 |
| <i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i> | | |
| Alcohol intolerance | 15 | 0 |
| Dairy intolerance | 6 | 0 |
| Food intolerance | 28 | 0 |
| Gluten sensitivity | 6 | 0 |
| Histamine intolerance | 5 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Metabolic disorders Metabolic disorders cont'd | | |
| General nutritional disorders NEC | | |
| Abnormal loss of weight | 94 | 0 |
| Abnormal weight gain | 43 | 0 |
| Cachexia | 3 | 0 |
| Feeding disorder | 220 | 0 |
| Food aversion | 57 | 0 |
| Malnutrition | 1 | 0 |
| Neonatal insufficient breast milk syndrome | 4 | 0 |
| Obesity | 2 | 0 |
| Overfeeding of infant | 1 | 0 |
| Overweight | 2 | 0 |
| Poor feeding infant | 17 | 0 |
| Protein deficiency | 1 | 0 |
| Starvation | 1 | 0 |
| Underweight | 2 | 0 |
| Weight gain poor | 1 | 0 |
| Weight loss poor | 4 | 0 |
| Hyperglycaemic conditions NEC | | |
| Glucose tolerance impaired | 5 | 0 |
| Hyperglycaemia | 137 | 0 |
| Insulin resistance | 10 | 0 |
| Metabolic syndrome | 1 | 0 |
| Hyperlipidaemias NEC | | |
| Hyperlipidaemia | 4 | 0 |
| Hypoglycaemic conditions NEC | | |
| Hyperinsulinaemic hypoglycaemia | 1 | 0 |
| Hypoglycaemia | 109 | 0 |
| Hypoglycaemia unawareness | 2 | 0 |
| Postprandial hypoglycaemia | 3 | 0 |
| Iron deficiencies | | |
| Iron deficiency | 20 | 0 |
| Iron excess | | |
| Haemochromatosis | 2 | 0 |
| Iron overload | 1 | 0 |
| Lipid metabolism and deposit disorders NEC | | |
| Lipoedema | 1 | 0 |
| Magnesium metabolism disorders | | |
| Hypomagnesaemia | 1 | 0 |
| Metabolic acidoses (excl diabetic acidoses) | | |
| Hyperlactacidaemia | 2 | 0 |
| Ketoacidosis | 1 | 0 |
| Ketosis | 6 | 0 |
| Lactic acidosis | 3 | 0 |
| Metabolic acidosis | 13 | 0 |
| Metabolic disorders NEC | | |
| Hypometabolism | 1 | 0 |
| Metabolic disorder | 2 | 0 |
| Mixed acid-base disorders | | |
| Acidosis | 5 | 0 |
| Phosphorus metabolism disorders | | |
| Hypophosphataemia | 2 | 0 |
| Potassium imbalance | | |
| Hyperkalaemia | 8 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------------|----------|
| Metabolic disorders Metabolic disorders cont'd | | |
| Hypokalaemia | 6 | 0 |
| Hypokalaemic syndrome | 3 | 0 |
| Protein metabolism disorders NEC | | |
| Hypoalbuminaemia | 2 | 0 |
| Sodium imbalance | | |
| Hypernatraemia | 3 | 0 |
| Hyponatraemia | 30 | 0 |
| Hyponatraemic syndrome | 4 | 1 |
| Sugar intolerance (excl glucose intolerance) | | |
| Lactose intolerance | 9 | 0 |
| Total fluid volume decreased | | |
| Dehydration | 702 | 0 |
| Hypovolaemia | 2 | 0 |
| Total fluid volume increased | | |
| Fluid retention | 102 | 0 |
| Hypervolaemia | 13 | 0 |
| Vitamin deficiencies NEC | | |
| Hypovitaminosis | 4 | 0 |
| Water soluble vitamin deficiencies | | |
| Folate deficiency | 14 | 0 |
| Vitamin B complex deficiency | 2 | 0 |
| Vitamin B12 deficiency | 19 | 0 |
| Metabolic disorders SOC TOTAL | 9017 | 3 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Muscle & tissue disorders | | |
| <i>Arthropathies NEC</i> | | |
| Arthritis | 665 | 0 |
| Arthritis enteropathic | 2 | 0 |
| Arthropathy | 44 | 0 |
| Autoimmune arthritis | 13 | 0 |
| Haemarthrosis | 9 | 0 |
| Oligoarthritis | 2 | 0 |
| Palindromic rheumatism | 9 | 0 |
| Polyarthritis | 22 | 0 |
| Rheumatic fever | 8 | 0 |
| Sacroiliitis | 4 | 0 |
| Seronegative arthritis | 4 | 0 |
| Sympathetic posterior cervical syndrome | 1 | 0 |
| <i>Bone disorders NEC</i> | | |
| Bone disorder | 4 | 0 |
| Bone erosion | 1 | 0 |
| Bone loss | 2 | 0 |
| Exostosis | 2 | 0 |
| Jaw cyst | 1 | 0 |
| Jaw disorder | 5 | 0 |
| Medial tibial stress syndrome | 9 | 0 |
| Osteitis | 12 | 0 |
| Osteonecrosis | 5 | 0 |
| Osteonecrosis of jaw | 4 | 0 |
| Osteosclerosis | 2 | 0 |
| Spinal disorder | 5 | 0 |
| <i>Bone related signs and symptoms</i> | | |
| Bone pain | 1132 | 0 |
| Bone swelling | 11 | 0 |
| Coccydynia | 8 | 0 |
| Pain in jaw | 642 | 0 |
| Pubic pain | 1 | 0 |
| Spinal pain | 286 | 0 |
| <i>Bursal disorders</i> | | |
| Bursitis | 240 | 0 |
| <i>Cartilage disorders</i> | | |
| Chondritis | 1 | 0 |
| Chondropathy | 2 | 0 |
| Costochondritis | 98 | 0 |
| Osteochondrosis | 1 | 0 |
| Polychondritis | 2 | 0 |
| <i>Connective tissue disorders NEC</i> | | |
| Collagen disorder | 2 | 0 |
| Connective tissue disorder | 7 | 0 |
| Eosinophilic fasciitis | 1 | 0 |
| Mixed connective tissue disease | 1 | 0 |
| Morphoea | 5 | 0 |
| Polymyalgia rheumatica | 123 | 0 |
| Reynold's syndrome | 7 | 0 |
| Scleroderma | 5 | 0 |
| Sjogren's syndrome | 5 | 0 |
| Systemic scleroderma | 3 | 0 |
| <i>Crystal arthropathic disorders</i> | | |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Muscle & tissue disorders | | |
| <i>Muscle & tissue disorders cont'd</i> | | |
| Chondrocalcinosis | 5 | 0 |
| Gouty tophus | 1 | 0 |
| Epiphyseal disorders | | |
| Epiphyses premature fusion | 1 | 0 |
| Extremity deformities | | |
| Acquired claw toe | 1 | 0 |
| Elbow deformity | 1 | 0 |
| Finger deformity | 6 | 0 |
| Foot deformity | 7 | 0 |
| Hand deformity | 4 | 0 |
| Knee deformity | 1 | 0 |
| Limb deformity | 10 | 0 |
| Wrist deformity | 2 | 0 |
| Fractures NEC | | |
| Osteoporotic fracture | 4 | 0 |
| Pathological fracture | 1 | 0 |
| Intervertebral disc disorders NEC | | |
| Intervertebral disc degeneration | 3 | 0 |
| Intervertebral disc disorder | 1 | 0 |
| Intervertebral disc protrusion | 13 | 0 |
| Joint related disorders NEC | | |
| Ankle impingement | 1 | 0 |
| Femoroacetabular impingement | 2 | 0 |
| Greater trochanteric pain syndrome | 10 | 0 |
| Joint adhesion | 1 | 0 |
| Joint ankylosis | 2 | 0 |
| Joint contracture | 1 | 0 |
| Joint instability | 3 | 0 |
| Joint laxity | 6 | 0 |
| Joint lock | 66 | 0 |
| Ligament laxity | 1 | 0 |
| Patellofemoral pain syndrome | 7 | 0 |
| Periarthritis | 573 | 0 |
| Rotator cuff syndrome | 112 | 0 |
| Temporomandibular joint syndrome | 25 | 0 |
| Joint related signs and symptoms | | |
| Arthralgia | 23701 | 0 |
| Jaw clicking | 6 | 0 |
| Joint effusion | 12 | 0 |
| Joint noise | 54 | 0 |
| Joint range of motion decreased | 7 | 0 |
| Joint stiffness | 504 | 0 |
| Joint swelling | 1138 | 0 |
| Joint vibration | 6 | 0 |
| Joint warmth | 39 | 0 |
| Loose body in joint | 1 | 0 |
| Ligament disorders | | |
| Ligament pain | 11 | 0 |
| Lupus erythematosus (incl subtypes) | | |
| Lupus-like syndrome | 4 | 0 |
| Systemic lupus erythematosus | 44 | 0 |
| Metabolic bone disorders | | |
| Dwarfism | 1 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Muscle & tissue disorders | | |
| <i>Muscle & tissue disorders cont'd</i> | | |
| Low turnover osteopathy | 1 | 0 |
| Osteopenia | 2 | 0 |
| Osteoporosis | 13 | 0 |
| <i>Muscle infections and inflammations</i> | | |
| Autoimmune myositis | 2 | 0 |
| Myositis | 59 | 0 |
| Polymyositis | 6 | 0 |
| <i>Muscle pains</i> | | |
| Fibromyalgia | 335 | 0 |
| Myalgia | 27170 | 0 |
| Myalgia intercostal | 3 | 0 |
| Myofascial pain syndrome | 31 | 0 |
| <i>Muscle related signs and symptoms NEC</i> | | |
| Haematoma muscle | 4 | 0 |
| Muscle atrophy | 46 | 0 |
| Muscle discomfort | 22 | 0 |
| Muscle disorder | 15 | 0 |
| Muscle fatigue | 1038 | 0 |
| Muscle haemorrhage | 5 | 0 |
| Muscle hypertrophy | 1 | 0 |
| Muscle mass | 14 | 0 |
| Muscle oedema | 4 | 0 |
| Muscle spasms | 3688 | 0 |
| Muscle swelling | 35 | 0 |
| Muscle tightness | 208 | 0 |
| Muscle twitching | 642 | 0 |
| Neuropathic muscular atrophy | 1 | 0 |
| Trigger points | 1 | 0 |
| <i>Muscle tone abnormalities</i> | | |
| Muscle rigidity | 55 | 0 |
| Nuchal rigidity | 19 | 0 |
| Torticollis | 14 | 0 |
| Trismus | 61 | 0 |
| <i>Muscle weakness conditions</i> | | |
| Muscular weakness | 2389 | 0 |
| Sarcopenia | 2 | 0 |
| <i>Musculoskeletal and connective tissue conditions NEC</i> | | |
| Back disorder | 4 | 0 |
| Camptocormia | 1 | 0 |
| Dupuytren's contracture | 6 | 0 |
| Extremity contracture | 2 | 0 |
| Infantile back arching | 1 | 0 |
| Limb mass | 22 | 0 |
| Mandibular mass | 1 | 0 |
| Mastication disorder | 9 | 0 |
| Mobility decreased | 216 | 0 |
| Muscle contracture | 6 | 0 |
| Musculoskeletal disorder | 3 | 0 |
| Musculoskeletal stiffness | 2486 | 0 |
| Pelvic misalignment | 1 | 0 |
| Posture abnormal | 3 | 0 |
| Somatic dysfunction | 1 | 0 |
| Weight bearing difficulty | 14 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Muscle & tissue disorders | | |
| <i>Muscle & tissue disorders cont'd</i> | | |
| Winged scapula | 2 | 0 |
| <i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i> | | |
| Facial asymmetry | 3 | 0 |
| Head deformity | 1 | 0 |
| <i>Musculoskeletal and connective tissue infections and inflammations NEC</i> | | |
| Connective tissue inflammation | 4 | 0 |
| Dactylitis | 3 | 0 |
| Fasciitis | 1 | 0 |
| Plantar fasciitis | 18 | 0 |
| <i>Musculoskeletal and connective tissue pain and discomfort</i> | | |
| Amplified musculoskeletal pain syndrome | 1 | 0 |
| Back pain | 6052 | 0 |
| Flank pain | 98 | 0 |
| Growing pains | 8 | 0 |
| Limb discomfort | 2463 | 0 |
| Musculoskeletal chest pain | 442 | 0 |
| Musculoskeletal discomfort | 176 | 0 |
| Musculoskeletal pain | 177 | 0 |
| Neck pain | 3241 | 0 |
| Pain in extremity | 22909 | 0 |
| Rheumatic disorder | 33 | 0 |
| Sacral pain | 7 | 0 |
| <i>Myopathies</i> | | |
| Compartment syndrome | 6 | 0 |
| Muscle necrosis | 2 | 0 |
| Myopathy | 6 | 0 |
| Rhabdomyolysis | 11 | 1 |
| <i>Osteoarthropathies</i> | | |
| Nodal osteoarthritis | 1 | 0 |
| Osteoarthritis | 113 | 0 |
| Spinal osteoarthritis | 11 | 0 |
| <i>Psoriatic arthropathies</i> | | |
| Psoriatic arthropathy | 36 | 0 |
| <i>Rheumatoid arthropathies</i> | | |
| Felty's syndrome | 1 | 0 |
| Juvenile idiopathic arthritis | 2 | 0 |
| Rheumatoid arthritis | 234 | 0 |
| Rheumatoid nodule | 1 | 0 |
| Still's disease | 6 | 0 |
| <i>Soft tissue disorders NEC</i> | | |
| Axillary mass | 87 | 0 |
| Clubbing | 1 | 0 |
| Fistula | 3 | 0 |
| Groin pain | 242 | 0 |
| Neck mass | 27 | 0 |
| Soft tissue disorder | 3 | 0 |
| Soft tissue mass | 3 | 0 |
| Soft tissue swelling | 7 | 0 |
| <i>Spine and neck deformities</i> | | |
| Cervical spinal stenosis | 1 | 0 |
| Kyphosis | 6 | 0 |
| Scoliosis | 5 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|---------------|----------|
| Muscle & tissue disorders | | |
| <i>Muscle & tissue disorders cont'd</i> | | |
| Spinal stenosis | 3 | 0 |
| Thoracic spinal stenosis | 1 | 0 |
| <i>Spondyloarthropathies</i> | | |
| Ankylosing spondylitis | 34 | 0 |
| Arthritis reactive | 75 | 0 |
| Axial spondyloarthritis | 2 | 0 |
| Spondylitis | 9 | 0 |
| Spondyloarthropathy | 3 | 0 |
| <i>Synovial disorders</i> | | |
| Synovial cyst | 19 | 0 |
| Synovitis | 23 | 0 |
| <i>Tendon disorders</i> | | |
| Enthesopathy | 2 | 0 |
| Tendon calcification | 1 | 0 |
| Tendon discomfort | 4 | 0 |
| Tendon disorder | 10 | 0 |
| Tendon pain | 52 | 0 |
| Tendon sheath disorder | 1 | 0 |
| Tendonitis | 117 | 0 |
| Tenosynovitis | 3 | 0 |
| Tenosynovitis stenosaurs | 4 | 0 |
| Trigger finger | 36 | 0 |
| Muscle & tissue disorders SOC TOTAL | 105332 | 1 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Neoplasms | | |
| <i>Anal canal neoplasms malignant</i> | | |
| Anal cancer | 1 | 0 |
| <i>Anaplastic large cell lymphomas T- and null-cell types</i> | | |
| T-cell lymphoma | 1 | 1 |
| <i>Aural neoplasms benign</i> | | |
| Benign ear neoplasm | 1 | 0 |
| Cholesterol granuloma | 1 | 0 |
| <i>B-cell lymphomas NEC</i> | | |
| B-cell lymphoma | 2 | 0 |
| Follicular lymphoma | 2 | 0 |
| <i>Bile duct neoplasms malignant</i> | | |
| Bile duct cancer | 1 | 0 |
| Cholangiocarcinoma | 1 | 0 |
| Cholangiosarcoma | 1 | 0 |
| <i>Bladder neoplasms malignant</i> | | |
| Bladder cancer | 2 | 0 |
| <i>Bone neoplasms benign (excl cysts)</i> | | |
| Osteoma | 1 | 0 |
| <i>Bone neoplasms malignant (excl sarcomas)</i> | | |
| Bone cancer | 2 | 0 |
| <i>Breast and nipple neoplasms benign</i> | | |
| Benign breast neoplasm | 4 | 0 |
| Fibroadenoma of breast | 1 | 0 |
| <i>Breast and nipple neoplasms malignant</i> | | |
| Breast cancer | 56 | 0 |
| Breast cancer female | 1 | 0 |
| Breast cancer in situ | 1 | 0 |
| Breast cancer male | 3 | 0 |
| Breast cancer metastatic | 1 | 0 |
| Breast cancer stage I | 1 | 0 |
| Breast cancer stage III | 3 | 0 |
| Breast cancer stage IV | 1 | 0 |
| Inflammatory carcinoma of breast stage III | 1 | 0 |
| Intraductal proliferative breast lesion | 1 | 0 |
| Triple negative breast cancer | 1 | 0 |
| <i>Cardiovascular neoplasms benign</i> | | |
| Haemangioma | 7 | 0 |
| <i>Central nervous system neoplasms malignant NEC</i> | | |
| Brain cancer metastatic | 2 | 0 |
| Brain neoplasm malignant | 3 | 0 |
| <i>Cervix neoplasms benign</i> | | |
| Cervix warts | 1 | 0 |
| <i>Cervix neoplasms malignant</i> | | |
| Cervix carcinoma | 3 | 0 |
| <i>Colorectal neoplasms malignant</i> | | |
| Colon cancer | 2 | 0 |
| Colorectal cancer | 3 | 0 |
| <i>Diffuse large B-cell lymphomas</i> | | |
| Diffuse large B-cell lymphoma | 1 | 0 |
| Diffuse large B-cell lymphoma stage IV | 1 | 0 |
| <i>Endocrine neoplasms benign NEC</i> | | |
| Pituitary tumour benign | 2 | 0 |
| <i>Endocrine neoplasms malignant and unspecified NEC</i> | | |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Neoplasms Neoplasms cont'd | | |
| Neuroendocrine tumour | 1 | 0 |
| <i>Endometrial neoplasms malignant</i> | | |
| Clear cell endometrial carcinoma | 1 | 0 |
| Endometrial cancer | 2 | 0 |
| <i>Gastric neoplasms malignant</i> | | |
| Gastric cancer | 2 | 0 |
| <i>Gastrointestinal neoplasms benign NEC</i> | | |
| Gastrointestinal tract adenoma | 1 | 0 |
| <i>Gastrointestinal neoplasms malignant NEC</i> | | |
| Gastrointestinal carcinoma | 8 | 0 |
| <i>Glial tumours malignant</i> | | |
| Glioblastoma | 4 | 0 |
| Glioblastoma multiforme | 1 | 0 |
| <i>Haematologic neoplasms NEC</i> | | |
| Benign lymph node neoplasm | 1 | 0 |
| Benign spleen tumour | 1 | 0 |
| Haematological malignancy | 2 | 0 |
| Systemic mastocytosis | 1 | 0 |
| <i>Hepatic neoplasms malignant</i> | | |
| Hepatic cancer | 1 | 0 |
| Hepatocellular carcinoma | 4 | 0 |
| <i>Hepatobiliary neoplasms benign</i> | | |
| Haemangioma of liver | 1 | 0 |
| <i>Hepatobiliary neoplasms malignancy unspecified</i> | | |
| Hepatic neoplasm | 1 | 0 |
| <i>Hepatoblastomas</i> | | |
| Hepatoblastoma | 1 | 0 |
| <i>Hodgkin's disease NEC</i> | | |
| Hodgkin's disease | 2 | 0 |
| <i>Leiomyosarcomas</i> | | |
| Pleomorphic leiomyosarcoma | 1 | 0 |
| <i>Leukaemias NEC</i> | | |
| Leukaemia | 6 | 1 |
| Leukaemia recurrent | 1 | 0 |
| <i>Leukaemias acute myeloid</i> | | |
| Acute myeloid leukaemia | 6 | 1 |
| <i>Leukaemias chronic lymphocytic</i> | | |
| Chronic lymphocytic leukaemia | 6 | 0 |
| <i>Leukaemias chronic myeloid</i> | | |
| Chronic myeloid leukaemia | 1 | 0 |
| <i>Leukaemias myeloid NEC</i> | | |
| Myeloid leukaemia | 1 | 0 |
| <i>Lip and oral cavity neoplasms benign</i> | | |
| Papillary cystadenoma lymphomatosum | 1 | 0 |
| <i>Lip and oral cavity neoplasms malignant</i> | | |
| Lip and/or oral cavity cancer | 1 | 0 |
| Lip neoplasm malignant stage unspecified | 1 | 0 |
| Squamous cell carcinoma of the oral cavity | 2 | 0 |
| <i>Lymphomas unspecified NEC</i> | | |
| Lymphoma | 21 | 0 |
| <i>Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)</i> | | |
| Epstein Barr virus positive mucocutaneous ulcer | 1 | 0 |
| Histiocytic necrotising lymphadenitis | 2 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Neoplasms Neoplasms cont'd | | |
| Lymphoproliferative disorder | 1 | 0 |
| Lymphoproliferative disorder in remission | 1 | 0 |
| Mediastinal neoplasms malignancy unspecified NEC | | |
| Good syndrome | 4 | 0 |
| Mesotheliomas malignant and unspecified | | |
| Mesothelioma | 1 | 0 |
| Metastases to specified sites | | |
| Metastases to bone | 2 | 0 |
| Metastases to central nervous system | 1 | 1 |
| Metastases to liver | 1 | 0 |
| Metastases to lung | 1 | 1 |
| Metastases to unknown and unspecified sites | | |
| Metastasis | 4 | 1 |
| Myelodysplastic syndromes | | |
| Myelodysplastic syndrome | 1 | 0 |
| Myeloproliferative disorders (excl leukaemias) | | |
| Essential thrombocythaemia | 2 | 0 |
| Myeloproliferative neoplasm | 1 | 0 |
| Neoplasms benign site unspecified NEC | | |
| Fibroma | 1 | 0 |
| Neoplasms malignant site unspecified NEC | | |
| Adenocarcinoma | 2 | 0 |
| Malignant neoplasm progression | 2 | 1 |
| Metastatic neoplasm | 3 | 0 |
| Neoplasm malignant | 16 | 4 |
| Recurrent cancer | 1 | 0 |
| Squamous cell carcinoma | 4 | 0 |
| Neoplasms unspecified malignancy and site unspecified NEC | | |
| Neoplasm | 3 | 0 |
| Neoplasm progression | 1 | 0 |
| Neoplasm recurrence | 9 | 0 |
| Nervous system neoplasms unspecified malignancy NEC | | |
| Brain neoplasm | 14 | 3 |
| Meningioma | 6 | 0 |
| Schwannoma | 1 | 0 |
| Neuromas | | |
| Acoustic neuroma | 7 | 0 |
| Non-Hodgkin's lymphomas NEC | | |
| Cutaneous lymphoma | 1 | 0 |
| Non-Hodgkin's lymphoma | 2 | 1 |
| Non-small cell neoplasms malignant of the respiratory tract cell type specified | | |
| Lung adenocarcinoma | 1 | 1 |
| Ocular neoplasms benign | | |
| Eye naevus | 4 | 0 |
| Oesophageal neoplasms malignant | | |
| Oesophageal cancer metastatic | 6 | 0 |
| Oesophageal carcinoma | 4 | 0 |
| Oesophageal squamous cell carcinoma | 1 | 0 |
| Oncologic complications and emergencies | | |
| Cancer fatigue | 4 | 0 |
| Cancer pain | 2 | 0 |
| Intracranial tumour haemorrhage | 1 | 0 |

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Neoplasms Neoplasms cont'd | | |
| Tumour pain | 1 | 0 |
| <i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i> | | |
| Tonsil cancer | 4 | 0 |
| <i>Ovarian neoplasms malignant (excl germ cell)</i> | | |
| Ovarian cancer | 11 | 0 |
| Ovarian cancer recurrent | 2 | 0 |
| Ovarian cancer stage IV | 1 | 0 |
| <i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i> | | |
| Pancreatic carcinoma | 7 | 1 |
| Pancreatic carcinoma metastatic | 1 | 0 |
| <i>Paranasal sinus and nasal cavity neoplasms malignant and unspecified</i> | | |
| Nasal cavity cancer | 1 | 0 |
| <i>Paraneoplastic syndromes NEC</i> | | |
| Paraneoplastic syndrome | 2 | 0 |
| <i>Penile neoplasms malignant</i> | | |
| Penile cancer | 1 | 0 |
| <i>Plasma cell myelomas</i> | | |
| Plasma cell myeloma | 3 | 0 |
| Plasmacytoma | 1 | 0 |
| <i>Plasma cell neoplasms NEC</i> | | |
| Hypergammaglobulinaemia benign monoclonal | 4 | 0 |
| <i>Prostatic neoplasms malignant</i> | | |
| Prostate cancer | 10 | 0 |
| <i>Renal neoplasms malignant</i> | | |
| Clear cell renal cell carcinoma | 2 | 0 |
| Metastatic renal cell carcinoma | 1 | 0 |
| Renal cancer | 2 | 0 |
| <i>Reproductive neoplasms female benign NEC</i> | | |
| Benign hydatidiform mole | 2 | 0 |
| <i>Reproductive neoplasms male benign NEC</i> | | |
| Testicle adenoma | 2 | 0 |
| <i>Respiratory tract and pleural neoplasms malignancy unspecified NEC</i> | | |
| Maxillofacial sinus neoplasm | 1 | 0 |
| <i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i> | | |
| Bronchial carcinoma | 4 | 0 |
| Lung cancer metastatic | 1 | 0 |
| Lung neoplasm malignant | 17 | 1 |
| Throat cancer | 2 | 0 |
| <i>Respiratory tract small cell carcinomas</i> | | |
| Small cell lung cancer | 1 | 0 |
| Small cell lung cancer metastatic | 1 | 1 |
| <i>Salivary gland neoplasms malignant</i> | | |
| Salivary gland cancer stage 0 | 1 | 0 |
| Salivary gland cancer stage III | 1 | 0 |
| <i>Skin melanomas (excl ocular)</i> | | |
| Acral lentiginous melanoma stage III | 1 | 0 |
| Malignant melanoma | 7 | 0 |
| Malignant melanoma in situ | 3 | 0 |
| Metastatic malignant melanoma | 1 | 0 |
| <i>Skin neoplasms benign</i> | | |
| Acrochordon | 7 | 0 |

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| Reaction Name | Total | Fatal |
|--|------------|-----------|
| Neoplasms Neoplasms cont'd | | |
| Anogenital warts | 4 | 0 |
| Haemangioma of skin | 19 | 0 |
| Melanocytic naevus | 5 | 0 |
| Seborrheic keratosis | 2 | 0 |
| Skin papilloma | 33 | 0 |
| <i>Skin neoplasms malignant and unspecified (excl melanoma)</i> | | |
| Basal cell carcinoma | 6 | 0 |
| Bowen's disease | 1 | 0 |
| Neoplasm skin | 4 | 0 |
| Skin cancer | 11 | 0 |
| Squamous cell carcinoma of skin | 1 | 0 |
| <i>Soft tissue neoplasms benign NEC</i> | | |
| Knuckle pads | 1 | 0 |
| Leiomyoma | 1 | 0 |
| Lipoma | 11 | 0 |
| <i>Soft tissue sarcomas histology unspecified</i> | | |
| Sarcoma | 1 | 0 |
| <i>Thyroid neoplasms benign</i> | | |
| Benign neoplasm of thyroid gland | 1 | 0 |
| Thyroid adenoma | 1 | 0 |
| <i>Uterine neoplasms benign</i> | | |
| Uterine leiomyoma | 24 | 0 |
| <i>Uterine neoplasms malignant NEC</i> | | |
| Uterine cancer | 5 | 0 |
| <i>Vulval neoplasms malignant</i> | | |
| Squamous cell carcinoma of the vulva | 1 | 0 |
| Vulval cancer | 1 | 0 |
| Neoplasms SOC TOTAL | 557 | 19 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Abnormal reflexes</i> | | |
| Areflexia | 35 | 0 |
| Extensor plantar response | 3 | 0 |
| Hyperreflexia | 10 | 0 |
| Hyporeflexia | 24 | 0 |
| Poor sucking reflex | 4 | 0 |
| Reflexes abnormal | 2 | 0 |
| <i>Abnormal sleep-related events</i> | | |
| Sleep paralysis | 27 | 0 |
| <i>Absence seizures</i> | | |
| Petit mal epilepsy | 44 | 0 |
| <i>Acute polyneuropathies</i> | | |
| Acute motor axonal neuropathy | 9 | 0 |
| Acute polyneuropathy | 3 | 0 |
| Guillain-Barre syndrome | 514 | 5 |
| Miller Fisher syndrome | 29 | 0 |
| Subacute inflammatory demyelinating polyneuropathy | 4 | 0 |
| <i>Alzheimer's disease (incl subtypes)</i> | | |
| Dementia Alzheimer's type | 1 | 0 |
| Mixed dementia | 1 | 0 |
| <i>Autonomic nervous system disorders</i> | | |
| Autonomic nervous system imbalance | 30 | 0 |
| Autonomic neuropathy | 2 | 0 |
| Horner's syndrome | 2 | 0 |
| Orthostatic intolerance | 11 | 0 |
| <i>Central nervous system aneurysms and dissections</i> | | |
| Carotid artery aneurysm | 2 | 0 |
| Carotid artery dissection | 1 | 0 |
| Intracranial aneurysm | 8 | 1 |
| Vertebrobasilar artery dissection | 3 | 0 |
| <i>Central nervous system haemorrhages and cerebrovascular accidents</i> | | |
| Basal ganglia haemorrhage | 3 | 0 |
| Basal ganglia infarction | 1 | 0 |
| Basal ganglia stroke | 2 | 1 |
| Basilar artery occlusion | 1 | 0 |
| Basilar artery thrombosis | 5 | 1 |
| Brain stem embolism | 1 | 1 |
| Brain stem haemorrhage | 5 | 1 |
| Brain stem infarction | 2 | 2 |
| Brain stem stroke | 9 | 2 |
| Brain stem thrombosis | 2 | 1 |
| Carotid artery occlusion | 3 | 0 |
| Carotid artery thrombosis | 12 | 0 |
| Cerebellar haemorrhage | 5 | 0 |
| Cerebellar infarction | 7 | 0 |
| Cerebellar stroke | 15 | 1 |
| Cerebral artery embolism | 12 | 0 |
| Cerebral artery occlusion | 5 | 1 |
| Cerebral artery thrombosis | 17 | 0 |
| Cerebral haematoma | 14 | 1 |
| Cerebral haemorrhage | 209 | 58 |
| Cerebral infarction | 101 | 7 |
| Cerebral ischaemia | 6 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Cerebral thrombosis | 47 | 5 |
| Cerebral vascular occlusion | 3 | 1 |
| Cerebrovascular accident | 1404 | 57 |
| Embolic cerebral infarction | 1 | 0 |
| Embolic stroke | 21 | 1 |
| Haemorrhage intracranial | 56 | 14 |
| Haemorrhagic cerebellar infarction | 1 | 0 |
| Haemorrhagic cerebral infarction | 3 | 1 |
| Haemorrhagic stroke | 52 | 9 |
| Haemorrhagic transformation stroke | 8 | 3 |
| Internal capsule infarction | 1 | 0 |
| Intracranial haematoma | 8 | 1 |
| Intraventricular haemorrhage | 6 | 0 |
| Ischaemic cerebral infarction | 3 | 0 |
| Ischaemic stroke | 170 | 8 |
| Lacunar infarction | 7 | 0 |
| Lacunar stroke | 30 | 0 |
| Perinatal stroke | 1 | 0 |
| Pseudostroke | 3 | 0 |
| Ruptured cerebral aneurysm | 1 | 0 |
| Spinal cord haematoma | 1 | 0 |
| Spinal cord infarction | 1 | 0 |
| Spinal stroke | 6 | 0 |
| Stroke in evolution | 1 | 0 |
| Subarachnoid haemorrhage | 124 | 9 |
| Thalamic infarction | 2 | 0 |
| Thalamus haemorrhage | 11 | 0 |
| Thrombotic stroke | 17 | 0 |
| Vertebral artery occlusion | 1 | 0 |
| Vertebral artery thrombosis | 2 | 0 |
| Central nervous system inflammatory disorders NEC | | |
| Arachnoiditis | 4 | 0 |
| Central nervous system inflammation | 15 | 0 |
| Neurosarcoidosis | 5 | 0 |
| Central nervous system vascular disorders NEC | | |
| Brain hypoxia | 1 | 0 |
| Brain stem microhaemorrhage | 1 | 0 |
| Carotid arteriosclerosis | 1 | 0 |
| Carotid artery stenosis | 5 | 0 |
| Central nervous system vasculitis | 3 | 0 |
| Cerebral amyloid angiopathy | 5 | 0 |
| Cerebral arteriosclerosis | 2 | 0 |
| Cerebral arteritis | 1 | 0 |
| Cerebral artery stenosis | 1 | 0 |
| Cerebral congestion | 4 | 0 |
| Cerebral microangiopathy | 1 | 0 |
| Cerebral microhaemorrhage | 4 | 0 |
| Cerebral small vessel ischaemic disease | 4 | 0 |
| Cerebral vasoconstriction | 3 | 0 |
| Cerebrovascular disorder | 4 | 0 |
| Cerebrovascular insufficiency | 1 | 0 |
| Dural arteriovenous fistula | 1 | 0 |
| Internal carotid artery deformity | 1 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| Reversible cerebral vasoconstriction syndrome | 5 | 0 |
| Cerebrovascular venous and sinus thrombosis | | |
| Cerebral venous sinus thrombosis | 226 | 28 |
| Cerebral venous thrombosis | 52 | 6 |
| Sigmoid sinus thrombosis | 2 | 1 |
| Superior sagittal sinus thrombosis | 34 | 3 |
| Transverse sinus thrombosis | 10 | 0 |
| Cervical spinal cord and nerve root disorders | | |
| Cervical radiculopathy | 4 | 0 |
| Cervicobrachial syndrome | 9 | 0 |
| Choreiform movements | | |
| Chorea | 3 | 0 |
| Choreoathetosis | 1 | 0 |
| Sydenham's chorea | 1 | 0 |
| Chronic polyneuropathies | | |
| Chronic inflammatory demyelinating polyradiculoneuropathy | 12 | 0 |
| Demyelinating polyneuropathy | 11 | 0 |
| Diabetic neuropathy | 3 | 0 |
| Polyneuropathy chronic | 2 | 0 |
| Coma states | | |
| Coma | 30 | 0 |
| Diabetic coma | 3 | 0 |
| Hypoglycaemic coma | 2 | 0 |
| Coordination and balance disturbances | | |
| Ataxia | 56 | 0 |
| Balance disorder | 1046 | 0 |
| Cerebellar ataxia | 5 | 0 |
| Cerebellar syndrome | 2 | 0 |
| Coordination abnormal | 147 | 0 |
| Dysdiadochokinesis | 1 | 0 |
| Dysstasia | 131 | 0 |
| Hand-eye coordination impaired | 3 | 0 |
| Nystagmus | 26 | 0 |
| Cortical dysfunction NEC | | |
| Agraphia | 1 | 0 |
| Alexia | 7 | 0 |
| Aphasia | 209 | 0 |
| Apraxia | 5 | 0 |
| Dysgraphia | 8 | 0 |
| Dyslexia | 2 | 0 |
| Dyspraxia | 8 | 0 |
| Neurologic neglect syndrome | 3 | 0 |
| Sensory processing disorder | 1 | 0 |
| Visuospatial deficit | 2 | 0 |
| Cranial nerve disorders NEC | | |
| Cranial nerve disorder | 3 | 0 |
| Cranial nerve paralysis | 1 | 0 |
| Neurovascular conflict | 1 | 0 |
| Paresis cranial nerve | 2 | 0 |
| Dementia (excl Alzheimer's type) | | |
| Dementia | 38 | 0 |
| Dementia with Lewy bodies | 3 | 0 |
| Frontotemporal dementia | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Senile dementia | 1 | 0 |
| Vascular dementia | 5 | 0 |
| <i>Demyelinating disorders NEC</i> | | |
| Acute disseminated encephalomyelitis | 16 | 0 |
| Autoimmune demyelinating disease | 1 | 0 |
| Clinically isolated syndrome | 3 | 0 |
| Demyelination | 30 | 1 |
| Neuromyelitis optica spectrum disorder | 6 | 0 |
| <i>Disturbances in consciousness NEC</i> | | |
| Altered state of consciousness | 21 | 0 |
| Consciousness fluctuating | 4 | 0 |
| Depressed level of consciousness | 95 | 0 |
| Hypoglycaemic unconsciousness | 1 | 0 |
| Lethargy | 5029 | 0 |
| Loss of consciousness | 1148 | 0 |
| Postictal state | 1 | 0 |
| Sedation | 19 | 0 |
| Somnolence | 2009 | 0 |
| Stupor | 10 | 0 |
| Syncope | 2721 | 0 |
| <i>Disturbances in sleep phase rhythm</i> | | |
| Advanced sleep phase | 1 | 0 |
| Circadian rhythm sleep disorder | 6 | 0 |
| Delayed sleep phase | 1 | 0 |
| Irregular sleep phase | 4 | 0 |
| Irregular sleep wake rhythm disorder | 1 | 0 |
| Non-24-hour sleep-wake disorder | 2 | 0 |
| <i>Dyskinesias and movement disorders NEC</i> | | |
| Akathisia | 10 | 0 |
| Akinesia | 1 | 0 |
| Ballismus | 1 | 0 |
| Bradykinesia | 40 | 0 |
| Clumsiness | 56 | 0 |
| Dyskinesia | 131 | 0 |
| Extrapyramidal disorder | 18 | 0 |
| Fine motor delay | 3 | 0 |
| Fine motor skill dysfunction | 23 | 0 |
| Hyperkinesia | 27 | 0 |
| Hypokinesia | 118 | 0 |
| Meige's syndrome | 1 | 0 |
| Micrographia | 1 | 0 |
| Motor dysfunction | 22 | 0 |
| Movement disorder | 127 | 0 |
| Psychomotor hyperactivity | 41 | 0 |
| Tardive dyskinesia | 1 | 0 |
| <i>Dystonias</i> | | |
| Dystonia | 23 | 0 |
| Dystonic tremor | 4 | 0 |
| Opisthotonus | 4 | 0 |
| Writer's cramp | 1 | 0 |
| <i>Encephalitis NEC</i> | | |
| Bickerstaff's encephalitis | 1 | 0 |
| Encephalitis autoimmune | 4 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Limbic encephalitis | 1 | 0 |
| Noninfective encephalitis | 19 | 0 |
| Encephalopathies NEC | | |
| Autoimmune encephalopathy | 6 | 1 |
| Encephalopathy | 13 | 0 |
| Hypertensive encephalopathy | 1 | 0 |
| Hypoxic-ischaemic encephalopathy | 1 | 0 |
| Posterior reversible encephalopathy syndrome | 5 | 0 |
| Encephalopathies toxic and metabolic | | |
| Hepatic encephalopathy | 2 | 0 |
| Eye movement disorders | | |
| IIIrd nerve disorder | 1 | 0 |
| IIIrd nerve paralysis | 8 | 0 |
| IIIrd nerve paresis | 1 | 0 |
| IVth nerve paralysis | 1 | 0 |
| Microvascular cranial nerve palsy | 2 | 0 |
| VIth nerve paralysis | 10 | 0 |
| Facial cranial nerve disorders | | |
| Bell's palsy | 646 | 0 |
| Facial nerve disorder | 9 | 0 |
| Facial paralysis | 380 | 0 |
| Facial paresis | 179 | 0 |
| Facial spasm | 48 | 0 |
| Oculofacial paralysis | 1 | 0 |
| Generalised tonic-clonic seizures | | |
| Generalised tonic-clonic seizure | 107 | 0 |
| Glossopharyngeal nerve disorders | | |
| Glossopharyngeal neuralgia | 1 | 0 |
| Headaches NEC | | |
| Cervicogenic headache | 6 | 0 |
| Chronic paroxysmal hemicrania | 1 | 0 |
| Cluster headache | 779 | 0 |
| Cold-stimulus headache | 93 | 0 |
| Drug withdrawal headache | 17 | 0 |
| Exertional headache | 12 | 0 |
| External compression headache | 5 | 0 |
| Headache | 82074 | 0 |
| Medication overuse headache | 19 | 0 |
| Menstrual headache | 12 | 0 |
| New daily persistent headache | 20 | 0 |
| Occipital neuralgia | 29 | 0 |
| Ophthalmoplegic migraine | 1 | 0 |
| Post-traumatic headache | 3 | 0 |
| Primary cough headache | 2 | 0 |
| Primary headache associated with sexual activity | 13 | 0 |
| Sinus headache | 964 | 0 |
| Tension headache | 1549 | 0 |
| Thunderclap headache | 54 | 1 |
| Vascular headache | 87 | 0 |
| Hydrocephalic conditions | | |
| Hydrocephalus | 18 | 1 |
| Hypoglossal nerve disorders | | |
| Tongue paralysis | 6 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| <i>Increased intracranial pressure disorders</i> | | |
| Brain compression | 4 | 0 |
| Brain oedema | 40 | 2 |
| Cerebrospinal fluid circulation disorder | 6 | 0 |
| Idiopathic intracranial hypertension | 7 | 0 |
| Intracranial pressure increased | 37 | 0 |
| Vasogenic cerebral oedema | 1 | 0 |
| <i>Intellectual disabilities</i> | | |
| Intellectual disability | 12 | 0 |
| <i>Lumbar spinal cord and nerve root disorders</i> | | |
| Cauda equina syndrome | 7 | 0 |
| Lumbar radiculopathy | 5 | 0 |
| Sciatica | 253 | 0 |
| <i>Memory loss (excl dementia)</i> | | |
| Amnesia | 488 | 0 |
| Memory impairment | 430 | 0 |
| Retrograde amnesia | 1 | 0 |
| Transient global amnesia | 25 | 0 |
| <i>Meningitis NEC</i> | | |
| Meningitis noninfective | 1 | 0 |
| <i>Mental impairment (excl dementia and memory loss)</i> | | |
| Cognitive disorder | 227 | 0 |
| Disturbance in attention | 798 | 0 |
| Judgement impaired | 5 | 0 |
| Mental impairment | 156 | 0 |
| <i>Migraine headaches</i> | | |
| Basilar migraine | 5 | 0 |
| Hemiplegic migraine | 55 | 0 |
| Migraine | 7845 | 0 |
| Migraine with aura | 409 | 0 |
| Migraine without aura | 49 | 0 |
| Ophthalmic migraine | 16 | 0 |
| Retinal migraine | 90 | 0 |
| Status migrainosus | 5 | 0 |
| Typical aura without headache | 19 | 0 |
| Vestibular migraine | 43 | 0 |
| <i>Mixed cranial nerve disorders</i> | | |
| Bulbar palsy | 4 | 0 |
| <i>Mononeuropathies</i> | | |
| Carpal tunnel syndrome | 49 | 0 |
| Cubital tunnel syndrome | 1 | 0 |
| Diabetic mononeuropathy | 1 | 0 |
| Long thoracic nerve palsy | 2 | 0 |
| Meralgia paraesthetica | 3 | 0 |
| Mononeuritis | 4 | 0 |
| Mononeuropathy | 3 | 0 |
| Nerve compression | 58 | 0 |
| Peripheral nerve lesion | 2 | 0 |
| Peroneal nerve palsy | 19 | 0 |
| Piriformis syndrome | 4 | 0 |
| Radial nerve palsy | 2 | 0 |
| Sciatic nerve neuropathy | 5 | 0 |
| Ulnar nerve palsy | 3 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders <small>Nervous system disorders cont'd</small> | | |
| Ulnar neuritis | 4 | 0 |
| Ulnar tunnel syndrome | 1 | 0 |
| Motor neurone diseases | | |
| Amyotrophic lateral sclerosis | 3 | 0 |
| Lower motor neurone lesion | 1 | 0 |
| Motor neurone disease | 11 | 1 |
| Multiple sclerosis acute and progressive | | |
| Band sensation | 7 | 0 |
| Multiple sclerosis | 72 | 0 |
| Multiple sclerosis pseudo relapse | 2 | 0 |
| Multiple sclerosis relapse | 62 | 0 |
| Progressive multiple sclerosis | 1 | 0 |
| Relapsing multiple sclerosis | 1 | 0 |
| Relapsing-remitting multiple sclerosis | 1 | 0 |
| Tumefactive multiple sclerosis | 1 | 0 |
| Uhthoff's phenomenon | 2 | 0 |
| Muscle tone abnormal | | |
| Drop attacks | 2 | 0 |
| Hypertonia | 5 | 0 |
| Hypotonia | 43 | 0 |
| Serotonin syndrome | 1 | 0 |
| Stiff leg syndrome | 10 | 0 |
| Stiff person syndrome | 1 | 0 |
| Myelitis (incl infective) | | |
| Acute flaccid myelitis | 1 | 0 |
| Myelitis transverse | 129 | 0 |
| Narcolepsy and hypersomnia | | |
| Cataplexy | 1 | 0 |
| Hypersomnia | 234 | 0 |
| Narcolepsy | 22 | 0 |
| Nervous system cysts and polyps | | |
| Arachnoid cyst | 2 | 0 |
| Cerebral cyst | 1 | 0 |
| Pineal gland cyst | 1 | 0 |
| Nervous system disorders NEC | | |
| Brain stem syndrome | 2 | 0 |
| Central nervous system lesion | 13 | 0 |
| Cerebral disorder | 9 | 0 |
| Microglial nodules | 1 | 0 |
| Nerve degeneration | 1 | 0 |
| Nervous system disorder | 101 | 0 |
| Neurotoxicity | 5 | 0 |
| Psychomotor skills impaired | 5 | 0 |
| Neurologic visual problems NEC | | |
| Hemianopia | 9 | 0 |
| Hemianopia homonymous | 3 | 0 |
| Quadrantanopia | 1 | 0 |
| Tunnel vision | 24 | 0 |
| Neurological signs and symptoms NEC | | |
| Agitation neonatal | 1 | 0 |
| Cerebrospinal fluid leakage | 1 | 0 |
| Clonus | 2 | 0 |
| Dizziness | 22915 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Dizziness exertional | 105 | 0 |
| Dizziness postural | 2194 | 1 |
| Drooling | 27 | 0 |
| Exaggerated startle response | 4 | 0 |
| Fontanelle bulging | 4 | 0 |
| Head discomfort | 808 | 0 |
| Hyporesponsive to stimuli | 5 | 0 |
| Inability to crawl | 2 | 0 |
| Infant irritability | 6 | 0 |
| Intracranial hypotension | 4 | 0 |
| Meningism | 3 | 0 |
| Myoclonus | 35 | 0 |
| Neurological decompensation | 4 | 0 |
| Neurological symptom | 161 | 0 |
| Patient elopement | 3 | 0 |
| Persistent postural-perceptual dizziness | 44 | 0 |
| Pleocytosis | 4 | 0 |
| Presyncope | 631 | 0 |
| Slow response to stimuli | 10 | 0 |
| Spontaneous cerebrospinal fluid leak syndrome | 2 | 0 |
| Tongue biting | 10 | 0 |
| Unresponsive to stimuli | 113 | 0 |
| Neuromuscular disorders NEC | | |
| Hypotonic-hyporesponsive episode | 1 | 0 |
| Muscle contractions involuntary | 46 | 0 |
| Muscle spasticity | 38 | 0 |
| Neuromuscular pain | 6 | 0 |
| Neuromyopathy | 4 | 0 |
| Neuromyotonia | 1 | 0 |
| Sensorimotor disorder | 2 | 0 |
| Neuromuscular junction dysfunction | | |
| Myasthenia gravis | 21 | 0 |
| Myasthenia gravis crisis | 4 | 0 |
| Olfactory nerve disorders | | |
| Anosmia | 374 | 0 |
| Hyposmia | 11 | 0 |
| Parosmia | 421 | 0 |
| Optic nerve disorders NEC | | |
| Optic neuritis | 68 | 0 |
| Paraesthesias and dysaesthesias | | |
| Anaesthesia | 3 | 0 |
| Burning feet syndrome | 36 | 0 |
| Burning sensation | 1088 | 0 |
| Burning sensation mucosal | 4 | 0 |
| Dysaesthesia | 17 | 0 |
| Formication | 89 | 0 |
| Hemianaesthesia | 2 | 0 |
| Hemihypoaesthesia | 2 | 0 |
| Hemiparaesthesia | 5 | 0 |
| Hyperaesthesia | 277 | 0 |
| Hypoaesthesia | 6326 | 0 |
| Lhermitte's sign | 4 | 0 |
| Paraesthesia | 10108 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| Nervous system disorders cont'd | | |
| Reversed hot-cold sensation | 1 | 0 |
| Vibration syndrome | 3 | 0 |
| <i>Paralysis and paresis (excl cranial nerve)</i> | | |
| Ascending flaccid paralysis | 1 | 0 |
| Diplegia | 38 | 0 |
| Gait spastic | 1 | 0 |
| Hemiparesis | 128 | 0 |
| Hemiplegia | 57 | 0 |
| Locked-in syndrome | 1 | 0 |
| Monoparesis | 125 | 0 |
| Monoplegia | 155 | 0 |
| Paralysis | 373 | 0 |
| Paraparesis | 6 | 0 |
| Paraplegia | 4 | 0 |
| Paresis | 12 | 0 |
| Peripheral nerve palsy | 1 | 0 |
| Peripheral paralysis | 2 | 0 |
| Postictal paralysis | 3 | 0 |
| Quadriparesis | 4 | 0 |
| Quadriplegia | 4 | 0 |
| Tick paralysis | 1 | 0 |
| <i>Parkinson's disease and parkinsonism</i> | | |
| Freezing phenomenon | 163 | 0 |
| Parkinson's disease | 20 | 0 |
| Parkinsonism | 14 | 1 |
| Reduced facial expression | 9 | 0 |
| Vascular parkinsonism | 1 | 0 |
| <i>Partial complex seizures</i> | | |
| Dreamy state | 21 | 0 |
| Focal dyscognitive seizures | 7 | 0 |
| Temporal lobe epilepsy | 7 | 0 |
| <i>Partial simple seizures NEC</i> | | |
| Autonomic seizure | 1 | 0 |
| Simple partial seizures | 7 | 0 |
| <i>Peripheral neuropathies NEC</i> | | |
| Autoimmune neuropathy | 3 | 0 |
| Axonal and demyelinating polyneuropathy | 1 | 0 |
| Axonal neuropathy | 2 | 0 |
| Brachial plexopathy | 1 | 0 |
| Ischaemic neuropathy | 2 | 0 |
| Lumbosacral plexopathy | 1 | 0 |
| Neuralgic amyotrophy | 12 | 0 |
| Neuritis | 19 | 0 |
| Neuropathy peripheral | 324 | 0 |
| Peripheral motor neuropathy | 3 | 0 |
| Peripheral sensorimotor neuropathy | 4 | 0 |
| Peripheral sensory neuropathy | 22 | 0 |
| Polyneuropathy | 16 | 0 |
| Small fibre neuropathy | 10 | 0 |
| Thoracic outlet syndrome | 2 | 0 |
| <i>Seizures and seizure disorders NEC</i> | | |
| Acute encephalitis with refractory, repetitive partial seizures | 1 | 0 |
| Alcoholic seizure | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Atonic seizures | 13 | 0 |
| Change in seizure presentation | 7 | 0 |
| Clonic convulsion | 10 | 0 |
| Convulsive threshold lowered | 1 | 0 |
| Drug withdrawal convulsions | 2 | 0 |
| Epilepsy | 365 | 1 |
| Epileptic aura | 4 | 0 |
| Febrile convulsion | 93 | 0 |
| Gelastic seizure | 1 | 0 |
| Hypoglycaemic seizure | 1 | 0 |
| Migraine-triggered seizure | 3 | 0 |
| Myoclonic epilepsy | 5 | 0 |
| Neonatal seizure | 1 | 0 |
| Partial seizures | 61 | 0 |
| Psychogenic seizure | 5 | 0 |
| Seizure | 1449 | 3 |
| Seizure anoxic | 4 | 0 |
| Seizure cluster | 9 | 0 |
| Seizure like phenomena | 3 | 0 |
| Status epilepticus | 31 | 2 |
| Tonic clonic movements | 3 | 0 |
| Tonic convulsion | 40 | 0 |
| Sensory abnormalities NEC | | |
| Ageusia | 1121 | 0 |
| Allodynia | 63 | 0 |
| Aura | 27 | 0 |
| Central pain syndrome | 2 | 0 |
| Complex regional pain syndrome | 15 | 0 |
| Decreased vibratory sense | 1 | 0 |
| Dysgeusia | 2036 | 0 |
| Electric shock sensation | 122 | 0 |
| Hypogeusia | 8 | 0 |
| Intercostal neuralgia | 3 | 0 |
| Loss of proprioception | 8 | 0 |
| Neuralgia | 1583 | 0 |
| Persistent genital arousal disorder | 2 | 0 |
| Phantom limb syndrome | 19 | 0 |
| Post herpetic neuralgia | 15 | 0 |
| Restless arm syndrome | 15 | 0 |
| Restless legs syndrome | 415 | 0 |
| Sensory disturbance | 183 | 0 |
| Sensory loss | 262 | 0 |
| Sensory overload | 12 | 0 |
| Taste disorder | 531 | 0 |
| Vibratory sense increased | 5 | 0 |
| Visual perseveration | 1 | 0 |
| Sleep disturbances NEC | | |
| Microsleep | 3 | 0 |
| Periodic limb movement disorder | 2 | 0 |
| Sleep deficit | 54 | 0 |
| Sudden onset of sleep | 1 | 0 |
| Speech and language abnormalities | | |
| Dysarthria | 480 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|---------------|------------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Incoherent | 21 | 0 |
| Language disorder | 3 | 0 |
| Muscle tension dysphonia | 1 | 0 |
| Repetitive speech | 4 | 0 |
| Slow speech | 44 | 0 |
| Speech disorder | 151 | 0 |
| Speech disorder developmental | 3 | 0 |
| Spinal cord and nerve root disorders NEC | | |
| Acquired syringomyelia | 1 | 0 |
| Myelopathy | 8 | 0 |
| Radicular pain | 1 | 0 |
| Radiculitis brachial | 33 | 0 |
| Radiculopathy | 5 | 0 |
| Spinal cord disorder | 8 | 0 |
| Spinal cord ischaemia | 1 | 0 |
| Spinal cord oedema | 1 | 0 |
| Subacute combined cord degeneration | 1 | 0 |
| Structural brain disorders NEC | | |
| Brain injury | 49 | 3 |
| Cerebral mass effect | 11 | 0 |
| Encephalomalacia | 1 | 0 |
| Intracranial mass | 4 | 0 |
| White matter lesion | 5 | 0 |
| Transient cerebrovascular events | | |
| Transient ischaemic attack | 543 | 2 |
| Tremor (excl congenital) | | |
| Action tremor | 5 | 0 |
| Asterixis | 1 | 0 |
| Essential tremor | 11 | 0 |
| Head titubation | 28 | 0 |
| Intention tremor | 1 | 0 |
| Postural tremor | 2 | 0 |
| Resting tremor | 8 | 0 |
| Tremor | 9961 | 1 |
| Trigeminal disorders | | |
| Numb chin syndrome | 3 | 0 |
| Trigeminal nerve disorder | 7 | 0 |
| Trigeminal neuralgia | 153 | 0 |
| Trigeminal neuritis | 2 | 0 |
| Trigeminal palsy | 1 | 0 |
| Vagus nerve disorders | | |
| Vagus nerve disorder | 1 | 0 |
| Vagus nerve paralysis | 1 | 0 |
| Vocal cord paralysis | 6 | 0 |
| Vertigos NEC | | |
| Vertigo CNS origin | 4 | 0 |
| Nervous system disorders SOC TOTAL | 184225 | 251 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Pregnancy conditions | | |
| <i>Abortion related conditions and complications</i> | | |
| Anembryonic gestation | 1 | 0 |
| <i>Abortions not specified as induced or spontaneous</i> | | |
| Abortion missed | 1 | 0 |
| <i>Abortions spontaneous</i> | | |
| Abortion spontaneous | 240 | 0 |
| <i>Foetal complications NEC</i> | | |
| Haemorrhage foetal | 1 | 0 |
| <i>Foetal position and presentation abnormalities</i> | | |
| Face presentation | 1 | 0 |
| <i>Gestational age and weight conditions</i> | | |
| Low birth weight baby | 1 | 0 |
| Premature baby | 2 | 0 |
| <i>Haemorrhagic complications of pregnancy</i> | | |
| Haemorrhage in pregnancy | 1 | 0 |
| Subchorionic haemorrhage | 1 | 0 |
| <i>High risk pregnancies</i> | | |
| Pregnancy of unknown location | 1 | 0 |
| Risk of future pregnancy miscarriage | 1 | 0 |
| <i>Hypertension associated disorders of pregnancy</i> | | |
| Pre-eclampsia | 4 | 0 |
| <i>Labour onset and length abnormalities</i> | | |
| Precipitate labour | 1 | 0 |
| Premature labour | 4 | 0 |
| Premature rupture of membranes | 3 | 0 |
| Prolonged labour | 1 | 0 |
| <i>Maternal complications of delivery NEC</i> | | |
| Traumatic delivery | 1 | 0 |
| <i>Maternal complications of labour NEC</i> | | |
| Uterine contractions abnormal | 2 | 0 |
| <i>Maternal complications of pregnancy NEC</i> | | |
| Biochemical pregnancy | 3 | 0 |
| Decidual cast | 3 | 0 |
| Ectopic pregnancy | 8 | 0 |
| Hyperemesis gravidarum | 2 | 0 |
| Morning sickness | 2 | 0 |
| Pelvic girdle pain | 2 | 0 |
| Preterm premature rupture of membranes | 1 | 0 |
| Somatic symptom disorder of pregnancy | 1 | 0 |
| <i>Multiple pregnancies</i> | | |
| Twin pregnancy | 2 | 0 |
| <i>Normal pregnancy, labour and delivery</i> | | |
| Delivery | 1 | 0 |
| Labour pain | 1 | 0 |
| Live birth | 2 | 0 |
| Pregnancy | 23 | 0 |
| Uterine contractions during pregnancy | 1 | 0 |
| <i>Placental abnormalities (excl neoplasms)</i> | | |
| Foetal vascular malperfusion | 1 | 0 |
| Placental calcification | 1 | 0 |
| Placental disorder | 1 | 0 |
| <i>Pregnancy complicated by maternal disorders</i> | | |
| Gestational diabetes | 6 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Pregnancy conditions <small>Pregnancy conditions cont'd</small> | | |
| Peripartum cardiomyopathy | 1 | 0 |
| Stillbirth and foetal death | | |
| Foetal death | 1 | 1 |
| Stillbirth | 5 | 5 |
| Umbilical cord complications | | |
| Umbilical cord around neck | 1 | 0 |
| Unintended pregnancies | | |
| Pregnancy after post coital contraception | 2 | 0 |
| Pregnancy on contraceptive | 5 | 0 |
| Pregnancy with implant contraceptive | 2 | 0 |
| Unintended pregnancy | 2 | 0 |
| Pregnancy conditions SOC TOTAL | 347 | 6 |

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|------------|----------|
| <i>Counterfeit, falsified and substandard products</i> | | |
| Suspected counterfeit product | 2 | 0 |
| <i>Device electrical issues</i> | | |
| Device electrical impedance issue | 1 | 0 |
| Electromagnetic interference | 1 | 0 |
| <i>Device incompatibility issues</i> | | |
| Patient-device incompatibility | 2 | 0 |
| <i>Device issues NEC</i> | | |
| Device dislocation | 2 | 0 |
| Device expulsion | 3 | 0 |
| Device issue | 4 | 0 |
| Device leakage | 2 | 0 |
| <i>Device malfunction events NEC</i> | | |
| Device occlusion | 1 | 0 |
| Oversensing | 35 | 0 |
| Stent malfunction | 1 | 0 |
| Thrombosis in device | 69 | 1 |
| Undersensing | 7 | 0 |
| <i>Device physical property and chemical issues</i> | | |
| Needle issue | 11 | 0 |
| Syringe issue | 1 | 0 |
| <i>Manufacturing facilities and equipment issues</i> | | |
| Manufacturing equipment issue | 1 | 0 |
| <i>Product contamination and sterility issues</i> | | |
| Product contamination | 1 | 0 |
| Suspected product contamination | 1 | 0 |
| <i>Product distribution and storage issues</i> | | |
| Product temperature excursion issue | 5 | 0 |
| <i>Product label issues</i> | | |
| Product barcode issue | 1 | 0 |
| Product label issue | 2 | 0 |
| <i>Product packaging issues</i> | | |
| Product container issue | 2 | 0 |
| <i>Product physical issues</i> | | |
| Liquid product physical issue | 1 | 0 |
| Product after taste | 8 | 0 |
| Product colour issue | 4 | 0 |
| Product leakage | 1 | 0 |
| Product odour abnormal | 3 | 0 |
| Product physical issue | 2 | 0 |
| Product taste abnormal | 8 | 0 |
| <i>Product quality issues NEC</i> | | |
| Product formulation issue | 1 | 0 |
| Product origin unknown | 3 | 0 |
| Product quality issue | 2 | 0 |
| Suspected product quality issue | 2 | 0 |
| <i>Product supply and availability issues</i> | | |
| Product availability issue | 4 | 0 |
| null SOC TOTAL | 194 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders | | |
| <i>Abnormal behaviour NEC</i> | | |
| Abnormal behaviour | 28 | 0 |
| Behaviour disorder | 1 | 0 |
| Breath holding | 5 | 0 |
| Sexually inappropriate behaviour | 1 | 0 |
| Staring | 14 | 0 |
| <i>Abnormal food elimination</i> | | |
| Self-induced vomiting | 1 | 0 |
| <i>Adjustment disorders</i> | | |
| Adjustment disorder | 1 | 0 |
| Adjustment disorder with depressed mood | 6 | 0 |
| Adjustment disorder with mixed anxiety and depressed mood | 2 | 0 |
| <i>Affect alterations NEC</i> | | |
| Affect lability | 14 | 0 |
| Blunted affect | 1 | 0 |
| Constricted affect | 16 | 0 |
| Flat affect | 12 | 0 |
| Inappropriate affect | 18 | 0 |
| <i>Amnesic symptoms</i> | | |
| Paramnesia | 9 | 0 |
| <i>Anxiety disorders NEC</i> | | |
| Anxiety disorder | 6 | 0 |
| Generalised anxiety disorder | 5 | 0 |
| Neurosis | 1 | 0 |
| <i>Anxiety symptoms</i> | | |
| Agitation | 217 | 0 |
| Anxiety | 1410 | 0 |
| Immunisation stress-related response | 2 | 0 |
| Nervousness | 616 | 0 |
| Procedural anxiety | 1 | 0 |
| Stress | 177 | 0 |
| Tension | 74 | 0 |
| <i>Attention deficit and disruptive behaviour disorders</i> | | |
| Attention deficit hyperactivity disorder | 21 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Aggression | 19 | 0 |
| Antisocial behaviour | 2 | 0 |
| Asocial behaviour | 1 | 0 |
| Attention-seeking behaviour | 1 | 0 |
| Aversion | 1 | 0 |
| Disinhibition | 2 | 0 |
| Homicidal ideation | 1 | 0 |
| Impatience | 2 | 0 |
| Indifference | 10 | 0 |
| Paranoia | 43 | 0 |
| Personality change | 13 | 0 |
| Social avoidant behaviour | 8 | 0 |
| Soliloquy | 3 | 0 |
| Violence-related symptom | 3 | 0 |
| <i>Bipolar disorders</i> | | |
| Bipolar I disorder | 8 | 0 |
| Bipolar disorder | 7 | 0 |
| <i>Cognitive and attention disorders and disturbances NEC</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

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Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Change in sustained attention | 1 | 0 |
| Daydreaming | 18 | 0 |
| Distractibility | 3 | 0 |
| Mental fatigue | 508 | 0 |
| Communications disorders | | |
| Communication disorder | 11 | 0 |
| Mutism | 6 | 0 |
| Speech sound disorder | 2 | 0 |
| Confusion and disorientation | | |
| Confusional state | 2249 | 0 |
| Disorientation | 752 | 0 |
| Decreased physical activity levels | | |
| Catatonia | 3 | 0 |
| Deliria | | |
| Delirium | 497 | 0 |
| Delirium febrile | 3 | 0 |
| Delusional disorders | | |
| Alice in wonderland syndrome | 3 | 0 |
| Delusional symptoms | | |
| Delusion | 54 | 0 |
| Delusion of parasitosis | 3 | 0 |
| Mixed delusion | 1 | 0 |
| Thought withdrawal | 1 | 0 |
| Dementia NEC | | |
| Pseudodementia | 1 | 0 |
| Depressive disorders | | |
| Agitated depression | 4 | 0 |
| Childhood depression | 1 | 0 |
| Depression | 750 | 0 |
| Depression suicidal | 18 | 0 |
| Major depression | 26 | 0 |
| Menopausal depression | 2 | 0 |
| Mixed anxiety and depressive disorder | 4 | 0 |
| Dissociative states | | |
| Depersonalisation/derealisation disorder | 21 | 0 |
| Dissociation | 82 | 0 |
| Dissociative amnesia | 1 | 0 |
| Dissociative disorder | 3 | 0 |
| Disturbances in initiating and maintaining sleep | | |
| Initial insomnia | 45 | 0 |
| Insomnia | 3214 | 0 |
| Middle insomnia | 74 | 0 |
| Terminal insomnia | 27 | 0 |
| Dyssomnias | | |
| Dyssomnia | 5 | 0 |
| Poor quality sleep | 684 | 0 |
| Eating disorders NEC | | |
| Binge eating | 1 | 0 |
| Eating disorder | 23 | 0 |
| Pica | 1 | 0 |
| Selective eating disorder | 2 | 0 |
| Emotional and mood disturbances NEC | | |
| Anger | 91 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Dysphoria | 2 | 0 |
| Emotional disorder | 104 | 0 |
| Emotional distress | 94 | 0 |
| Emotional poverty | 2 | 0 |
| Euphoric mood | 69 | 0 |
| Frustration tolerance decreased | 16 | 0 |
| Irritability | 328 | 0 |
| Mood altered | 92 | 0 |
| Factitious disorders | | |
| Factitious disorder | 4 | 0 |
| Fear symptoms and phobic disorders (incl social phobia) | | |
| Acrophobia | 2 | 0 |
| Agoraphobia | 5 | 0 |
| Astraphobia | 1 | 0 |
| Claustrophobia | 1 | 0 |
| Fear | 80 | 0 |
| Fear of death | 22 | 0 |
| Fear of disease | 2 | 0 |
| Fear of eating | 1 | 0 |
| Fear of falling | 6 | 0 |
| Fear of injection | 3 | 0 |
| Fear of open spaces | 1 | 0 |
| Fear-related avoidance of activities | 3 | 0 |
| Performance fear | 1 | 0 |
| Phobia | 3 | 0 |
| Phonophobia | 6 | 0 |
| Social anxiety disorder | 1 | 0 |
| Social fear | 2 | 0 |
| Thanatophobia | 1 | 0 |
| Fluctuating mood symptoms | | |
| Mood swings | 154 | 0 |
| Hallucinations (excl sleep-related) | | |
| Hallucination | 952 | 0 |
| Hallucination, auditory | 49 | 0 |
| Hallucination, olfactory | 15 | 0 |
| Hallucination, tactile | 1 | 0 |
| Hallucination, visual | 61 | 0 |
| Hallucinations, mixed | 9 | 0 |
| Somatic hallucination | 1 | 0 |
| Impulse control disorders | | |
| Clinomania | 1 | 0 |
| Impulse-control disorder | 3 | 0 |
| Impulsive behaviour | 2 | 0 |
| Intermittent explosive disorder | 1 | 0 |
| Pyromania | 1 | 0 |
| Increased physical activity levels | | |
| Restlessness | 495 | 0 |
| Infancy, childhood and adolescence psychiatric disorders NEC | | |
| Emotional disorder of childhood | 1 | 0 |
| Learning disorders | | |
| Reading disorder | 2 | 0 |
| Mental disorders NEC | | |
| Mental disorder | 38 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Psychiatric disorders ^{Psychiatric disorders cont'd} | | |
| Mental status changes | 6 | 0 |
| <i>Mental disorders due to a general medical condition NEC</i> | | |
| Mental disorder due to a general medical condition | 1 | 0 |
| Neuropsychiatric symptoms | 2 | 0 |
| <i>Mood alterations with depressive symptoms</i> | | |
| Anhedonia | 4 | 0 |
| Decreased interest | 20 | 0 |
| Depressed mood | 726 | 0 |
| Depressive symptom | 2 | 0 |
| Feeling guilty | 2 | 0 |
| Feeling of despair | 21 | 0 |
| Negative thoughts | 11 | 0 |
| Sense of a foreshortened future | 3 | 0 |
| Tearfulness | 104 | 0 |
| <i>Mood alterations with manic symptoms</i> | | |
| Hypomania | 1 | 0 |
| Mania | 32 | 0 |
| <i>Mood disorders NEC</i> | | |
| Affective disorder | 4 | 0 |
| Apathy | 83 | 0 |
| Laziness | 2 | 0 |
| Listless | 126 | 0 |
| Mood disorder due to a general medical condition | 1 | 0 |
| Substance-induced mood disorder | 1 | 0 |
| <i>Narcolepsy and associated conditions</i> | | |
| Hypnagogic hallucination | 4 | 0 |
| Sleep attacks | 2 | 0 |
| <i>Obsessive-compulsive disorders and symptoms</i> | | |
| Body dysmorphic disorder | 2 | 0 |
| Compulsive shopping | 2 | 0 |
| Dermatillomania | 2 | 0 |
| Obsessive thoughts | 3 | 0 |
| Obsessive-compulsive disorder | 2 | 0 |
| Obsessive-compulsive symptom | 1 | 0 |
| <i>Orgasmic disorders and disturbances</i> | | |
| Anorgasmia | 6 | 0 |
| Female orgasmic disorder | 1 | 0 |
| Orgasm abnormal | 1 | 0 |
| Orgasmic sensation decreased | 4 | 0 |
| Premature ejaculation | 4 | 0 |
| <i>Panic attacks and disorders</i> | | |
| Limited symptom panic attack | 1 | 0 |
| Panic attack | 369 | 0 |
| Panic disorder | 11 | 0 |
| Panic reaction | 44 | 0 |
| <i>Paraphilias and paraphilic disorders</i> | | |
| Fetishism | 2 | 0 |
| <i>Parasomnias</i> | | |
| Abnormal dreams | 374 | 0 |
| Abnormal sleep-related event | 2 | 0 |
| Confusional arousal | 3 | 0 |
| Exploding head syndrome | 7 | 0 |
| Nightmare | 471 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Parasomnia | 1 | 0 |
| Rapid eye movements sleep abnormal | 4 | 0 |
| Sleep inertia | 1 | 0 |
| Sleep talking | 17 | 0 |
| Sleep terror | 64 | 0 |
| Sleep-related eating disorder | 2 | 0 |
| Somnambulism | 11 | 0 |
| Perception disturbances NEC | | |
| Autoscopy | 29 | 0 |
| Deja vu | 4 | 0 |
| Delusional perception | 2 | 0 |
| Derealisation | 18 | 0 |
| Flashback | 3 | 0 |
| Illusion | 12 | 0 |
| Imperception | 1 | 0 |
| Jamais vu | 1 | 0 |
| Near death experience | 2 | 0 |
| Pseudohallucination | 1 | 0 |
| Time perception altered | 6 | 0 |
| Personality disorders NEC | | |
| Personality disorder | 1 | 0 |
| Self esteem decreased | 1 | 0 |
| Pervasive developmental disorders NEC | | |
| Autism spectrum disorder | 4 | 0 |
| Psychiatric elimination disorders | | |
| Enuresis | 62 | 0 |
| Psychiatric symptoms NEC | | |
| Abulia | 1 | 0 |
| Decreased eye contact | 2 | 0 |
| Helplessness | 3 | 0 |
| Hypervigilance | 12 | 0 |
| Psychiatric symptom | 16 | 0 |
| Psychological trauma | 5 | 0 |
| Psychotic disorder NEC | | |
| Acute psychosis | 6 | 0 |
| Psychotic behaviour | 2 | 0 |
| Psychotic disorder | 48 | 0 |
| Psychotic symptom | 1 | 0 |
| Rebound psychosis | 1 | 0 |
| Schizoaffective and schizophreniform disorders | | |
| Schizoaffective disorder | 1 | 0 |
| Schizophrenia NEC | | |
| Schizophrenia | 1 | 0 |
| Sexual arousal disorders | | |
| Disturbance in sexual arousal | 7 | 0 |
| Sexual desire disorders | | |
| Excessive masturbation | 1 | 0 |
| Hypersexuality | 2 | 0 |
| Libido decreased | 25 | 0 |
| Libido disorder | 1 | 0 |
| Libido increased | 9 | 0 |
| Loss of libido | 59 | 0 |
| Sexual dysfunction NEC | | |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Genito-pelvic pain/penetration disorder | 1 | 0 |
| Sleep disorders NEC | | |
| Sleep disorder | 466 | 0 |
| Sleep disorder due to a general medical condition | 1 | 0 |
| Sleep disorder due to general medical condition, insomnia type | 3 | 0 |
| Somatic symptom disorders | | |
| Conversion disorder | 52 | 0 |
| Habit cough | 39 | 0 |
| Illness anxiety disorder | 1 | 0 |
| Psychogenic tremor | 2 | 0 |
| Somatic symptom disorder | 2 | 0 |
| Speech and language usage disturbances | | |
| Disorganised speech | 22 | 0 |
| Logorrhoea | 3 | 0 |
| Pedantic speech | 1 | 0 |
| Poverty of speech | 1 | 0 |
| Verbigeration | 1 | 0 |
| Speech articulation and rhythm disturbances | | |
| Dysphemia | 39 | 0 |
| Lack of spontaneous speech | 3 | 0 |
| Stereotypies and automatisms | | |
| Bruxism | 35 | 0 |
| Head banging | 49 | 0 |
| Waxy flexibility | 2 | 0 |
| Stress disorders | | |
| Acute stress disorder | 4 | 0 |
| Burnout syndrome | 16 | 0 |
| Catastrophic reaction | 2 | 1 |
| Hyperarousal | 3 | 0 |
| Post-traumatic stress disorder | 16 | 0 |
| Substance related and addictive disorders | | |
| Alcohol abuse | 2 | 0 |
| Alcohol use disorder | 3 | 0 |
| Alcohol withdrawal syndrome | 1 | 0 |
| Alcoholic hangover | 1 | 0 |
| Alcoholism | 3 | 0 |
| Dependence | 2 | 0 |
| Drug abuse | 1 | 0 |
| Drug dependence | 1 | 0 |
| Nicotine dependence | 1 | 0 |
| Substance abuse | 2 | 0 |
| Suicidal and self-injurious behaviour | | |
| Completed suicide | 5 | 5 |
| Intentional self-injury | 9 | 0 |
| Self-injurious ideation | 3 | 0 |
| Suicidal behaviour | 7 | 0 |
| Suicidal ideation | 124 | 0 |
| Suicide attempt | 31 | 0 |
| Suicide threat | 1 | 0 |
| Thinking disturbances | | |
| Bradyphrenia | 99 | 0 |
| Confabulation | 1 | 0 |
| Illogical thinking | 1 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|--------------|----------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Impaired reasoning | 3 | 0 |
| Intrusive thoughts | 6 | 0 |
| Morbid thoughts | 5 | 0 |
| Tachyphrenia | 23 | 0 |
| Thinking abnormal | 30 | 0 |
| Thought blocking | 9 | 0 |
| <i>Tic disorders</i> | | |
| Secondary tic | 2 | 0 |
| Tic | 23 | 0 |
| Psychiatric disorders SOC TOTAL | 18699 | 6 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Renal & urinary disorders | | |
| <i>Bladder and urethral symptoms</i> | | |
| Bladder discomfort | 10 | 0 |
| Bladder irritation | 9 | 0 |
| Bladder pain | 68 | 0 |
| Bladder spasm | 1 | 0 |
| Dysuria | 95 | 0 |
| Incontinence | 103 | 0 |
| Micturition disorder | 4 | 0 |
| Micturition frequency decreased | 1 | 0 |
| Micturition urgency | 103 | 0 |
| Mixed incontinence | 1 | 0 |
| Pollakiuria | 310 | 0 |
| Stress urinary incontinence | 2 | 0 |
| Urethral pain | 6 | 0 |
| Urge incontinence | 2 | 0 |
| Urinary hesitation | 7 | 0 |
| Urinary incontinence | 142 | 0 |
| Urinary retention | 105 | 0 |
| Urine flow decreased | 23 | 0 |
| <i>Bladder disorders NEC</i> | | |
| Bladder dilatation | 1 | 0 |
| Bladder disorder | 25 | 0 |
| Bladder prolapse | 1 | 0 |
| Urinary bladder haemorrhage | 18 | 1 |
| Urinary bladder rupture | 1 | 0 |
| <i>Bladder infections and inflammations</i> | | |
| Cystitis haemorrhagic | 1 | 0 |
| Cystitis interstitial | 12 | 0 |
| Cystitis noninfective | 3 | 0 |
| <i>Bladder neoplasms</i> | | |
| Bladder cyst | 1 | 0 |
| <i>Genital and urinary tract disorders NEC</i> | | |
| Urinary tract disorder | 13 | 0 |
| Urogenital haemorrhage | 1 | 0 |
| <i>Glomerulonephritis and nephrotic syndrome</i> | | |
| Anti-glomerular basement membrane disease | 1 | 0 |
| Focal segmental glomerulosclerosis | 4 | 0 |
| Glomerulonephritis | 1 | 0 |
| Glomerulonephritis membranoproliferative | 1 | 0 |
| Glomerulonephritis membranous | 1 | 0 |
| Glomerulonephritis minimal lesion | 5 | 0 |
| IgA nephropathy | 5 | 0 |
| Nephrotic syndrome | 21 | 0 |
| <i>Myoneurogenic bladder disorders</i> | | |
| Atonic urinary bladder | 1 | 0 |
| Automatic bladder | 1 | 0 |
| Bladder dysfunction | 14 | 0 |
| Hypertonic bladder | 18 | 0 |
| Loss of bladder sensation | 13 | 0 |
| Neurogenic bladder | 4 | 0 |
| <i>Nephritis NEC</i> | | |
| Lupus nephritis | 4 | 0 |
| Nephritis | 7 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Renal & urinary disorders | | |
| Renal & urinary disorders cont'd | | |
| Tubulointerstitial nephritis | 8 | 0 |
| <i>Nephropathies and tubular disorders NEC</i> | | |
| Diabetic nephropathy | 1 | 0 |
| Nephropathy | 2 | 0 |
| Nephrosclerosis | 1 | 0 |
| <i>Renal disorders NEC</i> | | |
| Oedematous kidney | 1 | 0 |
| Renal disorder | 16 | 0 |
| Renal haemorrhage | 3 | 0 |
| <i>Renal failure and impairment</i> | | |
| Acute kidney injury | 78 | 1 |
| Anuria | 5 | 0 |
| Chronic kidney disease | 16 | 1 |
| End stage renal disease | 3 | 0 |
| Oliguria | 11 | 0 |
| Renal failure | 53 | 2 |
| Renal impairment | 27 | 0 |
| Renal injury | 9 | 1 |
| <i>Renal failure complications</i> | | |
| Malnutrition-inflammation-atherosclerosis syndrome | 1 | 0 |
| <i>Renal hypertension and related conditions</i> | | |
| Hypertensive nephropathy | 1 | 0 |
| <i>Renal lithiasis</i> | | |
| Nephrolithiasis | 24 | 0 |
| <i>Renal obstructive disorders</i> | | |
| Hydronephrosis | 1 | 0 |
| <i>Renal structural abnormalities and trauma</i> | | |
| Acquired cystic kidney disease | 1 | 0 |
| Kidney enlargement | 1 | 0 |
| Renal atrophy | 2 | 0 |
| <i>Renal vascular and ischaemic conditions</i> | | |
| Renal artery occlusion | 3 | 0 |
| Renal artery thrombosis | 2 | 0 |
| Renal cortical necrosis | 1 | 0 |
| Renal embolism | 1 | 0 |
| Renal infarct | 18 | 1 |
| Renal ischaemia | 2 | 0 |
| Renal tubular injury | 1 | 0 |
| Renal vascular thrombosis | 2 | 0 |
| Renal vasculitis | 2 | 0 |
| Renal vein embolism | 1 | 0 |
| Renal vein occlusion | 3 | 0 |
| Renal vein thrombosis | 9 | 0 |
| <i>Structural and obstructive urethral disorders (excl congenital)</i> | | |
| Urethral spasm | 1 | 0 |
| Urethral stenosis | 1 | 0 |
| <i>Ureteric disorders NEC</i> | | |
| Ureteral disorder | 2 | 0 |
| <i>Urinary abnormalities</i> | | |
| Chromaturia | 112 | 0 |
| Glycosuria | 1 | 0 |
| Haematuria | 1 | 0 |
| Haematuria | 70 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Renal & urinary disorders | | |
| Renal & urinary disorders cont'd | | |
| Microalbuminuria | 1 | 0 |
| Proteinuria | 13 | 0 |
| Urine abnormality | 20 | 0 |
| Urine odour abnormal | 23 | 0 |
| Urinary tract signs and symptoms NEC | | |
| Costovertebral angle tenderness | 1 | 0 |
| Haemorrhage urinary tract | 62 | 0 |
| Nocturia | 23 | 0 |
| Polyuria | 34 | 0 |
| Renal colic | 4 | 0 |
| Renal pain | 957 | 0 |
| Urinary tract discomfort | 2 | 0 |
| Urinary tract pain | 16 | 0 |
| Renal & urinary disorders SOC TOTAL | 2824 | 7 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Reproductive & breast disorders | | |
| <i>Benign and malignant breast neoplasms</i> | | |
| Breast cyst | 14 | 0 |
| <i>Breast disorders NEC</i> | | |
| Anisomastia | 1 | 0 |
| Breast disorder | 4 | 0 |
| Breast enlargement | 11 | 0 |
| Breast mass | 78 | 0 |
| Gynaecomastia | 11 | 0 |
| Mammary duct ectasia | 1 | 0 |
| Nipple disorder | 1 | 0 |
| <i>Breast infections and inflammations</i> | | |
| Breast inflammation | 4 | 0 |
| Nipple inflammation | 1 | 0 |
| <i>Breast signs and symptoms</i> | | |
| Breast discharge | 9 | 0 |
| Breast discolouration | 1 | 0 |
| Breast discomfort | 12 | 0 |
| Breast engorgement | 6 | 0 |
| Breast haemorrhage | 1 | 0 |
| Breast induration | 1 | 0 |
| Breast oedema | 2 | 0 |
| Breast pain | 511 | 0 |
| Breast swelling | 76 | 0 |
| Breast tenderness | 79 | 0 |
| Nipple exudate bloody | 1 | 0 |
| Nipple pain | 38 | 0 |
| Nipple swelling | 4 | 0 |
| <i>Cervix disorders NEC</i> | | |
| Cervical friability | 1 | 0 |
| Cervix haemorrhage uterine | 1 | 0 |
| Ectropion of cervix | 2 | 0 |
| <i>Cervix neoplasms</i> | | |
| Cervical polyp | 1 | 0 |
| <i>Erection and ejaculation conditions and disorders</i> | | |
| Ejaculation delayed | 2 | 0 |
| Ejaculation disorder | 4 | 0 |
| Ejaculation failure | 4 | 0 |
| Erectile dysfunction | 104 | 0 |
| Erection increased | 7 | 0 |
| Organic erectile dysfunction | 20 | 0 |
| Painful ejaculation | 1 | 0 |
| Painful erection | 2 | 0 |
| Priapism | 3 | 0 |
| Retrograde ejaculation | 4 | 0 |
| Spontaneous penile erection | 4 | 0 |
| <i>Fallopian tube and ovary infections and inflammations</i> | | |
| Noninfective oophoritis | 1 | 0 |
| <i>Lactation disorders</i> | | |
| Galactorrhoea | 3 | 0 |
| Galactostasis | 2 | 0 |
| Lactation disorder | 2 | 0 |
| Lactation puerperal increased | 6 | 0 |
| Suppressed lactation | 28 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| <i>Menopausal effects NEC</i> | | |
| Artificial menopause | 2 | 0 |
| Menopausal disorder | 3 | 0 |
| Menopausal symptoms | 70 | 0 |
| Menopause delayed | 5 | 0 |
| Premature menopause | 55 | 0 |
| <i>Menopausal effects on the genitourinary tract</i> | | |
| Atrophic vulvovaginitis | 1 | 0 |
| Postmenopausal haemorrhage | 313 | 0 |
| <i>Menstruation and uterine bleeding NEC</i> | | |
| Abnormal uterine bleeding | 9 | 0 |
| Abnormal withdrawal bleeding | 6 | 0 |
| Dysmenorrhoea | 1503 | 0 |
| Intermenstrual bleeding | 724 | 0 |
| Menstrual discomfort | 18 | 0 |
| Menstrual disorder | 1626 | 0 |
| Menstruation irregular | 2461 | 0 |
| Premenstrual dysphoric disorder | 7 | 0 |
| Premenstrual pain | 86 | 0 |
| Premenstrual syndrome | 61 | 0 |
| Retrograde menstruation | 4 | 0 |
| Withdrawal bleed | 14 | 0 |
| <i>Menstruation with decreased bleeding</i> | | |
| Amenorrhoea | 638 | 0 |
| Hypomenorrhoea | 446 | 0 |
| Menstruation delayed | 3355 | 0 |
| Oligomenorrhoea | 127 | 0 |
| <i>Menstruation with increased bleeding</i> | | |
| Heavy menstrual bleeding | 4873 | 0 |
| Menometrorrhagia | 18 | 0 |
| Polymenorrhoea | 730 | 0 |
| <i>Ovarian and fallopian tube cysts and neoplasms</i> | | |
| Ovarian cyst | 35 | 0 |
| Ovarian cyst ruptured | 3 | 0 |
| Polycystic ovaries | 45 | 0 |
| <i>Ovarian and fallopian tube disorders NEC</i> | | |
| Fallopian tube spasm | 1 | 0 |
| Ovarian adhesion | 1 | 0 |
| Ovarian enlargement | 3 | 0 |
| Ovarian failure | 4 | 0 |
| Ovarian haemorrhage | 5 | 0 |
| Ovarian hyperstimulation syndrome | 1 | 0 |
| Ovarian mass | 1 | 0 |
| Ovarian necrosis | 1 | 0 |
| Ovarian oedema | 1 | 0 |
| Ovarian vein thrombosis | 2 | 0 |
| Ovulation pain | 64 | 0 |
| Premature ovulation | 8 | 0 |
| <i>Pelvic prolapse conditions</i> | | |
| Cystocele | 1 | 0 |
| Vaginal prolapse | 2 | 0 |
| <i>Pelvis and broad ligament disorders NEC</i> | | |
| Adnexa uteri pain | 47 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Pelvic haematoma | 1 | 0 |
| Pelvic haemorrhage | 27 | 0 |
| Pelvic organ prolapse | 1 | 0 |
| <i>Penile and scrotal infections and inflammations</i> | | |
| Balanoposthitis | 4 | 0 |
| <i>Penile disorders NEC (excl erection and ejaculation)</i> | | |
| Penile blister | 6 | 0 |
| Penile burning sensation | 1 | 0 |
| Penile curvature | 4 | 0 |
| Penile discharge | 5 | 0 |
| Penile erosion | 1 | 0 |
| Penile exfoliation | 1 | 0 |
| Penile haemorrhage | 7 | 0 |
| Penile oedema | 3 | 0 |
| Penile pain | 2 | 0 |
| Penile size reduced | 2 | 0 |
| Penis disorder | 11 | 0 |
| Peyronie's disease | 4 | 0 |
| <i>Prostate and seminal vesicles infections and inflammations</i> | | |
| Prostatitis | 6 | 0 |
| <i>Prostatic neoplasms and hypertrophy</i> | | |
| Benign prostatic hyperplasia | 2 | 0 |
| <i>Prostatic signs, symptoms and disorders NEC</i> | | |
| Prostatic pain | 1 | 0 |
| Prostatism | 1 | 0 |
| Prostatomegaly | 4 | 0 |
| <i>Reproductive tract disorders NEC (excl neoplasms)</i> | | |
| Female genital tract fistula | 1 | 0 |
| Genital blister | 5 | 0 |
| Genital dysaesthesia | 1 | 0 |
| Genital haemorrhage | 35 | 0 |
| Genital hyperaesthesia | 1 | 0 |
| Genital hypoaesthesia | 2 | 0 |
| Genital lesion | 2 | 0 |
| Genital paraesthesia | 5 | 0 |
| Genital ulceration | 14 | 0 |
| Perineal disorder | 2 | 0 |
| Varicose veins pelvic | 1 | 0 |
| <i>Reproductive tract infections and inflammations NEC</i> | | |
| Genital tract inflammation | 2 | 0 |
| <i>Reproductive tract neoplasms NEC</i> | | |
| Genital cyst | 2 | 0 |
| <i>Reproductive tract signs and symptoms NEC</i> | | |
| Genital burning sensation | 8 | 0 |
| Genital discomfort | 3 | 0 |
| Genital erythema | 1 | 0 |
| Genital pain | 5 | 0 |
| Genital rash | 7 | 0 |
| Genital swelling | 2 | 0 |
| Pelvic discomfort | 4 | 0 |
| Pelvic pain | 182 | 0 |
| Perineal pain | 2 | 0 |
| Pruritus genital | 9 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Scrotal disorders NEC | | |
| Scrotal cyst | 1 | 0 |
| Scrotal dermatitis | 1 | 0 |
| Scrotal oedema | 1 | 0 |
| Scrotal pain | 20 | 0 |
| Scrotal swelling | 7 | 0 |
| Varicocele | 2 | 0 |
| Sexual function and fertility disorders NEC | | |
| Dyspareunia | 7 | 0 |
| Female sexual dysfunction | 1 | 0 |
| Infertility | 16 | 0 |
| Infertility female | 7 | 0 |
| Infertility male | 3 | 0 |
| Male sexual dysfunction | 2 | 0 |
| Sexual dysfunction | 15 | 0 |
| Spermatogenesis and semen disorders | | |
| Aspermia | 2 | 0 |
| Haematospermia | 19 | 0 |
| Semen discolouration | 2 | 0 |
| Testicular and epididymal disorders NEC | | |
| Testicular atrophy | 1 | 0 |
| Testicular disorder | 9 | 0 |
| Testicular mass | 1 | 0 |
| Testicular oedema | 2 | 0 |
| Testicular pain | 116 | 0 |
| Testicular retraction | 3 | 0 |
| Testicular swelling | 25 | 0 |
| Testis discomfort | 6 | 0 |
| Testicular and epididymal infections and inflammations | | |
| Orchitis noninfective | 1 | 0 |
| Testicular and epididymal neoplasms | | |
| Epididymal cyst | 1 | 0 |
| Testicular cyst | 1 | 0 |
| Uterine disorders NEC | | |
| Adenomyosis | 15 | 0 |
| Endometrial hyperplasia | 2 | 0 |
| Endometrial thickening | 3 | 0 |
| Endometriosis | 91 | 0 |
| Metrorrhoea | 1 | 0 |
| Uterine enlargement | 2 | 0 |
| Uterine haemorrhage | 74 | 0 |
| Uterine mass | 1 | 0 |
| Uterine pain | 10 | 0 |
| Uterine neoplasms | | |
| Uterine cyst | 1 | 0 |
| Uterine polyp | 5 | 0 |
| Uterine tone disorders | | |
| Uterine spasm | 25 | 0 |
| Vaginal and vulval infections and inflammations | | |
| Vulvovaginal inflammation | 3 | 0 |
| Vulvovaginal cysts and neoplasms | | |
| Bartholin's cyst | 3 | 0 |
| Vaginal cyst | 15 | 0 |

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| Reaction Name | Total | Fatal |
|--|--------------|----------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Vulva cyst | 1 | 0 |
| <i>Vulvovaginal disorders NEC</i> | | |
| Vaginal disorder | 2 | 0 |
| Vaginal haemorrhage | 1345 | 0 |
| Vaginal mucosal blistering | 1 | 0 |
| Vaginal ulceration | 7 | 0 |
| Vulval disorder | 3 | 0 |
| Vulval haemorrhage | 34 | 0 |
| Vulval ulceration | 7 | 0 |
| Vulvovaginal disorder | 1 | 0 |
| Vulvovaginal ulceration | 3 | 0 |
| <i>Vulvovaginal signs and symptoms</i> | | |
| Clitoral engorgement | 1 | 0 |
| Coital bleeding | 8 | 0 |
| Enlarged clitoris | 1 | 0 |
| Labia enlarged | 2 | 0 |
| Vaginal discharge | 92 | 0 |
| Vaginal lesion | 7 | 0 |
| Vaginal odour | 7 | 0 |
| Vulval oedema | 1 | 0 |
| Vulvovaginal burning sensation | 11 | 0 |
| Vulvovaginal discomfort | 10 | 0 |
| Vulvovaginal dryness | 14 | 0 |
| Vulvovaginal erythema | 1 | 0 |
| Vulvovaginal pain | 40 | 0 |
| Vulvovaginal pruritus | 12 | 0 |
| Vulvovaginal rash | 3 | 0 |
| Vulvovaginal swelling | 7 | 0 |
| Reproductive & breast disorders SOC TOTAL | 20983 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Agonal respiration | 1 | 0 |
| Apnoea | 13 | 0 |
| Apnoeic attack | 1 | 0 |
| Cheyne-Stokes respiration | 2 | 0 |
| Dyspnoea | 8274 | 0 |
| Dyspnoea at rest | 15 | 0 |
| Dyspnoea exertional | 68 | 0 |
| Dyspnoea paroxysmal nocturnal | 1 | 0 |
| Grunting | 2 | 0 |
| Hyperventilation | 104 | 0 |
| Hypopnoea | 243 | 0 |
| Hypoventilation | 1 | 0 |
| Irregular breathing | 30 | 0 |
| Mouth breathing | 8 | 0 |
| Orthopnoea | 3 | 0 |
| Respiration abnormal | 123 | 0 |
| Respiratory arrest | 29 | 0 |
| Respiratory distress | 13 | 0 |
| Respiratory fatigue | 8 | 0 |
| Sleep apnoea syndrome | 37 | 0 |
| Tachypnoea | 41 | 0 |
| <i>Bronchial conditions NEC</i> | | |
| Bronchial haemorrhage | 1 | 0 |
| Bronchial secretion retention | 2 | 0 |
| Bronchiectasis | 16 | 0 |
| <i>Bronchospasm and obstruction</i> | | |
| Asthma | 666 | 0 |
| Asthma exercise induced | 4 | 0 |
| Asthma late onset | 3 | 0 |
| Asthma-chronic obstructive pulmonary disease overlap syndrome | 2 | 0 |
| Asthmatic crisis | 6 | 0 |
| Bronchial oedema | 1 | 0 |
| Bronchitis chronic | 2 | 0 |
| Bronchospasm | 19 | 0 |
| Chronic obstructive pulmonary disease | 61 | 5 |
| Cough variant asthma | 9 | 0 |
| NSAID exacerbated respiratory disease | 1 | 0 |
| Obstructive airways disorder | 2 | 0 |
| Reversible airways obstruction | 1 | 0 |
| Wheezing | 656 | 0 |
| <i>Conditions associated with abnormal gas exchange</i> | | |
| Asphyxia | 4 | 1 |
| Hypercapnia | 1 | 0 |
| Hypoxia | 74 | 1 |
| <i>Coughing and associated symptoms</i> | | |
| Allergic cough | 8 | 0 |
| Cough | 4106 | 0 |
| Haemoptysis | 151 | 0 |
| Productive cough | 221 | 0 |
| Sputum discoloured | 15 | 0 |
| Sputum increased | 3 | 0 |
| Sputum retention | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| <i>Diaphragmatic disorders</i> | | |
| Acquired diaphragmatic eventration | 1 | 0 |
| Diaphragmatic paralysis | 1 | 0 |
| Diaphragmatic spasm | 2 | 0 |
| <i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i> | | |
| Reflux laryngitis | 4 | 0 |
| Vocal cord disorder | 5 | 0 |
| Vocal cord dysfunction | 8 | 0 |
| Vocal cord thickening | 2 | 0 |
| <i>Laryngeal spasm, oedema and obstruction</i> | | |
| Epiglottic oedema | 1 | 0 |
| Laryngeal oedema | 3 | 0 |
| Laryngospasm | 3 | 0 |
| Stridor | 23 | 0 |
| <i>Lower respiratory tract inflammatory and immunologic conditions</i> | | |
| Alveolitis | 2 | 0 |
| Autoimmune lung disease | 1 | 0 |
| Eosinophilic pneumonia | 3 | 0 |
| Hypersensitivity pneumonitis | 2 | 0 |
| Pneumonitis | 38 | 1 |
| Pulmonary sarcoidosis | 3 | 0 |
| Pulmonary vasculitis | 1 | 0 |
| <i>Lower respiratory tract signs and symptoms</i> | | |
| Hiccups | 49 | 0 |
| Lower respiratory tract congestion | 4 | 0 |
| Lung hyperinflation | 1 | 0 |
| Lung opacity | 8 | 0 |
| Pleuritic pain | 49 | 0 |
| Pulmonary haemorrhage | 8 | 1 |
| Pulmonary pain | 239 | 0 |
| Rales | 2 | 0 |
| <i>Mediastinal disorders</i> | | |
| Pulmonary hilum mass | 1 | 0 |
| <i>Nasal congestion and inflammations</i> | | |
| Nasal congestion | 483 | 0 |
| Nasal inflammation | 10 | 0 |
| Rhinitis allergic | 28 | 0 |
| Rhinitis perennial | 1 | 0 |
| <i>Nasal disorders NEC</i> | | |
| Epistaxis | 2307 | 0 |
| Intranasal hypoaesthesia | 1 | 0 |
| Nasal crusting | 6 | 0 |
| Nasal cyst | 2 | 0 |
| Nasal disorder | 9 | 0 |
| Nasal dryness | 71 | 0 |
| Nasal mucosal blistering | 1 | 0 |
| Nasal mucosal discolouration | 1 | 0 |
| Nasal odour | 2 | 0 |
| Nasal oedema | 17 | 0 |
| Nasal polyps | 1 | 0 |
| Nasal pruritus | 12 | 0 |
| Nasal septum deviation | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| Nasal septum perforation | 1 | 0 |
| Nasal ulcer | 5 | 0 |
| Neonatal hypoxic conditions | | |
| Brief resolved unexplained event | 1 | 0 |
| Gasping syndrome | 2 | 0 |
| Paranasal sinus disorders (excl infections and neoplasms) | | |
| Allergic sinusitis | 2 | 0 |
| Paranasal sinus haemorrhage | 5 | 0 |
| Paranasal sinus hypersecretion | 1 | 0 |
| Paranasal sinus inflammation | 4 | 0 |
| Sinonasal obstruction | 14 | 0 |
| Sinus congestion | 95 | 0 |
| Sinus disorder | 21 | 0 |
| Sinus polyp | 3 | 0 |
| Parenchymal lung disorders NEC | | |
| Alveolar proteinosis | 1 | 0 |
| Atelectasis | 8 | 0 |
| Cystic lung disease | 1 | 0 |
| Emphysema | 8 | 0 |
| Idiopathic pulmonary fibrosis | 4 | 1 |
| Interstitial lung disease | 11 | 2 |
| Lung consolidation | 10 | 0 |
| Lung cyst | 1 | 0 |
| Lung induration | 1 | 0 |
| Lung infiltration | 2 | 0 |
| Pulmonary alveolar haemorrhage | 1 | 0 |
| Pulmonary calcification | 1 | 0 |
| Pulmonary cavitation | 3 | 0 |
| Pulmonary fibrosis | 13 | 0 |
| Pharyngeal disorders (excl infections and neoplasms) | | |
| Oropharyngeal swelling | 2 | 0 |
| Pharyngeal erythema | 5 | 0 |
| Pharyngeal haemorrhage | 2 | 0 |
| Pharyngeal hypoaesthesia | 42 | 0 |
| Pharyngeal inflammation | 1 | 0 |
| Pharyngeal oedema | 14 | 0 |
| Pharyngeal paraesthesia | 38 | 0 |
| Pharyngeal swelling | 317 | 0 |
| Pharyngeal ulceration | 17 | 0 |
| Tonsillar disorder | 1 | 0 |
| Tonsillar erythema | 7 | 0 |
| Tonsillar exudate | 1 | 0 |
| Tonsillar haemorrhage | 1 | 0 |
| Tonsillar hypertrophy | 66 | 0 |
| Tonsillar inflammation | 5 | 0 |
| Tonsillar ulcer | 2 | 0 |
| Tonsillolith | 2 | 0 |
| Pleural conditions NEC | | |
| Pleural thickening | 1 | 0 |
| Pleural infections and inflammations | | |
| Lupus pleurisy | 2 | 0 |
| Pleurisy | 57 | 0 |
| Pneumothorax and pleural effusions NEC | | |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| Haemothorax | 1 | 0 |
| Pleural effusion | 57 | 1 |
| Pneumothorax | 14 | 0 |
| Pneumothorax spontaneous | 3 | 0 |
| <i>Pulmonary hypertensions</i> | | |
| Pulmonary hypertension | 7 | 1 |
| <i>Pulmonary oedemas</i> | | |
| Acute lung injury | 1 | 0 |
| Acute pulmonary oedema | 3 | 0 |
| Acute respiratory distress syndrome | 2 | 0 |
| Pulmonary congestion | 24 | 0 |
| Pulmonary oedema | 46 | 1 |
| <i>Pulmonary thrombotic and embolic conditions</i> | | |
| Pulmonary artery thrombosis | 4 | 0 |
| Pulmonary embolism | 1791 | 122 |
| Pulmonary infarction | 15 | 1 |
| Pulmonary thrombosis | 37 | 7 |
| Pulmonary venous thrombosis | 4 | 0 |
| <i>Respiratory failures (excl neonatal)</i> | | |
| Acute respiratory failure | 3 | 1 |
| Respiratory failure | 33 | 4 |
| <i>Respiratory signs and symptoms NEC</i> | | |
| Allergic respiratory symptom | 11 | 0 |
| Diaphragmalgia | 16 | 0 |
| Nasal flaring | 1 | 0 |
| Painful respiration | 12 | 0 |
| Pleural rub | 1 | 0 |
| Respiratory symptom | 26 | 0 |
| Suffocation feeling | 5 | 0 |
| Use of accessory respiratory muscles | 3 | 0 |
| <i>Respiratory tract disorders NEC</i> | | |
| Allergic respiratory disease | 1 | 0 |
| Aspiration | 11 | 2 |
| Chronic respiratory disease | 2 | 1 |
| Ear, nose and throat disorder | 1 | 0 |
| Lung disorder | 21 | 0 |
| Pulmonary mass | 11 | 0 |
| Respiratory disorder | 9 | 0 |
| Respiratory tract congestion | 10 | 0 |
| Respiratory tract haemorrhage | 2 | 0 |
| Respiratory tract irritation | 10 | 0 |
| Respiratory tract oedema | 4 | 0 |
| Ventilation perfusion mismatch | 1 | 0 |
| <i>Thoracic musculoskeletal disorders</i> | | |
| Respiratory muscle weakness | 2 | 0 |
| <i>Tracheal disorders (excl infections and neoplasms)</i> | | |
| Tracheal fistula | 1 | 0 |
| Tracheal pain | 4 | 0 |
| Tracheomalacia | 1 | 0 |
| <i>Upper respiratory tract signs and symptoms</i> | | |
| Aphonia | 126 | 0 |
| Catarrh | 70 | 0 |
| Choking | 26 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|--------------|------------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| Choking sensation | 14 | 0 |
| Dry throat | 264 | 0 |
| Dysphonia | 184 | 0 |
| Increased upper airway secretion | 4 | 0 |
| Increased viscosity of upper respiratory secretion | 24 | 0 |
| Laryngeal pain | 1 | 0 |
| Nasal discharge discolouration | 2 | 0 |
| Nasal discomfort | 39 | 0 |
| Nasal obstruction | 2 | 0 |
| Oropharyngeal blistering | 27 | 0 |
| Oropharyngeal discolouration | 1 | 0 |
| Oropharyngeal discomfort | 45 | 0 |
| Oropharyngeal pain | 4271 | 0 |
| Oropharyngeal plaque | 1 | 0 |
| Paranasal sinus discomfort | 80 | 0 |
| Rhinalgia | 112 | 0 |
| Rhinorrhoea | 1711 | 0 |
| Sinus pain | 614 | 0 |
| Sneezing | 534 | 0 |
| Snoring | 6 | 0 |
| Throat clearing | 10 | 0 |
| Throat irritation | 222 | 0 |
| Throat lesion | 1 | 0 |
| Throat tightness | 247 | 0 |
| Upper airway obstruction | 1 | 0 |
| Upper respiratory tract congestion | 1 | 0 |
| Upper-airway cough syndrome | 32 | 0 |
| Yawning | 73 | 0 |
| <i>Vascular pulmonary disorders NEC</i> | | |
| Pulmonary artery occlusion | 1 | 0 |
| Pulmonary vascular disorder | 1 | 0 |
| Respiratory disorders SOC TOTAL | 30230 | 153 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Skin disorders | | |
| <i>Acnes</i> | | |
| Acne | 153 | 0 |
| Acne cystic | 12 | 0 |
| Acne varioliformis | 1 | 0 |
| Dermatitis acneiform | 13 | 0 |
| <i>Alopecias</i> | | |
| Alopecia | 532 | 0 |
| Alopecia areata | 56 | 0 |
| Alopecia scarring | 2 | 0 |
| Alopecia totalis | 4 | 0 |
| Alopecia universalis | 3 | 0 |
| Androgenetic alopecia | 2 | 0 |
| Diffuse alopecia | 5 | 0 |
| Hypotrichosis | 1 | 0 |
| Lichen planopilaris | 2 | 0 |
| Madarosis | 6 | 0 |
| <i>Angioedemas</i> | | |
| Angioedema | 369 | 0 |
| Circumoral oedema | 2 | 0 |
| Idiopathic angioedema | 3 | 0 |
| <i>Apocrine and eccrine gland disorders</i> | | |
| Anhidrosis | 3 | 0 |
| Cold sweat | 1742 | 0 |
| Hidradenitis | 6 | 0 |
| Hyperhidrosis | 9335 | 0 |
| Hypohidrosis | 6 | 0 |
| Miliaria | 227 | 0 |
| Night sweats | 1968 | 0 |
| Sweat discolouration | 3 | 0 |
| Sweat gland disorder | 1 | 0 |
| <i>Bullous conditions</i> | | |
| Autoimmune blistering disease | 1 | 0 |
| Blister | 673 | 0 |
| Blister rupture | 7 | 0 |
| Blood blister | 115 | 0 |
| Bullous haemorrhagic dermatosis | 1 | 0 |
| Dermatitis bullous | 19 | 0 |
| Dermatitis herpetiformis | 2 | 0 |
| Erythema multiforme | 41 | 0 |
| Linear IgA disease | 1 | 0 |
| Oedema blister | 1 | 0 |
| Pemphigoid | 40 | 0 |
| Pemphigus | 11 | 0 |
| Stevens-Johnson syndrome | 7 | 0 |
| Toxic epidermal necrolysis | 2 | 0 |
| <i>Connective tissue disorders</i> | | |
| Chronic cutaneous lupus erythematosus | 4 | 0 |
| Dermatomyositis | 7 | 0 |
| Subacute cutaneous lupus erythematosus | 1 | 0 |
| <i>Dermal and epidermal conditions NEC</i> | | |
| Acute febrile neutrophilic dermatosis | 5 | 0 |
| Dermatosis | 1 | 0 |
| Dry skin | 477 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|-------------------------------------|-------|-------|
| Skin disorders | | |
| Skin disorders cont'd | | |
| Macule | 13 | 0 |
| Myxoid cyst | 2 | 0 |
| Neutrophilic dermatosis | 1 | 0 |
| Pain of skin | 954 | 0 |
| Papule | 127 | 0 |
| Parakeratosis | 1 | 0 |
| Scab | 34 | 0 |
| Scar discomfort | 1 | 0 |
| Scar pain | 20 | 0 |
| Sensitive skin | 607 | 0 |
| Skin burning sensation | 605 | 0 |
| Skin discolouration | 241 | 0 |
| Skin discomfort | 6 | 0 |
| Skin disorder | 54 | 0 |
| Skin fissures | 20 | 0 |
| Skin fragility | 3 | 0 |
| Skin indentation | 18 | 0 |
| Skin induration | 18 | 0 |
| Skin laxity | 1 | 0 |
| Skin lesion | 72 | 0 |
| Skin necrosis | 9 | 0 |
| Skin odour abnormal | 52 | 0 |
| Skin plaque | 3 | 0 |
| Skin reaction | 282 | 0 |
| Skin sensitisation | 90 | 0 |
| Skin swelling | 102 | 0 |
| Skin texture abnormal | 2 | 0 |
| Skin tightness | 44 | 0 |
| Skin warm | 593 | 0 |
| Skin weeping | 11 | 0 |
| Sticky skin | 9 | 0 |
| Target skin lesion | 2 | 0 |
| Transient acantholytic dermatosis | 2 | 0 |
| Yellow skin | 33 | 0 |
| <i>Dermatitis and eczema</i> | | |
| Autoimmune dermatitis | 2 | 0 |
| Dermatitis | 207 | 0 |
| Dermatitis allergic | 335 | 0 |
| Dermatitis atopic | 47 | 0 |
| Dermatitis contact | 39 | 0 |
| Dermatitis diaper | 3 | 0 |
| Dyshidrotic eczema | 21 | 0 |
| Eczema | 414 | 0 |
| Eczema asteatotic | 22 | 0 |
| Eczema nummular | 5 | 0 |
| Eczema weeping | 3 | 0 |
| Hand dermatitis | 8 | 0 |
| Intertrigo | 3 | 0 |
| Neurodermatitis | 4 | 0 |
| Perioral dermatitis | 5 | 0 |
| Prurigo | 2 | 0 |
| Rebound eczema | 1 | 0 |
| Seborrhoeic dermatitis | 17 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Skin irritation | 169 | 0 |
| Stasis dermatitis | 8 | 0 |
| Urticarial dermatitis | 2 | 0 |
| <i>Dermatitis ascribed to specific agent</i> | | |
| Drug eruption | 38 | 0 |
| Drug reaction with eosinophilia and systemic symptoms | 14 | 0 |
| Fixed eruption | 10 | 0 |
| Palmar-plantar erythrodysesthesia syndrome | 3 | 0 |
| Severe cutaneous adverse reaction | 1 | 0 |
| <i>Erythemas</i> | | |
| Erythema | 3469 | 0 |
| Erythema ab igne | 1 | 0 |
| Palmar erythema | 7 | 0 |
| Plantar erythema | 3 | 0 |
| <i>Exfoliative conditions</i> | | |
| Dermatitis exfoliative | 2 | 0 |
| Dermatitis exfoliative generalised | 9 | 0 |
| Exfoliative rash | 20 | 0 |
| Skin exfoliation | 205 | 0 |
| <i>Granulomatous and deep cutaneous inflammatory conditions</i> | | |
| Cutaneous sarcoidosis | 1 | 0 |
| Granuloma annulare | 10 | 0 |
| Granuloma skin | 1 | 0 |
| <i>Hyperkeratoses</i> | | |
| Hyperkeratosis | 3 | 0 |
| Lichenoid keratosis | 1 | 0 |
| <i>Hyperpigmentation disorders</i> | | |
| Chloasma | 2 | 0 |
| Ephelides | 1 | 0 |
| Melanoderma | 2 | 0 |
| Skin hyperpigmentation | 10 | 0 |
| Solar lentigo | 7 | 0 |
| <i>Hypertrichoses</i> | | |
| Hypertrichosis | 5 | 0 |
| <i>Hypopigmentation disorders</i> | | |
| Skin depigmentation | 9 | 0 |
| Skin hypopigmentation | 3 | 0 |
| Vitiligo | 45 | 0 |
| <i>Lipodystrophies</i> | | |
| Lipoatrophy | 2 | 0 |
| Lipohypertrophy | 2 | 0 |
| Progressive facial hemiatrophy | 1 | 0 |
| <i>Nail and nail bed conditions (excl infections and infestations)</i> | | |
| Anonychia | 1 | 0 |
| Ingrowing nail | 2 | 0 |
| Nail bed bleeding | 2 | 0 |
| Nail bed disorder | 2 | 0 |
| Nail bed inflammation | 1 | 0 |
| Nail bed tenderness | 2 | 0 |
| Nail discolouration | 17 | 0 |
| Nail disorder | 5 | 0 |
| Nail growth abnormal | 3 | 0 |
| Nail hypertrophy | 1 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Nail necrosis | 1 | 0 |
| Nail pigmentation | 2 | 0 |
| Nail pitting | 1 | 0 |
| Nail ridging | 9 | 0 |
| Onychalgia | 7 | 0 |
| Onychoclasia | 12 | 0 |
| Onycholysis | 4 | 0 |
| Onychomadesis | 5 | 0 |
| Splinter haemorrhages | 7 | 0 |
| <i>Panniculitides</i> | | |
| Erythema nodosum | 42 | 0 |
| Panniculitis | 6 | 0 |
| <i>Papulosquamous conditions</i> | | |
| Erythema annulare | 2 | 0 |
| Lichen planus | 49 | 0 |
| Lichen sclerosus | 11 | 0 |
| Lichen striatus | 1 | 0 |
| Parapsoriasis | 2 | 0 |
| Pityriasis lichenoides et varioliformis acuta | 1 | 0 |
| Pityriasis rosea | 69 | 0 |
| Pityriasis rubra pilaris | 2 | 0 |
| <i>Photosensitivity and photodermatosis conditions</i> | | |
| Photodermatosis | 2 | 0 |
| Photosensitivity reaction | 171 | 0 |
| Polymorphic light eruption | 6 | 0 |
| Solar dermatitis | 1 | 0 |
| <i>Pigmentation changes NEC</i> | | |
| Haemosiderin stain | 1 | 0 |
| Pigmentation disorder | 18 | 0 |
| <i>Pilar disorders NEC</i> | | |
| Hair colour changes | 16 | 0 |
| Hair disorder | 2 | 0 |
| Hair growth abnormal | 9 | 0 |
| Hair texture abnormal | 15 | 0 |
| Piloerection | 104 | 0 |
| Pseudofolliculitis | 2 | 0 |
| Trichodynia | 7 | 0 |
| Trichorrhexis | 7 | 0 |
| <i>Pruritus NEC</i> | | |
| Itching scar | 5 | 0 |
| Pruritus | 8481 | 0 |
| Pruritus allergic | 1 | 0 |
| Senile pruritus | 1 | 0 |
| <i>Psoriatic conditions</i> | | |
| Dermatitis psoriasiform | 3 | 0 |
| Erythrodermic psoriasis | 4 | 0 |
| Guttate psoriasis | 33 | 0 |
| Nail psoriasis | 1 | 0 |
| Palmoplantar pustulosis | 4 | 0 |
| Psoriasis | 292 | 0 |
| Pustular psoriasis | 10 | 0 |
| <i>Purpura and related conditions</i> | | |
| Ecchymosis | 6 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Henoch-Schonlein purpura | 18 | 0 |
| Petechiae | 385 | 0 |
| Purpura | 153 | 0 |
| Pustular conditions | | |
| Acute generalised exanthematous pustulosis | 1 | 0 |
| Rash follicular | 4 | 0 |
| Rashes, eruptions and exanthems NEC | | |
| Butterfly rash | 8 | 0 |
| Nodular rash | 1 | 0 |
| Rash | 9353 | 0 |
| Rash erythematous | 2316 | 0 |
| Rash macular | 792 | 0 |
| Rash maculo-papular | 71 | 0 |
| Rash morbilliform | 50 | 0 |
| Rash papular | 585 | 0 |
| Rash pruritic | 2011 | 0 |
| Rash rubelliform | 1 | 0 |
| Rash scarlatiniform | 2 | 0 |
| Rash vesicular | 108 | 0 |
| Systemic lupus erythematosus rash | 9 | 0 |
| Rosaceas | | |
| Erythematotelangiectatic rosacea | 3 | 0 |
| Granulomatous rosacea | 1 | 0 |
| Papulopustular rosacea | 1 | 0 |
| Rosacea | 50 | 0 |
| Scaly conditions | | |
| Dandruff | 4 | 0 |
| Pityriasis | 16 | 0 |
| Sebaceous gland disorders | | |
| Sebaceous glands overactivity | 1 | 0 |
| Seborrhoea | 16 | 0 |
| Skin and subcutaneous conditions NEC | | |
| Cellulite | 3 | 0 |
| Cutaneous symptom | 12 | 0 |
| Skin discharge | 1 | 0 |
| Skin mass | 50 | 0 |
| Skin and subcutaneous tissue ulcerations | | |
| Diabetic foot | 2 | 0 |
| Diabetic ulcer | 1 | 0 |
| Ischaemic skin ulcer | 1 | 0 |
| Pyoderma gangrenosum | 3 | 0 |
| Skin erosion | 61 | 0 |
| Skin ulcer | 39 | 0 |
| Vasculitic ulcer | 1 | 0 |
| Skin cysts and polyps | | |
| Dermal cyst | 28 | 0 |
| Skin dystrophies | | |
| Keloid scar | 3 | 0 |
| Skin wrinkling | 6 | 0 |
| Skin haemorrhages | | |
| Haemorrhage subcutaneous | 24 | 0 |
| Mucocutaneous haemorrhage | 3 | 0 |
| Skin haemorrhage | 54 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|--------------|----------|
| Skin disorders Skin disorders cont'd | | |
| <i>Skin hyperplasias and hypertrophies</i> | | |
| Acanthosis | 1 | 0 |
| Skin hypertrophy | 4 | 0 |
| <i>Skin hypoplasias and atrophies</i> | | |
| Skin atrophy | 13 | 0 |
| Skin striae | 13 | 0 |
| <i>Skin injuries and mechanical dermatoses</i> | | |
| Decubitus ulcer | 9 | 0 |
| Needle track marks | 3 | 0 |
| <i>Skin preneoplastic conditions NEC</i> | | |
| Actinic keratosis | 3 | 0 |
| Leukoplakia | 1 | 0 |
| <i>Skin vascular conditions NEC</i> | | |
| Angiodermatitis | 1 | 0 |
| Haemangioma-thrombocytopenia syndrome | 1 | 0 |
| Skin oedema | 3 | 0 |
| Vascular skin disorder | 1 | 0 |
| <i>Skin vasculitides</i> | | |
| Capillaritis | 1 | 0 |
| Cutaneous vasculitis | 15 | 0 |
| Hypersensitivity vasculitis | 4 | 0 |
| Nodular vasculitis | 1 | 0 |
| Vasculitic rash | 30 | 0 |
| <i>Skin vasomotor conditions</i> | | |
| Livedo reticularis | 60 | 0 |
| <i>Telangiectasia and related conditions</i> | | |
| Spider naevus | 5 | 0 |
| Telangiectasia | 6 | 0 |
| <i>Urticarias</i> | | |
| Chronic spontaneous urticaria | 11 | 0 |
| Cold urticaria | 13 | 0 |
| Idiopathic urticaria | 11 | 0 |
| Mechanical urticaria | 10 | 0 |
| Solar urticaria | 1 | 0 |
| Urticaria | 2686 | 0 |
| Urticaria cholinergic | 2 | 0 |
| Urticaria chronic | 57 | 0 |
| Urticaria contact | 3 | 0 |
| Urticaria papular | 4 | 0 |
| Urticaria pigmentosa | 1 | 0 |
| Urticaria thermal | 7 | 0 |
| Urticarial vasculitis | 6 | 0 |
| Skin disorders SOC TOTAL | 53819 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022
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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Social circumstances | | |
| <i>Age related issues</i> | | |
| Childhood | 1 | 0 |
| Life expectancy shortened | 2 | 0 |
| Menarche | 3 | 0 |
| Menopause | 84 | 0 |
| Postmenopause | 18 | 0 |
| <i>Alcohol product use</i> | | |
| Alcoholic | 4 | 0 |
| <i>Crime victims</i> | | |
| Victim of abuse | 1 | 0 |
| <i>Criminal activity</i> | | |
| Chemical submission | 1 | 0 |
| Verbal abuse | 1 | 0 |
| <i>Dependents</i> | | |
| Sick relative | 1 | 0 |
| <i>Dietary and nutritional issues</i> | | |
| Inadequate diet | 1 | 0 |
| Kosher diet | 1 | 0 |
| <i>Disability issues</i> | | |
| Bedridden | 105 | 0 |
| Breast prosthesis user | 2 | 0 |
| Corrective lens user | 1 | 0 |
| Dependence on oxygen therapy | 1 | 0 |
| Disability | 13 | 0 |
| Hearing aid user | 3 | 0 |
| Hearing disability | 3 | 0 |
| Housebound | 7 | 0 |
| Immobile | 58 | 0 |
| Immobilisation prolonged | 4 | 0 |
| Impaired driving ability | 9 | 0 |
| Impaired work ability | 47 | 0 |
| Loss of personal independence in daily activities | 18 | 0 |
| Mental disability | 1 | 0 |
| Paralytic disability | 1 | 0 |
| Physical disability | 5 | 0 |
| Sight disability | 28 | 0 |
| Sitting disability | 3 | 0 |
| Walking aid user | 1 | 0 |
| Walking disability | 12 | 0 |
| Wheelchair user | 3 | 0 |
| <i>Educational issues</i> | | |
| Educational problem | 1 | 0 |
| Illiteracy | 4 | 0 |
| <i>Employment issues</i> | | |
| Job dissatisfaction | 4 | 0 |
| Retirement | 5 | 0 |
| Stress at work | 2 | 0 |
| Unemployment | 1 | 0 |
| <i>Family and partner issues</i> | | |
| Homosexual parent | 1 | 0 |
| Partner stress | 1 | 0 |
| <i>Non-occupational and unspecified environmental problems</i> | | |
| Food contamination | 1 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Social circumstances <small>Social circumstances cont'd</small> | | |
| Water pollution | 4 | 0 |
| <i>Pregnancy related circumstances</i> | | |
| Breast feeding | 9 | 0 |
| <i>Sexuality issues</i> | | |
| Anal sex | 1 | 0 |
| Homosexuality | 1 | 0 |
| <i>Social issues NEC</i> | | |
| Blood donor | 2 | 0 |
| Contraindication to medical treatment | 1 | 0 |
| Contraindication to vaccination | 2 | 0 |
| Convalescent | 1 | 0 |
| Hair dye user | 1 | 0 |
| Impaired quality of life | 10 | 0 |
| Refusal of treatment by patient | 1 | 0 |
| Refusal of vaccination | 3 | 0 |
| Tanning | 2 | 0 |
| Tattoo | 1 | 0 |
| Unhealthy lifestyle | 1 | 0 |
| <i>Tobacco use</i> | | |
| Non-tobacco user | 7 | 0 |
| Tobacco user | 2 | 0 |
| Social circumstances SOC TOTAL | 512 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Surgical & medical procedures | | |
| <i>Adrenal gland therapeutic procedures</i> | | |
| Adrenalectomy | 1 | 0 |
| <i>Anaesthesia and allied procedures</i> | | |
| Local anaesthesia | 3 | 0 |
| Nerve block | 5 | 0 |
| <i>Analgesia supportive care</i> | | |
| Analgesic therapy | 1 | 0 |
| <i>Antiinfective therapies</i> | | |
| Antibiotic therapy | 2 | 0 |
| COVID-19 treatment | 7 | 0 |
| <i>Arterial therapeutic procedures (excl aortic)</i> | | |
| Cerebral revascularisation | 1 | 0 |
| Coronary artery bypass | 2 | 0 |
| <i>Autonomic nerve therapeutic procedures</i> | | |
| Vagotomy | 3 | 0 |
| <i>Biliary tract and gallbladder therapeutic procedures</i> | | |
| Cholecystectomy | 1 | 0 |
| Cholelithotomy | 1 | 0 |
| <i>Bladder therapeutic procedures</i> | | |
| Bladder training | 1 | 0 |
| <i>Blood and blood product treatment</i> | | |
| Photopheresis | 1 | 0 |
| Transfusion | 1 | 0 |
| <i>Breast therapeutic procedures NEC</i> | | |
| Axillary lymphadenectomy | 1 | 0 |
| <i>Bronchial and pulmonary therapeutic procedures</i> | | |
| Airway secretion clearance therapy | 1 | 0 |
| Antitussive therapy | 1 | 0 |
| Lung transplant | 1 | 0 |
| <i>Cardiac device therapeutic procedures</i> | | |
| Cardiac pacemaker insertion | 3 | 0 |
| Pacemaker generated rhythm | 1 | 0 |
| <i>Cardiac therapeutic procedures NEC</i> | | |
| Cardiac operation | 1 | 0 |
| Pericardial excision | 2 | 0 |
| <i>Cardiac valve therapeutic procedures</i> | | |
| Aortic valve replacement | 1 | 0 |
| Heart valve replacement | 1 | 0 |
| <i>Chemotherapies</i> | | |
| Chemotherapy toxicity attenuation | 1 | 0 |
| <i>Contraceptive methods female</i> | | |
| Contraception | 3 | 0 |
| Contraceptive diaphragm | 3 | 0 |
| Intrauterine contraception | 1 | 0 |
| Oral contraception | 2 | 0 |
| <i>Corneal and scleral therapeutic procedures</i> | | |
| Corneal transplant | 2 | 0 |
| <i>Dental and gingival therapeutic procedures</i> | | |
| Dental care | 1 | 0 |
| Tooth extraction | 5 | 0 |
| Tooth restoration | 4 | 0 |
| <i>Dietary and nutritional therapies</i> | | |
| Fluid replacement | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 Vaccine AstraZeneca Vaccine Analysis Print

Report Run Date: 24-Nov-2022
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MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Surgical & medical procedures | | |
| <i>Surgical & medical procedures cont'd</i> | | |
| Gluten free diet | 2 | 0 |
| Medical diet | 6 | 0 |
| Mineral supplementation | 1 | 0 |
| Nothing by mouth order | 9 | 0 |
| External ear therapeutic procedures | | |
| Cerumen removal | 2 | 0 |
| Eye therapeutic procedures NEC | | |
| Eye irrigation | 4 | 0 |
| Facial therapeutic procedures | | |
| Face lift | 3 | 0 |
| Fallopian tube therapeutic procedures | | |
| Fallopian tube operation | 1 | 0 |
| Fascial and bursal therapeutic procedures | | |
| Bursa removal | 1 | 0 |
| Fertility and fertilisation interventions female | | |
| Ovulation induction | 2 | 0 |
| Gastric therapeutic procedures | | |
| Antacid therapy | 1 | 0 |
| Gastrointestinal therapeutic procedures NEC | | |
| Intestinal resection | 1 | 0 |
| Prophylaxis against gastrointestinal ulcer | 1 | 0 |
| Prophylaxis of nausea and vomiting | 28 | 0 |
| Gynaecological therapeutic procedures NEC | | |
| Gynaecological disorder prophylaxis | 1 | 0 |
| Menstrual cycle management | 4 | 0 |
| Haematological therapeutic procedures NEC | | |
| Anticoagulant therapy | 2 | 0 |
| Haemofiltration | 1 | 0 |
| Thrombosis prophylaxis | 2 | 0 |
| Head, neck and oral cavity therapeutic procedures NEC | | |
| Neck lift | 1 | 0 |
| Hormonal therapeutic procedures NEC | | |
| Hormone replacement therapy | 6 | 0 |
| Hormone therapy | 9 | 0 |
| Steroid therapy | 2 | 0 |
| Immunisations | | |
| COVID-19 immunisation | 221 | 0 |
| Immunisation | 118 | 0 |
| Influenza immunisation | 1 | 0 |
| Tuberculosis immunisation | 1 | 0 |
| Vaccine coadministration | 1 | 0 |
| Induced abortions | | |
| Abortion induced | 1 | 0 |
| Iris and ciliary body therapeutic procedures | | |
| Pupil constriction procedure | 1 | 0 |
| Joint therapeutic procedures | | |
| Hip surgery | 1 | 0 |
| Joint injection | 6 | 0 |
| Joint stabilisation | 3 | 0 |
| Knee operation | 2 | 0 |
| Shoulder operation | 3 | 0 |
| Large intestine therapeutic procedures | | |
| Appendectomy | 8 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Surgical & medical procedures | | |
| Surgical & medical procedures cont'd | | |
| Colectomy | 2 | 0 |
| Limb therapeutic procedures | | |
| Arm amputation | 1 | 0 |
| Foot amputation | 2 | 0 |
| Leg amputation | 5 | 0 |
| Limb immobilisation | 28 | 0 |
| Limb operation | 16 | 0 |
| Limb reattachment surgery | 1 | 0 |
| Toe amputation | 5 | 0 |
| Lymphoid tissue therapeutic procedures | | |
| Splenectomy | 1 | 0 |
| Mastectomies | | |
| Breast conserving surgery | 2 | 0 |
| Muscle therapeutic procedures | | |
| Muscle relaxant therapy | 3 | 0 |
| Nail therapeutic procedures | | |
| Nail operation | 2 | 0 |
| Nasal therapeutic procedures | | |
| Nasal irrigation | 1 | 0 |
| Nervous system therapeutic procedures NEC | | |
| Central nervous system stimulation | 3 | 0 |
| Multiple sclerosis relapse prophylaxis | 2 | 0 |
| Neurological rehabilitation | 1 | 0 |
| Orbit and globe therapeutic procedures | | |
| Eye muscle operation | 1 | 0 |
| Patient positioning | | |
| Prone position | 1 | 0 |
| Peripheral nerve therapeutic procedures | | |
| Carpal tunnel decompression | 1 | 0 |
| Phototherapies | | |
| UV light therapy | 1 | 0 |
| Prophylactic procedures NEC | | |
| Anaphylaxis prophylaxis | 3 | 0 |
| Reproductive system disorder prophylaxis | 1 | 0 |
| Psychiatric therapies | | |
| Antidepressant therapy | 1 | 0 |
| Psychotherapy | 1 | 0 |
| Renal therapeutic procedures | | |
| Dialysis | 1 | 0 |
| Respiratory tract therapeutic procedures NEC | | |
| Asthma prophylaxis | 1 | 0 |
| Respiratory therapy | 1 | 0 |
| Skin and subcutaneous tissue therapeutic procedures NEC | | |
| Dermal filler injection | 1 | 0 |
| Skin grafts | | |
| Skin graft | 1 | 0 |
| Skin lesion excisions | | |
| Skin neoplasm excision | 1 | 0 |
| Tattoo excision | 1 | 0 |
| Skull and brain therapeutic procedures | | |
| Brain operation | 1 | 0 |
| Small intestine therapeutic procedures | | |
| Ileostomy | 3 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Surgical & medical procedures | | |
| <i>Surgical & medical procedures cont'd</i> | | |
| <i>Spine and spinal cord therapeutic procedures</i> | | |
| Spinal operation | 1 | 0 |
| Spinal rod insertion | 1 | 0 |
| <i>Testicular and scrotal therapeutic procedures</i> | | |
| Testes exploration | 1 | 0 |
| <i>Therapeutic bladder catheterisation</i> | | |
| Bladder catheterisation | 1 | 0 |
| <i>Therapeutic procedures NEC</i> | | |
| Anaphylaxis treatment | 4 | 0 |
| Antiallergic therapy | 1 | 0 |
| Bed rest | 26 | 0 |
| Catheter management | 4 | 0 |
| Catheter placement | 2 | 0 |
| Continuous passive motion machine therapy | 1 | 0 |
| Fatigue management | 1 | 0 |
| Heat therapy | 3 | 0 |
| Hospitalisation | 31 | 0 |
| Immobilisation bandage | 1 | 0 |
| Injection | 54 | 0 |
| Interchange of vaccine products | 154 | 0 |
| Lesion excision | 1 | 0 |
| Localised alternating hot and cold therapy | 6 | 0 |
| Magnetic therapy | 1 | 0 |
| Manipulation | 1 | 0 |
| Mass excision | 10 | 0 |
| Medication dilution | 3 | 0 |
| Occupational therapy | 1 | 0 |
| Physical fitness training | 4 | 0 |
| Physiotherapy | 1 | 0 |
| Product used for unknown indication | 2 | 0 |
| Promotion of wound healing | 1 | 0 |
| Self-medication | 1 | 0 |
| Smoking cessation therapy | 1 | 0 |
| Specialist consultation | 1 | 0 |
| Stent placement | 1 | 0 |
| Stoma care | 1 | 0 |
| Surgery | 2 | 0 |
| Therapeutic hypothermia | 2 | 0 |
| Therapy change | 3 | 0 |
| Transgender operation | 1 | 0 |
| Tumour excision | 1 | 0 |
| Wound treatment | 1 | 0 |
| <i>Tonsillar therapeutic procedures</i> | | |
| Tonsillectomy | 1 | 0 |
| <i>Tracheal therapeutic procedures</i> | | |
| Tracheostomy | 1 | 0 |
| <i>Tumour vaccine therapies</i> | | |
| Tumour vaccine therapy | 1 | 0 |
| <i>Uterine therapeutic procedures</i> | | |
| Endometrial ablation | 6 | 0 |
| Hysterectomy | 1 | 0 |
| Uterine dilation and evacuation | 1 | 0 |
| <i>Vascular therapeutic procedures NEC</i> | | |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Surgical & medical procedures | | |
| Surgical & medical procedures cont'd | | |
| Arteriovenous fistula operation | 1 | 0 |
| Clamping of blood vessel | 1 | 0 |
| Thrombectomy | 3 | 0 |
| Thromboembolectomy | 1 | 0 |
| Thrombolysis | 3 | 0 |
| Vascular graft | 1 | 0 |
| <i>Venous therapeutic procedures</i> | | |
| Phlebotomy | 2 | 0 |
| Surgical & medical procedures SOC TOTAL | 974 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Vascular disorders | | |
| <i>Accelerated and malignant hypertension</i> | | |
| Accelerated hypertension | 1 | 0 |
| Hypertensive crisis | 16 | 0 |
| Hypertensive emergency | 2 | 0 |
| Hypertensive urgency | 4 | 0 |
| Malignant hypertension | 7 | 0 |
| Tyramine reaction | 1 | 0 |
| <i>Aneurysms and dissections non-site specific</i> | | |
| Aneurysm | 18 | 1 |
| Aneurysm ruptured | 2 | 0 |
| Artery dissection | 5 | 0 |
| Venous aneurysm | 1 | 0 |
| <i>Aortic aneurysms and dissections</i> | | |
| Acute aortic syndrome | 1 | 0 |
| Aortic aneurysm | 7 | 0 |
| Aortic aneurysm rupture | 1 | 1 |
| Aortic dissection | 5 | 2 |
| Aortic intramural haematoma | 1 | 0 |
| Penetrating aortic ulcer | 1 | 0 |
| <i>Aortic embolism and thrombosis</i> | | |
| Aortic embolus | 24 | 1 |
| Aortic thrombosis | 15 | 3 |
| <i>Aortic infections and inflammations</i> | | |
| Aortitis | 3 | 0 |
| <i>Aortic necrosis and vascular insufficiency</i> | | |
| Aortic arteriosclerosis | 2 | 0 |
| Aortic occlusion | 1 | 0 |
| Aortic stenosis | 5 | 0 |
| <i>Arterial infections and inflammations</i> | | |
| Arteritis | 6 | 0 |
| Giant cell arteritis | 69 | 0 |
| <i>Blood pressure disorders NEC</i> | | |
| Blood pressure fluctuation | 29 | 0 |
| Labile blood pressure | 5 | 0 |
| <i>Bruising, ecchymosis and purpura</i> | | |
| Achenbach syndrome | 10 | 0 |
| <i>Circulatory collapse and shock</i> | | |
| CT hypotension complex | 1 | 0 |
| Circulatory collapse | 145 | 2 |
| Distributive shock | 2 | 0 |
| Hypoperfusion | 2 | 0 |
| Hypovolaemic shock | 1 | 0 |
| Neurogenic shock | 10 | 0 |
| Peripheral circulatory failure | 4 | 0 |
| Shock | 60 | 1 |
| Shock haemorrhagic | 1 | 0 |
| Shock symptom | 6 | 0 |
| <i>Haemorrhages NEC</i> | | |
| Bloody discharge | 17 | 0 |
| Haematoma | 119 | 0 |
| Haemorrhage | 1500 | 2 |
| Internal haemorrhage | 32 | 0 |
| Venous haemorrhage | 11 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Vascular disorders <small>Vascular disorders cont'd</small> | | |
| <i>Lymphangiopathies</i> | | |
| Lymphangiopathy | 2 | 0 |
| Lymphocele | 2 | 0 |
| Lymphorrhoea | 1 | 0 |
| <i>Lymphoedemas</i> | | |
| Lymphoedema | 83 | 0 |
| <i>Non-site specific embolism and thrombosis</i> | | |
| Air embolism | 1 | 0 |
| Arterial thrombosis | 34 | 2 |
| Atheroembolism | 1 | 0 |
| Embolism | 258 | 2 |
| Embolism arterial | 4 | 0 |
| Embolism venous | 14 | 1 |
| Microembolism | 3 | 0 |
| Paradoxical embolism | 1 | 0 |
| Post thrombotic syndrome | 5 | 0 |
| Thrombophlebitis migrans | 2 | 0 |
| Thrombosis | 2005 | 45 |
| Venous recanalisation | 1 | 0 |
| Venous thrombosis | 41 | 0 |
| <i>Non-site specific necrosis and vascular insufficiency NEC</i> | | |
| Arterial occlusive disease | 18 | 0 |
| Arterial spasm | 2 | 0 |
| Arterial stenosis | 2 | 0 |
| Arteriosclerosis | 10 | 0 |
| Haemorrhagic infarction | 2 | 0 |
| Infarction | 15 | 0 |
| Ischaemia | 17 | 0 |
| Peripheral venous disease | 12 | 0 |
| Vascular compression | 2 | 0 |
| Vascular occlusion | 3 | 0 |
| Vasospasm | 13 | 0 |
| Venous occlusion | 1 | 0 |
| <i>Non-site specific vascular disorders NEC</i> | | |
| Angiopathy | 7 | 0 |
| Arterial rupture | 1 | 0 |
| Capillary disorder | 1 | 0 |
| Capillary fragility | 12 | 0 |
| Collateral circulation | 1 | 0 |
| Haemodynamic instability | 4 | 0 |
| Hyperaemia | 2 | 0 |
| Neovascularisation | 1 | 0 |
| Superficial vein prominence | 10 | 0 |
| Vascular fragility | 1 | 0 |
| Vascular pain | 141 | 0 |
| Vascular rupture | 2 | 0 |
| Vascular wall discolouration | 1 | 0 |
| Vasodilatation | 131 | 0 |
| Vein collapse | 2 | 0 |
| Vein discolouration | 10 | 0 |
| Vein disorder | 27 | 0 |
| Vein rupture | 17 | 0 |
| <i>Peripheral aneurysms and dissections</i> | | |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Vascular disorders <small>Vascular disorders cont'd</small> | | |
| Peripheral artery aneurysm | 3 | 0 |
| Peripheral embolism and thrombosis | | |
| Axillary vein thrombosis | 2 | 0 |
| Blue toe syndrome | 42 | 0 |
| Deep vein thrombosis | 1328 | 10 |
| Femoral artery embolism | 2 | 0 |
| Iliac artery embolism | 2 | 0 |
| Jugular vein thrombosis | 33 | 0 |
| Pelvic venous thrombosis | 24 | 1 |
| Peripheral artery thrombosis | 22 | 0 |
| Peripheral embolism | 11 | 0 |
| Peripheral vein thrombus extension | 1 | 0 |
| Subclavian artery embolism | 3 | 0 |
| Subclavian artery thrombosis | 1 | 0 |
| Subclavian vein thrombosis | 5 | 0 |
| Superficial vein thrombosis | 74 | 0 |
| Thrombophlebitis | 148 | 0 |
| Venous thrombosis limb | 7 | 0 |
| Peripheral vascular disorders NEC | | |
| Cyanosis | 126 | 0 |
| Erythromelalgia | 9 | 0 |
| Flushing | 723 | 0 |
| Hot flush | 2218 | 0 |
| Peripheral vascular disorder | 8 | 0 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | | |
| Dry gangrene | 2 | 0 |
| Extremity necrosis | 3 | 0 |
| Iliac artery occlusion | 2 | 0 |
| Intermittent claudication | 7 | 0 |
| Ischaemic limb pain | 5 | 0 |
| Jugular vein occlusion | 2 | 0 |
| May-Thurner syndrome | 1 | 0 |
| Peripheral arterial occlusive disease | 5 | 0 |
| Peripheral artery occlusion | 10 | 0 |
| Peripheral coldness | 1355 | 0 |
| Peripheral ischaemia | 37 | 2 |
| Poor peripheral circulation | 61 | 0 |
| Raynaud's phenomenon | 164 | 0 |
| Phlebitis NEC | | |
| Phlebitis | 69 | 0 |
| Phlebitis superficial | 13 | 0 |
| Site specific embolism and thrombosis NEC | | |
| Brachiocephalic vein thrombosis | 1 | 0 |
| Site specific necrosis and vascular insufficiency NEC | | |
| Superior vena cava syndrome | 1 | 0 |
| Site specific vascular disorders NEC | | |
| Aortic dilatation | 1 | 0 |
| Aortic rupture | 1 | 0 |
| Pallor | 437 | 0 |
| Plethoric face | 1 | 0 |
| Varicose veins NEC | | |
| Bleeding varicose vein | 2 | 0 |
| Spider vein | 21 | 0 |

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| Reaction Name | Total | Fatal |
|---|---------------|-------------|
| Vascular disorders <i>Vascular disorders cont'd</i> | | |
| Varicophlebitis | 11 | 0 |
| Varicose ulceration | 1 | 0 |
| Varicose vein | 158 | 0 |
| Varicose vein ruptured | 1 | 0 |
| Venous valve ruptured | 1 | 0 |
| <i>Vascular hypertensive disorders NEC</i> | | |
| Diastolic hypertension | 5 | 0 |
| Essential hypertension | 1 | 0 |
| Hypertension | 1100 | 1 |
| Labile hypertension | 2 | 0 |
| Neurogenic hypertension | 1 | 0 |
| Secondary hypertension | 1 | 0 |
| Systolic hypertension | 3 | 0 |
| Venous hypertension | 4 | 0 |
| White coat hypertension | 12 | 0 |
| <i>Vascular hypotensive disorders</i> | | |
| Capillary leak syndrome | 18 | 0 |
| Diastolic hypotension | 1 | 0 |
| Hypotension | 578 | 0 |
| Orthostatic hypotension | 50 | 0 |
| <i>Vascular malformations and acquired anomalies</i> | | |
| Arteriovenous fistula | 1 | 0 |
| <i>Vasculitides NEC</i> | | |
| Behcet's syndrome | 4 | 0 |
| Diffuse vasculitis | 2 | 1 |
| Granulomatosis with polyangiitis | 3 | 0 |
| MAGIC syndrome | 3 | 1 |
| Vasculitis | 118 | 2 |
| <i>Vena caval embolism and thrombosis</i> | | |
| Vena cava thrombosis | 9 | 1 |
| Vascular disorders SOC TOTAL | 14160 | 82 |
| TOTAL REACTIONS FOR DRUG | 874912 | 1334 |
| TOTAL REPORTS | 246866 | |
| TOTAL FATAL OUTCOME REPORTS | | 1334 |