

COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Data Lock Date: 21-Mar-2021 19:00:03

All UK spontaneous reports received between 4/01/21 and 21/03/21 for
COVID-19 vaccine Oxford University/AstraZeneca

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Blood disorders | | |
| <i>Anaemia deficiencies</i> | | |
| Anaemia vitamin B12 deficiency | 2 | 0 |
| Pernicious anaemia | 1 | 0 |
| <i>Anaemias NEC</i> | | |
| Anaemia | 10 | 0 |
| <i>Anaemias haemolytic NEC</i> | | |
| Haemolytic anaemia | 2 | 0 |
| <i>Anaemias haemolytic immune</i> | | |
| Autoimmune haemolytic anaemia | 1 | 0 |
| <i>Bleeding tendencies</i> | | |
| Increased tendency to bruise | 14 | 0 |
| Spontaneous haematoma | 1 | 0 |
| <i>Coagulation factor deficiencies</i> | | |
| Hypofibrinogenaemia | 1 | 0 |
| <i>Coagulopathies</i> | | |
| Abnormal clotting factor | 2 | 0 |
| Antiphospholipid syndrome | 5 | 0 |
| Coagulopathy | 8 | 0 |
| Disseminated intravascular coagulation | 3 | 0 |
| Hypercoagulation | 7 | 0 |
| <i>Eosinophilic disorders</i> | | |
| Eosinophilia | 6 | 0 |
| <i>Haematological disorders</i> | | |
| Bone marrow disorder | 1 | 0 |
| Bone marrow oedema | 1 | 0 |
| Mast cell activation syndrome | 3 | 0 |
| Mastocytosis | 1 | 0 |
| Methaemoglobinaemia | 1 | 0 |
| <i>Haemolyses NEC</i> | | |
| Haemolysis | 2 | 0 |
| <i>Leukocytoses NEC</i> | | |
| Lymphocytosis | 1 | 0 |
| <i>Leukopenias NEC</i> | | |
| Leukopenia | 4 | 0 |
| Lymphopenia | 5 | 0 |
| <i>Lymphatic system disorders NEC</i> | | |
| Lymph node fibrosis | 1 | 0 |
| Lymph node pain | 214 | 0 |
| Lymphadenitis | 12 | 0 |
| Lymphadenopathy | 1955 | 0 |
| Lymphatic disorder | 1 | 0 |
| <i>Marrow depression and hypoplastic anaemias</i> | | |
| Pancytopenia | 4 | 0 |
| <i>Neutropenias</i> | | |
| Agranulocytosis | 1 | 0 |
| Neutropenia | 34 | 0 |
| <i>Platelet disorders NEC</i> | | |
| Platelet disorder | 1 | 0 |
| <i>Polycythaemia (excl rubra vera)</i> | | |
| Stress polycythaemia | 1 | 0 |
| <i>Sickle cell trait and disorders</i> | | |
| Sickle cell anaemia with crisis | 2 | 0 |
| <i>Spleen disorders</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Blood disorders Blood disorders cont'd | | |
| Spleen disorder | 1 | 0 |
| Splenic artery thrombosis | 1 | 0 |
| Splenic infarction | 2 | 0 |
| Splenic vein thrombosis | 2 | 0 |
| Splenomegaly | 2 | 0 |
| <i>Thrombocytopenias</i> | | |
| Immune thrombocytopenia | 44 | 1 |
| Thrombocytopenia | 44 | 1 |
| Thrombocytopenic purpura | 4 | 0 |
| Thrombotic thrombocytopenic purpura | 1 | 0 |
| <i>Thrombocytoses</i> | | |
| Thrombocytosis | 1 | 0 |
| <i>White blood cell abnormal findings NEC</i> | | |
| White blood cell disorder | 1 | 0 |
| Blood disorders SOC TOTAL | 2411 | 2 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Cardiac disorders | | |
| <i>Aortic valvular disorders</i> | | |
| Aortic valve stenosis | 1 | 0 |
| <i>Cardiac conduction disorders</i> | | |
| Atrioventricular block | 6 | 0 |
| Bundle branch block left | 3 | 0 |
| Long QT syndrome | 1 | 0 |
| Trifascicular block | 1 | 0 |
| <i>Cardiac disorders NEC</i> | | |
| Acute cardiac event | 2 | 1 |
| Cardiac disorder | 14 | 0 |
| Cardiovascular disorder | 1 | 0 |
| Cardiovascular insufficiency | 3 | 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 | 5 | 0 |
| Palpitations | 2313 | 0 |
| <i>Cardiac valve disorders NEC</i> | | |
| Cardiac valve disease | 1 | 1 |
| <i>Cardiomyopathies</i> | | |
| Cardiomyopathy | 3 | 0 |
| Congestive cardiomyopathy | 5 | 0 |
| <i>Coronary artery disorders NEC</i> | | |
| Coronary artery thrombosis | 1 | 0 |
| <i>Heart failures NEC</i> | | |
| Cardiac failure | 13 | 4 |
| Cardiac failure acute | 1 | 0 |
| Cardiogenic shock | 2 | 1 |
| Cardiopulmonary failure | 1 | 1 |
| <i>Ischaemic coronary artery disorders</i> | | |
| Acute myocardial infarction | 12 | 2 |
| Angina pectoris | 53 | 0 |
| Angina unstable | 7 | 0 |
| Arteriospasm coronary | 2 | 0 |
| Microvascular coronary artery disease | 2 | 0 |
| Myocardial infarction | 74 | 19 |
| Myocardial ischaemia | 8 | 4 |
| Prinzmetal angina | 1 | 0 |
| <i>Left ventricular failures</i> | | |
| Left ventricular failure | 1 | 1 |
| <i>Mitral valvular disorders</i> | | |
| Mitral valve incompetence | 1 | 0 |
| <i>Myocardial disorders NEC</i> | | |
| Cardiomegaly | 2 | 0 |
| Left ventricular dilatation | 1 | 0 |
| Left ventricular dysfunction | 2 | 0 |
| Myocardial rupture | 1 | 0 |
| <i>Noninfectious myocarditis</i> | | |
| Myocarditis | 6 | 1 |
| <i>Noninfectious pericarditis</i> | | |
| Pericarditis | 12 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------------|-----------|
| Cardiac disorders Cardiac disorders cont'd | | |
| <i>Pericardial disorders NEC</i> | | |
| Pericardial effusion | 3 | 0 |
| Pericardial haemorrhage | 1 | 1 |
| <i>Rate and rhythm disorders NEC</i> | | |
| Arrhythmia | 51 | 0 |
| Bradycardia | 32 | 0 |
| Cardiac flutter | 75 | 0 |
| Extrasystoles | 34 | 0 |
| Heart alternation | 1 | 0 |
| Paroxysmal arrhythmia | 1 | 0 |
| Postural orthostatic tachycardia syndrome | 4 | 0 |
| Tachyarrhythmia | 9 | 0 |
| Tachycardia | 741 | 0 |
| <i>Right ventricular failures</i> | | |
| Cor pulmonale | 1 | 0 |
| Right ventricular failure | 1 | 1 |
| <i>Supraventricular arrhythmias</i> | | |
| Arrhythmia supraventricular | 9 | 0 |
| Atrial fibrillation | 105 | 0 |
| Atrial flutter | 13 | 0 |
| Sinus arrhythmia | 1 | 0 |
| Sinus bradycardia | 1 | 0 |
| Sinus tachycardia | 39 | 0 |
| Supraventricular extrasystoles | 1 | 0 |
| Supraventricular tachycardia | 11 | 0 |
| <i>Ventricular arrhythmias and cardiac arrest</i> | | |
| Cardiac arrest | 58 | 14 |
| Ventricular arrhythmia | 1 | 0 |
| Ventricular extrasystoles | 2 | 0 |
| Ventricular fibrillation | 2 | 0 |
| Ventricular tachycardia | 7 | 0 |
| Cardiac disorders SOC TOTAL | 3768 | 51 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Congenital disorders | | |
| <i>Cardiac disorders congenital NEC</i> | | |
| Heart disease congenital | 2 | 0 |
| <i>Cardiac septal defects congenital</i> | | |
| Hypertrophic cardiomyopathy | 3 | 0 |
| <i>Central nervous system disorders congenital NEC</i> | | |
| Syringomyelia | 1 | 0 |
| <i>Cerebellar disorders congenital</i> | | |
| Arnold-Chiari malformation | 2 | 0 |
| <i>Cerebral disorders congenital</i> | | |
| Cerebral palsy | 3 | 0 |
| <i>Coagulation disorders congenital</i> | | |
| Haemophilia | 1 | 0 |
| Protein S deficiency | 1 | 0 |
| <i>Connective tissue disorders congenital</i> | | |
| Ehlers-Danlos syndrome | 2 | 0 |
| <i>Lymphatic system disorders congenital</i> | | |
| Cystic lymphangioma | 1 | 0 |
| <i>Musculoskeletal disorders congenital NEC</i> | | |
| Congenital multiplex arthrogyposis | 1 | 0 |
| <i>Neurological disorders congenital NEC</i> | | |
| Familial hemiplegic migraine | 1 | 0 |
| Familial periodic paralysis | 1 | 0 |
| <i>Pancreatic disorders congenital</i> | | |
| Hereditary pancreatitis | 1 | 0 |
| <i>Peripheral nervous system disorders congenital NEC</i> | | |
| Paroxysmal extreme pain disorder | 6 | 0 |
| <i>Pulmonary and bronchial disorders congenital</i> | | |
| Cystic fibrosis | 3 | 0 |
| Congenital disorders SOC TOTAL | 29 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------------|----------|
| Ear disorders | | |
| <i>Ear disorders NEC</i> | | |
| Ear congestion | 4 | 0 |
| Ear discomfort | 28 | 0 |
| Ear disorder | 3 | 0 |
| Ear haemorrhage | 2 | 0 |
| Ear pain | 919 | 0 |
| Ear pruritus | 1 | 0 |
| Ear swelling | 23 | 0 |
| Otorrhoea | 1 | 0 |
| <i>Eustachian tube disorders</i> | | |
| Eustachian tube dysfunction | 1 | 0 |
| <i>External ear disorders NEC</i> | | |
| Excessive cerumen production | 3 | 0 |
| External ear pain | 6 | 0 |
| Red ear syndrome | 5 | 0 |
| <i>Hearing disorders NEC</i> | | |
| Auditory disorder | 1 | 0 |
| <i>Hearing losses</i> | | |
| Deafness | 69 | 0 |
| Deafness bilateral | 1 | 0 |
| Deafness neurosensory | 1 | 0 |
| Deafness transitory | 2 | 0 |
| Deafness unilateral | 7 | 0 |
| Hypoacusis | 58 | 0 |
| Sudden hearing loss | 13 | 0 |
| <i>Hyperacusia</i> | | |
| Hyperacusis | 35 | 0 |
| <i>Inner ear disorders NEC</i> | | |
| Inner ear disorder | 2 | 0 |
| Meniere's disease | 7 | 0 |
| <i>Inner ear infections and inflammations</i> | | |
| Inner ear inflammation | 1 | 0 |
| <i>Inner ear signs and symptoms</i> | | |
| Motion sickness | 36 | 0 |
| Phobic postural vertigo | 1 | 0 |
| Tinnitus | 739 | 0 |
| Vertigo | 567 | 0 |
| Vertigo labyrinthine | 5 | 0 |
| Vertigo positional | 31 | 0 |
| <i>Middle ear disorders NEC</i> | | |
| Middle ear effusion | 1 | 0 |
| <i>Tympanic membrane disorders (excl infections)</i> | | |
| Tympanic membrane perforation | 1 | 0 |
| Ear disorders SOC TOTAL | 2574 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Endocrine disorders | | |
| <i>Acute and chronic thyroiditis</i> | | |
| Thyroiditis | 3 | 0 |
| Thyroiditis chronic | 1 | 0 |
| <i>Adrenal cortical hyperfunctions</i> | | |
| Cushingoid | 1 | 0 |
| <i>Adrenal cortical hypofunctions</i> | | |
| Adrenal insufficiency | 9 | 0 |
| Adrenocortical insufficiency acute | 21 | 0 |
| Glucocorticoid deficiency | 1 | 0 |
| <i>Adrenal gland disorders NEC</i> | | |
| Adrenal haemorrhage | 2 | 0 |
| <i>Anterior pituitary hypofunction</i> | | |
| Hypopituitarism | 1 | 0 |
| <i>Female gonadal function disorders</i> | | |
| Ovulation delayed | 1 | 0 |
| <i>Posterior pituitary disorders</i> | | |
| Diabetes insipidus | 3 | 0 |
| <i>Thyroid disorders NEC</i> | | |
| Thyroid mass | 1 | 0 |
| Thyroid pain | 2 | 0 |
| <i>Thyroid hyperfunction disorders</i> | | |
| Hyperthyroidism | 2 | 0 |
| Thyrotoxic crisis | 1 | 0 |
| <i>Thyroid hypofunction disorders</i> | | |
| Hypothyroidism | 11 | 0 |
| Endocrine disorders SOC TOTAL | 60 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Eye disorders | | |
| <i>Amblyopic vision impairment</i> | | |
| Amblyopia | 1 | 0 |
| <i>Cataract conditions</i> | | |
| Cataract | 6 | 0 |
| <i>Choroid and vitreous haemorrhages and vascular disorders</i> | | |
| Vitreous haemorrhage | 1 | 0 |
| <i>Choroid and vitreous structural change, deposit and degeneration</i> | | |
| Chorioretinopathy | 1 | 0 |
| Vitreous detachment | 9 | 0 |
| Vitreous floaters | 32 | 0 |
| <i>Colour blindness (incl acquired)</i> | | |
| Dyschromatopsia | 5 | 0 |
| <i>Conjunctival and corneal bleeding and vascular disorders</i> | | |
| Conjunctival haemorrhage | 18 | 0 |
| <i>Corneal infections, oedemas and inflammations</i> | | |
| Keratitis | 2 | 0 |
| <i>Eyelid movement disorders</i> | | |
| Blepharospasm | 19 | 0 |
| Eyelid ptosis | 13 | 0 |
| <i>Glaucomas (excl congenital)</i> | | |
| Angle closure glaucoma | 1 | 0 |
| Glaucoma | 3 | 0 |
| <i>Iris and ciliary body structural change, deposit and degeneration</i> | | |
| Eye colour change | 5 | 0 |
| <i>Iris and uveal tract infections, irritations and inflammations</i> | | |
| Autoimmune uveitis | 1 | 0 |
| Iridocyclitis | 4 | 0 |
| Iritis | 2 | 0 |
| Uveitis | 8 | 0 |
| <i>Lacrimation disorders</i> | | |
| Dry eye | 113 | 0 |
| Lacrimation increased | 96 | 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 | 3 | 0 |
| Erythema of eyelid | 2 | 0 |
| Eyelid cyst | 2 | 0 |
| Eyelid margin crusting | 1 | 0 |
| Eyelid oedema | 6 | 0 |
| Eyelid rash | 2 | 0 |
| Swelling of eyelid | 29 | 0 |
| <i>Lid, lash and lacrimal structural disorders</i> | | |
| Eyelid skin dryness | 1 | 0 |
| Eyelid thickening | 1 | 0 |
| Growth of eyelashes | 3 | 0 |
| <i>Ocular bleeding and vascular disorders NEC</i> | | |
| Eye haemorrhage | 12 | 0 |
| Ocular vascular disorder | 1 | 0 |
| <i>Ocular disorders NEC</i> | | |
| Dark circles under eyes | 2 | 0 |
| Eye disorder | 4 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Eye disorders Eye disorders cont'd | | |
| Eye oedema | 4 | 0 |
| Eye pain | 1607 | 0 |
| Eye swelling | 218 | 0 |
| Eye symptom | 1 | 0 |
| Eye ulcer | 3 | 0 |
| Eyelid disorder | 1 | 0 |
| Eyelid pain | 4 | 0 |
| Eyelids pruritus | 2 | 0 |
| Ocular discomfort | 14 | 0 |
| Periorbital oedema | 7 | 0 |
| Periorbital pain | 3 | 0 |
| Periorbital swelling | 36 | 0 |
| <i>Ocular infections, inflammations and associated manifestations</i> | | |
| Eye allergy | 10 | 0 |
| Eye discharge | 9 | 0 |
| Eye inflammation | 8 | 0 |
| Eye irritation | 98 | 0 |
| Eye pruritus | 118 | 0 |
| Limbal swelling | 1 | 0 |
| Ocular hyperaemia | 124 | 0 |
| <i>Ocular nerve and muscle disorders</i> | | |
| Extraocular muscle paresis | 4 | 0 |
| Eye movement disorder | 13 | 0 |
| Ocular myasthenia | 1 | 0 |
| <i>Ocular sensation disorders</i> | | |
| Abnormal sensation in eye | 13 | 0 |
| Asthenopia | 138 | 0 |
| Eyelid sensory disorder | 2 | 0 |
| Foreign body sensation in eyes | 14 | 0 |
| Hypoaesthesia eye | 7 | 0 |
| Photophobia | 475 | 0 |
| <i>Optic disc abnormalities NEC</i> | | |
| Papilloedema | 1 | 0 |
| <i>Pupil disorders</i> | | |
| Miosis | 4 | 0 |
| Mydriasis | 9 | 0 |
| Pupil fixed | 1 | 0 |
| Pupils unequal | 2 | 0 |
| <i>Refractive and accommodative disorders</i> | | |
| Altered visual depth perception | 2 | 0 |
| Hypermetropia | 1 | 0 |
| <i>Retinal bleeding and vascular disorders (excl retinopathy)</i> | | |
| Retinal aneurysm | 1 | 0 |
| Retinal artery embolism | 1 | 0 |
| Retinal artery occlusion | 1 | 0 |
| Retinal haemorrhage | 2 | 0 |
| Retinal vascular thrombosis | 1 | 0 |
| Retinal vein occlusion | 4 | 0 |
| Retinal vein thrombosis | 1 | 0 |
| Retinal vein varices | 1 | 0 |
| <i>Retinal structural change, deposit and degeneration</i> | | |
| Macular degeneration | 1 | 0 |
| Macular detachment | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Eye disorders Eye disorders cont'd | | |
| Neovascular age-related macular degeneration | 3 | 0 |
| Retinal detachment | 2 | 0 |
| Retinal drusen | 1 | 0 |
| Retinal toxicity | 1 | 0 |
| Vitreoretinal traction syndrome | 1 | 0 |
| <i>Retinal, choroid and vitreous infections and inflammations</i> | | |
| Macular oedema | 1 | 0 |
| <i>Retinopathies NEC</i> | | |
| Acute macular outer retinopathy | 3 | 0 |
| Retinal exudates | 1 | 0 |
| <i>Scleral infections, irritations and inflammations</i> | | |
| Episcleritis | 5 | 0 |
| Scleritis | 2 | 0 |
| <i>Structural change, deposit and degeneration of eye NEC</i> | | |
| Deposit eye | 1 | 0 |
| Endocrine ophthalmopathy | 2 | 0 |
| <i>Visual colour distortions</i> | | |
| Chromatopsia | 1 | 0 |
| Xanthopsia | 4 | 0 |
| <i>Visual disorders NEC</i> | | |
| Diplopia | 92 | 0 |
| Halo vision | 7 | 0 |
| Metamorphopsia | 12 | 0 |
| Photopsia | 104 | 0 |
| Vision blurred | 678 | 0 |
| Visual brightness | 4 | 0 |
| Visual snow syndrome | 1 | 0 |
| <i>Visual impairment and blindness (excl colour blindness)</i> | | |
| Amaurosis fugax | 3 | 0 |
| Blindness | 59 | 0 |
| Blindness transient | 3 | 0 |
| Blindness unilateral | 2 | 0 |
| Night blindness | 3 | 0 |
| Sudden visual loss | 1 | 0 |
| Visual acuity reduced | 6 | 0 |
| Visual impairment | 183 | 0 |
| Eye disorders SOC TOTAL | 4566 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Abdominal findings abnormal</i> | | |
| Abdominal mass | 1 | 0 |
| Gastrointestinal sounds abnormal | 6 | 0 |
| <i>Acute and chronic pancreatitis</i> | | |
| Obstructive pancreatitis | 1 | 1 |
| Pancreatitis | 16 | 1 |
| Pancreatitis acute | 2 | 0 |
| Pancreatitis chronic | 1 | 0 |
| <i>Anal and rectal disorders NEC</i> | | |
| Anal fissure | 1 | 0 |
| <i>Anal and rectal pains</i> | | |
| Proctalgia | 8 | 0 |
| <i>Anal and rectal signs and symptoms</i> | | |
| Anal hypoaesthesia | 3 | 0 |
| Anal paraesthesia | 1 | 0 |
| Anal pruritus | 2 | 0 |
| Anorectal discomfort | 3 | 0 |
| Rectal discharge | 1 | 0 |
| <i>Benign oral cavity neoplasms</i> | | |
| Mouth cyst | 4 | 0 |
| Tongue cyst | 1 | 0 |
| <i>Colitis (excl infective)</i> | | |
| Autoimmune colitis | 1 | 0 |
| Colitis | 10 | 0 |
| Colitis ischaemic | 1 | 0 |
| Colitis microscopic | 1 | 0 |
| Colitis ulcerative | 31 | 0 |
| Crohn's disease | 33 | 0 |
| Neutropenic colitis | 1 | 0 |
| Terminal ileitis | 1 | 0 |
| <i>Dental and periodontal infections and inflammations</i> | | |
| Dental caries | 1 | 0 |
| <i>Dental disorders NEC</i> | | |
| Teething | 10 | 0 |
| <i>Dental pain and sensation disorders</i> | | |
| Dental discomfort | 6 | 0 |
| Dental paraesthesia | 5 | 0 |
| Hyperaesthesia teeth | 16 | 0 |
| Toothache | 134 | 0 |
| <i>Dental pulp disorders</i> | | |
| Dental pulp disorder | 1 | 0 |
| <i>Dental surface disorders</i> | | |
| Tooth discolouration | 2 | 0 |
| <i>Diaphragmatic hernias</i> | | |
| Hiatus hernia | 1 | 0 |
| <i>Diarrhoea (excl infective)</i> | | |
| Diarrhoea | 4461 | 0 |
| Diarrhoea haemorrhagic | 11 | 0 |
| <i>Diverticula</i> | | |
| Diverticulum | 2 | 0 |
| <i>Duodenal ulcers and perforation</i> | | |
| Duodenal ulcer | 1 | 0 |
| <i>Dyspeptic signs and symptoms</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Dyspepsia | 358 | 0 |
| Epigastric discomfort | 9 | 0 |
| Eructation | 40 | 0 |
| <i>Faecal abnormalities NEC</i> | | |
| Abnormal faeces | 5 | 0 |
| Faecaloma | 1 | 0 |
| Faeces discoloured | 20 | 0 |
| Faeces hard | 2 | 0 |
| Faeces pale | 1 | 0 |
| Faeces soft | 9 | 0 |
| Mucous stools | 3 | 0 |
| <i>Flatulence, bloating and distension</i> | | |
| Abdominal distension | 164 | 0 |
| Flatulence | 187 | 0 |
| <i>Gastric and oesophageal haemorrhages</i> | | |
| Gastric haemorrhage | 3 | 0 |
| <i>Gastric ulcers and perforation</i> | | |
| Gastric ulcer | 4 | 0 |
| Gastric ulcer perforation | 1 | 0 |
| <i>Gastritis (excl infective)</i> | | |
| Chronic gastritis | 2 | 0 |
| Gastritis | 25 | 0 |
| Reflux gastritis | 6 | 0 |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> | | |
| Abdominal migraine | 1 | 0 |
| Abdominal pain | 2108 | 0 |
| Abdominal pain lower | 99 | 0 |
| Abdominal pain upper | 2345 | 0 |
| Abdominal rigidity | 18 | 0 |
| Abdominal tenderness | 9 | 0 |
| Gastrointestinal pain | 147 | 0 |
| Oesophageal pain | 3 | 0 |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i> | | |
| Constipation | 159 | 0 |
| Duodenogastric reflux | 1 | 0 |
| Gastric dilatation | 5 | 0 |
| Gastrooesophageal reflux disease | 85 | 0 |
| Impaired gastric emptying | 1 | 0 |
| Infrequent bowel movements | 1 | 0 |
| <i>Gastrointestinal disorders NEC</i> | | |
| Food poisoning | 2 | 0 |
| Functional gastrointestinal disorder | 7 | 0 |
| Gastric disorder | 4 | 0 |
| Gastrointestinal disorder | 10 | 0 |
| Neurogenic bowel | 1 | 0 |
| <i>Gastrointestinal dyskinetic disorders</i> | | |
| Bowel movement irregularity | 1 | 0 |
| Change of bowel habit | 4 | 0 |
| Dyschezia | 3 | 0 |
| Oesophageal achalasia | 2 | 0 |
| <i>Gastrointestinal inflammatory disorders NEC</i> | | |
| Appendicitis noninfective | 1 | 0 |
| Gastrointestinal tract irritation | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

Data Lock Date: 21-Mar-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> | | |
| <i>Gastrointestinal mucosal dystrophies and secretion disorders</i> | | |
| Hyperchlorhydria | 1 | 0 |
| <i>Gastrointestinal necrosis and gangrene (excl gangrenous hernia)</i> | | |
| Gastrointestinal necrosis | 1 | 0 |
| <i>Gastrointestinal signs and symptoms NEC</i> | | |
| Abdominal discomfort | 747 | 0 |
| Abdominal symptom | 2 | 0 |
| Acute abdomen | 8 | 0 |
| Anal incontinence | 15 | 0 |
| Breath odour | 12 | 0 |
| Dysphagia | 77 | 1 |
| Intestinal congestion | 1 | 0 |
| <i>Gastrointestinal spastic and hypermotility disorders</i> | | |
| Defaecation urgency | 7 | 0 |
| Frequent bowel movements | 19 | 0 |
| Irritable bowel syndrome | 32 | 0 |
| Oesophageal spasm | 3 | 0 |
| <i>Gastrointestinal stenosis and obstruction NEC</i> | | |
| Intestinal obstruction | 3 | 0 |
| <i>Gastrointestinal vascular malformations</i> | | |
| Gastric antral vascular ectasia | 2 | 0 |
| <i>Gastrointestinal vascular occlusion and infarction</i> | | |
| Intestinal ischaemia | 2 | 0 |
| Mesenteric vein thrombosis | 1 | 0 |
| Mesenteric venous occlusion | 1 | 0 |
| Visceral venous thrombosis | 1 | 0 |
| <i>Gingival disorders, signs and symptoms NEC</i> | | |
| Gingival blister | 10 | 0 |
| Gingival discomfort | 1 | 0 |
| Gingival disorder | 8 | 0 |
| Gingival hypertrophy | 1 | 0 |
| Gingival oedema | 2 | 0 |
| Gingival pain | 87 | 0 |
| Gingival pruritus | 1 | 0 |
| Gingival swelling | 20 | 0 |
| Gingival ulceration | 3 | 0 |
| Noninfective gingivitis | 9 | 0 |
| <i>Gingival haemorrhages</i> | | |
| Gingival bleeding | 32 | 0 |
| <i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i> | | |
| Haemorrhoidal haemorrhage | 1 | 0 |
| Haemorrhoids | 12 | 0 |
| Haemorrhoids thrombosed | 3 | 0 |
| <i>Inguinal hernias</i> | | |
| Inguinal hernia | 2 | 0 |
| <i>Intestinal haemorrhages</i> | | |
| Anal haemorrhage | 8 | 0 |
| Mesenteric haemorrhage | 1 | 0 |
| Rectal haemorrhage | 24 | 0 |
| Small intestinal haemorrhage | 10 | 0 |
| <i>Intestinal ulcers and perforation NEC</i> | | |
| Intestinal perforation | 1 | 0 |
| <i>Large intestinal stenosis and obstruction</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Large intestinal stenosis | 1 | 0 |
| Malabsorption syndromes | | |
| Coeliac disease | 4 | 0 |
| Nausea and vomiting symptoms | | |
| Acetonaemic vomiting | 1 | 0 |
| Discoloured vomit | 11 | 0 |
| Faecal vomiting | 1 | 0 |
| Nausea | 18548 | 0 |
| Regurgitation | 1 | 0 |
| Retching | 151 | 0 |
| Vomiting | 6245 | 2 |
| Vomiting projectile | 85 | 0 |
| Non-site specific gastrointestinal haemorrhages | | |
| Gastrointestinal haemorrhage | 6 | 1 |
| Haematemesis | 29 | 0 |
| Haematochezia | 27 | 0 |
| Melaena | 2 | 0 |
| Oesophageal stenosis and obstruction | | |
| Oesophageal obstruction | 1 | 0 |
| Oesophagitis (excl infective) | | |
| Eosinophilic oesophagitis | 2 | 0 |
| Oesophagitis | 5 | 0 |
| Oral dryness and saliva altered | | |
| Aptyalism | 2 | 0 |
| Dry mouth | 605 | 0 |
| Lip dry | 27 | 0 |
| Saliva altered | 3 | 0 |
| Salivary hypersecretion | 17 | 0 |
| Oral soft tissue disorders NEC | | |
| Angina bullosa haemorrhagica | 1 | 0 |
| Chapped lips | 5 | 0 |
| Cheilitis | 17 | 0 |
| Chronic cheek biting | 1 | 0 |
| Enlarged uvula | 4 | 0 |
| Leukoplakia oral | 1 | 0 |
| Lip blister | 17 | 0 |
| Lip disorder | 1 | 0 |
| Oral disorder | 6 | 0 |
| Oral lichen planus | 2 | 0 |
| Uvulitis | 3 | 0 |
| Oral soft tissue haemorrhages | | |
| Mouth haemorrhage | 7 | 0 |
| Oral blood blister | 17 | 0 |
| Oral soft tissue infections | | |
| Angular cheilitis | 2 | 0 |
| Oral soft tissue signs and symptoms | | |
| Anaesthesia oral | 3 | 0 |
| Burning mouth syndrome | 3 | 0 |
| Coating in mouth | 2 | 0 |
| Hypoaesthesia oral | 265 | 0 |
| Lip discolouration | 1 | 0 |
| Lip erythema | 3 | 0 |
| Lip exfoliation | 6 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| Gastrointestinal disorders cont'd | | |
| Lip pain | 31 | 0 |
| Lip pruritus | 8 | 0 |
| Odynophagia | 9 | 0 |
| Oral discomfort | 36 | 0 |
| Oral mucosal blistering | 15 | 0 |
| Oral mucosal eruption | 8 | 0 |
| Oral mucosal erythema | 1 | 0 |
| Oral mucosal exfoliation | 4 | 0 |
| Oral mucosal roughening | 2 | 0 |
| Oral pain | 157 | 0 |
| Oral pruritus | 11 | 0 |
| Paraesthesia oral | 387 | 0 |
| Oral soft tissue swelling and oedema | | |
| Lip oedema | 5 | 0 |
| Lip swelling | 416 | 0 |
| Mouth swelling | 57 | 0 |
| Oedema mouth | 1 | 0 |
| Palatal swelling | 6 | 0 |
| Rectal inflammations NEC | | |
| Proctitis | 1 | 0 |
| Salivary gland disorders NEC | | |
| Salivary gland calculus | 1 | 0 |
| Salivary gland pain | 4 | 0 |
| Salivary gland enlargements | | |
| Parotid gland enlargement | 5 | 0 |
| Salivary gland enlargement | 2 | 0 |
| Salivary gland infections and inflammations | | |
| Noninfective sialoadenitis | 1 | 0 |
| Stomatitis and ulceration | | |
| Apthous ulcer | 31 | 0 |
| Lip ulceration | 9 | 0 |
| Mouth ulceration | 283 | 0 |
| Stomatitis | 37 | 0 |
| Tongue disorders | | |
| Glossitis | 10 | 0 |
| Plicated tongue | 1 | 0 |
| Tongue disorder | 16 | 0 |
| Tongue geographic | 1 | 0 |
| Tongue ulceration | 15 | 0 |
| Trichoglossia | 2 | 0 |
| Tongue signs and symptoms | | |
| Glossodynia | 121 | 0 |
| Scalloped tongue | 3 | 0 |
| Swollen tongue | 253 | 0 |
| Tongue blistering | 14 | 0 |
| Tongue coated | 14 | 0 |
| Tongue discolouration | 9 | 0 |
| Tongue discomfort | 21 | 0 |
| Tongue dry | 8 | 0 |
| Tongue eruption | 2 | 0 |
| Tongue exfoliation | 1 | 0 |
| Tongue movement disturbance | 3 | 0 |
| Tongue oedema | 10 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|--------------|----------|
| Gastrointestinal disorders | | |
| Gastrointestinal disorders cont'd | | |
| Tongue pruritus | 1 | 0 |
| Tongue rough | 1 | 0 |
| Tongue spasm | 2 | 0 |
| Tooth missing | | |
| Tooth loss | 1 | 0 |
| Gastrointestinal disorders SOC TOTAL | 39988 | 6 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders | | |
| <i>Administration site reactions NEC</i> | | |
| Administration site bruise | 8 | 0 |
| Administration site coldness | 1 | 0 |
| Administration site erythema | 1 | 0 |
| Administration site induration | 1 | 0 |
| Administration site mass | 1 | 0 |
| Administration site pain | 28 | 0 |
| Administration site rash | 1 | 0 |
| Administration site reaction | 2 | 0 |
| Administration site urticaria | 1 | 0 |
| Puncture site bruise | 28 | 0 |
| Puncture site haemorrhage | 1 | 0 |
| Puncture site pain | 10 | 0 |
| Puncture site reaction | 3 | 0 |
| Puncture site swelling | 1 | 0 |
| <i>Adverse effect absent</i> | | |
| No adverse event | 9 | 0 |
| <i>Application and instillation site reactions</i> | | |
| Application site bruise | 12 | 0 |
| Application site burn | 1 | 0 |
| Application site erythema | 12 | 0 |
| Application site haemorrhage | 1 | 0 |
| Application site hypersensitivity | 1 | 0 |
| Application site inflammation | 1 | 0 |
| Application site irritation | 1 | 0 |
| Application site joint pain | 1 | 0 |
| Application site pain | 20 | 0 |
| Application site pruritus | 6 | 0 |
| Application site swelling | 2 | 0 |
| Application site vesicles | 1 | 0 |
| Application site warmth | 1 | 0 |
| Application site wound | 1 | 0 |
| Instillation site discomfort | 1 | 0 |
| Instillation site pain | 2 | 0 |
| Instillation site pruritus | 1 | 0 |
| Instillation site warmth | 7 | 0 |
| <i>Asthenic conditions</i> | | |
| Asthenia | 2279 | 3 |
| Chronic fatigue syndrome | 32 | 0 |
| Decreased activity | 2 | 0 |
| Fatigue | 24907 | 0 |
| Malaise | 6527 | 3 |
| Sluggishness | 9 | 0 |
| <i>Body temperature altered</i> | | |
| Hyperthermia | 5 | 0 |
| Hypothermia | 32 | 0 |
| Temperature regulation disorder | 9 | 0 |
| <i>Breast complications associated with device</i> | | |
| Capsular contracture associated with breast implant | 1 | 0 |
| <i>Complications associated with device NEC</i> | | |
| Injury associated with device | 2 | 0 |
| Medical device site joint pain | 1 | 0 |
| Phantom shocks | 3 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| <i>Death and sudden death</i> | | |
| Brain death | 1 | 1 |
| Death | 168 | 168 |
| Drowning | 1 | 0 |
| Sudden death | 16 | 16 |
| <i>Febrile disorders</i> | | |
| Hyperpyrexia | 31 | 0 |
| Masked fever | 1 | 0 |
| Pyrexia | 32496 | 0 |
| <i>Feelings and sensations NEC</i> | | |
| Chills | 26031 | 0 |
| Early satiety | 1 | 0 |
| Feeling abnormal | 1149 | 0 |
| Feeling cold | 3039 | 0 |
| Feeling drunk | 57 | 0 |
| Feeling hot | 1153 | 0 |
| Feeling jittery | 15 | 0 |
| Feeling of body temperature change | 545 | 0 |
| Hangover | 67 | 0 |
| Hunger | 22 | 0 |
| Sensation of blood flow | 2 | 0 |
| Sensation of foreign body | 18 | 0 |
| Temperature intolerance | 26 | 0 |
| Thirst | 693 | 0 |
| Thirst decreased | 6 | 0 |
| <i>Fibrosis NEC</i> | | |
| Fibrosis | 2 | 0 |
| <i>Gait disturbances</i> | | |
| Decreased gait velocity | 2 | 0 |
| Gait disturbance | 143 | 0 |
| Gait inability | 81 | 0 |
| Loss of control of legs | 17 | 0 |
| <i>General signs and symptoms NEC</i> | | |
| Apparent death | 1 | 0 |
| Chronic disease | 1 | 0 |
| Condition aggravated | 80 | 0 |
| Crepitations | 1 | 0 |
| Crying | 100 | 0 |
| Developmental delay | 1 | 0 |
| Discharge | 2 | 0 |
| Energy increased | 7 | 0 |
| Exercise tolerance decreased | 5 | 0 |
| Foaming at mouth | 3 | 0 |
| General physical health deterioration | 10 | 1 |
| General symptom | 7 | 0 |
| Glassy eyes | 2 | 0 |
| High-pitched crying | 1 | 0 |
| Ill-defined disorder | 1 | 0 |
| Illness | 2732 | 0 |
| Induration | 6 | 0 |
| Influenza like illness | 5358 | 1 |
| Irritability postvaccinal | 2 | 0 |
| Local reaction | 107 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Moaning | 6 | 0 |
| Multiple organ dysfunction syndrome | 4 | 0 |
| Nonspecific reaction | 2 | 0 |
| Peripheral swelling | 2436 | 0 |
| Screaming | 8 | 0 |
| Secretion discharge | 10 | 0 |
| Stenosis | 1 | 0 |
| Swelling | 1110 | 0 |
| Swelling face | 409 | 0 |
| Symptom recurrence | 1 | 0 |
| Tissue discolouration | 1 | 0 |
| Unevaluable event | 1 | 0 |
| Hernias NEC | | |
| Hernia | 1 | 0 |
| Implant and catheter site reactions | | |
| Implant site coldness | 1 | 0 |
| Implant site discolouration | 1 | 0 |
| Implant site hypoaesthesia | 1 | 0 |
| Implant site pain | 3 | 0 |
| Implant site rash | 1 | 0 |
| Implant site swelling | 2 | 0 |
| Implant site warmth | 4 | 0 |
| Inflammations | | |
| Inflammation | 245 | 0 |
| Systemic inflammatory response syndrome | 1 | 0 |
| Infusion site reactions | | |
| Infusion site bruising | 1 | 0 |
| Infusion site nodule | 1 | 0 |
| Infusion site pain | 4 | 0 |
| Infusion site urticaria | 1 | 0 |
| Infusion site warmth | 2 | 0 |
| Injection site reactions | | |
| Injected limb mobility decreased | 19 | 0 |
| Injection site atrophy | 1 | 0 |
| Injection site bruising | 59 | 0 |
| Injection site coldness | 3 | 0 |
| Injection site cyst | 1 | 0 |
| Injection site discolouration | 2 | 0 |
| Injection site discomfort | 8 | 0 |
| Injection site erythema | 317 | 0 |
| Injection site exfoliation | 1 | 0 |
| Injection site haematoma | 1 | 0 |
| Injection site haemorrhage | 1 | 0 |
| Injection site hypersensitivity | 4 | 0 |
| Injection site hypoaesthesia | 6 | 0 |
| Injection site indentation | 5 | 0 |
| Injection site induration | 1 | 0 |
| Injection site inflammation | 36 | 0 |
| Injection site injury | 1 | 0 |
| Injection site irritation | 2 | 0 |
| Injection site joint erythema | 5 | 0 |
| Injection site joint pain | 24 | 0 |
| Injection site mass | 733 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Injection site movement impairment | 1 | 0 |
| Injection site muscle weakness | 1 | 0 |
| Injection site nodule | 2 | 0 |
| Injection site oedema | 19 | 0 |
| Injection site pain | 2413 | 0 |
| Injection site papule | 1 | 0 |
| Injection site paraesthesia | 9 | 0 |
| Injection site pruritus | 168 | 0 |
| Injection site rash | 135 | 0 |
| Injection site reaction | 65 | 0 |
| Injection site scab | 3 | 0 |
| Injection site scar | 2 | 0 |
| Injection site swelling | 118 | 0 |
| Injection site urticaria | 19 | 0 |
| Injection site vesicles | 4 | 0 |
| Injection site warmth | 211 | 0 |
| Interactions | | |
| Drug interaction | 11 | 0 |
| Inhibitory drug interaction | 2 | 0 |
| Mass conditions NEC | | |
| Cyst | 4 | 0 |
| Mass | 22 | 0 |
| Nodule | 3 | 0 |
| Mucosal findings abnormal | | |
| Mucosal disorder | 1 | 0 |
| Mucosal dryness | 1 | 0 |
| Mucosal haemorrhage | 2 | 0 |
| Mucosal inflammation | 2 | 0 |
| Mucosal pain | 1 | 0 |
| Mucosal ulceration | 1 | 0 |
| Oedema mucosal | 1 | 0 |
| Oedema NEC | | |
| Face oedema | 14 | 0 |
| Localised oedema | 5 | 0 |
| Oedema | 11 | 0 |
| Oedema peripheral | 28 | 0 |
| Pain and discomfort NEC | | |
| Axillary pain | 285 | 0 |
| Chest discomfort | 913 | 0 |
| Chest pain | 1862 | 0 |
| Discomfort | 126 | 0 |
| Facial discomfort | 6 | 0 |
| Facial pain | 112 | 0 |
| Inflammatory pain | 9 | 0 |
| Non-cardiac chest pain | 17 | 0 |
| Pain | 7579 | 0 |
| Tenderness | 1042 | 0 |
| Visceral pain | 1 | 0 |
| Therapeutic and nontherapeutic responses | | |
| Adverse drug reaction | 270 | 3 |
| Adverse event | 3 | 0 |
| Adverse reaction | 8 | 0 |
| Diet failure | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Drug ineffective | 29 | 0 |
| Drug intolerance | 1 | 0 |
| Immediate post-injection reaction | 1 | 0 |
| Inadequate analgesia | 5 | 0 |
| No reaction on previous exposure to drug | 22 | 0 |
| Therapeutic product effect decreased | 1 | 0 |
| Therapeutic response shortened | 1 | 0 |
| Therapeutic response unexpected | 22 | 0 |
| Treatment failure | 4 | 0 |
| Vaccine positive rechallenge | 1 | 0 |
| Trophic disorders | | |
| Atrophy | 1 | 0 |
| Calcinosis | 1 | 0 |
| Ulcers NEC | | |
| Ulcer | 10 | 0 |
| Vaccination site reactions | | |
| Extensive swelling of vaccinated limb | 9 | 0 |
| Shoulder injury related to vaccine administration | 4 | 0 |
| Vaccination site bruising | 48 | 0 |
| Vaccination site coldness | 1 | 0 |
| Vaccination site discharge | 1 | 0 |
| Vaccination site discolouration | 4 | 0 |
| Vaccination site discomfort | 16 | 0 |
| Vaccination site erythema | 304 | 0 |
| Vaccination site extravasation | 1 | 0 |
| Vaccination site granuloma | 4 | 0 |
| Vaccination site haemorrhage | 2 | 0 |
| Vaccination site hyperaesthesia | 1 | 0 |
| Vaccination site hypersensitivity | 3 | 0 |
| Vaccination site hypoaesthesia | 6 | 0 |
| Vaccination site induration | 30 | 0 |
| Vaccination site inflammation | 32 | 0 |
| Vaccination site injury | 1 | 0 |
| Vaccination site irritation | 7 | 0 |
| Vaccination site joint erythema | 1 | 0 |
| Vaccination site joint movement impairment | 5 | 0 |
| Vaccination site joint pain | 30 | 0 |
| Vaccination site joint swelling | 2 | 0 |
| Vaccination site joint warmth | 1 | 0 |
| Vaccination site lymphadenopathy | 1 | 0 |
| Vaccination site mass | 252 | 0 |
| Vaccination site movement impairment | 18 | 0 |
| Vaccination site oedema | 2 | 0 |
| Vaccination site pain | 878 | 0 |
| Vaccination site papule | 2 | 0 |
| Vaccination site paraesthesia | 5 | 0 |
| Vaccination site pruritus | 52 | 0 |
| Vaccination site rash | 64 | 0 |
| Vaccination site reaction | 12 | 0 |
| Vaccination site scar | 1 | 0 |
| Vaccination site swelling | 237 | 0 |
| Vaccination site urticaria | 6 | 0 |
| Vaccination site vesicles | 3 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

Data Lock Date: 21-Mar-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 warmth | 181 | 0 |
| Vascular complications associated with device | | |
| Vascular stent occlusion | 1 | 0 |
| Withdrawal and rebound effects | | |
| Drug withdrawal syndrome | 2 | 0 |
| Withdrawal syndrome | 15 | 0 |
| General disorders SOC TOTAL | 131533 | 196 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Hepatic disorders | | |
| <i>Bile duct infections and inflammations</i> | | |
| Biliary colic | 8 | 0 |
| <i>Cholecystitis and cholelithiasis</i> | | |
| Cholecystitis | 5 | 0 |
| Cholelithiasis | 4 | 0 |
| <i>Cholestasis and jaundice</i> | | |
| Jaundice | 16 | 0 |
| Jaundice cholestatic | 3 | 0 |
| Ocular icterus | 1 | 0 |
| <i>Hepatic and hepatobiliary disorders NEC</i> | | |
| Liver disorder | 1 | 0 |
| <i>Hepatic enzymes and function abnormalities</i> | | |
| Hepatic function abnormal | 1 | 0 |
| <i>Hepatic fibrosis and cirrhosis</i> | | |
| Hepatic cirrhosis | 2 | 0 |
| <i>Hepatic vascular disorders</i> | | |
| Hepatic vein thrombosis | 1 | 0 |
| Portal vein thrombosis | 4 | 0 |
| <i>Hepatobiliary signs and symptoms</i> | | |
| Hepatic pain | 28 | 0 |
| Liver tenderness | 3 | 0 |
| <i>Hepatocellular damage and hepatitis NEC</i> | | |
| Hepatitis | 6 | 0 |
| Hepatitis acute | 1 | 0 |
| Liver injury | 3 | 0 |
| Hepatic disorders SOC TOTAL | 87 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Immune system disorders | | |
| <i>Acute and chronic sarcoidosis</i> | | |
| Sarcoidosis | 8 | 0 |
| <i>Allergic conditions NEC</i> | | |
| Allergic oedema | 12 | 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 | 524 | 0 |
| Infusion related hypersensitivity reaction | 3 | 0 |
| Multiple allergies | 7 | 0 |
| Serum sickness | 14 | 0 |
| Serum sickness-like reaction | 11 | 0 |
| Type III immune complex mediated reaction | 3 | 0 |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> | | |
| Allergic reaction to excipient | 1 | 0 |
| Allergy to chemicals | 3 | 0 |
| Allergy to vaccine | 23 | 0 |
| Contrast media reaction | 1 | 0 |
| Drug hypersensitivity | 35 | 0 |
| Food allergy | 3 | 0 |
| Reaction to excipient | 3 | 0 |
| Reaction to preservatives | 6 | 0 |
| <i>Anaphylactic and anaphylactoid responses</i> | | |
| Anaphylactic reaction | 324 | 1 |
| Anaphylactic shock | 55 | 0 |
| Anaphylactoid reaction | 8 | 0 |
| Anaphylactoid shock | 3 | 0 |
| <i>Atopic disorders</i> | | |
| Seasonal allergy | 18 | 0 |
| <i>Autoimmune disorders NEC</i> | | |
| Autoimmune disorder | 3 | 0 |
| <i>Immune and associated conditions NEC</i> | | |
| Bacille Calmette-Guerin scar reactivation | 8 | 0 |
| Immune system disorder | 8 | 0 |
| Immunisation reaction | 1 | 0 |
| Pre-engraftment immune reaction | 1 | 0 |
| Sensitisation | 14 | 0 |
| <i>Immunodeficiency disorders NEC</i> | | |
| Immunodeficiency | 1 | 0 |
| <i>Transplant rejections</i> | | |
| Corneal graft rejection | 1 | 0 |
| Transplant rejection | 1 | 0 |
| Immune system disorders SOC TOTAL | 1109 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections | | |
| <i>Abdominal and gastrointestinal infections</i> | | |
| Anal abscess | 1 | 0 |
| Appendicitis | 6 | 0 |
| Diverticulitis | 3 | 0 |
| Dysentery | 3 | 0 |
| Gastroenteritis | 16 | 0 |
| Gastrointestinal infection | 3 | 0 |
| <i>Bacterial infections NEC</i> | | |
| Administration site cellulitis | 1 | 0 |
| Arthritis bacterial | 2 | 0 |
| Bacterial infection | 7 | 1 |
| Cellulitis | 236 | 1 |
| Injection site cellulitis | 5 | 0 |
| Perichondritis | 1 | 0 |
| Pneumonia bacterial | 1 | 0 |
| Urinary tract infection bacterial | 1 | 0 |
| Vaccination site cellulitis | 13 | 0 |
| <i>Bone and joint infections</i> | | |
| Arthritis infective | 1 | 0 |
| Intervertebral discitis | 1 | 0 |
| <i>Bordetella infections</i> | | |
| Pertussis | 1 | 0 |
| <i>Borrelial infections</i> | | |
| Erythema migrans | 1 | 0 |
| Lyme disease | 1 | 0 |
| <i>Breast infections</i> | | |
| Mastitis | 6 | 0 |
| <i>Candida infections</i> | | |
| Anal candidiasis | 1 | 0 |
| Balanitis candida | 1 | 0 |
| Candida infection | 21 | 0 |
| Oral candidiasis | 10 | 0 |
| Skin candida | 1 | 0 |
| Vulvovaginal candidiasis | 10 | 0 |
| <i>Central nervous system and spinal infections</i> | | |
| Cavernous sinus thrombosis | 1 | 0 |
| Encephalitis | 5 | 0 |
| Meningitis | 5 | 0 |
| Myelitis | 3 | 0 |
| <i>Chlamydial infections</i> | | |
| Chlamydial infection | 1 | 0 |
| <i>Clostridia infections</i> | | |
| Clostridium difficile colitis | 1 | 0 |
| <i>Coronavirus infections</i> | | |
| Asymptomatic COVID-19 | 2 | 0 |
| COVID-19 | 225 | 14 |
| COVID-19 pneumonia | 11 | 5 |
| Coronavirus infection | 2 | 0 |
| Severe acute respiratory syndrome | 4 | 0 |
| Suspected COVID-19 | 18 | 0 |
| <i>Coxiella infections</i> | | |
| Q fever | 67 | 0 |
| <i>Dental and oral soft tissue infections</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Infections Infections cont'd | | |
| Abscess oral | 1 | 0 |
| Gingival abscess | 2 | 0 |
| Gingivitis | 9 | 0 |
| Oral pustule | 2 | 0 |
| Parotitis | 7 | 0 |
| Pericoronitis | 1 | 0 |
| Tongue abscess | 2 | 0 |
| Tooth abscess | 2 | 0 |
| Tooth infection | 3 | 0 |
| Ear infections | | |
| Ear infection | 14 | 0 |
| Labyrinthitis | 45 | 0 |
| Otitis externa | 1 | 0 |
| Otitis media | 3 | 0 |
| Ectoparasitic infestations | | |
| Trombidiasis | 1 | 0 |
| Epstein-Barr viral infections | | |
| Epstein-Barr virus infection | 1 | 0 |
| Infectious mononucleosis | 22 | 0 |
| Escherichia infections | | |
| Escherichia sepsis | 1 | 0 |
| Eye and eyelid infections | | |
| Conjunctivitis | 29 | 0 |
| Eye infection | 4 | 0 |
| Eyelid infection | 2 | 0 |
| Hordeolum | 8 | 0 |
| Keratouveitis | 1 | 0 |
| Female reproductive tract infections | | |
| Vaginal abscess | 1 | 0 |
| Vaginal infection | 1 | 0 |
| Flaviviral infections | | |
| Yellow fever | 1 | 0 |
| Yellow fever vaccine-associated neurotropic disease | 1 | 0 |
| Fungal infections NEC | | |
| Fungal infection | 4 | 0 |
| Fungal skin infection | 3 | 0 |
| Severe asthma with fungal sensitisation | 1 | 0 |
| Tonsillitis fungal | 1 | 0 |
| Vulvovaginal mycotic infection | 1 | 0 |
| Hepatitis viral infections | | |
| Hepatitis E | 1 | 0 |
| Hepatobiliary and spleen infections | | |
| Biliary sepsis | 2 | 1 |
| Herpes viral infections | | |
| Genital herpes | 10 | 0 |
| Genital herpes simplex | 1 | 0 |
| Herpes ophthalmic | 7 | 0 |
| Herpes simplex | 13 | 0 |
| Herpes simplex reactivation | 1 | 0 |
| Herpes virus infection | 6 | 0 |
| Herpes zoster | 297 | 0 |
| Herpes zoster oticus | 1 | 0 |
| Nasal herpes | 4 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Infections Infections cont'd | | |
| Ophthalmic herpes zoster | 1 | 0 |
| Oral herpes | 290 | 0 |
| Varicella | 6 | 0 |
| <i>Infections NEC</i> | | |
| Abscess | 7 | 0 |
| Abscess limb | 1 | 0 |
| Catheter site infection | 1 | 0 |
| Coinfection | 1 | 0 |
| Genital abscess | 1 | 0 |
| Infected cyst | 1 | 0 |
| Infection | 144 | 3 |
| Infection in an immunocompromised host | 1 | 0 |
| Injection site abscess | 1 | 0 |
| Injection site infection | 7 | 0 |
| Localised infection | 47 | 0 |
| Lymph gland infection | 1 | 0 |
| Pathogen resistance | 1 | 0 |
| Respiratory tract infection | 4 | 0 |
| Toxic shock syndrome | 1 | 0 |
| Vaccination site abscess | 2 | 0 |
| Vaccination site infection | 12 | 0 |
| Vestibulitis | 1 | 0 |
| <i>Infectious transmissions</i> | | |
| Secondary transmission | 2 | 0 |
| <i>Influenza viral infections</i> | | |
| H2N2 influenza | 1 | 0 |
| Influenza | 3701 | 0 |
| <i>Lower respiratory tract and lung infections</i> | | |
| Bronchitis | 6 | 0 |
| Infective exacerbation of bronchiectasis | 1 | 0 |
| Lower respiratory tract infection | 68 | 3 |
| Pneumonia | 62 | 14 |
| <i>Male reproductive tract infections</i> | | |
| Orchitis | 1 | 0 |
| <i>Mumps viral infections</i> | | |
| Mumps | 2 | 0 |
| <i>Muscle and soft tissue infections</i> | | |
| Muscle abscess | 1 | 0 |
| Soft tissue infection | 1 | 0 |
| <i>Phleboviral infections</i> | | |
| Severe fever with thrombocytopenia syndrome | 4 | 0 |
| <i>Pneumocystis infections</i> | | |
| Pneumocystis jirovecii pneumonia | 1 | 0 |
| <i>Retroviral infections</i> | | |
| Acquired immunodeficiency syndrome | 1 | 0 |
| HIV-associated neurocognitive disorder | 1 | 0 |
| <i>Rubeola viral infections</i> | | |
| Measles | 1 | 0 |
| <i>Salmonella infections</i> | | |
| Typhoid fever | 1 | 0 |
| <i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i> | | |
| Neutropenic sepsis | 4 | 0 |
| Sepsis | 31 | 2 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections | | |
| Infections cont'd | | |
| Sepsis syndrome | 1 | 0 |
| Septic rash | 3 | 0 |
| Septic shock | 1 | 0 |
| Urosepsis | 3 | 1 |
| Viraemia | 2 | 0 |
| <i>Skin structures and soft tissue infections</i> | | |
| Dermatitis infected | 3 | 0 |
| Folliculitis | 3 | 0 |
| Infected dermal cyst | 2 | 0 |
| Pustule | 1 | 0 |
| Rash pustular | 7 | 0 |
| Skin infection | 31 | 0 |
| Subcutaneous abscess | 5 | 0 |
| Vaccination site pustule | 1 | 0 |
| <i>Staphylococcal infections</i> | | |
| Furuncle | 13 | 0 |
| Staphylococcal scalded skin syndrome | 1 | 0 |
| Staphylococcal sepsis | 1 | 1 |
| <i>Streptococcal infections</i> | | |
| Cellulitis streptococcal | 1 | 0 |
| Erysipelas | 1 | 0 |
| Pharyngitis streptococcal | 2 | 0 |
| Tonsillitis streptococcal | 1 | 0 |
| <i>Tinea infections</i> | | |
| Body tinea | 2 | 0 |
| Tinea cruris | 1 | 0 |
| <i>Treponema infections</i> | | |
| Syphilis | 1 | 0 |
| <i>Trypanosomal infections</i> | | |
| African trypanosomiasis | 3 | 0 |
| <i>Tuberculous infections</i> | | |
| Lymph node tuberculosis | 2 | 0 |
| Tuberculosis | 2 | 0 |
| <i>Upper respiratory tract infections</i> | | |
| Acute sinusitis | 2 | 0 |
| Chronic sinusitis | 3 | 0 |
| Laryngitis | 9 | 0 |
| Nasopharyngitis | 795 | 0 |
| Pharyngitis | 9 | 0 |
| Rhinitis | 19 | 0 |
| Sinobronchitis | 1 | 0 |
| Sinusitis | 93 | 0 |
| Tonsillitis | 26 | 0 |
| Tracheitis | 1 | 0 |
| Upper respiratory tract infection | 2 | 0 |
| <i>Urinary tract infections</i> | | |
| Cystitis | 29 | 0 |
| Kidney infection | 14 | 0 |
| Urinary tract infection | 67 | 0 |
| <i>Vascular infections</i> | | |
| Infected lymphocele | 1 | 0 |
| Lymphangitis | 3 | 0 |
| <i>Viral infections NEC</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|-----------------------------|-------------|-----------|
| Infections | | |
| Infections cont'd | | |
| Arthritis viral | 1 | 0 |
| Encephalitis viral | 1 | 0 |
| Gastroenteritis viral | 31 | 0 |
| Meningitis viral | 3 | 0 |
| Pneumonia viral | 3 | 1 |
| Post viral fatigue syndrome | 36 | 0 |
| Sweating fever | 432 | 0 |
| Vestibular neuronitis | 6 | 0 |
| Viral diarrhoea | 3 | 0 |
| Viral infection | 12 | 0 |
| Viral labyrinthitis | 2 | 0 |
| Viral myocarditis | 1 | 0 |
| Viral pharyngitis | 11 | 0 |
| Viral rash | 26 | 0 |
| Viral sepsis | 1 | 0 |
| Infections SOC TOTAL | 7375 | 47 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries | | |
| <i>Abdominal and gastrointestinal injuries NEC</i> | | |
| Abdomen crushing | 1 | 0 |
| Lip injury | 1 | 0 |
| Oral contusion | 2 | 0 |
| Palate injury | 1 | 0 |
| Splenic rupture | 1 | 0 |
| <i>Accidental exposures to product</i> | | |
| Accidental exposure to product | 7 | 0 |
| <i>Anaesthetic and allied procedural complications</i> | | |
| Anaesthetic complication neurological | 1 | 0 |
| Delayed recovery from anaesthesia | 3 | 0 |
| Sedation complication | 1 | 0 |
| <i>Atmospheric pressure injuries</i> | | |
| Barotrauma | 1 | 0 |
| Hypobarism | 2 | 0 |
| <i>Bone and joint injuries NEC</i> | | |
| Bursa injury | 1 | 0 |
| Joint injury | 1 | 0 |
| <i>Cardiovascular injuries</i> | | |
| Vascular injury | 1 | 0 |
| <i>Cerebral injuries NEC</i> | | |
| Brain contusion | 3 | 0 |
| Concussion | 1 | 0 |
| Cranio-cerebral injury | 1 | 0 |
| Subdural haematoma | 2 | 0 |
| Subdural haemorrhage | 1 | 0 |
| <i>Chemical injuries</i> | | |
| Chemical burn of skin | 1 | 0 |
| <i>Chest and respiratory tract injuries NEC</i> | | |
| Chest crushing | 2 | 0 |
| Traumatic lung injury | 1 | 0 |
| <i>Conditions caused by cold</i> | | |
| Chillblains | 19 | 0 |
| <i>Cranial nerve injuries</i> | | |
| Optic nerve injury | 1 | 0 |
| <i>Exposures associated with pregnancy, delivery and lactation</i> | | |
| Exposure during pregnancy | 2 | 0 |
| Exposure via breast milk | 10 | 0 |
| Foetal exposure during pregnancy | 18 | 0 |
| Maternal exposure during breast feeding | 365 | 0 |
| Maternal exposure during pregnancy | 84 | 0 |
| Maternal exposure timing unspecified | 1 | 0 |
| Paternal exposure during pregnancy | 3 | 0 |
| <i>Exposures to agents or circumstances NEC</i> | | |
| Exposure to SARS-CoV-2 | 3 | 0 |
| <i>Eye injuries NEC</i> | | |
| Eye contusion | 10 | 0 |
| Eye injury | 4 | 0 |
| Foreign body in eye | 1 | 0 |
| Periorbital haematoma | 1 | 0 |
| Retinal injury | 1 | 0 |
| Superficial injury of eye | 1 | 0 |
| <i>Fractures and dislocations NEC</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries Injuries cont'd | | |
| Joint dislocation | 1 | 0 |
| Stress fracture | 2 | 0 |
| <i>Gastrointestinal and hepatobiliary procedural complications</i> | | |
| Procedural nausea | 21 | 0 |
| Procedural vomiting | 5 | 0 |
| <i>Heat injuries (excl thermal burns)</i> | | |
| Heat exhaustion | 3 | 0 |
| Heat oedema | 8 | 0 |
| Heat stroke | 3 | 0 |
| <i>Limb fractures and dislocations</i> | | |
| Ankle fracture | 1 | 0 |
| Clavicle fracture | 5 | 0 |
| Lower limb fracture | 1 | 0 |
| Patella fracture | 1 | 0 |
| Upper limb fracture | 1 | 0 |
| <i>Medication errors, product use errors and issues NEC</i> | | |
| Device use issue | 1 | 0 |
| Medication error | 4 | 0 |
| Product use issue | 1 | 0 |
| Vaccination error | 1 | 0 |
| Wrong drug | 1 | 0 |
| Wrong technique in product usage process | 2 | 0 |
| <i>Muscle, tendon and ligament injuries</i> | | |
| Epicondylitis | 5 | 0 |
| Ligament sprain | 5 | 0 |
| Muscle injury | 7 | 0 |
| Muscle rupture | 3 | 0 |
| Muscle strain | 9 | 0 |
| Post-traumatic neck syndrome | 1 | 0 |
| Repetitive strain injury | 1 | 0 |
| Tendon rupture | 4 | 0 |
| <i>Nerve injuries NEC</i> | | |
| Nerve injury | 23 | 0 |
| <i>Neurological and psychiatric procedural complications</i> | | |
| Post lumbar puncture syndrome | 6 | 0 |
| Procedural dizziness | 17 | 0 |
| <i>Non-occupational environmental exposures</i> | | |
| Exposure to chemical pollution | 1 | 0 |
| Exposure to extreme temperature | 5 | 0 |
| Exposure to noise | 2 | 0 |
| <i>Non-site specific injuries NEC</i> | | |
| Animal bite | 1 | 0 |
| Arthropod bite | 2 | 0 |
| Arthropod sting | 6 | 0 |
| Bite | 1 | 0 |
| Electric shock | 6 | 0 |
| Fall | 87 | 1 |
| Inflammation of wound | 3 | 0 |
| Injury | 1 | 0 |
| Nervous system injury | 1 | 0 |
| Road traffic accident | 1 | 0 |
| Tissue injury | 1 | 0 |
| Traumatic haematoma | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries Injuries cont'd | | |
| Traumatic shock | 1 | 0 |
| Wound complication | 5 | 0 |
| Wound haemorrhage | 3 | 0 |
| <i>Non-site specific procedural complications</i> | | |
| Incision site pain | 6 | 0 |
| Infusion related reaction | 16 | 0 |
| Injection related reaction | 461 | 0 |
| Post procedural complication | 26 | 0 |
| Procedural pain | 2 | 0 |
| Procedural site reaction | 1 | 0 |
| Suture related complication | 1 | 0 |
| <i>Occupational exposures</i> | | |
| Occupational exposure to product | 1 | 0 |
| <i>Overdoses NEC</i> | | |
| Intentional overdose | 1 | 0 |
| Overdose | 6 | 0 |
| <i>Peripheral nerve injuries</i> | | |
| Ulnar nerve injury | 1 | 0 |
| <i>Poisoning and toxicity</i> | | |
| Alcohol poisoning | 2 | 0 |
| Poisoning | 2 | 0 |
| Systemic toxicity | 1 | 0 |
| Toxicity to various agents | 4 | 0 |
| <i>Product administration errors and issues</i> | | |
| Accidental overdose | 2 | 0 |
| Contraindicated product administered | 2 | 0 |
| Duplicate therapy error | 1 | 0 |
| Expired product administered | 5 | 0 |
| Extra dose administered | 2 | 0 |
| Inappropriate schedule of product administration | 2 | 0 |
| Incorrect dose administered | 1 | 0 |
| Incorrect route of product administration | 4 | 0 |
| Lack of vaccination site rotation | 1 | 0 |
| Product administered at inappropriate site | 1 | 0 |
| Product administered to patient of inappropriate age | 2 | 0 |
| Product administration error | 4 | 0 |
| Wrong patient received product | 1 | 0 |
| Wrong product administered | 1 | 0 |
| <i>Product confusion errors and issues</i> | | |
| Product label confusion | 1 | 0 |
| <i>Product dispensing errors and issues</i> | | |
| Product dispensing error | 5 | 0 |
| <i>Product monitoring errors and issues</i> | | |
| Product monitoring error | 1 | 0 |
| <i>Product prescribing errors and issues</i> | | |
| Contraindicated product prescribed | 2 | 0 |
| Product prescribing error | 1 | 0 |
| <i>Product storage errors and issues in the product use system</i> | | |
| Product storage error | 1 | 0 |
| <i>Radiation injuries</i> | | |
| Sunburn | 9 | 0 |
| <i>Renal and urinary tract injuries NEC</i> | | |
| Bladder injury | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Injuries Injuries cont'd | | |
| <i>Reproductive system and breast injuries</i> | | |
| Penile contusion | 1 | 0 |
| <i>Reproductive tract and breast procedural complications</i> | | |
| Postmastectomy lymphoedema syndrome | 1 | 0 |
| <i>Site specific injuries NEC</i> | | |
| Back injury | 4 | 0 |
| Central nervous system injury | 1 | 0 |
| Head injury | 6 | 0 |
| Limb crushing injury | 4 | 0 |
| Limb injury | 38 | 0 |
| Neck crushing | 1 | 0 |
| Neck injury | 1 | 0 |
| <i>Skin injuries NEC</i> | | |
| Contusion | 604 | 0 |
| Scar | 4 | 0 |
| Skin abrasion | 2 | 0 |
| Skin injury | 1 | 0 |
| Skin wound | 3 | 0 |
| Subcutaneous haematoma | 1 | 0 |
| <i>Spinal cord injuries NEC</i> | | |
| Spinal cord injury sacral | 1 | 0 |
| <i>Stoma complications</i> | | |
| Gastrointestinal stoma complication | 2 | 0 |
| <i>Thermal burns</i> | | |
| Airway burns | 1 | 0 |
| Burn of internal organs | 3 | 0 |
| Burn oral cavity | 2 | 0 |
| Burns second degree | 1 | 0 |
| Cold burn | 1 | 0 |
| Thermal burn | 24 | 0 |
| Thermal burns of eye | 23 | 0 |
| <i>Underdoses NEC</i> | | |
| Intentional underdose | 1 | 0 |
| Underdose | 1 | 0 |
| <i>Vaccination related complications</i> | | |
| Vaccination complication | 53 | 0 |
| Vaccination failure | 4 | 0 |
| Injuries SOC TOTAL | 2201 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 21-Mar-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 | 1 | 0 |
| <i>Autoimmunity analyses</i> | | |
| Cold agglutinins positive | 1 | 0 |
| DNA antibody positive | 1 | 0 |
| <i>Blood counts NEC</i> | | |
| Blood count | 1 | 0 |
| Full blood count | 2 | 0 |
| Full blood count decreased | 1 | 0 |
| <i>Blood gas and acid base analyses</i> | | |
| Blood lactic acid | 1 | 0 |
| Blood pH | 7 | 0 |
| Blood pH increased | 5 | 0 |
| Oxygen consumption | 1 | 0 |
| Oxygen saturation | 15 | 0 |
| Oxygen saturation decreased | 98 | 0 |
| <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 | 15 | 0 |
| Blood glucose abnormal | 7 | 0 |
| Blood glucose decreased | 23 | 0 |
| Blood glucose fluctuation | 16 | 0 |
| Blood glucose increased | 117 | 0 |
| Glycosylated haemoglobin increased | 2 | 0 |
| <i>Cardiac auscultatory investigations</i> | | |
| Cardiac murmur | 5 | 0 |
| Heart sounds | 10 | 0 |
| Heart sounds abnormal | 2 | 0 |
| <i>Cardiac function diagnostic procedures</i> | | |
| Myocardial strain | 1 | 0 |
| <i>Central nervous system imaging procedures</i> | | |
| Computerised tomogram head | 2 | 0 |
| Magnetic resonance imaging brain | 35 | 0 |
| <i>Cerebrospinal fluid tests (excl microbiology)</i> | | |
| CSF pressure | 1 | 0 |
| <i>Chemistry analyses NEC</i> | | |
| Histamine level increased | 1 | 0 |
| Inflammatory marker decreased | 1 | 0 |
| Inflammatory marker increased | 2 | 0 |
| <i>Cholesterol analyses</i> | | |
| Blood cholesterol increased | 1 | 0 |
| <i>Coagulation and bleeding analyses</i> | | |
| Bleeding time abnormal | 1 | 0 |
| Coagulation time | 3 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations Investigations cont'd | | |
| Coagulation time prolonged | 3 | 0 |
| Coagulation time shortened | 1 | 0 |
| Fibrin D dimer increased | 1 | 0 |
| International normalised ratio | 1 | 0 |
| International normalised ratio abnormal | 1 | 0 |
| International normalised ratio decreased | 22 | 0 |
| International normalised ratio increased | 28 | 0 |
| <i>ECG investigations</i> | | |
| Electrocardiogram T wave inversion | 1 | 0 |
| Electrocardiogram abnormal | 3 | 0 |
| <i>Endocrine analyses and imaging NEC</i> | | |
| Hormone level abnormal | 1 | 0 |
| <i>Faecal analyses NEC</i> | | |
| Faecal calprotectin increased | 3 | 0 |
| <i>Fertility analyses</i> | | |
| Semen volume decreased | 1 | 0 |
| <i>Gastrointestinal and abdominal imaging procedures</i> | | |
| Computerised tomogram abdomen | 2 | 0 |
| <i>Gastrointestinal function diagnostic procedures</i> | | |
| Gastrointestinal stoma output increased | 1 | 0 |
| Swallow study | 1 | 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 | 2 | 0 |
| <i>Haematological analyses NEC</i> | | |
| Blood viscosity increased | 1 | 0 |
| <i>Heart rate and pulse investigations</i> | | |
| Brachial pulse decreased | 1 | 0 |
| Heart rate | 535 | 0 |
| Heart rate abnormal | 21 | 0 |
| Heart rate decreased | 38 | 0 |
| Heart rate increased | 1030 | 0 |
| Heart rate irregular | 76 | 0 |
| Maximum heart rate | 2 | 0 |
| Maximum heart rate decreased | 1 | 0 |
| Orthostatic heart rate response increased | 1 | 0 |
| Pulse abnormal | 11 | 0 |
| Pulse absent | 3 | 0 |
| Pulse waveform abnormal | 1 | 0 |
| Sinus rhythm | 2 | 0 |
| <i>Imaging procedures NEC</i> | | |
| Computerised tomogram | 1 | 0 |
| Scan | 1 | 0 |
| <i>Immunoglobulin analyses</i> | | |
| Blood immunoglobulin E increased | 2 | 0 |
| <i>Immunology analyses NEC</i> | | |
| Immunology test | 2 | 0 |
| Immunology test normal | 1 | 0 |
| Mast cell degranulation present | 1 | 0 |
| <i>Immunology skin tests NEC</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations Investigations cont'd | | |
| Allergy alert test | 1 | 0 |
| Skin test positive | 1 | 0 |
| Investigations NEC | | |
| Blood test | 11 | 0 |
| Blood test abnormal | 6 | 0 |
| Investigation | 1 | 0 |
| Polymerase chain reaction positive | 1 | 0 |
| Liver function analyses | | |
| Alanine aminotransferase increased | 3 | 0 |
| Aspartate aminotransferase increased | 2 | 0 |
| Bile output | 2 | 0 |
| Blood bilirubin increased | 1 | 0 |
| Gamma-glutamyltransferase increased | 2 | 0 |
| Hepatic enzyme increased | 1 | 0 |
| Liver function test | 1 | 0 |
| Liver function test abnormal | 7 | 0 |
| Transaminases increased | 2 | 0 |
| Metabolism tests NEC | | |
| Blood ketone body | 8 | 0 |
| Ubiquinone | 2 | 0 |
| Mineral and electrolyte analyses | | |
| Blood iron decreased | 1 | 0 |
| Blood phosphorus decreased | 1 | 0 |
| Blood phosphorus increased | 1 | 0 |
| Blood potassium decreased | 2 | 0 |
| Blood potassium increased | 1 | 0 |
| Blood sodium decreased | 1 | 0 |
| Sweat test | 1 | 0 |
| Musculoskeletal and soft tissue imaging procedures | | |
| Skull X-ray | 1 | 0 |
| Musculoskeletal and soft tissue tests NEC | | |
| Swollen joint count increased | 1 | 0 |
| Tender joint count | 2 | 0 |
| Mycobacteria identification and serology | | |
| Interferon gamma release assay positive | 1 | 0 |
| Neurologic diagnostic procedures | | |
| Coma scale abnormal | 1 | 0 |
| Lumbar puncture | 4 | 0 |
| Ophthalmic function diagnostic procedures | | |
| Intraocular pressure increased | 1 | 0 |
| Intraocular pressure test | 3 | 0 |
| Visual tracking test | 1 | 0 |
| Physical examination procedures and organ system status | | |
| Body surface area | 1 | 0 |
| Body temperature | 620 | 0 |
| Body temperature abnormal | 42 | 0 |
| Body temperature decreased | 69 | 0 |
| Body temperature fluctuation | 89 | 0 |
| Body temperature increased | 695 | 0 |
| Breath sounds abnormal | 3 | 0 |
| Grip strength | 2 | 0 |
| Grip strength decreased | 13 | 0 |
| Head lag | 6 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations Investigations cont'd | | |
| Lymph node palpable | 1 | 0 |
| Male genital examination abnormal | 1 | 0 |
| Muscle strength abnormal | 1 | 0 |
| Neurological examination | 1 | 0 |
| Psoriasis area severity index decreased | 1 | 0 |
| Respiratory rate | 7 | 0 |
| Respiratory rate decreased | 11 | 0 |
| Respiratory rate increased | 40 | 0 |
| Skin temperature | 109 | 0 |
| Temperature difference of extremities | 2 | 0 |
| Urological examination | 1 | 0 |
| Weight decreased | 57 | 0 |
| Weight increased | 2 | 0 |
| <i>Pituitary analyses anterior</i> | | |
| Blood thyroid stimulating hormone decreased | 1 | 0 |
| Blood thyroid stimulating hormone increased | 2 | 0 |
| <i>Platelet analyses</i> | | |
| Platelet count | 1 | 0 |
| Platelet count decreased | 21 | 0 |
| Platelet count increased | 1 | 0 |
| <i>Protein analyses NEC</i> | | |
| C-reactive protein abnormal | 2 | 0 |
| C-reactive protein increased | 3 | 0 |
| <i>Red blood cell analyses</i> | | |
| Haematocrit | 2 | 0 |
| Haemoglobin | 2 | 0 |
| Haemoglobin decreased | 2 | 0 |
| Mean cell volume abnormal | 1 | 0 |
| <i>Renal function analyses</i> | | |
| Blood creatinine decreased | 1 | 0 |
| Blood creatinine increased | 1 | 0 |
| Blood urea increased | 1 | 0 |
| <i>Reproductive hormone analyses</i> | | |
| Pregnancy test | 2 | 0 |
| Pregnancy test negative | 1 | 0 |
| <i>Respiratory and pulmonary function diagnostic procedures</i> | | |
| Forced expiratory volume | 2 | 0 |
| Forced expiratory volume increased | 7 | 0 |
| Forced expiratory volume normal | 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 | 1 | 0 |
| <i>Respiratory tract and thoracic imaging procedures</i> | | |
| Chest X-ray | 1 | 0 |
| Computerised tomogram thorax | 1 | 0 |
| Laryngoscopy | 1 | 0 |
| <i>Skeletal and cardiac muscle analyses</i> | | |
| Blood creatine phosphokinase increased | 1 | 0 |
| Myocardial necrosis marker increased | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations Investigations cont'd | | |
| <i>Therapeutic drug monitoring analyses</i> | | |
| Analgesic drug level | 10 | 0 |
| Analgesic drug level therapeutic | 1 | 0 |
| Anticoagulation drug level above therapeutic | 3 | 0 |
| Anticoagulation drug level below therapeutic | 2 | 0 |
| <i>Thyroid analyses</i> | | |
| Thyroxine | 1 | 0 |
| Thyroxine abnormal | 1 | 0 |
| Tri-iodothyronine decreased | 2 | 0 |
| <i>Tissue enzyme analyses NEC</i> | | |
| Lactate dehydrogenase urine increased | 1 | 0 |
| <i>Toxicology laboratory analyses</i> | | |
| Blood carbon monoxide increased | 1 | 0 |
| Blood heavy metal test | 1 | 0 |
| <i>Urinalysis NEC</i> | | |
| Blood urine | 11 | 0 |
| Blood urine present | 13 | 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 | 6 | 0 |
| Urine analysis normal | 1 | 0 |
| pH urine | 8 | 0 |
| pH urine decreased | 1 | 0 |
| pH urine increased | 2 | 0 |
| <i>Urinary tract function analyses NEC</i> | | |
| Urine output | 26 | 0 |
| Urine output decreased | 6 | 0 |
| Urine output increased | 5 | 0 |
| <i>Vascular tests NEC (incl blood pressure)</i> | | |
| Blood pressure abnormal | 1 | 0 |
| Blood pressure decreased | 35 | 0 |
| Blood pressure diastolic increased | 2 | 0 |
| Blood pressure increased | 121 | 0 |
| Blood pressure measurement | 32 | 0 |
| Blood pressure normal | 1 | 0 |
| Blood pressure systolic increased | 2 | 0 |
| Capillary nail refill test | 1 | 0 |
| <i>Virus identification and serology</i> | | |
| Coronavirus test | 18 | 0 |
| HIV antibody negative | 1 | 0 |
| Herpes virus test | 1 | 0 |
| SARS-CoV-2 antibody test | 1 | 0 |
| SARS-CoV-2 antibody test negative | 5 | 0 |
| SARS-CoV-2 antibody test positive | 1 | 0 |
| SARS-CoV-2 test | 15 | 0 |
| SARS-CoV-2 test false negative | 1 | 0 |
| SARS-CoV-2 test false positive | 1 | 0 |
| SARS-CoV-2 test negative | 8 | 0 |
| SARS-CoV-2 test positive | 41 | 0 |
| Viral test | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Investigations Investigations cont'd | | |
| <i>Vitamin analyses</i> | | |
| Vitamin B12 decreased | 1 | 0 |
| <i>Water and electrolyte analyses NEC</i> | | |
| Blood osmolarity | 1 | 0 |
| Volume blood | 2 | 0 |
| <i>White blood cell analyses</i> | | |
| Eosinophil count increased | 1 | 0 |
| Lymphocyte count | 1 | 0 |
| Lymphocyte count decreased | 1 | 0 |
| Neutrophil count | 2 | 0 |
| Neutrophil count decreased | 4 | 0 |
| White blood cell count | 6 | 0 |
| White blood cell count decreased | 8 | 0 |
| White blood cell count increased | 3 | 0 |
| Investigations SOC TOTAL | 4542 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Appetite disorder | 16 | 0 |
| Decreased appetite | 3778 | 0 |
| Diet refusal | 2 | 0 |
| Food craving | 8 | 0 |
| Food refusal | 26 | 0 |
| Hyperphagia | 3 | 0 |
| Hypophagia | 15 | 0 |
| Increased appetite | 23 | 0 |
| Salt craving | 1 | 0 |
| <i>Calcium metabolism disorders</i> | | |
| Hypocalcaemia | 3 | 0 |
| Tetany | 1 | 0 |
| <i>Diabetes mellitus (incl subtypes)</i> | | |
| Diabetes mellitus | 33 | 0 |
| Diabetes mellitus inadequate control | 19 | 0 |
| Increased insulin requirement | 1 | 0 |
| Type 1 diabetes mellitus | 7 | 0 |
| <i>Diabetic complications NEC</i> | | |
| Diabetic ketoacidosis | 14 | 2 |
| Diabetic ketosis | 4 | 0 |
| Euglycaemic diabetic ketoacidosis | 1 | 0 |
| <i>Disorders of purine metabolism</i> | | |
| Gout | 34 | 0 |
| <i>Electrolyte imbalance NEC</i> | | |
| Electrolyte imbalance | 1 | 0 |
| <i>Fluid intake decreased</i> | | |
| Fluid intake reduced | 5 | 0 |
| <i>Fluid intake increased</i> | | |
| Polydipsia | 10 | 0 |
| <i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i> | | |
| Alcohol intolerance | 1 | 0 |
| Food intolerance | 4 | 0 |
| Gluten sensitivity | 1 | 0 |
| Histamine intolerance | 1 | 0 |
| <i>General nutritional disorders NEC</i> | | |
| Abnormal loss of weight | 14 | 0 |
| Abnormal weight gain | 4 | 0 |
| Cachexia | 1 | 0 |
| Feeding disorder | 73 | 0 |
| Food aversion | 33 | 0 |
| Neonatal insufficient breast milk syndrome | 1 | 0 |
| Poor feeding infant | 1 | 0 |
| Starvation | 1 | 0 |
| Underweight | 1 | 0 |
| <i>Hyperglycaemic conditions NEC</i> | | |
| Hyperglycaemia | 87 | 0 |
| Insulin resistance | 6 | 0 |
| Metabolic syndrome | 1 | 0 |
| <i>Hyperlipidaemias NEC</i> | | |
| Hyperlipidaemia | 1 | 0 |
| <i>Hypoglycaemic conditions NEC</i> | | |
| Hyperinsulinaemic hypoglycaemia | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------------|----------|
| Metabolic disorders Metabolic disorders cont'd | | |
| Hypoglycaemia | 55 | 0 |
| Hypoglycaemia unawareness | 2 | 0 |
| Postprandial hypoglycaemia | 1 | 0 |
| Iron deficiencies | | |
| Iron deficiency | 1 | 0 |
| Magnesium metabolism disorders | | |
| Hypomagnesaemia | 1 | 0 |
| Metabolic acidoses (excl diabetic acidoses) | | |
| Ketoacidosis | 1 | 0 |
| Ketosis | 1 | 0 |
| Lactic acidosis | 1 | 0 |
| Metabolic acidosis | 2 | 0 |
| Mixed acid-base disorders | | |
| Acidosis | 1 | 0 |
| Phosphorus metabolism disorders | | |
| Hypophosphataemia | 1 | 0 |
| Potassium imbalance | | |
| Hyperkalaemia | 2 | 0 |
| Hypokalaemia | 2 | 0 |
| Protein metabolism disorders NEC | | |
| Hypoalbuminaemia | 1 | 0 |
| Sodium imbalance | | |
| Hypernatraemia | 1 | 0 |
| Hyponatraemia | 8 | 0 |
| Hyponatraemic syndrome | 1 | 0 |
| Sugar intolerance (excl glucose intolerance) | | |
| Lactose intolerance | 2 | 0 |
| Total fluid volume decreased | | |
| Dehydration | 328 | 0 |
| Hypovolaemia | 1 | 0 |
| Total fluid volume increased | | |
| Fluid overload | 3 | 0 |
| Fluid retention | 26 | 0 |
| Metabolic disorders SOC TOTAL | 4679 | 2 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Muscle & tissue disorders | | |
| <i>Arthropathies NEC</i> | | |
| Arthritis | 117 | 0 |
| Arthropathy | 7 | 0 |
| Autoimmune arthritis | 1 | 0 |
| Haemarthrosis | 1 | 0 |
| Palindromic rheumatism | 1 | 0 |
| Polyarthritis | 5 | 0 |
| Rheumatic fever | 1 | 0 |
| Sacroiliitis | 3 | 0 |
| <i>Bone disorders NEC</i> | | |
| Jaw disorder | 2 | 0 |
| Medial tibial stress syndrome | 6 | 0 |
| Osteitis | 3 | 0 |
| Osteonecrosis of jaw | 1 | 0 |
| <i>Bone related signs and symptoms</i> | | |
| Bone pain | 533 | 0 |
| Coccydynia | 1 | 0 |
| Pain in jaw | 253 | 0 |
| Spinal pain | 109 | 0 |
| <i>Bursal disorders</i> | | |
| Bursitis | 20 | 0 |
| <i>Cartilage disorders</i> | | |
| Chondritis | 1 | 0 |
| Costochondritis | 12 | 0 |
| <i>Connective tissue disorders NEC</i> | | |
| Connective tissue disorder | 1 | 0 |
| Mixed connective tissue disease | 1 | 0 |
| Morphoea | 1 | 0 |
| Polymyalgia rheumatica | 19 | 0 |
| Reynold's syndrome | 2 | 0 |
| <i>Extremity deformities</i> | | |
| Finger deformity | 1 | 0 |
| Hand deformity | 1 | 0 |
| Limb deformity | 1 | 0 |
| <i>Intervertebral disc disorders NEC</i> | | |
| Intervertebral disc protrusion | 1 | 0 |
| <i>Joint related disorders NEC</i> | | |
| Joint laxity | 3 | 0 |
| Joint lock | 18 | 0 |
| Patellofemoral pain syndrome | 1 | 0 |
| Periarthritis | 57 | 0 |
| Rotator cuff syndrome | 12 | 0 |
| Temporomandibular joint syndrome | 5 | 0 |
| <i>Joint related signs and symptoms</i> | | |
| Arthralgia | 11709 | 0 |
| Jaw clicking | 2 | 0 |
| Joint effusion | 1 | 0 |
| Joint noise | 10 | 0 |
| Joint stiffness | 179 | 0 |
| Joint swelling | 215 | 0 |
| Joint vibration | 1 | 0 |
| Joint warmth | 12 | 0 |
| Loose body in joint | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Muscle & tissue disorders | | |
| <i>Muscle & tissue disorders cont'd</i> | | |
| <i>Ligament disorders</i> | | |
| Ligament pain | 1 | 0 |
| <i>Lupus erythematosus (incl subtypes)</i> | | |
| Lupus-like syndrome | 1 | 0 |
| Systemic lupus erythematosus | 8 | 0 |
| <i>Metabolic bone disorders</i> | | |
| Osteopenia | 1 | 0 |
| Osteoporosis | 4 | 0 |
| <i>Muscle infections and inflammations</i> | | |
| Myositis | 6 | 0 |
| Polymyositis | 1 | 0 |
| <i>Muscle pains</i> | | |
| Fibromyalgia | 98 | 1 |
| Myalgia | 15329 | 0 |
| Myofascial pain syndrome | 5 | 0 |
| <i>Muscle related signs and symptoms NEC</i> | | |
| Muscle atrophy | 1 | 0 |
| Muscle discomfort | 5 | 0 |
| Muscle disorder | 1 | 0 |
| Muscle fatigue | 458 | 0 |
| Muscle haemorrhage | 1 | 0 |
| Muscle mass | 3 | 0 |
| Muscle oedema | 2 | 0 |
| Muscle spasms | 1079 | 0 |
| Muscle swelling | 13 | 0 |
| Muscle tightness | 66 | 0 |
| Muscle twitching | 158 | 0 |
| <i>Muscle tone abnormalities</i> | | |
| Muscle rigidity | 22 | 0 |
| Nuchal rigidity | 6 | 0 |
| Torticollis | 5 | 0 |
| Trismus | 31 | 0 |
| <i>Muscle weakness conditions</i> | | |
| Muscular weakness | 812 | 0 |
| <i>Musculoskeletal and connective tissue conditions NEC</i> | | |
| Extremity contracture | 1 | 0 |
| Infantile back arching | 1 | 0 |
| Limb mass | 2 | 0 |
| Mastication disorder | 1 | 0 |
| Mobility decreased | 57 | 0 |
| Muscle contracture | 1 | 0 |
| Musculoskeletal disorder | 1 | 0 |
| Musculoskeletal stiffness | 946 | 0 |
| Somatic dysfunction | 1 | 0 |
| Weight bearing difficulty | 3 | 0 |
| <i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i> | | |
| Head deformity | 1 | 0 |
| <i>Musculoskeletal and connective tissue infections and inflammations NEC</i> | | |
| Connective tissue inflammation | 1 | 0 |
| Dactylitis | 1 | 0 |
| <i>Musculoskeletal and connective tissue pain and discomfort</i> | | |
| Back pain | 2782 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|--------------|----------|
| Muscle & tissue disorders | | |
| <i>Muscle & tissue disorders cont'd</i> | | |
| Flank pain | 33 | 0 |
| Growing pains | 5 | 0 |
| Limb discomfort | 964 | 0 |
| Musculoskeletal chest pain | 188 | 0 |
| Musculoskeletal discomfort | 55 | 0 |
| Musculoskeletal pain | 29 | 0 |
| Neck pain | 1277 | 0 |
| Pain in extremity | 8964 | 0 |
| Rheumatic disorder | 5 | 0 |
| Myopathies | | |
| Compartment syndrome | 1 | 0 |
| Myopathy | 1 | 0 |
| Rhabdomyolysis | 5 | 0 |
| Osteoarthropathies | | |
| Nodal osteoarthritis | 1 | 0 |
| Osteoarthritis | 12 | 0 |
| Spinal osteoarthritis | 2 | 0 |
| Psoriatic arthropathies | | |
| Psoriatic arthropathy | 12 | 0 |
| Rheumatoid arthropathies | | |
| Juvenile idiopathic arthritis | 1 | 0 |
| Rheumatoid arthritis | 55 | 0 |
| Still's disease | 3 | 0 |
| Soft tissue disorders NEC | | |
| Axillary mass | 17 | 0 |
| Groin pain | 71 | 0 |
| Neck mass | 6 | 0 |
| Soft tissue mass | 1 | 0 |
| Soft tissue swelling | 3 | 0 |
| Spine and neck deformities | | |
| Kyphosis | 1 | 0 |
| Scoliosis | 1 | 0 |
| Spinal stenosis | 1 | 0 |
| Spondyloarthropathies | | |
| Ankylosing spondylitis | 13 | 0 |
| Arthritis reactive | 10 | 0 |
| Synovial disorders | | |
| Synovial cyst | 2 | 0 |
| Synovitis | 3 | 0 |
| Tendon disorders | | |
| Tendon pain | 7 | 0 |
| Tendonitis | 13 | 0 |
| Trigger finger | 6 | 0 |
| Muscle & tissue disorders SOC TOTAL | 47015 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| 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 malignant</i> | | |
| Breast cancer | 11 | 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 |
| <i>Hepatoblastomas</i> | | |
| Hepatoblastoma | 1 | 0 |
| <i>Leukaemias chronic lymphocytic</i> | | |
| Chronic lymphocytic leukaemia | 4 | 0 |
| <i>Lymphomas unspecified NEC</i> | | |
| Lymphoma | 4 | 0 |
| <i>Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)</i> | | |
| Lymphoproliferative disorder in remission | 1 | 0 |
| <i>Metastases to unknown and unspecified sites</i> | | |
| Metastasis | 1 | 0 |
| <i>Neoplasms malignant site unspecified NEC</i> | | |
| Metastatic neoplasm | 2 | 0 |
| Neoplasm malignant | 2 | 1 |
| <i>Neoplasms unspecified malignancy and site unspecified NEC</i> | | |
| Neoplasm recurrence | 2 | 0 |
| <i>Neuromas</i> | | |
| Acoustic neuroma | 1 | 0 |
| <i>Ocular neoplasms benign</i> | | |
| Eye naevus | 1 | 0 |
| <i>Oesophageal neoplasms malignant</i> | | |
| Oesophageal carcinoma | 1 | 0 |
| Oesophageal squamous cell carcinoma | 1 | 0 |
| <i>Oncologic complications and emergencies</i> | | |
| Cancer fatigue | 2 | 0 |
| <i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i> | | |
| Tonsil cancer | 2 | 0 |
| <i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i> | | |
| Pancreatic carcinoma | 1 | 0 |
| <i>Plasma cell myelomas</i> | | |
| Plasma cell myeloma | 1 | 0 |
| <i>Prostatic neoplasms malignant</i> | | |
| Prostate cancer | 1 | 0 |
| <i>Renal neoplasms malignant</i> | | |
| Clear cell renal cell carcinoma | 1 | 0 |
| Metastatic renal cell carcinoma | 1 | 0 |
| <i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i> | | |
| Bronchial carcinoma | 2 | 0 |
| Lung neoplasm malignant | 3 | 0 |
| <i>Salivary gland neoplasms malignant</i> | | |
| Salivary gland cancer stage III | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Neoplasms Neoplasms cont'd | | |
| <i>Skin melanomas (excl ocular)</i> | | |
| Acral lentiginous melanoma stage III | 1 | 0 |
| <i>Skin neoplasms benign</i> | | |
| Haemangioma of skin | 1 | 0 |
| Melanocytic naevus | 1 | 0 |
| Skin papilloma | 3 | 0 |
| <i>Skin neoplasms malignant and unspecified (excl melanoma)</i> | | |
| Squamous cell carcinoma of skin | 1 | 0 |
| <i>Soft tissue neoplasms benign NEC</i> | | |
| Knuckle pads | 1 | 0 |
| Lipoma | 1 | 0 |
| <i>Uterine neoplasms benign</i> | | |
| Uterine leiomyoma | 1 | 0 |
| Neoplasms SOC TOTAL | 63 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <i>Abnormal reflexes</i> | | |
| Areflexia | 4 | 0 |
| Hyporeflexia | 3 | 0 |
| Poor sucking reflex | 1 | 0 |
| <i>Abnormal sleep-related events</i> | | |
| Sleep paralysis | 12 | 0 |
| <i>Absence seizures</i> | | |
| Petit mal epilepsy | 11 | 0 |
| <i>Acute polyneuropathies</i> | | |
| Acute motor axonal neuropathy | 2 | 0 |
| Guillain-Barre syndrome | 52 | 1 |
| Miller Fisher syndrome | 3 | 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 | 5 | 0 |
| Orthostatic intolerance | 1 | 0 |
| <i>Central nervous system haemorrhages and cerebrovascular accidents</i> | | |
| Basal ganglia stroke | 1 | 0 |
| Brain stem infarction | 1 | 1 |
| Brain stem stroke | 1 | 0 |
| Carotid artery occlusion | 1 | 0 |
| Carotid artery thrombosis | 1 | 0 |
| Cerebellar stroke | 2 | 0 |
| Cerebral artery occlusion | 1 | 0 |
| Cerebral haematoma | 1 | 0 |
| Cerebral haemorrhage | 31 | 10 |
| Cerebral infarction | 9 | 1 |
| Cerebral ischaemia | 1 | 0 |
| Cerebral thrombosis | 4 | 1 |
| Cerebrovascular accident | 197 | 18 |
| Embolic stroke | 3 | 0 |
| Haemorrhage intracranial | 9 | 0 |
| Haemorrhagic cerebral infarction | 1 | 1 |
| Haemorrhagic stroke | 9 | 2 |
| Ischaemic stroke | 25 | 1 |
| Lacunar infarction | 1 | 0 |
| Lacunar stroke | 3 | 0 |
| Subarachnoid haemorrhage | 6 | 0 |
| Thrombotic stroke | 1 | 0 |
| <i>Central nervous system inflammatory disorders NEC</i> | | |
| Arachnoiditis | 1 | 0 |
| Central nervous system inflammation | 4 | 0 |
| Neurosarcoidosis | 1 | 0 |
| <i>Central nervous system vascular disorders NEC</i> | | |
| Cerebral congestion | 1 | 0 |
| Cerebral small vessel ischaemic disease | 1 | 0 |
| Cerebrovascular disorder | 2 | 0 |
| Internal carotid artery deformity | 1 | 0 |
| <i>Cerebrovascular venous and sinus thrombosis</i> | | |
| Cerebral venous sinus thrombosis | 24 | 4 |
| Superior sagittal sinus thrombosis | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
 Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| <i>Cervical spinal cord and nerve root disorders</i> | | |
| Cervicobrachial syndrome | 4 | 0 |
| <i>Choreiform movements</i> | | |
| Chorea | 1 | 0 |
| Sydenham's chorea | 1 | 0 |
| <i>Chronic polyneuropathies</i> | | |
| Diabetic neuropathy | 2 | 0 |
| <i>Coma states</i> | | |
| Coma | 6 | 0 |
| <i>Coordination and balance disturbances</i> | | |
| Ataxia | 7 | 0 |
| Balance disorder | 321 | 0 |
| Cerebellar ataxia | 1 | 0 |
| Coordination abnormal | 45 | 0 |
| Dysstasia | 37 | 0 |
| Nystagmus | 7 | 0 |
| <i>Cortical dysfunction NEC</i> | | |
| Aphasia | 34 | 0 |
| Dyslexia | 2 | 0 |
| Dyspraxia | 2 | 0 |
| Neurologic neglect syndrome | 1 | 0 |
| <i>Cranial nerve disorders NEC</i> | | |
| Cranial nerve disorder | 1 | 0 |
| <i>Dementia (excl Alzheimer's type)</i> | | |
| Dementia | 9 | 0 |
| Frontotemporal dementia | 1 | 0 |
| Senile dementia | 1 | 0 |
| Vascular dementia | 3 | 0 |
| <i>Demyelinating disorders NEC</i> | | |
| Acute disseminated encephalomyelitis | 1 | 0 |
| Demyelination | 3 | 0 |
| <i>Disturbances in consciousness NEC</i> | | |
| Altered state of consciousness | 6 | 0 |
| Consciousness fluctuating | 3 | 0 |
| Depressed level of consciousness | 32 | 0 |
| Lethargy | 2421 | 0 |
| Loss of consciousness | 409 | 0 |
| Sedation | 5 | 0 |
| Somnolence | 855 | 1 |
| Stupor | 4 | 0 |
| Syncope | 1056 | 0 |
| <i>Disturbances in sleep phase rhythm</i> | | |
| Advanced sleep phase | 1 | 0 |
| Circadian rhythm sleep disorder | 1 | 0 |
| <i>Dyskinesias and movement disorders NEC</i> | | |
| Akathisia | 8 | 0 |
| Bradykinesia | 10 | 0 |
| Clumsiness | 12 | 0 |
| Dyskinesia | 48 | 0 |
| Extrapyramidal disorder | 14 | 0 |
| Fine motor skill dysfunction | 4 | 0 |
| Hyperkinesia | 5 | 0 |
| Hypokinesia | 16 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders <small>Nervous system disorders cont'd</small> | | |
| Motor dysfunction | 6 | 0 |
| Movement disorder | 23 | 0 |
| Psychomotor hyperactivity | 19 | 0 |
| Dystonias | | |
| Dystonia | 7 | 0 |
| Dystonic tremor | 2 | 0 |
| Opisthotonus | 3 | 0 |
| Encephalitis NEC | | |
| Noninfective encephalitis | 2 | 0 |
| Encephalopathies NEC | | |
| Autoimmune encephalopathy | 1 | 0 |
| Encephalopathy | 3 | 0 |
| Hypoxic-ischaemic encephalopathy | 1 | 0 |
| Encephalopathies toxic and metabolic | | |
| Hepatic encephalopathy | 2 | 0 |
| Eye movement disorders | | |
| IIIrd nerve paralysis | 3 | 0 |
| Facial cranial nerve disorders | | |
| Facial nerve disorder | 2 | 0 |
| Facial paralysis | 170 | 0 |
| Facial paresis | 32 | 0 |
| Facial spasm | 10 | 0 |
| Generalised tonic-clonic seizures | | |
| Generalised tonic-clonic seizure | 29 | 0 |
| Headaches NEC | | |
| Cervicogenic headache | 2 | 0 |
| Cluster headache | 285 | 0 |
| Cold-stimulus headache | 22 | 0 |
| Drug withdrawal headache | 9 | 0 |
| Exertional headache | 5 | 0 |
| External compression headache | 2 | 0 |
| Headache | 42226 | 1 |
| Medication overuse headache | 5 | 0 |
| New daily persistent headache | 3 | 0 |
| Occipital neuralgia | 4 | 0 |
| Ophthalmoplegic migraine | 1 | 0 |
| Post-traumatic headache | 1 | 0 |
| Primary headache associated with sexual activity | 3 | 0 |
| Sinus headache | 408 | 0 |
| Tension headache | 650 | 0 |
| Thunderclap headache | 11 | 0 |
| Vascular headache | 32 | 0 |
| Hydrocephalic conditions | | |
| Hydrocephalus | 1 | 0 |
| Hypoglossal nerve disorders | | |
| Tongue paralysis | 2 | 0 |
| Increased intracranial pressure disorders | | |
| Brain compression | 1 | 0 |
| Brain oedema | 4 | 0 |
| Idiopathic intracranial hypertension | 2 | 0 |
| Intracranial pressure increased | 3 | 0 |
| Intellectual disabilities | | |
| Intellectual disability | 4 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| <i>Lumbar spinal cord and nerve root disorders</i> | | |
| Sciatica | 40 | 0 |
| <i>Memory loss (excl dementia)</i> | | |
| Amnesia | 95 | 0 |
| Memory impairment | 78 | 0 |
| Transient global amnesia | 6 | 0 |
| <i>Mental impairment (excl dementia and memory loss)</i> | | |
| Cognitive disorder | 46 | 1 |
| Disturbance in attention | 210 | 0 |
| Judgement impaired | 1 | 0 |
| Mental impairment | 42 | 0 |
| <i>Migraine headaches</i> | | |
| Basilar migraine | 2 | 0 |
| Hemiplegic migraine | 9 | 0 |
| Migraine | 3165 | 0 |
| Migraine with aura | 121 | 0 |
| Migraine without aura | 22 | 0 |
| Retinal migraine | 24 | 0 |
| Status migrainosus | 1 | 0 |
| Typical aura without headache | 6 | 0 |
| Vestibular migraine | 5 | 0 |
| <i>Mononeuropathies</i> | | |
| Carpal tunnel syndrome | 6 | 0 |
| Diabetic mononeuropathy | 1 | 0 |
| Nerve compression | 9 | 0 |
| Peroneal nerve palsy | 2 | 0 |
| Piriformis syndrome | 1 | 0 |
| Ulnar nerve palsy | 1 | 0 |
| Ulnar neuritis | 1 | 0 |
| <i>Multiple sclerosis acute and progressive</i> | | |
| Band sensation | 1 | 0 |
| Multiple sclerosis | 28 | 0 |
| Multiple sclerosis relapse | 24 | 0 |
| Relapsing multiple sclerosis | 1 | 0 |
| Uhthoff's phenomenon | 3 | 0 |
| <i>Muscle tone abnormal</i> | | |
| Hypotonia | 9 | 0 |
| Serotonin syndrome | 1 | 0 |
| Stiff leg syndrome | 2 | 0 |
| <i>Myelitis (incl infective)</i> | | |
| Myelitis transverse | 16 | 0 |
| <i>Narcolepsy and hypersomnia</i> | | |
| Hypersomnia | 79 | 0 |
| Narcolepsy | 8 | 0 |
| <i>Nervous system cysts and polyps</i> | | |
| Pineal gland cyst | 1 | 0 |
| <i>Nervous system disorders NEC</i> | | |
| Cerebral disorder | 1 | 0 |
| Nervous system disorder | 9 | 0 |
| Psychomotor skills impaired | 3 | 0 |
| <i>Neurologic visual problems NEC</i> | | |
| Tunnel vision | 7 | 0 |
| Visual field defect | 6 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Neurological signs and symptoms NEC | | |
| Dizziness | 10288 | 0 |
| Dizziness exertional | 48 | 0 |
| Dizziness postural | 1125 | 1 |
| Drooling | 4 | 0 |
| Exaggerated startle response | 3 | 0 |
| Fontanelle bulging | 2 | 0 |
| Head discomfort | 170 | 0 |
| Hyporesponsive to stimuli | 1 | 0 |
| Infant irritability | 3 | 0 |
| Myoclonus | 12 | 0 |
| Neurological decompensation | 1 | 0 |
| Neurological symptom | 38 | 0 |
| Patient elopement | 1 | 0 |
| Persistent postural-perceptual dizziness | 11 | 0 |
| Presyncope | 291 | 0 |
| Sensory overload | 4 | 0 |
| Slow response to stimuli | 1 | 0 |
| Tongue biting | 1 | 0 |
| Unresponsive to stimuli | 40 | 0 |
| Neuromuscular disorders NEC | | |
| Muscle contractions involuntary | 11 | 0 |
| Muscle spasticity | 12 | 0 |
| Neuromuscular pain | 2 | 0 |
| Neuromyopathy | 2 | 0 |
| Neuromyotonia | 1 | 0 |
| Neuromuscular junction dysfunction | | |
| Myasthenia gravis | 3 | 0 |
| Myasthenia gravis crisis | 1 | 0 |
| Olfactory nerve disorders | | |
| Anosmia | 108 | 0 |
| Hyposmia | 7 | 0 |
| Parosmia | 165 | 0 |
| Optic nerve disorders NEC | | |
| Optic neuritis | 7 | 0 |
| Paraesthesias and dysaesthesias | | |
| Anaesthesia | 2 | 0 |
| Burning feet syndrome | 8 | 0 |
| Burning sensation | 256 | 0 |
| Dysaesthesia | 4 | 0 |
| Formication | 22 | 0 |
| Hemianaesthesia | 2 | 0 |
| Hyperaesthesia | 133 | 0 |
| Hypoaesthesia | 1762 | 0 |
| Lhermitte's sign | 1 | 0 |
| Paraesthesia | 3086 | 0 |
| Paralysis and paresis (excl cranial nerve) | | |
| Diplegia | 12 | 0 |
| Hemiparesis | 25 | 0 |
| Hemiplegia | 9 | 0 |
| Monoparesis | 24 | 0 |
| Monoplegia | 45 | 0 |
| Paralysis | 111 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Paraparesis | 3 | 0 |
| Paraplegia | 1 | 0 |
| Paresis | 3 | 0 |
| Peripheral nerve palsy | 1 | 0 |
| Postictal paralysis | 1 | 0 |
| Parkinson's disease and parkinsonism | | |
| Freezing phenomenon | 84 | 0 |
| Parkinson's disease | 9 | 0 |
| Parkinsonism | 7 | 0 |
| Reduced facial expression | 3 | 0 |
| Partial complex seizures | | |
| Dreamy state | 7 | 0 |
| Focal dyscognitive seizures | 2 | 0 |
| Temporal lobe epilepsy | 2 | 0 |
| Partial simple seizures NEC | | |
| Simple partial seizures | 3 | 0 |
| Peripheral neuropathies NEC | | |
| Neuritis | 2 | 0 |
| Neuropathy peripheral | 62 | 0 |
| Peripheral sensory neuropathy | 1 | 0 |
| Polyneuropathy | 4 | 0 |
| Seizures and seizure disorders NEC | | |
| Alcoholic seizure | 1 | 0 |
| Atonic seizures | 5 | 0 |
| Clonic convulsion | 4 | 0 |
| Drug withdrawal convulsions | 2 | 0 |
| Epilepsy | 98 | 0 |
| Epileptic aura | 1 | 0 |
| Febrile convulsion | 46 | 0 |
| Migraine-triggered seizure | 1 | 0 |
| Myoclonic epilepsy | 2 | 0 |
| Partial seizures | 28 | 0 |
| Psychogenic seizure | 4 | 0 |
| Seizure | 460 | 2 |
| Seizure anoxic | 1 | 0 |
| Seizure cluster | 3 | 0 |
| Seizure like phenomena | 2 | 0 |
| Status epilepticus | 19 | 1 |
| Tonic convulsion | 15 | 0 |
| Sensory abnormalities NEC | | |
| Ageusia | 480 | 0 |
| Allodynia | 30 | 0 |
| Aura | 7 | 0 |
| Central pain syndrome | 2 | 0 |
| Complex regional pain syndrome | 5 | 0 |
| Dysgeusia | 848 | 0 |
| Hypogeusia | 2 | 0 |
| Loss of proprioception | 2 | 0 |
| Neuralgia | 437 | 0 |
| Persistent genital arousal disorder | 1 | 0 |
| Phantom limb syndrome | 10 | 0 |
| Post herpetic neuralgia | 2 | 0 |
| Restless arm syndrome | 7 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|--------------|-----------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Restless legs syndrome | 159 | 0 |
| Sensory disturbance | 27 | 0 |
| Sensory loss | 53 | 0 |
| Taste disorder | 235 | 0 |
| <i>Sleep disturbances NEC</i> | | |
| Microsleep | 1 | 0 |
| Poor quality sleep | 351 | 0 |
| Sleep deficit | 22 | 0 |
| <i>Speech and language abnormalities</i> | | |
| Dysarthria | 108 | 1 |
| Incoherent | 2 | 0 |
| Language disorder | 2 | 0 |
| Slow speech | 8 | 0 |
| Speech disorder | 19 | 0 |
| <i>Spinal cord and nerve root disorders NEC</i> | | |
| Cauda equina syndrome | 1 | 0 |
| Myelopathy | 2 | 0 |
| Radiculitis brachial | 2 | 0 |
| Radiculopathy | 1 | 0 |
| <i>Structural brain disorders NEC</i> | | |
| Brain injury | 5 | 0 |
| <i>Transient cerebrovascular events</i> | | |
| Transient ischaemic attack | 107 | 0 |
| <i>Tremor (excl congenital)</i> | | |
| Action tremor | 2 | 0 |
| Asterixis | 1 | 0 |
| Essential tremor | 3 | 0 |
| Head titubation | 5 | 0 |
| Intention tremor | 1 | 0 |
| Postural tremor | 1 | 0 |
| Resting tremor | 3 | 0 |
| Tremor | 6029 | 1 |
| <i>Trigeminal disorders</i> | | |
| Facial neuralgia | 7 | 0 |
| Numb chin syndrome | 1 | 0 |
| Trigeminal neuralgia | 22 | 0 |
| Trigeminal neuritis | 1 | 0 |
| Nervous system disorders SOC TOTAL | 81702 | 49 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Pregnancy conditions | | |
| <i>Abortions spontaneous</i> | | |
| Abortion spontaneous | 13 | 0 |
| <i>Foetal position and presentation abnormalities</i> | | |
| Face presentation | 1 | 0 |
| <i>Labour onset and length abnormalities</i> | | |
| Precipitate labour | 1 | 0 |
| Premature labour | 2 | 0 |
| Premature rupture of membranes | 1 | 0 |
| <i>Maternal complications of pregnancy NEC</i> | | |
| Hyperemesis gravidarum | 2 | 0 |
| Morning sickness | 21 | 0 |
| <i>Normal pregnancy, labour and delivery</i> | | |
| Delivery | 1 | 0 |
| Pregnancy | 4 | 0 |
| <i>Pregnancy complicated by maternal disorders</i> | | |
| Gestational diabetes | 4 | 0 |
| <i>Stillbirth and foetal death</i> | | |
| Stillbirth | 1 | 0 |
| <i>Unintended pregnancies</i> | | |
| Pregnancy after post coital contraception | 1 | 0 |
| Pregnancy with contraceptive device | 1 | 0 |
| Unintended pregnancy | 2 | 0 |
| Unwanted pregnancy | 1 | 0 |
| Pregnancy conditions SOC TOTAL | 56 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| 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 information output issues</i> | | |
| Device information output issue | 1 | 0 |
| <i>Device issues NEC</i> | | |
| Device issue | 2 | 0 |
| Device leakage | 2 | 0 |
| <i>Device malfunction events NEC</i> | | |
| Oversensing | 9 | 0 |
| Stent malfunction | 1 | 0 |
| Thrombosis in device | 12 | 0 |
| Undersensing | 1 | 0 |
| <i>Device physical property and chemical issues</i> | | |
| Needle issue | 1 | 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 odour abnormal | 1 | 0 |
| Product physical issue | 2 | 0 |
| Product taste abnormal | 2 | 0 |
| <i>Product quality issues NEC</i> | | |
| Product origin unknown | 1 | 0 |
| null SOC TOTAL | 39 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders | | |
| <i>Abnormal behaviour NEC</i> | | |
| Abnormal behaviour | 4 | 0 |
| Breath holding | 1 | 0 |
| Staring | 4 | 0 |
| <i>Adjustment disorders</i> | | |
| Adjustment disorder with depressed mood | 2 | 0 |
| <i>Affect alterations NEC</i> | | |
| Affect lability | 1 | 0 |
| Constricted affect | 3 | 0 |
| Flat affect | 4 | 0 |
| Inappropriate affect | 2 | 0 |
| <i>Amnesic symptoms</i> | | |
| Paramnesia | 2 | 0 |
| <i>Anxiety disorders NEC</i> | | |
| Anxiety disorder | 1 | 0 |
| Neurosis | 1 | 0 |
| <i>Anxiety symptoms</i> | | |
| Agitation | 89 | 0 |
| Anxiety | 338 | 0 |
| Nervousness | 339 | 0 |
| Stress | 17 | 0 |
| Tension | 18 | 0 |
| <i>Attention deficit and disruptive behaviour disorders</i> | | |
| Attention deficit hyperactivity disorder | 6 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Aggression | 4 | 0 |
| Asocial behaviour | 1 | 0 |
| Indifference | 1 | 0 |
| Paranoia | 12 | 0 |
| Personality change | 1 | 0 |
| Social avoidant behaviour | 1 | 0 |
| Soliloquy | 1 | 0 |
| Violence-related symptom | 2 | 0 |
| <i>Bipolar disorders</i> | | |
| Bipolar I disorder | 1 | 0 |
| Bipolar disorder | 2 | 0 |
| <i>Cognitive and attention disorders and disturbances NEC</i> | | |
| Daydreaming | 6 | 0 |
| Mental fatigue | 182 | 0 |
| <i>Communications disorders</i> | | |
| Communication disorder | 1 | 0 |
| Mutism | 2 | 0 |
| Speech sound disorder | 1 | 0 |
| <i>Confusion and disorientation</i> | | |
| Confusional state | 838 | 0 |
| Disorientation | 354 | 0 |
| <i>Decreased physical activity levels</i> | | |
| Catatonia | 1 | 0 |
| <i>Deliria</i> | | |
| Delirium | 263 | 0 |
| <i>Delusional symptoms</i> | | |
| Delusion | 19 | 0 |
| Thought withdrawal | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| <i>Depressive disorders</i> | | |
| Agitated depression | 2 | 0 |
| Depression | 185 | 0 |
| Depression suicidal | 2 | 0 |
| Major depression | 9 | 0 |
| Mixed anxiety and depressive disorder | 1 | 0 |
| <i>Dissociative states</i> | | |
| Depersonalisation/derealisation disorder | 7 | 0 |
| Dissociation | 22 | 0 |
| Dissociative disorder | 1 | 0 |
| <i>Disturbances in initiating and maintaining sleep</i> | | |
| Initial insomnia | 11 | 0 |
| Insomnia | 1494 | 0 |
| Middle insomnia | 29 | 0 |
| Terminal insomnia | 2 | 0 |
| <i>Dyssomnias</i> | | |
| Dyssomnia | 2 | 0 |
| <i>Eating disorders NEC</i> | | |
| Eating disorder | 2 | 0 |
| <i>Emotional and mood disturbances NEC</i> | | |
| Anger | 24 | 0 |
| Dysphoria | 1 | 0 |
| Emotional disorder | 40 | 0 |
| Emotional distress | 27 | 0 |
| Emotional poverty | 2 | 0 |
| Euphoric mood | 31 | 0 |
| Frustration tolerance decreased | 2 | 0 |
| Irritability | 108 | 0 |
| Mood altered | 19 | 0 |
| <i>Factitious disorders</i> | | |
| Factitious disorder | 3 | 0 |
| <i>Fear symptoms and phobic disorders (incl social phobia)</i> | | |
| Agoraphobia | 1 | 0 |
| Fear | 11 | 0 |
| Fear of death | 6 | 0 |
| Fear of disease | 1 | 0 |
| Fear of eating | 1 | 0 |
| Fear of falling | 1 | 0 |
| Fear of open spaces | 1 | 0 |
| Phobia | 2 | 0 |
| Phonophobia | 2 | 0 |
| <i>Fluctuating mood symptoms</i> | | |
| Mood swings | 12 | 0 |
| <i>Hallucinations (excl sleep-related)</i> | | |
| Hallucination | 496 | 0 |
| Hallucination, auditory | 14 | 0 |
| Hallucination, olfactory | 1 | 0 |
| Hallucination, tactile | 1 | 0 |
| Hallucination, visual | 27 | 0 |
| Hallucinations, mixed | 5 | 0 |
| <i>Impulse control disorders</i> | | |
| Impulse-control disorder | 2 | 0 |
| Impulsive behaviour | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| <i>Increased physical activity levels</i> | | |
| Restlessness | 237 | 0 |
| <i>Infancy, childhood and adolescence psychiatric disorders NEC</i> | | |
| Emotional disorder of childhood | 1 | 0 |
| <i>Mental disorders NEC</i> | | |
| Mental disorder | 4 | 0 |
| Mental status changes | 1 | 0 |
| <i>Mental disorders due to a general medical condition NEC</i> | | |
| Neuropsychiatric symptoms | 1 | 0 |
| <i>Mood alterations with depressive symptoms</i> | | |
| Anhedonia | 2 | 0 |
| Decreased interest | 7 | 0 |
| Depressed mood | 187 | 0 |
| Feeling of despair | 7 | 0 |
| Negative thoughts | 4 | 0 |
| Sense of a foreshortened future | 1 | 0 |
| Tearfulness | 46 | 0 |
| <i>Mood alterations with manic symptoms</i> | | |
| Mania | 9 | 0 |
| <i>Mood disorders NEC</i> | | |
| Apathy | 18 | 0 |
| Listless | 73 | 0 |
| <i>Narcolepsy and associated conditions</i> | | |
| Hypnagogic hallucination | 3 | 0 |
| <i>Obsessive-compulsive disorders and symptoms</i> | | |
| Compulsive shopping | 1 | 0 |
| Dermatillomania | 1 | 0 |
| Obsessive thoughts | 1 | 0 |
| Obsessive-compulsive disorder | 1 | 0 |
| <i>Orgasmic disorders and disturbances</i> | | |
| Orgasmic sensation decreased | 1 | 0 |
| Premature ejaculation | 1 | 0 |
| <i>Panic attacks and disorders</i> | | |
| Limited symptom panic attack | 1 | 0 |
| Panic attack | 104 | 0 |
| Panic disorder | 2 | 0 |
| Panic reaction | 16 | 0 |
| <i>Parasomnias</i> | | |
| Abnormal dreams | 176 | 0 |
| Confusional arousal | 2 | 0 |
| Exploding head syndrome | 4 | 0 |
| Nightmare | 215 | 0 |
| Rapid eye movements sleep abnormal | 2 | 0 |
| Sleep inertia | 1 | 0 |
| Sleep talking | 10 | 0 |
| Sleep terror | 28 | 0 |
| Sleep-related eating disorder | 1 | 0 |
| Somnambulism | 3 | 0 |
| <i>Perception disturbances NEC</i> | | |
| Autoscopy | 13 | 0 |
| Derealisation | 5 | 0 |
| Flashback | 2 | 0 |
| Illusion | 6 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Time perception altered | 4 | 0 |
| Psychiatric elimination disorders | | |
| Enuresis | 20 | 0 |
| Psychiatric symptoms NEC | | |
| Hypervigilance | 7 | 0 |
| Psychiatric symptom | 1 | 0 |
| Psychological trauma | 2 | 0 |
| Psychotic disorder NEC | | |
| Psychotic behaviour | 1 | 0 |
| Psychotic disorder | 13 | 0 |
| Schizophrenia NEC | | |
| Schizophrenia | 1 | 0 |
| Sexual and gender identity disorders NEC | | |
| Gender dysphoria | 1 | 0 |
| Sexual arousal disorders | | |
| Disturbance in sexual arousal | 1 | 0 |
| Sexual desire disorders | | |
| Libido decreased | 3 | 0 |
| Libido increased | 4 | 0 |
| Loss of libido | 16 | 0 |
| Sleep disorders NEC | | |
| Sleep disorder | 160 | 0 |
| Sleep disorder due to general medical condition, insomnia type | 1 | 0 |
| Somatic symptom disorders | | |
| Conversion disorder | 3 | 0 |
| Habit cough | 20 | 0 |
| Illness anxiety disorder | 1 | 0 |
| Somatic symptom disorder | 1 | 0 |
| Speech and language usage disturbances | | |
| Disorganised speech | 2 | 0 |
| Logorrhoea | 2 | 0 |
| Pedantic speech | 1 | 0 |
| Verbigeration | 1 | 0 |
| Speech articulation and rhythm disturbances | | |
| Dysphemia | 6 | 0 |
| Lack of spontaneous speech | 1 | 0 |
| Stereotypies and automatisms | | |
| Bruxism | 13 | 0 |
| Head banging | 21 | 0 |
| Waxy flexibility | 1 | 0 |
| Stress disorders | | |
| Acute stress disorder | 2 | 0 |
| Burnout syndrome | 2 | 0 |
| Hyperarousal | 2 | 0 |
| Post-traumatic stress disorder | 9 | 0 |
| Substance related and addictive disorders | | |
| Alcohol abuse | 1 | 0 |
| Alcoholism | 1 | 0 |
| Drug dependence | 1 | 0 |
| Substance abuse | 1 | 0 |
| Suicidal and self-injurious behaviour | | |
| Completed suicide | 1 | 0 |
| Intentional self-injury | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Suicidal behaviour | 2 | 0 |
| Suicidal ideation | 29 | 0 |
| Suicide threat | 1 | 0 |
| <i>Thinking disturbances</i> | | |
| Bradyphrenia | 30 | 0 |
| Intrusive thoughts | 2 | 0 |
| Morbid thoughts | 2 | 0 |
| Tachyphrenia | 14 | 0 |
| Thinking abnormal | 9 | 0 |
| Thought blocking | 1 | 0 |
| <i>Tic disorders</i> | | |
| Tic | 2 | 0 |
| Psychiatric disorders SOC TOTAL | 6756 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Renal & urinary disorders | | |
| <i>Bladder and urethral symptoms</i> | | |
| Bladder discomfort | 3 | 0 |
| Bladder irritation | 2 | 0 |
| Bladder pain | 20 | 0 |
| Bladder spasm | 1 | 0 |
| Dysuria | 40 | 0 |
| Incontinence | 38 | 0 |
| Micturition disorder | 1 | 0 |
| Micturition frequency decreased | 1 | 0 |
| Micturition urgency | 57 | 0 |
| Mixed incontinence | 1 | 0 |
| Pollakiuria | 136 | 0 |
| Urethral pain | 1 | 0 |
| Urge incontinence | 1 | 0 |
| Urinary hesitation | 3 | 0 |
| Urinary incontinence | 51 | 0 |
| Urinary retention | 32 | 0 |
| Urine flow decreased | 2 | 0 |
| <i>Bladder disorders NEC</i> | | |
| Bladder dilatation | 1 | 0 |
| Bladder disorder | 6 | 0 |
| Urinary bladder haemorrhage | 1 | 0 |
| <i>Bladder infections and inflammations</i> | | |
| Cystitis interstitial | 3 | 0 |
| Cystitis noninfective | 1 | 0 |
| <i>Glomerulonephritis and nephrotic syndrome</i> | | |
| Anti-glomerular basement membrane disease | 1 | 0 |
| IgA nephropathy | 1 | 0 |
| Nephrotic syndrome | 1 | 0 |
| <i>Myoneurogenic bladder disorders</i> | | |
| Automatic bladder | 1 | 0 |
| Bladder dysfunction | 1 | 0 |
| Hypertonic bladder | 7 | 0 |
| Loss of bladder sensation | 6 | 0 |
| Neurogenic bladder | 1 | 0 |
| <i>Nephritis NEC</i> | | |
| Nephritis | 4 | 0 |
| Tubulointerstitial nephritis | 1 | 0 |
| <i>Nephropathies and tubular disorders NEC</i> | | |
| Nephropathy | 1 | 0 |
| <i>Renal disorders NEC</i> | | |
| Renal disorder | 3 | 0 |
| <i>Renal failure and impairment</i> | | |
| Acute kidney injury | 18 | 0 |
| Anuria | 1 | 0 |
| Chronic kidney disease | 4 | 0 |
| Oliguria | 6 | 0 |
| Renal failure | 5 | 1 |
| Renal impairment | 2 | 0 |
| Renal injury | 1 | 0 |
| <i>Renal structural abnormalities and trauma</i> | | |
| Kidney enlargement | 1 | 0 |
| <i>Structural and obstructive urethral disorders (excl congenital)</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Renal & urinary disorders | | |
| <i>Renal & urinary disorders cont'd</i> | | |
| Urethral spasm | 1 | 0 |
| <i>Urinary abnormalities</i> | | |
| Chromaturia | 53 | 0 |
| Glycosuria | 1 | 0 |
| Haematuria | 12 | 0 |
| Proteinuria | 2 | 0 |
| Urine abnormality | 8 | 0 |
| Urine odour abnormal | 16 | 0 |
| <i>Urinary tract signs and symptoms NEC</i> | | |
| Haemorrhage urinary tract | 9 | 0 |
| Nocturia | 6 | 0 |
| Polyuria | 17 | 0 |
| Renal colic | 2 | 0 |
| Renal pain | 446 | 0 |
| Urinary tract discomfort | 1 | 0 |
| Urinary tract pain | 2 | 0 |
| Renal & urinary disorders SOC TOTAL | 1044 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Reproductive & breast disorders | | |
| <i>Benign and malignant breast neoplasms</i> | | |
| Breast cyst | 1 | 0 |
| <i>Breast disorders NEC</i> | | |
| Breast disorder | 1 | 0 |
| Breast enlargement | 2 | 0 |
| Breast mass | 9 | 0 |
| Gynaecomastia | 1 | 0 |
| <i>Breast infections and inflammations</i> | | |
| Breast inflammation | 1 | 0 |
| Nipple inflammation | 1 | 0 |
| <i>Breast signs and symptoms</i> | | |
| Breast discomfort | 2 | 0 |
| Breast engorgement | 1 | 0 |
| Breast oedema | 1 | 0 |
| Breast pain | 114 | 0 |
| Breast swelling | 10 | 0 |
| Breast tenderness | 14 | 0 |
| Nipple pain | 7 | 0 |
| Nipple swelling | 1 | 0 |
| <i>Erection and ejaculation conditions and disorders</i> | | |
| Ejaculation delayed | 1 | 0 |
| Ejaculation failure | 1 | 0 |
| Erectile dysfunction | 23 | 0 |
| Organic erectile dysfunction | 6 | 0 |
| Painful erection | 1 | 0 |
| Retrograde ejaculation | 1 | 0 |
| Spontaneous penile erection | 1 | 0 |
| <i>Fallopian tube and ovary infections and inflammations</i> | | |
| Noninfective oophoritis | 1 | 0 |
| <i>Lactation disorders</i> | | |
| Lactation puerperal increased | 1 | 0 |
| Suppressed lactation | 1 | 0 |
| <i>Menopausal effects NEC</i> | | |
| Menopausal symptoms | 5 | 0 |
| <i>Menopausal effects on the genitourinary tract</i> | | |
| Postmenopausal haemorrhage | 9 | 0 |
| <i>Menstruation and uterine bleeding NEC</i> | | |
| Dysmenorrhoea | 27 | 0 |
| Menstrual disorder | 40 | 0 |
| Menstruation irregular | 45 | 0 |
| Metrorrhagia | 20 | 0 |
| Premenstrual pain | 4 | 0 |
| Premenstrual syndrome | 1 | 0 |
| Withdrawal bleed | 2 | 0 |
| <i>Menstruation with decreased bleeding</i> | | |
| Amenorrhoea | 13 | 0 |
| Hypomenorrhoea | 21 | 0 |
| Menstruation delayed | 48 | 0 |
| Oligomenorrhoea | 2 | 0 |
| <i>Menstruation with increased bleeding</i> | | |
| Menorrhagia | 82 | 0 |
| Polymenorrhoea | 9 | 0 |
| <i>Ovarian and fallopian tube cysts and neoplasms</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Polycystic ovaries | 1 | 0 |
| Ovarian and fallopian tube disorders NEC | | |
| Premature ovulation | 2 | 0 |
| Pelvic prolapse conditions | | |
| Vaginal prolapse | 1 | 0 |
| Pelvis and broad ligament disorders NEC | | |
| Adnexa uteri pain | 4 | 0 |
| Pelvic haemorrhage | 1 | 0 |
| Penile and scrotal infections and inflammations | | |
| Balanoposthitis | 1 | 0 |
| Penile disorders NEC (excl erection and ejaculation) | | |
| Penile blister | 1 | 0 |
| Penile curvature | 1 | 0 |
| Penile oedema | 2 | 0 |
| Penile pain | 1 | 0 |
| Penis disorder | 2 | 0 |
| Peyronie's disease | 2 | 0 |
| Prostate and seminal vesicles infections and inflammations | | |
| Prostatitis | 1 | 0 |
| Prostatic neoplasms and hypertrophy | | |
| Benign prostatic hyperplasia | 1 | 0 |
| Reproductive tract disorders NEC (excl neoplasms) | | |
| Female genital tract fistula | 1 | 0 |
| Genital blister | 1 | 0 |
| Genital haemorrhage | 2 | 0 |
| Genital hyperaesthesia | 1 | 0 |
| Genital ulceration | 5 | 0 |
| Reproductive tract signs and symptoms NEC | | |
| Genital burning sensation | 2 | 0 |
| Genital discomfort | 3 | 0 |
| Genital pain | 1 | 0 |
| Pelvic discomfort | 2 | 0 |
| Pelvic pain | 44 | 0 |
| Pruritus genital | 1 | 0 |
| Scrotal disorders NEC | | |
| Scrotal oedema | 1 | 0 |
| Scrotal pain | 2 | 0 |
| Scrotal swelling | 3 | 0 |
| Sexual function and fertility disorders NEC | | |
| Female sexual dysfunction | 1 | 0 |
| Sexual dysfunction | 1 | 0 |
| Spermatogenesis and semen disorders | | |
| Haemospermia | 2 | 0 |
| Semen discolouration | 1 | 0 |
| Testicular and epididymal disorders NEC | | |
| Testicular disorder | 1 | 0 |
| Testicular pain | 36 | 0 |
| Testicular retraction | 1 | 0 |
| Testicular swelling | 5 | 0 |
| Uterine disorders NEC | | |
| Endometriosis | 5 | 0 |
| Uterine enlargement | 1 | 0 |
| Uterine haemorrhage | 6 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Uterine pain | 1 | 0 |
| <i>Uterine tone disorders</i> | | |
| Uterine spasm | 3 | 0 |
| <i>Vaginal and vulval infections and inflammations</i> | | |
| Vulvovaginal inflammation | 1 | 0 |
| <i>Vulvovaginal cysts and neoplasms</i> | | |
| Vaginal cyst | 1 | 0 |
| <i>Vulvovaginal disorders NEC</i> | | |
| Vaginal haemorrhage | 106 | 0 |
| Vaginal ulceration | 2 | 0 |
| Vulval haemorrhage | 4 | 0 |
| Vulval ulceration | 1 | 0 |
| Vulvovaginal ulceration | 1 | 0 |
| <i>Vulvovaginal signs and symptoms</i> | | |
| Enlarged clitoris | 1 | 0 |
| Vaginal discharge | 13 | 0 |
| Vaginal lesion | 3 | 0 |
| Vulval oedema | 1 | 0 |
| Vulvovaginal burning sensation | 5 | 0 |
| Vulvovaginal discomfort | 1 | 0 |
| Vulvovaginal dryness | 1 | 0 |
| Vulvovaginal pain | 8 | 0 |
| Vulvovaginal rash | 2 | 0 |
| Vulvovaginal swelling | 3 | 0 |
| Reproductive & breast disorders SOC TOTAL | 839 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Apnoea | 5 | 0 |
| Apnoeic attack | 1 | 0 |
| Dyspnoea | 2576 | 3 |
| Dyspnoea at rest | 7 | 0 |
| Dyspnoea exertional | 15 | 0 |
| Grunting | 1 | 0 |
| Hyperventilation | 42 | 0 |
| Hypopnoea | 103 | 0 |
| Hypoventilation | 1 | 0 |
| Irregular breathing | 13 | 0 |
| Mouth breathing | 7 | 0 |
| Orthopnoea | 2 | 0 |
| Respiration abnormal | 53 | 1 |
| Respiratory arrest | 7 | 0 |
| Respiratory distress | 3 | 0 |
| Respiratory fatigue | 1 | 0 |
| Sleep apnoea syndrome | 10 | 0 |
| Tachypnoea | 25 | 0 |
| <i>Bronchial conditions NEC</i> | | |
| Bronchiectasis | 8 | 0 |
| <i>Bronchospasm and obstruction</i> | | |
| Aspirin-exacerbated respiratory disease | 1 | 0 |
| Asthma | 212 | 0 |
| Asthma late onset | 1 | 0 |
| Asthmatic crisis | 2 | 0 |
| Bronchospasm | 11 | 0 |
| Chronic obstructive pulmonary disease | 20 | 2 |
| Cough variant asthma | 5 | 0 |
| Obstructive airways disorder | 2 | 0 |
| Reversible airways obstruction | 1 | 0 |
| Wheezing | 264 | 0 |
| <i>Conditions associated with abnormal gas exchange</i> | | |
| Asphyxia | 1 | 0 |
| Hypoxia | 27 | 0 |
| <i>Coughing and associated symptoms</i> | | |
| Allergic cough | 2 | 0 |
| Cough | 1732 | 0 |
| Haemoptysis | 25 | 0 |
| Productive cough | 66 | 0 |
| Sputum discoloured | 3 | 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 | 12 | 0 |
| <i>Lower respiratory tract inflammatory and immunologic conditions</i> | | |
| Alveolitis | 1 | 0 |
| Pneumonia aspiration | 8 | 3 |
| Pneumonitis | 6 | 0 |
| <i>Lower respiratory tract signs and symptoms</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| Hiccups | 13 | 0 |
| Lower respiratory tract congestion | 2 | 0 |
| Lung opacity | 3 | 0 |
| Pleuritic pain | 8 | 0 |
| Pulmonary haemorrhage | 1 | 0 |
| Pulmonary pain | 88 | 0 |
| <i>Nasal congestion and inflammations</i> | | |
| Nasal congestion | 225 | 0 |
| Nasal inflammation | 3 | 0 |
| Rhinitis allergic | 8 | 0 |
| Rhinitis perennial | 1 | 0 |
| <i>Nasal disorders NEC</i> | | |
| Epistaxis | 486 | 0 |
| Nasal crusting | 2 | 0 |
| Nasal cyst | 1 | 0 |
| Nasal disorder | 1 | 0 |
| Nasal dryness | 25 | 0 |
| Nasal odour | 2 | 0 |
| Nasal oedema | 6 | 0 |
| Nasal pruritus | 2 | 0 |
| Nasal ulcer | 1 | 0 |
| <i>Neonatal hypoxic conditions</i> | | |
| Gasping syndrome | 1 | 0 |
| <i>Paranasal sinus disorders (excl infections and neoplasms)</i> | | |
| Paranasal sinus haemorrhage | 2 | 0 |
| Paranasal sinus inflammation | 1 | 0 |
| Sinonasal obstruction | 5 | 0 |
| Sinus congestion | 25 | 0 |
| Sinus disorder | 3 | 0 |
| <i>Parenchymal lung disorders NEC</i> | | |
| Emphysema | 1 | 0 |
| Idiopathic pulmonary fibrosis | 1 | 0 |
| Interstitial lung disease | 1 | 0 |
| Lung consolidation | 1 | 0 |
| Pulmonary cavitation | 1 | 0 |
| <i>Pharyngeal disorders (excl infections and neoplasms)</i> | | |
| Oropharyngeal swelling | 1 | 0 |
| Pharyngeal erythema | 3 | 0 |
| Pharyngeal hypoaesthesia | 13 | 0 |
| Pharyngeal oedema | 8 | 0 |
| Pharyngeal paraesthesia | 14 | 0 |
| Pharyngeal swelling | 108 | 0 |
| Pharyngeal ulceration | 8 | 0 |
| Tonsillar disorder | 1 | 0 |
| Tonsillar erythema | 4 | 0 |
| Tonsillar hypertrophy | 27 | 0 |
| Tonsillar inflammation | 2 | 0 |
| <i>Pleural infections and inflammations</i> | | |
| Lupus pleurisy | 1 | 0 |
| Pleurisy | 9 | 0 |
| <i>Pneumothorax and pleural effusions NEC</i> | | |
| Pleural effusion | 3 | 0 |
| Pneumothorax | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| <i>Pulmonary hypertension</i> | | |
| Pulmonary hypertension | 2 | 1 |
| <i>Pulmonary oedemas</i> | | |
| Acute pulmonary oedema | 2 | 0 |
| Pulmonary congestion | 8 | 0 |
| Pulmonary oedema | 9 | 0 |
| <i>Pulmonary thrombotic and embolic conditions</i> | | |
| Pulmonary embolism | 223 | 27 |
| Pulmonary infarction | 1 | 1 |
| Pulmonary thrombosis | 1 | 0 |
| <i>Respiratory failures (excl neonatal)</i> | | |
| Respiratory failure | 3 | 0 |
| <i>Respiratory signs and symptoms NEC</i> | | |
| Allergic respiratory symptom | 2 | 0 |
| Diaphragmalgia | 7 | 0 |
| Painful respiration | 2 | 0 |
| Respiratory symptom | 7 | 0 |
| Suffocation feeling | 2 | 0 |
| <i>Respiratory tract disorders NEC</i> | | |
| Aspiration | 3 | 2 |
| Lung disorder | 3 | 0 |
| Respiratory tract congestion | 3 | 0 |
| Respiratory tract irritation | 3 | 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 | 30 | 0 |
| Catarrh | 31 | 0 |
| Choking | 7 | 0 |
| Choking sensation | 5 | 0 |
| Dry throat | 130 | 0 |
| Dysphonia | 55 | 0 |
| Increased upper airway secretion | 1 | 0 |
| Increased viscosity of upper respiratory secretion | 7 | 0 |
| Laryngeal pain | 1 | 0 |
| Nasal discomfort | 45 | 0 |
| Oropharyngeal blistering | 10 | 0 |
| Oropharyngeal discomfort | 13 | 0 |
| Oropharyngeal pain | 2077 | 0 |
| Paranasal sinus discomfort | 19 | 0 |
| Rhinalgia | 13 | 0 |
| Rhinorrhoea | 831 | 0 |
| Sinus pain | 238 | 0 |
| Sneezing | 210 | 0 |
| Throat clearing | 2 | 0 |
| Throat irritation | 91 | 0 |
| Throat lesion | 1 | 0 |
| Throat tightness | 85 | 0 |
| Upper respiratory tract congestion | 1 | 0 |
| Upper-airway cough syndrome | 10 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|--------------|-----------|
| Respiratory disorders Respiratory disorders cont'd | | |
| Yawning | 36 | 0 |
| Respiratory disorders SOC TOTAL | 10643 | 40 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Skin disorders | | |
| <i>Acnes</i> | | |
| Acne | 13 | 0 |
| Acne cystic | 1 | 0 |
| Dermatitis acneiform | 1 | 0 |
| <i>Alopecias</i> | | |
| Alopecia | 28 | 0 |
| Alopecia totalis | 1 | 0 |
| Madarosis | 1 | 0 |
| <i>Angioedemas</i> | | |
| Angioedema | 133 | 0 |
| Circumoral oedema | 1 | 0 |
| Idiopathic angioedema | 3 | 0 |
| <i>Apocrine and eccrine gland disorders</i> | | |
| Anhidrosis | 1 | 0 |
| Cold sweat | 928 | 0 |
| Hyperhidrosis | 5105 | 0 |
| Hypohidrosis | 1 | 0 |
| Miliaria | 76 | 0 |
| Night sweats | 942 | 0 |
| Sweat discolouration | 1 | 0 |
| Sweat gland disorder | 1 | 0 |
| <i>Bullous conditions</i> | | |
| Blister | 132 | 0 |
| Blood blister | 10 | 0 |
| Dermatitis bullous | 4 | 0 |
| Erythema multiforme | 6 | 0 |
| Oedema blister | 1 | 0 |
| Pemphigoid | 3 | 0 |
| Pemphigus | 1 | 0 |
| Stevens-Johnson syndrome | 1 | 0 |
| <i>Connective tissue disorders</i> | | |
| Subacute cutaneous lupus erythematosus | 1 | 0 |
| <i>Dermal and epidermal conditions NEC</i> | | |
| Acute febrile neutrophilic dermatosis | 1 | 0 |
| Dry skin | 134 | 0 |
| Macule | 3 | 0 |
| Myxoid cyst | 1 | 0 |
| Pain of skin | 508 | 0 |
| Papule | 16 | 0 |
| Peau d'orange | 1 | 0 |
| Scab | 7 | 0 |
| Scar pain | 4 | 0 |
| Sensitive skin | 319 | 0 |
| Skin burning sensation | 256 | 0 |
| Skin discolouration | 50 | 0 |
| Skin disorder | 9 | 0 |
| Skin fissures | 3 | 0 |
| Skin fragility | 1 | 0 |
| Skin indentation | 1 | 0 |
| Skin induration | 4 | 0 |
| Skin lesion | 6 | 0 |
| Skin necrosis | 1 | 0 |
| Skin odour abnormal | 22 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Skin reaction | 103 | 0 |
| Skin sensitisation | 47 | 0 |
| Skin swelling | 41 | 0 |
| Skin texture abnormal | 1 | 0 |
| Skin tightness | 12 | 0 |
| Skin warm | 265 | 0 |
| Skin weeping | 1 | 0 |
| Sticky skin | 1 | 0 |
| Yellow skin | 14 | 0 |
| <i>Dermatitis and eczema</i> | | |
| Dermatitis | 77 | 0 |
| Dermatitis allergic | 110 | 0 |
| Dermatitis atopic | 7 | 0 |
| Dermatitis contact | 1 | 0 |
| Dermatitis diaper | 1 | 0 |
| Dyshidrotic eczema | 2 | 0 |
| Eczema | 51 | 0 |
| Eczema asteatotic | 3 | 0 |
| Eczema nummular | 1 | 0 |
| Eczema weeping | 1 | 0 |
| Intertrigo | 1 | 0 |
| Perioral dermatitis | 1 | 0 |
| Prurigo | 1 | 0 |
| Rebound eczema | 1 | 0 |
| Seborrhoeic dermatitis | 2 | 0 |
| Skin irritation | 52 | 0 |
| Stasis dermatitis | 1 | 0 |
| <i>Dermatitis ascribed to specific agent</i> | | |
| Drug eruption | 15 | 0 |
| Drug reaction with eosinophilia and systemic symptoms | 3 | 0 |
| Fixed eruption | 2 | 0 |
| Palmar-plantar erythrodysesthesia syndrome | 1 | 0 |
| <i>Erythemas</i> | | |
| Erythema | 1523 | 0 |
| Palmar erythema | 4 | 0 |
| <i>Exfoliative conditions</i> | | |
| Dermatitis exfoliative generalised | 2 | 0 |
| Exfoliative rash | 5 | 0 |
| Skin exfoliation | 41 | 0 |
| <i>Granulomatous and deep cutaneous inflammatory conditions</i> | | |
| Granuloma annulare | 2 | 0 |
| <i>Hyperpigmentation disorders</i> | | |
| Solar lentigo | 1 | 0 |
| <i>Hypopigmentation disorders</i> | | |
| Skin depigmentation | 1 | 0 |
| Skin hypopigmentation | 1 | 0 |
| Vitiligo | 2 | 0 |
| <i>Lipodystrophies</i> | | |
| Lipoatrophy | 2 | 0 |
| Lipohypertrophy | 2 | 0 |
| <i>Nail and nail bed conditions (excl infections and infestations)</i> | | |
| Nail bed tenderness | 1 | 0 |
| Nail discolouration | 3 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Nail disorder | 1 | 0 |
| Nail hypertrophy | 1 | 0 |
| Nail pigmentation | 1 | 0 |
| Nail pitting | 1 | 0 |
| Nail ridging | 1 | 0 |
| Onychalgia | 1 | 0 |
| Onychoclasia | 3 | 0 |
| Onychomadesis | 1 | 0 |
| <i>Panniculitides</i> | | |
| Erythema nodosum | 3 | 0 |
| <i>Papulosquamous conditions</i> | | |
| Lichen planus | 5 | 0 |
| Pityriasis rosea | 5 | 0 |
| Pityriasis rubra pilaris | 1 | 0 |
| <i>Photosensitivity and photodermatosis conditions</i> | | |
| Photosensitivity reaction | 72 | 0 |
| Polymorphic light eruption | 1 | 0 |
| <i>Pigmentation changes NEC</i> | | |
| Pigmentation disorder | 4 | 0 |
| <i>Pilar disorders NEC</i> | | |
| Hair colour changes | 1 | 0 |
| Hair growth abnormal | 1 | 0 |
| Hair texture abnormal | 1 | 0 |
| Piloerection | 48 | 0 |
| Trichodynia | 3 | 0 |
| <i>Pruritus NEC</i> | | |
| Itching scar | 1 | 0 |
| Pruritus | 3016 | 0 |
| Pruritus allergic | 1 | 0 |
| <i>Psoriatic conditions</i> | | |
| Guttate psoriasis | 5 | 0 |
| Psoriasis | 40 | 0 |
| Pustular psoriasis | 1 | 0 |
| <i>Purpura and related conditions</i> | | |
| Ecchymosis | 1 | 0 |
| Henoch-Schonlein purpura | 2 | 0 |
| Petechiae | 40 | 0 |
| Purpura | 19 | 0 |
| <i>Rashes, eruptions and exanthems NEC</i> | | |
| Butterfly rash | 4 | 0 |
| Rash | 2940 | 0 |
| Rash erythematous | 875 | 0 |
| Rash macular | 247 | 0 |
| Rash maculo-papular | 23 | 0 |
| Rash morbilliform | 10 | 0 |
| Rash papular | 153 | 0 |
| Rash pruritic | 674 | 0 |
| Rash rubelliform | 1 | 0 |
| Rash vesicular | 25 | 0 |
| Systemic lupus erythematosus rash | 3 | 0 |
| <i>Rosaceas</i> | | |
| Rosacea | 7 | 0 |
| <i>Sebaceous gland disorders</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|--------------|----------|
| Skin disorders Skin disorders cont'd | | |
| Seborrhoea | 1 | 0 |
| Skin and subcutaneous conditions NEC | | |
| Cutaneous symptom | 4 | 0 |
| Skin mass | 10 | 0 |
| Skin and subcutaneous tissue ulcerations | | |
| Skin erosion | 19 | 0 |
| Skin ulcer | 7 | 0 |
| Skin cysts and polyps | | |
| Dermal cyst | 4 | 0 |
| Skin dystrophies | | |
| Skin wrinkling | 1 | 0 |
| Skin haemorrhages | | |
| Haemorrhage subcutaneous | 1 | 0 |
| Skin haemorrhage | 7 | 0 |
| Skin hyperplasias and hypertrophies | | |
| Skin hypertrophy | 1 | 0 |
| Skin hypoplasias and atrophies | | |
| Skin striae | 1 | 0 |
| Skin injuries and mechanical dermatoses | | |
| Decubitus ulcer | 2 | 0 |
| Needle track marks | 2 | 0 |
| Skin preneoplastic conditions NEC | | |
| Actinic keratosis | 1 | 0 |
| Leukoplakia | 1 | 0 |
| Skin vasculitides | | |
| Cutaneous vasculitis | 1 | 0 |
| Hypersensitivity vasculitis | 1 | 0 |
| Vasculitic rash | 9 | 0 |
| Skin vasomotor conditions | | |
| Livedo reticularis | 17 | 0 |
| Urticarias | | |
| Chronic spontaneous urticaria | 1 | 0 |
| Cold urticaria | 1 | 0 |
| Idiopathic urticaria | 3 | 0 |
| Urticaria | 877 | 0 |
| Urticaria chronic | 6 | 0 |
| Urticaria papular | 1 | 0 |
| Urticaria thermal | 4 | 0 |
| Urticularial vasculitis | 1 | 0 |
| Skin disorders SOC TOTAL | 20379 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

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

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Social circumstances | | |
| <i>Criminal activity</i> | | |
| Chemical submission | 1 | 0 |
| <i>Dietary and nutritional issues</i> | | |
| Inadequate diet | 1 | 0 |
| <i>Disability issues</i> | | |
| Bedridden | 38 | 0 |
| Disability | 1 | 0 |
| Immobile | 16 | 0 |
| Impaired driving ability | 2 | 0 |
| Impaired work ability | 5 | 0 |
| Loss of personal independence in daily activities | 2 | 0 |
| Sight disability | 6 | 0 |
| <i>Employment issues</i> | | |
| Retirement | 4 | 0 |
| <i>Non-occupational and unspecified environmental problems</i> | | |
| Food contamination | 1 | 0 |
| Water pollution | 1 | 0 |
| <i>Pregnancy related circumstances</i> | | |
| Breast feeding | 2 | 0 |
| <i>Social issues NEC</i> | | |
| Contraindication to medical treatment | 1 | 0 |
| Contraindication to vaccination | 2 | 0 |
| Convalescent | 1 | 0 |
| Impaired quality of life | 1 | 0 |
| Tattoo | 1 | 0 |
| <i>Tobacco use</i> | | |
| Tobacco user | 2 | 0 |
| Social circumstances SOC TOTAL | 88 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Surgical & medical procedures | | |
| <i>Anaesthesia and allied procedures</i> | | |
| Nerve block | 1 | 0 |
| <i>Analgesia supportive care</i> | | |
| Analgesic therapy | 1 | 0 |
| <i>Antiinfective therapies</i> | | |
| COVID-19 treatment | 2 | 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>Dietary and nutritional therapies</i> | | |
| Medical diet | 1 | 0 |
| <i>External ear therapeutic procedures</i> | | |
| Cerumen removal | 1 | 0 |
| <i>Eye therapeutic procedures NEC</i> | | |
| Eye irrigation | 1 | 0 |
| <i>Facial therapeutic procedures</i> | | |
| Face lift | 1 | 0 |
| <i>Gastrointestinal therapeutic procedures NEC</i> | | |
| Prophylaxis against gastrointestinal ulcer | 1 | 0 |
| Prophylaxis of nausea and vomiting | 22 | 0 |
| <i>Hormonal therapeutic procedures NEC</i> | | |
| Hormone replacement therapy | 2 | 0 |
| <i>Immunisations</i> | | |
| COVID-19 immunisation | 94 | 1 |
| Immunisation | 49 | 0 |
| <i>Induced abortions</i> | | |
| Abortion induced | 1 | 0 |
| <i>Joint therapeutic procedures</i> | | |
| Hip surgery | 1 | 0 |
| Joint injection | 1 | 0 |
| <i>Large intestine therapeutic procedures</i> | | |
| Appendectomy | 1 | 0 |
| <i>Limb therapeutic procedures</i> | | |
| Limb immobilisation | 14 | 0 |
| Limb operation | 3 | 0 |
| Limb reattachment surgery | 1 | 0 |
| Toe amputation | 1 | 0 |
| <i>Mastectomies</i> | | |
| Breast conserving surgery | 1 | 0 |
| <i>Muscle therapeutic procedures</i> | | |
| Muscle relaxant therapy | 1 | 0 |
| <i>Nasal therapeutic procedures</i> | | |
| Nasal irrigation | 1 | 0 |
| <i>Nervous system therapeutic procedures NEC</i> | | |
| Central nervous system stimulation | 2 | 0 |
| <i>Patient positioning</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021

Data Lock Date: 21-Mar-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 | | |
| Prone position | 1 | 0 |
| Prophylactic procedures NEC | | |
| Anaphylaxis prophylaxis | 2 | 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 |
| Therapeutic procedures NEC | | |
| Anaphylaxis treatment | 2 | 0 |
| Bed rest | 13 | 0 |
| Catheter management | 1 | 0 |
| Fatigue management | 1 | 0 |
| Hospitalisation | 4 | 0 |
| Injection | 22 | 0 |
| Localised alternating hot and cold therapy | 5 | 0 |
| Mass excision | 5 | 0 |
| Product used for unknown indication | 1 | 0 |
| Self-medication | 1 | 0 |
| Smoking cessation therapy | 1 | 0 |
| Specialist consultation | 1 | 0 |
| Surgery | 1 | 0 |
| Therapeutic hypothermia | 2 | 0 |
| Therapy change | 1 | 0 |
| Uterine therapeutic procedures | | |
| Endometrial ablation | 1 | 0 |
| Vascular therapeutic procedures NEC | | |
| Thromboembolectomy | 1 | 0 |
| Surgical & medical procedures SOC TOTAL | 279 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Vascular disorders | | |
| <i>Accelerated and malignant hypertension</i> | | |
| Hypertensive crisis | 4 | 0 |
| Hypertensive emergency | 1 | 0 |
| Hypertensive urgency | 1 | 0 |
| Malignant hypertension | 1 | 0 |
| Tyramine reaction | 1 | 0 |
| <i>Aneurysms and dissections non-site specific</i> | | |
| Aneurysm | 3 | 1 |
| <i>Aortic aneurysms and dissections</i> | | |
| Aortic aneurysm | 3 | 0 |
| <i>Aortic embolism and thrombosis</i> | | |
| Aortic embolus | 3 | 0 |
| Aortic thrombosis | 1 | 1 |
| <i>Arterial infections and inflammations</i> | | |
| Arteritis | 1 | 0 |
| Giant cell arteritis | 15 | 0 |
| <i>Blood pressure disorders NEC</i> | | |
| Blood pressure fluctuation | 5 | 0 |
| Labile blood pressure | 1 | 0 |
| <i>Bruising, ecchymosis and purpura</i> | | |
| Achenbach syndrome | 1 | 0 |
| <i>Circulatory collapse and shock</i> | | |
| Circulatory collapse | 39 | 1 |
| Neurogenic shock | 6 | 0 |
| Peripheral circulatory failure | 1 | 0 |
| Shock | 28 | 0 |
| Shock symptom | 4 | 0 |
| <i>Haemorrhages NEC</i> | | |
| Bloody discharge | 2 | 0 |
| Haematoma | 27 | 0 |
| Haemorrhage | 80 | 2 |
| Internal haemorrhage | 2 | 0 |
| Venous haemorrhage | 1 | 0 |
| <i>Lymphoedemas</i> | | |
| Lymphoedema | 23 | 0 |
| <i>Non-site specific embolism and thrombosis</i> | | |
| Arterial thrombosis | 1 | 0 |
| Embolism | 8 | 0 |
| Embolism venous | 3 | 0 |
| Thrombophlebitis migrans | 1 | 0 |
| Thrombosis | 230 | 13 |
| Venous thrombosis | 7 | 0 |
| <i>Non-site specific necrosis and vascular insufficiency NEC</i> | | |
| Arterial occlusive disease | 1 | 0 |
| Arterial spasm | 1 | 0 |
| Arteriosclerosis | 1 | 0 |
| Ischaemia | 1 | 0 |
| Peripheral venous disease | 1 | 0 |
| Vasospasm | 1 | 0 |
| <i>Non-site specific vascular disorders NEC</i> | | |
| Neovascularisation | 1 | 0 |
| Vascular pain | 21 | 0 |
| Vascular rupture | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 28-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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

| Reaction Name | Total | Fatal |
|---|---------------|------------|
| Vascular disorders Vascular disorders cont'd | | |
| Vasodilatation | 20 | 0 |
| Vein disorder | 1 | 0 |
| Vein rupture | 2 | 0 |
| Peripheral embolism and thrombosis | | |
| Blue toe syndrome | 9 | 0 |
| Deep vein thrombosis | 185 | 2 |
| Iliac artery embolism | 1 | 0 |
| Pelvic venous thrombosis | 1 | 0 |
| Thrombophlebitis | 18 | 0 |
| Thrombophlebitis superficial | 5 | 0 |
| Venous thrombosis limb | 1 | 0 |
| Peripheral vascular disorders NEC | | |
| Cyanosis | 53 | 0 |
| Erythromelalgia | 1 | 0 |
| Flushing | 381 | 0 |
| Hot flush | 1000 | 0 |
| Peripheral vascular disorder | 2 | 0 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | | |
| Intermittent claudication | 1 | 0 |
| Ischaemic limb pain | 2 | 0 |
| Peripheral coldness | 624 | 0 |
| Poor peripheral circulation | 11 | 0 |
| Raynaud's phenomenon | 48 | 0 |
| Phlebitis NEC | | |
| Phlebitis | 13 | 0 |
| Site specific vascular disorders NEC | | |
| Pallor | 206 | 0 |
| Plethoric face | 1 | 0 |
| Varicose veins NEC | | |
| Bleeding varicose vein | 1 | 0 |
| Spider vein | 2 | 0 |
| Varicophlebitis | 2 | 0 |
| Varicose vein | 12 | 0 |
| Vascular hypertensive disorders NEC | | |
| Diastolic hypertension | 1 | 0 |
| Hypertension | 243 | 0 |
| Systolic hypertension | 2 | 0 |
| White coat hypertension | 2 | 0 |
| Vascular hypotensive disorders | | |
| Capillary leak syndrome | 3 | 0 |
| Hypotension | 231 | 0 |
| Orthostatic hypotension | 22 | 0 |
| Vasculitides NEC | | |
| Diffuse vasculitis | 1 | 1 |
| MAGIC syndrome | 3 | 1 |
| Vasculitis | 18 | 0 |
| Vascular disorders SOC TOTAL | 3662 | 22 |
| TOTAL REACTIONS FOR DRUG | 377487 | 421 |
| TOTAL REPORTS | 99817 | |
| TOTAL FATAL OUTCOME REPORTS | | 421 |