

COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021
Data Lock Date: 21-Apr-2021 19:00:03

All UK spontaneous reports received between 04/01/2021 to 21/04/21 for COVID-19 vaccine Oxford University/AstraZeneca

Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Blood disorders | | |
| <i>Anaemia deficiencies</i> | | |
| Anaemia vitamin B12 deficiency | 4 | 0 |
| Iron deficiency anaemia | 1 | 0 |
| Pernicious anaemia | 1 | 0 |
| <i>Anaemias NEC</i> | | |
| Anaemia | 34 | 0 |
| Blood loss anaemia | 1 | 0 |
| Microcytic anaemia | 1 | 0 |
| Normocytic anaemia | 1 | 0 |
| <i>Anaemias haemolytic NEC</i> | | |
| Haemolytic anaemia | 3 | 0 |
| <i>Anaemias haemolytic immune</i> | | |
| Autoimmune haemolytic anaemia | 1 | 0 |
| <i>Bleeding tendencies</i> | | |
| Increased tendency to bruise | 57 | 0 |
| Spontaneous haematoma | 3 | 0 |
| <i>Coagulation factor deficiencies</i> | | |
| Hypofibrinogenaemia | 2 | 0 |
| <i>Coagulopathies</i> | | |
| Abnormal clotting factor | 3 | 0 |
| Antiphospholipid syndrome | 15 | 0 |
| Coagulopathy | 27 | 0 |
| Disseminated intravascular coagulation | 10 | 0 |
| Hypercoagulation | 13 | 1 |
| <i>Eosinophilic disorders</i> | | |
| Eosinophilia | 10 | 0 |
| Hypereosinophilic syndrome | 1 | 0 |
| <i>Haematological disorders</i> | | |
| Blood disorder | 1 | 0 |
| Bone marrow disorder | 1 | 0 |
| Bone marrow oedema | 1 | 0 |
| Mast cell activation syndrome | 5 | 0 |
| Mastocytosis | 1 | 0 |
| Methaemoglobinaemia | 1 | 0 |
| <i>Haemolyses NEC</i> | | |
| Haemolysis | 3 | 0 |
| <i>Leukocytoses NEC</i> | | |
| Leukocytosis | 3 | 0 |
| Lymphocytosis | 2 | 0 |
| Neutrophilia | 7 | 0 |
| <i>Leukopenias NEC</i> | | |
| Leukopenia | 7 | 0 |
| Lymphopenia | 7 | 0 |
| <i>Lymphatic system disorders NEC</i> | | |
| Lymph node fibrosis | 1 | 0 |
| Lymph node pain | 378 | 0 |
| Lymphadenitis | 18 | 0 |
| Lymphadenopathy | 3369 | 0 |
| Lymphatic disorder | 1 | 0 |
| Pseudolymphoma | 1 | 0 |
| <i>Marrow depression and hypoplastic anaemias</i> | | |
| Aplastic anaemia | 1 | 0 |
| Myelosuppression | 1 | 0 |

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|---|-------------|----------|
| Blood disorders Blood disorders cont'd | | |
| Pancytopenia | 10 | 0 |
| Neutropenias | | |
| Agranulocytosis | 4 | 0 |
| Autoimmune neutropenia | 2 | 0 |
| Febrile neutropenia | 1 | 0 |
| Neutropenia | 60 | 0 |
| Platelet disorders NEC | | |
| Platelet anisocytosis | 2 | 0 |
| Platelet disorder | 4 | 0 |
| Polycythaemia (excl rubra vera) | | |
| Stress polycythaemia | 2 | 0 |
| Purpuras (excl thrombocytopenic) | | |
| Purpura non-thrombocytopenic | 3 | 0 |
| Red blood cell abnormal findings NEC | | |
| Polychromasia | 1 | 0 |
| Sickle cell trait and disorders | | |
| Sickle cell anaemia with crisis | 3 | 0 |
| Spleen disorders | | |
| Spleen disorder | 1 | 0 |
| Splenic artery thrombosis | 2 | 0 |
| Splenic infarction | 6 | 0 |
| Splenic varices | 1 | 0 |
| Splenic vein thrombosis | 6 | 0 |
| Splenomegaly | 4 | 0 |
| Thrombocytopenias | | |
| Autoimmune heparin-induced thrombocytopenia | 1 | 0 |
| Heparin-induced thrombocytopenia | 6 | 0 |
| Immune thrombocytopenia | 122 | 1 |
| Thrombocytopenia | 398 | 3 |
| Thrombocytopenic purpura | 7 | 0 |
| Thrombotic thrombocytopenic purpura | 1 | 0 |
| Thrombocytoses | | |
| Thrombocytosis | 6 | 0 |
| White blood cell abnormal findings NEC | | |
| White blood cell disorder | 2 | 0 |
| Blood disorders SOC TOTAL | 4652 | 5 |

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| Cardiac disorders | | |
| <i>Aortic valvular disorders</i> | | |
| Aortic valve stenosis | 1 | 0 |
| <i>Cardiac conduction disorders</i> | | |
| Atrioventricular block | 13 | 0 |
| Atrioventricular block complete | 2 | 0 |
| Atrioventricular block second degree | 1 | 0 |
| Brugada syndrome | 1 | 0 |
| Bundle branch block | 1 | 0 |
| Bundle branch block left | 3 | 0 |
| Long QT syndrome | 1 | 0 |
| Trifascicular block | 1 | 0 |
| <i>Cardiac disorders NEC</i> | | |
| Acute cardiac event | 3 | 1 |
| Atrial thrombosis | 2 | 0 |
| Cardiac disorder | 32 | 0 |
| Cardiac ventricular thrombosis | 4 | 2 |
| Cardiovascular disorder | 3 | 0 |
| Cardiovascular insufficiency | 8 | 0 |
| Intracardiac thrombus | 1 | 0 |
| <i>Cardiac hypertensive complications</i> | | |
| Hypertensive heart disease | 1 | 0 |
| <i>Cardiac infections and inflammations NEC</i> | | |
| Carditis | 1 | 0 |
| <i>Cardiac signs and symptoms NEC</i> | | |
| Cardiac discomfort | 9 | 0 |
| Palpitations | 3492 | 0 |
| <i>Cardiac valve disorders NEC</i> | | |
| Cardiac valve disease | 1 | 1 |
| Heart valve incompetence | 1 | 0 |
| <i>Cardiomyopathies</i> | | |
| Cardiomyopathy | 5 | 0 |
| Congestive cardiomyopathy | 5 | 0 |
| Stress cardiomyopathy | 1 | 0 |
| <i>Coronary artery disorders NEC</i> | | |
| Arteriosclerosis coronary artery | 1 | 0 |
| Coronary artery disease | 4 | 0 |
| Coronary artery dissection | 1 | 0 |
| Coronary artery thrombosis | 7 | 1 |
| <i>Heart failures NEC</i> | | |
| Cardiac failure | 28 | 5 |
| Cardiac failure acute | 2 | 0 |
| Cardiac failure congestive | 1 | 0 |
| Cardiogenic shock | 4 | 2 |
| Cardiopulmonary failure | 1 | 1 |
| <i>Ischaemic coronary artery disorders</i> | | |
| Acute coronary syndrome | 2 | 0 |
| Acute myocardial infarction | 35 | 5 |
| Angina pectoris | 114 | 0 |
| Angina unstable | 10 | 0 |
| Arteriospasm coronary | 2 | 0 |
| Microvascular coronary artery disease | 2 | 0 |
| Myocardial infarction | 170 | 31 |
| Myocardial ischaemia | 16 | 7 |

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|---|-------|-------|
| Cardiac disorders Cardiac disorders cont'd | | |
| Prinzmetal angina | 1 | 0 |
| Left ventricular failures | | |
| Acute left ventricular failure | 1 | 0 |
| Left ventricular failure | 2 | 1 |
| Mitral valvular disorders | | |
| Mitral valve incompetence | 1 | 0 |
| Myocardial disorders NEC | | |
| Cardiomegaly | 5 | 0 |
| Left ventricular dilatation | 1 | 0 |
| Left ventricular dysfunction | 7 | 0 |
| Myocardial rupture | 1 | 0 |
| Right ventricular dysfunction | 1 | 0 |
| Noninfectious myocarditis | | |
| Myocarditis | 16 | 1 |
| Noninfectious pericarditis | | |
| Pericarditis | 33 | 0 |
| Pericardial disorders NEC | | |
| Cardiac tamponade | 1 | 1 |
| Pericardial effusion | 9 | 0 |
| Pericardial haemorrhage | 4 | 2 |
| Rate and rhythm disorders NEC | | |
| Arrhythmia | 73 | 0 |
| Bradycardia | 43 | 0 |
| Cardiac fibrillation | 1 | 0 |
| Cardiac flutter | 129 | 0 |
| Extrasystoles | 69 | 0 |
| Heart alternation | 2 | 0 |
| Paroxysmal arrhythmia | 1 | 0 |
| Postural orthostatic tachycardia syndrome | 8 | 0 |
| Tachyarrhythmia | 10 | 0 |
| Tachycardia | 974 | 0 |
| Right ventricular failures | | |
| Cor pulmonale | 1 | 0 |
| Right ventricular failure | 2 | 1 |
| Supraventricular arrhythmias | | |
| Arrhythmia supraventricular | 10 | 0 |
| Atrial fibrillation | 175 | 0 |
| Atrial flutter | 21 | 0 |
| Atrial tachycardia | 1 | 0 |
| Sinus arrest | 1 | 0 |
| Sinus arrhythmia | 2 | 0 |
| Sinus bradycardia | 1 | 0 |
| Sinus node dysfunction | 1 | 0 |
| Sinus tachycardia | 51 | 1 |
| Supraventricular extrasystoles | 1 | 0 |
| Supraventricular tachycardia | 20 | 0 |
| Tricuspid valvular disorders | | |
| Tricuspid valve incompetence | 1 | 0 |
| Ventricular arrhythmias and cardiac arrest | | |
| Cardiac arrest | 103 | 23 |
| Pulseless electrical activity | 2 | 0 |
| Ventricular arrhythmia | 1 | 0 |
| Ventricular extrasystoles | 2 | 0 |

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| Cardiac disorders Cardiac disorders cont'd | | |
| Ventricular fibrillation | 5 | 0 |
| Ventricular tachycardia | 11 | 0 |
| Cardiac disorders SOC TOTAL | 5798 | 86 |

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|--|-------|-------|
| Congenital disorders | | |
| <i>Cardiac disorders congenital NEC</i> | | |
| Heart disease congenital | 6 | 0 |
| <i>Cardiac septal defects congenital</i> | | |
| Hypertrophic cardiomyopathy | 4 | 0 |
| Ventricular septal defect | 2 | 0 |
| <i>Central nervous system disorders congenital NEC</i> | | |
| Neural tube defect | 1 | 1 |
| Syringomyelia | 2 | 0 |
| <i>Cerebellar disorders congenital</i> | | |
| Arnold-Chiari malformation | 3 | 0 |
| <i>Cerebral disorders congenital</i> | | |
| Anencephaly | 1 | 0 |
| Cerebral palsy | 4 | 0 |
| <i>Coagulation disorders congenital</i> | | |
| Haemophilia | 1 | 0 |
| Protein C deficiency | 2 | 0 |
| Protein S deficiency | 1 | 0 |
| <i>Congenital disorders NEC</i> | | |
| Foetal malformation | 1 | 0 |
| Young's syndrome | 1 | 0 |
| <i>Connective tissue disorders congenital</i> | | |
| Ehlers-Danlos syndrome | 5 | 0 |
| <i>Great vessel disorders congenital</i> | | |
| Transposition of the great vessels | 2 | 0 |
| <i>Haematological disorders congenital NEC</i> | | |
| Neonatal alloimmune thrombocytopenia | 1 | 0 |
| <i>Immune system abnormalities congenital</i> | | |
| Combined immunodeficiency | 1 | 0 |
| <i>Inborn errors of porphyrin metabolism</i> | | |
| Porphyria | 1 | 0 |
| Porphyria acute | 1 | 0 |
| <i>Lymphatic system disorders congenital</i> | | |
| Cystic lymphangioma | 1 | 0 |
| <i>Lysosomal storage disorders</i> | | |
| Mucopolysaccharidosis | 1 | 0 |
| <i>Male reproductive tract disorders congenital</i> | | |
| Hydrocele | 1 | 0 |
| Micropenis | 2 | 0 |
| <i>Musculoskeletal and connective tissue disorders of limbs congenital</i> | | |
| Congenital hand malformation | 1 | 0 |
| Limb reduction defect | 1 | 0 |
| Polydactyly | 1 | 0 |
| <i>Musculoskeletal disorders congenital NEC</i> | | |
| Congenital multiplex arthrogryposis | 1 | 0 |
| Dysmorphism | 2 | 0 |
| <i>Neurological disorders congenital NEC</i> | | |
| Epilepsy with myoclonic-atonic seizures | 1 | 0 |
| Familial hemiplegic migraine | 1 | 0 |
| Familial periodic paralysis | 1 | 0 |
| Spinal muscular atrophy | 1 | 0 |
| <i>Non-site specific muscle disorders congenital</i> | | |
| Muscular dystrophy | 2 | 0 |
| <i>Ocular disorders congenital NEC</i> | | |

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| Congenital disorders Congenital disorders cont'd | | |
| Colour blindness | 1 | 0 |
| <i>Pancreatic disorders congenital</i> | | |
| Hereditary pancreatitis | 1 | 0 |
| <i>Peripheral nervous system disorders congenital NEC</i> | | |
| Paroxysmal extreme pain disorder | 9 | 0 |
| <i>Pulmonary and bronchial disorders congenital</i> | | |
| Cystic fibrosis | 4 | 0 |
| <i>Renal disorders congenital</i> | | |
| Congenital cystic kidney disease | 1 | 0 |
| <i>Vascular anomalies congenital NEC</i> | | |
| Arteriovenous malformation | 1 | 0 |
| Klippel-Trenaunay syndrome | 2 | 0 |
| Congenital disorders SOC TOTAL | 76 | 1 |

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| Ear disorders | | |
| <i>Ear disorders NEC</i> | | |
| Ear congestion | 15 | 0 |
| Ear discomfort | 55 | 0 |
| Ear disorder | 7 | 0 |
| Ear haemorrhage | 7 | 0 |
| Ear pain | 1407 | 0 |
| Ear pruritus | 2 | 0 |
| Ear swelling | 41 | 0 |
| Otorrhoea | 4 | 0 |
| <i>Eustachian tube disorders</i> | | |
| Eustachian tube disorder | 1 | 0 |
| Eustachian tube dysfunction | 1 | 0 |
| Eustachian tube obstruction | 1 | 0 |
| <i>External ear disorders NEC</i> | | |
| Excessive cerumen production | 15 | 0 |
| External ear pain | 9 | 0 |
| Red ear syndrome | 5 | 0 |
| <i>Hearing disorders NEC</i> | | |
| Auditory disorder | 3 | 0 |
| <i>Hearing losses</i> | | |
| Deafness | 162 | 0 |
| Deafness bilateral | 5 | 0 |
| Deafness neurosensory | 7 | 0 |
| Deafness transitory | 2 | 0 |
| Deafness unilateral | 23 | 0 |
| Hypoacusis | 101 | 0 |
| Sudden hearing loss | 35 | 0 |
| <i>Hyperacusia</i> | | |
| Hyperacusis | 69 | 0 |
| <i>Inner ear disorders NEC</i> | | |
| Inner ear disorder | 3 | 0 |
| Meniere's disease | 16 | 0 |
| Vestibular disorder | 4 | 0 |
| <i>Inner ear infections and inflammations</i> | | |
| Inner ear inflammation | 2 | 0 |
| <i>Inner ear signs and symptoms</i> | | |
| Motion sickness | 70 | 0 |
| Phobic postural vertigo | 1 | 0 |
| Tinnitus | 1720 | 0 |
| Vertigo | 1110 | 0 |
| Vertigo labyrinthine | 7 | 0 |
| Vertigo positional | 60 | 0 |
| <i>Middle ear disorders NEC</i> | | |
| Middle ear disorder | 1 | 0 |
| Middle ear effusion | 2 | 0 |
| <i>Tympanic membrane disorders (excl infections)</i> | | |
| Tympanic membrane perforation | 1 | 0 |
| Ear disorders SOC TOTAL | 4974 | 0 |

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| Endocrine disorders | | |
| <i>Acute and chronic thyroiditis</i> | | |
| Autoimmune thyroiditis | 2 | 0 |
| Thyroiditis | 4 | 0 |
| Thyroiditis acute | 1 | 0 |
| Thyroiditis chronic | 1 | 0 |
| Thyroiditis subacute | 1 | 0 |
| <i>Adrenal cortical hyperfunctions</i> | | |
| Cushing's syndrome | 1 | 0 |
| Cushingoid | 5 | 0 |
| <i>Adrenal cortical hypofunctions</i> | | |
| Addison's disease | 1 | 0 |
| Adrenal insufficiency | 12 | 0 |
| Adrenocortical insufficiency acute | 26 | 0 |
| Glucocorticoid deficiency | 1 | 0 |
| <i>Adrenal gland disorders NEC</i> | | |
| Adrenal disorder | 1 | 0 |
| Adrenal haemorrhage | 5 | 0 |
| Adrenal mass | 1 | 0 |
| Haemorrhagic adrenal infarction | 1 | 0 |
| <i>Anterior pituitary hypofunction</i> | | |
| Hypopituitarism | 1 | 0 |
| <i>Endocrine abnormalities of puberty</i> | | |
| Premature menarche | 1 | 0 |
| <i>Female gonadal function disorders</i> | | |
| Anovulatory cycle | 5 | 0 |
| Ovulation delayed | 3 | 0 |
| <i>Posterior pituitary disorders</i> | | |
| Diabetes insipidus | 3 | 0 |
| Inappropriate antidiuretic hormone secretion | 1 | 0 |
| <i>Thyroid disorders NEC</i> | | |
| Goitre | 9 | 0 |
| Thyroid disorder | 4 | 0 |
| Thyroid mass | 2 | 0 |
| Thyroid pain | 7 | 0 |
| <i>Thyroid hyperfunction disorders</i> | | |
| Basedow's disease | 3 | 0 |
| Hyperthyroidism | 10 | 0 |
| Thyrotoxic crisis | 2 | 0 |
| <i>Thyroid hypofunction disorders</i> | | |
| Hypothyroidism | 24 | 0 |
| Endocrine disorders SOC TOTAL | 138 | 0 |

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| Eye disorders | | |
| <i>Amblyopic vision impairment</i> | | |
| Amblyopia | 3 | 0 |
| <i>Cataract conditions</i> | | |
| Cataract | 6 | 0 |
| Cataract cortical | 3 | 0 |
| Cataract subcapsular | 2 | 0 |
| <i>Choroid and vitreous haemorrhages and vascular disorders</i> | | |
| Vitreous haemorrhage | 3 | 0 |
| <i>Choroid and vitreous structural change, deposit and degeneration</i> | | |
| Chorioretinopathy | 2 | 0 |
| Vitreous detachment | 20 | 0 |
| Vitreous floaters | 81 | 0 |
| Vitreous opacities | 1 | 0 |
| <i>Colour blindness (incl acquired)</i> | | |
| Dyschromatopsia | 13 | 0 |
| <i>Conjunctival and corneal bleeding and vascular disorders</i> | | |
| Conjunctival haemorrhage | 66 | 0 |
| <i>Conjunctival infections, irritations and inflammations</i> | | |
| Conjunctival hyperaemia | 1 | 0 |
| <i>Corneal infections, oedemas and inflammations</i> | | |
| Keratitis | 2 | 0 |
| Ulcerative keratitis | 2 | 0 |
| <i>Corneal structural change, deposit and degeneration</i> | | |
| Corneal perforation | 1 | 0 |
| <i>Eyelid movement disorders</i> | | |
| Blepharospasm | 57 | 0 |
| Excessive eye blinking | 3 | 0 |
| Eyelid ptosis | 25 | 0 |
| <i>Glaucomas (excl congenital)</i> | | |
| Angle closure glaucoma | 1 | 0 |
| Glaucoma | 5 | 0 |
| <i>Iris and ciliary body structural change, deposit and degeneration</i> | | |
| Eye colour change | 6 | 0 |
| <i>Iris and uveal tract infections, irritations and inflammations</i> | | |
| Autoimmune uveitis | 1 | 0 |
| Iridocyclitis | 10 | 0 |
| Iritis | 6 | 0 |
| Uveitis | 20 | 0 |
| <i>Lacrimation disorders</i> | | |
| Dry eye | 184 | 0 |
| Lacrimation increased | 156 | 0 |
| <i>Lens structural change, deposit and degeneration (excl cataracts)</i> | | |
| Anterior capsule contraction | 1 | 0 |
| <i>Lid bleeding and vascular disorders</i> | | |
| Eyelid bleeding | 1 | 0 |
| Eyelid haematoma | 1 | 0 |
| <i>Lid, lash and lacrimal infections, irritations and inflammations</i> | | |
| Blepharitis | 5 | 0 |
| Chalazion | 1 | 0 |
| Eczema eyelids | 1 | 0 |
| Erythema of eyelid | 4 | 0 |
| Eyelid cyst | 6 | 0 |
| Eyelid irritation | 1 | 0 |

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| Eye disorders Eye disorders cont'd | | |
| Eyelid margin crusting | 1 | 0 |
| Eyelid oedema | 9 | 0 |
| Eyelid rash | 5 | 0 |
| Swelling of eyelid | 66 | 0 |
| Lid, lash and lacrimal structural disorders | | |
| Eyelid exfoliation | 1 | 0 |
| Eyelid skin dryness | 1 | 0 |
| Eyelid thickening | 3 | 0 |
| Growth of eyelashes | 4 | 0 |
| Lagophthalmos | 1 | 0 |
| Ocular bleeding and vascular disorders NEC | | |
| Eye haematoma | 1 | 0 |
| Eye haemorrhage | 49 | 0 |
| Ocular vascular disorder | 1 | 0 |
| Ophthalmic vein thrombosis | 1 | 0 |
| Ocular disorders NEC | | |
| Dark circles under eyes | 6 | 0 |
| Eye disorder | 11 | 0 |
| Eye oedema | 11 | 0 |
| Eye pain | 2455 | 0 |
| Eye swelling | 378 | 0 |
| Eye symptom | 4 | 0 |
| Eye ulcer | 6 | 0 |
| Eyelid disorder | 3 | 0 |
| Eyelid pain | 11 | 0 |
| Eyelids pruritus | 3 | 0 |
| Ocular discomfort | 38 | 0 |
| Periorbital oedema | 11 | 0 |
| Periorbital pain | 3 | 0 |
| Periorbital swelling | 65 | 0 |
| Retinal disorder | 1 | 0 |
| Ocular infections, inflammations and associated manifestations | | |
| Eye allergy | 14 | 0 |
| Eye discharge | 16 | 0 |
| Eye inflammation | 24 | 0 |
| Eye irritation | 146 | 0 |
| Eye pruritus | 205 | 0 |
| Limbal swelling | 4 | 0 |
| Ocular hyperaemia | 262 | 0 |
| Ocular rosacea | 1 | 0 |
| Ocular nerve and muscle disorders | | |
| Extraocular muscle paresis | 7 | 0 |
| Eye movement disorder | 29 | 0 |
| Gaze palsy | 2 | 0 |
| Ocular myasthenia | 1 | 0 |
| Ophthalmoplegia | 1 | 0 |
| Strabismus | 2 | 0 |
| Ocular sensation disorders | | |
| Abnormal sensation in eye | 18 | 0 |
| Asthenopia | 237 | 0 |
| Eyelid sensory disorder | 3 | 0 |
| Foreign body sensation in eyes | 26 | 0 |
| Hypoaesthesia eye | 15 | 0 |

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| Eye disorders Eye disorders cont'd | | |
| Photophobia | 746 | 0 |
| Optic disc abnormalities NEC | | |
| Papilloedema | 7 | 0 |
| Optic nerve bleeding and vascular disorders | | |
| Optic disc haemorrhage | 1 | 0 |
| Optic ischaemic neuropathy | 3 | 0 |
| Orbital structural change, deposit and degeneration | | |
| Lid sulcus deepened | 2 | 0 |
| Pupil disorders | | |
| Miosis | 7 | 0 |
| Mydriasis | 19 | 0 |
| Pupil fixed | 5 | 0 |
| Pupils unequal | 7 | 0 |
| Refractive and accommodative disorders | | |
| Altered visual depth perception | 3 | 0 |
| Hypermetropia | 1 | 0 |
| Retinal bleeding and vascular disorders (excl retinopathy) | | |
| Retinal aneurysm | 1 | 0 |
| Retinal artery embolism | 1 | 0 |
| Retinal artery occlusion | 9 | 0 |
| Retinal haemorrhage | 6 | 0 |
| Retinal vascular thrombosis | 1 | 0 |
| Retinal vein occlusion | 18 | 0 |
| Retinal vein thrombosis | 2 | 0 |
| Retinal vein varices | 1 | 0 |
| Retinal structural change, deposit and degeneration | | |
| Macular degeneration | 3 | 0 |
| Macular detachment | 1 | 0 |
| Macular hole | 1 | 0 |
| Neovascular age-related macular degeneration | 7 | 0 |
| Retinal detachment | 7 | 0 |
| Retinal drusen | 1 | 0 |
| Retinal tear | 5 | 0 |
| Retinal toxicity | 1 | 0 |
| Vitreoretinal traction syndrome | 1 | 0 |
| Retinal, choroid and vitreous infections and inflammations | | |
| Macular oedema | 4 | 0 |
| Retinopathies NEC | | |
| Acute macular outer retinopathy | 4 | 0 |
| Retinal exudates | 9 | 0 |
| Retinopathy | 4 | 0 |
| Scleral infections, irritations and inflammations | | |
| Episcleritis | 8 | 0 |
| Scleritis | 3 | 0 |
| Scleral structural change, deposit and degeneration | | |
| Scleral discolouration | 1 | 0 |
| Structural change, deposit and degeneration of eye NEC | | |
| Deposit eye | 1 | 0 |
| Endocrine ophthalmopathy | 2 | 0 |
| Exophthalmos | 3 | 0 |
| Visual colour distortions | | |
| Chloropsia | 1 | 0 |
| Chromatopsia | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Eye disorders Eye disorders cont'd | | |
| Erythropsia | 3 | 0 |
| Xanthopsia | 5 | 0 |
| Visual disorders NEC | | |
| Diplopia | 189 | 0 |
| Halo vision | 8 | 0 |
| Metamorphopsia | 21 | 0 |
| Photopsia | 198 | 0 |
| Scintillating scotoma | 3 | 0 |
| Vision blurred | 1534 | 0 |
| Visual brightness | 4 | 0 |
| Visual snow syndrome | 1 | 0 |
| Visual impairment and blindness (excl colour blindness) | | |
| Amaurosis fugax | 5 | 0 |
| Blindness | 134 | 0 |
| Blindness transient | 10 | 0 |
| Blindness unilateral | 11 | 0 |
| Central vision loss | 1 | 0 |
| Night blindness | 4 | 0 |
| Sudden visual loss | 3 | 0 |
| Visual acuity reduced | 14 | 0 |
| Visual impairment | 391 | 0 |
| Visual pathway disorders | | |
| Optic nerve disorder | 1 | 0 |
| Eye disorders SOC TOTAL | 8311 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Abdominal findings abnormal</i> | | |
| Abdominal mass | 2 | 0 |
| Gastrointestinal sounds abnormal | 15 | 0 |
| <i>Acute and chronic pancreatitis</i> | | |
| Obstructive pancreatitis | 1 | 1 |
| Pancreatitis | 22 | 1 |
| Pancreatitis acute | 7 | 0 |
| Pancreatitis chronic | 1 | 0 |
| <i>Anal and rectal disorders NEC</i> | | |
| Anal fissure | 2 | 0 |
| <i>Anal and rectal pains</i> | | |
| Proctalgia | 18 | 0 |
| <i>Anal and rectal signs and symptoms</i> | | |
| Anal blister | 2 | 0 |
| Anal hypoaesthesia | 3 | 0 |
| Anal inflammation | 1 | 0 |
| Anal paraesthesia | 1 | 0 |
| Anal pruritus | 3 | 0 |
| Anorectal discomfort | 4 | 0 |
| Rectal discharge | 1 | 0 |
| <i>Benign oral cavity neoplasms</i> | | |
| Mouth cyst | 11 | 0 |
| Tongue cyst | 1 | 0 |
| Tongue polyp | 2 | 0 |
| <i>Colitis (excl infective)</i> | | |
| Autoimmune colitis | 2 | 0 |
| Colitis | 28 | 0 |
| Colitis ischaemic | 2 | 1 |
| Colitis microscopic | 2 | 0 |
| Colitis ulcerative | 49 | 0 |
| Crohn's disease | 50 | 0 |
| Inflammatory bowel disease | 6 | 0 |
| Terminal ileitis | 1 | 0 |
| <i>Dental and periodontal infections and inflammations</i> | | |
| Dental caries | 2 | 0 |
| <i>Dental disorders NEC</i> | | |
| Diastema | 1 | 0 |
| Loose tooth | 1 | 0 |
| Malpositioned teeth | 1 | 0 |
| Teething | 17 | 0 |
| Tooth disorder | 1 | 0 |
| Tooth socket haemorrhage | 1 | 0 |
| <i>Dental pain and sensation disorders</i> | | |
| Dental discomfort | 10 | 0 |
| Dental paraesthesia | 14 | 0 |
| Hyperaesthesia teeth | 34 | 0 |
| Hypoaesthesia teeth | 2 | 0 |
| Toothache | 220 | 0 |
| <i>Dental pulp disorders</i> | | |
| Dental pulp disorder | 1 | 0 |
| <i>Dental surface disorders</i> | | |
| Tooth discolouration | 6 | 0 |
| <i>Diaphragmatic hernias</i> | | |

Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Hiatus hernia | 8 | 0 |
| <i>Diarrhoea (excl infective)</i> | | |
| Diarrhoea | 6470 | 0 |
| Diarrhoea haemorrhagic | 20 | 0 |
| <i>Diverticula</i> | | |
| Diverticulum | 5 | 0 |
| <i>Duodenal and small intestinal stenosis and obstruction</i> | | |
| Small intestinal obstruction | 1 | 0 |
| <i>Duodenal ulcers and perforation</i> | | |
| Duodenal ulcer | 1 | 0 |
| Duodenal ulcer haemorrhage | 1 | 1 |
| <i>Dyspeptic signs and symptoms</i> | | |
| Dyspepsia | 583 | 0 |
| Epigastric discomfort | 13 | 0 |
| Eructation | 61 | 0 |
| <i>Faecal abnormalities NEC</i> | | |
| Abnormal faeces | 12 | 0 |
| Faecaloma | 3 | 0 |
| Faeces discoloured | 34 | 0 |
| Faeces hard | 4 | 0 |
| Faeces pale | 5 | 0 |
| Faeces soft | 14 | 0 |
| Mucous stools | 10 | 0 |
| <i>Flatulence, bloating and distension</i> | | |
| Abdominal distension | 303 | 0 |
| Flatulence | 298 | 0 |
| <i>Gastric and oesophageal haemorrhages</i> | | |
| Gastric haemorrhage | 5 | 0 |
| <i>Gastric ulcers and perforation</i> | | |
| Gastric ulcer | 6 | 0 |
| Gastric ulcer haemorrhage | 1 | 0 |
| Gastric ulcer perforation | 1 | 0 |
| <i>Gastritis (excl infective)</i> | | |
| Chronic gastritis | 2 | 0 |
| Gastritis | 55 | 0 |
| Reflux gastritis | 10 | 0 |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> | | |
| Abdominal migraine | 3 | 0 |
| Abdominal pain | 3174 | 0 |
| Abdominal pain lower | 157 | 0 |
| Abdominal pain upper | 3618 | 0 |
| Abdominal rigidity | 35 | 0 |
| Abdominal tenderness | 16 | 0 |
| Gastrointestinal pain | 230 | 0 |
| Oesophageal pain | 5 | 0 |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i> | | |
| Constipation | 289 | 0 |
| Duodenogastric reflux | 2 | 0 |
| Gastric dilatation | 12 | 0 |
| Gastrooesophageal reflux disease | 136 | 0 |
| Impaired gastric emptying | 2 | 0 |
| Infrequent bowel movements | 3 | 0 |
| Intestinal dilatation | 1 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021
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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| <i>Gastrointestinal disorders NEC</i> | | |
| Appendix disorder | 1 | 0 |
| Food poisoning | 9 | 0 |
| Functional gastrointestinal disorder | 7 | 0 |
| Gastric disorder | 6 | 0 |
| Gastrointestinal disorder | 19 | 0 |
| Gastrointestinal oedema | 2 | 0 |
| Gastroptosis | 1 | 0 |
| Neurogenic bowel | 1 | 0 |
| <i>Gastrointestinal dyskinetic disorders</i> | | |
| Bowel movement irregularity | 3 | 0 |
| Change of bowel habit | 9 | 0 |
| Defaecation disorder | 1 | 0 |
| Dyschezia | 9 | 0 |
| Gastrointestinal motility disorder | 1 | 0 |
| Oesophageal achalasia | 2 | 0 |
| <i>Gastrointestinal inflammatory disorders NEC</i> | | |
| Appendicitis noninfective | 1 | 0 |
| Gastrointestinal tract irritation | 3 | 0 |
| Intestinal angioedema | 1 | 0 |
| <i>Gastrointestinal mucosal dystrophies and secretion disorders</i> | | |
| Achlorhydria | 1 | 0 |
| Hyperchlorhydria | 2 | 0 |
| <i>Gastrointestinal necrosis and gangrene (excl gangrenous hernia)</i> | | |
| Gastrointestinal necrosis | 1 | 0 |
| <i>Gastrointestinal signs and symptoms NEC</i> | | |
| Abdominal discomfort | 1140 | 0 |
| Abdominal symptom | 5 | 0 |
| Acute abdomen | 10 | 0 |
| Anal incontinence | 27 | 0 |
| Breath odour | 16 | 0 |
| Dysphagia | 143 | 0 |
| Intestinal congestion | 1 | 0 |
| <i>Gastrointestinal spastic and hypermotility disorders</i> | | |
| Cardiospasm | 1 | 1 |
| Defaecation urgency | 11 | 0 |
| Frequent bowel movements | 29 | 0 |
| Irritable bowel syndrome | 69 | 0 |
| Oesophageal spasm | 4 | 0 |
| <i>Gastrointestinal stenosis and obstruction NEC</i> | | |
| Intestinal obstruction | 4 | 0 |
| Intussusception | 1 | 0 |
| <i>Gastrointestinal vascular malformations</i> | | |
| Gastric antral vascular ectasia | 4 | 0 |
| <i>Gastrointestinal vascular occlusion and infarction</i> | | |
| Intestinal infarction | 3 | 0 |
| Intestinal ischaemia | 14 | 1 |
| Mesenteric artery embolism | 1 | 0 |
| Mesenteric artery thrombosis | 2 | 0 |
| Mesenteric vein thrombosis | 8 | 0 |
| Mesenteric venous occlusion | 1 | 0 |
| Thrombosis mesenteric vessel | 3 | 0 |
| Visceral venous thrombosis | 6 | 1 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| <i>Gingival disorders, signs and symptoms NEC</i> | | |
| Gingival blister | 18 | 0 |
| Gingival discomfort | 3 | 0 |
| Gingival disorder | 11 | 0 |
| Gingival hypertrophy | 1 | 0 |
| Gingival oedema | 2 | 0 |
| Gingival pain | 160 | 0 |
| Gingival pruritus | 1 | 0 |
| Gingival recession | 1 | 0 |
| Gingival swelling | 32 | 0 |
| Gingival ulceration | 5 | 0 |
| Gingivitis ulcerative | 1 | 0 |
| Noninfective gingivitis | 15 | 0 |
| <i>Gingival haemorrhages</i> | | |
| Gingival bleeding | 71 | 0 |
| <i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i> | | |
| Haemorrhoidal haemorrhage | 1 | 0 |
| Haemorrhoids | 33 | 0 |
| Haemorrhoids thrombosed | 7 | 0 |
| <i>Inguinal hernias</i> | | |
| Inguinal hernia | 3 | 0 |
| <i>Intestinal haemorrhages</i> | | |
| Anal haemorrhage | 20 | 0 |
| Intestinal haemorrhage | 1 | 0 |
| Mesenteric haemorrhage | 1 | 0 |
| Rectal haemorrhage | 56 | 0 |
| Small intestinal haemorrhage | 22 | 0 |
| <i>Intestinal ulcers and perforation NEC</i> | | |
| Intestinal perforation | 2 | 0 |
| Large intestine perforation | 1 | 0 |
| <i>Large intestinal stenosis and obstruction</i> | | |
| Large intestinal stenosis | 1 | 0 |
| <i>Malabsorption syndromes</i> | | |
| Coeliac disease | 11 | 0 |
| Steatorrhoea | 1 | 0 |
| <i>Nausea and vomiting symptoms</i> | | |
| Acetonaemic vomiting | 1 | 0 |
| Discoloured vomit | 16 | 0 |
| Faecal vomiting | 2 | 0 |
| Infantile vomiting | 1 | 0 |
| Nausea | 26214 | 0 |
| Regurgitation | 2 | 0 |
| Retching | 187 | 0 |
| Vomiting | 8777 | 3 |
| Vomiting projectile | 120 | 0 |
| <i>Non-site specific gastrointestinal haemorrhages</i> | | |
| Gastrointestinal haemorrhage | 16 | 0 |
| Haematemesis | 49 | 0 |
| Haematochezia | 47 | 0 |
| Melaena | 4 | 0 |
| Upper gastrointestinal haemorrhage | 2 | 0 |
| <i>Oesophageal disorders NEC</i> | | |
| Oesophageal disorder | 2 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| <i>Oesophageal stenosis and obstruction</i> | | |
| Oesophageal obstruction | 1 | 0 |
| <i>Oesophagitis (excl infective)</i> | | |
| Eosinophilic oesophagitis | 3 | 0 |
| Oesophagitis | 8 | 0 |
| <i>Oral dryness and saliva altered</i> | | |
| Aptyalism | 3 | 0 |
| Dry mouth | 879 | 0 |
| Lip dry | 56 | 0 |
| Saliva altered | 4 | 0 |
| Saliva discolouration | 1 | 0 |
| Salivary hypersecretion | 47 | 0 |
| <i>Oral soft tissue disorders NEC</i> | | |
| Angina bullosa haemorrhagica | 1 | 0 |
| Chapped lips | 13 | 0 |
| Cheilitis | 23 | 0 |
| Chronic cheek biting | 1 | 0 |
| Enlarged uvula | 6 | 0 |
| Leukoplakia oral | 2 | 0 |
| Lip blister | 21 | 0 |
| Lip disorder | 3 | 0 |
| Oral disorder | 9 | 0 |
| Oral lichen planus | 7 | 0 |
| Oral papule | 1 | 0 |
| Palatal disorder | 1 | 0 |
| Uvulitis | 4 | 0 |
| <i>Oral soft tissue haemorrhages</i> | | |
| Lip haemorrhage | 2 | 0 |
| Mouth haemorrhage | 23 | 0 |
| Oral blood blister | 33 | 0 |
| Oral purpura | 2 | 0 |
| <i>Oral soft tissue infections</i> | | |
| Angular cheilitis | 5 | 0 |
| <i>Oral soft tissue signs and symptoms</i> | | |
| Anaesthesia oral | 6 | 0 |
| Burning mouth syndrome | 7 | 0 |
| Coating in mouth | 3 | 0 |
| Hypoaesthesia oral | 423 | 0 |
| Lip discolouration | 1 | 0 |
| Lip erythema | 4 | 0 |
| Lip exfoliation | 8 | 0 |
| Lip pain | 43 | 0 |
| Lip pruritus | 13 | 0 |
| Odynophagia | 22 | 0 |
| Oral discomfort | 54 | 0 |
| Oral mucosal blistering | 20 | 0 |
| Oral mucosal eruption | 15 | 0 |
| Oral mucosal erythema | 2 | 0 |
| Oral mucosal exfoliation | 8 | 0 |
| Oral mucosal roughening | 2 | 0 |
| Oral pain | 250 | 0 |
| Oral pruritus | 15 | 0 |
| Paraesthesia oral | 598 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| <i>Oral soft tissue swelling and oedema</i> | | |
| Lip oedema | 6 | 0 |
| Lip swelling | 634 | 0 |
| Mouth swelling | 87 | 0 |
| Oedema mouth | 1 | 0 |
| Palatal oedema | 1 | 0 |
| Palatal swelling | 11 | 0 |
| <i>Pancreatic disorders NEC</i> | | |
| Pancreatic disorder | 1 | 0 |
| Pancreatic mass | 1 | 0 |
| <i>Peritoneal and retroperitoneal disorders</i> | | |
| Ascites | 3 | 0 |
| <i>Peritoneal and retroperitoneal haemorrhages</i> | | |
| Retroperitoneal haemorrhage | 1 | 0 |
| <i>Rectal inflammations NEC</i> | | |
| Proctitis | 2 | 0 |
| <i>Salivary gland disorders NEC</i> | | |
| Salivary gland calculus | 3 | 0 |
| Salivary gland pain | 5 | 0 |
| <i>Salivary gland enlargements</i> | | |
| Parotid gland enlargement | 7 | 0 |
| Salivary gland enlargement | 4 | 0 |
| <i>Salivary gland infections and inflammations</i> | | |
| Noninfective sialoadenitis | 2 | 0 |
| <i>Stomatitis and ulceration</i> | | |
| Aphthous ulcer | 45 | 0 |
| Lip ulceration | 12 | 0 |
| Mouth ulceration | 507 | 0 |
| Stomatitis | 65 | 0 |
| <i>Tongue disorders</i> | | |
| Glossitis | 13 | 0 |
| Plicated tongue | 3 | 0 |
| Tongue disorder | 21 | 0 |
| Tongue geographic | 2 | 0 |
| Tongue haemorrhage | 2 | 0 |
| Tongue ulceration | 23 | 0 |
| Trichoglossia | 4 | 0 |
| <i>Tongue signs and symptoms</i> | | |
| Glossodynia | 175 | 0 |
| Scalloped tongue | 3 | 0 |
| Stiff tongue | 2 | 0 |
| Strawberry tongue | 1 | 0 |
| Swollen tongue | 413 | 0 |
| Tongue blistering | 17 | 0 |
| Tongue coated | 26 | 0 |
| Tongue discolouration | 19 | 0 |
| Tongue discomfort | 33 | 0 |
| Tongue dry | 16 | 0 |
| Tongue eruption | 6 | 0 |
| Tongue erythema | 3 | 0 |
| Tongue exfoliation | 1 | 0 |
| Tongue movement disturbance | 6 | 0 |
| Tongue oedema | 13 | 0 |

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| Reaction Name | Total | Fatal |
|---|--------------|-----------|
| Gastrointestinal disorders | | |
| Gastrointestinal disorders cont'd | | |
| Tongue pruritus | 1 | 0 |
| Tongue rough | 1 | 0 |
| Tongue spasm | 3 | 0 |
| Tooth missing | | |
| Tooth loss | 2 | 0 |
| Gastrointestinal disorders SOC TOTAL | 58521 | 10 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders | | |
| <i>Administration site reactions NEC</i> | | |
| Administration site bruise | 11 | 0 |
| Administration site coldness | 1 | 0 |
| Administration site erythema | 5 | 0 |
| Administration site extravasation | 2 | 0 |
| Administration site induration | 1 | 0 |
| Administration site mass | 1 | 0 |
| Administration site pain | 35 | 0 |
| Administration site rash | 2 | 0 |
| Administration site reaction | 4 | 0 |
| Administration site swelling | 2 | 0 |
| Administration site urticaria | 2 | 0 |
| Puncture site bruise | 47 | 0 |
| Puncture site haemorrhage | 1 | 0 |
| Puncture site pain | 18 | 0 |
| Puncture site reaction | 3 | 0 |
| Puncture site swelling | 1 | 0 |
| <i>Adverse effect absent</i> | | |
| No adverse event | 15 | 0 |
| <i>Application and instillation site reactions</i> | | |
| Application site acne | 1 | 0 |
| Application site bruise | 19 | 0 |
| Application site burn | 3 | 0 |
| Application site discolouration | 1 | 0 |
| Application site erythema | 21 | 0 |
| Application site exfoliation | 1 | 0 |
| Application site haemorrhage | 1 | 0 |
| Application site hypersensitivity | 1 | 0 |
| Application site inflammation | 1 | 0 |
| Application site joint pain | 1 | 0 |
| Application site pain | 29 | 0 |
| Application site pruritus | 14 | 0 |
| Application site rash | 1 | 0 |
| Application site scar | 1 | 0 |
| Application site swelling | 4 | 0 |
| Application site vesicles | 5 | 0 |
| Application site warmth | 1 | 0 |
| Application site wound | 1 | 0 |
| Instillation site bruise | 1 | 0 |
| Instillation site discomfort | 1 | 0 |
| Instillation site pain | 4 | 0 |
| Instillation site pruritus | 1 | 0 |
| Instillation site warmth | 12 | 0 |
| <i>Asthenic conditions</i> | | |
| Asthenia | 3377 | 3 |
| Chronic fatigue syndrome | 74 | 0 |
| Decreased activity | 4 | 0 |
| Fatigue | 36661 | 0 |
| Malaise | 9281 | 3 |
| Sluggishness | 16 | 0 |
| <i>Body temperature altered</i> | | |
| Hyperthermia | 8 | 0 |
| Hypothermia | 45 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Temperature regulation disorder | 14 | 0 |
| Complications associated with device NEC | | |
| Injury associated with device | 3 | 0 |
| Medical device site joint pain | 1 | 0 |
| Phantom shocks | 3 | 0 |
| Death and sudden death | | |
| Brain death | 3 | 3 |
| Death | 216 | 216 |
| Drowning | 1 | 0 |
| Sudden death | 24 | 24 |
| Febrile disorders | | |
| Hyperpyrexia | 37 | 0 |
| Masked fever | 1 | 0 |
| PFAPA syndrome | 1 | 0 |
| Pyrexia | 44382 | 0 |
| Feelings and sensations NEC | | |
| Chills | 35426 | 0 |
| Early satiety | 1 | 0 |
| Feeling abnormal | 2005 | 0 |
| Feeling cold | 4133 | 0 |
| Feeling drunk | 88 | 0 |
| Feeling hot | 1772 | 0 |
| Feeling jittery | 30 | 0 |
| Feeling of body temperature change | 763 | 0 |
| Hangover | 126 | 0 |
| Hunger | 52 | 0 |
| Sensation of blood flow | 9 | 0 |
| Sensation of foreign body | 28 | 0 |
| Temperature intolerance | 49 | 0 |
| Thirst | 987 | 0 |
| Thirst decreased | 8 | 0 |
| Fibrosis NEC | | |
| Fibrosis | 2 | 0 |
| Gait disturbances | | |
| Decreased gait velocity | 2 | 0 |
| Gait disturbance | 234 | 0 |
| Gait inability | 126 | 0 |
| Loss of control of legs | 31 | 0 |
| General signs and symptoms NEC | | |
| Chronic disease | 1 | 0 |
| Condition aggravated | 146 | 0 |
| Crepitations | 4 | 0 |
| Crying | 184 | 0 |
| Developmental delay | 3 | 0 |
| Discharge | 4 | 0 |
| Disease progression | 1 | 0 |
| Disease recurrence | 1 | 0 |
| Energy increased | 16 | 0 |
| Exercise tolerance decreased | 19 | 0 |
| Foaming at mouth | 4 | 0 |
| General physical health deterioration | 13 | 1 |
| General symptom | 9 | 0 |
| Glassy eyes | 5 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| High-pitched crying | 3 | 0 |
| Ill-defined disorder | 2 | 0 |
| Illness | 3790 | 0 |
| Induration | 13 | 0 |
| Influenza like illness | 7522 | 1 |
| Irritability postvaccinal | 2 | 0 |
| Local reaction | 137 | 0 |
| Moaning | 8 | 0 |
| Multiple organ dysfunction syndrome | 8 | 1 |
| Nonspecific reaction | 3 | 0 |
| Organ failure | 1 | 0 |
| Peripheral swelling | 4015 | 0 |
| Pre-existing condition improved | 9 | 0 |
| Premature ageing | 1 | 0 |
| Prolapse | 1 | 0 |
| Screaming | 13 | 0 |
| Secretion discharge | 17 | 0 |
| Stenosis | 1 | 0 |
| Swelling | 1852 | 0 |
| Swelling face | 672 | 0 |
| Symptom recurrence | 2 | 0 |
| Tissue discolouration | 1 | 0 |
| Tissue infiltration | 1 | 0 |
| Unevaluable event | 2 | 0 |
| Healing abnormal NEC | | |
| Impaired healing | 1 | 0 |
| Hernias NEC | | |
| Hernia | 2 | 0 |
| Implant and catheter site reactions | | |
| Catheter site urticaria | 1 | 0 |
| Implant site coldness | 1 | 0 |
| Implant site discharge | 1 | 0 |
| Implant site discolouration | 3 | 0 |
| Implant site hypoaesthesia | 2 | 0 |
| Implant site pain | 3 | 0 |
| Implant site rash | 1 | 0 |
| Implant site swelling | 2 | 0 |
| Implant site warmth | 7 | 0 |
| Inflammations | | |
| Inflammation | 438 | 0 |
| Systemic inflammatory response syndrome | 1 | 0 |
| Infusion site reactions | | |
| Infusion site bruising | 1 | 0 |
| Infusion site erythema | 2 | 0 |
| Infusion site mass | 2 | 0 |
| Infusion site nodule | 2 | 0 |
| Infusion site pain | 8 | 0 |
| Infusion site urticaria | 1 | 0 |
| Infusion site warmth | 6 | 0 |
| Injection site reactions | | |
| Injected limb mobility decreased | 28 | 0 |
| Injection site atrophy | 5 | 0 |
| Injection site bruising | 90 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Injection site coldness | 3 | 0 |
| Injection site cyst | 2 | 0 |
| Injection site discolouration | 4 | 0 |
| Injection site discomfort | 13 | 0 |
| Injection site dryness | 1 | 0 |
| Injection site erythema | 468 | 0 |
| Injection site exfoliation | 1 | 0 |
| Injection site extravasation | 1 | 0 |
| Injection site haematoma | 2 | 0 |
| Injection site haemorrhage | 8 | 0 |
| Injection site hypersensitivity | 4 | 0 |
| Injection site hypoaesthesia | 10 | 0 |
| Injection site indentation | 9 | 0 |
| Injection site induration | 6 | 0 |
| Injection site inflammation | 47 | 0 |
| Injection site injury | 3 | 0 |
| Injection site irritation | 2 | 0 |
| Injection site joint discomfort | 1 | 0 |
| Injection site joint erythema | 7 | 0 |
| Injection site joint pain | 30 | 0 |
| Injection site mass | 1140 | 0 |
| Injection site movement impairment | 2 | 0 |
| Injection site muscle weakness | 1 | 0 |
| Injection site necrosis | 1 | 0 |
| Injection site nodule | 4 | 0 |
| Injection site oedema | 22 | 0 |
| Injection site pain | 3543 | 0 |
| Injection site papule | 2 | 0 |
| Injection site paraesthesia | 15 | 0 |
| Injection site pruritus | 235 | 0 |
| Injection site rash | 229 | 0 |
| Injection site reaction | 89 | 0 |
| Injection site scab | 4 | 0 |
| Injection site scar | 5 | 0 |
| Injection site swelling | 184 | 0 |
| Injection site ulcer | 1 | 0 |
| Injection site urticaria | 31 | 0 |
| Injection site vesicles | 8 | 0 |
| Injection site warmth | 287 | 0 |
| Interactions | | |
| Drug interaction | 18 | 0 |
| Inhibitory drug interaction | 9 | 0 |
| Mass conditions NEC | | |
| Cyst | 11 | 0 |
| Mass | 57 | 0 |
| Nodule | 9 | 0 |
| Mucosal findings abnormal | | |
| Mucosal disorder | 1 | 0 |
| Mucosal dryness | 1 | 0 |
| Mucosal haemorrhage | 2 | 0 |
| Mucosal inflammation | 5 | 0 |
| Mucosal pain | 2 | 0 |
| Mucosal ulceration | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Oedema mucosal | 2 | 0 |
| Polyp | 1 | 0 |
| Necrosis NEC | | |
| Necrosis | 3 | 0 |
| Oedema NEC | | |
| Face oedema | 25 | 0 |
| Localised oedema | 8 | 0 |
| Oedema | 41 | 0 |
| Oedema peripheral | 66 | 0 |
| Pain and discomfort NEC | | |
| Axillary pain | 501 | 0 |
| Chest discomfort | 1415 | 0 |
| Chest pain | 3182 | 0 |
| Discomfort | 318 | 0 |
| Facial discomfort | 8 | 0 |
| Facial pain | 179 | 0 |
| Hernia pain | 2 | 0 |
| Inflammatory pain | 16 | 0 |
| Non-cardiac chest pain | 26 | 0 |
| Pain | 11731 | 0 |
| Tenderness | 1483 | 0 |
| Visceral pain | 2 | 0 |
| Therapeutic and nontherapeutic responses | | |
| Adverse drug reaction | 673 | 3 |
| Adverse event | 6 | 0 |
| Adverse reaction | 27 | 0 |
| Diet failure | 1 | 0 |
| Drug ineffective | 77 | 0 |
| Drug intolerance | 3 | 0 |
| Immediate post-injection reaction | 4 | 0 |
| Inadequate analgesia | 11 | 0 |
| No reaction on previous exposure to drug | 40 | 0 |
| Remission not achieved | 1 | 0 |
| Therapeutic product effect decreased | 1 | 0 |
| Therapeutic product ineffective | 1 | 0 |
| Therapeutic reaction time decreased | 1 | 0 |
| Therapeutic response decreased | 1 | 0 |
| Therapeutic response shortened | 1 | 0 |
| Therapeutic response unexpected | 56 | 0 |
| Therapy non-responder | 2 | 0 |
| Treatment failure | 3 | 0 |
| Vaccine positive rechallenge | 1 | 0 |
| Trophic disorders | | |
| Atrophy | 2 | 0 |
| Calcinosis | 1 | 0 |
| Dysplasia | 1 | 0 |
| Ulcers NEC | | |
| Ulcer | 26 | 0 |
| Ulcer haemorrhage | 1 | 0 |
| Vaccination site reactions | | |
| Extensive swelling of vaccinated limb | 15 | 0 |
| Shoulder injury related to vaccine administration | 17 | 0 |
| Vaccination site bruising | 98 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|---------------|------------|
| General disorders General disorders cont'd | | |
| Vaccination site coldness | 1 | 0 |
| Vaccination site cyst | 2 | 0 |
| Vaccination site discharge | 1 | 0 |
| Vaccination site discolouration | 8 | 0 |
| Vaccination site discomfort | 30 | 0 |
| Vaccination site dryness | 1 | 0 |
| Vaccination site erythema | 521 | 0 |
| Vaccination site extravasation | 1 | 0 |
| Vaccination site granuloma | 7 | 0 |
| Vaccination site haemorrhage | 4 | 0 |
| Vaccination site hyperaesthesia | 1 | 0 |
| Vaccination site hypersensitivity | 3 | 0 |
| Vaccination site hypoaesthesia | 16 | 0 |
| Vaccination site induration | 53 | 0 |
| Vaccination site inflammation | 42 | 0 |
| Vaccination site injury | 3 | 0 |
| Vaccination site irritation | 10 | 0 |
| Vaccination site joint erythema | 3 | 0 |
| Vaccination site joint movement impairment | 7 | 0 |
| Vaccination site joint pain | 38 | 0 |
| Vaccination site joint swelling | 3 | 0 |
| Vaccination site joint warmth | 1 | 0 |
| Vaccination site lymphadenopathy | 2 | 0 |
| Vaccination site mass | 415 | 0 |
| Vaccination site movement impairment | 41 | 0 |
| Vaccination site nodule | 1 | 0 |
| Vaccination site oedema | 2 | 0 |
| Vaccination site pain | 1493 | 0 |
| Vaccination site papule | 3 | 0 |
| Vaccination site paraesthesia | 10 | 0 |
| Vaccination site pruritus | 81 | 0 |
| Vaccination site rash | 136 | 0 |
| Vaccination site reaction | 18 | 0 |
| Vaccination site scar | 3 | 0 |
| Vaccination site swelling | 372 | 0 |
| Vaccination site urticaria | 8 | 0 |
| Vaccination site vesicles | 6 | 0 |
| Vaccination site warmth | 294 | 0 |
| <i>Vascular complications associated with device</i> | | |
| Vascular stent occlusion | 1 | 0 |
| <i>Withdrawal and rebound effects</i> | | |
| Drug withdrawal syndrome | 4 | 0 |
| Withdrawal syndrome | 54 | 0 |
| General disorders SOC TOTAL | 189718 | 254 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Hepatic disorders | | |
| <i>Bile duct infections and inflammations</i> | | |
| Biliary colic | 17 | 0 |
| Cholangitis | 3 | 0 |
| <i>Cholecystitis and cholelithiasis</i> | | |
| Cholecystitis | 7 | 0 |
| Cholelithiasis | 7 | 0 |
| <i>Cholestasis and jaundice</i> | | |
| Cholestasis | 3 | 0 |
| Jaundice | 29 | 0 |
| Jaundice cholestatic | 6 | 0 |
| Ocular icterus | 1 | 0 |
| <i>Gallbladder disorders NEC</i> | | |
| Gallbladder disorder | 1 | 0 |
| Gallbladder oedema | 1 | 0 |
| <i>Hepatic and hepatobiliary disorders NEC</i> | | |
| Liver disorder | 5 | 0 |
| <i>Hepatic enzymes and function abnormalities</i> | | |
| Hepatic function abnormal | 3 | 0 |
| <i>Hepatic failure and associated disorders</i> | | |
| Hepatic failure | 2 | 0 |
| Subacute hepatic failure | 1 | 0 |
| <i>Hepatic fibrosis and cirrhosis</i> | | |
| Hepatic cirrhosis | 4 | 0 |
| <i>Hepatic vascular disorders</i> | | |
| Budd-Chiari syndrome | 1 | 1 |
| Hepatic artery thrombosis | 1 | 0 |
| Hepatic haemorrhage | 1 | 0 |
| Hepatic infarction | 1 | 0 |
| Hepatic vein thrombosis | 6 | 0 |
| Portal hypertension | 1 | 0 |
| Portal vein thrombosis | 28 | 5 |
| Portosplenomesenteric venous thrombosis | 1 | 0 |
| <i>Hepatobiliary signs and symptoms</i> | | |
| Hepatic pain | 45 | 0 |
| Hepatomegaly | 2 | 0 |
| Liver tenderness | 3 | 0 |
| <i>Hepatocellular damage and hepatitis NEC</i> | | |
| Autoimmune hepatitis | 1 | 0 |
| Drug-induced liver injury | 2 | 0 |
| Hepatic steatosis | 1 | 0 |
| Hepatitis | 14 | 0 |
| Hepatitis acute | 3 | 0 |
| Immune-mediated hepatitis | 1 | 0 |
| Ischaemic hepatitis | 2 | 0 |
| Liver injury | 12 | 0 |
| Reye's syndrome | 1 | 0 |
| <i>Obstructive bile duct disorders (excl neoplasms)</i> | | |
| Sphincter of Oddi dysfunction | 1 | 0 |
| Hepatic disorders SOC TOTAL | 218 | 6 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Immune system disorders | | |
| <i>Acute and chronic sarcoidosis</i> | | |
| Sarcoidosis | 12 | 0 |
| <i>Allergic conditions NEC</i> | | |
| Allergic oedema | 16 | 0 |
| Allergy to animal | 1 | 0 |
| Allergy to arthropod sting | 2 | 0 |
| Allergy to metals | 1 | 0 |
| Allergy to sting | 1 | 0 |
| Allergy to venom | 1 | 0 |
| Dust allergy | 1 | 0 |
| Hypersensitivity | 913 | 0 |
| Infusion related hypersensitivity reaction | 3 | 0 |
| Mite allergy | 2 | 0 |
| Multiple allergies | 10 | 0 |
| Serum sickness | 15 | 0 |
| Serum sickness-like reaction | 12 | 0 |
| Type III immune complex mediated reaction | 4 | 0 |
| Type IV hypersensitivity reaction | 2 | 0 |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> | | |
| Allergic reaction to excipient | 1 | 0 |
| Allergy to chemicals | 5 | 0 |
| Allergy to vaccine | 42 | 0 |
| Contrast media allergy | 1 | 0 |
| Contrast media reaction | 1 | 0 |
| Drug hypersensitivity | 52 | 0 |
| Food allergy | 10 | 0 |
| Oral allergy syndrome | 1 | 0 |
| Reaction to excipient | 11 | 0 |
| Reaction to preservatives | 10 | 0 |
| Smoke sensitivity | 1 | 0 |
| <i>Anaphylactic and anaphylactoid responses</i> | | |
| Anaphylactic reaction | 462 | 1 |
| Anaphylactic shock | 81 | 0 |
| Anaphylactoid reaction | 15 | 0 |
| Anaphylactoid shock | 3 | 0 |
| <i>Atopic disorders</i> | | |
| Atopy | 1 | 0 |
| Seasonal allergy | 40 | 0 |
| <i>Autoimmune disorders NEC</i> | | |
| Autoimmune disorder | 16 | 0 |
| <i>Endocrine autoimmune disorders</i> | | |
| Hashitoxicosis | 1 | 0 |
| <i>Immune and associated conditions NEC</i> | | |
| Bacille Calmette-Guerin scar reactivation | 17 | 0 |
| Cytokine release syndrome | 1 | 0 |
| Cytokine storm | 1 | 0 |
| Haemophagocytic lymphohistiocytosis | 3 | 0 |
| Immune system disorder | 13 | 0 |
| Immune-mediated adverse reaction | 3 | 0 |
| Immunisation reaction | 1 | 0 |
| Pre-engraftment immune reaction | 1 | 0 |
| Sensitisation | 22 | 0 |
| <i>Immunodeficiency disorders NEC</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------------|----------|
| Immune system disorders | | |
| Immune system disorders cont'd | | |
| Immunodeficiency | 2 | 0 |
| Immunosuppression | 1 | 0 |
| Transplant rejections | | |
| Corneal graft rejection | 1 | 0 |
| Transplant rejection | 4 | 0 |
| Vasculitides | | |
| Eosinophilic granulomatosis with polyangiitis | 1 | 0 |
| Immune system disorders SOC TOTAL | 1821 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections | | |
| <i>Abdominal and gastrointestinal infections</i> | | |
| Anal abscess | 1 | 0 |
| Appendicitis | 20 | 0 |
| Appendicitis perforated | 1 | 0 |
| Diarrhoea infectious | 1 | 0 |
| Diverticulitis | 13 | 0 |
| Dysentery | 4 | 0 |
| Gastroenteritis | 21 | 0 |
| Gastrointestinal infection | 3 | 0 |
| Large intestine infection | 1 | 0 |
| Peritonitis | 1 | 0 |
| <i>Bacterial infections NEC</i> | | |
| Administration site cellulitis | 1 | 0 |
| Arthritis bacterial | 3 | 0 |
| Bacterial infection | 15 | 1 |
| Cellulitis | 382 | 1 |
| Endocarditis bacterial | 2 | 0 |
| Injection site cellulitis | 6 | 0 |
| Perichondritis | 1 | 0 |
| Periorbital cellulitis | 1 | 0 |
| Pneumonia bacterial | 3 | 1 |
| Skin bacterial infection | 2 | 0 |
| Urinary tract infection bacterial | 1 | 0 |
| Vaccination site cellulitis | 16 | 0 |
| <i>Bone and joint infections</i> | | |
| Arthritis infective | 2 | 0 |
| Intervertebral discitis | 2 | 0 |
| Osteomyelitis | 1 | 0 |
| <i>Bordetella infections</i> | | |
| Pertussis | 1 | 0 |
| <i>Borrelial infections</i> | | |
| Erythema migrans | 2 | 0 |
| Lyme disease | 4 | 0 |
| Relapsing fever | 1 | 0 |
| <i>Breast infections</i> | | |
| Mastitis | 12 | 0 |
| <i>Brucella infections</i> | | |
| Brucellosis | 1 | 0 |
| <i>Candida infections</i> | | |
| Anal candidiasis | 1 | 0 |
| Balanitis candida | 1 | 0 |
| Candida infection | 32 | 0 |
| Oral candidiasis | 27 | 0 |
| Skin candida | 2 | 0 |
| Vulvovaginal candidiasis | 26 | 0 |
| <i>Central nervous system and spinal infections</i> | | |
| Cavernous sinus thrombosis | 4 | 0 |
| Encephalitis | 16 | 0 |
| Encephalomyelitis | 1 | 0 |
| Extradural abscess | 1 | 0 |
| Meningitis | 16 | 0 |
| Myelitis | 6 | 0 |
| <i>Chlamydial infections</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections | | |
| Infections cont'd | | |
| Chlamydial infection | 1 | 0 |
| <i>Clostridia infections</i> | | |
| Clostridium difficile colitis | 2 | 0 |
| Clostridium difficile infection | 2 | 0 |
| Tetanus | 1 | 0 |
| <i>Coronavirus infections</i> | | |
| Asymptomatic COVID-19 | 3 | 0 |
| COVID-19 | 335 | 21 |
| COVID-19 pneumonia | 19 | 7 |
| Coronavirus infection | 4 | 0 |
| Severe acute respiratory syndrome | 4 | 0 |
| Suspected COVID-19 | 29 | 0 |
| <i>Corynebacteria infections</i> | | |
| Diphtheria | 1 | 0 |
| <i>Coxiella infections</i> | | |
| Q fever | 92 | 0 |
| <i>Dental and oral soft tissue infections</i> | | |
| Abscess oral | 3 | 0 |
| Gingival abscess | 3 | 0 |
| Gingivitis | 18 | 0 |
| Lip infection | 1 | 0 |
| Oral infection | 1 | 0 |
| Oral pustule | 2 | 0 |
| Parotitis | 10 | 0 |
| Pericoronitis | 2 | 0 |
| Periodontitis | 1 | 0 |
| Sialoadenitis | 1 | 0 |
| Tongue abscess | 3 | 0 |
| Tooth abscess | 8 | 0 |
| Tooth infection | 5 | 0 |
| <i>Ear infections</i> | | |
| Ear infection | 47 | 0 |
| Labyrinthitis | 81 | 0 |
| Mastoiditis | 2 | 0 |
| Otitis externa | 2 | 0 |
| Otitis media | 6 | 0 |
| Otosalpingitis | 1 | 0 |
| <i>Ectoparasitic infestations</i> | | |
| Acarodermatitis | 1 | 0 |
| Infestation | 1 | 0 |
| Trombidiasis | 2 | 0 |
| <i>Epstein-Barr viral infections</i> | | |
| Epstein-Barr virus infection | 1 | 0 |
| Infectious mononucleosis | 35 | 0 |
| <i>Escherichia infections</i> | | |
| Escherichia infection | 1 | 0 |
| Escherichia sepsis | 1 | 0 |
| <i>Eye and eyelid infections</i> | | |
| Conjunctivitis | 46 | 0 |
| Eye infection | 16 | 0 |
| Eyelid boil | 1 | 0 |
| Eyelid infection | 3 | 0 |
| Hordeolum | 18 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Infections Infections cont'd | | |
| Keratouveitis | 1 | 0 |
| Female reproductive tract infections | | |
| Endometritis | 1 | 0 |
| Pyometra | 1 | 1 |
| Vaginal abscess | 1 | 0 |
| Vaginal infection | 2 | 0 |
| Flaviviral infections | | |
| Yellow fever | 1 | 0 |
| Yellow fever vaccine-associated neurotropic disease | 1 | 0 |
| Fungal infections NEC | | |
| Ear infection fungal | 1 | 0 |
| Fungal infection | 8 | 0 |
| Fungal skin infection | 3 | 0 |
| Severe asthma with fungal sensitisation | 2 | 0 |
| Tonsillitis fungal | 1 | 0 |
| Vulvovaginal mycotic infection | 3 | 0 |
| Hepatitis viral infections | | |
| Hepatitis E | 1 | 0 |
| Hepatobiliary and spleen infections | | |
| Biliary sepsis | 4 | 1 |
| Herpes viral infections | | |
| Eczema herpeticum | 2 | 0 |
| Genital herpes | 32 | 0 |
| Genital herpes simplex | 1 | 0 |
| Haemorrhagic varicella syndrome | 1 | 0 |
| Herpes dermatitis | 1 | 0 |
| Herpes ophthalmic | 11 | 0 |
| Herpes simplex | 20 | 0 |
| Herpes simplex reactivation | 2 | 0 |
| Herpes virus infection | 8 | 0 |
| Herpes zoster | 592 | 0 |
| Herpes zoster oticus | 6 | 0 |
| Herpes zoster reactivation | 1 | 0 |
| Nasal herpes | 10 | 0 |
| Ophthalmic herpes simplex | 1 | 0 |
| Ophthalmic herpes zoster | 4 | 0 |
| Oral herpes | 469 | 0 |
| Varicella | 13 | 0 |
| Varicella zoster virus infection | 1 | 0 |
| Infections NEC | | |
| Abscess | 17 | 0 |
| Abscess limb | 12 | 0 |
| Catheter site infection | 1 | 0 |
| Coinfection | 1 | 0 |
| Genital abscess | 1 | 0 |
| Infected bite | 1 | 0 |
| Infected cyst | 1 | 0 |
| Infection | 301 | 3 |
| Infection in an immunocompromised host | 3 | 0 |
| Infectious thyroiditis | 1 | 0 |
| Injection site abscess | 1 | 0 |
| Injection site infection | 12 | 0 |
| Localised infection | 79 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Infections Infections cont'd | | |
| Lymph gland infection | 3 | 0 |
| Omphalitis | 1 | 0 |
| Pathogen resistance | 2 | 0 |
| Respiratory tract infection | 4 | 0 |
| Toxic shock syndrome | 1 | 0 |
| Vaccination site abscess | 2 | 0 |
| Vaccination site infection | 19 | 0 |
| Vestibulitis | 1 | 0 |
| <i>Infectious transmissions</i> | | |
| Secondary transmission | 4 | 0 |
| <i>Influenza viral infections</i> | | |
| H2N2 influenza | 1 | 0 |
| Influenza | 5247 | 0 |
| <i>Lower respiratory tract and lung infections</i> | | |
| Atypical pneumonia | 1 | 0 |
| Bronchitis | 14 | 0 |
| Infectious pleural effusion | 3 | 0 |
| Infective exacerbation of bronchiectasis | 1 | 0 |
| Lower respiratory tract infection | 135 | 3 |
| Pneumonia | 122 | 17 |
| <i>Male reproductive tract infections</i> | | |
| Epididymitis | 1 | 0 |
| Orchitis | 1 | 0 |
| <i>Mumps viral infections</i> | | |
| Mumps | 3 | 0 |
| <i>Muscle and soft tissue infections</i> | | |
| Muscle abscess | 1 | 0 |
| Soft tissue infection | 4 | 0 |
| <i>Paravaccinia infections</i> | | |
| Paravaccinia | 1 | 0 |
| <i>Phleboviral infections</i> | | |
| Severe fever with thrombocytopenia syndrome | 5 | 0 |
| <i>Plasmodia infections</i> | | |
| Malaria | 4 | 0 |
| <i>Pneumocystis infections</i> | | |
| Pneumocystis jirovecii pneumonia | 1 | 0 |
| <i>Polyomavirus infections</i> | | |
| Progressive multifocal leukoencephalopathy | 1 | 0 |
| <i>Prion-associated disorders</i> | | |
| Creutzfeldt-Jakob disease | 1 | 0 |
| <i>Retroviral infections</i> | | |
| Acquired immunodeficiency syndrome | 1 | 0 |
| HIV-associated neurocognitive disorder | 1 | 0 |
| <i>Rubeola viral infections</i> | | |
| Measles | 2 | 0 |
| <i>Salmonella infections</i> | | |
| Typhoid fever | 1 | 0 |
| <i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i> | | |
| Abdominal sepsis | 1 | 0 |
| Neutropenic sepsis | 6 | 0 |
| Sepsis | 54 | 5 |
| Sepsis syndrome | 1 | 0 |
| Septic rash | 6 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections | | |
| Infections cont'd | | |
| Septic shock | 2 | 0 |
| Urosepsis | 5 | 1 |
| Viraemia | 3 | 0 |
| <i>Skin structures and soft tissue infections</i> | | |
| Carbuncle | 1 | 0 |
| Dermatitis infected | 8 | 0 |
| Eczema infected | 1 | 0 |
| Folliculitis | 4 | 0 |
| Impetigo | 2 | 0 |
| Infected dermal cyst | 2 | 0 |
| Pilonidal cyst | 1 | 0 |
| Pustule | 8 | 0 |
| Rash pustular | 12 | 0 |
| Skin infection | 52 | 0 |
| Subcutaneous abscess | 7 | 0 |
| Vaccination site pustule | 3 | 0 |
| <i>Staphylococcal infections</i> | | |
| Furuncle | 27 | 0 |
| Staphylococcal bacteraemia | 1 | 0 |
| Staphylococcal scalded skin syndrome | 1 | 0 |
| Staphylococcal sepsis | 3 | 1 |
| Toxic shock syndrome staphylococcal | 1 | 0 |
| <i>Streptococcal infections</i> | | |
| Cellulitis streptococcal | 1 | 0 |
| Erysipelas | 1 | 0 |
| Pharyngitis streptococcal | 6 | 0 |
| Scarlet fever | 1 | 0 |
| Tonsillitis streptococcal | 1 | 0 |
| <i>Tinea infections</i> | | |
| Body tinea | 3 | 0 |
| Tinea cruris | 1 | 0 |
| Tinea infection | 1 | 0 |
| Tinea pedis | 2 | 0 |
| Tinea versicolour | 1 | 0 |
| <i>Trypanosomal infections</i> | | |
| African trypanosomiasis | 5 | 0 |
| <i>Tuberculous infections</i> | | |
| Disseminated Bacillus Calmette-Guerin infection | 1 | 0 |
| Lymph node tuberculosis | 3 | 0 |
| Pulmonary tuberculosis | 1 | 0 |
| Tuberculosis | 3 | 0 |
| <i>Upper respiratory tract infections</i> | | |
| Acute sinusitis | 3 | 0 |
| Chronic sinusitis | 8 | 0 |
| Epiglottitis | 1 | 0 |
| Laryngitis | 17 | 0 |
| Nasopharyngitis | 1247 | 0 |
| Pharyngitis | 16 | 0 |
| Rhinitis | 27 | 0 |
| Sinobronchitis | 1 | 0 |
| Sinusitis | 203 | 0 |
| Tonsillitis | 49 | 0 |
| Tracheitis | 1 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|-------------------------------------|--------------|-----------|
| Infections Infections cont'd | | |
| Upper respiratory tract infection | 2 | 0 |
| Urinary tract infections | | |
| Cystitis | 52 | 0 |
| Genitourinary tract infection | 1 | 0 |
| Kidney infection | 30 | 0 |
| Pyelonephritis | 2 | 0 |
| Urinary tract infection | 124 | 0 |
| Vascular infections | | |
| Haematoma infection | 1 | 0 |
| Infected lymphocele | 1 | 0 |
| Lymphangitis | 6 | 0 |
| Viral infections NEC | | |
| Arthritis viral | 1 | 0 |
| Bronchitis viral | 1 | 0 |
| Encephalitis viral | 4 | 0 |
| Gastroenteritis viral | 49 | 0 |
| Meningitis viral | 10 | 0 |
| Pneumonia viral | 5 | 1 |
| Post viral fatigue syndrome | 73 | 0 |
| Sweating fever | 606 | 0 |
| Vestibular neuronitis | 13 | 0 |
| Viral diarrhoea | 4 | 0 |
| Viral infection | 40 | 0 |
| Viral labyrinthitis | 2 | 0 |
| Viral myocarditis | 1 | 0 |
| Viral pharyngitis | 20 | 0 |
| Viral rash | 54 | 0 |
| Viral sepsis | 1 | 0 |
| Viral sinusitis | 1 | 0 |
| Viral tonsillitis | 1 | 0 |
| Infections SOC TOTAL | 11621 | 64 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries | | |
| <i>Abdominal and gastrointestinal injuries NEC</i> | | |
| Abdomen crushing | 3 | 0 |
| Colon injury | 1 | 0 |
| Lip injury | 1 | 0 |
| Oral contusion | 10 | 0 |
| Palate injury | 1 | 0 |
| Splenic rupture | 2 | 0 |
| Tongue injury | 2 | 0 |
| Tooth injury | 1 | 0 |
| <i>Accidental exposures to product</i> | | |
| Accidental exposure to product | 12 | 0 |
| <i>Anaesthetic and allied procedural complications</i> | | |
| Anaesthetic complication | 1 | 0 |
| Anaesthetic complication neurological | 1 | 0 |
| Delayed recovery from anaesthesia | 4 | 0 |
| Sedation complication | 2 | 0 |
| <i>Atmospheric pressure injuries</i> | | |
| Barotrauma | 1 | 0 |
| Decompression sickness | 1 | 0 |
| Hypobarism | 2 | 0 |
| <i>Bone and joint injuries NEC</i> | | |
| Bursa injury | 1 | 0 |
| Cartilage injury | 1 | 0 |
| Joint injury | 3 | 0 |
| Synovial rupture | 1 | 0 |
| <i>Cardiac and vascular procedural complications</i> | | |
| Vascular access site bruising | 1 | 0 |
| <i>Cardiovascular injuries</i> | | |
| Heart injury | 3 | 0 |
| Vascular injury | 2 | 0 |
| <i>Cerebral injuries NEC</i> | | |
| Brain contusion | 8 | 0 |
| Brain herniation | 3 | 0 |
| Concussion | 3 | 0 |
| Cranio-cerebral injury | 1 | 0 |
| Extradural haematoma | 1 | 0 |
| Subarachnoid haematoma | 1 | 0 |
| Subdural haematoma | 5 | 0 |
| Subdural haemorrhage | 1 | 0 |
| <i>Chemical injuries</i> | | |
| Chemical burn | 1 | 0 |
| Chemical burn of oral cavity | 1 | 0 |
| Chemical burn of skin | 3 | 0 |
| Chemical phlebitis | 2 | 0 |
| <i>Chest and respiratory tract injuries NEC</i> | | |
| Chest crushing | 9 | 0 |
| Foreign body in throat | 1 | 0 |
| Traumatic lung injury | 1 | 0 |
| <i>Conditions caused by cold</i> | | |
| Chillblains | 45 | 0 |
| <i>Cranial nerve injuries</i> | | |
| Cranial nerve injury | 1 | 0 |
| Optic nerve injury | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries Injuries cont'd | | |
| <i>Exposures associated with pregnancy, delivery and lactation</i> | | |
| Exposure during pregnancy | 5 | 0 |
| Exposure via breast milk | 40 | 0 |
| Foetal exposure during pregnancy | 31 | 0 |
| Maternal exposure during breast feeding | 715 | 0 |
| Maternal exposure during pregnancy | 150 | 0 |
| Maternal exposure timing unspecified | 1 | 0 |
| Paternal exposure before pregnancy | 1 | 0 |
| Paternal exposure during pregnancy | 6 | 0 |
| <i>Exposures to agents or circumstances NEC</i> | | |
| Exposure to SARS-CoV-2 | 2 | 0 |
| Exposure to toxic agent | 1 | 0 |
| <i>Eye injuries NEC</i> | | |
| Cataract traumatic | 1 | 0 |
| Eye contusion | 37 | 0 |
| Eye injury | 12 | 0 |
| Foreign body in eye | 1 | 0 |
| Injury corneal | 1 | 0 |
| Periorbital haematoma | 1 | 0 |
| Periorbital haemorrhage | 1 | 0 |
| Retinal injury | 2 | 0 |
| Superficial injury of eye | 1 | 0 |
| <i>Fractures and dislocations NEC</i> | | |
| Fracture | 1 | 0 |
| Joint dislocation | 6 | 0 |
| Stress fracture | 3 | 0 |
| <i>Gastrointestinal and hepatobiliary procedural complications</i> | | |
| Procedural nausea | 24 | 0 |
| Procedural vomiting | 7 | 0 |
| <i>Heat injuries (excl thermal burns)</i> | | |
| Heat exhaustion | 3 | 0 |
| Heat illness | 3 | 0 |
| Heat oedema | 12 | 0 |
| Heat stroke | 6 | 0 |
| <i>Intentional product use issues</i> | | |
| Intentional product use issue | 1 | 0 |
| <i>Limb fractures and dislocations</i> | | |
| Ankle fracture | 2 | 0 |
| Clavicle fracture | 10 | 0 |
| Femoral neck fracture | 1 | 0 |
| Femur fracture | 2 | 0 |
| Lower limb fracture | 1 | 0 |
| Patella fracture | 1 | 0 |
| Tibia fracture | 1 | 0 |
| Upper limb fracture | 1 | 0 |
| <i>Medication errors, product use errors and issues NEC</i> | | |
| Circumstance or information capable of leading to medication error | 2 | 0 |
| Device use issue | 1 | 0 |
| Drug titration error | 1 | 0 |
| Intercepted medication error | 1 | 0 |
| Medication error | 16 | 0 |
| Product use issue | 1 | 0 |
| Vaccination error | 3 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Injuries Injuries cont'd | | |
| Wrong drug | 3 | 0 |
| Wrong technique in product usage process | 5 | 0 |
| Muscle, tendon and ligament injuries | | |
| Epicondylitis | 10 | 0 |
| Ligament injury | 2 | 0 |
| Ligament rupture | 1 | 0 |
| Ligament sprain | 9 | 0 |
| Muscle injury | 16 | 0 |
| Muscle rupture | 9 | 0 |
| Muscle strain | 23 | 0 |
| Post-traumatic neck syndrome | 3 | 0 |
| Repetitive strain injury | 2 | 0 |
| Tendon injury | 2 | 0 |
| Tendon rupture | 9 | 0 |
| Nerve injuries NEC | | |
| Nerve injury | 50 | 0 |
| Neurological and psychiatric procedural complications | | |
| Post lumbar puncture syndrome | 6 | 0 |
| Procedural dizziness | 26 | 0 |
| Non-occupational environmental exposures | | |
| Exposure to chemical pollution | 1 | 0 |
| Exposure to extreme temperature | 4 | 0 |
| Exposure to noise | 2 | 0 |
| Non-site specific injuries NEC | | |
| Animal bite | 1 | 0 |
| Arthropod bite | 4 | 0 |
| Arthropod sting | 9 | 0 |
| Bite | 1 | 0 |
| Electric shock | 16 | 0 |
| Fall | 159 | 1 |
| Inflammation of wound | 3 | 0 |
| Injury | 6 | 0 |
| Internal injury | 1 | 0 |
| Nervous system injury | 2 | 0 |
| Post concussion syndrome | 2 | 0 |
| Road traffic accident | 1 | 0 |
| Soft tissue injury | 1 | 0 |
| Tissue injury | 1 | 0 |
| Traumatic haematoma | 2 | 0 |
| Traumatic shock | 1 | 0 |
| Wound | 4 | 0 |
| Wound complication | 8 | 0 |
| Wound haemorrhage | 7 | 0 |
| Wound secretion | 2 | 0 |
| Non-site specific procedural complications | | |
| Incision site erythema | 1 | 0 |
| Incision site haemorrhage | 1 | 0 |
| Incision site oedema | 1 | 0 |
| Incision site pain | 9 | 0 |
| Infusion related reaction | 18 | 0 |
| Injection related reaction | 550 | 0 |
| Needle fatigue | 1 | 0 |
| Post procedural complication | 33 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Injuries Injuries cont'd | | |
| Post procedural contusion | 2 | 0 |
| Procedural hypertension | 1 | 0 |
| Procedural pain | 3 | 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 | 3 | 0 |
| Overdoses NEC | | |
| Intentional overdose | 2 | 0 |
| Overdose | 14 | 0 |
| Peripheral nerve injuries | | |
| Brachial plexus injury | 1 | 0 |
| Median nerve injury | 2 | 0 |
| Sciatic nerve injury | 1 | 0 |
| Ulnar nerve injury | 1 | 0 |
| Poisoning and toxicity | | |
| Alcohol poisoning | 3 | 0 |
| Chemical poisoning | 1 | 0 |
| Poisoning | 5 | 0 |
| Systemic toxicity | 1 | 0 |
| Toxicity to various agents | 5 | 0 |
| Product administration errors and issues | | |
| Accidental overdose | 2 | 0 |
| Accidental underdose | 1 | 0 |
| Contraindicated product administered | 4 | 0 |
| Duplicate therapy error | 2 | 0 |
| Expired product administered | 17 | 0 |
| Extra dose administered | 5 | 0 |
| Inappropriate schedule of product administration | 5 | 0 |
| Incorrect dose administered | 1 | 0 |
| Incorrect product formulation administered | 1 | 0 |
| Incorrect route of product administration | 10 | 0 |
| Intercepted product administration error | 1 | 0 |
| Lack of vaccination site rotation | 1 | 0 |
| Product administered at inappropriate site | 5 | 0 |
| Product administered to patient of inappropriate age | 6 | 0 |
| Product administration error | 8 | 0 |
| Wrong patient received product | 1 | 0 |
| Wrong product administered | 12 | 0 |
| Product confusion errors and issues | | |
| Product label confusion | 1 | 0 |
| Product dispensing errors and issues | | |
| Product dispensing error | 9 | 0 |
| Product monitoring errors and issues | | |
| Product monitoring error | 1 | 0 |
| Product prescribing errors and issues | | |
| Contraindicated product prescribed | 5 | 0 |
| Product prescribing error | 1 | 0 |
| Product storage errors and issues in the product use system | | |
| Product storage error | 2 | 0 |
| Radiation injuries | | |

Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries Injuries cont'd | | |
| Sunburn | 29 | 0 |
| Renal and urinary tract injuries NEC | | |
| Bladder injury | 1 | 0 |
| Reproductive system and breast injuries | | |
| Penile contusion | 1 | 0 |
| Reproductive tract and breast procedural complications | | |
| Postmastectomy lymphoedema syndrome | 1 | 0 |
| Respiratory tract and thoracic cavity procedural complications | | |
| Pulmonary oil microembolism | 1 | 0 |
| Site specific injuries NEC | | |
| Back injury | 5 | 0 |
| Central nervous system injury | 1 | 0 |
| Face crushing | 1 | 0 |
| Face injury | 1 | 0 |
| Head injury | 17 | 0 |
| Limb crushing injury | 5 | 0 |
| Limb injury | 110 | 0 |
| Neck crushing | 1 | 0 |
| Neck injury | 2 | 0 |
| Site specific procedural complications NEC | | |
| Axillary web syndrome | 2 | 0 |
| Skin injuries NEC | | |
| Contusion | 1761 | 0 |
| Scar | 12 | 0 |
| Skin abrasion | 4 | 0 |
| Skin injury | 8 | 0 |
| Skin laceration | 1 | 0 |
| Skin pressure mark | 1 | 0 |
| Skin wound | 6 | 0 |
| Subcutaneous haematoma | 1 | 0 |
| Skin procedural complications | | |
| Recall phenomenon | 1 | 0 |
| Spinal cord injuries NEC | | |
| Prevertebral soft tissue swelling of cervical space | 1 | 0 |
| Spinal cord injury sacral | 1 | 0 |
| Spinal fractures and dislocations | | |
| Spinal compression fracture | 2 | 0 |
| Spinal fracture | 1 | 0 |
| Stoma complications | | |
| Gastrointestinal stoma complication | 2 | 0 |
| Stoma obstruction | 1 | 0 |
| Stoma site rash | 1 | 0 |
| Thermal burns | | |
| Airway burns | 1 | 0 |
| Burn of internal organs | 4 | 0 |
| Burn oral cavity | 5 | 0 |
| Burns second degree | 5 | 0 |
| Cold burn | 3 | 0 |
| Thermal burn | 34 | 0 |
| Thermal burns of eye | 34 | 0 |
| Underdoses NEC | | |
| Intentional underdose | 1 | 0 |
| Underdose | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------------|----------|
| Injuries Injuries cont'd | | |
| <i>Vaccination related complications</i> | | |
| Adverse event following immunisation | 3 | 0 |
| Post vaccination syndrome | 1 | 0 |
| Vaccination complication | 77 | 0 |
| Vaccination failure | 20 | 0 |
| Injuries SOC TOTAL | 4613 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations | | |
| <i>Adrenal cortex tests</i> | | |
| Blood cortisol | 1 | 0 |
| Cortisol decreased | 1 | 0 |
| Cortisol increased | 1 | 0 |
| <i>Adrenal medulla tests</i> | | |
| Norepinephrine increased | 2 | 0 |
| <i>Auditory function diagnostic procedures</i> | | |
| Acoustic stimulation tests | 3 | 0 |
| Audiogram | 1 | 0 |
| <i>Autoimmunity analyses</i> | | |
| Cold agglutinins positive | 1 | 0 |
| DNA antibody positive | 1 | 0 |
| Rheumatoid factor | 1 | 0 |
| Rheumatoid factor increased | 1 | 0 |
| <i>Bacteria identification and serology (excl mycobacteria)</i> | | |
| Bacterial test | 1 | 0 |
| <i>Blood counts NEC</i> | | |
| Blood count | 4 | 0 |
| Blood count abnormal | 2 | 0 |
| Full blood count | 6 | 0 |
| Full blood count abnormal | 1 | 0 |
| Full blood count decreased | 2 | 0 |
| <i>Blood gas and acid base analyses</i> | | |
| Blood gases | 1 | 0 |
| Blood lactic acid | 2 | 0 |
| Blood lactic acid increased | 3 | 0 |
| Blood pH | 12 | 0 |
| Blood pH increased | 9 | 0 |
| Oxygen consumption | 1 | 0 |
| Oxygen saturation | 19 | 0 |
| Oxygen saturation abnormal | 1 | 0 |
| Oxygen saturation decreased | 138 | 1 |
| <i>Blood grouping and cross-matching analyses</i> | | |
| Blood group O | 1 | 0 |
| <i>Bone marrow and immune tissue imaging procedures</i> | | |
| Scan lymph nodes | 1 | 0 |
| <i>Carbohydrate tolerance analyses (incl diabetes)</i> | | |
| Blood glucose | 17 | 0 |
| Blood glucose abnormal | 11 | 0 |
| Blood glucose decreased | 33 | 0 |
| Blood glucose fluctuation | 22 | 0 |
| Blood glucose increased | 141 | 0 |
| Glycosylated haemoglobin increased | 2 | 0 |
| <i>Cardiac auscultatory investigations</i> | | |
| Cardiac murmur | 17 | 0 |
| Heart sounds | 13 | 0 |
| Heart sounds abnormal | 3 | 0 |
| <i>Cardiac function diagnostic procedures</i> | | |
| Cardiac monitoring | 1 | 0 |
| Central venous pressure | 1 | 0 |
| Echocardiogram | 1 | 0 |
| Ejection fraction decreased | 1 | 0 |
| Myocardial strain | 6 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| Venous pressure jugular increased | 1 | 0 |
| Cardiac imaging procedures | | |
| Magnetic resonance imaging heart | 1 | 0 |
| Cell marker analyses | | |
| Carcinoembryonic antigen increased | 1 | 0 |
| Central nervous system histopathology procedures | | |
| Biopsy brain | 1 | 0 |
| Central nervous system imaging procedures | | |
| Computerised tomogram head | 9 | 0 |
| Magnetic resonance imaging brain | 37 | 0 |
| Cerebrospinal fluid tests (excl microbiology) | | |
| CSF pressure | 2 | 0 |
| CSF protein increased | 1 | 0 |
| Chemistry analyses NEC | | |
| Histamine abnormal | 1 | 0 |
| Histamine level increased | 1 | 0 |
| Inflammatory marker decreased | 1 | 0 |
| Inflammatory marker increased | 4 | 0 |
| Cholesterol analyses | | |
| Blood cholesterol increased | 6 | 0 |
| Low density lipoprotein increased | 1 | 0 |
| Very low density lipoprotein decreased | 1 | 0 |
| Coagulation and bleeding analyses | | |
| Activated partial thromboplastin time | 1 | 0 |
| Activated partial thromboplastin time prolonged | 62 | 0 |
| Bleeding time | 2 | 0 |
| Bleeding time abnormal | 2 | 0 |
| Bleeding time prolonged | 1 | 0 |
| Blood fibrinogen | 1 | 0 |
| Blood fibrinogen decreased | 3 | 0 |
| Blood fibrinogen increased | 1 | 0 |
| Coagulation factor | 1 | 0 |
| Coagulation time | 6 | 0 |
| Coagulation time prolonged | 7 | 0 |
| Coagulation time shortened | 2 | 0 |
| Fibrin D dimer | 1 | 0 |
| Fibrin D dimer increased | 21 | 0 |
| International normalised ratio | 2 | 0 |
| International normalised ratio abnormal | 9 | 0 |
| International normalised ratio decreased | 33 | 0 |
| International normalised ratio increased | 61 | 0 |
| Prothrombin level increased | 1 | 0 |
| Prothrombin time prolonged | 1 | 0 |
| Thrombin time | 1 | 0 |
| Digestive enzymes | | |
| Pancreatic enzymes increased | 1 | 0 |
| ECG investigations | | |
| Electrocardiogram | 3 | 0 |
| Electrocardiogram ST-T segment abnormal | 4 | 0 |
| Electrocardiogram T wave inversion | 1 | 0 |
| Electrocardiogram abnormal | 10 | 0 |
| Electrocardiogram change | 1 | 0 |
| Electrocardiogram normal | 1 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations Investigations cont'd | | |
| <i>Endocrine analyses and imaging NEC</i> | | |
| Hormone level abnormal | 6 | 0 |
| <i>Faecal analyses NEC</i> | | |
| Faecal calprotectin increased | 4 | 0 |
| Stool analysis abnormal | 1 | 0 |
| <i>Fertility analyses</i> | | |
| Semen volume decreased | 1 | 0 |
| <i>Foetal and neonatal diagnostic procedures</i> | | |
| Foetal heart rate | 1 | 0 |
| <i>Gastrointestinal and abdominal imaging procedures</i> | | |
| Computerised tomogram abdomen | 2 | 0 |
| <i>Gastrointestinal function diagnostic procedures</i> | | |
| Gastric pH | 1 | 0 |
| Gastric pH decreased | 1 | 0 |
| Gastrointestinal stoma output increased | 1 | 0 |
| Swallow study | 2 | 0 |
| <i>Gastrointestinal, pancreatic and APUD hormone analyses</i> | | |
| Blood gastrin | 1 | 0 |
| Blood gastrin normal | 1 | 0 |
| Blood insulin | 4 | 0 |
| Blood insulin decreased | 2 | 0 |
| Blood insulin increased | 3 | 0 |
| <i>Haematological analyses NEC</i> | | |
| Blood viscosity abnormal | 1 | 0 |
| Blood viscosity decreased | 1 | 0 |
| Blood viscosity increased | 1 | 0 |
| Haematology test abnormal | 1 | 0 |
| Plasma viscosity abnormal | 1 | 0 |
| Red blood cell sedimentation rate increased | 2 | 0 |
| <i>Heart rate and pulse investigations</i> | | |
| Brachial pulse decreased | 1 | 0 |
| Heart rate | 787 | 0 |
| Heart rate abnormal | 33 | 0 |
| Heart rate decreased | 67 | 0 |
| Heart rate increased | 1491 | 0 |
| Heart rate irregular | 106 | 0 |
| Heart rate variability decreased | 1 | 0 |
| Heart rate variability increased | 1 | 0 |
| Maximum heart rate | 4 | 0 |
| Maximum heart rate decreased | 1 | 0 |
| Orthostatic heart rate response increased | 1 | 0 |
| Pulse abnormal | 17 | 0 |
| Pulse absent | 3 | 0 |
| Pulse pressure increased | 3 | 0 |
| Pulse waveform abnormal | 1 | 0 |
| Sinus rhythm | 4 | 0 |
| <i>Imaging procedures NEC</i> | | |
| Computerised tomogram | 4 | 0 |
| Magnetic resonance imaging | 1 | 0 |
| Scan | 1 | 0 |
| <i>Immunoglobulin analyses</i> | | |
| Blood immunoglobulin E | 1 | 0 |
| Blood immunoglobulin E increased | 2 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021
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MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| Blood immunoglobulin M | 1 | 0 |
| Immunology analyses NEC | | |
| Antibody test | 1 | 0 |
| Antibody test abnormal | 1 | 0 |
| Antibody test negative | 2 | 0 |
| Immunology test | 3 | 0 |
| Immunology test normal | 1 | 0 |
| Mast cell degranulation present | 1 | 0 |
| Immunology skin tests NEC | | |
| Allergy alert test | 2 | 0 |
| Skin test positive | 3 | 0 |
| Investigations NEC | | |
| Blood test | 25 | 0 |
| Blood test abnormal | 20 | 0 |
| Investigation | 1 | 0 |
| Laboratory test | 1 | 0 |
| Polymerase chain reaction positive | 1 | 0 |
| Liver function analyses | | |
| Alanine aminotransferase increased | 11 | 0 |
| Aspartate aminotransferase increased | 2 | 0 |
| Bile output | 3 | 0 |
| Blood bilirubin | 1 | 0 |
| Blood bilirubin increased | 1 | 0 |
| Gamma-glutamyltransferase increased | 2 | 0 |
| Hepatic enzyme increased | 4 | 0 |
| Liver function test | 2 | 0 |
| Liver function test abnormal | 13 | 0 |
| Liver function test increased | 1 | 0 |
| Transaminases | 1 | 0 |
| Transaminases increased | 7 | 0 |
| Metabolism tests NEC | | |
| Blood ketone body | 9 | 0 |
| Ubiquinone | 2 | 0 |
| Microbiology and serology tests NEC | | |
| Blood culture | 2 | 0 |
| Mineral and electrolyte analyses | | |
| Blood iron | 5 | 0 |
| Blood iron decreased | 3 | 0 |
| Blood magnesium decreased | 1 | 0 |
| Blood phosphorus decreased | 3 | 0 |
| Blood phosphorus increased | 2 | 0 |
| Blood potassium decreased | 5 | 0 |
| Blood potassium increased | 5 | 0 |
| Blood sodium | 2 | 0 |
| Blood sodium decreased | 3 | 0 |
| Serum ferritin increased | 1 | 0 |
| Sweat test | 1 | 0 |
| Urine copper | 1 | 0 |
| Musculoskeletal and soft tissue imaging procedures | | |
| Bone densitometry | 1 | 0 |
| Skull X-ray | 2 | 0 |
| Musculoskeletal and soft tissue tests NEC | | |
| Swollen joint count | 2 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| Swollen joint count increased | 2 | 0 |
| Tender joint count | 3 | 0 |
| <i>Mycobacteria identification and serology</i> | | |
| Interferon gamma release assay positive | 1 | 0 |
| <i>Neurologic diagnostic procedures</i> | | |
| Coma scale abnormal | 5 | 0 |
| Lumbar puncture | 6 | 0 |
| <i>Ophthalmic function diagnostic procedures</i> | | |
| Corneal reflex decreased | 1 | 0 |
| Intraocular pressure increased | 1 | 0 |
| Intraocular pressure test | 4 | 0 |
| Visual tracking test | 1 | 0 |
| <i>Physical examination procedures and organ system status</i> | | |
| Body height decreased | 1 | 0 |
| Body surface area | 2 | 0 |
| Body temperature | 837 | 0 |
| Body temperature abnormal | 62 | 0 |
| Body temperature decreased | 107 | 0 |
| Body temperature fluctuation | 132 | 0 |
| Body temperature increased | 913 | 0 |
| Body temperature normal | 1 | 0 |
| Breath sounds | 1 | 0 |
| Breath sounds abnormal | 3 | 0 |
| Dermatologic examination abnormal | 1 | 0 |
| General physical condition abnormal | 1 | 0 |
| Grip strength | 4 | 0 |
| Grip strength decreased | 22 | 0 |
| Head lag | 13 | 0 |
| Lymph node palpable | 3 | 0 |
| Male genital examination abnormal | 1 | 0 |
| Menstruation normal | 1 | 0 |
| Muscle strength abnormal | 2 | 0 |
| Neurological examination | 1 | 0 |
| Neurological examination normal | 1 | 0 |
| Psoriasis area severity index decreased | 1 | 0 |
| Respiratory rate | 9 | 0 |
| Respiratory rate decreased | 18 | 0 |
| Respiratory rate increased | 53 | 0 |
| Skin temperature | 150 | 0 |
| Temperature difference of extremities | 4 | 0 |
| Urological examination | 1 | 0 |
| Vital signs measurement | 1 | 0 |
| Weight decreased | 98 | 0 |
| Weight increased | 16 | 0 |
| <i>Pituitary analyses anterior</i> | | |
| Blood corticotrophin | 1 | 0 |
| Blood thyroid stimulating hormone | 1 | 0 |
| Blood thyroid stimulating hormone decreased | 1 | 0 |
| Blood thyroid stimulating hormone increased | 4 | 0 |
| <i>Platelet analyses</i> | | |
| Platelet count | 2 | 0 |
| Platelet count decreased | 149 | 0 |
| Platelet count increased | 4 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| Platelet count normal | 1 | 0 |
| Protein analyses NEC | | |
| C-reactive protein abnormal | 2 | 0 |
| C-reactive protein increased | 10 | 0 |
| Red blood cell analyses | | |
| Haematocrit | 7 | 0 |
| Haemoglobin | 3 | 0 |
| Haemoglobin decreased | 5 | 0 |
| Mean cell haemoglobin concentration | 1 | 0 |
| Mean cell volume abnormal | 2 | 0 |
| Red blood cell count | 1 | 0 |
| Renal function analyses | | |
| Blood creatine increased | 1 | 0 |
| Blood creatinine abnormal | 1 | 0 |
| Blood creatinine decreased | 1 | 0 |
| Blood creatinine increased | 1 | 0 |
| Blood urea | 4 | 0 |
| Blood urea increased | 1 | 0 |
| Glomerular filtration rate decreased | 1 | 0 |
| Reproductive hormone analyses | | |
| Blood oestrogen increased | 1 | 0 |
| Dihydrotestosterone decreased | 1 | 0 |
| Human chorionic gonadotropin decreased | 1 | 0 |
| Pregnancy test | 4 | 0 |
| Pregnancy test negative | 1 | 0 |
| Respiratory and pulmonary function diagnostic procedures | | |
| Forced expiratory volume | 2 | 0 |
| Forced expiratory volume decreased | 1 | 0 |
| Forced expiratory volume increased | 9 | 0 |
| Forced expiratory volume normal | 1 | 0 |
| Forced vital capacity decreased | 1 | 0 |
| Maximal voluntary ventilation | 1 | 0 |
| Peak expiratory flow rate | 1 | 0 |
| Peak expiratory flow rate decreased | 4 | 0 |
| Pulmonary function test | 1 | 0 |
| Pulmonary function test decreased | 1 | 0 |
| Slow vital capacity | 1 | 0 |
| Total lung capacity decreased | 3 | 0 |
| Respiratory tract and thoracic histopathology procedures | | |
| Sputum abnormal | 2 | 0 |
| Respiratory tract and thoracic imaging procedures | | |
| Chest X-ray | 7 | 0 |
| Computerised tomogram thorax | 2 | 0 |
| Laryngoscopy | 1 | 0 |
| Skeletal and cardiac muscle analyses | | |
| Blood creatine phosphokinase increased | 3 | 0 |
| Myocardial necrosis marker | 1 | 0 |
| Myocardial necrosis marker increased | 1 | 0 |
| Troponin | 2 | 0 |
| Troponin T | 1 | 0 |
| Troponin T increased | 1 | 0 |
| Therapeutic drug monitoring analyses | | |
| Analgesic drug level | 16 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| Analgesic drug level increased | 1 | 0 |
| Analgesic drug level therapeutic | 1 | 0 |
| Anticoagulation drug level above therapeutic | 3 | 0 |
| Anticoagulation drug level below therapeutic | 2 | 0 |
| Anticoagulation drug level increased | 1 | 0 |
| Antidepressant drug level decreased | 1 | 0 |
| Thyroid analyses | | |
| Thyroid function test abnormal | 1 | 0 |
| Thyroxine | 1 | 0 |
| Thyroxine abnormal | 1 | 0 |
| Tri-iodothyronine decreased | 6 | 0 |
| Tissue enzyme analyses NEC | | |
| Blood lactate dehydrogenase | 1 | 0 |
| Lactate dehydrogenase urine increased | 1 | 0 |
| Toxicology laboratory analyses | | |
| Blood cannabinoids | 1 | 0 |
| Blood carbon monoxide increased | 1 | 0 |
| Blood heavy metal test | 1 | 0 |
| Blood lead | 1 | 0 |
| Urinalysis NEC | | |
| Blood urine | 20 | 0 |
| Blood urine present | 46 | 0 |
| Cells in urine | 1 | 0 |
| Protein urine present | 1 | 0 |
| Red blood cells urine | 1 | 0 |
| Urea urine increased | 1 | 0 |
| Urine analysis | 1 | 0 |
| Urine analysis abnormal | 10 | 0 |
| Urine analysis normal | 3 | 0 |
| pH urine | 8 | 0 |
| pH urine decreased | 1 | 0 |
| pH urine increased | 2 | 0 |
| Urinary tract function analyses NEC | | |
| Urine output | 34 | 0 |
| Urine output decreased | 14 | 0 |
| Urine output increased | 6 | 0 |
| Vascular auscultatory investigations | | |
| Abdominal bruit | 1 | 0 |
| Carotid bruit | 1 | 0 |
| Vascular imaging procedures NEC | | |
| Venogram | 1 | 0 |
| Vascular tests NEC (incl blood pressure) | | |
| Blood pressure abnormal | 3 | 0 |
| Blood pressure decreased | 60 | 0 |
| Blood pressure diastolic decreased | 1 | 0 |
| Blood pressure diastolic increased | 3 | 0 |
| Blood pressure increased | 200 | 0 |
| Blood pressure measurement | 60 | 0 |
| Blood pressure normal | 1 | 0 |
| Blood pressure systolic | 1 | 0 |
| Blood pressure systolic increased | 5 | 0 |
| Capillary nail refill test | 1 | 0 |
| Virus identification and serology | | |

Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------------|----------|
| Investigations | | |
| Investigations cont'd | | |
| Coronavirus test | 32 | 0 |
| HIV antibody negative | 2 | 0 |
| Hepatitis B core antibody positive | 1 | 0 |
| Herpes virus test | 1 | 0 |
| Human papilloma virus test positive | 1 | 0 |
| SARS-CoV-1 test positive | 1 | 0 |
| SARS-CoV-2 antibody test | 5 | 0 |
| SARS-CoV-2 antibody test negative | 12 | 0 |
| SARS-CoV-2 antibody test positive | 2 | 0 |
| SARS-CoV-2 test | 17 | 0 |
| SARS-CoV-2 test false negative | 3 | 0 |
| SARS-CoV-2 test false positive | 1 | 0 |
| SARS-CoV-2 test negative | 12 | 0 |
| SARS-CoV-2 test positive | 62 | 0 |
| Viral test | 3 | 0 |
| Vitamin analyses | | |
| Blood folate | 2 | 0 |
| Blood folate decreased | 2 | 0 |
| Vitamin B12 decreased | 1 | 0 |
| Water and electrolyte analyses NEC | | |
| Blood osmolarity | 1 | 0 |
| Volume blood | 3 | 0 |
| White blood cell analyses | | |
| CD4 lymphocytes decreased | 1 | 0 |
| Eosinophil count increased | 1 | 0 |
| Lymphocyte count | 1 | 0 |
| Lymphocyte count decreased | 2 | 0 |
| Lymphocyte count increased | 2 | 0 |
| Mononuclear cell count abnormal | 1 | 0 |
| Neutrophil count | 2 | 0 |
| Neutrophil count decreased | 10 | 0 |
| Neutrophil count increased | 1 | 0 |
| Neutrophil toxic granulation present | 1 | 0 |
| White blood cell count | 11 | 0 |
| White blood cell count decreased | 15 | 0 |
| White blood cell count increased | 4 | 0 |
| Investigations SOC TOTAL | 7009 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Appetite disorder | 31 | 0 |
| Decreased appetite | 5224 | 0 |
| Diet refusal | 2 | 0 |
| Food craving | 15 | 0 |
| Food refusal | 30 | 0 |
| Hyperphagia | 5 | 0 |
| Hypophagia | 20 | 0 |
| Increased appetite | 40 | 0 |
| Salt craving | 4 | 0 |
| <i>Calcium metabolism disorders</i> | | |
| Hypocalcaemia | 4 | 0 |
| Tetany | 1 | 0 |
| <i>Diabetes mellitus (incl subtypes)</i> | | |
| Diabetes mellitus | 52 | 0 |
| Diabetes mellitus inadequate control | 23 | 0 |
| Increased insulin requirement | 1 | 0 |
| Insulin resistant diabetes | 1 | 0 |
| Type 1 diabetes mellitus | 14 | 0 |
| Type 2 diabetes mellitus | 1 | 0 |
| <i>Diabetic complications NEC</i> | | |
| Diabetic ketoacidosis | 25 | 2 |
| Diabetic ketosis | 5 | 0 |
| Euglycaemic diabetic ketoacidosis | 1 | 0 |
| <i>Diabetic complications neurological</i> | | |
| Hyperglycaemic hyperosmolar nonketotic syndrome | 1 | 0 |
| <i>Disorders of purine metabolism</i> | | |
| Gout | 67 | 0 |
| <i>Electrolyte imbalance NEC</i> | | |
| Electrolyte imbalance | 1 | 0 |
| Hyperosmolar state | 1 | 1 |
| <i>Fat soluble vitamin deficiencies and disorders</i> | | |
| Vitamin D deficiency | 4 | 0 |
| <i>Fluid intake decreased</i> | | |
| Fluid intake reduced | 7 | 0 |
| <i>Fluid intake increased</i> | | |
| Polydipsia | 12 | 0 |
| <i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i> | | |
| Alcohol intolerance | 3 | 0 |
| Food intolerance | 8 | 0 |
| Gluten sensitivity | 3 | 0 |
| Histamine intolerance | 3 | 0 |
| <i>General nutritional disorders NEC</i> | | |
| Abnormal loss of weight | 30 | 0 |
| Abnormal weight gain | 14 | 0 |
| Cachexia | 1 | 0 |
| Feeding disorder | 139 | 0 |
| Food aversion | 46 | 0 |
| Neonatal insufficient breast milk syndrome | 2 | 0 |
| Obesity | 1 | 0 |
| Overweight | 1 | 0 |
| Poor feeding infant | 8 | 0 |
| Starvation | 1 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Metabolic disorders <small>Metabolic disorders cont'd</small> | | |
| Underweight | 1 | 0 |
| Weight loss poor | 1 | 0 |
| Hyperglycaemic conditions NEC | | |
| Glucose tolerance impaired | 1 | 0 |
| Hyperglycaemia | 110 | 0 |
| Insulin resistance | 8 | 0 |
| Metabolic syndrome | 1 | 0 |
| Hyperlipidaemias NEC | | |
| Hyperlipidaemia | 1 | 0 |
| Hypoglycaemic conditions NEC | | |
| Hyperinsulinaemic hypoglycaemia | 1 | 0 |
| Hypoglycaemia | 71 | 0 |
| Hypoglycaemia unawareness | 2 | 0 |
| Postprandial hypoglycaemia | 2 | 0 |
| Iron deficiencies | | |
| Iron deficiency | 4 | 0 |
| Lipid metabolism and deposit disorders NEC | | |
| Lipoedema | 1 | 0 |
| Magnesium metabolism disorders | | |
| Hypomagnesaemia | 1 | 0 |
| Metabolic acidoses (excl diabetic acidoses) | | |
| Ketoacidosis | 1 | 0 |
| Ketosis | 3 | 0 |
| Lactic acidosis | 2 | 0 |
| Metabolic acidosis | 8 | 0 |
| Metabolic disorders NEC | | |
| Metabolic disorder | 1 | 0 |
| Mixed acid-base disorders | | |
| Acidosis | 1 | 0 |
| Phosphorus metabolism disorders | | |
| Hypophosphataemia | 1 | 0 |
| Potassium imbalance | | |
| Hyperkalaemia | 3 | 0 |
| Hypokalaemia | 3 | 0 |
| Protein metabolism disorders NEC | | |
| Hypoalbuminaemia | 1 | 0 |
| Sodium imbalance | | |
| Hypernatraemia | 2 | 0 |
| Hyponatraemia | 14 | 0 |
| Hyponatraemic syndrome | 2 | 1 |
| Sugar intolerance (excl glucose intolerance) | | |
| Lactose intolerance | 4 | 0 |
| Total fluid volume decreased | | |
| Dehydration | 504 | 0 |
| Hypovolaemia | 1 | 0 |
| Total fluid volume increased | | |
| Fluid overload | 5 | 0 |
| Fluid retention | 37 | 0 |
| Water soluble vitamin deficiencies | | |
| Folate deficiency | 2 | 0 |
| Metabolic disorders SOC TOTAL | 6652 | 4 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Muscle & tissue disorders | | |
| <i>Arthropathies NEC</i> | | |
| Arthritis | 223 | 0 |
| Arthritis enteropathic | 1 | 0 |
| Arthropathy | 13 | 0 |
| Autoimmune arthritis | 2 | 0 |
| Haemarthrosis | 3 | 0 |
| Palindromic rheumatism | 2 | 0 |
| Polyarthritis | 8 | 0 |
| Rheumatic fever | 1 | 0 |
| Sacroiliitis | 3 | 0 |
| <i>Bone disorders NEC</i> | | |
| Bone erosion | 1 | 0 |
| Bone loss | 1 | 0 |
| Jaw disorder | 3 | 0 |
| Medial tibial stress syndrome | 7 | 0 |
| Osteitis | 6 | 0 |
| Osteonecrosis of jaw | 3 | 0 |
| <i>Bone related signs and symptoms</i> | | |
| Bone pain | 778 | 0 |
| Coccydynia | 3 | 0 |
| Pain in jaw | 406 | 0 |
| Pubic pain | 1 | 0 |
| Spinal pain | 169 | 0 |
| <i>Bursal disorders</i> | | |
| Bursitis | 63 | 0 |
| <i>Cartilage disorders</i> | | |
| Chondritis | 1 | 0 |
| Chondropathy | 1 | 0 |
| Costochondritis | 22 | 0 |
| <i>Connective tissue disorders NEC</i> | | |
| Connective tissue disorder | 1 | 0 |
| Mixed connective tissue disease | 1 | 0 |
| Morphoea | 1 | 0 |
| Polymyalgia rheumatica | 42 | 0 |
| Reynold's syndrome | 5 | 0 |
| Scleroderma | 2 | 0 |
| <i>Crystal arthropathic disorders</i> | | |
| Gouty tophus | 1 | 0 |
| <i>Epiphyseal disorders</i> | | |
| Epiphyses premature fusion | 1 | 0 |
| <i>Extremity deformities</i> | | |
| Finger deformity | 2 | 0 |
| Hand deformity | 1 | 0 |
| Limb deformity | 4 | 0 |
| Wrist deformity | 1 | 0 |
| <i>Intervertebral disc disorders NEC</i> | | |
| Intervertebral disc protrusion | 1 | 0 |
| <i>Joint related disorders NEC</i> | | |
| Joint ankylosis | 1 | 0 |
| Joint laxity | 3 | 0 |
| Joint lock | 29 | 0 |
| Patellofemoral pain syndrome | 3 | 0 |
| Periarthritis | 143 | 0 |

Case Series Drug Analysis Print

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Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Muscle & tissue disorders | | |
| Rotator cuff syndrome | 34 | 0 |
| Temporomandibular joint syndrome | 9 | 0 |
| Joint related signs and symptoms | | |
| Arthralgia | 16893 | 0 |
| Jaw clicking | 3 | 0 |
| Joint effusion | 1 | 0 |
| Joint noise | 21 | 0 |
| Joint range of motion decreased | 3 | 0 |
| Joint stiffness | 280 | 0 |
| Joint swelling | 440 | 0 |
| Joint vibration | 2 | 0 |
| Joint warmth | 24 | 0 |
| Loose body in joint | 1 | 0 |
| Ligament disorders | | |
| Ligament pain | 2 | 0 |
| Lupus erythematosus (incl subtypes) | | |
| Lupus-like syndrome | 1 | 0 |
| Systemic lupus erythematosus | 17 | 0 |
| Metabolic bone disorders | | |
| Osteopenia | 1 | 0 |
| Osteoporosis | 8 | 0 |
| Muscle infections and inflammations | | |
| Myositis | 13 | 0 |
| Polymyositis | 1 | 0 |
| Muscle pains | | |
| Fibromyalgia | 182 | 0 |
| Myalgia | 21240 | 0 |
| Myalgia intercostal | 1 | 0 |
| Myofascial pain syndrome | 16 | 0 |
| Muscle related signs and symptoms NEC | | |
| Haematoma muscle | 1 | 0 |
| Muscle atrophy | 10 | 0 |
| Muscle discomfort | 6 | 0 |
| Muscle disorder | 3 | 0 |
| Muscle fatigue | 699 | 0 |
| Muscle haemorrhage | 1 | 0 |
| Muscle mass | 5 | 0 |
| Muscle oedema | 2 | 0 |
| Muscle spasms | 1877 | 0 |
| Muscle swelling | 18 | 0 |
| Muscle tightness | 112 | 0 |
| Muscle twitching | 290 | 0 |
| Muscle tone abnormalities | | |
| Muscle rigidity | 34 | 0 |
| Nuchal rigidity | 12 | 0 |
| Torticollis | 6 | 0 |
| Trismus | 45 | 0 |
| Muscle weakness conditions | | |
| Muscular weakness | 1319 | 0 |
| Musculoskeletal and connective tissue conditions NEC | | |
| Extremity contracture | 1 | 0 |
| Infantile back arching | 1 | 0 |
| Limb mass | 4 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Muscle & tissue disorders | | |
| Muscle & tissue disorders cont'd | | |
| Mandibular mass | 1 | 0 |
| Mastication disorder | 2 | 0 |
| Mobility decreased | 78 | 0 |
| Muscle contracture | 3 | 0 |
| Musculoskeletal disorder | 1 | 0 |
| Musculoskeletal stiffness | 1512 | 0 |
| Somatic dysfunction | 1 | 0 |
| Weight bearing difficulty | 5 | 0 |
| Musculoskeletal and connective tissue deformities of skull, face and buccal cavity | | |
| Facial asymmetry | 2 | 0 |
| Head deformity | 1 | 0 |
| Musculoskeletal and connective tissue infections and inflammations NEC | | |
| Connective tissue inflammation | 1 | 0 |
| Dactylitis | 1 | 0 |
| Fasciitis | 1 | 0 |
| Plantar fasciitis | 4 | 0 |
| Musculoskeletal and connective tissue pain and discomfort | | |
| Amplified musculoskeletal pain syndrome | 1 | 0 |
| Back pain | 4151 | 0 |
| Flank pain | 53 | 0 |
| Growing pains | 7 | 0 |
| Limb discomfort | 1539 | 0 |
| Musculoskeletal chest pain | 291 | 0 |
| Musculoskeletal discomfort | 87 | 0 |
| Musculoskeletal pain | 46 | 0 |
| Neck pain | 2104 | 0 |
| Pain in extremity | 14614 | 0 |
| Rheumatic disorder | 10 | 0 |
| Myopathies | | |
| Compartment syndrome | 2 | 0 |
| Myopathy | 3 | 0 |
| Rhabdomyolysis | 6 | 0 |
| Osteoarthropathies | | |
| Nodal osteoarthritis | 1 | 0 |
| Osteoarthritis | 21 | 0 |
| Spinal osteoarthritis | 3 | 0 |
| Psoriatic arthropathies | | |
| Psoriatic arthropathy | 19 | 0 |
| Rheumatoid arthropathies | | |
| Felty's syndrome | 1 | 0 |
| Juvenile idiopathic arthritis | 2 | 0 |
| Rheumatoid arthritis | 91 | 0 |
| Still's disease | 3 | 0 |
| Soft tissue disorders NEC | | |
| Axillary mass | 34 | 0 |
| Fistula | 1 | 0 |
| Groin pain | 126 | 0 |
| Neck mass | 11 | 0 |
| Soft tissue disorder | 2 | 0 |
| Soft tissue mass | 2 | 0 |
| Soft tissue swelling | 4 | 0 |
| Spine and neck deformities | | |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|--------------|----------|
| Muscle & tissue disorders | | |
| <i>Muscle & tissue disorders cont'd</i> | | |
| Kyphosis | 1 | 0 |
| Scoliosis | 2 | 0 |
| Spinal stenosis | 1 | 0 |
| <i>Spondyloarthropathies</i> | | |
| Ankylosing spondylitis | 18 | 0 |
| Arthritis reactive | 17 | 0 |
| <i>Synovial disorders</i> | | |
| Synovial cyst | 4 | 0 |
| Synovitis | 6 | 0 |
| <i>Tendon disorders</i> | | |
| Enthesopathy | 1 | 0 |
| Tendon discomfort | 2 | 0 |
| Tendon disorder | 3 | 0 |
| Tendon pain | 22 | 0 |
| Tendonitis | 31 | 0 |
| Tenosynovitis stenosaurs | 1 | 0 |
| Trigger finger | 14 | 0 |
| Muscle & tissue disorders SOC TOTAL | 70573 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Neoplasms | | |
| <i>Bladder neoplasms malignant</i> | | |
| Bladder cancer | 1 | 0 |
| <i>Bone neoplasms malignant (excl sarcomas)</i> | | |
| Bone cancer | 1 | 0 |
| <i>Breast and nipple neoplasms benign</i> | | |
| Benign breast neoplasm | 1 | 0 |
| <i>Breast and nipple neoplasms malignant</i> | | |
| Breast cancer | 24 | 0 |
| Breast cancer male | 1 | 0 |
| Breast cancer metastatic | 1 | 0 |
| Breast cancer stage III | 1 | 0 |
| <i>Cardiovascular neoplasms benign</i> | | |
| Haemangioma | 2 | 0 |
| <i>Central nervous system neoplasms malignant NEC</i> | | |
| Brain cancer metastatic | 1 | 0 |
| Brain neoplasm malignant | 1 | 0 |
| <i>Colorectal neoplasms malignant</i> | | |
| Colon cancer | 1 | 0 |
| Colorectal cancer | 1 | 0 |
| <i>Endometrial neoplasms malignant</i> | | |
| Endometrial cancer | 2 | 0 |
| <i>Gastrointestinal neoplasms benign NEC</i> | | |
| Gastrointestinal tract adenoma | 1 | 0 |
| <i>Gastrointestinal neoplasms malignant NEC</i> | | |
| Gastrointestinal carcinoma | 1 | 0 |
| <i>Hepatic neoplasms malignant</i> | | |
| Hepatocellular carcinoma | 3 | 0 |
| <i>Hepatoblastomas</i> | | |
| Hepatoblastoma | 1 | 0 |
| <i>Hodgkin's disease NEC</i> | | |
| Hodgkin's disease | 1 | 0 |
| <i>Leukaemias NEC</i> | | |
| Leukaemia recurrent | 1 | 0 |
| <i>Leukaemias chronic lymphocytic</i> | | |
| Chronic lymphocytic leukaemia | 4 | 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 |
| Squamous cell carcinoma of the oral cavity | 1 | 0 |
| <i>Lymphomas unspecified NEC</i> | | |
| Lymphoma | 8 | 0 |
| <i>Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)</i> | | |
| Lymphoproliferative disorder in remission | 1 | 0 |
| <i>Metastases to specified sites</i> | | |
| Metastases to bone | 1 | 0 |
| Metastases to central nervous system | 1 | 1 |
| Metastases to lung | 1 | 1 |
| <i>Metastases to unknown and unspecified sites</i> | | |
| Metastasis | 2 | 0 |
| <i>Myeloproliferative disorders (excl leukaemias)</i> | | |
| Essential thrombocythaemia | 1 | 0 |
| <i>Neoplasms benign site unspecified NEC</i> | | |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Neoplasms Neoplasms cont'd | | |
| Fibroma | 1 | 0 |
| Neoplasms malignant site unspecified NEC | | |
| Adenocarcinoma | 1 | 0 |
| Metastatic neoplasm | 3 | 0 |
| Neoplasm malignant | 3 | 1 |
| Squamous cell carcinoma | 1 | 0 |
| Neoplasms unspecified malignancy and site unspecified NEC | | |
| Neoplasm recurrence | 5 | 0 |
| Nervous system neoplasms unspecified malignancy NEC | | |
| Brain neoplasm | 1 | 0 |
| Meningioma | 1 | 0 |
| Neuromas | | |
| Acoustic neuroma | 2 | 0 |
| Ocular neoplasms benign | | |
| Eye naevus | 2 | 0 |
| Oesophageal neoplasms malignant | | |
| Oesophageal cancer metastatic | 3 | 0 |
| Oesophageal carcinoma | 1 | 0 |
| Oesophageal squamous cell carcinoma | 1 | 0 |
| Oncologic complications and emergencies | | |
| Cancer fatigue | 4 | 0 |
| Cancer pain | 1 | 0 |
| Intracranial tumour haemorrhage | 1 | 0 |
| Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified | | |
| Tonsil cancer | 2 | 0 |
| Ovarian neoplasms malignant (excl germ cell) | | |
| Ovarian cancer | 3 | 0 |
| Ovarian cancer stage IV | 2 | 0 |
| Pancreatic neoplasms malignant (excl islet cell and carcinoid) | | |
| Pancreatic carcinoma | 2 | 0 |
| Plasma cell myelomas | | |
| Plasma cell myeloma | 1 | 0 |
| Prostatic neoplasms malignant | | |
| Prostate cancer | 5 | 0 |
| Renal neoplasms malignant | | |
| Clear cell renal cell carcinoma | 1 | 0 |
| Metastatic renal cell carcinoma | 1 | 0 |
| Renal cancer | 1 | 0 |
| Respiratory tract and pleural neoplasms malignancy unspecified NEC | | |
| Maxillofacial sinus neoplasm | 1 | 0 |
| Respiratory tract and pleural neoplasms malignant cell type unspecified NEC | | |
| Bronchial carcinoma | 4 | 0 |
| Lung cancer metastatic | 1 | 0 |
| Lung neoplasm malignant | 5 | 0 |
| Throat cancer | 1 | 0 |
| Salivary gland neoplasms malignant | | |
| Salivary gland cancer stage 0 | 1 | 0 |
| Salivary gland cancer stage III | 1 | 0 |
| Skin melanomas (excl ocular) | | |
| Acral lentiginous melanoma stage III | 1 | 0 |
| Malignant melanoma | 1 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Neoplasms Neoplasms cont'd | | |
| Malignant melanoma in situ | 1 | 0 |
| <i>Skin neoplasms benign</i> | | |
| Haemangioma of skin | 6 | 0 |
| Melanocytic naevus | 2 | 0 |
| Skin papilloma | 10 | 0 |
| <i>Skin neoplasms malignant and unspecified (excl melanoma)</i> | | |
| Bowen's disease | 1 | 0 |
| Skin cancer | 2 | 0 |
| Squamous cell carcinoma of skin | 1 | 0 |
| <i>Soft tissue neoplasms benign NEC</i> | | |
| Knuckle pads | 1 | 0 |
| Lipoma | 4 | 0 |
| <i>Uterine neoplasms benign</i> | | |
| Uterine leiomyoma | 1 | 0 |
| Neoplasms SOC TOTAL | 162 | 3 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Abnormal reflexes</i> | | |
| Areflexia | 10 | 0 |
| Extensor plantar response | 1 | 0 |
| Hyperreflexia | 1 | 0 |
| Hyporeflexia | 8 | 0 |
| Poor sucking reflex | 1 | 0 |
| Reflexes abnormal | 1 | 0 |
| <i>Abnormal sleep-related events</i> | | |
| Sleep paralysis | 18 | 0 |
| <i>Absence seizures</i> | | |
| Petit mal epilepsy | 22 | 0 |
| <i>Acute polyneuropathies</i> | | |
| Acute motor axonal neuropathy | 3 | 0 |
| Acute polyneuropathy | 1 | 0 |
| Guillain-Barre syndrome | 156 | 3 |
| Miller Fisher syndrome | 7 | 0 |
| Subacute inflammatory demyelinating polyneuropathy | 1 | 0 |
| <i>Auditory nerve disorders</i> | | |
| Acoustic neuritis | 1 | 0 |
| <i>Autonomic nervous system disorders</i> | | |
| Autonomic nervous system imbalance | 8 | 0 |
| Horner's syndrome | 1 | 0 |
| Orthostatic intolerance | 2 | 0 |
| <i>Central nervous system aneurysms and dissections</i> | | |
| Carotid artery dissection | 1 | 0 |
| Intracranial aneurysm | 1 | 0 |
| <i>Central nervous system haemorrhages and cerebrovascular accidents</i> | | |
| Basal ganglia haemorrhage | 1 | 0 |
| Basal ganglia stroke | 1 | 0 |
| Basilar artery thrombosis | 1 | 0 |
| Brain stem haemorrhage | 3 | 0 |
| Brain stem infarction | 2 | 2 |
| Brain stem stroke | 1 | 0 |
| Carotid artery occlusion | 1 | 0 |
| Carotid artery thrombosis | 4 | 0 |
| Cerebellar haemorrhage | 2 | 0 |
| Cerebellar infarction | 3 | 0 |
| Cerebellar stroke | 6 | 0 |
| Cerebral artery embolism | 5 | 0 |
| Cerebral artery occlusion | 2 | 0 |
| Cerebral artery thrombosis | 3 | 0 |
| Cerebral haematoma | 9 | 1 |
| Cerebral haemorrhage | 93 | 25 |
| Cerebral infarction | 37 | 2 |
| Cerebral ischaemia | 3 | 0 |
| Cerebral thrombosis | 19 | 2 |
| Cerebral vascular occlusion | 1 | 0 |
| Cerebrovascular accident | 556 | 31 |
| Embolic stroke | 12 | 0 |
| Haemorrhage intracranial | 29 | 5 |
| Haemorrhagic cerebral infarction | 1 | 1 |
| Haemorrhagic stroke | 19 | 4 |
| Haemorrhagic transformation stroke | 2 | 1 |

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Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| Intracranial haematoma | 5 | 1 |
| Intraventricular haemorrhage | 3 | 0 |
| Ischaemic cerebral infarction | 2 | 0 |
| Ischaemic stroke | 62 | 3 |
| Lacunar infarction | 3 | 0 |
| Lacunar stroke | 12 | 0 |
| Subarachnoid haemorrhage | 52 | 4 |
| Thalamus haemorrhage | 6 | 0 |
| Thrombotic stroke | 3 | 0 |
| Central nervous system inflammatory disorders NEC | | |
| Arachnoiditis | 2 | 0 |
| Central nervous system inflammation | 7 | 0 |
| Neurosarcoidosis | 1 | 0 |
| Central nervous system vascular disorders NEC | | |
| Brain hypoxia | 1 | 1 |
| Carotid artery stenosis | 1 | 0 |
| Cerebral amyloid angiopathy | 2 | 0 |
| Cerebral congestion | 2 | 0 |
| Cerebral microhaemorrhage | 1 | 0 |
| Cerebral small vessel ischaemic disease | 1 | 0 |
| Cerebral vasoconstriction | 1 | 0 |
| Cerebrovascular disorder | 3 | 0 |
| Internal carotid artery deformity | 1 | 0 |
| Reversible cerebral vasoconstriction syndrome | 1 | 0 |
| Cerebrovascular venous and sinus thrombosis | | |
| Cerebral venous sinus thrombosis | 130 | 9 |
| Cerebral venous thrombosis | 23 | 2 |
| Superior sagittal sinus thrombosis | 18 | 3 |
| Transverse sinus thrombosis | 2 | 0 |
| Cervical spinal cord and nerve root disorders | | |
| Cervical radiculopathy | 3 | 0 |
| Cervicobrachial syndrome | 5 | 0 |
| Choreiform movements | | |
| Chorea | 2 | 0 |
| Choreoathetosis | 1 | 0 |
| Sydenham's chorea | 1 | 0 |
| Chronic polyneuropathies | | |
| Diabetic neuropathy | 2 | 0 |
| Coma states | | |
| Coma | 11 | 0 |
| Diabetic coma | 2 | 0 |
| Coordination and balance disturbances | | |
| Ataxia | 16 | 0 |
| Balance disorder | 532 | 0 |
| Cerebellar ataxia | 1 | 0 |
| Coordination abnormal | 79 | 0 |
| Dysdiadochokinesis | 1 | 0 |
| Dysstasia | 60 | 0 |
| Nystagmus | 11 | 0 |
| Cortical dysfunction NEC | | |
| Alexia | 3 | 0 |
| Aphasia | 76 | 0 |
| Apraxia | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders <small>Nervous system disorders cont'd</small> | | |
| Dysgraphia | 3 | 0 |
| Dyslexia | 2 | 0 |
| Dyspraxia | 3 | 0 |
| Neurologic neglect syndrome | 3 | 0 |
| Visuospatial deficit | 2 | 0 |
| Cranial nerve disorders NEC | | |
| Cranial nerve disorder | 1 | 0 |
| Cranial nerve paralysis | 1 | 0 |
| Neurovascular conflict | 1 | 0 |
| Paresis cranial nerve | 1 | 0 |
| Dementia (excl Alzheimer's type) | | |
| Dementia | 13 | 0 |
| Dementia with Lewy bodies | 1 | 0 |
| Frontotemporal dementia | 1 | 0 |
| Senile dementia | 1 | 0 |
| Vascular dementia | 4 | 0 |
| Demyelinating disorders NEC | | |
| Acute disseminated encephalomyelitis | 5 | 0 |
| Demyelination | 8 | 0 |
| Neuromyelitis optica spectrum disorder | 1 | 0 |
| Disturbances in consciousness NEC | | |
| Altered state of consciousness | 9 | 0 |
| Consciousness fluctuating | 4 | 0 |
| Depressed level of consciousness | 55 | 0 |
| Lethargy | 3564 | 0 |
| Loss of consciousness | 697 | 0 |
| Postictal state | 1 | 0 |
| Sedation | 7 | 0 |
| Somnolence | 1292 | 1 |
| Stupor | 7 | 0 |
| Syncope | 1691 | 0 |
| Disturbances in sleep phase rhythm | | |
| Advanced sleep phase | 1 | 0 |
| Circadian rhythm sleep disorder | 1 | 0 |
| Irregular sleep phase | 1 | 0 |
| Dyskinesias and movement disorders NEC | | |
| Akathisia | 9 | 0 |
| Bradykinesia | 20 | 0 |
| Clumsiness | 25 | 0 |
| Dyskinesia | 77 | 0 |
| Extrapyramidal disorder | 17 | 0 |
| Fine motor delay | 1 | 0 |
| Fine motor skill dysfunction | 7 | 0 |
| Hyperkinesia | 20 | 0 |
| Hypokinesia | 29 | 0 |
| Motor dysfunction | 8 | 0 |
| Movement disorder | 44 | 0 |
| Psychomotor hyperactivity | 28 | 0 |
| Dystonias | | |
| Dystonia | 10 | 0 |
| Dystonic tremor | 3 | 0 |
| Opisthotonus | 4 | 0 |
| Encephalitis NEC | | |

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MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| Nervous system disorders cont'd | | |
| Noninfective encephalitis | 3 | 0 |
| Encephalopathies NEC | | |
| Autoimmune encephalopathy | 2 | 0 |
| Encephalopathy | 4 | 0 |
| Hypoxic-ischaemic encephalopathy | 1 | 0 |
| Posterior reversible encephalopathy syndrome | 1 | 0 |
| Encephalopathies toxic and metabolic | | |
| Hepatic encephalopathy | 2 | 0 |
| Eye movement disorders | | |
| IIIrd nerve paralysis | 4 | 0 |
| Microvascular cranial nerve palsy | 1 | 0 |
| VIth nerve paralysis | 4 | 0 |
| Facial cranial nerve disorders | | |
| Facial nerve disorder | 2 | 0 |
| Facial paralysis | 376 | 0 |
| Facial paresis | 76 | 0 |
| Facial spasm | 22 | 0 |
| Oculofacial paralysis | 1 | 0 |
| Generalised tonic-clonic seizures | | |
| Generalised tonic-clonic seizure | 50 | 0 |
| Headaches NEC | | |
| Cervicogenic headache | 2 | 0 |
| Cluster headache | 475 | 0 |
| Cold-stimulus headache | 48 | 0 |
| Drug withdrawal headache | 12 | 0 |
| Exertional headache | 6 | 0 |
| External compression headache | 2 | 0 |
| Headache | 61211 | 4 |
| Medication overuse headache | 13 | 0 |
| New daily persistent headache | 8 | 0 |
| Occipital neuralgia | 13 | 0 |
| Ophthalmoplegic migraine | 1 | 0 |
| Post-traumatic headache | 2 | 0 |
| Primary cough headache | 2 | 0 |
| Primary headache associated with sexual activity | 8 | 0 |
| Sinus headache | 693 | 0 |
| Tension headache | 1007 | 0 |
| Thunderclap headache | 30 | 0 |
| Vascular headache | 56 | 0 |
| Hydrocephalic conditions | | |
| Hydrocephalus | 7 | 0 |
| Hypoglossal nerve disorders | | |
| Tongue paralysis | 5 | 0 |
| Increased intracranial pressure disorders | | |
| Brain compression | 2 | 0 |
| Brain oedema | 17 | 1 |
| Cerebrospinal fluid circulation disorder | 3 | 0 |
| Idiopathic intracranial hypertension | 3 | 0 |
| Intracranial pressure increased | 14 | 0 |
| Intellectual disabilities | | |
| Intellectual disability | 7 | 0 |
| Lumbar spinal cord and nerve root disorders | | |
| Sciatica | 101 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders <small>Nervous system disorders cont'd</small> | | |
| <i>Memory loss (excl dementia)</i> | | |
| Amnesia | 170 | 0 |
| Memory impairment | 151 | 0 |
| Transient global amnesia | 9 | 0 |
| <i>Mental impairment (excl dementia and memory loss)</i> | | |
| Cognitive disorder | 87 | 1 |
| Disturbance in attention | 390 | 0 |
| Judgement impaired | 3 | 0 |
| Mental impairment | 79 | 0 |
| <i>Migraine headaches</i> | | |
| Basilar migraine | 3 | 0 |
| Hemiplegic migraine | 18 | 0 |
| Migraine | 5127 | 0 |
| Migraine with aura | 224 | 0 |
| Migraine without aura | 35 | 0 |
| Retinal migraine | 45 | 0 |
| Status migrainosus | 1 | 0 |
| Typical aura without headache | 6 | 0 |
| Vestibular migraine | 15 | 0 |
| <i>Mononeuropathies</i> | | |
| Carpal tunnel syndrome | 13 | 0 |
| Diabetic mononeuropathy | 1 | 0 |
| Meralgia paraesthetica | 1 | 0 |
| Mononeuritis | 2 | 0 |
| Mononeuropathy | 1 | 0 |
| Nerve compression | 23 | 0 |
| Peroneal nerve palsy | 6 | 0 |
| Piriformis syndrome | 1 | 0 |
| Radial nerve palsy | 1 | 0 |
| Sciatic nerve neuropathy | 1 | 0 |
| Ulnar nerve palsy | 1 | 0 |
| Ulnar neuritis | 2 | 0 |
| Ulnar tunnel syndrome | 1 | 0 |
| <i>Multiple sclerosis acute and progressive</i> | | |
| Band sensation | 3 | 0 |
| Multiple sclerosis | 35 | 0 |
| Multiple sclerosis relapse | 31 | 0 |
| Relapsing multiple sclerosis | 1 | 0 |
| Uhthoff's phenomenon | 4 | 0 |
| <i>Muscle tone abnormal</i> | | |
| Hypertonia | 1 | 0 |
| Hypotonia | 19 | 0 |
| Serotonin syndrome | 1 | 0 |
| Stiff leg syndrome | 5 | 0 |
| <i>Myelitis (incl infective)</i> | | |
| Myelitis transverse | 38 | 1 |
| <i>Narcolepsy and hypersomnia</i> | | |
| Cataplexy | 1 | 0 |
| Hypersomnia | 133 | 0 |
| Narcolepsy | 12 | 0 |
| <i>Nervous system cysts and polyps</i> | | |
| Pineal gland cyst | 1 | 0 |
| <i>Nervous system disorders NEC</i> | | |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Brain stem syndrome | 2 | 0 |
| Cerebral disorder | 1 | 0 |
| Nervous system disorder | 21 | 0 |
| Psychomotor skills impaired | 3 | 0 |
| Neurologic visual problems NEC | | |
| Hemianopia | 3 | 0 |
| Hemianopia homonymous | 1 | 0 |
| Tunnel vision | 11 | 0 |
| Visual field defect | 16 | 0 |
| Neurological signs and symptoms NEC | | |
| Agitation neonatal | 1 | 0 |
| Dizziness | 15759 | 0 |
| Dizziness exertional | 68 | 0 |
| Dizziness postural | 1617 | 1 |
| Drooling | 11 | 0 |
| Exaggerated startle response | 3 | 0 |
| Fontanelle bulging | 3 | 0 |
| Head discomfort | 366 | 0 |
| Hyporesponsive to stimuli | 2 | 0 |
| Infant irritability | 4 | 0 |
| Intracranial hypotension | 1 | 0 |
| Meningism | 1 | 0 |
| Myoclonus | 19 | 0 |
| Neurological decompensation | 3 | 0 |
| Neurological symptom | 58 | 0 |
| Patient elopement | 1 | 0 |
| Persistent postural-perceptual dizziness | 18 | 0 |
| Pleocytosis | 1 | 0 |
| Presyncope | 437 | 0 |
| Sensory overload | 8 | 0 |
| Slow response to stimuli | 4 | 0 |
| Tongue biting | 5 | 0 |
| Unresponsive to stimuli | 62 | 0 |
| Neuromuscular disorders NEC | | |
| Muscle contractions involuntary | 18 | 0 |
| Muscle spasticity | 17 | 0 |
| Neuromuscular pain | 3 | 0 |
| Neuromyopathy | 3 | 0 |
| Neuromyotonia | 1 | 0 |
| Neuromuscular junction dysfunction | | |
| Myasthenia gravis | 6 | 0 |
| Myasthenia gravis crisis | 1 | 0 |
| Olfactory nerve disorders | | |
| Anosmia | 187 | 0 |
| Hyposmia | 10 | 0 |
| Parosmia | 256 | 0 |
| Optic nerve disorders NEC | | |
| Optic neuritis | 18 | 0 |
| Paraesthesias and dysaesthesias | | |
| Anaesthesia | 2 | 0 |
| Burning feet syndrome | 13 | 0 |
| Burning sensation | 496 | 0 |
| Burning sensation mucosal | 2 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Dysaesthesia | 6 | 0 |
| Formication | 35 | 0 |
| Hand-arm vibration syndrome | 1 | 0 |
| Hemianaesthesia | 3 | 0 |
| Hemiparaesthesia | 1 | 0 |
| Hyperaesthesia | 200 | 0 |
| Hypoaesthesia | 3234 | 0 |
| Lhermitte's sign | 1 | 0 |
| Paraesthesia | 5564 | 0 |
| <i>Paralysis and paresis (excl cranial nerve)</i> | | |
| Diplegia | 18 | 0 |
| Hemiparesis | 52 | 0 |
| Hemiplegia | 18 | 0 |
| Monoparesis | 57 | 0 |
| Monoplegia | 81 | 0 |
| Paralysis | 192 | 0 |
| Paraparesis | 5 | 0 |
| Paraplegia | 1 | 0 |
| Paresis | 5 | 0 |
| Peripheral nerve palsy | 1 | 0 |
| Postictal paralysis | 1 | 0 |
| Quadriplegia | 1 | 0 |
| <i>Parkinson's disease and parkinsonism</i> | | |
| Freezing phenomenon | 128 | 0 |
| Parkinson's disease | 15 | 0 |
| Parkinsonism | 10 | 0 |
| Reduced facial expression | 3 | 0 |
| Vascular parkinsonism | 1 | 0 |
| <i>Partial complex seizures</i> | | |
| Dreamy state | 13 | 0 |
| Focal dyscognitive seizures | 3 | 0 |
| Temporal lobe epilepsy | 3 | 0 |
| <i>Partial simple seizures NEC</i> | | |
| Simple partial seizures | 4 | 0 |
| <i>Peripheral neuropathies NEC</i> | | |
| Autoimmune neuropathy | 2 | 0 |
| Neuritis | 5 | 0 |
| Neuropathy peripheral | 101 | 0 |
| Peripheral sensorimotor neuropathy | 1 | 0 |
| Peripheral sensory neuropathy | 4 | 0 |
| Polyneuropathy | 5 | 0 |
| Small fibre neuropathy | 2 | 0 |
| Thoracic outlet syndrome | 1 | 0 |
| <i>Seizures and seizure disorders NEC</i> | | |
| Alcoholic seizure | 1 | 0 |
| Atonic seizures | 7 | 0 |
| Change in seizure presentation | 2 | 0 |
| Clonic convulsion | 7 | 0 |
| Drug withdrawal convulsions | 2 | 0 |
| Epilepsy | 158 | 0 |
| Epileptic aura | 2 | 0 |
| Febrile convulsion | 68 | 0 |
| Migraine-triggered seizure | 1 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Myoclonic epilepsy | 4 | 0 |
| Partial seizures | 35 | 0 |
| Psychogenic seizure | 5 | 0 |
| Seizure | 761 | 2 |
| Seizure anoxic | 1 | 0 |
| Seizure cluster | 4 | 0 |
| Seizure like phenomena | 2 | 0 |
| Status epilepticus | 71 | 1 |
| Tonic clonic movements | 1 | 0 |
| Tonic convulsion | 23 | 0 |
| Sensory abnormalities NEC | | |
| Ageusia | 730 | 0 |
| Allodynia | 42 | 0 |
| Aura | 16 | 0 |
| Central pain syndrome | 2 | 0 |
| Complex regional pain syndrome | 8 | 0 |
| Dysgeusia | 1448 | 0 |
| Hypogeusia | 4 | 0 |
| Intercostal neuralgia | 1 | 0 |
| Loss of proprioception | 2 | 0 |
| Neuralgia | 753 | 0 |
| Persistent genital arousal disorder | 1 | 0 |
| Phantom limb syndrome | 15 | 0 |
| Post herpetic neuralgia | 2 | 0 |
| Restless arm syndrome | 9 | 0 |
| Restless legs syndrome | 251 | 0 |
| Sensory disturbance | 60 | 0 |
| Sensory loss | 117 | 0 |
| Taste disorder | 356 | 0 |
| Sleep disturbances NEC | | |
| Microsleep | 2 | 0 |
| Poor quality sleep | 516 | 0 |
| Sleep deficit | 31 | 0 |
| Speech and language abnormalities | | |
| Dysarthria | 213 | 0 |
| Incoherent | 9 | 0 |
| Language disorder | 2 | 0 |
| Muscle tension dysphonia | 1 | 0 |
| Slow speech | 17 | 0 |
| Speech disorder | 40 | 0 |
| Spinal cord and nerve root disorders NEC | | |
| Cauda equina syndrome | 3 | 0 |
| Myelopathy | 2 | 0 |
| Radicular pain | 1 | 0 |
| Radiculitis brachial | 6 | 0 |
| Radiculopathy | 1 | 0 |
| Structural brain disorders NEC | | |
| Brain injury | 16 | 0 |
| Brain midline shift | 1 | 0 |
| Intracranial mass | 3 | 0 |
| Transient cerebrovascular events | | |
| Transient ischaemic attack | 249 | 0 |
| Tremor (excl congenital) | | |

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| Reaction Name | Total | Fatal |
|---|---------------|------------|
| Nervous system disorders | | |
| Nervous system disorders cont'd | | |
| Action tremor | 2 | 0 |
| Asterixis | 1 | 0 |
| Essential tremor | 3 | 0 |
| Head titubation | 10 | 0 |
| Intention tremor | 1 | 0 |
| Postural tremor | 1 | 0 |
| Resting tremor | 5 | 0 |
| Tremor | 7933 | 3 |
| Trigeminal disorders | | |
| Facial neuralgia | 23 | 0 |
| Numb chin syndrome | 2 | 0 |
| Trigeminal neuralgia | 40 | 0 |
| Trigeminal neuritis | 1 | 0 |
| Trigeminal palsy | 1 | 0 |
| Vagus nerve disorders | | |
| Vagus nerve paralysis | 1 | 0 |
| Nervous system disorders SOC TOTAL | 124324 | 115 |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Pregnancy conditions | | |
| <i>Abortions spontaneous</i> | | |
| Abortion spontaneous | 37 | 0 |
| <i>Foetal position and presentation abnormalities</i> | | |
| Face presentation | 1 | 0 |
| <i>High risk pregnancies</i> | | |
| Pregnancy with young maternal age | 1 | 0 |
| <i>Labour onset and length abnormalities</i> | | |
| Precipitate labour | 1 | 0 |
| Premature labour | 3 | 0 |
| Premature rupture of membranes | 1 | 0 |
| Prolonged labour | 1 | 0 |
| <i>Maternal complications of labour NEC</i> | | |
| Uterine contractions abnormal | 1 | 0 |
| Uterine hypertonus | 1 | 0 |
| <i>Maternal complications of pregnancy NEC</i> | | |
| Ectopic pregnancy | 2 | 0 |
| Hyperemesis gravidarum | 2 | 0 |
| Morning sickness | 23 | 0 |
| Pelvic girdle pain | 1 | 0 |
| <i>Normal pregnancy, labour and delivery</i> | | |
| Pregnancy | 10 | 0 |
| Uterine contractions during pregnancy | 1 | 0 |
| <i>Pregnancy complicated by maternal disorders</i> | | |
| Gestational diabetes | 4 | 0 |
| <i>Stillbirth and foetal death</i> | | |
| Stillbirth | 3 | 0 |
| <i>Unintended pregnancies</i> | | |
| Pregnancy after post coital contraception | 2 | 0 |
| Pregnancy on contraceptive | 1 | 0 |
| Pregnancy with contraceptive device | 1 | 0 |
| Pregnancy with implant contraceptive | 1 | 0 |
| Unintended pregnancy | 4 | 0 |
| Pregnancy conditions SOC TOTAL | 102 | 0 |

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| <i>Device electrical issues</i> | | |
| Device electrical impedance issue | 1 | 0 |
| <i>Device incompatibility issues</i> | | |
| Patient-device incompatibility | 1 | 0 |
| <i>Device issues NEC</i> | | |
| Device issue | 2 | 0 |
| Device leakage | 2 | 0 |
| <i>Device malfunction events NEC</i> | | |
| Oversensing | 20 | 0 |
| Stent malfunction | 1 | 0 |
| Thrombosis in device | 23 | 0 |
| Undersensing | 2 | 0 |
| <i>Device physical property and chemical issues</i> | | |
| Needle issue | 3 | 0 |
| <i>Product contamination and sterility issues</i> | | |
| Product contamination | 1 | 0 |
| <i>Product label issues</i> | | |
| Product label issue | 1 | 0 |
| <i>Product physical issues</i> | | |
| Product leakage | 1 | 0 |
| Product physical issue | 1 | 0 |
| Product taste abnormal | 2 | 0 |
| <i>Product quality issues NEC</i> | | |
| Product origin unknown | 2 | 0 |
| Product quality issue | 1 | 0 |
| Suspected product quality issue | 2 | 0 |
| null SOC TOTAL | 66 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders | | |
| <i>Abnormal behaviour NEC</i> | | |
| Abnormal behaviour | 11 | 0 |
| Breath holding | 2 | 0 |
| Staring | 6 | 0 |
| <i>Adjustment disorders</i> | | |
| Adjustment disorder with depressed mood | 5 | 0 |
| <i>Affect alterations NEC</i> | | |
| Affect lability | 5 | 0 |
| Constricted affect | 5 | 0 |
| Flat affect | 7 | 0 |
| Inappropriate affect | 12 | 0 |
| <i>Amnesic symptoms</i> | | |
| Paramnesia | 3 | 0 |
| <i>Anxiety disorders NEC</i> | | |
| Anxiety disorder | 2 | 0 |
| Generalised anxiety disorder | 2 | 0 |
| Neurosis | 1 | 0 |
| <i>Anxiety symptoms</i> | | |
| Agitation | 140 | 0 |
| Anxiety | 612 | 0 |
| Immunisation anxiety related reaction | 1 | 0 |
| Nervousness | 461 | 0 |
| Stress | 55 | 0 |
| Tension | 37 | 0 |
| <i>Attention deficit and disruptive behaviour disorders</i> | | |
| Attention deficit hyperactivity disorder | 12 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Aggression | 7 | 0 |
| Asocial behaviour | 1 | 0 |
| Aversion | 1 | 0 |
| Impatience | 2 | 0 |
| Indifference | 5 | 0 |
| Paranoia | 24 | 0 |
| Personality change | 2 | 0 |
| Social avoidant behaviour | 3 | 0 |
| Soliloquy | 2 | 0 |
| Violence-related symptom | 2 | 0 |
| <i>Bipolar disorders</i> | | |
| Bipolar I disorder | 4 | 0 |
| Bipolar disorder | 2 | 0 |
| <i>Cognitive and attention disorders and disturbances NEC</i> | | |
| Change in sustained attention | 1 | 0 |
| Daydreaming | 9 | 0 |
| Distractibility | 1 | 0 |
| Mental fatigue | 306 | 0 |
| <i>Communications disorders</i> | | |
| Communication disorder | 1 | 0 |
| Mutism | 2 | 0 |
| Speech sound disorder | 1 | 0 |
| <i>Confusion and disorientation</i> | | |
| Confusional state | 1333 | 1 |
| Disorientation | 526 | 0 |
| <i>Decreased physical activity levels</i> | | |

Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

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MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Catatonia | 2 | 0 |
| Deliria | | |
| Delirium | 369 | 0 |
| Delirium febrile | 2 | 0 |
| Delusional disorders | | |
| Alice in wonderland syndrome | 1 | 0 |
| Delusional symptoms | | |
| Delusion | 31 | 0 |
| Mixed delusion | 1 | 0 |
| Thought withdrawal | 1 | 0 |
| Depressive disorders | | |
| Agitated depression | 3 | 0 |
| Depression | 330 | 0 |
| Depression suicidal | 7 | 0 |
| Major depression | 16 | 0 |
| Mixed anxiety and depressive disorder | 1 | 0 |
| Dissociative states | | |
| Depersonalisation/derealisation disorder | 11 | 0 |
| Dissociation | 46 | 0 |
| Dissociative disorder | 1 | 0 |
| Disturbances in initiating and maintaining sleep | | |
| Initial insomnia | 21 | 0 |
| Insomnia | 2254 | 0 |
| Middle insomnia | 55 | 0 |
| Terminal insomnia | 6 | 0 |
| Dyssomnias | | |
| Dyssomnia | 4 | 0 |
| Eating disorders NEC | | |
| Eating disorder | 6 | 0 |
| Emotional and mood disturbances NEC | | |
| Anger | 51 | 0 |
| Dysphoria | 1 | 0 |
| Emotional disorder | 65 | 0 |
| Emotional distress | 45 | 0 |
| Emotional poverty | 2 | 0 |
| Euphoric mood | 48 | 0 |
| Frustration tolerance decreased | 2 | 0 |
| Irritability | 199 | 0 |
| Mood altered | 44 | 0 |
| Factitious disorders | | |
| Factitious disorder | 4 | 0 |
| Fear symptoms and phobic disorders (incl social phobia) | | |
| Acrophobia | 1 | 0 |
| Agoraphobia | 2 | 0 |
| Claustrophobia | 1 | 0 |
| Fear | 13 | 0 |
| Fear of death | 7 | 0 |
| Fear of disease | 1 | 0 |
| Fear of eating | 1 | 0 |
| Fear of falling | 2 | 0 |
| Fear of injection | 1 | 0 |
| Fear of open spaces | 1 | 0 |
| Performance fear | 1 | 0 |

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Report Run Date: 26-Apr-2021
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MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Phobia | 2 | 0 |
| Phonophobia | 3 | 0 |
| Fluctuating mood symptoms | | |
| Mood swings | 40 | 0 |
| Hallucinations (excl sleep-related) | | |
| Hallucination | 718 | 0 |
| Hallucination, auditory | 28 | 0 |
| Hallucination, olfactory | 6 | 0 |
| Hallucination, tactile | 1 | 0 |
| Hallucination, visual | 36 | 0 |
| Hallucinations, mixed | 6 | 0 |
| Impulse control disorders | | |
| Impulse-control disorder | 2 | 0 |
| Impulsive behaviour | 1 | 0 |
| Intermittent explosive disorder | 1 | 0 |
| Increased physical activity levels | | |
| Restlessness | 367 | 0 |
| Infancy, childhood and adolescence psychiatric disorders NEC | | |
| Emotional disorder of childhood | 1 | 0 |
| Mental disorders NEC | | |
| Mental disorder | 4 | 0 |
| Mental status changes | 3 | 0 |
| Mental disorders due to a general medical condition NEC | | |
| Neuropsychiatric symptoms | 1 | 0 |
| Mood alterations with depressive symptoms | | |
| Anhedonia | 3 | 0 |
| Decreased interest | 10 | 0 |
| Depressed mood | 367 | 0 |
| Depressive symptom | 1 | 0 |
| Feeling guilty | 1 | 0 |
| Feeling of despair | 12 | 0 |
| Negative thoughts | 6 | 0 |
| Sense of a foreshortened future | 1 | 0 |
| Tearfulness | 73 | 0 |
| Mood alterations with manic symptoms | | |
| Hypomania | 1 | 0 |
| Mania | 21 | 0 |
| Mood disorders NEC | | |
| Affective disorder | 1 | 0 |
| Apathy | 33 | 0 |
| Listless | 97 | 0 |
| Mood disorder due to a general medical condition | 1 | 0 |
| Substance-induced mood disorder | 1 | 0 |
| Narcolepsy and associated conditions | | |
| Hypnagogic hallucination | 4 | 0 |
| Sleep attacks | 1 | 0 |
| Obsessive-compulsive disorders and symptoms | | |
| Compulsive shopping | 2 | 0 |
| Dermatillomania | 1 | 0 |
| Obsessive thoughts | 1 | 0 |
| Obsessive-compulsive disorder | 1 | 0 |
| Orgasmic disorders and disturbances | | |
| Anorgasmia | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Orgasmic sensation decreased | 4 | 0 |
| Premature ejaculation | 1 | 0 |
| <i>Panic attacks and disorders</i> | | |
| Limited symptom panic attack | 1 | 0 |
| Panic attack | 181 | 0 |
| Panic disorder | 2 | 0 |
| Panic reaction | 25 | 0 |
| <i>Paraphilias and paraphilic disorders</i> | | |
| Fetishism | 1 | 0 |
| <i>Parasomnias</i> | | |
| Abnormal dreams | 266 | 0 |
| Abnormal sleep-related event | 1 | 0 |
| Confusional arousal | 2 | 0 |
| Exploding head syndrome | 4 | 0 |
| Nightmare | 340 | 0 |
| Parasomnia | 1 | 0 |
| Rapid eye movements sleep abnormal | 3 | 0 |
| Sleep inertia | 1 | 0 |
| Sleep talking | 13 | 0 |
| Sleep terror | 40 | 0 |
| Sleep-related eating disorder | 2 | 0 |
| Somnambulism | 6 | 0 |
| <i>Perception disturbances NEC</i> | | |
| Autoscopy | 16 | 0 |
| Deja vu | 2 | 0 |
| Delusional perception | 1 | 0 |
| Derealisation | 10 | 0 |
| Flashback | 2 | 0 |
| Illusion | 11 | 0 |
| Time perception altered | 5 | 0 |
| <i>Pervasive developmental disorders NEC</i> | | |
| Autism spectrum disorder | 2 | 0 |
| <i>Psychiatric elimination disorders</i> | | |
| Enuresis | 37 | 0 |
| <i>Psychiatric symptoms NEC</i> | | |
| Helplessness | 1 | 0 |
| Hypervigilance | 9 | 0 |
| Psychiatric symptom | 3 | 0 |
| Psychological trauma | 2 | 0 |
| <i>Psychotic disorder NEC</i> | | |
| Acute psychosis | 1 | 0 |
| Psychotic behaviour | 1 | 0 |
| Psychotic disorder | 21 | 0 |
| <i>Schizoaffective and schizophreniform disorders</i> | | |
| Schizoaffective disorder | 1 | 0 |
| <i>Schizophrenia NEC</i> | | |
| Schizophrenia | 1 | 0 |
| <i>Sexual arousal disorders</i> | | |
| Disturbance in sexual arousal | 3 | 0 |
| <i>Sexual desire disorders</i> | | |
| Hypersexuality | 1 | 0 |
| Libido decreased | 8 | 0 |
| Libido increased | 4 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Loss of libido | 25 | 0 |
| Sleep disorders NEC | | |
| Sleep disorder | 263 | 0 |
| Sleep disorder due to general medical condition, insomnia type | 2 | 0 |
| Somatic symptom disorders | | |
| Conversion disorder | 8 | 0 |
| Habit cough | 26 | 0 |
| Illness anxiety disorder | 1 | 0 |
| Psychogenic tremor | 1 | 0 |
| Somatic symptom disorder | 1 | 0 |
| Speech and language usage disturbances | | |
| Disorganised speech | 8 | 0 |
| Logorrhoea | 2 | 0 |
| Pedantic speech | 1 | 0 |
| Poverty of speech | 1 | 0 |
| Verbigeration | 1 | 0 |
| Speech articulation and rhythm disturbances | | |
| Dysphemia | 13 | 0 |
| Lack of spontaneous speech | 2 | 0 |
| Stereotypies and automatisms | | |
| Bruxism | 20 | 0 |
| Head banging | 29 | 0 |
| Waxy flexibility | 2 | 0 |
| Stress disorders | | |
| Acute stress disorder | 2 | 0 |
| Burnout syndrome | 7 | 0 |
| Hyperarousal | 2 | 0 |
| Post-traumatic stress disorder | 11 | 0 |
| Substance related and addictive disorders | | |
| Alcohol abuse | 1 | 0 |
| Alcohol use disorder | 2 | 0 |
| Alcoholism | 1 | 0 |
| Dependence | 1 | 0 |
| Drug dependence | 1 | 0 |
| Substance abuse | 1 | 0 |
| Suicidal and self-injurious behaviour | | |
| Completed suicide | 2 | 1 |
| Intentional self-injury | 6 | 0 |
| Self-injurious ideation | 1 | 0 |
| Suicidal behaviour | 2 | 0 |
| Suicidal ideation | 62 | 0 |
| Suicide attempt | 8 | 0 |
| Suicide threat | 1 | 0 |
| Thinking disturbances | | |
| Bradyphrenia | 58 | 0 |
| Confabulation | 1 | 0 |
| Impaired reasoning | 2 | 0 |
| Intrusive thoughts | 2 | 0 |
| Morbid thoughts | 3 | 0 |
| Tachyphrenia | 17 | 0 |
| Thinking abnormal | 14 | 0 |
| Thought blocking | 3 | 0 |
| Tic disorders | | |

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| Reaction Name | Total | Fatal |
|--|--------------|----------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Tic | 5 | 0 |
| Psychiatric disorders SOC TOTAL | 10792 | 2 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Renal & urinary disorders | | |
| <i>Bladder and urethral symptoms</i> | | |
| Bladder discomfort | 5 | 0 |
| Bladder irritation | 5 | 0 |
| Bladder pain | 35 | 0 |
| Bladder spasm | 1 | 0 |
| Dysuria | 55 | 0 |
| Incontinence | 54 | 0 |
| Micturition disorder | 3 | 0 |
| Micturition frequency decreased | 1 | 0 |
| Micturition urgency | 78 | 0 |
| Mixed incontinence | 1 | 0 |
| Pollakiuria | 207 | 0 |
| Urethral pain | 1 | 0 |
| Urge incontinence | 1 | 0 |
| Urinary hesitation | 4 | 0 |
| Urinary incontinence | 76 | 0 |
| Urinary retention | 46 | 0 |
| Urine flow decreased | 8 | 0 |
| <i>Bladder disorders NEC</i> | | |
| Bladder dilatation | 1 | 0 |
| Bladder disorder | 10 | 0 |
| Urinary bladder haemorrhage | 6 | 1 |
| <i>Bladder infections and inflammations</i> | | |
| Cystitis haemorrhagic | 1 | 0 |
| Cystitis interstitial | 4 | 0 |
| Cystitis noninfective | 1 | 0 |
| <i>Genital and urinary tract disorders NEC</i> | | |
| Urinary tract disorder | 2 | 0 |
| <i>Glomerulonephritis and nephrotic syndrome</i> | | |
| Anti-glomerular basement membrane disease | 1 | 0 |
| Focal segmental glomerulosclerosis | 1 | 0 |
| Glomerulonephritis minimal lesion | 2 | 0 |
| Henoch-Schonlein purpura nephritis | 1 | 0 |
| IgA nephropathy | 2 | 0 |
| Nephrotic syndrome | 7 | 0 |
| <i>Myoneurogenic bladder disorders</i> | | |
| Automatic bladder | 1 | 0 |
| Bladder dysfunction | 1 | 0 |
| Hypertonic bladder | 12 | 0 |
| Loss of bladder sensation | 8 | 0 |
| Neurogenic bladder | 2 | 0 |
| <i>Nephritis NEC</i> | | |
| Nephritis | 5 | 0 |
| Tubulointerstitial nephritis | 3 | 0 |
| <i>Nephropathies and tubular disorders NEC</i> | | |
| Nephropathy | 1 | 0 |
| <i>Renal disorders NEC</i> | | |
| Oedematous kidney | 1 | 0 |
| Renal disorder | 4 | 0 |
| <i>Renal failure and impairment</i> | | |
| Acute kidney injury | 28 | 0 |
| Anuria | 2 | 0 |
| Chronic kidney disease | 4 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------------|----------|
| Renal & urinary disorders | | |
| <i>Renal & urinary disorders cont'd</i> | | |
| Oliguria | 10 | 0 |
| Renal failure | 11 | 2 |
| Renal impairment | 6 | 0 |
| Renal injury | 3 | 0 |
| <i>Renal hypertension and related conditions</i> | | |
| Hypertensive nephropathy | 1 | 0 |
| <i>Renal lithiasis</i> | | |
| Nephrolithiasis | 6 | 0 |
| <i>Renal structural abnormalities and trauma</i> | | |
| Kidney enlargement | 1 | 0 |
| Renal atrophy | 1 | 0 |
| <i>Renal vascular and ischaemic conditions</i> | | |
| Renal embolism | 1 | 0 |
| Renal infarct | 6 | 0 |
| Renal vein thrombosis | 4 | 0 |
| <i>Structural and obstructive urethral disorders (excl congenital)</i> | | |
| Urethral spasm | 1 | 0 |
| <i>Ureteric disorders NEC</i> | | |
| Ureteral disorder | 2 | 0 |
| <i>Urinary abnormalities</i> | | |
| Chromaturia | 73 | 0 |
| Glycosuria | 1 | 0 |
| Haematuria | 36 | 0 |
| Proteinuria | 5 | 0 |
| Urine abnormality | 10 | 0 |
| Urine odour abnormal | 18 | 0 |
| <i>Urinary tract signs and symptoms NEC</i> | | |
| Haemorrhage urinary tract | 28 | 0 |
| Nocturia | 11 | 0 |
| Polyuria | 23 | 0 |
| Renal colic | 2 | 0 |
| Renal pain | 691 | 0 |
| Urinary tract discomfort | 1 | 0 |
| Urinary tract pain | 6 | 0 |
| Renal & urinary disorders SOC TOTAL | 1650 | 3 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Reproductive & breast disorders | | |
| <i>Benign and malignant breast neoplasms</i> | | |
| Breast cyst | 2 | 0 |
| <i>Breast disorders NEC</i> | | |
| Breast disorder | 1 | 0 |
| Breast enlargement | 4 | 0 |
| Breast mass | 22 | 0 |
| Gynaecomastia | 4 | 0 |
| <i>Breast infections and inflammations</i> | | |
| Breast inflammation | 2 | 0 |
| Nipple inflammation | 1 | 0 |
| <i>Breast signs and symptoms</i> | | |
| Breast discharge | 4 | 0 |
| Breast discomfort | 6 | 0 |
| Breast engorgement | 2 | 0 |
| Breast haemorrhage | 1 | 0 |
| Breast induration | 1 | 0 |
| Breast oedema | 1 | 0 |
| Breast pain | 223 | 0 |
| Breast swelling | 30 | 0 |
| Breast tenderness | 26 | 0 |
| Nipple pain | 22 | 0 |
| Nipple swelling | 1 | 0 |
| <i>Erection and ejaculation conditions and disorders</i> | | |
| Ejaculation delayed | 1 | 0 |
| Ejaculation disorder | 1 | 0 |
| Ejaculation failure | 2 | 0 |
| Erectile dysfunction | 56 | 0 |
| Erection increased | 2 | 0 |
| Organic erectile dysfunction | 16 | 0 |
| Painful erection | 1 | 0 |
| Priapism | 2 | 0 |
| Retrograde ejaculation | 1 | 0 |
| Spontaneous penile erection | 2 | 0 |
| <i>Fallopian tube and ovary infections and inflammations</i> | | |
| Noninfective oophoritis | 1 | 0 |
| <i>Lactation disorders</i> | | |
| Galactorrhoea | 1 | 0 |
| Lactation disorder | 2 | 0 |
| Lactation puerperal increased | 1 | 0 |
| Suppressed lactation | 9 | 0 |
| <i>Menopausal effects NEC</i> | | |
| Artificial menopause | 2 | 0 |
| Menopausal disorder | 1 | 0 |
| Menopausal symptoms | 13 | 0 |
| Menopause delayed | 2 | 0 |
| Premature menopause | 1 | 0 |
| <i>Menopausal effects on the genitourinary tract</i> | | |
| Postmenopausal haemorrhage | 31 | 0 |
| <i>Menstruation and uterine bleeding NEC</i> | | |
| Abnormal withdrawal bleeding | 1 | 0 |
| Dysmenorrhoea | 88 | 0 |
| Menstrual disorder | 146 | 0 |
| Menstruation irregular | 160 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Metrorrhagia | 72 | 0 |
| Premenstrual pain | 7 | 0 |
| Premenstrual syndrome | 2 | 0 |
| Withdrawal bleed | 4 | 0 |
| <i>Menstruation with decreased bleeding</i> | | |
| Amenorrhoea | 57 | 0 |
| Hypomenorrhoea | 51 | 0 |
| Menstruation delayed | 264 | 0 |
| Oligomenorrhoea | 17 | 0 |
| <i>Menstruation with increased bleeding</i> | | |
| Menometrorrhagia | 1 | 0 |
| Menorrhagia | 326 | 0 |
| Polymenorrhoea | 28 | 0 |
| <i>Ovarian and fallopian tube cysts and neoplasms</i> | | |
| Ovarian cyst | 4 | 0 |
| Ovarian cyst ruptured | 1 | 0 |
| Polycystic ovaries | 4 | 0 |
| <i>Ovarian and fallopian tube disorders NEC</i> | | |
| Ovarian enlargement | 1 | 0 |
| Ovarian haemorrhage | 2 | 0 |
| Ovarian necrosis | 1 | 0 |
| Ovarian vein thrombosis | 2 | 0 |
| Ovulation pain | 4 | 0 |
| Premature ovulation | 2 | 0 |
| <i>Pelvic prolapse conditions</i> | | |
| Vaginal prolapse | 1 | 0 |
| <i>Pelvis and broad ligament disorders NEC</i> | | |
| Adnexa uteri pain | 13 | 0 |
| Pelvic haematoma | 1 | 0 |
| Pelvic haemorrhage | 5 | 0 |
| <i>Penile and scrotal infections and inflammations</i> | | |
| Balanoposthitis | 1 | 0 |
| <i>Penile disorders NEC (excl erection and ejaculation)</i> | | |
| Penile blister | 4 | 0 |
| Penile burning sensation | 1 | 0 |
| Penile curvature | 2 | 0 |
| Penile discharge | 1 | 0 |
| Penile exfoliation | 1 | 0 |
| Penile oedema | 2 | 0 |
| Penile pain | 1 | 0 |
| Penis disorder | 4 | 0 |
| Peyronie's disease | 2 | 0 |
| <i>Prostate and seminal vesicles infections and inflammations</i> | | |
| Prostatitis | 4 | 0 |
| <i>Prostatic neoplasms and hypertrophy</i> | | |
| Benign prostatic hyperplasia | 2 | 0 |
| <i>Reproductive tract disorders NEC (excl neoplasms)</i> | | |
| Female genital tract fistula | 1 | 0 |
| Genital blister | 3 | 0 |
| Genital haemorrhage | 3 | 0 |
| Genital hyperaesthesia | 1 | 0 |
| Genital hypoaesthesia | 2 | 0 |
| Genital paraesthesia | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Reproductive & breast disorders | | |
| Reproductive & breast disorders cont'd | | |
| Genital ulceration | 7 | 0 |
| Perineal disorder | 1 | 0 |
| Reproductive tract infections and inflammations NEC | | |
| Genital tract inflammation | 1 | 0 |
| Reproductive tract signs and symptoms NEC | | |
| Genital burning sensation | 6 | 0 |
| Genital discomfort | 3 | 0 |
| Genital erythema | 1 | 0 |
| Genital pain | 2 | 0 |
| Genital rash | 2 | 0 |
| Pelvic discomfort | 2 | 0 |
| Pelvic pain | 79 | 0 |
| Perineal pain | 1 | 0 |
| Pruritus genital | 3 | 0 |
| Scrotal disorders NEC | | |
| Scrotal dermatitis | 1 | 0 |
| Scrotal oedema | 1 | 0 |
| Scrotal pain | 8 | 0 |
| Scrotal swelling | 5 | 0 |
| Sexual function and fertility disorders NEC | | |
| Dyspareunia | 2 | 0 |
| Female sexual dysfunction | 1 | 0 |
| Infertility male | 1 | 0 |
| Sexual dysfunction | 4 | 0 |
| Spermatogenesis and semen disorders | | |
| Haemospermia | 6 | 0 |
| Semen discolouration | 1 | 0 |
| Testicular and epididymal disorders NEC | | |
| Testicular disorder | 2 | 0 |
| Testicular mass | 1 | 0 |
| Testicular oedema | 1 | 0 |
| Testicular pain | 61 | 0 |
| Testicular retraction | 1 | 0 |
| Testicular swelling | 10 | 0 |
| Testicular and epididymal neoplasms | | |
| Epididymal cyst | 1 | 0 |
| Testicular cyst | 1 | 0 |
| Uterine disorders NEC | | |
| Adenomyosis | 1 | 0 |
| Endometriosis | 19 | 0 |
| Uterine enlargement | 1 | 0 |
| Uterine haemorrhage | 9 | 0 |
| Uterine pain | 2 | 0 |
| Uterine neoplasms | | |
| Uterine polyp | 1 | 0 |
| Uterine tone disorders | | |
| Uterine spasm | 7 | 0 |
| Vaginal and vulval infections and inflammations | | |
| Vulvovaginal inflammation | 2 | 0 |
| Vulvovaginal cysts and neoplasms | | |
| Bartholin's cyst | 1 | 0 |
| Vaginal cyst | 5 | 0 |
| Vulvovaginal disorders NEC | | |

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| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Vaginal haemorrhage | 253 | 0 |
| Vaginal ulceration | 3 | 0 |
| Vulval disorder | 2 | 0 |
| Vulval haemorrhage | 6 | 0 |
| Vulval ulceration | 3 | 0 |
| Vulvovaginal ulceration | 2 | 0 |
| <i>Vulvovaginal signs and symptoms</i> | | |
| Enlarged clitoris | 1 | 0 |
| Labia enlarged | 1 | 0 |
| Vaginal discharge | 26 | 0 |
| Vaginal lesion | 4 | 0 |
| Vulval oedema | 1 | 0 |
| Vulvovaginal burning sensation | 7 | 0 |
| Vulvovaginal discomfort | 2 | 0 |
| Vulvovaginal dryness | 1 | 0 |
| Vulvovaginal erythema | 1 | 0 |
| Vulvovaginal pain | 13 | 0 |
| Vulvovaginal pruritus | 4 | 0 |
| Vulvovaginal rash | 2 | 0 |
| Vulvovaginal swelling | 3 | 0 |
| Reproductive & breast disorders SOC TOTAL | 2401 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Apnoea | 8 | 0 |
| Apnoeic attack | 1 | 0 |
| Dyspnoea | 4318 | 4 |
| Dyspnoea at rest | 9 | 0 |
| Dyspnoea exertional | 27 | 0 |
| Dyspnoea paroxysmal nocturnal | 1 | 0 |
| Grunting | 1 | 0 |
| Hyperventilation | 68 | 0 |
| Hypopnoea | 161 | 0 |
| Hypoventilation | 1 | 0 |
| Irregular breathing | 19 | 0 |
| Mouth breathing | 7 | 0 |
| Orthopnoea | 2 | 0 |
| Respiration abnormal | 69 | 0 |
| Respiratory arrest | 16 | 0 |
| Respiratory distress | 7 | 1 |
| Respiratory fatigue | 3 | 0 |
| Sleep apnoea syndrome | 18 | 0 |
| Tachypnoea | 31 | 0 |
| <i>Bronchial conditions NEC</i> | | |
| Bronchiectasis | 12 | 0 |
| <i>Bronchospasm and obstruction</i> | | |
| Aspirin-exacerbated respiratory disease | 1 | 0 |
| Asthma | 371 | 0 |
| Asthma exercise induced | 1 | 0 |
| Asthma late onset | 1 | 0 |
| Asthmatic crisis | 4 | 0 |
| Bronchitis chronic | 1 | 0 |
| Bronchospasm | 12 | 0 |
| Chronic obstructive pulmonary disease | 22 | 2 |
| Cough variant asthma | 6 | 0 |
| Obstructive airways disorder | 2 | 0 |
| Reversible airways obstruction | 1 | 0 |
| Wheezing | 400 | 0 |
| <i>Conditions associated with abnormal gas exchange</i> | | |
| Asphyxia | 1 | 0 |
| Hypercapnia | 1 | 0 |
| Hypoxia | 46 | 1 |
| <i>Coughing and associated symptoms</i> | | |
| Allergic cough | 4 | 0 |
| Cough | 2658 | 0 |
| Haemoptysis | 70 | 0 |
| Productive cough | 123 | 0 |
| Sputum discoloured | 6 | 0 |
| Sputum increased | 1 | 0 |
| <i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i> | | |
| Reflux laryngitis | 1 | 0 |
| <i>Laryngeal spasm, oedema and obstruction</i> | | |
| Laryngeal oedema | 2 | 0 |
| Laryngospasm | 1 | 0 |
| Stridor | 15 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| <i>Lower respiratory tract inflammatory and immunologic conditions</i> | | |
| Alveolitis | 2 | 0 |
| Pneumonia aspiration | 19 | 4 |
| Pneumonitis | 17 | 1 |
| <i>Lower respiratory tract signs and symptoms</i> | | |
| Hiccups | 30 | 0 |
| Lower respiratory tract congestion | 3 | 0 |
| Lung opacity | 4 | 0 |
| Pleuritic pain | 18 | 0 |
| Pulmonary haemorrhage | 3 | 0 |
| Pulmonary pain | 144 | 0 |
| Rales | 1 | 0 |
| <i>Nasal congestion and inflammations</i> | | |
| Nasal congestion | 336 | 0 |
| Nasal inflammation | 6 | 0 |
| Rhinitis allergic | 13 | 0 |
| Rhinitis perennial | 1 | 0 |
| <i>Nasal disorders NEC</i> | | |
| Epistaxis | 1197 | 0 |
| Intranasal hyposaesthesia | 1 | 0 |
| Nasal crusting | 5 | 0 |
| Nasal cyst | 2 | 0 |
| Nasal disorder | 2 | 0 |
| Nasal dryness | 41 | 0 |
| Nasal mucosal discolouration | 1 | 0 |
| Nasal odour | 2 | 0 |
| Nasal oedema | 7 | 0 |
| Nasal polyps | 1 | 0 |
| Nasal pruritus | 6 | 0 |
| Nasal ulcer | 2 | 0 |
| <i>Neonatal hypoxic conditions</i> | | |
| Cyanosis neonatal | 1 | 0 |
| Gasping syndrome | 2 | 0 |
| <i>Paranasal sinus disorders (excl infections and neoplasms)</i> | | |
| Paranasal sinus haemorrhage | 5 | 0 |
| Paranasal sinus inflammation | 1 | 0 |
| Sinonasal obstruction | 6 | 0 |
| Sinus congestion | 56 | 0 |
| Sinus disorder | 9 | 0 |
| <i>Parenchymal lung disorders NEC</i> | | |
| Emphysema | 1 | 0 |
| Idiopathic pulmonary fibrosis | 1 | 0 |
| Interstitial lung disease | 3 | 0 |
| Lung consolidation | 1 | 0 |
| Lung cyst | 1 | 0 |
| Lung infiltration | 1 | 0 |
| Pulmonary cavitation | 3 | 0 |
| Pulmonary fibrosis | 4 | 0 |
| <i>Pharyngeal disorders (excl infections and neoplasms)</i> | | |
| Oropharyngeal swelling | 2 | 0 |
| Pharyngeal erythema | 3 | 0 |
| Pharyngeal haemorrhage | 1 | 0 |
| Pharyngeal hyposaesthesia | 27 | 0 |

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Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| Pharyngeal oedema | 11 | 0 |
| Pharyngeal paraesthesia | 24 | 0 |
| Pharyngeal swelling | 181 | 0 |
| Pharyngeal ulceration | 11 | 0 |
| Tonsillar disorder | 1 | 0 |
| Tonsillar erythema | 4 | 0 |
| Tonsillar haemorrhage | 1 | 0 |
| Tonsillar hypertrophy | 38 | 0 |
| Tonsillar inflammation | 3 | 0 |
| <i>Pleural infections and inflammations</i> | | |
| Lupus pleurisy | 1 | 0 |
| Pleurisy | 24 | 0 |
| <i>Pneumothorax and pleural effusions NEC</i> | | |
| Haemothorax | 1 | 0 |
| Pleural effusion | 11 | 0 |
| Pneumothorax | 2 | 0 |
| <i>Pulmonary hypertensions</i> | | |
| Pulmonary hypertension | 2 | 1 |
| <i>Pulmonary oedemas</i> | | |
| Acute lung injury | 1 | 0 |
| Acute pulmonary oedema | 2 | 0 |
| Acute respiratory distress syndrome | 1 | 0 |
| Pulmonary congestion | 14 | 0 |
| Pulmonary oedema | 13 | 1 |
| <i>Pulmonary thrombotic and embolic conditions</i> | | |
| Pulmonary embolism | 714 | 65 |
| Pulmonary infarction | 5 | 1 |
| Pulmonary thrombosis | 10 | 1 |
| Pulmonary venous thrombosis | 1 | 0 |
| <i>Respiratory failures (excl neonatal)</i> | | |
| Acute respiratory failure | 1 | 0 |
| Respiratory failure | 11 | 2 |
| <i>Respiratory signs and symptoms NEC</i> | | |
| Allergic respiratory symptom | 4 | 0 |
| Diaphragmalgia | 13 | 0 |
| Painful respiration | 2 | 0 |
| Respiratory symptom | 15 | 0 |
| Suffocation feeling | 3 | 0 |
| <i>Respiratory tract disorders NEC</i> | | |
| Aspiration | 7 | 2 |
| Chronic respiratory disease | 1 | 0 |
| Lung disorder | 4 | 0 |
| Respiratory disorder | 5 | 0 |
| Respiratory tract congestion | 6 | 0 |
| Respiratory tract haemorrhage | 1 | 0 |
| Respiratory tract irritation | 5 | 0 |
| <i>Thoracic musculoskeletal disorders</i> | | |
| Respiratory muscle weakness | 1 | 0 |
| <i>Tracheal disorders (excl infections and neoplasms)</i> | | |
| Tracheal fistula | 1 | 0 |
| Tracheal pain | 1 | 0 |
| <i>Upper respiratory tract signs and symptoms</i> | | |
| Aphonia | 53 | 0 |

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Report Run Date: 26-Apr-2021

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|--------------|-----------|
| Respiratory disorders Respiratory disorders cont'd | | |
| Catarrh | 45 | 0 |
| Choking | 13 | 0 |
| Choking sensation | 7 | 0 |
| Dry throat | 192 | 0 |
| Dysphonia | 92 | 0 |
| Increased upper airway secretion | 3 | 0 |
| Increased viscosity of upper respiratory secretion | 15 | 0 |
| Laryngeal pain | 1 | 0 |
| Nasal discharge discolouration | 1 | 0 |
| Nasal discomfort | 80 | 0 |
| Oropharyngeal blistering | 18 | 0 |
| Oropharyngeal discomfort | 22 | 0 |
| Oropharyngeal pain | 3061 | 0 |
| Paranasal sinus discomfort | 38 | 0 |
| Rhinalgia | 27 | 0 |
| Rhinorrhoea | 1257 | 0 |
| Sinus pain | 436 | 0 |
| Sneezing | 351 | 0 |
| Snoring | 2 | 0 |
| Throat clearing | 3 | 0 |
| Throat irritation | 139 | 0 |
| Throat lesion | 1 | 0 |
| Throat tightness | 145 | 0 |
| Upper respiratory tract congestion | 1 | 0 |
| Upper-airway cough syndrome | 17 | 0 |
| Yawning | 56 | 0 |
| Respiratory disorders SOC TOTAL | 17755 | 86 |

Case Series Drug Analysis Print

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Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Skin disorders | | |
| <i>Acnes</i> | | |
| Acne | 50 | 0 |
| Acne cystic | 3 | 0 |
| Dermatitis acneiform | 4 | 0 |
| <i>Alopecias</i> | | |
| Alopecia | 119 | 0 |
| Alopecia areata | 4 | 0 |
| Alopecia totalis | 1 | 0 |
| Alopecia universalis | 1 | 0 |
| Androgenetic alopecia | 1 | 0 |
| Diffuse alopecia | 3 | 0 |
| Madarosis | 2 | 0 |
| <i>Angioedemas</i> | | |
| Angioedema | 221 | 0 |
| Circumoral oedema | 1 | 0 |
| Idiopathic angioedema | 3 | 0 |
| <i>Apocrine and eccrine gland disorders</i> | | |
| Anhidrosis | 2 | 0 |
| Cold sweat | 1310 | 0 |
| Hyperhidrosis | 7182 | 0 |
| Hypohidrosis | 2 | 0 |
| Miliaria | 147 | 0 |
| Night sweats | 1399 | 0 |
| Sweat discolouration | 1 | 0 |
| Sweat gland disorder | 1 | 0 |
| <i>Bullous conditions</i> | | |
| Blister | 273 | 0 |
| Blister rupture | 4 | 0 |
| Blood blister | 43 | 0 |
| Dermatitis bullous | 9 | 0 |
| Dermatitis herpetiformis | 2 | 0 |
| Erythema multiforme | 22 | 0 |
| Oedema blister | 1 | 0 |
| Pemphigoid | 10 | 0 |
| Pemphigus | 1 | 0 |
| Stevens-Johnson syndrome | 6 | 0 |
| Toxic epidermal necrolysis | 1 | 0 |
| <i>Connective tissue disorders</i> | | |
| Cutaneous lupus erythematosus | 1 | 0 |
| Dermatomyositis | 2 | 0 |
| Subacute cutaneous lupus erythematosus | 1 | 0 |
| <i>Dermal and epidermal conditions NEC</i> | | |
| Dry skin | 259 | 0 |
| Macule | 4 | 0 |
| Myxoid cyst | 1 | 0 |
| Pain of skin | 725 | 0 |
| Papule | 46 | 0 |
| Peau d'orange | 2 | 0 |
| Scab | 14 | 0 |
| Scar pain | 7 | 0 |
| Sensitive skin | 445 | 0 |
| Skin burning sensation | 399 | 0 |
| Skin discolouration | 111 | 0 |

Case Series Drug Analysis Print

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Skin discomfort | 1 | 0 |
| Skin disorder | 12 | 0 |
| Skin fissures | 8 | 0 |
| Skin fragility | 1 | 0 |
| Skin indentation | 5 | 0 |
| Skin induration | 12 | 0 |
| Skin laxity | 1 | 0 |
| Skin lesion | 22 | 0 |
| Skin necrosis | 2 | 0 |
| Skin odour abnormal | 35 | 0 |
| Skin plaque | 1 | 0 |
| Skin reaction | 177 | 0 |
| Skin sensitisation | 70 | 0 |
| Skin swelling | 68 | 0 |
| Skin texture abnormal | 1 | 0 |
| Skin tightness | 18 | 0 |
| Skin warm | 436 | 0 |
| Skin weeping | 4 | 0 |
| Sticky skin | 1 | 0 |
| Transient acantholytic dermatosis | 1 | 0 |
| Yellow skin | 19 | 0 |
| <i>Dermatitis and eczema</i> | | |
| Dermatitis | 120 | 0 |
| Dermatitis allergic | 207 | 0 |
| Dermatitis atopic | 12 | 0 |
| Dermatitis contact | 9 | 0 |
| Dermatitis diaper | 2 | 0 |
| Dyshidrotic eczema | 5 | 0 |
| Eczema | 139 | 0 |
| Eczema asteatotic | 8 | 0 |
| Eczema nummular | 1 | 0 |
| Eczema weeping | 1 | 0 |
| Hand dermatitis | 4 | 0 |
| Intertrigo | 2 | 0 |
| Perioral dermatitis | 3 | 0 |
| Prurigo | 1 | 0 |
| Rebound eczema | 1 | 0 |
| Seborrhoeic dermatitis | 5 | 0 |
| Skin irritation | 88 | 0 |
| Stasis dermatitis | 3 | 0 |
| <i>Dermatitis ascribed to specific agent</i> | | |
| Drug eruption | 27 | 0 |
| Drug reaction with eosinophilia and systemic symptoms | 10 | 0 |
| Fixed eruption | 3 | 0 |
| Palmar-plantar erythrodysesthesia syndrome | 1 | 0 |
| <i>Erythemas</i> | | |
| Erythema | 2496 | 0 |
| Erythema ab igne | 1 | 0 |
| Palmar erythema | 4 | 0 |
| <i>Exfoliative conditions</i> | | |
| Dermatitis exfoliative | 1 | 0 |
| Dermatitis exfoliative generalised | 3 | 0 |
| Exfoliative rash | 12 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Skin exfoliation | 73 | 0 |
| <i>Granulomatous and deep cutaneous inflammatory conditions</i> | | |
| Granuloma annulare | 2 | 0 |
| <i>Hyperpigmentation disorders</i> | | |
| Melanoderma | 1 | 0 |
| Skin hyperpigmentation | 1 | 0 |
| Solar lentigo | 2 | 0 |
| <i>Hypopigmentation disorders</i> | | |
| Skin depigmentation | 5 | 0 |
| Skin hypopigmentation | 1 | 0 |
| Vitiligo | 7 | 0 |
| <i>Lipodystrophies</i> | | |
| Lipoatrophy | 2 | 0 |
| Lipohypertrophy | 2 | 0 |
| <i>Nail and nail bed conditions (excl infections and infestations)</i> | | |
| Nail bed disorder | 1 | 0 |
| Nail bed tenderness | 1 | 0 |
| Nail discolouration | 6 | 0 |
| Nail disorder | 1 | 0 |
| Nail hypertrophy | 1 | 0 |
| Nail pigmentation | 1 | 0 |
| Nail pitting | 1 | 0 |
| Nail ridging | 1 | 0 |
| Onychalgia | 2 | 0 |
| Onychoclasia | 3 | 0 |
| Onycholysis | 1 | 0 |
| Onychomadesis | 1 | 0 |
| <i>Panniculitides</i> | | |
| Erythema nodosum | 8 | 0 |
| Panniculitis | 1 | 0 |
| <i>Papulosquamous conditions</i> | | |
| Erythema annulare | 1 | 0 |
| Lichen planus | 9 | 0 |
| Lichen sclerosus | 2 | 0 |
| Pityriasis rosea | 16 | 0 |
| Pityriasis rubra pilaris | 1 | 0 |
| <i>Photosensitivity and photodermatosis conditions</i> | | |
| Photosensitivity reaction | 107 | 0 |
| Polymorphic light eruption | 1 | 0 |
| <i>Pigmentation changes NEC</i> | | |
| Pigmentation disorder | 6 | 0 |
| <i>Pilar disorders NEC</i> | | |
| Hair colour changes | 3 | 0 |
| Hair disorder | 1 | 0 |
| Hair growth abnormal | 3 | 0 |
| Hair texture abnormal | 2 | 0 |
| Piloerection | 71 | 0 |
| Pseudofolliculitis | 1 | 0 |
| Trichodynia | 5 | 0 |
| <i>Pruritus NEC</i> | | |
| Itching scar | 2 | 0 |
| Pruritus | 5399 | 0 |
| Pruritus allergic | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| <i>Psoriatic conditions</i> | | |
| Guttate psoriasis | 11 | 0 |
| Psoriasis | 91 | 0 |
| Pustular psoriasis | 1 | 0 |
| <i>Purpura and related conditions</i> | | |
| Ecchymosis | 2 | 0 |
| Henoch-Schonlein purpura | 4 | 0 |
| Petechiae | 145 | 0 |
| Purpura | 62 | 1 |
| <i>Pustular conditions</i> | | |
| Rash follicular | 3 | 0 |
| <i>Rashes, eruptions and exanthems NEC</i> | | |
| Butterfly rash | 5 | 0 |
| Rash | 5523 | 0 |
| Rash erythematous | 1565 | 0 |
| Rash macular | 486 | 0 |
| Rash maculo-papular | 37 | 0 |
| Rash morbilliform | 27 | 0 |
| Rash papular | 335 | 0 |
| Rash pruritic | 1244 | 0 |
| Rash rubelliform | 1 | 0 |
| Rash scarlatiniform | 1 | 0 |
| Rash vesicular | 45 | 0 |
| Systemic lupus erythematosus rash | 3 | 0 |
| <i>Rosaceas</i> | | |
| Erythematotelangiectatic rosacea | 1 | 0 |
| Rosacea | 18 | 0 |
| <i>Scaly conditions</i> | | |
| Pityriasis | 4 | 0 |
| <i>Sebaceous gland disorders</i> | | |
| Seborrhoea | 5 | 0 |
| <i>Skin and subcutaneous conditions NEC</i> | | |
| Cutaneous symptom | 7 | 0 |
| Skin mass | 25 | 0 |
| <i>Skin and subcutaneous tissue ulcerations</i> | | |
| Diabetic foot | 1 | 0 |
| Mucocutaneous ulceration | 2 | 0 |
| Pyoderma gangrenosum | 1 | 0 |
| Skin erosion | 30 | 0 |
| Skin ulcer | 17 | 0 |
| <i>Skin cysts and polyps</i> | | |
| Dermal cyst | 10 | 0 |
| <i>Skin dystrophies</i> | | |
| Skin wrinkling | 2 | 0 |
| <i>Skin haemorrhages</i> | | |
| Haemorrhage subcutaneous | 8 | 0 |
| Skin haemorrhage | 19 | 0 |
| <i>Skin hyperplasias and hypertrophies</i> | | |
| Skin hypertrophy | 1 | 0 |
| <i>Skin hypoplasias and atrophies</i> | | |
| Skin atrophy | 3 | 0 |
| Skin striae | 5 | 0 |
| <i>Skin injuries and mechanical dermatoses</i> | | |

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| Reaction Name | Total | Fatal |
|---|--------------|----------|
| Skin disorders Skin disorders cont'd | | |
| Decubitus ulcer | 2 | 0 |
| Needle track marks | 3 | 0 |
| <i>Skin preneoplastic conditions NEC</i> | | |
| Actinic keratosis | 1 | 0 |
| Leukoplakia | 1 | 0 |
| <i>Skin vascular conditions NEC</i> | | |
| Skin oedema | 2 | 0 |
| <i>Skin vasculitides</i> | | |
| Cutaneous vasculitis | 3 | 0 |
| Hypersensitivity vasculitis | 2 | 0 |
| Vasculitic rash | 15 | 1 |
| <i>Skin vasomotor conditions</i> | | |
| Livedo reticularis | 29 | 0 |
| <i>Telangiectasia and related conditions</i> | | |
| Spider naevus | 1 | 0 |
| <i>Urticarias</i> | | |
| Chronic spontaneous urticaria | 2 | 0 |
| Cold urticaria | 2 | 0 |
| Idiopathic urticaria | 5 | 0 |
| Mechanical urticaria | 1 | 0 |
| Solar urticaria | 1 | 0 |
| Urticaria | 1561 | 0 |
| Urticaria chronic | 14 | 0 |
| Urticaria contact | 2 | 0 |
| Urticaria papular | 1 | 0 |
| Urticaria thermal | 5 | 0 |
| Urticarial vasculitis | 5 | 0 |
| Skin disorders SOC TOTAL | 34074 | 2 |

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| Reaction Name | Total | Fatal |
|---|------------|----------|
| Social circumstances | | |
| <i>Age related issues</i> | | |
| Childhood | 1 | 0 |
| Menarche | 1 | 0 |
| Menopause | 3 | 0 |
| <i>Bereavement issues</i> | | |
| Death of relative | 1 | 1 |
| <i>Criminal activity</i> | | |
| Chemical submission | 1 | 0 |
| <i>Dietary and nutritional issues</i> | | |
| Inadequate diet | 1 | 0 |
| <i>Disability issues</i> | | |
| Bedridden | 58 | 0 |
| Breast prosthesis user | 1 | 0 |
| Dependence on oxygen therapy | 1 | 0 |
| Disability | 1 | 0 |
| Hearing disability | 1 | 0 |
| Housebound | 1 | 0 |
| Immobile | 25 | 0 |
| Immobilisation prolonged | 2 | 0 |
| Impaired driving ability | 2 | 0 |
| Impaired work ability | 8 | 0 |
| Loss of personal independence in daily activities | 2 | 0 |
| Sight disability | 13 | 0 |
| Sitting disability | 2 | 0 |
| Walking disability | 2 | 0 |
| <i>Employment issues</i> | | |
| Retirement | 3 | 0 |
| Stress at work | 1 | 0 |
| <i>Family and partner issues</i> | | |
| Homosexual parent | 1 | 0 |
| <i>Non-occupational and unspecified environmental problems</i> | | |
| Food contamination | 1 | 0 |
| Water pollution | 3 | 0 |
| <i>Pregnancy related circumstances</i> | | |
| Breast feeding | 4 | 0 |
| <i>Sexuality issues</i> | | |
| Anal sex | 1 | 0 |
| <i>Social issues NEC</i> | | |
| Blood donor | 1 | 0 |
| Contraindication to medical treatment | 1 | 0 |
| Contraindication to vaccination | 2 | 0 |
| Convalescent | 1 | 0 |
| <i>Tobacco use</i> | | |
| Non-tobacco user | 2 | 0 |
| Tobacco user | 2 | 0 |
| Social circumstances SOC TOTAL | 150 | 1 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Surgical & medical procedures | | |
| <i>Anaesthesia and allied procedures</i> | | |
| Local anaesthesia | 3 | 0 |
| Nerve block | 2 | 0 |
| <i>Analgesia supportive care</i> | | |
| Analgesic therapy | 1 | 0 |
| <i>Antiinfective therapies</i> | | |
| COVID-19 treatment | 4 | 0 |
| <i>Arterial therapeutic procedures (excl aortic)</i> | | |
| Coronary artery bypass | 1 | 0 |
| <i>Blood and blood product treatment</i> | | |
| Photopheresis | 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 |
| <i>Cardiac device therapeutic procedures</i> | | |
| Pacemaker generated rhythm | 1 | 0 |
| <i>Cardiac therapeutic procedures NEC</i> | | |
| Pericardial excision | 1 | 0 |
| <i>Contraceptive methods female</i> | | |
| Contraceptive diaphragm | 2 | 0 |
| <i>Corneal and scleral therapeutic procedures</i> | | |
| Corneal transplant | 1 | 0 |
| <i>Dietary and nutritional therapies</i> | | |
| Fluid replacement | 1 | 0 |
| Medical diet | 1 | 0 |
| Nothing by mouth order | 1 | 0 |
| <i>External ear therapeutic procedures</i> | | |
| Cerumen removal | 1 | 0 |
| <i>Eye therapeutic procedures NEC</i> | | |
| Eye irrigation | 3 | 0 |
| <i>Facial therapeutic procedures</i> | | |
| Face lift | 2 | 0 |
| <i>Fertility and fertilisation interventions female</i> | | |
| Ovulation induction | 1 | 0 |
| <i>Gastrointestinal therapeutic procedures NEC</i> | | |
| Intestinal resection | 1 | 0 |
| Prophylaxis against gastrointestinal ulcer | 1 | 0 |
| Prophylaxis of nausea and vomiting | 25 | 0 |
| <i>Gynaecological therapeutic procedures NEC</i> | | |
| Menstrual cycle management | 1 | 0 |
| <i>Haematological therapeutic procedures NEC</i> | | |
| Anticoagulant therapy | 1 | 0 |
| Haemofiltration | 1 | 0 |
| <i>Head, neck and oral cavity therapeutic procedures NEC</i> | | |
| Neck lift | 1 | 0 |
| <i>Hormonal therapeutic procedures NEC</i> | | |
| Hormone replacement therapy | 3 | 0 |
| <i>Immunisations</i> | | |
| COVID-19 immunisation | 149 | 1 |
| Immunisation | 67 | 0 |
| Tuberculosis immunisation | 1 | 0 |
| <i>Induced abortions</i> | | |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Surgical & medical procedures | | |
| <i>Surgical & medical procedures cont'd</i> | | |
| Abortion induced | 1 | 0 |
| Joint therapeutic procedures | | |
| Hip surgery | 1 | 0 |
| Joint injection | 1 | 0 |
| Large intestine therapeutic procedures | | |
| Appendectomy | 2 | 0 |
| Limb therapeutic procedures | | |
| Leg amputation | 1 | 0 |
| Limb immobilisation | 20 | 0 |
| Limb operation | 4 | 0 |
| Limb reattachment surgery | 1 | 0 |
| Toe amputation | 3 | 0 |
| Mastectomies | | |
| Breast conserving surgery | 2 | 0 |
| Muscle therapeutic procedures | | |
| Muscle relaxant therapy | 1 | 0 |
| Nasal therapeutic procedures | | |
| Nasal irrigation | 1 | 0 |
| Nervous system therapeutic procedures NEC | | |
| Central nervous system stimulation | 3 | 0 |
| Orbit and globe therapeutic procedures | | |
| Eye muscle operation | 1 | 0 |
| Patient positioning | | |
| Prone position | 1 | 0 |
| Prophylactic procedures NEC | | |
| Anaphylaxis prophylaxis | 3 | 0 |
| Skin and subcutaneous tissue therapeutic procedures NEC | | |
| Dermal filler injection | 1 | 0 |
| Small intestine therapeutic procedures | | |
| Ileostomy | 2 | 0 |
| Spine and spinal cord therapeutic procedures | | |
| Spinal operation | 1 | 0 |
| Testicular and scrotal therapeutic procedures | | |
| Testes exploration | 1 | 0 |
| Therapeutic procedures NEC | | |
| Anaphylaxis treatment | 3 | 0 |
| Bed rest | 19 | 0 |
| Catheter management | 1 | 0 |
| Catheter placement | 1 | 0 |
| Fatigue management | 1 | 0 |
| Heat therapy | 1 | 0 |
| Hospitalisation | 14 | 0 |
| Injection | 32 | 0 |
| Localised alternating hot and cold therapy | 5 | 0 |
| Manipulation | 1 | 0 |
| Mass excision | 9 | 0 |
| Medication dilution | 1 | 0 |
| Product used for unknown indication | 1 | 0 |
| Promotion of wound healing | 1 | 0 |
| Self-medication | 1 | 0 |
| Smoking cessation therapy | 1 | 0 |
| Specialist consultation | 1 | 0 |
| Stoma care | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Surgical & medical procedures | | |
| Surgical & medical procedures cont'd | | |
| Therapeutic hypothermia | 2 | 0 |
| Therapy change | 1 | 0 |
| Transgender operation | 1 | 0 |
| <i>Uterine therapeutic procedures</i> | | |
| Endometrial ablation | 1 | 0 |
| <i>Vascular therapeutic procedures NEC</i> | | |
| Thrombectomy | 3 | 0 |
| <i>Venous therapeutic procedures</i> | | |
| Phlebotomy | 1 | 0 |
| Surgical & medical procedures SOC TOTAL | 434 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Apr-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Apr-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Vascular disorders | | |
| <i>Accelerated and malignant hypertension</i> | | |
| Accelerated hypertension | 1 | 0 |
| Hypertensive crisis | 7 | 0 |
| Hypertensive emergency | 1 | 0 |
| Hypertensive urgency | 1 | 0 |
| Malignant hypertension | 2 | 0 |
| Tyramine reaction | 1 | 0 |
| <i>Aneurysms and dissections non-site specific</i> | | |
| Aneurysm | 7 | 2 |
| Artery dissection | 1 | 0 |
| <i>Aortic aneurysms and dissections</i> | | |
| Aortic aneurysm | 4 | 0 |
| Aortic dissection | 1 | 0 |
| <i>Aortic embolism and thrombosis</i> | | |
| Aortic embolus | 11 | 0 |
| Aortic thrombosis | 6 | 1 |
| <i>Aortic infections and inflammations</i> | | |
| Aortitis | 2 | 0 |
| <i>Aortic necrosis and vascular insufficiency</i> | | |
| Aortic stenosis | 1 | 0 |
| <i>Arterial infections and inflammations</i> | | |
| Arteritis | 1 | 0 |
| Giant cell arteritis | 32 | 0 |
| <i>Blood pressure disorders NEC</i> | | |
| Blood pressure fluctuation | 11 | 0 |
| Labile blood pressure | 1 | 0 |
| <i>Bruising, ecchymosis and purpura</i> | | |
| Achenbach syndrome | 2 | 0 |
| <i>Circulatory collapse and shock</i> | | |
| Circulatory collapse | 65 | 1 |
| Distributive shock | 1 | 0 |
| Hypoperfusion | 2 | 0 |
| Neurogenic shock | 8 | 0 |
| Peripheral circulatory failure | 3 | 0 |
| Shock | 34 | 0 |
| Shock symptom | 5 | 0 |
| <i>Haemorrhages NEC</i> | | |
| Bloody discharge | 6 | 0 |
| Haematoma | 61 | 0 |
| Haemorrhage | 287 | 2 |
| Internal haemorrhage | 16 | 0 |
| Venous haemorrhage | 1 | 0 |
| <i>Lymphoedemas</i> | | |
| Lymphoedema | 40 | 0 |
| <i>Non-site specific embolism and thrombosis</i> | | |
| Arterial thrombosis | 15 | 1 |
| Embolism | 188 | 3 |
| Embolism arterial | 2 | 0 |
| Embolism venous | 11 | 1 |
| Microembolism | 2 | 0 |
| Thrombophlebitis migrans | 1 | 0 |
| Thrombosis | 759 | 18 |
| Venous thrombosis | 20 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Vascular disorders <small>Vascular disorders cont'd</small> | | |
| <i>Non-site specific necrosis and vascular insufficiency NEC</i> | | |
| Arterial occlusive disease | 3 | 0 |
| Arterial spasm | 1 | 0 |
| Arterial stenosis | 1 | 0 |
| Arteriosclerosis | 2 | 0 |
| Infarction | 5 | 0 |
| Ischaemia | 7 | 0 |
| Peripheral venous disease | 3 | 0 |
| Vascular compression | 1 | 0 |
| Vasospasm | 4 | 0 |
| <i>Non-site specific vascular disorders NEC</i> | | |
| Angiopathy | 1 | 0 |
| Capillary fragility | 5 | 0 |
| Hyperaemia | 1 | 0 |
| Neovascularisation | 1 | 0 |
| Vascular pain | 58 | 0 |
| Vascular rupture | 1 | 0 |
| Vasodilatation | 62 | 0 |
| Vein collapse | 1 | 0 |
| Vein discolouration | 3 | 0 |
| Vein disorder | 4 | 0 |
| Vein rupture | 9 | 0 |
| <i>Peripheral aneurysms and dissections</i> | | |
| Peripheral artery aneurysm | 1 | 0 |
| <i>Peripheral embolism and thrombosis</i> | | |
| Blue toe syndrome | 13 | 0 |
| Deep vein thrombosis | 536 | 3 |
| Femoral artery embolism | 1 | 0 |
| Iliac artery embolism | 1 | 0 |
| Jugular vein thrombosis | 9 | 0 |
| Pelvic venous thrombosis | 5 | 0 |
| Peripheral artery thrombosis | 8 | 0 |
| Peripheral embolism | 4 | 0 |
| Peripheral vein thrombus extension | 1 | 0 |
| Subclavian artery thrombosis | 1 | 0 |
| Thrombophlebitis | 61 | 0 |
| Thrombophlebitis superficial | 25 | 0 |
| Venous thrombosis limb | 2 | 0 |
| <i>Peripheral vascular disorders NEC</i> | | |
| Cyanosis | 70 | 0 |
| Erythromelalgia | 2 | 0 |
| Flushing | 546 | 0 |
| Hot flush | 1497 | 0 |
| Peripheral vascular disorder | 3 | 0 |
| <i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i> | | |
| Extremity necrosis | 1 | 0 |
| Intermittent claudication | 2 | 0 |
| Ischaemic limb pain | 3 | 0 |
| Peripheral artery occlusion | 4 | 0 |
| Peripheral coldness | 959 | 0 |
| Peripheral ischaemia | 17 | 2 |
| Poor peripheral circulation | 29 | 0 |
| Raynaud's phenomenon | 79 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|---------------|------------|
| Vascular disorders Vascular disorders cont'd | | |
| <i>Phlebitis NEC</i> | | |
| Phlebitis | 30 | 0 |
| Phlebitis superficial | 5 | 0 |
| <i>Site specific embolism and thrombosis NEC</i> | | |
| Brachiocephalic vein thrombosis | 1 | 0 |
| <i>Site specific vascular disorders NEC</i> | | |
| Pallor | 303 | 0 |
| Plethoric face | 1 | 0 |
| <i>Varicose veins NEC</i> | | |
| Spider vein | 2 | 0 |
| Varicophlebitis | 3 | 0 |
| Varicose vein | 58 | 0 |
| <i>Vascular hypertensive disorders NEC</i> | | |
| Diastolic hypertension | 3 | 0 |
| Hypertension | 495 | 0 |
| Labile hypertension | 1 | 0 |
| Systolic hypertension | 2 | 0 |
| Venous hypertension | 3 | 0 |
| White coat hypertension | 6 | 0 |
| <i>Vascular hypotensive disorders</i> | | |
| Capillary leak syndrome | 4 | 0 |
| Hypotension | 360 | 0 |
| Orthostatic hypotension | 30 | 0 |
| <i>Vasculitides NEC</i> | | |
| Diffuse vasculitis | 1 | 1 |
| MAGIC syndrome | 3 | 1 |
| Vasculitis | 63 | 2 |
| <i>Vena caval embolism and thrombosis</i> | | |
| Vena cava thrombosis | 1 | 0 |
| Vascular disorders SOC TOTAL | 7048 | 38 |
| TOTAL REACTIONS FOR DRUG | 573650 | 685 |
| TOTAL REPORTS | 153098 | |
| TOTAL FATAL OUTCOME REPORTS | | 685 |