

COVID-19 vaccine AstraZeneca analysis print

Á

All UK spontaneous reports received between 04/01/21 and 04/02/21 for COVID-19 vaccine Oxford University/AstraZeneca

Á
OÁ^][!oÁ Á~·]^&c^áOÜÁ Á@Á^||, ÁOááÁ&@{ ^Á[^·Á[oÁ^&··æã Á ^æ Á@æÁÁ æ Á
&æ·^áÁ Á@Áç&á^É} | Á@Á@Á^][!oÁ@ÁÁ·] áá} ÁÁ æ Á@Á^ÉV, á!| á * Á!Á!çá·| Á
~} áæ}[·^áÁ| ^·Á} |^æ^áÁ Áç&á áá} Áæ Áæ [Á^Á&á |·Á Á~ &@Á^][!o ÉV@Á^|æÁ^ { à^!Á
æ áÁ æ !^Á Á^][!o Á @ |áÁ@!^ |!Á [oÁ^Á·^áÁ Á [] æ^Á@Á æ^c Á Á@Áá^!^} oç&á ^·É
!^][!o Á^Á^] Á} á!Á} çá æÁ^çá, Á Á!á!Á Á^} çÁ [··ã|Á^, Áá\·É

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Blood disorders | | |
| <i>Anaemia deficiencies</i> | | |
| Anaemia folate deficiency | 3 | 0 |
| Anaemia vitamin B12 deficiency | 16 | 0 |
| Deficiency anaemia | 1 | 0 |
| Iron deficiency anaemia | 17 | 0 |
| Pernicious anaemia | 6 | 0 |
| <i>Anaemias NEC</i> | | |
| Anaemia | 177 | 0 |
| Autoimmune anaemia | 1 | 0 |
| Blood loss anaemia | 4 | 0 |
| Hypochromic anaemia | 3 | 0 |
| Microcytic anaemia | 1 | 0 |
| Normocytic anaemia | 4 | 0 |
| <i>Anaemias haemolytic NEC</i> | | |
| Haemolytic anaemia | 10 | 0 |
| <i>Anaemias haemolytic immune</i> | | |
| Autoimmune haemolytic anaemia | 10 | 0 |
| Cold type haemolytic anaemia | 1 | 0 |
| Evans syndrome | 1 | 0 |
| <i>Anaemias haemolytic mechanical factor</i> | | |
| Atypical haemolytic uraemic syndrome | 1 | 0 |
| Red cell fragmentation syndrome | 1 | 0 |
| <i>Bleeding tendencies</i> | | |
| Increased tendency to bruise | 137 | 0 |
| Spontaneous haematoma | 8 | 0 |
| Spontaneous haemorrhage | 2 | 0 |
| <i>Coagulation factor deficiencies</i> | | |
| Acquired haemophilia | 1 | 0 |
| Hypofibrinogenaemia | 4 | 0 |
| <i>Coagulopathies</i> | | |
| Abnormal clotting factor | 12 | 0 |
| Antiphospholipid syndrome | 29 | 0 |
| Coagulopathy | 79 | 0 |
| Disseminated intravascular coagulation | 19 | 2 |
| Hypercoagulation | 25 | 1 |
| Hyperfibrinogenaemia | 1 | 0 |
| Hypocoagulable state | 1 | 0 |
| <i>Eosinophilic disorders</i> | | |
| Eosinophilia | 22 | 0 |
| Hypereosinophilic syndrome | 1 | 0 |
| <i>Haematological cysts and polyps</i> | | |
| Splenic cyst | 1 | 0 |
| <i>Haematological disorders</i> | | |
| Blood disorder | 14 | 1 |
| Bone marrow disorder | 2 | 0 |
| Bone marrow oedema | 1 | 0 |
| Mast cell activation syndrome | 10 | 0 |
| Mastocytosis | 3 | 0 |
| Methaemoglobinaemia | 1 | 0 |
| <i>Haemolyses NEC</i> | | |
| Haemolysis | 11 | 0 |
| <i>Leukocytoses NEC</i> | | |
| Leukocytosis | 4 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Blood disorders Blood disorders cont'd | | |
| Lymphocytosis | 11 | 0 |
| Monocytosis | 2 | 0 |
| Neutrophilia | 14 | 0 |
| Leukopenias NEC | | |
| Leukopenia | 15 | 0 |
| Lymphopenia | 9 | 0 |
| Lymphatic system disorders NEC | | |
| Abdominal lymphadenopathy | 1 | 0 |
| Hilar lymphadenopathy | 1 | 0 |
| Lymph node fibrosis | 1 | 0 |
| Lymph node pain | 585 | 0 |
| Lymphadenitis | 33 | 0 |
| Lymphadenopathy | 4938 | 0 |
| Lymphadenopathy mediastinal | 1 | 0 |
| Lymphatic disorder | 2 | 0 |
| Lymphoid tissue hyperplasia | 1 | 0 |
| Pseudolymphoma | 4 | 0 |
| Marrow depression and hypoplastic anaemias | | |
| Aplastic anaemia | 6 | 0 |
| Cytopenia | 1 | 0 |
| Myelosuppression | 5 | 0 |
| Pancytopenia | 18 | 0 |
| Neutropenias | | |
| Agranulocytosis | 4 | 0 |
| Autoimmune neutropenia | 2 | 0 |
| Febrile neutropenia | 1 | 0 |
| Neutropenia | 83 | 0 |
| Platelet disorders NEC | | |
| Platelet anisocytosis | 4 | 0 |
| Platelet disorder | 6 | 0 |
| Polycythaemia (excl rubra vera) | | |
| Polycythaemia | 3 | 0 |
| Stress polycythaemia | 3 | 0 |
| Purpuras (excl thrombocytopenic) | | |
| Purpura non-thrombocytopenic | 4 | 0 |
| Red blood cell abnormal findings NEC | | |
| Anisocytosis | 3 | 0 |
| Macrocytosis | 3 | 0 |
| Poikilocytosis | 1 | 0 |
| Polychromasia | 4 | 0 |
| Rouleaux formation | 1 | 0 |
| Sickle cell trait and disorders | | |
| Sickle cell anaemia with crisis | 6 | 0 |
| Spleen disorders | | |
| Spleen disorder | 1 | 0 |
| Splenic artery thrombosis | 3 | 0 |
| Splenic haemorrhage | 1 | 0 |
| Splenic infarction | 16 | 0 |
| Splenic thrombosis | 1 | 0 |
| Splenic varices | 1 | 0 |
| Splenic vein thrombosis | 11 | 0 |
| Splenomegaly | 7 | 0 |
| Splenorenal shunt | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------------|-----------|
| Blood disorders Blood disorders cont'd | | |
| <i>Thrombocytopenias</i> | | |
| Autoimmune heparin-induced thrombocytopenia | 1 | 0 |
| Heparin-induced thrombocytopenia | 14 | 0 |
| Immune thrombocytopenia | 213 | 1 |
| Thrombocytopenia | 879 | 7 |
| Thrombocytopenic purpura | 11 | 0 |
| Thrombosis with thrombocytopenia syndrome | 5 | 0 |
| Thrombotic thrombocytopenic purpura | 10 | 0 |
| <i>Thrombocytoses</i> | | |
| Thrombocytosis | 11 | 0 |
| <i>White blood cell abnormal findings NEC</i> | | |
| White blood cell disorder | 4 | 0 |
| Blood disorders SOC TOTAL | 7611 | 12 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Cardiac disorders | | |
| <i>Aortic valvular disorders</i> | | |
| Aortic valve incompetence | 4 | 0 |
| Aortic valve sclerosis | 1 | 0 |
| Aortic valve stenosis | 1 | 0 |
| <i>Cardiac conduction disorders</i> | | |
| Atrioventricular block | 29 | 1 |
| Atrioventricular block complete | 3 | 0 |
| Atrioventricular block first degree | 3 | 0 |
| Atrioventricular block second degree | 5 | 0 |
| Bundle branch block | 2 | 0 |
| Bundle branch block left | 10 | 0 |
| Bundle branch block right | 4 | 0 |
| Long QT syndrome | 1 | 0 |
| Trifascicular block | 2 | 0 |
| <i>Cardiac disorders NEC</i> | | |
| Acute cardiac event | 4 | 2 |
| Atrial thrombosis | 5 | 0 |
| Cardiac disorder | 81 | 1 |
| Cardiac dysfunction | 2 | 0 |
| Cardiac ventricular thrombosis | 12 | 2 |
| Cardiovascular disorder | 10 | 0 |
| Cardiovascular insufficiency | 10 | 0 |
| Intracardiac thrombus | 17 | 2 |
| <i>Cardiac hypertensive complications</i> | | |
| Hypertensive heart disease | 2 | 0 |
| <i>Cardiac infections and inflammations NEC</i> | | |
| Carditis | 2 | 0 |
| <i>Cardiac signs and symptoms NEC</i> | | |
| Cardiac discomfort | 17 | 0 |
| Cardiovascular symptom | 3 | 0 |
| Palpitations | 5504 | 0 |
| <i>Cardiac valve disorders NEC</i> | | |
| Cardiac valve disease | 4 | 1 |
| Heart valve incompetence | 4 | 0 |
| <i>Cardiomyopathies</i> | | |
| Cardiomyopathy | 15 | 1 |
| Congestive cardiomyopathy | 12 | 1 |
| Stress cardiomyopathy | 5 | 0 |
| <i>Coronary artery disorders NEC</i> | | |
| Arteriosclerosis coronary artery | 6 | 1 |
| Coronary artery disease | 8 | 0 |
| Coronary artery dissection | 5 | 1 |
| Coronary artery embolism | 1 | 0 |
| Coronary artery occlusion | 3 | 0 |
| Coronary artery thrombosis | 23 | 3 |
| <i>Heart failures NEC</i> | | |
| Cardiac failure | 98 | 12 |
| Cardiac failure acute | 13 | 4 |
| Cardiac failure chronic | 2 | 1 |
| Cardiac failure congestive | 6 | 2 |
| Cardiogenic shock | 10 | 2 |
| Cardiopulmonary failure | 1 | 1 |
| Ventricular failure | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Cardiac disorders Cardiac disorders cont'd | | |
| <i>Ischaemic coronary artery disorders</i> | | |
| Acute coronary syndrome | 9 | 0 |
| Acute myocardial infarction | 86 | 13 |
| Angina pectoris | 241 | 0 |
| Angina unstable | 17 | 0 |
| Arteriospasm coronary | 6 | 0 |
| Microvascular coronary artery disease | 2 | 0 |
| Myocardial infarction | 437 | 52 |
| Myocardial ischaemia | 28 | 12 |
| Prinzmetal angina | 2 | 0 |
| <i>Left ventricular failures</i> | | |
| Acute left ventricular failure | 2 | 0 |
| Left ventricular failure | 9 | 1 |
| <i>Mitral valvular disorders</i> | | |
| Ischaemic mitral regurgitation | 1 | 0 |
| Mitral valve disease | 1 | 0 |
| Mitral valve incompetence | 9 | 0 |
| Mitral valve prolapse | 4 | 0 |
| <i>Myocardial disorders NEC</i> | | |
| Cardiac aneurysm | 1 | 0 |
| Cardiac sarcoidosis | 1 | 0 |
| Cardiomegaly | 33 | 1 |
| Diastolic dysfunction | 2 | 0 |
| Dilatation ventricular | 1 | 0 |
| Left atrial dilatation | 1 | 0 |
| Left ventricular dilatation | 2 | 0 |
| Left ventricular dysfunction | 21 | 0 |
| Left ventricular hypertrophy | 1 | 0 |
| Myocardial fibrosis | 2 | 0 |
| Myocardial injury | 14 | 0 |
| Myocardial oedema | 1 | 0 |
| Myocardial rupture | 1 | 0 |
| Right atrial dilatation | 2 | 0 |
| Right ventricular dilatation | 3 | 0 |
| Right ventricular dysfunction | 4 | 0 |
| Systolic dysfunction | 1 | 0 |
| Ventricular dyskinesia | 1 | 0 |
| Ventricular hypertrophy | 5 | 1 |
| Ventricular hypokinesia | 3 | 0 |
| <i>Noninfectious myocarditis</i> | | |
| Autoimmune myocarditis | 1 | 0 |
| Myocarditis | 165 | 2 |
| <i>Noninfectious pericarditis</i> | | |
| Pericarditis | 195 | 0 |
| <i>Pericardial disorders NEC</i> | | |
| Cardiac tamponade | 2 | 2 |
| Pericardial effusion | 38 | 0 |
| Pericardial haemorrhage | 6 | 3 |
| Pericardial rub | 1 | 0 |
| <i>Rate and rhythm disorders NEC</i> | | |
| Arrhythmia | 149 | 3 |
| Arrhythmia neonatal | 1 | 0 |
| Bradycardia | 85 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|--------------|------------|
| Cardiac disorders Cardiac disorders cont'd | | |
| Brugada syndrome | 1 | 0 |
| Cardiac fibrillation | 9 | 0 |
| Cardiac flutter | 284 | 0 |
| Extrasystoles | 157 | 0 |
| Heart alternation | 3 | 0 |
| Paroxysmal arrhythmia | 2 | 0 |
| Postural orthostatic tachycardia syndrome | 23 | 0 |
| Tachyarrhythmia | 11 | 0 |
| Tachycardia | 1400 | 0 |
| Right ventricular failures | | |
| Right ventricular failure | 3 | 1 |
| Supraventricular arrhythmias | | |
| Arrhythmia supraventricular | 16 | 0 |
| Atrial fibrillation | 335 | 1 |
| Atrial flutter | 46 | 0 |
| Atrial tachycardia | 3 | 0 |
| Sinus arrest | 1 | 0 |
| Sinus arrhythmia | 3 | 0 |
| Sinus bradycardia | 4 | 0 |
| Sinus node dysfunction | 2 | 0 |
| Sinus tachycardia | 71 | 0 |
| Supraventricular extrasystoles | 1 | 0 |
| Supraventricular tachycardia | 43 | 0 |
| Tricuspid valvular disorders | | |
| Tricuspid valve incompetence | 8 | 0 |
| Ventricular arrhythmias and cardiac arrest | | |
| Cardiac arrest | 179 | 36 |
| Cardio-respiratory arrest | 2 | 1 |
| Pulseless electrical activity | 7 | 0 |
| Ventricular arrhythmia | 2 | 0 |
| Ventricular extrasystoles | 21 | 0 |
| Ventricular fibrillation | 9 | 1 |
| Ventricular tachycardia | 17 | 0 |
| Cardiac disorders SOC TOTAL | 10211 | 168 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Congenital disorders | | |
| <i>Autosomal chromosomal abnormalities</i> | | |
| Trisomy 18 | 1 | 0 |
| Trisomy 21 | 1 | 0 |
| <i>Cardiac disorders congenital NEC</i> | | |
| Heart disease congenital | 10 | 0 |
| <i>Cardiac septal defects congenital</i> | | |
| Atrial septal defect | 1 | 0 |
| Hypertrophic cardiomyopathy | 3 | 0 |
| <i>Central nervous system disorders congenital NEC</i> | | |
| Brain malformation | 1 | 0 |
| Neural tube defect | 1 | 1 |
| Spina bifida | 2 | 0 |
| Syringomyelia | 1 | 0 |
| <i>Cerebellar disorders congenital</i> | | |
| Arnold-Chiari malformation | 2 | 0 |
| <i>Cerebral disorders congenital</i> | | |
| Anencephaly | 1 | 0 |
| Cerebral palsy | 2 | 0 |
| <i>Coagulation disorders congenital</i> | | |
| Factor VII deficiency | 1 | 0 |
| <i>Congenital disorders NEC</i> | | |
| Congenital anomaly | 3 | 0 |
| Congenital midline defect | 1 | 0 |
| Multiple congenital abnormalities | 1 | 0 |
| Young's syndrome | 1 | 0 |
| <i>Connective tissue disorders congenital</i> | | |
| Ehlers-Danlos syndrome | 6 | 0 |
| <i>Diaphragmatic disorders congenital</i> | | |
| Congenital diaphragmatic hernia | 2 | 0 |
| <i>Gene mutations and other alterations NEC</i> | | |
| Tuberous sclerosis complex | 1 | 0 |
| <i>Great vessel disorders congenital</i> | | |
| Coarctation of the aorta | 1 | 0 |
| Transposition of the great vessels | 1 | 0 |
| <i>Immune system abnormalities congenital</i> | | |
| Combined immunodeficiency | 1 | 0 |
| <i>Inborn errors of porphyrin metabolism</i> | | |
| Porphyria acute | 1 | 0 |
| <i>Lacrimal system disorders congenital</i> | | |
| Dacryostenosis congenital | 1 | 0 |
| <i>Lysosomal storage disorders</i> | | |
| Mucopolipidosis | 1 | 0 |
| <i>Male reproductive tract disorders congenital</i> | | |
| Hydrocele | 2 | 0 |
| Micropenis | 2 | 0 |
| Penoscrotal fusion | 3 | 0 |
| <i>Musculoskeletal and connective tissue disorders of face, neck and jaw congenital</i> | | |
| Branchial cyst | 3 | 0 |
| <i>Musculoskeletal and connective tissue disorders of limbs congenital</i> | | |
| Limb reduction defect | 2 | 0 |
| Os trigonum | 1 | 0 |
| <i>Musculoskeletal disorders congenital NEC</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Congenital disorders Congenital disorders cont'd | | |
| Congenital multiplex arthrogryposis | 1 | 0 |
| Dysmorphism | 2 | 0 |
| Neurological disorders congenital NEC | | |
| Epilepsy with myoclonic-atonic seizures | 1 | 0 |
| Familial hemiplegic migraine | 1 | 0 |
| Spinal muscular atrophy | 1 | 0 |
| Tourette's disorder | 2 | 0 |
| Ocular disorders congenital NEC | | |
| Colour blindness | 9 | 0 |
| Pancreatic disorders congenital | | |
| Hereditary pancreatitis | 1 | 0 |
| Peripheral nervous system disorders congenital NEC | | |
| Paroxysmal extreme pain disorder | 13 | 0 |
| Pulmonary and bronchial disorders congenital | | |
| Cystic fibrosis | 1 | 0 |
| Sex chromosomal abnormalities | | |
| Klinefelter's syndrome | 1 | 0 |
| Skin and subcutaneous tissue disorders congenital NEC | | |
| Benign familial pemphigus | 1 | 0 |
| Tongue disorders congenital | | |
| Ankyloglossia congenital | 1 | 0 |
| Macroglossia | 1 | 0 |
| Vascular anomalies congenital NEC | | |
| Arteriovenous malformation | 1 | 0 |
| Congenital disorders SOC TOTAL | 98 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Ear disorders | | |
| <i>Ear disorders NEC</i> | | |
| Aural polyp | 1 | 0 |
| Ear canal erythema | 1 | 0 |
| Ear congestion | 34 | 0 |
| Ear discomfort | 120 | 0 |
| Ear disorder | 22 | 0 |
| Ear haemorrhage | 18 | 0 |
| Ear inflammation | 1 | 0 |
| Ear pain | 2073 | 0 |
| Ear pruritus | 7 | 0 |
| Ear swelling | 72 | 0 |
| Otorrhoea | 8 | 0 |
| Paraesthesia ear | 1 | 0 |
| <i>Eustachian tube disorders</i> | | |
| Eustachian tube disorder | 7 | 0 |
| Eustachian tube dysfunction | 6 | 0 |
| Eustachian tube obstruction | 8 | 0 |
| <i>External ear disorders NEC</i> | | |
| Excessive cerumen production | 40 | 0 |
| External ear pain | 14 | 0 |
| Juvenile spring eruption | 1 | 0 |
| Red ear syndrome | 5 | 0 |
| <i>External ear infections and inflammations</i> | | |
| External ear inflammation | 4 | 0 |
| <i>Hearing disorders NEC</i> | | |
| Auditory disorder | 8 | 0 |
| <i>Hearing losses</i> | | |
| Conductive deafness | 1 | 0 |
| Deafness | 401 | 1 |
| Deafness bilateral | 18 | 0 |
| Deafness neurosensory | 39 | 0 |
| Deafness transitory | 4 | 0 |
| Deafness unilateral | 57 | 0 |
| Hypoacusis | 243 | 0 |
| Mixed deafness | 3 | 0 |
| Neurosensory hypoacusis | 2 | 0 |
| Sudden hearing loss | 78 | 0 |
| <i>Hyperacusia</i> | | |
| Hyperacusis | 173 | 0 |
| <i>Inner ear disorders NEC</i> | | |
| Endolymphatic hydrops | 1 | 0 |
| Inner ear disorder | 7 | 0 |
| Meniere's disease | 30 | 0 |
| Vestibular disorder | 8 | 0 |
| <i>Inner ear infections and inflammations</i> | | |
| Autoimmune inner ear disease | 1 | 0 |
| Inner ear inflammation | 5 | 0 |
| <i>Inner ear signs and symptoms</i> | | |
| Motion sickness | 129 | 0 |
| Phobic postural vertigo | 2 | 0 |
| Tinnitus | 4230 | 0 |
| Vertigo | 2240 | 0 |
| Vertigo labyrinthine | 13 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|--------------|----------|
| Ear disorders Ear disorders cont'd | | |
| Vertigo positional | 155 | 0 |
| Middle ear disorders NEC | | |
| Middle ear disorder | 1 | 0 |
| Middle ear effusion | 6 | 0 |
| Tympanic membrane disorders (excl infections) | | |
| Tympanic membrane perforation | 7 | 0 |
| Ear disorders SOC TOTAL | 10305 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Endocrine disorders | | |
| <i>Acute and chronic thyroiditis</i> | | |
| Autoimmune thyroiditis | 10 | 0 |
| Thyroiditis | 19 | 0 |
| Thyroiditis acute | 7 | 0 |
| Thyroiditis chronic | 1 | 0 |
| Thyroiditis subacute | 8 | 0 |
| <i>Adrenal cortical hyperfunctions</i> | | |
| Cushing's syndrome | 2 | 0 |
| Cushingoid | 5 | 0 |
| <i>Adrenal cortical hypofunctions</i> | | |
| Addison's disease | 3 | 0 |
| Adrenal insufficiency | 22 | 0 |
| Adrenocortical insufficiency acute | 30 | 0 |
| Glucocorticoid deficiency | 1 | 0 |
| <i>Adrenal gland disorders NEC</i> | | |
| Adrenal disorder | 1 | 0 |
| Adrenal haemorrhage | 7 | 0 |
| Adrenal mass | 1 | 0 |
| Adrenal thrombosis | 1 | 0 |
| Adrenomegaly | 2 | 0 |
| Haemorrhagic adrenal infarction | 4 | 0 |
| <i>Anterior pituitary hyperfunction</i> | | |
| Hyperprolactinaemia | 2 | 0 |
| <i>Anterior pituitary hypofunction</i> | | |
| Hypopituitarism | 2 | 0 |
| Luteal phase deficiency | 2 | 0 |
| <i>Ectopic endocrine disorders</i> | | |
| Carcinoid syndrome | 1 | 0 |
| <i>Endocrine abnormalities of gonadal function NEC</i> | | |
| Oestrogenic effect | 1 | 0 |
| <i>Endocrine abnormalities of puberty</i> | | |
| Delayed menarche | 1 | 0 |
| Premature menarche | 17 | 0 |
| <i>Female gonadal function disorders</i> | | |
| Anovulatory cycle | 22 | 0 |
| Ovulation delayed | 15 | 0 |
| <i>Hyperparathyroid disorders</i> | | |
| Hyperparathyroidism | 2 | 0 |
| <i>Hypoparathyroid disorders</i> | | |
| Hypoparathyroidism | 2 | 0 |
| Primary hypoparathyroidism | 1 | 0 |
| <i>Hypothalamic and pituitary disorders NEC</i> | | |
| Hypothalamo-pituitary disorder | 2 | 0 |
| Pituitary apoplexy | 2 | 0 |
| Pituitary haemorrhage | 1 | 0 |
| Secondary adrenocortical insufficiency | 1 | 0 |
| <i>Posterior pituitary disorders</i> | | |
| Diabetes insipidus | 8 | 0 |
| Inappropriate antidiuretic hormone secretion | 1 | 0 |
| <i>Thyroid disorders NEC</i> | | |
| Autoimmune thyroid disorder | 1 | 0 |
| Euthyroid sick syndrome | 1 | 0 |
| Goitre | 26 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Endocrine disorders Endocrine disorders cont'd | | |
| Thyroid disorder | 21 | 0 |
| Thyroid mass | 8 | 0 |
| Thyroid pain | 18 | 0 |
| <i>Thyroid hyperfunction disorders</i> | | |
| Basedow's disease | 21 | 0 |
| Hyperthyroidism | 59 | 0 |
| Thyrotoxic crisis | 6 | 0 |
| <i>Thyroid hypofunction disorders</i> | | |
| Hypothyroidism | 60 | 0 |
| <i>Thyroid neoplasms</i> | | |
| Thyroid cyst | 1 | 0 |
| Endocrine disorders SOC TOTAL | 429 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Eye disorders | | |
| <i>Amblyopic vision impairment</i> | | |
| Amblyopia | 12 | 0 |
| <i>Cataract conditions</i> | | |
| Cataract | 20 | 0 |
| Cataract cortical | 2 | 0 |
| Cataract subcapsular | 4 | 0 |
| <i>Choroid and vitreous haemorrhages and vascular disorders</i> | | |
| Vitreous haematoma | 1 | 0 |
| Vitreous haemorrhage | 7 | 0 |
| <i>Choroid and vitreous structural change, deposit and degeneration</i> | | |
| Chorioretinopathy | 2 | 0 |
| Vitreous detachment | 56 | 0 |
| Vitreous floaters | 202 | 0 |
| Vitreous opacities | 1 | 0 |
| <i>Colour blindness (incl acquired)</i> | | |
| Dyschromatopsia | 17 | 0 |
| <i>Conjunctival and corneal bleeding and vascular disorders</i> | | |
| Conjunctival haemorrhage | 129 | 0 |
| Corneal neovascularisation | 1 | 0 |
| Scleral haemorrhage | 1 | 0 |
| <i>Conjunctival infections, irritations and inflammations</i> | | |
| Conjunctival hyperaemia | 2 | 0 |
| Conjunctivitis allergic | 2 | 0 |
| <i>Conjunctival structural change, deposit and degeneration</i> | | |
| Conjunctival bleb | 1 | 0 |
| Conjunctival disorder | 1 | 0 |
| <i>Corneal infections, oedemas and inflammations</i> | | |
| Keratitis | 5 | 0 |
| Ulcerative keratitis | 4 | 0 |
| <i>Corneal structural change, deposit and degeneration</i> | | |
| Corneal perforation | 1 | 0 |
| Corneal scar | 1 | 0 |
| <i>Eyelid movement disorders</i> | | |
| Blepharospasm | 151 | 0 |
| Excessive eye blinking | 8 | 0 |
| Eyelid function disorder | 1 | 0 |
| Eyelid myokymia | 2 | 0 |
| Eyelid ptosis | 61 | 0 |
| Paralytic lagophthalmos | 1 | 0 |
| <i>Glaucomas (excl congenital)</i> | | |
| Angle closure glaucoma | 6 | 0 |
| Glaucoma | 14 | 0 |
| <i>Iris and ciliary body structural change, deposit and degeneration</i> | | |
| Eye colour change | 9 | 0 |
| <i>Iris and uveal tract infections, irritations and inflammations</i> | | |
| Autoimmune uveitis | 1 | 0 |
| Iridocyclitis | 25 | 0 |
| Iritis | 13 | 0 |
| Uveitis | 51 | 0 |
| <i>Lacrimation disorders</i> | | |
| Dry eye | 315 | 0 |
| Lacrimation increased | 260 | 0 |
| <i>Lens structural change, deposit and degeneration (excl cataracts)</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Eye disorders Eye disorders cont'd | | |
| Anterior capsule contraction | 1 | 0 |
| Lid bleeding and vascular disorders | | |
| Eyelid bleeding | 3 | 0 |
| Eyelid haematoma | 3 | 0 |
| Lid, lash and lacrimal infections, irritations and inflammations | | |
| Blepharitis | 29 | 0 |
| Chalazion | 2 | 0 |
| Eczema eyelids | 6 | 0 |
| Erythema of eyelid | 7 | 0 |
| Eyelid cyst | 17 | 0 |
| Eyelid irritation | 4 | 0 |
| Eyelid margin crusting | 1 | 0 |
| Eyelid oedema | 12 | 0 |
| Eyelid rash | 15 | 0 |
| Meibomianitis | 1 | 0 |
| Swelling of eyelid | 136 | 0 |
| Lid, lash and lacrimal structural disorders | | |
| Blepharal pigmentation | 1 | 0 |
| Ectropion | 1 | 0 |
| Eyelid exfoliation | 3 | 0 |
| Eyelid skin dryness | 5 | 0 |
| Eyelid thickening | 4 | 0 |
| Growth of eyelashes | 10 | 0 |
| Lagophthalmos | 4 | 0 |
| Ocular bleeding and vascular disorders NEC | | |
| Eye haematoma | 4 | 0 |
| Eye haemorrhage | 112 | 0 |
| Ocular retrobulbar haemorrhage | 1 | 0 |
| Ocular vascular disorder | 2 | 0 |
| Ophthalmic vein thrombosis | 3 | 0 |
| Ocular cysts and polyps | | |
| Vitreous cyst | 1 | 0 |
| Ocular disorders NEC | | |
| Dark circles under eyes | 11 | 0 |
| Eye disorder | 43 | 0 |
| Eye oedema | 18 | 0 |
| Eye pain | 3344 | 0 |
| Eye swelling | 631 | 0 |
| Eye symptom | 11 | 0 |
| Eye ulcer | 10 | 0 |
| Eyelid disorder | 17 | 0 |
| Eyelid pain | 20 | 0 |
| Eyelids pruritus | 12 | 0 |
| Ocular discomfort | 83 | 0 |
| Periorbital discomfort | 1 | 0 |
| Periorbital oedema | 18 | 0 |
| Periorbital pain | 4 | 0 |
| Periorbital swelling | 107 | 0 |
| Retinal disorder | 2 | 0 |
| Retinal fovea disorder | 1 | 0 |
| Ocular infections, inflammations and associated manifestations | | |
| Autoimmune eye disorder | 1 | 0 |
| Eye allergy | 31 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Eye disorders Eye disorders cont'd | | |
| Eye discharge | 28 | 0 |
| Eye inflammation | 34 | 0 |
| Eye irritation | 204 | 0 |
| Eye pruritus | 304 | 0 |
| Limbal swelling | 8 | 0 |
| Ocular hyperaemia | 462 | 0 |
| Ocular rosacea | 1 | 0 |
| Ocular nerve and muscle disorders | | |
| Extraocular muscle paresis | 13 | 0 |
| Eye movement disorder | 55 | 0 |
| Gaze palsy | 4 | 0 |
| Ocular myasthenia | 3 | 0 |
| Ophthalmoplegia | 1 | 0 |
| Parinaud syndrome | 1 | 0 |
| Strabismus | 5 | 0 |
| Ocular sensation disorders | | |
| Abnormal sensation in eye | 28 | 0 |
| Asthenopia | 362 | 0 |
| Eye paraesthesia | 5 | 0 |
| Eyelid sensory disorder | 5 | 0 |
| Foreign body sensation in eyes | 36 | 0 |
| Hypoaesthesia eye | 29 | 0 |
| Photophobia | 1073 | 0 |
| Optic disc abnormalities NEC | | |
| Optic atrophy | 1 | 0 |
| Optic discs blurred | 3 | 0 |
| Papilloedema | 14 | 0 |
| Optic nerve bleeding and vascular disorders | | |
| Optic disc haemorrhage | 2 | 0 |
| Optic ischaemic neuropathy | 11 | 0 |
| Optic nerve sheath haemorrhage | 1 | 0 |
| Orbital infections, inflammations and irritations | | |
| Parophthalmia | 1 | 0 |
| Orbital structural change, deposit and degeneration | | |
| Lid sulcus deepened | 3 | 0 |
| Orbital oedema | 1 | 0 |
| Pupil disorders | | |
| Holmes-Adie pupil | 1 | 0 |
| Miosis | 15 | 0 |
| Mydriasis | 35 | 0 |
| Pupil fixed | 14 | 0 |
| Pupillary deformity | 1 | 0 |
| Pupillary reflex impaired | 3 | 0 |
| Pupils unequal | 11 | 0 |
| Refractive and accommodative disorders | | |
| Altered visual depth perception | 5 | 0 |
| Hypermetropia | 2 | 0 |
| Myopia | 5 | 0 |
| Refraction disorder | 1 | 0 |
| Retinal bleeding and vascular disorders (excl retinopathy) | | |
| Retinal aneurysm | 2 | 0 |
| Retinal artery embolism | 5 | 0 |
| Retinal artery occlusion | 25 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Eye disorders Eye disorders cont'd | | |
| Retinal haemorrhage | 19 | 0 |
| Retinal infarction | 1 | 0 |
| Retinal ischaemia | 2 | 0 |
| Retinal vascular occlusion | 3 | 0 |
| Retinal vascular thrombosis | 4 | 0 |
| Retinal vein occlusion | 97 | 0 |
| Retinal vein thrombosis | 8 | 0 |
| Retinal vein varices | 1 | 0 |
| Retinal vessel avulsion | 1 | 0 |
| <i>Retinal structural change, deposit and degeneration</i> | | |
| Macular cyst | 1 | 0 |
| Macular degeneration | 9 | 0 |
| Macular detachment | 1 | 0 |
| Macular hole | 2 | 0 |
| Macular rupture | 1 | 0 |
| Maculopathy | 3 | 0 |
| Neovascular age-related macular degeneration | 12 | 0 |
| Retinal detachment | 29 | 0 |
| Retinal drusen | 1 | 0 |
| Retinal tear | 19 | 0 |
| Retinal toxicity | 5 | 0 |
| Vitreoretinal traction syndrome | 1 | 0 |
| <i>Retinal, choroid and vitreous infections and inflammations</i> | | |
| Cystoid macular oedema | 1 | 0 |
| Macular oedema | 8 | 0 |
| Retinal oedema | 2 | 0 |
| Retinal vasculitis | 1 | 0 |
| <i>Retinopathies NEC</i> | | |
| Acute macular neuroretinopathy | 5 | 0 |
| Diabetic retinopathy | 2 | 0 |
| Retinal exudates | 18 | 0 |
| Retinopathy | 8 | 0 |
| <i>Scleral infections, irritations and inflammations</i> | | |
| Episcleritis | 20 | 0 |
| Scleritis | 13 | 0 |
| <i>Scleral structural change, deposit and degeneration</i> | | |
| Scleral discolouration | 1 | 0 |
| <i>Structural change, deposit and degeneration of eye NEC</i> | | |
| Deposit eye | 1 | 0 |
| Endocrine ophthalmopathy | 4 | 0 |
| Exophthalmos | 6 | 0 |
| Eye opacity | 1 | 0 |
| <i>Visual colour distortions</i> | | |
| Chloropsia | 2 | 0 |
| Chromatopsia | 1 | 0 |
| Cyanopsia | 3 | 0 |
| Erythropsia | 7 | 0 |
| Xanthopsia | 9 | 0 |
| <i>Visual disorders NEC</i> | | |
| Charles Bonnet syndrome | 1 | 0 |
| Delayed dark adaptation | 1 | 0 |
| Diplopia | 342 | 0 |
| Dysmetropsia | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|--------------|----------|
| Eye disorders Eye disorders cont'd | | |
| Halo vision | 13 | 0 |
| Metamorphopsia | 39 | 0 |
| Oscillopsia | 1 | 0 |
| Photopsia | 335 | 0 |
| Scintillating scotoma | 10 | 0 |
| Vision blurred | 3055 | 0 |
| Visual brightness | 10 | 0 |
| Visual snow syndrome | 5 | 0 |
| Visual field disorders | | |
| Visual field defect | 43 | 0 |
| Visual impairment and blindness (excl colour blindness) | | |
| Amaurosis fugax | 9 | 0 |
| Blindness | 304 | 0 |
| Blindness day | 1 | 0 |
| Blindness transient | 26 | 0 |
| Blindness unilateral | 44 | 0 |
| Central vision loss | 3 | 0 |
| Night blindness | 5 | 0 |
| Sudden visual loss | 5 | 0 |
| Visual acuity reduced | 40 | 0 |
| Visual acuity reduced transiently | 1 | 0 |
| Visual impairment | 797 | 0 |
| Visual pathway disorders | | |
| Optic nerve compression | 1 | 0 |
| Optic nerve disorder | 4 | 0 |
| Optic neuropathy | 9 | 0 |
| Eye disorders SOC TOTAL | 14404 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Abdominal findings abnormal</i> | | |
| Abdominal mass | 4 | 0 |
| Gastrointestinal sounds abnormal | 26 | 0 |
| <i>Abdominal hernias NEC</i> | | |
| Abdominal hernia | 1 | 0 |
| Internal hernia | 1 | 0 |
| <i>Acute and chronic pancreatitis</i> | | |
| Obstructive pancreatitis | 1 | 1 |
| Pancreatitis | 39 | 2 |
| Pancreatitis acute | 19 | 0 |
| Pancreatitis chronic | 1 | 0 |
| Pancreatitis necrotising | 2 | 0 |
| <i>Anal and rectal disorders NEC</i> | | |
| Anal fissure | 2 | 0 |
| <i>Anal and rectal pains</i> | | |
| Proctalgia | 28 | 0 |
| <i>Anal and rectal signs and symptoms</i> | | |
| Anal blister | 2 | 0 |
| Anal hypoaesthesia | 7 | 0 |
| Anal inflammation | 2 | 0 |
| Anal paraesthesia | 2 | 0 |
| Anal pruritus | 6 | 0 |
| Anal spasm | 1 | 0 |
| Anorectal discomfort | 12 | 0 |
| Anorectal swelling | 1 | 0 |
| Rectal discharge | 1 | 0 |
| Rectal spasm | 2 | 0 |
| Rectal tenesmus | 2 | 0 |
| <i>Anal and rectal ulcers and perforation</i> | | |
| Anal ulcer | 2 | 0 |
| <i>Benign oral cavity neoplasms</i> | | |
| Mouth cyst | 14 | 0 |
| Tongue cyst | 5 | 0 |
| Tongue polyp | 2 | 0 |
| <i>Colitis (excl infective)</i> | | |
| Autoimmune colitis | 4 | 0 |
| Colitis | 61 | 0 |
| Colitis ischaemic | 7 | 1 |
| Colitis microscopic | 6 | 0 |
| Colitis ulcerative | 111 | 0 |
| Crohn's disease | 108 | 0 |
| Inflammatory bowel disease | 12 | 0 |
| Terminal ileitis | 1 | 0 |
| <i>Cystic pancreatic disorders</i> | | |
| Pancreatic cyst | 1 | 0 |
| Pancreatic pseudocyst | 1 | 0 |
| <i>Dental and periodontal infections and inflammations</i> | | |
| Dental caries | 6 | 0 |
| Periodontal inflammation | 1 | 0 |
| <i>Dental developmental disorders and anomalies</i> | | |
| Tooth impacted | 1 | 0 |
| <i>Dental disorders NEC</i> | | |
| Diastema | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Loose tooth | 3 | 0 |
| Malpositioned teeth | 3 | 0 |
| Teething | 22 | 0 |
| Tooth disorder | 5 | 0 |
| Tooth socket haemorrhage | 2 | 0 |
| <i>Dental pain and sensation disorders</i> | | |
| Dental discomfort | 12 | 0 |
| Dental paraesthesia | 18 | 0 |
| Hyperaesthesia teeth | 66 | 0 |
| Hypoaesthesia teeth | 2 | 0 |
| Toothache | 342 | 0 |
| <i>Dental pulp disorders</i> | | |
| Dental pulp disorder | 1 | 0 |
| <i>Dental surface disorders</i> | | |
| Tooth discolouration | 19 | 0 |
| <i>Diaphragmatic hernias</i> | | |
| Hiatus hernia | 21 | 0 |
| <i>Diarrhoea (excl infective)</i> | | |
| Diarrhoea | 8926 | 0 |
| Diarrhoea haemorrhagic | 34 | 0 |
| <i>Diverticula</i> | | |
| Diverticulum | 11 | 0 |
| Diverticulum intestinal | 1 | 0 |
| <i>Duodenal and small intestinal stenosis and obstruction</i> | | |
| Small intestinal obstruction | 1 | 0 |
| Superior mesenteric artery syndrome | 1 | 0 |
| <i>Duodenal ulcers and perforation</i> | | |
| Duodenal ulcer | 2 | 0 |
| Duodenal ulcer haemorrhage | 2 | 1 |
| <i>Dyspeptic signs and symptoms</i> | | |
| Dyspepsia | 895 | 0 |
| Epigastric discomfort | 20 | 0 |
| Eructation | 107 | 0 |
| <i>Faecal abnormalities NEC</i> | | |
| Abnormal faeces | 25 | 0 |
| Faecaloma | 4 | 0 |
| Faeces discoloured | 54 | 0 |
| Faeces hard | 4 | 0 |
| Faeces pale | 7 | 0 |
| Faeces soft | 23 | 0 |
| Mucous stools | 16 | 0 |
| <i>Flatulence, bloating and distension</i> | | |
| Abdominal distension | 713 | 0 |
| Flatulence | 400 | 0 |
| <i>Gastric and oesophageal haemorrhages</i> | | |
| Gastric haemorrhage | 15 | 1 |
| <i>Gastric ulcers and perforation</i> | | |
| Gastric ulcer | 13 | 0 |
| Gastric ulcer haemorrhage | 1 | 0 |
| Gastric ulcer perforation | 1 | 0 |
| <i>Gastritis (excl infective)</i> | | |
| Chronic gastritis | 5 | 0 |
| Gastritis | 111 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Gastrointestinal disorders | | |
| Gastrointestinal disorders cont'd | | |
| Reflux gastritis | 17 | 0 |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> | | |
| Abdominal migraine | 3 | 0 |
| Abdominal pain | 4574 | 0 |
| Abdominal pain lower | 267 | 0 |
| Abdominal pain upper | 5280 | 0 |
| Abdominal rigidity | 63 | 0 |
| Abdominal tenderness | 22 | 0 |
| Gastrointestinal pain | 327 | 0 |
| Oesophageal pain | 9 | 0 |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i> | | |
| Constipation | 496 | 0 |
| Duodenogastric reflux | 4 | 0 |
| Gastric dilatation | 18 | 0 |
| Gastrooesophageal reflux disease | 242 | 0 |
| Impaired gastric emptying | 6 | 0 |
| Infrequent bowel movements | 3 | 0 |
| Intestinal dilatation | 1 | 0 |
| <i>Gastrointestinal disorders NEC</i> | | |
| Appendix disorder | 3 | 0 |
| Food poisoning | 13 | 0 |
| Functional gastrointestinal disorder | 20 | 0 |
| Gastric disorder | 15 | 0 |
| Gastrointestinal disorder | 48 | 0 |
| Gastrointestinal oedema | 3 | 0 |
| Gastroptosis | 1 | 0 |
| Neurogenic bowel | 3 | 0 |
| Stomach mass | 2 | 0 |
| <i>Gastrointestinal dyskinetic disorders</i> | | |
| Bowel movement irregularity | 8 | 0 |
| Change of bowel habit | 21 | 0 |
| Dyschezia | 13 | 0 |
| Gastrointestinal motility disorder | 5 | 0 |
| Oesophageal achalasia | 5 | 0 |
| <i>Gastrointestinal fistulae</i> | | |
| Anal fistula | 1 | 0 |
| <i>Gastrointestinal inflammatory disorders NEC</i> | | |
| Appendicitis noninfective | 2 | 0 |
| Duodenitis | 1 | 0 |
| Enteritis | 1 | 0 |
| Gastrointestinal inflammation | 2 | 0 |
| Gastrointestinal tract irritation | 4 | 0 |
| Intestinal angioedema | 1 | 0 |
| Ischaemic enteritis | 1 | 0 |
| <i>Gastrointestinal mucosal dystrophies and secretion disorders</i> | | |
| Achlorhydria | 1 | 0 |
| Barrett's oesophagus | 1 | 0 |
| Hyperchlorhydria | 4 | 0 |
| <i>Gastrointestinal necrosis and gangrene (excl gangrenous hernia)</i> | | |
| Gastrointestinal necrosis | 1 | 0 |
| <i>Gastrointestinal signs and symptoms NEC</i> | | |
| Abdominal discomfort | 1598 | 0 |
| Abdominal symptom | 6 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Acute abdomen | 18 | 0 |
| Anal incontinence | 54 | 0 |
| Breath odour | 25 | 0 |
| Dysphagia | 286 | 0 |
| Intestinal congestion | 1 | 0 |
| Odynophagia | 34 | 0 |
| Oesophageal discomfort | 1 | 0 |
| <i>Gastrointestinal spastic and hypermotility disorders</i> | | |
| Cardiospasm | 2 | 1 |
| Defaecation urgency | 17 | 0 |
| Frequent bowel movements | 49 | 0 |
| Irritable bowel syndrome | 151 | 0 |
| Oesophageal spasm | 8 | 0 |
| <i>Gastrointestinal stenosis and obstruction NEC</i> | | |
| Intestinal obstruction | 5 | 0 |
| Intussusception | 1 | 0 |
| Volvulus | 1 | 1 |
| <i>Gastrointestinal ulcers and perforation, site unspecified</i> | | |
| Diverticular perforation | 2 | 0 |
| Gastrointestinal perforation | 1 | 0 |
| Gastrointestinal ulcer | 1 | 0 |
| <i>Gastrointestinal vascular malformations</i> | | |
| Gastric antral vascular ectasia | 11 | 0 |
| <i>Gastrointestinal vascular occlusion and infarction</i> | | |
| Intestinal infarction | 6 | 1 |
| Intestinal ischaemia | 34 | 1 |
| Mesenteric artery embolism | 1 | 0 |
| Mesenteric artery stenosis | 1 | 0 |
| Mesenteric artery thrombosis | 4 | 0 |
| Mesenteric vein thrombosis | 20 | 0 |
| Mesenteric venous occlusion | 1 | 0 |
| Thrombosis mesenteric vessel | 4 | 0 |
| Visceral venous thrombosis | 14 | 1 |
| <i>Gingival disorders, signs and symptoms NEC</i> | | |
| Amalgam tattoo | 1 | 0 |
| Epulis | 1 | 0 |
| Gingival atrophy | 1 | 0 |
| Gingival blister | 23 | 0 |
| Gingival discomfort | 7 | 0 |
| Gingival disorder | 17 | 0 |
| Gingival hypertrophy | 1 | 0 |
| Gingival oedema | 2 | 0 |
| Gingival pain | 236 | 0 |
| Gingival pruritus | 1 | 0 |
| Gingival recession | 3 | 0 |
| Gingival swelling | 53 | 0 |
| Gingival ulceration | 10 | 0 |
| Gingivitis ulcerative | 2 | 0 |
| Noninfective gingivitis | 24 | 0 |
| <i>Gingival haemorrhages</i> | | |
| Gingival bleeding | 175 | 0 |
| <i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i> | | |
| Anorectal varices | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Haemorrhoidal haemorrhage | 4 | 0 |
| Haemorrhoids | 68 | 0 |
| Haemorrhoids thrombosed | 13 | 0 |
| <i>Inguinal hernias</i> | | |
| Inguinal hernia | 3 | 0 |
| <i>Intestinal haemorrhages</i> | | |
| Anal haemorrhage | 45 | 0 |
| Intestinal haemorrhage | 1 | 0 |
| Lower gastrointestinal haemorrhage | 2 | 0 |
| Mesenteric haemorrhage | 5 | 0 |
| Rectal haemorrhage | 119 | 0 |
| Small intestinal haemorrhage | 27 | 0 |
| <i>Intestinal ulcers and perforation NEC</i> | | |
| Intestinal perforation | 5 | 0 |
| Large intestine perforation | 1 | 0 |
| <i>Large intestinal stenosis and obstruction</i> | | |
| Large intestinal obstruction | 1 | 0 |
| Large intestinal stenosis | 1 | 0 |
| <i>Malabsorption syndromes</i> | | |
| Bile acid malabsorption | 1 | 0 |
| Coeliac disease | 24 | 0 |
| Steatorrhoea | 2 | 0 |
| <i>Nausea and vomiting symptoms</i> | | |
| Acetonaemic vomiting | 1 | 0 |
| Cyclic vomiting syndrome | 2 | 0 |
| Discoloured vomit | 19 | 0 |
| Faecal vomiting | 3 | 0 |
| Infantile spitting up | 1 | 0 |
| Infantile vomiting | 6 | 0 |
| Nausea | 33440 | 0 |
| Regurgitation | 3 | 0 |
| Retching | 237 | 0 |
| Vomiting | 11378 | 0 |
| Vomiting projectile | 155 | 0 |
| <i>Non-site specific gastrointestinal haemorrhages</i> | | |
| Gastrointestinal haemorrhage | 39 | 1 |
| Haematemesis | 79 | 0 |
| Haematochezia | 104 | 0 |
| Intra-abdominal haematoma | 2 | 0 |
| Intra-abdominal haemorrhage | 2 | 0 |
| Melaena | 10 | 0 |
| Upper gastrointestinal haemorrhage | 9 | 0 |
| <i>Oesophageal disorders NEC</i> | | |
| Oesophageal disorder | 2 | 0 |
| <i>Oesophageal stenosis and obstruction</i> | | |
| Acquired oesophageal web | 1 | 0 |
| Oesophageal obstruction | 1 | 0 |
| <i>Oesophageal ulcers and perforation</i> | | |
| Oesophageal rupture | 1 | 1 |
| Oesophageal ulcer | 1 | 0 |
| <i>Oesophageal varices</i> | | |
| Varices oesophageal | 3 | 0 |
| <i>Oesophagitis (excl infective)</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Eosinophilic oesophagitis | 3 | 0 |
| Oesophagitis | 21 | 0 |
| Oral dryness and saliva altered | | |
| Aptyalism | 5 | 0 |
| Dry mouth | 1152 | 0 |
| Lip dry | 78 | 0 |
| Saliva altered | 7 | 0 |
| Saliva discolouration | 1 | 0 |
| Salivary hypersecretion | 94 | 0 |
| Oral soft tissue disorders NEC | | |
| Angina bullosa haemorrhagica | 4 | 0 |
| Chapped lips | 24 | 0 |
| Cheilitis | 39 | 0 |
| Chronic cheek biting | 1 | 0 |
| Enlarged uvula | 11 | 0 |
| Leukoplakia oral | 2 | 0 |
| Lip blister | 36 | 0 |
| Lip disorder | 6 | 0 |
| Oral disorder | 19 | 0 |
| Oral lichen planus | 16 | 0 |
| Oral papule | 2 | 0 |
| Palatal disorder | 2 | 0 |
| Uvulitis | 5 | 0 |
| Oral soft tissue haemorrhages | | |
| Lip haemorrhage | 4 | 0 |
| Mouth haemorrhage | 58 | 0 |
| Oral blood blister | 54 | 0 |
| Oral purpura | 2 | 0 |
| Oral soft tissue infections | | |
| Angular cheilitis | 11 | 0 |
| Oral soft tissue signs and symptoms | | |
| Anaesthesia oral | 8 | 0 |
| Burning mouth syndrome | 16 | 0 |
| Coating in mouth | 4 | 0 |
| Hypoaesthesia oral | 667 | 0 |
| Lip discolouration | 1 | 0 |
| Lip erythema | 4 | 0 |
| Lip exfoliation | 9 | 0 |
| Lip pain | 61 | 0 |
| Lip pruritus | 16 | 0 |
| Oral discharge | 1 | 0 |
| Oral discomfort | 107 | 0 |
| Oral dysaesthesia | 1 | 0 |
| Oral mucosal blistering | 34 | 0 |
| Oral mucosal discolouration | 1 | 0 |
| Oral mucosal eruption | 30 | 0 |
| Oral mucosal erythema | 3 | 0 |
| Oral mucosal exfoliation | 10 | 0 |
| Oral mucosal roughening | 3 | 0 |
| Oral pain | 363 | 0 |
| Oral pruritus | 21 | 0 |
| Paraesthesia oral | 859 | 0 |
| Oral soft tissue swelling and oedema | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Gastrointestinal disorders | | |
| Gastrointestinal disorders cont'd | | |
| Lip oedema | 10 | 0 |
| Lip swelling | 984 | 0 |
| Mouth swelling | 132 | 0 |
| Oedema mouth | 1 | 0 |
| Palatal oedema | 1 | 0 |
| Palatal swelling | 14 | 0 |
| <i>Pancreatic disorders NEC</i> | | |
| Pancreatic disorder | 1 | 0 |
| Pancreatic failure | 1 | 0 |
| Pancreatic mass | 1 | 0 |
| Pancreatic steatosis | 1 | 0 |
| <i>Peptic ulcers and perforation</i> | | |
| Peptic ulcer | 2 | 0 |
| Peptic ulcer haemorrhage | 8 | 0 |
| <i>Peritoneal and retroperitoneal disorders</i> | | |
| Ascites | 9 | 0 |
| Pneumoperitoneum | 1 | 0 |
| <i>Peritoneal and retroperitoneal fibrosis and adhesions</i> | | |
| Abdominal adhesions | 2 | 0 |
| <i>Peritoneal and retroperitoneal haemorrhages</i> | | |
| Haemoperitoneum | 2 | 0 |
| Retroperitoneal haemorrhage | 1 | 0 |
| <i>Rectal inflammations NEC</i> | | |
| Proctitis | 5 | 0 |
| <i>Salivary gland disorders NEC</i> | | |
| Salivary gland calculus | 4 | 0 |
| Salivary gland cyst | 1 | 0 |
| Salivary gland mass | 2 | 0 |
| Salivary gland pain | 13 | 0 |
| <i>Salivary gland enlargements</i> | | |
| Parotid gland enlargement | 14 | 0 |
| Salivary gland enlargement | 6 | 0 |
| <i>Salivary gland infections and inflammations</i> | | |
| Noninfective sialoadenitis | 2 | 0 |
| <i>Stomatitis and ulceration</i> | | |
| Aphthous ulcer | 64 | 0 |
| Lip ulceration | 17 | 0 |
| Mouth ulceration | 766 | 0 |
| Stomatitis | 108 | 0 |
| <i>Tongue disorders</i> | | |
| Acquired macroglossia | 1 | 0 |
| Glossitis | 18 | 0 |
| Plicated tongue | 4 | 0 |
| Tongue disorder | 34 | 0 |
| Tongue geographic | 5 | 0 |
| Tongue haemorrhage | 2 | 0 |
| Tongue ulceration | 32 | 0 |
| Trichoglossia | 7 | 0 |
| <i>Tongue signs and symptoms</i> | | |
| Glossodynia | 264 | 0 |
| Scalloped tongue | 4 | 0 |
| Stiff tongue | 6 | 0 |
| Strawberry tongue | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|--------------|-----------|
| Gastrointestinal disorders | | |
| Gastrointestinal disorders cont'd | | |
| Swollen tongue | 630 | 0 |
| Tongue blistering | 28 | 0 |
| Tongue coated | 36 | 0 |
| Tongue discolouration | 40 | 0 |
| Tongue discomfort | 57 | 0 |
| Tongue dry | 23 | 0 |
| Tongue eruption | 12 | 0 |
| Tongue erythema | 7 | 0 |
| Tongue exfoliation | 2 | 0 |
| Tongue movement disturbance | 9 | 0 |
| Tongue oedema | 17 | 0 |
| Tongue pruritus | 3 | 0 |
| Tongue rough | 2 | 0 |
| Tongue spasm | 5 | 0 |
| <i>Tooth missing</i> | | |
| Tooth loss | 10 | 0 |
| Gastrointestinal disorders SOC TOTAL | 79970 | 13 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders | | |
| <i>Administration site reactions NEC</i> | | |
| Administration site bruise | 18 | 0 |
| Administration site coldness | 1 | 0 |
| Administration site erythema | 6 | 0 |
| Administration site extravasation | 1 | 0 |
| Administration site haemorrhage | 1 | 0 |
| Administration site indentation | 1 | 0 |
| Administration site induration | 1 | 0 |
| Administration site injury | 1 | 0 |
| Administration site irritation | 1 | 0 |
| Administration site mass | 1 | 0 |
| Administration site movement impairment | 1 | 0 |
| Administration site pain | 45 | 0 |
| Administration site rash | 5 | 0 |
| Administration site reaction | 6 | 0 |
| Administration site swelling | 3 | 0 |
| Administration site urticaria | 5 | 0 |
| Administration site warmth | 2 | 0 |
| Puncture site bruise | 61 | 0 |
| Puncture site haemorrhage | 1 | 0 |
| Puncture site pain | 22 | 0 |
| Puncture site reaction | 3 | 0 |
| Puncture site swelling | 1 | 0 |
| Vessel puncture site bruise | 2 | 0 |
| <i>Adverse effect absent</i> | | |
| No adverse event | 4 | 0 |
| <i>Application and instillation site reactions</i> | | |
| Application site acne | 1 | 0 |
| Application site bruise | 25 | 0 |
| Application site burn | 4 | 0 |
| Application site coldness | 2 | 0 |
| Application site discharge | 1 | 0 |
| Application site discolouration | 2 | 0 |
| Application site erythema | 29 | 0 |
| Application site exfoliation | 1 | 0 |
| Application site haemorrhage | 1 | 0 |
| Application site hypersensitivity | 1 | 0 |
| Application site hypoaesthesia | 2 | 0 |
| Application site inflammation | 2 | 0 |
| Application site joint pain | 1 | 0 |
| Application site laceration | 1 | 0 |
| Application site movement impairment | 1 | 0 |
| Application site odour | 1 | 0 |
| Application site pain | 52 | 0 |
| Application site pruritus | 20 | 0 |
| Application site rash | 4 | 0 |
| Application site reaction | 1 | 0 |
| Application site scar | 1 | 0 |
| Application site swelling | 4 | 0 |
| Application site vesicles | 14 | 0 |
| Application site warmth | 2 | 0 |
| Application site wound | 1 | 0 |
| Instillation site bruise | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Instillation site discomfort | 1 | 0 |
| Instillation site pain | 5 | 0 |
| Instillation site pruritus | 1 | 0 |
| Instillation site warmth | 12 | 0 |
| <i>Asthenic conditions</i> | | |
| Asthenia | 5048 | 2 |
| Chronic fatigue syndrome | 164 | 0 |
| Decreased activity | 16 | 0 |
| Fatigue | 50427 | 0 |
| Malaise | 12644 | 0 |
| Sluggishness | 31 | 0 |
| <i>Body temperature altered</i> | | |
| Hyperthermia | 13 | 0 |
| Hypothermia | 58 | 0 |
| Temperature regulation disorder | 29 | 0 |
| <i>Breast complications associated with device</i> | | |
| Capsular contracture associated with breast implant | 1 | 0 |
| <i>Complications associated with device NEC</i> | | |
| Complication of device removal | 1 | 0 |
| Injury associated with device | 10 | 0 |
| Medical device site joint pain | 1 | 0 |
| Phantom shocks | 4 | 0 |
| <i>Death and sudden death</i> | | |
| Brain death | 4 | 3 |
| Cardiac death | 5 | 5 |
| Death | 313 | 312 |
| Drowning | 1 | 0 |
| Hanging | 1 | 1 |
| Sudden death | 41 | 41 |
| Sudden unexplained death in epilepsy | 1 | 1 |
| <i>Febrile disorders</i> | | |
| Hyperpyrexia | 42 | 0 |
| Masked fever | 1 | 0 |
| PFAPA syndrome | 1 | 0 |
| Pyrexia | 55247 | 0 |
| <i>Feelings and sensations NEC</i> | | |
| Chills | 43094 | 0 |
| Early satiety | 1 | 0 |
| Feeling abnormal | 3345 | 0 |
| Feeling cold | 5260 | 0 |
| Feeling drunk | 132 | 0 |
| Feeling hot | 2456 | 0 |
| Feeling jittery | 45 | 0 |
| Feeling of body temperature change | 965 | 0 |
| Feeling of relaxation | 1 | 0 |
| Hangover | 197 | 0 |
| Humidity intolerance | 1 | 0 |
| Hunger | 83 | 0 |
| Sensation of blood flow | 17 | 0 |
| Sensation of foreign body | 54 | 0 |
| Temperature intolerance | 89 | 0 |
| Thirst | 1268 | 0 |
| Thirst decreased | 11 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| <i>Fibrosis NEC</i> | | |
| Fibrosis | 7 | 0 |
| <i>Gait disturbances</i> | | |
| Decreased gait velocity | 3 | 0 |
| Gait disturbance | 478 | 0 |
| Gait inability | 228 | 0 |
| Loss of control of legs | 59 | 0 |
| <i>General signs and symptoms NEC</i> | | |
| Apparent death | 1 | 0 |
| Chronic disease | 1 | 0 |
| Condition aggravated | 321 | 0 |
| Crepitations | 10 | 0 |
| Crying | 302 | 0 |
| Deformity | 1 | 0 |
| Developmental delay | 3 | 0 |
| Discharge | 11 | 0 |
| Disease prodromal stage | 1 | 0 |
| Disease progression | 3 | 1 |
| Disease recurrence | 2 | 0 |
| Effusion | 1 | 0 |
| Energy increased | 26 | 0 |
| Exercise tolerance decreased | 44 | 0 |
| Foaming at mouth | 6 | 0 |
| General physical health deterioration | 32 | 2 |
| General symptom | 11 | 0 |
| Glassy eyes | 7 | 0 |
| High-pitched crying | 8 | 0 |
| Ill-defined disorder | 12 | 0 |
| Illness | 5083 | 1 |
| Impaired self-care | 1 | 0 |
| Induration | 21 | 0 |
| Influenza like illness | 9634 | 0 |
| Irritability postvaccinal | 3 | 0 |
| Local reaction | 155 | 0 |
| Moaning | 9 | 0 |
| Multiple organ dysfunction syndrome | 24 | 12 |
| Nonspecific reaction | 3 | 0 |
| Organ failure | 2 | 0 |
| Perforation | 2 | 0 |
| Performance status decreased | 1 | 0 |
| Peripheral swelling | 5948 | 0 |
| Pre-existing condition improved | 18 | 0 |
| Premature ageing | 3 | 0 |
| Prolapse | 1 | 0 |
| Screaming | 31 | 0 |
| Secretion discharge | 36 | 0 |
| Sensitivity to weather change | 3 | 0 |
| Stenosis | 2 | 0 |
| Swelling | 2789 | 0 |
| Swelling face | 1091 | 0 |
| Symptom masked | 1 | 0 |
| Symptom recurrence | 4 | 0 |
| Tissue discolouration | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Tissue infiltration | 1 | 0 |
| Unevaluable event | 9 | 0 |
| Healing abnormal NEC | | |
| Impaired healing | 6 | 0 |
| Hernias NEC | | |
| Hernia | 6 | 0 |
| Implant and catheter site reactions | | |
| Catheter site urticaria | 1 | 0 |
| Implant site coldness | 1 | 0 |
| Implant site discharge | 1 | 0 |
| Implant site discolouration | 4 | 0 |
| Implant site hypoaesthesia | 2 | 0 |
| Implant site pain | 4 | 0 |
| Implant site rash | 1 | 0 |
| Implant site swelling | 3 | 0 |
| Implant site urticaria | 3 | 0 |
| Implant site vesicles | 1 | 0 |
| Implant site warmth | 7 | 0 |
| Inflamations | | |
| Granuloma | 1 | 0 |
| Inflammation | 853 | 0 |
| Papillitis | 1 | 0 |
| Systemic inflammatory response syndrome | 7 | 0 |
| Infusion site reactions | | |
| Infusion site bruising | 1 | 0 |
| Infusion site discomfort | 1 | 0 |
| Infusion site erythema | 3 | 0 |
| Infusion site joint pain | 1 | 0 |
| Infusion site mass | 5 | 0 |
| Infusion site mobility decreased | 1 | 0 |
| Infusion site nodule | 2 | 0 |
| Infusion site pain | 14 | 0 |
| Infusion site urticaria | 2 | 0 |
| Infusion site warmth | 6 | 0 |
| Injection site reactions | | |
| Injected limb mobility decreased | 46 | 0 |
| Injection site atrophy | 9 | 0 |
| Injection site bruising | 126 | 0 |
| Injection site coldness | 6 | 0 |
| Injection site cyst | 6 | 0 |
| Injection site deformation | 1 | 0 |
| Injection site discharge | 1 | 0 |
| Injection site discolouration | 8 | 0 |
| Injection site discomfort | 21 | 0 |
| Injection site dryness | 1 | 0 |
| Injection site erythema | 591 | 0 |
| Injection site exfoliation | 1 | 0 |
| Injection site extravasation | 2 | 0 |
| Injection site haematoma | 3 | 0 |
| Injection site haemorrhage | 19 | 0 |
| Injection site hypersensitivity | 5 | 0 |
| Injection site hypoaesthesia | 15 | 0 |
| Injection site indentation | 22 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Injection site induration | 10 | 0 |
| Injection site inflammation | 67 | 0 |
| Injection site injury | 4 | 0 |
| Injection site irritation | 4 | 0 |
| Injection site joint discomfort | 1 | 0 |
| Injection site joint erythema | 8 | 0 |
| Injection site joint pain | 35 | 0 |
| Injection site joint swelling | 1 | 0 |
| Injection site mass | 1425 | 0 |
| Injection site movement impairment | 5 | 0 |
| Injection site muscle weakness | 2 | 0 |
| Injection site necrosis | 7 | 0 |
| Injection site nerve damage | 2 | 0 |
| Injection site nodule | 4 | 0 |
| Injection site oedema | 27 | 0 |
| Injection site pain | 4510 | 0 |
| Injection site papule | 2 | 0 |
| Injection site paraesthesia | 26 | 0 |
| Injection site pruritus | 300 | 0 |
| Injection site rash | 309 | 0 |
| Injection site reaction | 123 | 0 |
| Injection site scab | 4 | 0 |
| Injection site scar | 6 | 0 |
| Injection site swelling | 258 | 0 |
| Injection site thrombosis | 1 | 0 |
| Injection site ulcer | 1 | 0 |
| Injection site urticaria | 41 | 0 |
| Injection site vesicles | 15 | 0 |
| Injection site warmth | 355 | 0 |
| Interactions | | |
| Drug interaction | 35 | 0 |
| Food interaction | 2 | 0 |
| Inhibitory drug interaction | 12 | 0 |
| Mass conditions NEC | | |
| Cyst | 34 | 0 |
| Mass | 91 | 0 |
| Nodule | 25 | 0 |
| Pelvic mass | 1 | 0 |
| Mucosal findings abnormal | | |
| Mucosa vesicle | 2 | 0 |
| Mucosal disorder | 2 | 0 |
| Mucosal dryness | 1 | 0 |
| Mucosal haemorrhage | 12 | 0 |
| Mucosal inflammation | 11 | 0 |
| Mucosal pain | 2 | 0 |
| Mucosal ulceration | 1 | 0 |
| Oedema mucosal | 3 | 0 |
| Polyp | 5 | 0 |
| Necrosis NEC | | |
| Fat necrosis | 4 | 0 |
| Necrosis | 8 | 0 |
| Oedema NEC | | |
| Face oedema | 36 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| General disorders General disorders cont'd | | |
| Localised oedema | 12 | 0 |
| Oedema | 89 | 0 |
| Oedema peripheral | 164 | 0 |
| <i>Pain and discomfort NEC</i> | | |
| Axillary pain | 760 | 0 |
| Chest discomfort | 2103 | 0 |
| Chest pain | 5717 | 0 |
| Discomfort | 640 | 0 |
| Facial discomfort | 21 | 0 |
| Facial pain | 291 | 0 |
| Hernia pain | 2 | 0 |
| Inflammatory pain | 32 | 0 |
| Non-cardiac chest pain | 46 | 0 |
| Pain | 17600 | 0 |
| Suprapubic pain | 1 | 0 |
| Tenderness | 1840 | 0 |
| Visceral pain | 2 | 0 |
| <i>Therapeutic and nontherapeutic responses</i> | | |
| Adverse drug reaction | 33 | 0 |
| Adverse event | 7 | 0 |
| Adverse food reaction | 1 | 0 |
| Adverse reaction | 11 | 0 |
| Diet failure | 1 | 0 |
| Drug effect less than expected | 1 | 0 |
| Drug ineffective | 175 | 1 |
| Drug intolerance | 9 | 0 |
| Idiosyncratic drug reaction | 1 | 0 |
| Immediate post-injection reaction | 4 | 0 |
| Inadequate analgesia | 32 | 0 |
| No reaction on previous exposure to drug | 16 | 0 |
| Remission not achieved | 1 | 0 |
| Similar reaction on previous exposure to drug | 1 | 0 |
| Therapeutic product effect decreased | 3 | 0 |
| Therapeutic product effect delayed | 1 | 0 |
| Therapeutic product effect incomplete | 2 | 0 |
| Therapeutic product effect prolonged | 1 | 0 |
| Therapeutic product ineffective | 9 | 0 |
| Therapeutic reaction time decreased | 1 | 0 |
| Therapeutic response changed | 1 | 0 |
| Therapeutic response decreased | 1 | 0 |
| Therapeutic response delayed | 1 | 0 |
| Therapeutic response shortened | 2 | 0 |
| Therapeutic response unexpected | 178 | 0 |
| Therapy non-responder | 3 | 0 |
| Treatment failure | 19 | 0 |
| Treatment noncompliance | 1 | 0 |
| Vaccination failure | 42 | 0 |
| Vaccine positive rechallenge | 1 | 0 |
| <i>Trophic disorders</i> | | |
| Atrophy | 4 | 0 |
| Calcinosis | 2 | 0 |
| Dysplasia | 3 | 0 |
| Hyperplasia | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| <i>Ulcers NEC</i> | | |
| Ulcer | 48 | 0 |
| Ulcer haemorrhage | 3 | 0 |
| <i>Vaccination site reactions</i> | | |
| Extensive swelling of vaccinated limb | 19 | 0 |
| Shoulder injury related to vaccine administration | 88 | 0 |
| Vaccination site atrophy | 1 | 0 |
| Vaccination site bruising | 138 | 0 |
| Vaccination site coldness | 1 | 0 |
| Vaccination site cyst | 3 | 0 |
| Vaccination site discharge | 1 | 0 |
| Vaccination site discolouration | 17 | 0 |
| Vaccination site discomfort | 49 | 0 |
| Vaccination site dryness | 1 | 0 |
| Vaccination site erythema | 716 | 0 |
| Vaccination site extravasation | 1 | 0 |
| Vaccination site granuloma | 8 | 0 |
| Vaccination site haematoma | 1 | 0 |
| Vaccination site haemorrhage | 10 | 0 |
| Vaccination site hyperaesthesia | 1 | 0 |
| Vaccination site hypersensitivity | 4 | 0 |
| Vaccination site hypoaesthesia | 25 | 0 |
| Vaccination site induration | 70 | 0 |
| Vaccination site inflammation | 56 | 0 |
| Vaccination site injury | 4 | 0 |
| Vaccination site irritation | 15 | 0 |
| Vaccination site joint discomfort | 2 | 0 |
| Vaccination site joint erythema | 5 | 0 |
| Vaccination site joint inflammation | 1 | 0 |
| Vaccination site joint movement impairment | 18 | 0 |
| Vaccination site joint pain | 54 | 0 |
| Vaccination site joint swelling | 3 | 0 |
| Vaccination site joint warmth | 2 | 0 |
| Vaccination site lymphadenopathy | 2 | 0 |
| Vaccination site mass | 565 | 0 |
| Vaccination site movement impairment | 102 | 0 |
| Vaccination site nodule | 1 | 0 |
| Vaccination site oedema | 3 | 0 |
| Vaccination site pain | 2108 | 0 |
| Vaccination site papule | 3 | 0 |
| Vaccination site paraesthesia | 12 | 0 |
| Vaccination site pruritus | 112 | 0 |
| Vaccination site rash | 191 | 0 |
| Vaccination site reaction | 26 | 0 |
| Vaccination site scab | 2 | 0 |
| Vaccination site scar | 7 | 0 |
| Vaccination site swelling | 513 | 0 |
| Vaccination site urticaria | 12 | 0 |
| Vaccination site vesicles | 11 | 0 |
| Vaccination site warmth | 381 | 0 |
| <i>Vascular complications associated with device</i> | | |
| Vascular stent occlusion | 1 | 0 |
| Vascular stent thrombosis | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|---------------|------------|
| General disorders General disorders cont'd | | |
| <i>Withdrawal and rebound effects</i> | | |
| Drug withdrawal syndrome | 8 | 0 |
| Withdrawal syndrome | 102 | 0 |
| General disorders SOC TOTAL | 253043 | 382 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Hepatic disorders | | |
| <i>Bile duct infections and inflammations</i> | | |
| Biliary colic | 32 | 0 |
| Cholangitis | 3 | 0 |
| <i>Cholecystitis and cholelithiasis</i> | | |
| Cholecystitis | 16 | 0 |
| Cholecystitis acute | 3 | 0 |
| Cholelithiasis | 15 | 0 |
| <i>Cholestasis and jaundice</i> | | |
| Cholestasis | 6 | 0 |
| Jaundice | 57 | 0 |
| Jaundice cholestatic | 12 | 0 |
| Ocular icterus | 1 | 0 |
| <i>Gallbladder disorders NEC</i> | | |
| Gallbladder disorder | 3 | 0 |
| Gallbladder oedema | 1 | 0 |
| Gallbladder polyp | 1 | 0 |
| <i>Hepatic and hepatobiliary disorders NEC</i> | | |
| Liver disorder | 19 | 0 |
| <i>Hepatic enzymes and function abnormalities</i> | | |
| Hepatic function abnormal | 13 | 0 |
| <i>Hepatic failure and associated disorders</i> | | |
| Acute hepatic failure | 2 | 0 |
| Hepatic failure | 12 | 1 |
| Hepatorenal syndrome | 1 | 1 |
| Subacute hepatic failure | 3 | 0 |
| <i>Hepatic fibrosis and cirrhosis</i> | | |
| Hepatic cirrhosis | 10 | 1 |
| <i>Hepatic vascular disorders</i> | | |
| Budd-Chiari syndrome | 2 | 1 |
| Hepatic artery thrombosis | 1 | 0 |
| Hepatic haemorrhage | 1 | 0 |
| Hepatic hypoperfusion | 1 | 0 |
| Hepatic infarction | 2 | 1 |
| Hepatic vascular thrombosis | 2 | 0 |
| Hepatic vein thrombosis | 16 | 0 |
| Portal hypertension | 5 | 0 |
| Portal vein phlebitis | 1 | 0 |
| Portal vein thrombosis | 70 | 4 |
| Portosplenomesenteric venous thrombosis | 2 | 0 |
| <i>Hepatobiliary signs and symptoms</i> | | |
| Hepatic pain | 80 | 0 |
| Hepatomegaly | 5 | 0 |
| Liver tenderness | 6 | 0 |
| <i>Hepatocellular damage and hepatitis NEC</i> | | |
| Acute yellow liver atrophy | 1 | 0 |
| Autoimmune hepatitis | 10 | 0 |
| Cholestatic liver injury | 1 | 0 |
| Drug-induced liver injury | 1 | 0 |
| Hepatic necrosis | 1 | 0 |
| Hepatic steatosis | 12 | 0 |
| Hepatitis | 32 | 0 |
| Hepatitis acute | 7 | 1 |
| Immune-mediated hepatitis | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|------------|-----------|
| Hepatic disorders Hepatic disorders cont'd | | |
| Ischaemic hepatitis | 1 | 0 |
| Liver injury | 29 | 0 |
| Nonalcoholic fatty liver disease | 1 | 0 |
| Reye's syndrome | 1 | 0 |
| <i>Obstructive bile duct disorders (excl neoplasms)</i> | | |
| Biliary obstruction | 1 | 0 |
| Sphincter of Oddi dysfunction | 3 | 0 |
| Hepatic disorders SOC TOTAL | 506 | 10 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Immune system disorders | | |
| <i>Acute and chronic sarcoidosis</i> | | |
| Sarcoidosis | 28 | 0 |
| <i>Allergic conditions NEC</i> | | |
| Allergic oedema | 22 | 0 |
| Allergy to animal | 1 | 0 |
| Allergy to arthropod bite | 1 | 0 |
| Allergy to arthropod sting | 5 | 0 |
| Allergy to metals | 1 | 0 |
| Allergy to sting | 1 | 0 |
| Allergy to venom | 1 | 0 |
| Dust allergy | 3 | 0 |
| Hypersensitivity | 1516 | 1 |
| Infusion related hypersensitivity reaction | 5 | 0 |
| Mite allergy | 2 | 0 |
| Multiple allergies | 23 | 0 |
| Serum sickness | 15 | 0 |
| Serum sickness-like reaction | 13 | 0 |
| Type I hypersensitivity | 1 | 0 |
| Type III immune complex mediated reaction | 7 | 0 |
| Type IV hypersensitivity reaction | 4 | 0 |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> | | |
| Allergic reaction to excipient | 3 | 0 |
| Allergy to chemicals | 8 | 0 |
| Allergy to vaccine | 61 | 0 |
| Contrast media reaction | 4 | 0 |
| Drug hypersensitivity | 71 | 0 |
| Food allergy | 52 | 0 |
| Milk allergy | 1 | 0 |
| Oral allergy syndrome | 4 | 0 |
| Polymers allergy | 1 | 0 |
| Reaction to colouring | 2 | 0 |
| Reaction to excipient | 14 | 0 |
| Reaction to preservatives | 15 | 0 |
| Rubber sensitivity | 3 | 0 |
| Smoke sensitivity | 3 | 0 |
| <i>Anaphylactic and anaphylactoid responses</i> | | |
| Anaphylactic reaction | 697 | 2 |
| Anaphylactic shock | 122 | 0 |
| Anaphylactoid reaction | 23 | 0 |
| Anaphylactoid shock | 4 | 0 |
| <i>Atopic disorders</i> | | |
| Atopy | 3 | 0 |
| Seasonal allergy | 143 | 0 |
| <i>Autoimmune disorders NEC</i> | | |
| Autoimmune disorder | 62 | 0 |
| <i>Autoinflammatory diseases</i> | | |
| Autoinflammatory disease | 1 | 0 |
| <i>Endocrine autoimmune disorders</i> | | |
| Hashitoxicosis | 1 | 0 |
| <i>Immune and associated conditions NEC</i> | | |
| Bacille Calmette-Guerin scar reactivation | 35 | 0 |
| Cytokine release syndrome | 2 | 0 |
| Cytokine storm | 4 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Immune system disorders | | |
| Immune system disorders cont'd | | |
| Decreased immune responsiveness | 1 | 0 |
| Haemophagocytic lymphohistiocytosis | 13 | 1 |
| Hypocomplementaemia | 1 | 0 |
| Immune system disorder | 55 | 0 |
| Immune-mediated adverse reaction | 10 | 0 |
| Immunisation reaction | 1 | 0 |
| Multiple chemical sensitivity | 2 | 0 |
| Pre-engraftment immune reaction | 1 | 0 |
| Sensitisation | 33 | 0 |
| Immunodeficiency disorders NEC | | |
| Immunodeficiency | 11 | 0 |
| Immunosuppression | 6 | 0 |
| Transplant rejections | | |
| Corneal graft rejection | 3 | 0 |
| Transplant rejection | 7 | 0 |
| Vasculitides | | |
| Anti-neutrophil cytoplasmic antibody positive vasculitis | 4 | 1 |
| Eosinophilic granulomatosis with polyangiitis | 2 | 0 |
| Immune system disorders SOC TOTAL | 3138 | 5 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Infections | | |
| <i>Abdominal and gastrointestinal infections</i> | | |
| Abdominal infection | 1 | 0 |
| Abdominal wall infection | 1 | 0 |
| Anal abscess | 1 | 0 |
| Appendicitis | 41 | 0 |
| Appendicitis perforated | 3 | 0 |
| Diarrhoea infectious | 4 | 0 |
| Diverticulitis | 32 | 0 |
| Dysentery | 5 | 0 |
| Gastric infection | 1 | 0 |
| Gastroenteritis | 43 | 0 |
| Gastrointestinal infection | 5 | 0 |
| Large intestine infection | 2 | 0 |
| Peritonitis | 3 | 0 |
| <i>Adenoviral infections</i> | | |
| Adenovirus infection | 1 | 0 |
| <i>Bacillary infections</i> | | |
| Bacillus infection | 1 | 0 |
| <i>Bacterial infections NEC</i> | | |
| Abscess bacterial | 1 | 0 |
| Administration site cellulitis | 1 | 0 |
| Arthritis bacterial | 10 | 0 |
| Bacterial infection | 34 | 1 |
| Bacterial vaginosis | 4 | 0 |
| Bacterial vulvovaginitis | 1 | 0 |
| Cellulitis | 534 | 0 |
| Cellulitis orbital | 2 | 0 |
| Ear infection bacterial | 2 | 0 |
| Endocarditis bacterial | 2 | 0 |
| Eye infection bacterial | 1 | 0 |
| Folliculitis | 11 | 0 |
| Gangrene | 3 | 0 |
| Injection site cellulitis | 8 | 0 |
| Meningitis bacterial | 1 | 0 |
| Perichondritis | 1 | 0 |
| Periorbital cellulitis | 5 | 0 |
| Pneumonia bacterial | 6 | 1 |
| Post procedural cellulitis | 1 | 0 |
| Skin bacterial infection | 6 | 0 |
| Urinary tract infection bacterial | 5 | 0 |
| Vaccination site cellulitis | 22 | 0 |
| <i>Bone and joint infections</i> | | |
| Abscess jaw | 1 | 0 |
| Arthritis infective | 4 | 0 |
| Bursitis infective | 3 | 0 |
| Intervertebral discitis | 3 | 0 |
| Osteomyelitis | 2 | 1 |
| <i>Bordetella infections</i> | | |
| Pertussis | 3 | 0 |
| <i>Borreliac infections</i> | | |
| Erythema migrans | 2 | 0 |
| Lyme disease | 8 | 0 |
| Relapsing fever | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections | | |
| Infections cont'd | | |
| <i>Breast infections</i> | | |
| Breast abscess | 2 | 0 |
| Mastitis | 47 | 0 |
| <i>Brucella infections</i> | | |
| Brucellosis | 1 | 0 |
| <i>Caliciviral infections</i> | | |
| Gastroenteritis norovirus | 1 | 0 |
| Norovirus infection | 1 | 0 |
| <i>Campylobacter infections</i> | | |
| Campylobacter colitis | 1 | 0 |
| Campylobacter gastroenteritis | 1 | 0 |
| Campylobacter infection | 1 | 0 |
| <i>Candida infections</i> | | |
| Anal candidiasis | 2 | 0 |
| Balanitis candida | 1 | 0 |
| Candida infection | 81 | 0 |
| Oral candidiasis | 61 | 0 |
| Skin candida | 3 | 0 |
| Vulvovaginal candidiasis | 59 | 0 |
| <i>Cardiac infections</i> | | |
| Acute endocarditis | 2 | 0 |
| Cardiac infection | 1 | 0 |
| Endocarditis | 8 | 0 |
| Myocarditis infectious | 1 | 0 |
| <i>Central nervous system and spinal infections</i> | | |
| Brain abscess | 2 | 0 |
| Cavernous sinus thrombosis | 9 | 0 |
| Central nervous system infection | 2 | 0 |
| Encephalitis | 46 | 0 |
| Encephalomyelitis | 3 | 0 |
| Extradural abscess | 1 | 0 |
| Meningitis | 29 | 0 |
| Myelitis | 24 | 0 |
| <i>Chlamydial infections</i> | | |
| Chlamydial infection | 1 | 0 |
| <i>Clostridia infections</i> | | |
| Clostridium difficile colitis | 5 | 0 |
| Clostridium difficile infection | 3 | 0 |
| Tetanus | 4 | 0 |
| <i>Coronavirus infections</i> | | |
| Asymptomatic COVID-19 | 5 | 0 |
| COVID-19 | 1167 | 29 |
| COVID-19 pneumonia | 72 | 10 |
| Coronavirus infection | 7 | 0 |
| Post-acute COVID-19 syndrome | 15 | 0 |
| SARS-CoV-2 sepsis | 1 | 0 |
| Severe acute respiratory syndrome | 5 | 0 |
| Suspected COVID-19 | 46 | 0 |
| Vaccine derived SARS-CoV-2 infection | 1 | 0 |
| <i>Corynebacteria infections</i> | | |
| Diphtheria | 3 | 0 |
| <i>Coxiella infections</i> | | |
| Q fever | 113 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections Infections cont'd | | |
| <i>Coxsackie viral infections</i> | | |
| Coxsackie bronchitis | 1 | 0 |
| <i>Cytomegaloviral infections</i> | | |
| Encephalitis cytomegalovirus | 1 | 0 |
| <i>Dental and oral soft tissue infections</i> | | |
| Abscess oral | 5 | 0 |
| Gingival abscess | 9 | 0 |
| Gingivitis | 31 | 0 |
| Lip infection | 1 | 0 |
| Oral infection | 1 | 0 |
| Oral pustule | 3 | 0 |
| Parotitis | 15 | 0 |
| Pericoronitis | 3 | 0 |
| Periodontitis | 2 | 0 |
| Pulpitis dental | 1 | 0 |
| Sialoadenitis | 3 | 0 |
| Tongue abscess | 4 | 0 |
| Tooth abscess | 16 | 0 |
| Tooth infection | 14 | 0 |
| <i>Ear infections</i> | | |
| Ear infection | 143 | 0 |
| Labyrinthitis | 189 | 0 |
| Mastoiditis | 5 | 0 |
| Otitis externa | 7 | 0 |
| Otitis media | 8 | 0 |
| Otitis media chronic | 14 | 0 |
| Otosalpingitis | 1 | 0 |
| <i>Ectoparasitic infestations</i> | | |
| Acarodermatitis | 10 | 0 |
| Infestation | 1 | 0 |
| Trombidiasis | 3 | 0 |
| <i>Epstein-Barr viral infections</i> | | |
| Epstein-Barr virus infection | 6 | 0 |
| Epstein-Barr virus infection reactivation | 2 | 0 |
| Infectious mononucleosis | 59 | 0 |
| <i>Escherichia infections</i> | | |
| Escherichia infection | 2 | 0 |
| Escherichia sepsis | 2 | 0 |
| Gastroenteritis Escherichia coli | 1 | 0 |
| <i>Eye and eyelid infections</i> | | |
| Conjunctivitis | 85 | 0 |
| Eye infection | 46 | 0 |
| Eyelid boil | 3 | 0 |
| Eyelid infection | 4 | 0 |
| Hordeolum | 42 | 0 |
| Keratouveitis | 1 | 0 |
| Retinitis | 2 | 0 |
| <i>Female reproductive tract infections</i> | | |
| Endometritis | 3 | 0 |
| Fallopian tube abscess | 1 | 0 |
| Genital infection female | 1 | 0 |
| Ovarian abscess | 1 | 0 |
| Pelvic inflammatory disease | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Infections | | |
| Infections cont'd | | |
| Pyometra | 2 | 1 |
| Vaginal abscess | 3 | 0 |
| Vaginal infection | 6 | 0 |
| Vulval abscess | 1 | 0 |
| Flaviviral infections | | |
| Dengue fever | 1 | 0 |
| Yellow fever | 1 | 0 |
| Yellow fever vaccine-associated neurotropic disease | 1 | 0 |
| Fungal infections NEC | | |
| Ear infection fungal | 2 | 0 |
| Fungal infection | 30 | 0 |
| Fungal skin infection | 10 | 0 |
| Oral fungal infection | 1 | 0 |
| Overgrowth fungal | 1 | 0 |
| Severe asthma with fungal sensitisation | 5 | 0 |
| Tonsillitis fungal | 1 | 0 |
| Vulvovaginal mycotic infection | 4 | 0 |
| Helicobacter infections | | |
| Helicobacter infection | 1 | 0 |
| Hepatitis virus infections | | |
| Hepatitis E | 1 | 0 |
| Hepatobiliary and spleen infections | | |
| Biliary sepsis | 5 | 1 |
| Liver abscess | 1 | 0 |
| Splenic infection | 1 | 0 |
| Herpes viral infections | | |
| Eczema herpeticum | 3 | 0 |
| Genital herpes | 81 | 0 |
| Genital herpes simplex | 1 | 0 |
| Genital herpes zoster | 1 | 0 |
| Haemorrhagic varicella syndrome | 1 | 0 |
| Herpes dermatitis | 2 | 0 |
| Herpes ophthalmic | 16 | 0 |
| Herpes pharyngitis | 1 | 0 |
| Herpes simplex | 48 | 0 |
| Herpes simplex reactivation | 4 | 0 |
| Herpes virus infection | 15 | 0 |
| Herpes zoster | 1621 | 0 |
| Herpes zoster disseminated | 1 | 0 |
| Herpes zoster oticus | 14 | 0 |
| Herpes zoster reactivation | 2 | 0 |
| Meningoencephalitis herpetic | 1 | 0 |
| Nasal herpes | 16 | 0 |
| Ophthalmic herpes simplex | 2 | 0 |
| Ophthalmic herpes zoster | 10 | 0 |
| Oral herpes | 715 | 0 |
| Varicella | 41 | 0 |
| Varicella zoster virus infection | 4 | 0 |
| Infections NEC | | |
| Abscess | 52 | 0 |
| Abscess limb | 25 | 0 |
| Abscess soft tissue | 3 | 0 |
| Catheter site infection | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Infections | | |
| Infections cont'd | | |
| Coinfection | 1 | 0 |
| Device related infection | 3 | 0 |
| Empyema | 1 | 0 |
| Genital abscess | 1 | 0 |
| Groin abscess | 2 | 0 |
| Groin infection | 1 | 0 |
| Infected bite | 4 | 0 |
| Infected cyst | 4 | 0 |
| Infection | 532 | 4 |
| Infection in an immunocompromised host | 3 | 0 |
| Infectious thyroiditis | 1 | 0 |
| Injection site abscess | 3 | 0 |
| Injection site infection | 21 | 0 |
| Localised infection | 106 | 0 |
| Lymph gland infection | 8 | 0 |
| Lymph node abscess | 2 | 0 |
| Omphalitis | 1 | 0 |
| Pathogen resistance | 3 | 0 |
| Pelvic infection | 1 | 0 |
| Pyuria | 1 | 0 |
| Respiratory tract infection | 9 | 0 |
| Toxic shock syndrome | 1 | 0 |
| Vaccination site abscess | 7 | 0 |
| Vaccination site infection | 24 | 0 |
| Vaccine breakthrough infection | 3 | 0 |
| Vestibulitis | 4 | 0 |
| Wound abscess | 1 | 0 |
| Infectious disorders carrier | | |
| SARS-CoV-2 carrier | 1 | 0 |
| Infectious transmissions | | |
| Secondary transmission | 16 | 0 |
| Vaccine virus shedding | 1 | 0 |
| Influenza viral infections | | |
| H1N1 influenza | 1 | 0 |
| H2N2 influenza | 3 | 0 |
| Influenza | 6802 | 0 |
| Klebsiella infections | | |
| Cystitis klebsiella | 1 | 0 |
| Pneumonia klebsiella | 1 | 0 |
| Lower respiratory tract and lung infections | | |
| Atypical pneumonia | 2 | 0 |
| Bronchitis | 28 | 0 |
| Infectious pleural effusion | 4 | 0 |
| Infective exacerbation of bronchiectasis | 1 | 0 |
| Infective pulmonary exacerbation of cystic fibrosis | 1 | 1 |
| Lower respiratory tract infection | 320 | 4 |
| Pleural infection | 1 | 0 |
| Pneumonia | 271 | 28 |
| Pneumonia aspiration | 26 | 6 |
| Sputum purulent | 2 | 0 |
| Male reproductive tract infections | | |
| Epididymitis | 8 | 0 |
| Orchitis | 5 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Infections | | |
| Infections cont'd | | |
| <i>Molluscum contagiosum viral infections</i> | | |
| Molluscum contagiosum | 1 | 0 |
| <i>Mumps viral infections</i> | | |
| Mumps | 13 | 0 |
| <i>Muscle and soft tissue infections</i> | | |
| Muscle abscess | 1 | 0 |
| Necrotising fasciitis | 1 | 0 |
| Soft tissue infection | 5 | 0 |
| <i>Neisseria infections</i> | | |
| Gonorrhoea | 1 | 0 |
| <i>Orthopox viral infections</i> | | |
| Cow pox | 1 | 0 |
| Vaccinia virus infection | 2 | 0 |
| <i>Papilloma viral infections</i> | | |
| Papilloma viral infection | 1 | 0 |
| <i>Paravaccinia infections</i> | | |
| Paravaccinia | 1 | 0 |
| <i>Phleboviral infections</i> | | |
| Severe fever with thrombocytopenia syndrome | 2 | 0 |
| <i>Plasmodia infections</i> | | |
| Malaria | 7 | 0 |
| <i>Pneumocystis infections</i> | | |
| Pneumocystis jirovecii pneumonia | 1 | 0 |
| <i>Prion-associated disorders</i> | | |
| Creutzfeldt-Jakob disease | 3 | 0 |
| <i>Pseudomonal infections</i> | | |
| Pseudomonas infection | 1 | 0 |
| <i>Retroviral infections</i> | | |
| Acquired immunodeficiency syndrome | 2 | 0 |
| HIV infection | 3 | 0 |
| HIV-associated neurocognitive disorder | 1 | 0 |
| Persistent generalised lymphadenopathy | 1 | 0 |
| <i>Rotaviral infections</i> | | |
| Gastroenteritis rotavirus | 1 | 0 |
| Rotavirus infection | 1 | 0 |
| <i>Rubella viral infections</i> | | |
| Rubella | 1 | 0 |
| <i>Rubeola viral infections</i> | | |
| Measles | 6 | 0 |
| <i>Salmonella infections</i> | | |
| Typhoid fever | 2 | 0 |
| <i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i> | | |
| Abdominal sepsis | 2 | 0 |
| Bacteraemia | 1 | 0 |
| Neutropenic sepsis | 9 | 0 |
| Pelvic sepsis | 1 | 0 |
| Pulmonary sepsis | 1 | 0 |
| Sepsis | 116 | 13 |
| Sepsis syndrome | 1 | 0 |
| Septic pulmonary embolism | 1 | 0 |
| Septic rash | 13 | 0 |
| Septic shock | 5 | 1 |
| Urosepsis | 10 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections | | |
| Infections cont'd | | |
| Viraemia | 4 | 0 |
| <i>Skin structures and soft tissue infections</i> | | |
| Blister infected | 1 | 0 |
| Carbuncle | 1 | 0 |
| Dermatitis infected | 10 | 0 |
| Dermo-hypodermatitis | 1 | 0 |
| Eczema infected | 3 | 0 |
| Impetigo | 12 | 0 |
| Infected dermal cyst | 3 | 0 |
| Pilonidal cyst | 2 | 0 |
| Pustule | 26 | 0 |
| Pyoderma | 1 | 0 |
| Rash pustular | 19 | 0 |
| Skin infection | 73 | 0 |
| Subcutaneous abscess | 9 | 0 |
| Vaccination site pustule | 5 | 0 |
| <i>Staphylococcal infections</i> | | |
| Furuncle | 56 | 0 |
| Pneumonia staphylococcal | 1 | 0 |
| Staphylococcal bacteraemia | 2 | 0 |
| Staphylococcal infection | 2 | 0 |
| Staphylococcal scalded skin syndrome | 1 | 0 |
| Staphylococcal sepsis | 4 | 1 |
| Toxic shock syndrome staphylococcal | 1 | 0 |
| Vulvovaginitis staphylococcal | 1 | 0 |
| <i>Streptococcal infections</i> | | |
| Beta haemolytic streptococcal infection | 1 | 0 |
| Cellulitis streptococcal | 1 | 0 |
| Erysipelas | 1 | 0 |
| Meningitis pneumococcal | 2 | 1 |
| Pharyngitis streptococcal | 9 | 0 |
| Pneumonia pneumococcal | 1 | 0 |
| Scarlet fever | 1 | 0 |
| Streptococcal bacteraemia | 1 | 0 |
| Streptococcal infection | 3 | 0 |
| Streptococcal sepsis | 1 | 0 |
| Tonsillitis streptococcal | 1 | 0 |
| <i>Tinea infections</i> | | |
| Body tinea | 8 | 0 |
| Tinea cruris | 3 | 0 |
| Tinea infection | 3 | 0 |
| Tinea pedis | 4 | 0 |
| Tinea versicolour | 2 | 0 |
| <i>Treponema infections</i> | | |
| Neurosyphilis | 1 | 0 |
| Syphilis | 4 | 0 |
| <i>Trypanosomal infections</i> | | |
| African trypanosomiasis | 6 | 0 |
| <i>Tuberculous infections</i> | | |
| Disseminated Bacillus Calmette-Guerin infection | 1 | 0 |
| Erythema induratum | 1 | 0 |
| Lymph node tuberculosis | 3 | 0 |
| Meningitis tuberculous | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections | | |
| Infections cont'd | | |
| Pulmonary tuberculosis | 2 | 0 |
| Tuberculosis | 4 | 0 |
| <i>Upper respiratory tract infections</i> | | |
| Acute sinusitis | 6 | 0 |
| Chronic sinusitis | 17 | 0 |
| Croup infectious | 1 | 0 |
| Epiglottitis | 1 | 0 |
| Laryngitis | 38 | 0 |
| Nasal vestibulitis | 1 | 0 |
| Nasopharyngitis | 1909 | 0 |
| Peritonsillar abscess | 1 | 0 |
| Pharyngeal abscess | 1 | 0 |
| Pharyngitis | 42 | 0 |
| Rhinitis | 55 | 0 |
| Sinobronchitis | 1 | 0 |
| Sinusitis | 392 | 0 |
| Tonsillitis | 89 | 0 |
| Tracheitis | 2 | 0 |
| Upper respiratory tract infection | 10 | 0 |
| <i>Urinary tract infections</i> | | |
| Cystitis | 102 | 0 |
| Genitourinary tract infection | 1 | 0 |
| Kidney infection | 61 | 0 |
| Pyelonephritis | 7 | 0 |
| Pyelonephritis acute | 1 | 0 |
| Pyelonephritis chronic | 1 | 0 |
| Renal abscess | 2 | 0 |
| Urethritis | 1 | 0 |
| Urinary tract infection | 265 | 0 |
| <i>Vascular infections</i> | | |
| Haematoma infection | 2 | 0 |
| Infected lymphocele | 1 | 0 |
| Infected varicose vein | 1 | 0 |
| Lymphangitis | 6 | 0 |
| <i>Viral infections NEC</i> | | |
| Arthritis viral | 2 | 0 |
| Bronchitis viral | 1 | 0 |
| Conjunctivitis viral | 1 | 0 |
| Ear infection viral | 2 | 0 |
| Encephalitis viral | 8 | 0 |
| Eye infection viral | 1 | 0 |
| Gastritis viral | 1 | 0 |
| Gastroenteritis viral | 69 | 0 |
| Gastrointestinal viral infection | 1 | 0 |
| Hepatitis viral | 2 | 0 |
| Meningitis viral | 21 | 0 |
| Pleurisy viral | 1 | 0 |
| Pneumonia viral | 10 | 1 |
| Post viral fatigue syndrome | 144 | 0 |
| Sweating fever | 739 | 0 |
| Vestibular neuronitis | 43 | 0 |
| Viral diarrhoea | 4 | 0 |
| Viral infection | 87 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|--------------|------------|
| Infections Infections cont'd | | |
| Viral labyrinthitis | 7 | 0 |
| Viral myelitis | 1 | 0 |
| Viral myocarditis | 2 | 0 |
| Viral pericarditis | 5 | 0 |
| Viral pharyngitis | 31 | 0 |
| Viral rash | 81 | 0 |
| Viral sepsis | 1 | 0 |
| Viral sinusitis | 1 | 0 |
| Viral tonsillitis | 1 | 0 |
| Viral upper respiratory tract infection | 1 | 0 |
| Infections SOC TOTAL | 19233 | 105 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries | | |
| <i>Abdominal and gastrointestinal injuries NEC</i> | | |
| Abdomen crushing | 3 | 0 |
| Abdominal injury | 1 | 0 |
| Colon injury | 1 | 0 |
| Lip injury | 2 | 0 |
| Mouth injury | 3 | 0 |
| Oral contusion | 13 | 0 |
| Palate injury | 2 | 0 |
| Pelvic bone injury | 1 | 0 |
| Splenic rupture | 4 | 0 |
| Tongue injury | 3 | 0 |
| Tooth fracture | 2 | 0 |
| Tooth injury | 2 | 0 |
| <i>Accidental exposures to product</i> | | |
| Accidental exposure to product | 23 | 0 |
| Accidental exposure to product packaging | 1 | 0 |
| <i>Anaesthetic and allied procedural complications</i> | | |
| Airway complication of anaesthesia | 1 | 0 |
| Anaesthetic complication | 3 | 0 |
| Anaesthetic complication neurological | 1 | 0 |
| Delayed recovery from anaesthesia | 5 | 0 |
| Sedation complication | 4 | 0 |
| <i>Atmospheric pressure injuries</i> | | |
| Barotrauma | 1 | 0 |
| Decompression sickness | 2 | 0 |
| Hypobarism | 3 | 0 |
| <i>Bone and joint injuries NEC</i> | | |
| Bursa injury | 2 | 0 |
| Cartilage injury | 2 | 0 |
| Joint injury | 15 | 0 |
| Synovial rupture | 2 | 0 |
| <i>Cardiac and vascular procedural complications</i> | | |
| Deep vein thrombosis postoperative | 1 | 0 |
| Ischaemic contracture of the left ventricle | 1 | 0 |
| Vascular access site bruising | 1 | 0 |
| Vascular graft occlusion | 1 | 0 |
| Vascular graft thrombosis | 1 | 0 |
| Vascular pseudoaneurysm | 1 | 0 |
| Vasoplegia syndrome | 1 | 0 |
| <i>Cardiovascular injuries</i> | | |
| Vascular injury | 13 | 0 |
| Venous injury | 1 | 0 |
| <i>Cerebral injuries NEC</i> | | |
| Brain contusion | 16 | 0 |
| Brain herniation | 5 | 0 |
| Concussion | 9 | 0 |
| Cranio-cerebral injury | 1 | 0 |
| Epidural haemorrhage | 1 | 0 |
| Extradural haematoma | 2 | 0 |
| Subarachnoid haematoma | 3 | 0 |
| Subdural haematoma | 18 | 1 |
| Subdural haemorrhage | 5 | 0 |
| Traumatic intracranial haemorrhage | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries Injuries cont'd | | |
| <i>Chemical injuries</i> | | |
| Chemical burn | 2 | 0 |
| Chemical burn of oral cavity | 2 | 0 |
| Chemical burn of skin | 7 | 0 |
| Chemical phlebitis | 2 | 0 |
| <i>Chest and respiratory tract injuries NEC</i> | | |
| Asbestosis | 1 | 0 |
| Chest crushing | 14 | 0 |
| Chest injury | 2 | 0 |
| Foreign body in throat | 2 | 0 |
| Traumatic haemothorax | 1 | 0 |
| Traumatic lung injury | 1 | 0 |
| <i>Conditions caused by cold</i> | | |
| Chillblains | 76 | 0 |
| Frostbite | 1 | 0 |
| <i>Cranial nerve injuries</i> | | |
| Cranial nerve injury | 1 | 0 |
| Optic nerve injury | 7 | 0 |
| Vth nerve injury | 1 | 0 |
| <i>Ear injuries NEC</i> | | |
| Deafness traumatic | 1 | 0 |
| <i>Exposures associated with pregnancy, delivery and lactation</i> | | |
| Drug exposure before pregnancy | 1 | 0 |
| Exposure during pregnancy | 17 | 0 |
| Exposure via breast milk | 112 | 0 |
| Foetal exposure during pregnancy | 33 | 0 |
| Maternal exposure before pregnancy | 13 | 0 |
| Maternal exposure during breast feeding | 1372 | 0 |
| Maternal exposure during pregnancy | 371 | 0 |
| Maternal exposure timing unspecified | 2 | 0 |
| Paternal exposure during pregnancy | 2 | 0 |
| <i>Exposures to agents or circumstances NEC</i> | | |
| Exposure to SARS-CoV-2 | 7 | 0 |
| Exposure to household chemicals | 1 | 0 |
| Exposure to toxic agent | 1 | 0 |
| Exposure to vaccinated person | 3 | 0 |
| <i>Eye injuries NEC</i> | | |
| Cataract traumatic | 1 | 0 |
| Eye contusion | 57 | 0 |
| Eye injury | 50 | 0 |
| Eyelid contusion | 5 | 0 |
| Foreign body in eye | 2 | 0 |
| Hyphaema | 1 | 0 |
| Injury corneal | 1 | 0 |
| Periorbital haematoma | 1 | 0 |
| Periorbital haemorrhage | 1 | 0 |
| Retinal injury | 4 | 0 |
| Superficial injury of eye | 1 | 0 |
| Traumatic iritis | 1 | 0 |
| <i>Foetal and neonatal conditions associated with product exposure</i> | | |
| Intoxication by breast feeding | 1 | 0 |
| <i>Fractures and dislocations NEC</i> | | |
| Fracture | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries | | |
| Injuries cont'd | | |
| Joint dislocation | 13 | 0 |
| Multiple fractures | 2 | 0 |
| Stress fracture | 4 | 0 |
| Traumatic fracture | 1 | 0 |
| <i>Gastrointestinal and hepatobiliary procedural complications</i> | | |
| Anastomotic ulcer | 1 | 0 |
| Peripancreatic fluid collection | 1 | 0 |
| Procedural nausea | 27 | 0 |
| Procedural vomiting | 7 | 0 |
| <i>Heat injuries (excl thermal burns)</i> | | |
| Heat cramps | 2 | 0 |
| Heat exhaustion | 4 | 0 |
| Heat illness | 4 | 0 |
| Heat oedema | 13 | 0 |
| Heat stroke | 11 | 0 |
| <i>Intentional product misuses</i> | | |
| Intentional product misuse | 14 | 0 |
| <i>Intentional product use issues</i> | | |
| Intentional dose omission | 20 | 0 |
| Intentional product use issue | 1 | 0 |
| <i>Limb fractures and dislocations</i> | | |
| Ankle fracture | 3 | 0 |
| Atypical femur fracture | 1 | 0 |
| Clavicle fracture | 22 | 0 |
| Femoral neck fracture | 2 | 0 |
| Femur fracture | 2 | 0 |
| Foot fracture | 3 | 0 |
| Humerus fracture | 1 | 0 |
| Lower limb fracture | 3 | 0 |
| Patella fracture | 1 | 0 |
| Tibia fracture | 1 | 0 |
| Upper limb fracture | 3 | 0 |
| Wrist fracture | 3 | 0 |
| <i>Medication errors, product use errors and issues NEC</i> | | |
| Circumstance or information capable of leading to medication error | 14 | 0 |
| Device use issue | 1 | 0 |
| Dose calculation error | 3 | 0 |
| Drug titration error | 1 | 0 |
| Inadequate aseptic technique in use of product | 2 | 0 |
| Intercepted medication error | 5 | 0 |
| Medication error | 97 | 0 |
| Prescription drug used without a prescription | 2 | 0 |
| Product use in unapproved indication | 1 | 0 |
| Product use issue | 8 | 0 |
| Vaccination error | 9 | 0 |
| Wrong device used | 1 | 0 |
| Wrong drug | 5 | 0 |
| Wrong route | 1 | 0 |
| Wrong schedule | 2 | 0 |
| Wrong technique in product usage process | 10 | 0 |
| <i>Muscle, tendon and ligament injuries</i> | | |
| Epicondylitis | 28 | 0 |
| Ligament injury | 3 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries | | |
| Injuries cont'd | | |
| Ligament rupture | 2 | 0 |
| Ligament sprain | 22 | 0 |
| Muscle injury | 64 | 0 |
| Muscle rupture | 19 | 0 |
| Muscle strain | 53 | 0 |
| Post-traumatic neck syndrome | 4 | 0 |
| Repetitive strain injury | 3 | 0 |
| Tendon injury | 6 | 0 |
| Tendon rupture | 29 | 0 |
| <i>Nerve injuries NEC</i> | | |
| Nerve injury | 188 | 0 |
| <i>Neurological and psychiatric procedural complications</i> | | |
| Post lumbar puncture syndrome | 8 | 0 |
| Posterior fossa syndrome | 1 | 0 |
| Procedural dizziness | 37 | 0 |
| <i>Non-occupational environmental exposures</i> | | |
| Exposure to chemical pollution | 1 | 0 |
| Exposure to extreme temperature | 4 | 0 |
| Exposure to noise | 2 | 0 |
| <i>Non-site specific injuries NEC</i> | | |
| Accident | 1 | 0 |
| Animal bite | 1 | 0 |
| Arthropod bite | 7 | 0 |
| Arthropod sting | 13 | 0 |
| Bite | 1 | 0 |
| Child maltreatment syndrome | 1 | 0 |
| Electric shock | 35 | 0 |
| Extraskeletal ossification | 1 | 0 |
| Fall | 287 | 0 |
| Foreign body | 2 | 0 |
| Inflammation of wound | 4 | 0 |
| Injury | 20 | 0 |
| Internal injury | 1 | 0 |
| Nervous system injury | 4 | 0 |
| Post concussion syndrome | 2 | 0 |
| Road traffic accident | 2 | 0 |
| Soft tissue injury | 6 | 0 |
| Sports injury | 1 | 0 |
| Struck by lightning | 1 | 0 |
| Tissue injury | 4 | 0 |
| Traumatic haematoma | 3 | 0 |
| Traumatic shock | 1 | 0 |
| Wound | 10 | 0 |
| Wound complication | 15 | 0 |
| Wound haemorrhage | 11 | 0 |
| Wound secretion | 4 | 0 |
| <i>Non-site specific procedural complications</i> | | |
| Administration related reaction | 1 | 0 |
| Incision site erythema | 1 | 0 |
| Incision site haemorrhage | 1 | 0 |
| Incision site oedema | 1 | 0 |
| Incision site pain | 10 | 0 |
| Infusion related reaction | 19 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Injuries Injuries cont'd | | |
| Injection related reaction | 611 | 0 |
| Needle fatigue | 1 | 0 |
| Post procedural complication | 35 | 0 |
| Post procedural contusion | 2 | 0 |
| Post procedural discomfort | 1 | 0 |
| Post procedural haematoma | 1 | 0 |
| Post procedural haemorrhage | 1 | 0 |
| Procedural hypertension | 1 | 0 |
| Procedural pain | 8 | 0 |
| Procedural site reaction | 1 | 0 |
| Suture related complication | 1 | 0 |
| Occupational exposures | | |
| Occupational exposure to product | 1 | 0 |
| Off label uses | | |
| Off label use | 60 | 0 |
| Overdoses NEC | | |
| Intentional overdose | 14 | 0 |
| Overdose | 58 | 0 |
| Prescribed overdose | 1 | 0 |
| Pathways and sources of exposure | | |
| Exposure via body fluid | 1 | 0 |
| Exposure via partner | 1 | 0 |
| Exposure via unknown route | 1 | 0 |
| Peripheral nerve injuries | | |
| Brachial plexus injury | 2 | 0 |
| Median nerve injury | 2 | 0 |
| Radial nerve injury | 1 | 0 |
| Sciatic nerve injury | 1 | 0 |
| Ulnar nerve injury | 3 | 0 |
| Poisoning and toxicity | | |
| Alcohol poisoning | 3 | 0 |
| Chemical poisoning | 1 | 0 |
| Metal poisoning | 2 | 0 |
| Poisoning | 6 | 0 |
| Systemic toxicity | 2 | 0 |
| Toxicity to various agents | 10 | 0 |
| Product administration errors and issues | | |
| Accidental overdose | 4 | 0 |
| Accidental underdose | 2 | 0 |
| Contraindicated product administered | 5 | 0 |
| Drug administered in wrong device | 1 | 0 |
| Duplicate therapy error | 2 | 0 |
| Expired product administered | 26 | 0 |
| Extra dose administered | 10 | 0 |
| Inappropriate schedule of product administration | 117 | 0 |
| Incomplete course of vaccination | 53 | 0 |
| Incorrect dose administered | 12 | 0 |
| Incorrect product administration duration | 2 | 0 |
| Incorrect product formulation administered | 1 | 0 |
| Incorrect route of product administration | 56 | 0 |
| Intercepted product administration error | 2 | 0 |
| Lack of vaccination site rotation | 1 | 0 |
| Poor quality product administered | 3 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries | | |
| Injuries cont'd | | |
| Product administered at inappropriate site | 23 | 0 |
| Product administered to patient of inappropriate age | 31 | 0 |
| Product administration error | 29 | 0 |
| Product dose omission in error | 2 | 0 |
| Product dose omission issue | 36 | 0 |
| Wrong patient received product | 1 | 0 |
| Wrong product administered | 22 | 0 |
| Product confusion errors and issues | | |
| Product label confusion | 1 | 0 |
| Product name confusion | 2 | 0 |
| Product packaging confusion | 1 | 0 |
| Product dispensing errors and issues | | |
| Product dispensing error | 16 | 0 |
| Product monitoring errors and issues | | |
| Documented hypersensitivity to administered product | 1 | 0 |
| Labelled drug-drug interaction medication error | 1 | 0 |
| Product monitoring error | 1 | 0 |
| Product prescribing errors and issues | | |
| Contraindicated product prescribed | 10 | 0 |
| Product prescribing error | 5 | 0 |
| Product selection errors and issues | | |
| Product selection error | 3 | 0 |
| Product storage errors and issues in the product use system | | |
| Intercepted product storage error | 1 | 0 |
| Product storage error | 7 | 0 |
| Product transcribing errors and communication issues | | |
| Product communication issue | 1 | 0 |
| Radiation injuries | | |
| Sunburn | 53 | 0 |
| Renal and urinary tract injuries NEC | | |
| Bladder injury | 1 | 0 |
| Kidney rupture | 2 | 0 |
| Reproductive system and breast injuries | | |
| Penile contusion | 3 | 0 |
| Penis injury | 1 | 0 |
| Uterine rupture | 1 | 0 |
| Reproductive tract and breast procedural complications | | |
| Ovarian injury | 1 | 0 |
| Postmastectomy lymphoedema syndrome | 1 | 0 |
| Respiratory tract and thoracic cavity procedural complications | | |
| Pulmonary oil microembolism | 2 | 0 |
| Site specific injuries NEC | | |
| Back injury | 7 | 0 |
| Central nervous system injury | 1 | 0 |
| Face crushing | 1 | 0 |
| Face injury | 2 | 0 |
| Head injury | 42 | 0 |
| Limb crushing injury | 9 | 0 |
| Limb injury | 330 | 0 |
| Nasal injury | 2 | 0 |
| Neck crushing | 1 | 0 |
| Neck injury | 3 | 0 |
| Pharyngeal contusion | 3 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Injuries | | |
| Injuries cont'd | | |
| Site specific procedural complications NEC | | |
| Axillary web syndrome | 3 | 0 |
| Skin injuries NEC | | |
| Contusion | 3348 | 0 |
| Hair injury | 2 | 0 |
| Nail injury | 1 | 0 |
| Scar | 44 | 0 |
| Scratch | 6 | 0 |
| Skin abrasion | 6 | 0 |
| Skin injury | 23 | 0 |
| Skin laceration | 5 | 0 |
| Skin pressure mark | 1 | 0 |
| Skin wound | 7 | 0 |
| Subcutaneous haematoma | 3 | 0 |
| Skin procedural complications | | |
| Dermal filler overcorrection | 1 | 0 |
| Recall phenomenon | 2 | 0 |
| Skull fractures, facial bone fractures and dislocations | | |
| Skull fracture | 1 | 0 |
| Spinal cord injuries NEC | | |
| Prevertebral soft tissue swelling of cervical space | 1 | 0 |
| Spinal cord injury | 5 | 0 |
| Spinal cord injury sacral | 1 | 0 |
| Spinal cord injury thoracic | 1 | 0 |
| Spinal fractures and dislocations | | |
| Spinal compression fracture | 3 | 0 |
| Spinal fracture | 9 | 0 |
| Stoma complications | | |
| Gastrointestinal stoma complication | 2 | 0 |
| Stoma obstruction | 1 | 0 |
| Stoma site haemorrhage | 1 | 0 |
| Stoma site pain | 2 | 0 |
| Stoma site rash | 1 | 0 |
| Thermal burns | | |
| Airway burns | 1 | 0 |
| Burn oesophageal | 1 | 0 |
| Burn of internal organs | 4 | 0 |
| Burn oral cavity | 11 | 0 |
| Burns second degree | 11 | 0 |
| Cold burn | 3 | 0 |
| Thermal burn | 54 | 0 |
| Thermal burns of eye | 47 | 0 |
| Thoracic cage fractures and dislocations | | |
| Rib fracture | 1 | 0 |
| Transplantation complications | | |
| Transplant failure | 1 | 0 |
| Underdoses NEC | | |
| Intentional underdose | 1 | 0 |
| Underdose | 10 | 0 |
| Vaccination related complications | | |
| Adverse event following immunisation | 4 | 0 |
| Post vaccination syndrome | 5 | 0 |
| Reaction to previous exposure to any vaccine | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---------------------------------|-------------|----------|
| Injuries Injuries cont'd | | |
| Vaccination complication | 104 | 0 |
| Injuries SOC TOTAL | 9174 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations | | |
| <i>Adrenal cortex tests</i> | | |
| Blood cortisol | 1 | 0 |
| Cortisol decreased | 3 | 0 |
| Cortisol increased | 2 | 0 |
| <i>Adrenal medulla tests</i> | | |
| Epinephrine increased | 1 | 0 |
| Norepinephrine increased | 2 | 0 |
| <i>Auditory and vestibular diagnostic procedures</i> | | |
| Acoustic stimulation tests | 8 | 0 |
| Audiogram | 1 | 0 |
| <i>Autoimmunity analyses</i> | | |
| Anti-sperm antibody | 1 | 0 |
| Antimitochondrial antibody positive | 2 | 0 |
| Antineutrophil cytoplasmic antibody positive | 1 | 0 |
| Antinuclear antibody | 1 | 0 |
| Antinuclear antibody positive | 3 | 0 |
| Antiphospholipid antibodies | 3 | 0 |
| Antiphospholipid antibodies positive | 3 | 0 |
| Cold agglutinins positive | 2 | 0 |
| DNA antibody negative | 1 | 0 |
| DNA antibody positive | 1 | 0 |
| Rheumatoid factor | 3 | 0 |
| Rheumatoid factor increased | 3 | 0 |
| Smooth muscle antibody | 1 | 0 |
| <i>Bacteria identification and serology (excl mycobacteria)</i> | | |
| Bacterial test | 1 | 0 |
| Helicobacter test positive | 1 | 0 |
| Staphylococcus test positive | 1 | 0 |
| Streptococcus test positive | 1 | 0 |
| Treponema test positive | 1 | 0 |
| <i>Blood counts NEC</i> | | |
| Full blood count | 21 | 0 |
| Full blood count abnormal | 12 | 0 |
| Full blood count decreased | 3 | 0 |
| Full blood count increased | 1 | 0 |
| <i>Blood gas and acid base analyses</i> | | |
| Blood gases | 1 | 0 |
| Blood gases abnormal | 1 | 0 |
| Blood lactic acid | 4 | 0 |
| Blood lactic acid increased | 5 | 0 |
| Blood pH | 17 | 0 |
| Blood pH increased | 14 | 0 |
| Carbon dioxide increased | 1 | 0 |
| Oxygen consumption | 2 | 0 |
| Oxygen saturation | 26 | 0 |
| Oxygen saturation abnormal | 2 | 0 |
| Oxygen saturation decreased | 192 | 0 |
| Oxygen saturation normal | 1 | 0 |
| PO2 decreased | 1 | 0 |
| <i>Blood grouping and cross-matching analyses</i> | | |
| Blood group O | 2 | 0 |
| Blood grouping | 1 | 0 |
| Rhesus antigen negative | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations Investigations cont'd | | |
| <i>Bone marrow and immune tissue imaging procedures</i> | | |
| Scan lymph nodes | 2 | 0 |
| <i>Carbohydrate tolerance analyses (incl diabetes)</i> | | |
| Blood glucose | 20 | 0 |
| Blood glucose abnormal | 20 | 0 |
| Blood glucose decreased | 44 | 0 |
| Blood glucose fluctuation | 34 | 0 |
| Blood glucose increased | 191 | 0 |
| Glycosylated haemoglobin increased | 2 | 0 |
| <i>Cardiac auscultatory investigations</i> | | |
| Cardiac murmur | 38 | 0 |
| Heart sounds | 18 | 0 |
| Heart sounds abnormal | 8 | 0 |
| <i>Cardiac function diagnostic procedures</i> | | |
| Cardiac monitoring | 1 | 0 |
| Central venous pressure | 1 | 0 |
| Echocardiogram | 3 | 0 |
| Ejection fraction decreased | 3 | 0 |
| Myocardial strain imaging | 21 | 0 |
| Stroke volume decreased | 2 | 0 |
| Venous pressure jugular increased | 1 | 0 |
| <i>Cardiac imaging procedures</i> | | |
| Magnetic resonance imaging heart | 1 | 0 |
| <i>Cell marker analyses</i> | | |
| Carbohydrate antigen 15-3 | 1 | 0 |
| Carcinoembryonic antigen increased | 2 | 0 |
| Prostatic specific antigen decreased | 1 | 0 |
| Prostatic specific antigen increased | 3 | 0 |
| Tumour marker increased | 1 | 0 |
| <i>Central nervous system histopathology procedures</i> | | |
| Biopsy brain | 1 | 0 |
| <i>Central nervous system imaging procedures</i> | | |
| Brain scan abnormal | 1 | 0 |
| Computerised tomogram head | 28 | 0 |
| Magnetic resonance imaging head | 47 | 0 |
| Magnetic resonance imaging head abnormal | 1 | 0 |
| Scan brain | 1 | 0 |
| <i>Cerebrospinal fluid tests (excl microbiology)</i> | | |
| CSF cell count abnormal | 1 | 0 |
| CSF oligoclonal band present | 1 | 0 |
| CSF pressure | 4 | 0 |
| CSF protein increased | 1 | 0 |
| CSF test abnormal | 1 | 0 |
| CSF white blood cell count increased | 1 | 0 |
| Xanthochromia | 1 | 0 |
| <i>Chemistry analyses NEC</i> | | |
| Histamine abnormal | 4 | 0 |
| Histamine level | 3 | 0 |
| Histamine level increased | 1 | 0 |
| Inflammatory marker decreased | 1 | 0 |
| Inflammatory marker increased | 13 | 0 |
| Serum serotonin increased | 1 | 0 |
| <i>Cholesterol analyses</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| Blood cholesterol increased | 20 | 0 |
| Low density lipoprotein | 1 | 0 |
| Low density lipoprotein increased | 1 | 0 |
| Very low density lipoprotein decreased | 1 | 0 |
| Coagulation and bleeding analyses | | |
| ADAMTS13 activity abnormal | 1 | 0 |
| ADAMTS13 activity decreased | 1 | 0 |
| Activated partial thromboplastin time | 1 | 0 |
| Activated partial thromboplastin time abnormal | 1 | 0 |
| Activated partial thromboplastin time prolonged | 123 | 0 |
| Anti factor VIII antibody positive | 1 | 0 |
| Anti-platelet factor 4 antibody positive | 2 | 0 |
| Bleeding time | 11 | 0 |
| Bleeding time abnormal | 3 | 0 |
| Bleeding time prolonged | 6 | 0 |
| Bleeding time shortened | 2 | 0 |
| Blood fibrinogen abnormal | 2 | 0 |
| Blood fibrinogen decreased | 7 | 0 |
| Blood fibrinogen increased | 2 | 0 |
| Blood thromboplastin | 1 | 0 |
| Blood thromboplastin abnormal | 1 | 0 |
| Clot retraction | 1 | 0 |
| Coagulation factor | 1 | 0 |
| Coagulation factor VIII level decreased | 6 | 0 |
| Coagulation test abnormal | 1 | 0 |
| Coagulation time | 9 | 0 |
| Coagulation time prolonged | 14 | 0 |
| Coagulation time shortened | 4 | 0 |
| Fibrin D dimer | 1 | 0 |
| Fibrin D dimer decreased | 1 | 0 |
| Fibrin D dimer increased | 65 | 0 |
| Heparin-induced thrombocytopenia test positive | 1 | 0 |
| International normalised ratio | 3 | 0 |
| International normalised ratio abnormal | 11 | 0 |
| International normalised ratio decreased | 44 | 0 |
| International normalised ratio fluctuation | 5 | 0 |
| International normalised ratio increased | 90 | 0 |
| Prothrombin level increased | 1 | 0 |
| Prothrombin time | 1 | 0 |
| Prothrombin time prolonged | 1 | 0 |
| Thrombin time | 1 | 0 |
| Thrombin time abnormal | 2 | 0 |
| Digestive enzymes | | |
| Amylase increased | 1 | 0 |
| Lipase increased | 1 | 0 |
| Pancreatic enzymes increased | 1 | 0 |
| ECG investigations | | |
| Cardiac telemetry | 1 | 0 |
| Electrocardiogram | 8 | 0 |
| Electrocardiogram P wave abnormal | 1 | 0 |
| Electrocardiogram QT prolonged | 4 | 0 |
| Electrocardiogram ST segment elevation | 7 | 0 |
| Electrocardiogram ST-T segment abnormal | 6 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations | | |
| Investigations cont'd | | |
| Electrocardiogram T wave inversion | 5 | 0 |
| Electrocardiogram abnormal | 21 | 0 |
| Electrocardiogram change | 2 | 0 |
| Electrocardiogram normal | 1 | 0 |
| Electrocardiogram pacemaker spike | 1 | 0 |
| Exercise electrocardiogram | 1 | 0 |
| Endocrine analyses and imaging NEC | | |
| Hormone level abnormal | 61 | 0 |
| Faecal analyses NEC | | |
| Faecal calprotectin | 1 | 0 |
| Faecal calprotectin increased | 9 | 0 |
| Occult blood | 1 | 0 |
| Stool analysis abnormal | 2 | 0 |
| Fertility analyses | | |
| Semen analysis abnormal | 1 | 0 |
| Semen volume decreased | 2 | 0 |
| Sperm concentration | 1 | 0 |
| Spermatozoa abnormal | 1 | 0 |
| Foetal and neonatal diagnostic procedures | | |
| Foetal heart rate | 1 | 0 |
| Foetal heart rate abnormal | 1 | 0 |
| Fungus identification and serology | | |
| Fungal test | 1 | 0 |
| Gastrointestinal and abdominal imaging procedures | | |
| Barium swallow | 1 | 0 |
| Computerised tomogram abdomen | 4 | 0 |
| Stomach scan | 1 | 0 |
| Gastrointestinal function diagnostic procedures | | |
| Gastric pH | 2 | 0 |
| Gastric pH decreased | 2 | 0 |
| Gastrointestinal stoma output increased | 1 | 0 |
| Swallow study | 3 | 0 |
| Gastrointestinal, pancreatic and APUD hormone analyses | | |
| Blood gastrin | 1 | 0 |
| Blood gastrin normal | 1 | 0 |
| Blood insulin | 4 | 0 |
| Blood insulin abnormal | 1 | 0 |
| Blood insulin decreased | 2 | 0 |
| Blood insulin increased | 3 | 0 |
| Haematological analyses NEC | | |
| Blood viscosity abnormal | 1 | 0 |
| Blood viscosity decreased | 1 | 0 |
| Blood viscosity increased | 3 | 0 |
| Haematology test abnormal | 2 | 0 |
| Plasma viscosity abnormal | 1 | 0 |
| Red blood cell sedimentation rate | 1 | 0 |
| Red blood cell sedimentation rate abnormal | 1 | 0 |
| Red blood cell sedimentation rate increased | 11 | 0 |
| Heart rate and pulse investigations | | |
| Brachial pulse decreased | 1 | 0 |
| Carotid pulse | 1 | 0 |
| Femoral pulse | 1 | 0 |
| Heart rate | 1112 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| Heart rate abnormal | 64 | 0 |
| Heart rate decreased | 140 | 0 |
| Heart rate increased | 2104 | 0 |
| Heart rate irregular | 255 | 0 |
| Heart rate variability decreased | 1 | 0 |
| Heart rate variability increased | 2 | 0 |
| Maximum heart rate | 7 | 0 |
| Maximum heart rate decreased | 1 | 0 |
| Maximum heart rate increased | 2 | 0 |
| Orthostatic heart rate response increased | 1 | 0 |
| Popliteal pulse | 1 | 0 |
| Pulse abnormal | 30 | 0 |
| Pulse absent | 4 | 0 |
| Pulse pressure increased | 3 | 0 |
| Pulse waveform abnormal | 1 | 0 |
| Radial pulse | 1 | 0 |
| Sinus rhythm | 9 | 0 |
| <i>Histopathology procedures NEC</i> | | |
| Biopsy | 1 | 0 |
| Smear test | 1 | 0 |
| <i>Imaging procedures NEC</i> | | |
| Computerised tomogram | 7 | 0 |
| Computerised tomogram normal | 1 | 0 |
| Magnetic resonance imaging | 2 | 0 |
| Magnetic resonance imaging abnormal | 1 | 0 |
| Magnetic resonance imaging whole body | 1 | 0 |
| Scan | 1 | 0 |
| Ultrasound scan | 1 | 0 |
| X-ray | 1 | 0 |
| <i>Immunoglobulin analyses</i> | | |
| Blood immunoglobulin A increased | 1 | 0 |
| Blood immunoglobulin E | 1 | 0 |
| Blood immunoglobulin E increased | 2 | 0 |
| Blood immunoglobulin G | 1 | 0 |
| Blood immunoglobulin M | 1 | 0 |
| Blood immunoglobulin M increased | 2 | 0 |
| Immunoglobulins decreased | 2 | 0 |
| <i>Immunology analyses NEC</i> | | |
| Antibody test | 4 | 0 |
| Antibody test abnormal | 7 | 0 |
| Antibody test negative | 17 | 0 |
| Antibody test positive | 1 | 0 |
| Immunology test | 12 | 0 |
| Immunology test normal | 1 | 0 |
| Mast cell degranulation present | 1 | 0 |
| Tryptase increased | 1 | 0 |
| <i>Immunology skin tests NEC</i> | | |
| Allergy alert test | 3 | 0 |
| Skin test positive | 7 | 0 |
| <i>Investigations NEC</i> | | |
| APACHE II score | 1 | 0 |
| Blood test | 53 | 0 |
| Blood test abnormal | 93 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| Blood test normal | 1 | 0 |
| Laboratory test | 1 | 0 |
| Laboratory test abnormal | 1 | 0 |
| Polymerase chain reaction positive | 2 | 0 |
| Quality of life decreased | 3 | 0 |
| Liver function analyses | | |
| Alanine aminotransferase decreased | 1 | 0 |
| Alanine aminotransferase increased | 32 | 0 |
| Ammonia | 1 | 0 |
| Aspartate aminotransferase | 1 | 0 |
| Aspartate aminotransferase increased | 4 | 0 |
| Bile output | 4 | 0 |
| Blood bilirubin | 1 | 0 |
| Blood bilirubin increased | 6 | 0 |
| Gamma-glutamyltransferase increased | 5 | 0 |
| Hepatic enzyme abnormal | 1 | 0 |
| Hepatic enzyme increased | 15 | 0 |
| Liver function test | 4 | 0 |
| Liver function test abnormal | 54 | 0 |
| Liver function test increased | 17 | 0 |
| Transaminases increased | 12 | 0 |
| Metabolism tests NEC | | |
| Blood ketone body | 10 | 0 |
| Blood ketone body increased | 1 | 0 |
| Blood uric acid increased | 4 | 0 |
| Brain natriuretic peptide increased | 1 | 0 |
| Ubiquinone | 4 | 0 |
| Ubiquinone decreased | 2 | 0 |
| Urine ketone body present | 2 | 0 |
| Microbiology and serology tests NEC | | |
| Blood culture | 2 | 0 |
| Blood culture negative | 1 | 0 |
| Septic screen | 1 | 0 |
| Serology test | 1 | 0 |
| Mineral and electrolyte analyses | | |
| Blood calcium | 2 | 0 |
| Blood calcium increased | 1 | 0 |
| Blood cyanide | 1 | 0 |
| Blood iron | 12 | 0 |
| Blood iron decreased | 29 | 0 |
| Blood iron increased | 5 | 0 |
| Blood magnesium decreased | 3 | 0 |
| Blood phosphorus abnormal | 1 | 0 |
| Blood phosphorus decreased | 7 | 0 |
| Blood phosphorus increased | 4 | 0 |
| Blood potassium decreased | 11 | 0 |
| Blood potassium increased | 9 | 0 |
| Blood sodium | 2 | 0 |
| Blood sodium decreased | 5 | 0 |
| Blood zinc increased | 1 | 0 |
| Iron binding capacity total decreased | 1 | 0 |
| Serum ferritin | 1 | 0 |
| Serum ferritin decreased | 5 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| Serum ferritin increased | 5 | 0 |
| Sweat test | 3 | 0 |
| Transferrin decreased | 1 | 0 |
| Urine copper | 2 | 0 |
| <i>Musculoskeletal and soft tissue imaging procedures</i> | | |
| Bone densitometry | 1 | 0 |
| Discogram abnormal | 1 | 0 |
| Magnetic resonance imaging neck | 1 | 0 |
| Skull X-ray | 12 | 0 |
| X-ray limb | 3 | 0 |
| X-ray limb abnormal | 1 | 0 |
| X-ray of pelvis and hip | 2 | 0 |
| <i>Musculoskeletal and soft tissue tests NEC</i> | | |
| Swollen joint count | 2 | 0 |
| Swollen joint count increased | 4 | 0 |
| Tender joint count | 4 | 0 |
| <i>Mycobacteria identification and serology</i> | | |
| Interferon gamma release assay positive | 2 | 0 |
| <i>Neurologic diagnostic procedures</i> | | |
| Coma scale abnormal | 19 | 0 |
| Electroencephalogram abnormal | 1 | 0 |
| Electromyogram abnormal | 3 | 0 |
| Hoover's sign of leg paresis | 1 | 0 |
| Joint position sense decreased | 2 | 0 |
| Lumbar puncture | 20 | 0 |
| Nerve conduction studies abnormal | 2 | 0 |
| Neurotransmitter level altered | 1 | 0 |
| Sensory level abnormal | 1 | 0 |
| Sleep study normal | 1 | 0 |
| <i>Ophthalmic function diagnostic procedures</i> | | |
| Corneal reflex decreased | 2 | 0 |
| Intraocular pressure increased | 7 | 0 |
| Intraocular pressure test | 8 | 0 |
| Pupillary light reflex tests abnormal | 1 | 0 |
| Retinal function test abnormal | 1 | 0 |
| Visual tracking test | 1 | 0 |
| <i>Parathyroid analyses</i> | | |
| Blood parathyroid hormone decreased | 1 | 0 |
| <i>Physical examination procedures and organ system status</i> | | |
| Body height decreased | 1 | 0 |
| Body surface area | 3 | 0 |
| Body surface area decreased | 1 | 0 |
| Body temperature | 1036 | 0 |
| Body temperature abnormal | 89 | 0 |
| Body temperature decreased | 139 | 0 |
| Body temperature fluctuation | 190 | 0 |
| Body temperature increased | 1158 | 0 |
| Body temperature normal | 3 | 0 |
| Breath sounds | 3 | 0 |
| Breath sounds abnormal | 7 | 0 |
| Dermatologic examination abnormal | 1 | 0 |
| General physical condition abnormal | 4 | 0 |
| Grip strength | 12 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations | | |
| Investigations cont'd | | |
| Grip strength decreased | 37 | 0 |
| Head lag | 19 | 0 |
| Lymph node palpable | 6 | 0 |
| Male genital examination abnormal | 1 | 0 |
| Menstruation normal | 3 | 0 |
| Muscle strength abnormal | 6 | 0 |
| Neurological examination | 1 | 0 |
| Neurological examination abnormal | 1 | 0 |
| Neurological examination normal | 1 | 0 |
| Ophthalmological examination | 3 | 0 |
| Palpatory finding abnormal | 1 | 0 |
| Product residue present | 3 | 0 |
| Psoriasis area severity index decreased | 1 | 0 |
| Psoriasis area severity index increased | 1 | 0 |
| Respiratory rate | 14 | 0 |
| Respiratory rate decreased | 32 | 0 |
| Respiratory rate increased | 81 | 0 |
| Skin temperature | 178 | 0 |
| Temperature difference of extremities | 9 | 0 |
| Urological examination | 1 | 0 |
| Vital signs measurement | 1 | 0 |
| Weight decreased | 231 | 0 |
| Weight increased | 72 | 0 |
| <i>Pituitary analyses anterior</i> | | |
| Blood corticotrophin | 1 | 0 |
| Blood follicle stimulating hormone increased | 2 | 0 |
| Blood prolactin increased | 1 | 0 |
| Blood thyroid stimulating hormone | 2 | 0 |
| Blood thyroid stimulating hormone decreased | 5 | 0 |
| Blood thyroid stimulating hormone increased | 5 | 0 |
| <i>Platelet analyses</i> | | |
| Platelet count | 4 | 0 |
| Platelet count abnormal | 2 | 0 |
| Platelet count decreased | 340 | 1 |
| Platelet count increased | 7 | 0 |
| Platelet count normal | 1 | 0 |
| Platelet morphology abnormal | 1 | 0 |
| Plateletcrit | 1 | 0 |
| <i>Protein analyses NEC</i> | | |
| Blood albumin abnormal | 1 | 0 |
| C-reactive protein | 1 | 0 |
| C-reactive protein abnormal | 3 | 0 |
| C-reactive protein decreased | 2 | 0 |
| C-reactive protein increased | 41 | 0 |
| Protein total | 2 | 0 |
| Protein total abnormal | 1 | 0 |
| Protein total increased | 2 | 0 |
| Zinc sulphate turbidity increased | 1 | 0 |
| <i>Red blood cell analyses</i> | | |
| Haematocrit | 10 | 0 |
| Haematocrit decreased | 1 | 0 |
| Haematocrit increased | 3 | 0 |
| Haemoglobin | 7 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations | | |
| Investigations cont'd | | |
| Haemoglobin decreased | 21 | 0 |
| Haemoglobin increased | 2 | 0 |
| Mean cell haemoglobin concentration | 1 | 0 |
| Mean cell volume abnormal | 2 | 0 |
| Red blood cell count | 3 | 0 |
| Red blood cell count decreased | 2 | 0 |
| Red blood cell count increased | 1 | 0 |
| Red blood cell elliptocytes present | 1 | 0 |
| Red blood cell morphology abnormal | 1 | 0 |
| Red blood cell target cells present | 1 | 0 |
| Renal function analyses | | |
| Blood creatine increased | 1 | 0 |
| Blood creatinine abnormal | 1 | 0 |
| Blood creatinine decreased | 2 | 0 |
| Blood creatinine increased | 3 | 0 |
| Blood urea | 7 | 0 |
| Blood urea increased | 1 | 0 |
| Glomerular filtration rate decreased | 6 | 0 |
| Reproductive hormone analyses | | |
| 17 ketosteroids urine decreased | 1 | 0 |
| Anti-Muellerian hormone level decreased | 4 | 0 |
| Blood oestrogen | 2 | 0 |
| Blood oestrogen increased | 1 | 0 |
| Blood testosterone decreased | 2 | 0 |
| Blood testosterone increased | 1 | 0 |
| Dihydrotestosterone decreased | 1 | 0 |
| False negative pregnancy test | 4 | 0 |
| Female sex hormone level | 1 | 0 |
| Human chorionic gonadotropin decreased | 1 | 0 |
| Oestradiol | 2 | 0 |
| Oestradiol decreased | 1 | 0 |
| Oestriol | 1 | 0 |
| Pregnancy test | 17 | 0 |
| Pregnancy test false positive | 2 | 0 |
| Pregnancy test negative | 2 | 0 |
| Progesterone decreased | 1 | 0 |
| Reproductive organ and breast histopathology procedures | | |
| Biopsy breast | 1 | 0 |
| Biopsy vagina | 1 | 0 |
| Smear cervix | 1 | 0 |
| Reproductive organ and breast imaging procedures | | |
| Mammogram | 1 | 0 |
| Ultrasound scan vagina normal | 1 | 0 |
| Respiratory and pulmonary function diagnostic procedures | | |
| Forced expiratory volume | 2 | 0 |
| Forced expiratory volume decreased | 1 | 0 |
| Forced expiratory volume increased | 14 | 0 |
| Forced expiratory volume normal | 1 | 0 |
| Forced vital capacity decreased | 2 | 0 |
| Fractional exhaled nitric oxide normal | 1 | 0 |
| Maximal voluntary ventilation | 2 | 0 |
| Peak expiratory flow rate | 1 | 0 |
| Peak expiratory flow rate decreased | 7 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations Investigations cont'd | | |
| Pulmonary function test | 4 | 0 |
| Pulmonary function test decreased | 5 | 0 |
| Slow vital capacity | 1 | 0 |
| Total lung capacity decreased | 6 | 0 |
| <i>Respiratory tract and thoracic histopathology procedures</i> | | |
| Sputum abnormal | 3 | 0 |
| <i>Respiratory tract and thoracic imaging procedures</i> | | |
| Chest X-ray | 21 | 0 |
| Computerised tomogram thorax | 4 | 0 |
| Laryngoscopy | 1 | 0 |
| Ventilation/perfusion scan | 1 | 0 |
| <i>Skeletal and cardiac muscle analyses</i> | | |
| Blood creatine phosphokinase increased | 8 | 0 |
| Muscle enzyme increased | 1 | 0 |
| Myocardial necrosis marker | 1 | 0 |
| Myocardial necrosis marker increased | 1 | 0 |
| Troponin | 2 | 0 |
| Troponin I increased | 3 | 0 |
| Troponin T | 1 | 0 |
| Troponin T increased | 1 | 0 |
| Troponin increased | 12 | 0 |
| <i>Skin histopathology procedures</i> | | |
| Biopsy skin | 1 | 0 |
| <i>Special sense investigations NEC</i> | | |
| Olfactory test | 1 | 0 |
| <i>Therapeutic drug monitoring analyses</i> | | |
| Analgesic drug level | 17 | 0 |
| Analgesic drug level increased | 1 | 0 |
| Analgesic drug level therapeutic | 1 | 0 |
| Anticoagulation drug level above therapeutic | 3 | 0 |
| Anticoagulation drug level below therapeutic | 4 | 0 |
| Anticoagulation drug level increased | 1 | 0 |
| Antidepressant drug level decreased | 1 | 0 |
| Drug level increased | 2 | 0 |
| <i>Thyroid analyses</i> | | |
| Anti-thyroid antibody | 1 | 0 |
| Thyroid function test abnormal | 5 | 0 |
| Thyroxine | 1 | 0 |
| Thyroxine abnormal | 1 | 0 |
| Thyroxine increased | 2 | 0 |
| Tri-iodothyronine decreased | 7 | 0 |
| <i>Tissue enzyme analyses NEC</i> | | |
| Blood alkaline phosphatase decreased | 1 | 0 |
| Blood alkaline phosphatase increased | 3 | 0 |
| Blood lactate dehydrogenase | 1 | 0 |
| Blood lactate dehydrogenase increased | 1 | 0 |
| Lactate dehydrogenase urine increased | 1 | 0 |
| <i>Toxicology laboratory analyses</i> | | |
| Blood aluminium | 1 | 0 |
| Blood arsenic normal | 1 | 0 |
| Blood cannabinoids | 1 | 0 |
| Blood carbon monoxide increased | 3 | 0 |
| Blood lead | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations Investigations cont'd | | |
| Drug screen positive | 4 | 0 |
| Heavy metal test | 1 | 0 |
| <i>Triglyceride analyses</i> | | |
| Blood triglycerides | 1 | 0 |
| Blood triglycerides increased | 1 | 0 |
| <i>Urinalysis NEC</i> | | |
| Blood urine | 38 | 0 |
| Blood urine present | 89 | 0 |
| Cells in urine | 2 | 0 |
| Crystal urine | 4 | 0 |
| Glucose urine | 1 | 0 |
| Haemoglobin urine | 1 | 0 |
| Medication crystals in urine present | 1 | 0 |
| Protein urine | 3 | 0 |
| Protein urine present | 1 | 0 |
| Red blood cells urine | 1 | 0 |
| Urea urine increased | 1 | 0 |
| Urine analysis | 1 | 0 |
| Urine analysis abnormal | 16 | 0 |
| Urine analysis normal | 3 | 0 |
| White blood cells urine positive | 1 | 0 |
| pH urine | 10 | 0 |
| pH urine decreased | 2 | 0 |
| pH urine increased | 3 | 0 |
| <i>Urinary tract function analyses NEC</i> | | |
| Urine output | 48 | 0 |
| Urine output decreased | 18 | 0 |
| Urine output increased | 11 | 0 |
| <i>Urinary tract histopathology procedures</i> | | |
| Biopsy kidney | 1 | 0 |
| <i>Urinary tract imaging procedures</i> | | |
| Cystoscopy | 3 | 0 |
| Ultrasound kidney | 1 | 0 |
| <i>Vascular auscultatory investigations</i> | | |
| Abdominal bruit | 1 | 0 |
| Aortic bruit | 1 | 0 |
| Carotid bruit | 1 | 0 |
| <i>Vascular imaging procedures NEC</i> | | |
| Arteriogram carotid | 1 | 0 |
| Venogram | 1 | 0 |
| <i>Vascular tests NEC (incl blood pressure)</i> | | |
| Blood pressure abnormal | 16 | 0 |
| Blood pressure decreased | 103 | 0 |
| Blood pressure diastolic | 1 | 0 |
| Blood pressure diastolic decreased | 1 | 0 |
| Blood pressure diastolic increased | 5 | 0 |
| Blood pressure difference of extremities | 1 | 0 |
| Blood pressure increased | 341 | 0 |
| Blood pressure measurement | 115 | 0 |
| Blood pressure normal | 5 | 0 |
| Blood pressure systolic | 1 | 0 |
| Blood pressure systolic abnormal | 1 | 0 |
| Blood pressure systolic increased | 5 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations | | |
| Investigations cont'd | | |
| Capillary nail refill test | 1 | 0 |
| Pulmonary arterial pressure abnormal | 1 | 0 |
| <i>Virus identification and serology</i> | | |
| Blood HIV RNA increased | 1 | 0 |
| Coronavirus test | 42 | 0 |
| Cytomegalovirus test | 1 | 0 |
| Epstein-Barr virus antibody positive | 1 | 0 |
| HIV antibody negative | 2 | 0 |
| Hepatitis B core antibody positive | 1 | 0 |
| Hepatitis B surface antibody positive | 1 | 0 |
| Herpes virus test | 1 | 0 |
| Human papilloma virus test positive | 1 | 0 |
| SARS-CoV-1 test positive | 1 | 0 |
| SARS-CoV-2 RNA | 1 | 0 |
| SARS-CoV-2 antibody test | 9 | 0 |
| SARS-CoV-2 antibody test negative | 34 | 0 |
| SARS-CoV-2 antibody test positive | 11 | 0 |
| SARS-CoV-2 test | 30 | 0 |
| SARS-CoV-2 test false negative | 5 | 0 |
| SARS-CoV-2 test false positive | 4 | 0 |
| SARS-CoV-2 test negative | 19 | 0 |
| SARS-CoV-2 test positive | 110 | 0 |
| Varicella virus test positive | 1 | 0 |
| Viral load | 1 | 0 |
| Viral test | 4 | 0 |
| Viral test positive | 1 | 0 |
| <i>Vitamin analyses</i> | | |
| Blood folate | 3 | 0 |
| Blood folate abnormal | 1 | 0 |
| Blood folate decreased | 13 | 0 |
| Vitamin B12 | 2 | 0 |
| Vitamin B12 abnormal | 2 | 0 |
| Vitamin B12 decreased | 6 | 0 |
| Vitamin D | 3 | 0 |
| Vitamin D decreased | 6 | 0 |
| Vitamin D increased | 1 | 0 |
| Vitamin E decreased | 1 | 0 |
| <i>Water and electrolyte analyses NEC</i> | | |
| Blood electrolytes decreased | 2 | 0 |
| Blood osmolarity | 1 | 0 |
| Volume blood | 7 | 0 |
| <i>White blood cell analyses</i> | | |
| CD4 lymphocytes decreased | 1 | 0 |
| Eosinophil count | 1 | 0 |
| Eosinophil count abnormal | 2 | 0 |
| Eosinophil count decreased | 1 | 0 |
| Eosinophil count increased | 7 | 0 |
| Lymphocyte count | 3 | 0 |
| Lymphocyte count abnormal | 1 | 0 |
| Lymphocyte count decreased | 6 | 0 |
| Lymphocyte count increased | 3 | 0 |
| Monocyte count increased | 1 | 0 |
| Mononuclear cell count abnormal | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|--------------|----------|
| Investigations Investigations cont'd | | |
| Neutrophil count | 4 | 0 |
| Neutrophil count abnormal | 1 | 0 |
| Neutrophil count decreased | 20 | 0 |
| Neutrophil count increased | 1 | 0 |
| Neutrophil toxic granulation present | 1 | 0 |
| White blood cell count | 21 | 0 |
| White blood cell count decreased | 36 | 0 |
| White blood cell count increased | 14 | 0 |
| White blood cell count normal | 1 | 0 |
| Investigations SOC TOTAL | 11304 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Appetite disorder | 38 | 0 |
| Decreased appetite | 6449 | 0 |
| Diet refusal | 2 | 0 |
| Eating disorder symptom | 1 | 0 |
| Food craving | 26 | 0 |
| Food refusal | 42 | 0 |
| Hyperphagia | 10 | 0 |
| Hypophagia | 38 | 0 |
| Increased appetite | 60 | 0 |
| Salt craving | 4 | 0 |
| <i>Calcium metabolism disorders</i> | | |
| Hypercalcaemia | 2 | 0 |
| Hypocalcaemia | 8 | 0 |
| Tetany | 1 | 0 |
| <i>Copper metabolism disorders</i> | | |
| Copper deficiency | 1 | 0 |
| <i>Diabetes mellitus (incl subtypes)</i> | | |
| Diabetes mellitus | 115 | 0 |
| Diabetes mellitus inadequate control | 29 | 0 |
| Increased insulin requirement | 1 | 0 |
| Insulin resistant diabetes | 1 | 0 |
| Steroid diabetes | 1 | 0 |
| Type 1 diabetes mellitus | 25 | 0 |
| Type 2 diabetes mellitus | 5 | 0 |
| <i>Diabetic complications NEC</i> | | |
| Diabetic ketoacidosis | 40 | 2 |
| Diabetic ketosis | 5 | 0 |
| Euglycaemic diabetic ketoacidosis | 1 | 0 |
| <i>Diabetic complications neurological</i> | | |
| Hyperglycaemic hyperosmolar nonketotic syndrome | 2 | 0 |
| <i>Disorders of purine metabolism</i> | | |
| Gout | 183 | 0 |
| <i>Electrolyte imbalance NEC</i> | | |
| Electrolyte imbalance | 4 | 0 |
| Fluid imbalance | 1 | 0 |
| Hyperosmolar state | 1 | 0 |
| <i>Fat soluble vitamin deficiencies and disorders</i> | | |
| Vitamin D deficiency | 16 | 0 |
| <i>Fluid intake decreased</i> | | |
| Fluid intake reduced | 10 | 0 |
| <i>Fluid intake increased</i> | | |
| Polydipsia | 14 | 0 |
| <i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i> | | |
| Alcohol intolerance | 14 | 0 |
| Dairy intolerance | 5 | 0 |
| Food intolerance | 23 | 0 |
| Gluten sensitivity | 4 | 0 |
| Histamine intolerance | 4 | 0 |
| <i>General nutritional disorders NEC</i> | | |
| Abnormal loss of weight | 77 | 0 |
| Abnormal weight gain | 37 | 0 |
| Cachexia | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Metabolic disorders Metabolic disorders cont'd | | |
| Feeding disorder | 212 | 0 |
| Food aversion | 57 | 0 |
| Neonatal insufficient breast milk syndrome | 4 | 0 |
| Obesity | 1 | 0 |
| Overfeeding of infant | 1 | 0 |
| Overweight | 2 | 0 |
| Poor feeding infant | 17 | 0 |
| Starvation | 1 | 0 |
| Underweight | 2 | 0 |
| Weight loss poor | 4 | 0 |
| Hyperglycaemic conditions NEC | | |
| Glucose tolerance impaired | 4 | 0 |
| Hyperglycaemia | 131 | 0 |
| Insulin resistance | 9 | 0 |
| Metabolic syndrome | 1 | 0 |
| Hyperlipidaemias NEC | | |
| Hyperlipidaemia | 4 | 0 |
| Hypoglycaemic conditions NEC | | |
| Hyperinsulinaemic hypoglycaemia | 1 | 0 |
| Hypoglycaemia | 104 | 0 |
| Hypoglycaemia unawareness | 2 | 0 |
| Postprandial hypoglycaemia | 2 | 0 |
| Iron deficiencies | | |
| Iron deficiency | 16 | 0 |
| Iron excess | | |
| Iron overload | 1 | 0 |
| Lipid metabolism and deposit disorders NEC | | |
| Lipoedema | 1 | 0 |
| Magnesium metabolism disorders | | |
| Hypomagnesaemia | 1 | 0 |
| Metabolic acidoses (excl diabetic acidoses) | | |
| Hyperlactacidaemia | 2 | 0 |
| Ketoacidosis | 1 | 0 |
| Ketosis | 6 | 0 |
| Lactic acidosis | 3 | 0 |
| Metabolic acidosis | 13 | 0 |
| Metabolic disorders NEC | | |
| Hypometabolism | 1 | 0 |
| Metabolic disorder | 2 | 0 |
| Mixed acid-base disorders | | |
| Acidosis | 5 | 0 |
| Phosphorus metabolism disorders | | |
| Hypophosphataemia | 2 | 0 |
| Potassium imbalance | | |
| Hyperkalaemia | 6 | 0 |
| Hypokalaemia | 6 | 0 |
| Hypokalaemic syndrome | 2 | 0 |
| Protein metabolism disorders NEC | | |
| Hypoalbuminaemia | 1 | 0 |
| Sodium imbalance | | |
| Hypernatraemia | 3 | 0 |
| Hyponatraemia | 29 | 0 |
| Hyponatraemic syndrome | 4 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Metabolic disorders <small>Metabolic disorders cont'd</small> | | |
| <i>Sugar intolerance (excl glucose intolerance)</i> | | |
| Lactose intolerance | 6 | 0 |
| <i>Total fluid volume decreased</i> | | |
| Dehydration | 693 | 0 |
| Hypovolaemia | 2 | 0 |
| <i>Total fluid volume increased</i> | | |
| Fluid retention | 96 | 0 |
| Hypervolaemia | 12 | 0 |
| <i>Vitamin deficiencies NEC</i> | | |
| Hypovitaminosis | 3 | 0 |
| <i>Water soluble vitamin deficiencies</i> | | |
| Folate deficiency | 12 | 0 |
| Vitamin B complex deficiency | 1 | 0 |
| Vitamin B12 deficiency | 15 | 0 |
| Metabolic disorders SOC TOTAL | 8806 | 3 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Muscle & tissue disorders | | |
| <i>Arthropathies NEC</i> | | |
| Arthritis | 599 | 0 |
| Arthritis enteropathic | 2 | 0 |
| Arthropathy | 40 | 0 |
| Autoimmune arthritis | 11 | 0 |
| Haemarthrosis | 9 | 0 |
| Oligoarthritis | 1 | 0 |
| Palindromic rheumatism | 7 | 0 |
| Polyarthritis | 19 | 0 |
| Rheumatic fever | 8 | 0 |
| Sacroiliitis | 4 | 0 |
| Seronegative arthritis | 3 | 0 |
| Sympathetic posterior cervical syndrome | 1 | 0 |
| <i>Bone disorders NEC</i> | | |
| Bone disorder | 3 | 0 |
| Bone erosion | 1 | 0 |
| Bone loss | 2 | 0 |
| Exostosis | 2 | 0 |
| Jaw disorder | 5 | 0 |
| Medial tibial stress syndrome | 9 | 0 |
| Osteitis | 12 | 0 |
| Osteonecrosis | 3 | 0 |
| Osteonecrosis of jaw | 4 | 0 |
| Osteosclerosis | 2 | 0 |
| Spinal disorder | 2 | 0 |
| <i>Bone related signs and symptoms</i> | | |
| Bone pain | 1087 | 0 |
| Bone swelling | 8 | 0 |
| Coccydynia | 8 | 0 |
| Pain in jaw | 620 | 0 |
| Pubic pain | 1 | 0 |
| Spinal pain | 266 | 0 |
| <i>Bursal disorders</i> | | |
| Bursitis | 216 | 0 |
| <i>Cartilage disorders</i> | | |
| Chondritis | 1 | 0 |
| Chondropathy | 2 | 0 |
| Costochondritis | 89 | 0 |
| Osteochondrosis | 1 | 0 |
| Polychondritis | 1 | 0 |
| <i>Connective tissue disorders NEC</i> | | |
| Collagen disorder | 2 | 0 |
| Connective tissue disorder | 3 | 0 |
| Eosinophilic fasciitis | 1 | 0 |
| Mixed connective tissue disease | 1 | 0 |
| Morphoea | 3 | 0 |
| Polymyalgia rheumatica | 99 | 0 |
| Reynold's syndrome | 6 | 0 |
| Scleroderma | 4 | 0 |
| Sjogren's syndrome | 4 | 0 |
| Systemic scleroderma | 1 | 0 |
| <i>Crystal arthropathic disorders</i> | | |
| Chondrocalcinosis pyrophosphate | 4 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Muscle & tissue disorders | | |
| Muscle & tissue disorders cont'd | | |
| Gouty tophus | 1 | 0 |
| Epiphyseal disorders | | |
| Epiphyses premature fusion | 1 | 0 |
| Extremity deformities | | |
| Acquired claw toe | 1 | 0 |
| Elbow deformity | 1 | 0 |
| Finger deformity | 4 | 0 |
| Foot deformity | 5 | 0 |
| Hand deformity | 4 | 0 |
| Knee deformity | 1 | 0 |
| Limb deformity | 9 | 0 |
| Wrist deformity | 2 | 0 |
| Fractures NEC | | |
| Osteoporotic fracture | 3 | 0 |
| Pathological fracture | 1 | 0 |
| Intervertebral disc disorders NEC | | |
| Intervertebral disc degeneration | 3 | 0 |
| Intervertebral disc protrusion | 10 | 0 |
| Joint related disorders NEC | | |
| Ankle impingement | 1 | 0 |
| Femoroacetabular impingement | 2 | 0 |
| Hypermobility syndrome | 3 | 0 |
| Joint adhesion | 1 | 0 |
| Joint ankylosis | 2 | 0 |
| Joint contracture | 1 | 0 |
| Joint instability | 3 | 0 |
| Joint laxity | 6 | 0 |
| Joint lock | 60 | 0 |
| Ligament laxity | 1 | 0 |
| Patellofemoral pain syndrome | 7 | 0 |
| Periarthritis | 475 | 0 |
| Rotator cuff syndrome | 93 | 0 |
| Temporomandibular joint syndrome | 22 | 0 |
| Joint related signs and symptoms | | |
| Arthralgia | 23107 | 0 |
| Jaw clicking | 5 | 0 |
| Joint effusion | 10 | 0 |
| Joint noise | 52 | 0 |
| Joint range of motion decreased | 6 | 0 |
| Joint stiffness | 471 | 0 |
| Joint swelling | 1063 | 0 |
| Joint vibration | 6 | 0 |
| Joint warmth | 38 | 0 |
| Loose body in joint | 1 | 0 |
| Ligament disorders | | |
| Ligament pain | 11 | 0 |
| Lupus erythematosus (incl subtypes) | | |
| Lupus-like syndrome | 2 | 0 |
| Systemic lupus erythematosus | 37 | 0 |
| Metabolic bone disorders | | |
| Dwarfism | 1 | 0 |
| Osteopenia | 2 | 0 |
| Osteoporosis | 12 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Muscle & tissue disorders | | |
| <i>Muscle & tissue disorders cont'd</i> | | |
| <i>Muscle infections and inflammations</i> | | |
| Autoimmune myositis | 1 | 0 |
| Myositis | 53 | 0 |
| Polymyositis | 4 | 0 |
| <i>Muscle pains</i> | | |
| Fibromyalgia | 300 | 0 |
| Myalgia | 26834 | 0 |
| Myalgia intercostal | 3 | 0 |
| Myofascial pain syndrome | 26 | 0 |
| <i>Muscle related signs and symptoms NEC</i> | | |
| Haematoma muscle | 3 | 0 |
| Muscle atrophy | 37 | 0 |
| Muscle discomfort | 21 | 0 |
| Muscle disorder | 12 | 0 |
| Muscle fatigue | 1003 | 0 |
| Muscle haemorrhage | 5 | 0 |
| Muscle hypertrophy | 1 | 0 |
| Muscle mass | 12 | 0 |
| Muscle oedema | 2 | 0 |
| Muscle spasms | 3551 | 0 |
| Muscle swelling | 33 | 0 |
| Muscle tightness | 195 | 0 |
| Muscle twitching | 597 | 0 |
| <i>Muscle tone abnormalities</i> | | |
| Muscle rigidity | 53 | 0 |
| Nuchal rigidity | 18 | 0 |
| Torticollis | 13 | 0 |
| Trismus | 55 | 0 |
| <i>Muscle weakness conditions</i> | | |
| Muscular weakness | 2226 | 0 |
| Sarcopenia | 1 | 0 |
| <i>Musculoskeletal and connective tissue conditions NEC</i> | | |
| Back disorder | 4 | 0 |
| Extremity contracture | 2 | 0 |
| Infantile back arching | 1 | 0 |
| Limb mass | 18 | 0 |
| Mandibular mass | 1 | 0 |
| Mastication disorder | 9 | 0 |
| Mobility decreased | 170 | 0 |
| Muscle contracture | 5 | 0 |
| Musculoskeletal disorder | 3 | 0 |
| Musculoskeletal stiffness | 2394 | 0 |
| Posture abnormal | 3 | 0 |
| Somatic dysfunction | 1 | 0 |
| Weight bearing difficulty | 13 | 0 |
| Winged scapula | 1 | 0 |
| <i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i> | | |
| Facial asymmetry | 3 | 0 |
| Head deformity | 1 | 0 |
| <i>Musculoskeletal and connective tissue infections and inflammations NEC</i> | | |
| Connective tissue inflammation | 4 | 0 |
| Dactylitis | 3 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Muscle & tissue disorders | | |
| Muscle & tissue disorders cont'd | | |
| Dupuytren's contracture | 4 | 0 |
| Fasciitis | 1 | 0 |
| Plantar fasciitis | 14 | 0 |
| Musculoskeletal and connective tissue pain and discomfort | | |
| Amplified musculoskeletal pain syndrome | 1 | 0 |
| Back pain | 5892 | 0 |
| Flank pain | 95 | 0 |
| Growing pains | 8 | 0 |
| Limb discomfort | 2373 | 0 |
| Musculoskeletal chest pain | 424 | 0 |
| Musculoskeletal discomfort | 156 | 0 |
| Musculoskeletal pain | 168 | 0 |
| Neck pain | 3145 | 0 |
| Pain in extremity | 22292 | 0 |
| Rheumatic disorder | 29 | 0 |
| Sacral pain | 6 | 0 |
| Myopathies | | |
| Compartment syndrome | 6 | 0 |
| Muscle necrosis | 1 | 0 |
| Myopathy | 6 | 0 |
| Rhabdomyolysis | 10 | 1 |
| Osteoarthropathies | | |
| Nodal osteoarthritis | 1 | 0 |
| Osteoarthritis | 100 | 0 |
| Spinal osteoarthritis | 10 | 0 |
| Psoriatic arthropathies | | |
| Psoriatic arthropathy | 31 | 0 |
| Rheumatoid arthropathies | | |
| Felty's syndrome | 1 | 0 |
| Juvenile idiopathic arthritis | 2 | 0 |
| Rheumatoid arthritis | 198 | 0 |
| Rheumatoid nodule | 1 | 0 |
| Still's disease | 6 | 0 |
| Soft tissue disorders NEC | | |
| Axillary mass | 83 | 0 |
| Clubbing | 1 | 0 |
| Fistula | 3 | 0 |
| Groin pain | 233 | 0 |
| Neck mass | 26 | 0 |
| Soft tissue disorder | 3 | 0 |
| Soft tissue mass | 3 | 0 |
| Soft tissue swelling | 7 | 0 |
| Spine and neck deformities | | |
| Kyphosis | 6 | 0 |
| Scoliosis | 4 | 0 |
| Spinal stenosis | 3 | 0 |
| Spondyloarthropathies | | |
| Ankylosing spondylitis | 33 | 0 |
| Arthritis reactive | 63 | 0 |
| Axial spondyloarthritis | 2 | 0 |
| Spondylitis | 7 | 0 |
| Synovial disorders | | |
| Synovial cyst | 14 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|---------------|----------|
| Muscle & tissue disorders | | |
| Muscle & tissue disorders cont'd | | |
| Synovitis | 19 | 0 |
| <i>Tendon disorders</i> | | |
| Enthesopathy | 1 | 0 |
| Tendon discomfort | 4 | 0 |
| Tendon disorder | 9 | 0 |
| Tendon pain | 47 | 0 |
| Tendon sheath disorder | 1 | 0 |
| Tendonitis | 107 | 0 |
| Tenosynovitis | 3 | 0 |
| Tenosynovitis stenosaurs | 4 | 0 |
| Trigger finger | 36 | 0 |
| Muscle & tissue disorders SOC TOTAL | 102122 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Neoplasms | | |
| <i>Anal canal neoplasms malignant</i> | | |
| Anal cancer | 1 | 0 |
| <i>Aural neoplasms benign</i> | | |
| Benign ear neoplasm | 1 | 0 |
| <i>B-cell lymphomas NEC</i> | | |
| B-cell lymphoma | 2 | 0 |
| Follicular lymphoma | 2 | 0 |
| <i>Bile duct neoplasms malignant</i> | | |
| Bile duct cancer | 1 | 0 |
| Cholangiocarcinoma | 1 | 0 |
| <i>Bladder neoplasms malignant</i> | | |
| Bladder cancer | 1 | 0 |
| <i>Bone neoplasms malignant (excl sarcomas)</i> | | |
| Bone cancer | 2 | 0 |
| <i>Breast and nipple neoplasms benign</i> | | |
| Benign breast neoplasm | 3 | 0 |
| Fibroadenoma of breast | 1 | 0 |
| <i>Breast and nipple neoplasms malignant</i> | | |
| Breast cancer | 55 | 0 |
| Breast cancer female | 1 | 0 |
| Breast cancer in situ | 1 | 0 |
| Breast cancer male | 3 | 0 |
| Breast cancer metastatic | 1 | 0 |
| Breast cancer stage I | 1 | 0 |
| Breast cancer stage III | 3 | 0 |
| Breast cancer stage IV | 1 | 0 |
| Intraductal proliferative breast lesion | 1 | 0 |
| <i>Cardiovascular neoplasms benign</i> | | |
| Haemangioma | 7 | 0 |
| <i>Central nervous system neoplasms malignant NEC</i> | | |
| Brain cancer metastatic | 3 | 0 |
| Brain neoplasm malignant | 2 | 0 |
| <i>Cervix neoplasms benign</i> | | |
| Cervix warts | 1 | 0 |
| <i>Cervix neoplasms malignant</i> | | |
| Cervix carcinoma | 3 | 0 |
| <i>Colorectal neoplasms malignant</i> | | |
| Colon cancer | 1 | 0 |
| Colorectal cancer | 3 | 0 |
| <i>Endocrine neoplasms benign NEC</i> | | |
| Pituitary tumour benign | 2 | 0 |
| <i>Endocrine neoplasms malignant and unspecified NEC</i> | | |
| Neuroendocrine tumour | 1 | 0 |
| <i>Endometrial neoplasms malignant</i> | | |
| Clear cell endometrial carcinoma | 1 | 0 |
| Endometrial cancer | 2 | 0 |
| <i>Gastrointestinal neoplasms benign NEC</i> | | |
| Gastrointestinal tract adenoma | 1 | 0 |
| <i>Gastrointestinal neoplasms malignant NEC</i> | | |
| Gastrointestinal carcinoma | 6 | 0 |
| <i>Glial tumours malignant</i> | | |
| Glioblastoma | 4 | 0 |
| Glioblastoma multiforme | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Neoplasms Neoplasms cont'd | | |
| <i>Haematologic neoplasms NEC</i> | | |
| Benign lymph node neoplasm | 1 | 0 |
| Haematological malignancy | 2 | 0 |
| Systemic mastocytosis | 1 | 0 |
| <i>Hepatic neoplasms malignant</i> | | |
| Hepatocellular carcinoma | 4 | 0 |
| <i>Hepatobiliary neoplasms malignancy unspecified</i> | | |
| Hepatic neoplasm | 1 | 0 |
| <i>Hepatoblastomas</i> | | |
| Hepatoblastoma | 1 | 0 |
| <i>Hodgkin's disease NEC</i> | | |
| Hodgkin's disease | 2 | 0 |
| <i>Leiomyosarcomas</i> | | |
| Pleomorphic leiomyosarcoma | 1 | 0 |
| <i>Leukaemias NEC</i> | | |
| Leukaemia | 4 | 0 |
| Leukaemia recurrent | 1 | 0 |
| <i>Leukaemias acute myeloid</i> | | |
| Acute myeloid leukaemia | 4 | 1 |
| <i>Leukaemias chronic lymphocytic</i> | | |
| Chronic lymphocytic leukaemia | 7 | 0 |
| <i>Leukaemias chronic myeloid</i> | | |
| Chronic myeloid leukaemia | 1 | 0 |
| <i>Leukaemias myeloid NEC</i> | | |
| Myeloid leukaemia | 1 | 0 |
| <i>Lip and oral cavity neoplasms benign</i> | | |
| Papillary cystadenoma lymphomatosum | 1 | 0 |
| <i>Lip and oral cavity neoplasms malignant</i> | | |
| Lip and/or oral cavity cancer | 1 | 0 |
| Squamous cell carcinoma of the oral cavity | 2 | 0 |
| <i>Lymphomas unspecified NEC</i> | | |
| Lymphoma | 21 | 0 |
| <i>Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)</i> | | |
| Epstein Barr virus positive mucocutaneous ulcer | 1 | 0 |
| Histiocytic necrotising lymphadenitis | 1 | 0 |
| Lymphoproliferative disorder | 1 | 0 |
| Lymphoproliferative disorder in remission | 1 | 0 |
| <i>Mediastinal neoplasms malignancy unspecified NEC</i> | | |
| Good syndrome | 4 | 0 |
| <i>Metastases to specified sites</i> | | |
| Metastases to bone | 2 | 0 |
| Metastases to central nervous system | 1 | 1 |
| Metastases to liver | 1 | 0 |
| Metastases to lung | 1 | 1 |
| <i>Metastases to unknown and unspecified sites</i> | | |
| Metastasis | 4 | 1 |
| <i>Myelodysplastic syndromes</i> | | |
| Myelodysplastic syndrome | 1 | 0 |
| <i>Myeloproliferative disorders (excl leukaemias)</i> | | |
| Essential thrombocythaemia | 2 | 0 |
| <i>Neoplasms benign site unspecified NEC</i> | | |
| Fibroma | 1 | 0 |
| <i>Neoplasms malignant site unspecified NEC</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Neoplasms <i>Neoplasms cont'd</i> | | |
| Adenocarcinoma | 2 | 0 |
| Malignant neoplasm progression | 1 | 0 |
| Metastatic neoplasm | 3 | 0 |
| Neoplasm malignant | 12 | 2 |
| Recurrent cancer | 1 | 0 |
| Squamous cell carcinoma | 4 | 0 |
| <i>Neoplasms unspecified malignancy and site unspecified NEC</i> | | |
| Neoplasm | 1 | 0 |
| Neoplasm recurrence | 8 | 0 |
| <i>Nervous system neoplasms unspecified malignancy NEC</i> | | |
| Brain neoplasm | 8 | 1 |
| Meningioma | 5 | 0 |
| Schwannoma | 1 | 0 |
| <i>Neuromas</i> | | |
| Acoustic neuroma | 5 | 0 |
| <i>Non-Hodgkin's lymphomas NEC</i> | | |
| Cutaneous lymphoma | 1 | 0 |
| Non-Hodgkin's lymphoma | 1 | 0 |
| <i>Non-small cell neoplasms malignant of the respiratory tract cell type specified</i> | | |
| Lung adenocarcinoma | 1 | 1 |
| <i>Ocular neoplasms benign</i> | | |
| Eye naevus | 4 | 0 |
| <i>Oesophageal neoplasms malignant</i> | | |
| Oesophageal cancer metastatic | 6 | 0 |
| Oesophageal carcinoma | 4 | 0 |
| Oesophageal squamous cell carcinoma | 1 | 0 |
| <i>Oncologic complications and emergencies</i> | | |
| Cancer fatigue | 4 | 0 |
| Cancer pain | 2 | 0 |
| Intracranial tumour haemorrhage | 1 | 0 |
| <i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i> | | |
| Tonsil cancer | 4 | 0 |
| <i>Ovarian neoplasms malignant (excl germ cell)</i> | | |
| Ovarian cancer | 10 | 0 |
| Ovarian cancer recurrent | 2 | 0 |
| Ovarian cancer stage IV | 1 | 0 |
| <i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i> | | |
| Pancreatic carcinoma | 5 | 0 |
| Pancreatic carcinoma metastatic | 1 | 0 |
| <i>Paranasal sinus and nasal cavity neoplasms malignant and unspecified</i> | | |
| Nasal cavity cancer | 1 | 0 |
| <i>Penile neoplasms malignant</i> | | |
| Penile cancer | 1 | 0 |
| <i>Plasma cell myelomas</i> | | |
| Plasma cell myeloma | 3 | 0 |
| Plasmacytoma | 1 | 0 |
| <i>Plasma cell neoplasms NEC</i> | | |
| Hypergammaglobulinaemia benign monoclonal | 2 | 0 |
| <i>Prostatic neoplasms malignant</i> | | |
| Prostate cancer | 8 | 0 |
| <i>Renal neoplasms malignant</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Neoplasms Neoplasms cont'd | | |
| Clear cell renal cell carcinoma | 2 | 0 |
| Metastatic renal cell carcinoma | 1 | 0 |
| Renal cancer | 2 | 0 |
| Reproductive neoplasms female benign NEC | | |
| Benign hydatidiform mole | 1 | 0 |
| Reproductive neoplasms male benign NEC | | |
| Testicle adenoma | 2 | 0 |
| Respiratory tract and pleural neoplasms malignancy unspecified NEC | | |
| Maxillofacial sinus neoplasm | 1 | 0 |
| Respiratory tract and pleural neoplasms malignant cell type unspecified NEC | | |
| Bronchial carcinoma | 4 | 0 |
| Lung cancer metastatic | 1 | 0 |
| Lung neoplasm malignant | 15 | 0 |
| Throat cancer | 1 | 0 |
| Respiratory tract small cell carcinomas | | |
| Small cell lung cancer | 1 | 0 |
| Salivary gland neoplasms malignant | | |
| Salivary gland cancer stage 0 | 1 | 0 |
| Salivary gland cancer stage III | 1 | 0 |
| Skin melanomas (excl ocular) | | |
| Acral lentiginous melanoma stage III | 1 | 0 |
| Malignant melanoma | 4 | 0 |
| Malignant melanoma in situ | 3 | 0 |
| Metastatic malignant melanoma | 1 | 0 |
| Skin neoplasms benign | | |
| Acrochordon | 7 | 0 |
| Anogenital warts | 4 | 0 |
| Haemangioma of skin | 18 | 0 |
| Melanocytic naevus | 5 | 0 |
| Seborrhoeic keratosis | 2 | 0 |
| Skin papilloma | 31 | 0 |
| Skin neoplasms malignant and unspecified (excl melanoma) | | |
| Basal cell carcinoma | 6 | 0 |
| Bowen's disease | 1 | 0 |
| Neoplasm skin | 1 | 0 |
| Skin cancer | 8 | 0 |
| Squamous cell carcinoma of skin | 1 | 0 |
| Soft tissue neoplasms benign NEC | | |
| Knuckle pads | 1 | 0 |
| Lipoma | 10 | 0 |
| Thyroid neoplasms benign | | |
| Benign neoplasm of thyroid gland | 1 | 0 |
| Thyroid adenoma | 1 | 0 |
| Uterine neoplasms benign | | |
| Uterine leiomyoma | 19 | 0 |
| Uterine neoplasms malignant NEC | | |
| Uterine cancer | 4 | 0 |
| Vulval neoplasms malignant | | |
| Squamous cell carcinoma of the vulva | 1 | 0 |
| Vulval cancer | 1 | 0 |
| Neoplasms SOC TOTAL | 476 | 8 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Abnormal reflexes</i> | | |
| Areflexia | 35 | 0 |
| Extensor plantar response | 3 | 0 |
| Hyperreflexia | 9 | 0 |
| Hyporeflexia | 22 | 0 |
| Poor sucking reflex | 4 | 0 |
| Reflexes abnormal | 1 | 0 |
| <i>Abnormal sleep-related events</i> | | |
| Sleep paralysis | 25 | 0 |
| <i>Absence seizures</i> | | |
| Petit mal epilepsy | 42 | 0 |
| <i>Acute polyneuropathies</i> | | |
| Acute motor axonal neuropathy | 6 | 0 |
| Acute polyneuropathy | 3 | 0 |
| Guillain-Barre syndrome | 468 | 4 |
| Miller Fisher syndrome | 27 | 0 |
| Subacute inflammatory demyelinating polyneuropathy | 4 | 0 |
| <i>Alzheimer's disease (incl subtypes)</i> | | |
| Dementia Alzheimer's type | 1 | 0 |
| Mixed dementia | 1 | 0 |
| <i>Autonomic nervous system disorders</i> | | |
| Autonomic nervous system imbalance | 21 | 0 |
| Autonomic neuropathy | 2 | 0 |
| Horner's syndrome | 2 | 0 |
| Orthostatic intolerance | 8 | 0 |
| <i>Central nervous system aneurysms and dissections</i> | | |
| Carotid artery aneurysm | 1 | 0 |
| Carotid artery dissection | 1 | 0 |
| Intracranial aneurysm | 3 | 1 |
| Vertebral artery dissection | 3 | 0 |
| <i>Central nervous system haemorrhages and cerebrovascular accidents</i> | | |
| Basal ganglia haemorrhage | 3 | 0 |
| Basal ganglia stroke | 1 | 0 |
| Basilar artery occlusion | 1 | 0 |
| Basilar artery thrombosis | 4 | 1 |
| Brain stem embolism | 1 | 1 |
| Brain stem haemorrhage | 5 | 1 |
| Brain stem infarction | 2 | 2 |
| Brain stem stroke | 8 | 2 |
| Brain stem thrombosis | 1 | 0 |
| Carotid artery occlusion | 3 | 0 |
| Carotid artery thrombosis | 10 | 0 |
| Cerebellar haemorrhage | 5 | 0 |
| Cerebellar infarction | 6 | 0 |
| Cerebellar stroke | 11 | 0 |
| Cerebral artery embolism | 12 | 0 |
| Cerebral artery occlusion | 4 | 0 |
| Cerebral artery thrombosis | 15 | 0 |
| Cerebral haematoma | 13 | 1 |
| Cerebral haemorrhage | 180 | 48 |
| Cerebral infarction | 96 | 5 |
| Cerebral ischaemia | 4 | 0 |
| Cerebral thrombosis | 41 | 4 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Cerebral vascular occlusion | 2 | 0 |
| Cerebrovascular accident | 1261 | 47 |
| Embolic stroke | 21 | 0 |
| Haemorrhage intracranial | 56 | 14 |
| Haemorrhagic cerebral infarction | 3 | 1 |
| Haemorrhagic stroke | 46 | 7 |
| Haemorrhagic transformation stroke | 8 | 3 |
| Internal capsule infarction | 1 | 0 |
| Intracranial haematoma | 8 | 1 |
| Intraventricular haemorrhage | 6 | 0 |
| Ischaemic cerebral infarction | 3 | 0 |
| Ischaemic stroke | 154 | 7 |
| Lacunar infarction | 5 | 0 |
| Lacunar stroke | 27 | 0 |
| Perinatal stroke | 1 | 0 |
| Pseudostroke | 1 | 0 |
| Spinal cord haematoma | 1 | 0 |
| Spinal cord infarction | 1 | 0 |
| Spinal stroke | 3 | 0 |
| Stroke in evolution | 1 | 0 |
| Subarachnoid haemorrhage | 114 | 7 |
| Thalamic infarction | 1 | 0 |
| Thalamus haemorrhage | 9 | 0 |
| Thrombotic stroke | 14 | 0 |
| Vertebral artery occlusion | 1 | 0 |
| Vertebral artery thrombosis | 1 | 0 |
| Central nervous system inflammatory disorders NEC | | |
| Arachnoiditis | 4 | 0 |
| Central nervous system inflammation | 15 | 0 |
| Neurosarcoidosis | 4 | 0 |
| Central nervous system vascular disorders NEC | | |
| Brain hypoxia | 1 | 0 |
| Brain stem microhaemorrhage | 1 | 0 |
| Carotid arteriosclerosis | 1 | 0 |
| Carotid artery stenosis | 4 | 0 |
| Central nervous system vasculitis | 2 | 0 |
| Cerebral amyloid angiopathy | 5 | 0 |
| Cerebral arteriosclerosis | 2 | 0 |
| Cerebral arteritis | 1 | 0 |
| Cerebral congestion | 4 | 0 |
| Cerebral microangiopathy | 1 | 0 |
| Cerebral microhaemorrhage | 4 | 0 |
| Cerebral small vessel ischaemic disease | 3 | 0 |
| Cerebral vasoconstriction | 2 | 0 |
| Cerebrovascular disorder | 4 | 0 |
| Cerebrovascular insufficiency | 1 | 0 |
| Dural arteriovenous fistula | 1 | 0 |
| Internal carotid artery deformity | 1 | 0 |
| Reversible cerebral vasoconstriction syndrome | 4 | 0 |
| Cerebrovascular venous and sinus thrombosis | | |
| Cerebral venous sinus thrombosis | 212 | 22 |
| Cerebral venous thrombosis | 51 | 5 |
| Superior sagittal sinus thrombosis | 32 | 3 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders <small>Nervous system disorders cont'd</small> | | |
| Transverse sinus thrombosis | 8 | 0 |
| Cervical spinal cord and nerve root disorders | | |
| Cervical radiculopathy | 4 | 0 |
| Cervicobrachial syndrome | 6 | 0 |
| Choreiform movements | | |
| Chorea | 3 | 0 |
| Choreoathetosis | 1 | 0 |
| Sydenham's chorea | 1 | 0 |
| Chronic polyneuropathies | | |
| Chronic inflammatory demyelinating polyradiculoneuropathy | 9 | 0 |
| Demyelinating polyneuropathy | 12 | 0 |
| Diabetic neuropathy | 2 | 0 |
| Polyneuropathy chronic | 2 | 0 |
| Coma states | | |
| Coma | 24 | 0 |
| Diabetic coma | 3 | 0 |
| Hypoglycaemic coma | 2 | 0 |
| Coordination and balance disturbances | | |
| Ataxia | 52 | 0 |
| Balance disorder | 955 | 0 |
| Cerebellar ataxia | 4 | 0 |
| Cerebellar syndrome | 2 | 0 |
| Coordination abnormal | 135 | 0 |
| Dysdiadochokinesis | 1 | 0 |
| Dysstasia | 118 | 0 |
| Hand-eye coordination impaired | 1 | 0 |
| Nystagmus | 23 | 0 |
| Cortical dysfunction NEC | | |
| Agraphia | 1 | 0 |
| Alexia | 7 | 0 |
| Aphasia | 181 | 0 |
| Apraxia | 3 | 0 |
| Dysgraphia | 7 | 0 |
| Dyslexia | 2 | 0 |
| Dyspraxia | 8 | 0 |
| Neurologic neglect syndrome | 3 | 0 |
| Visuospatial deficit | 2 | 0 |
| Cranial nerve disorders NEC | | |
| Cranial nerve disorder | 2 | 0 |
| Cranial nerve paralysis | 1 | 0 |
| Neurovascular conflict | 1 | 0 |
| Paresis cranial nerve | 2 | 0 |
| Dementia (excl Alzheimer's type) | | |
| Dementia | 33 | 0 |
| Dementia with Lewy bodies | 1 | 0 |
| Frontotemporal dementia | 1 | 0 |
| Senile dementia | 1 | 0 |
| Vascular dementia | 5 | 0 |
| Demyelinating disorders NEC | | |
| Acute disseminated encephalomyelitis | 16 | 0 |
| Clinically isolated syndrome | 3 | 0 |
| Demyelination | 26 | 0 |
| Neuromyelitis optica spectrum disorder | 5 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders <small>Nervous system disorders cont'd</small> | | |
| <i>Disturbances in consciousness NEC</i> | | |
| Altered state of consciousness | 20 | 0 |
| Consciousness fluctuating | 4 | 0 |
| Depressed level of consciousness | 92 | 0 |
| Hypoglycaemic unconsciousness | 1 | 0 |
| Lethargy | 4961 | 0 |
| Loss of consciousness | 1095 | 0 |
| Postictal state | 1 | 0 |
| Sedation | 17 | 0 |
| Somnolence | 1965 | 0 |
| Stupor | 9 | 0 |
| Syncope | 2545 | 0 |
| <i>Disturbances in sleep phase rhythm</i> | | |
| Advanced sleep phase | 1 | 0 |
| Circadian rhythm sleep disorder | 6 | 0 |
| Delayed sleep phase | 1 | 0 |
| Irregular sleep phase | 4 | 0 |
| Irregular sleep wake rhythm disorder | 1 | 0 |
| Non-24-hour sleep-wake disorder | 1 | 0 |
| <i>Dyskinesias and movement disorders NEC</i> | | |
| Akathisia | 10 | 0 |
| Akinesia | 1 | 0 |
| Ballismus | 1 | 0 |
| Bradykinesia | 33 | 0 |
| Clumsiness | 53 | 0 |
| Dyskinesia | 120 | 0 |
| Extrapyramidal disorder | 18 | 0 |
| Fine motor delay | 3 | 0 |
| Fine motor skill dysfunction | 20 | 0 |
| Hyperkinesia | 27 | 0 |
| Hypokinesia | 100 | 0 |
| Meige's syndrome | 1 | 0 |
| Motor dysfunction | 20 | 0 |
| Movement disorder | 111 | 0 |
| Psychomotor hyperactivity | 40 | 0 |
| Tardive dyskinesia | 1 | 0 |
| <i>Dystonias</i> | | |
| Dystonia | 22 | 0 |
| Dystonic tremor | 3 | 0 |
| Opisthotonus | 4 | 0 |
| Writer's cramp | 1 | 0 |
| <i>Encephalitis NEC</i> | | |
| Bickerstaff's encephalitis | 1 | 0 |
| Encephalitis autoimmune | 3 | 0 |
| Limbic encephalitis | 1 | 0 |
| Noninfective encephalitis | 12 | 0 |
| <i>Encephalopathies NEC</i> | | |
| Autoimmune encephalopathy | 5 | 1 |
| Encephalopathy | 10 | 0 |
| Hypertensive encephalopathy | 1 | 0 |
| Hypoxic-ischaemic encephalopathy | 1 | 0 |
| Posterior reversible encephalopathy syndrome | 3 | 0 |
| <i>Encephalopathies toxic and metabolic</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Hepatic encephalopathy | 2 | 0 |
| Eye movement disorders | | |
| IIIrd nerve disorder | 1 | 0 |
| IIIrd nerve paralysis | 6 | 0 |
| IIIrd nerve paresis | 1 | 0 |
| IVth nerve paralysis | 1 | 0 |
| Microvascular cranial nerve palsy | 2 | 0 |
| VIth nerve paralysis | 9 | 0 |
| Facial cranial nerve disorders | | |
| Bell's palsy | 601 | 0 |
| Facial nerve disorder | 8 | 0 |
| Facial paralysis | 356 | 0 |
| Facial paresis | 171 | 0 |
| Facial spasm | 45 | 0 |
| Oculofacial paralysis | 1 | 0 |
| Generalised tonic-clonic seizures | | |
| Generalised tonic-clonic seizure | 103 | 0 |
| Glossopharyngeal nerve disorders | | |
| Glossopharyngeal neuralgia | 1 | 0 |
| Headaches NEC | | |
| Cervicogenic headache | 6 | 0 |
| Chronic paroxysmal hemicrania | 1 | 0 |
| Cluster headache | 753 | 0 |
| Cold-stimulus headache | 91 | 0 |
| Drug withdrawal headache | 17 | 0 |
| Exertional headache | 12 | 0 |
| External compression headache | 5 | 0 |
| Headache | 81164 | 1 |
| Medication overuse headache | 19 | 0 |
| New daily persistent headache | 19 | 0 |
| Occipital neuralgia | 27 | 0 |
| Ophthalmoplegic migraine | 1 | 0 |
| Post-traumatic headache | 3 | 0 |
| Primary cough headache | 2 | 0 |
| Primary headache associated with sexual activity | 13 | 0 |
| Sinus headache | 960 | 0 |
| Tension headache | 1522 | 0 |
| Thunderclap headache | 49 | 0 |
| Vascular headache | 80 | 0 |
| Hydrocephalic conditions | | |
| Hydrocephalus | 18 | 1 |
| Hypoglossal nerve disorders | | |
| Tongue paralysis | 6 | 0 |
| Increased intracranial pressure disorders | | |
| Brain compression | 4 | 0 |
| Brain oedema | 36 | 2 |
| Cerebrospinal fluid circulation disorder | 6 | 0 |
| Cytotoxic oedema | 1 | 0 |
| Idiopathic intracranial hypertension | 7 | 0 |
| Intracranial pressure increased | 29 | 0 |
| Vasogenic cerebral oedema | 1 | 0 |
| Intellectual disabilities | | |
| Intellectual disability | 11 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders <small>Nervous system disorders cont'd</small> | | |
| <i>Lumbar spinal cord and nerve root disorders</i> | | |
| Lumbar radiculopathy | 4 | 0 |
| Sciatica | 229 | 0 |
| <i>Memory loss (excl dementia)</i> | | |
| Amnesia | 419 | 0 |
| Memory impairment | 383 | 0 |
| Retrograde amnesia | 1 | 0 |
| Transient global amnesia | 25 | 0 |
| <i>Meningitis NEC</i> | | |
| Meningitis noninfective | 1 | 0 |
| <i>Mental impairment (excl dementia and memory loss)</i> | | |
| Cognitive disorder | 200 | 0 |
| Disturbance in attention | 746 | 0 |
| Judgement impaired | 5 | 0 |
| Mental impairment | 141 | 0 |
| <i>Migraine headaches</i> | | |
| Basilar migraine | 5 | 0 |
| Hemiplegic migraine | 51 | 0 |
| Migraine | 7633 | 0 |
| Migraine with aura | 395 | 0 |
| Migraine without aura | 47 | 0 |
| Ophthalmic migraine | 14 | 0 |
| Retinal migraine | 88 | 0 |
| Status migrainosus | 5 | 0 |
| Typical aura without headache | 18 | 0 |
| Vestibular migraine | 40 | 0 |
| <i>Mixed cranial nerve disorders</i> | | |
| Bulbar palsy | 3 | 0 |
| <i>Mononeuropathies</i> | | |
| Carpal tunnel syndrome | 43 | 0 |
| Cubital tunnel syndrome | 1 | 0 |
| Diabetic mononeuropathy | 1 | 0 |
| Long thoracic nerve palsy | 1 | 0 |
| Meralgia paraesthetica | 3 | 0 |
| Mononeuritis | 4 | 0 |
| Mononeuropathy | 3 | 0 |
| Nerve compression | 55 | 0 |
| Peripheral nerve lesion | 1 | 0 |
| Peroneal nerve palsy | 18 | 0 |
| Piriformis syndrome | 4 | 0 |
| Radial nerve palsy | 2 | 0 |
| Sciatic nerve neuropathy | 3 | 0 |
| Ulnar nerve palsy | 3 | 0 |
| Ulnar neuritis | 4 | 0 |
| Ulnar tunnel syndrome | 1 | 0 |
| <i>Motor neurone diseases</i> | | |
| Amyotrophic lateral sclerosis | 1 | 0 |
| Lower motor neurone lesion | 1 | 0 |
| Motor neurone disease | 4 | 0 |
| <i>Multiple sclerosis acute and progressive</i> | | |
| Band sensation | 6 | 0 |
| Multiple sclerosis | 56 | 0 |
| Multiple sclerosis pseudo relapse | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Multiple sclerosis relapse | 60 | 0 |
| Progressive multiple sclerosis | 1 | 0 |
| Relapsing multiple sclerosis | 1 | 0 |
| Tumefactive multiple sclerosis | 1 | 0 |
| Uhthoff's phenomenon | 2 | 0 |
| Muscle tone abnormal | | |
| Drop attacks | 2 | 0 |
| Hypertonia | 5 | 0 |
| Hypotonia | 42 | 0 |
| Serotonin syndrome | 1 | 0 |
| Stiff leg syndrome | 10 | 0 |
| Stiff person syndrome | 1 | 0 |
| Myelitis (incl infective) | | |
| Myelitis transverse | 102 | 0 |
| Narcolepsy and hypersomnia | | |
| Cataplexy | 1 | 0 |
| Hypersomnia | 223 | 0 |
| Narcolepsy | 21 | 0 |
| Nervous system cysts and polyps | | |
| Arachnoid cyst | 1 | 0 |
| Pineal gland cyst | 1 | 0 |
| Nervous system disorders NEC | | |
| Brain stem syndrome | 2 | 0 |
| Central nervous system lesion | 7 | 0 |
| Cerebral disorder | 8 | 0 |
| Microglial nodules | 1 | 0 |
| Nervous system disorder | 77 | 0 |
| Neurotoxicity | 4 | 0 |
| Psychomotor skills impaired | 4 | 0 |
| Neurologic visual problems NEC | | |
| Hemianopia | 9 | 0 |
| Hemianopia homonymous | 3 | 0 |
| Quadrantanopia | 1 | 0 |
| Tunnel vision | 23 | 0 |
| Neurological signs and symptoms NEC | | |
| Agitation neonatal | 1 | 0 |
| Clonus | 2 | 0 |
| Dizziness | 22490 | 0 |
| Dizziness exertional | 100 | 0 |
| Dizziness postural | 2156 | 0 |
| Drooling | 26 | 0 |
| Exaggerated startle response | 4 | 0 |
| Fontanelle bulging | 4 | 0 |
| Head discomfort | 756 | 0 |
| Hyporesponsive to stimuli | 4 | 0 |
| Inability to crawl | 2 | 0 |
| Infant irritability | 6 | 0 |
| Intracranial hypotension | 3 | 0 |
| Meningism | 3 | 0 |
| Myoclonus | 34 | 0 |
| Neurological decompensation | 4 | 0 |
| Neurological symptom | 137 | 0 |
| Patient elopement | 3 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders <small>Nervous system disorders cont'd</small> | | |
| Persistent postural-perceptual dizziness | 43 | 0 |
| Pleocytosis | 4 | 0 |
| Presyncope | 611 | 0 |
| Sensory overload | 11 | 0 |
| Slow response to stimuli | 8 | 0 |
| Spontaneous cerebrospinal fluid leak syndrome | 1 | 0 |
| Tongue biting | 10 | 0 |
| Unresponsive to stimuli | 106 | 0 |
| Neuromuscular disorders NEC | | |
| Hypotonic-hyporesponsive episode | 1 | 0 |
| Muscle contractions involuntary | 38 | 0 |
| Muscle spasticity | 33 | 0 |
| Neuromuscular pain | 6 | 0 |
| Neuromyopathy | 3 | 0 |
| Neuromyotonia | 1 | 0 |
| Sensorimotor disorder | 1 | 0 |
| Neuromuscular junction dysfunction | | |
| Myasthenia gravis | 17 | 0 |
| Myasthenia gravis crisis | 3 | 0 |
| Olfactory nerve disorders | | |
| Anosmia | 347 | 0 |
| Hyposmia | 11 | 0 |
| Parosmia | 408 | 0 |
| Optic nerve disorders NEC | | |
| Optic neuritis | 58 | 0 |
| Paraesthesias and dysaesthesias | | |
| Anaesthesia | 3 | 0 |
| Burning feet syndrome | 30 | 0 |
| Burning sensation | 1027 | 0 |
| Burning sensation mucosal | 3 | 0 |
| Dysaesthesia | 17 | 0 |
| Formication | 83 | 0 |
| Hand-arm vibration syndrome | 3 | 0 |
| Hemianaesthesia | 5 | 0 |
| Hemiparaesthesia | 3 | 0 |
| Hyperaesthesia | 276 | 0 |
| Hypoaesthesia | 6031 | 0 |
| Lhermitte's sign | 4 | 0 |
| Paraesthesia | 9747 | 0 |
| Reversed hot-cold sensation | 1 | 0 |
| Paralysis and paresis (excl cranial nerve) | | |
| Diplegia | 36 | 0 |
| Gait spastic | 1 | 0 |
| Hemiparesis | 116 | 0 |
| Hemiplegia | 47 | 0 |
| Monoparesis | 114 | 0 |
| Monoplegia | 141 | 0 |
| Paralysis | 344 | 0 |
| Paraparesis | 6 | 0 |
| Paraplegia | 3 | 0 |
| Paresis | 8 | 0 |
| Peripheral nerve palsy | 1 | 0 |
| Peripheral paralysis | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders <small>Nervous system disorders cont'd</small> | | |
| Postictal paralysis | 3 | 0 |
| Quadriparesis | 3 | 0 |
| Quadriplegia | 3 | 0 |
| <i>Parkinson's disease and parkinsonism</i> | | |
| Freezing phenomenon | 159 | 0 |
| Parkinson's disease | 17 | 0 |
| Parkinsonism | 13 | 0 |
| Reduced facial expression | 8 | 0 |
| Vascular parkinsonism | 1 | 0 |
| <i>Partial complex seizures</i> | | |
| Dreamy state | 21 | 0 |
| Focal dyscognitive seizures | 7 | 0 |
| Temporal lobe epilepsy | 5 | 0 |
| <i>Partial simple seizures NEC</i> | | |
| Autonomic seizure | 1 | 0 |
| Simple partial seizures | 7 | 0 |
| <i>Peripheral neuropathies NEC</i> | | |
| Autoimmune neuropathy | 2 | 0 |
| Axonal and demyelinating polyneuropathy | 1 | 0 |
| Axonal neuropathy | 2 | 0 |
| Brachial plexopathy | 1 | 0 |
| Ischaemic neuropathy | 2 | 0 |
| Neuralgic amyotrophy | 9 | 0 |
| Neuritis | 19 | 0 |
| Neuropathy peripheral | 272 | 0 |
| Peripheral motor neuropathy | 2 | 0 |
| Peripheral sensorimotor neuropathy | 3 | 0 |
| Peripheral sensory neuropathy | 18 | 0 |
| Polyneuropathy | 16 | 0 |
| Small fibre neuropathy | 3 | 0 |
| Thoracic outlet syndrome | 2 | 0 |
| <i>Seizures and seizure disorders NEC</i> | | |
| Acute encephalitis with refractory, repetitive partial seizures | 1 | 0 |
| Alcoholic seizure | 1 | 0 |
| Atonic seizures | 12 | 0 |
| Change in seizure presentation | 7 | 0 |
| Clonic convulsion | 10 | 0 |
| Convulsive threshold lowered | 1 | 0 |
| Drug withdrawal convulsions | 2 | 0 |
| Epilepsy | 346 | 1 |
| Epileptic aura | 3 | 0 |
| Febrile convulsion | 91 | 0 |
| Hypoglycaemic seizure | 1 | 0 |
| Migraine-triggered seizure | 2 | 0 |
| Myoclonic epilepsy | 5 | 0 |
| Partial seizures | 58 | 0 |
| Psychogenic seizure | 5 | 0 |
| Seizure | 1361 | 3 |
| Seizure anoxic | 3 | 0 |
| Seizure cluster | 9 | 0 |
| Seizure like phenomena | 3 | 0 |
| Status epilepticus | 29 | 2 |
| Tonic clonic movements | 3 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Tonic convulsion | 38 | 0 |
| Sensory abnormalities NEC | | |
| Ageusia | 1098 | 0 |
| Allodynia | 63 | 0 |
| Aura | 26 | 0 |
| Central pain syndrome | 2 | 0 |
| Complex regional pain syndrome | 14 | 0 |
| Decreased vibratory sense | 1 | 0 |
| Dysgeusia | 2015 | 0 |
| Electric shock sensation | 109 | 0 |
| Hypogeusia | 7 | 0 |
| Intercostal neuralgia | 2 | 0 |
| Loss of proprioception | 6 | 0 |
| Neuralgia | 1464 | 0 |
| Persistent genital arousal disorder | 2 | 0 |
| Phantom limb syndrome | 18 | 0 |
| Post herpetic neuralgia | 13 | 0 |
| Restless arm syndrome | 15 | 0 |
| Restless legs syndrome | 402 | 0 |
| Sensory disturbance | 160 | 0 |
| Sensory loss | 244 | 0 |
| Taste disorder | 522 | 0 |
| Vibratory sense increased | 5 | 0 |
| Visual perseveration | 1 | 0 |
| Sleep disturbances NEC | | |
| Microsleep | 3 | 0 |
| Periodic limb movement disorder | 1 | 0 |
| Sleep deficit | 53 | 0 |
| Sudden onset of sleep | 1 | 0 |
| Speech and language abnormalities | | |
| Dysarthria | 453 | 0 |
| Incoherent | 20 | 0 |
| Language disorder | 3 | 0 |
| Muscle tension dysphonia | 1 | 0 |
| Repetitive speech | 1 | 0 |
| Slow speech | 40 | 0 |
| Speech disorder | 128 | 0 |
| Speech disorder developmental | 1 | 0 |
| Spinal cord and nerve root disorders NEC | | |
| Cauda equina syndrome | 6 | 0 |
| Myelopathy | 6 | 0 |
| Radicular pain | 1 | 0 |
| Radiculitis brachial | 27 | 0 |
| Radiculopathy | 3 | 0 |
| Spinal cord disorder | 7 | 0 |
| Spinal cord ischaemia | 1 | 0 |
| Spinal cord oedema | 1 | 0 |
| Subacute combined cord degeneration | 1 | 0 |
| Structural brain disorders NEC | | |
| Brain injury | 39 | 3 |
| Cerebral mass effect | 10 | 0 |
| Encephalomalacia | 1 | 0 |
| Intracranial mass | 4 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|---------------|------------|
| Nervous system disorders | | |
| Nervous system disorders cont'd | | |
| White matter lesion | 5 | 0 |
| <i>Transient cerebrovascular events</i> | | |
| Transient ischaemic attack | 502 | 2 |
| <i>Tremor (excl congenital)</i> | | |
| Action tremor | 4 | 0 |
| Asterixis | 1 | 0 |
| Essential tremor | 7 | 0 |
| Head titubation | 25 | 0 |
| Intention tremor | 1 | 0 |
| Postural tremor | 2 | 0 |
| Resting tremor | 8 | 0 |
| Tremor | 9799 | 1 |
| <i>Trigeminal disorders</i> | | |
| Numb chin syndrome | 3 | 0 |
| Trigeminal nerve disorder | 6 | 0 |
| Trigeminal neuralgia | 146 | 0 |
| Trigeminal neuritis | 2 | 0 |
| Trigeminal palsy | 1 | 0 |
| <i>Vagus nerve disorders</i> | | |
| Vagus nerve paralysis | 1 | 0 |
| Vocal cord paralysis | 4 | 0 |
| <i>Vertigos NEC</i> | | |
| Vertigo CNS origin | 3 | 0 |
| Nervous system disorders SOC TOTAL | 179330 | 204 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Pregnancy conditions | | |
| <i>Abortion related conditions and complications</i> | | |
| Anembryonic gestation | 1 | 0 |
| <i>Abortions not specified as induced or spontaneous</i> | | |
| Abortion missed | 1 | 0 |
| <i>Abortions spontaneous</i> | | |
| Abortion spontaneous | 215 | 0 |
| <i>Foetal complications NEC</i> | | |
| Haemorrhage foetal | 1 | 0 |
| <i>Foetal position and presentation abnormalities</i> | | |
| Face presentation | 1 | 0 |
| <i>Gestational age and weight conditions</i> | | |
| Low birth weight baby | 1 | 0 |
| Premature baby | 2 | 0 |
| <i>Haemorrhagic complications of pregnancy</i> | | |
| Haemorrhage in pregnancy | 1 | 0 |
| <i>High risk pregnancies</i> | | |
| Pregnancy of unknown location | 1 | 0 |
| <i>Hypertension associated disorders of pregnancy</i> | | |
| Pre-eclampsia | 3 | 0 |
| <i>Labour onset and length abnormalities</i> | | |
| Precipitate labour | 1 | 0 |
| Premature labour | 3 | 0 |
| Premature rupture of membranes | 2 | 0 |
| Prolonged labour | 1 | 0 |
| <i>Maternal complications of delivery NEC</i> | | |
| Traumatic delivery | 1 | 0 |
| <i>Maternal complications of labour NEC</i> | | |
| Uterine contractions abnormal | 1 | 0 |
| <i>Maternal complications of pregnancy NEC</i> | | |
| Biochemical pregnancy | 3 | 0 |
| Decidual cast | 3 | 0 |
| Ectopic pregnancy | 8 | 0 |
| Hyperemesis gravidarum | 2 | 0 |
| Morning sickness | 1 | 0 |
| Pelvic girdle pain | 2 | 0 |
| Preterm premature rupture of membranes | 1 | 0 |
| Somatic symptom disorder of pregnancy | 1 | 0 |
| <i>Multiple pregnancies</i> | | |
| Twin pregnancy | 2 | 0 |
| <i>Normal pregnancy, labour and delivery</i> | | |
| Delivery | 1 | 0 |
| Labour pain | 1 | 0 |
| Live birth | 2 | 0 |
| Pregnancy | 24 | 0 |
| Uterine contractions during pregnancy | 1 | 0 |
| <i>Placental abnormalities (excl neoplasms)</i> | | |
| Foetal vascular malperfusion | 1 | 0 |
| <i>Pregnancy complicated by maternal disorders</i> | | |
| Gestational diabetes | 6 | 0 |
| Peripartum cardiomyopathy | 1 | 0 |
| <i>Stillbirth and foetal death</i> | | |
| Stillbirth | 5 | 5 |
| <i>Umbilical cord complications</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Pregnancy conditions <small>Pregnancy conditions cont'd</small> | | |
| Umbilical cord around neck | 1 | 0 |
| <i>Unintended pregnancies</i> | | |
| Pregnancy after post coital contraception | 2 | 0 |
| Pregnancy on contraceptive | 4 | 0 |
| Pregnancy with implant contraceptive | 2 | 0 |
| Unintended pregnancy | 2 | 0 |
| Pregnancy conditions SOC TOTAL | 312 | 5 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|------------|----------|
| <i>Counterfeit, falsified and substandard products</i> | | |
| Suspected counterfeit product | 2 | 0 |
| <i>Device electrical issues</i> | | |
| Device electrical impedance issue | 1 | 0 |
| Electromagnetic interference | 1 | 0 |
| <i>Device incompatibility issues</i> | | |
| Patient-device incompatibility | 2 | 0 |
| <i>Device issues NEC</i> | | |
| Device expulsion | 3 | 0 |
| Device issue | 4 | 0 |
| Device leakage | 2 | 0 |
| <i>Device malfunction events NEC</i> | | |
| Device occlusion | 1 | 0 |
| Oversensing | 35 | 0 |
| Stent malfunction | 1 | 0 |
| Thrombosis in device | 68 | 1 |
| Undersensing | 7 | 0 |
| <i>Device physical property and chemical issues</i> | | |
| Needle issue | 11 | 0 |
| Syringe issue | 1 | 0 |
| <i>Manufacturing facilities and equipment issues</i> | | |
| Manufacturing equipment issue | 1 | 0 |
| <i>Product contamination and sterility issues</i> | | |
| Product contamination | 1 | 0 |
| Suspected product contamination | 1 | 0 |
| <i>Product distribution and storage issues</i> | | |
| Product temperature excursion issue | 5 | 0 |
| <i>Product label issues</i> | | |
| Product barcode issue | 1 | 0 |
| Product label issue | 2 | 0 |
| <i>Product packaging issues</i> | | |
| Product container issue | 2 | 0 |
| <i>Product physical issues</i> | | |
| Liquid product physical issue | 1 | 0 |
| Product after taste | 8 | 0 |
| Product colour issue | 4 | 0 |
| Product leakage | 1 | 0 |
| Product odour abnormal | 3 | 0 |
| Product physical issue | 2 | 0 |
| Product taste abnormal | 8 | 0 |
| <i>Product quality issues NEC</i> | | |
| Product formulation issue | 1 | 0 |
| Product origin unknown | 3 | 0 |
| Product quality issue | 1 | 0 |
| Suspected product quality issue | 2 | 0 |
| <i>Product supply and availability issues</i> | | |
| Product availability issue | 2 | 0 |
| null SOC TOTAL | 188 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders | | |
| <i>Abnormal behaviour NEC</i> | | |
| Abnormal behaviour | 25 | 0 |
| Behaviour disorder | 1 | 0 |
| Breath holding | 5 | 0 |
| Sexually inappropriate behaviour | 1 | 0 |
| Staring | 13 | 0 |
| <i>Abnormal food elimination</i> | | |
| Self-induced vomiting | 1 | 0 |
| <i>Adjustment disorders</i> | | |
| Adjustment disorder | 1 | 0 |
| Adjustment disorder with depressed mood | 6 | 0 |
| Adjustment disorder with mixed anxiety and depressed mood | 2 | 0 |
| <i>Affect alterations NEC</i> | | |
| Affect lability | 14 | 0 |
| Blunted affect | 1 | 0 |
| Constricted affect | 15 | 0 |
| Flat affect | 10 | 0 |
| Inappropriate affect | 18 | 0 |
| <i>Amnesic symptoms</i> | | |
| Paramnesia | 6 | 0 |
| <i>Anxiety disorders NEC</i> | | |
| Anxiety disorder | 4 | 0 |
| Generalised anxiety disorder | 4 | 0 |
| Neurosis | 1 | 0 |
| <i>Anxiety symptoms</i> | | |
| Agitation | 204 | 0 |
| Anxiety | 1281 | 0 |
| Immunisation anxiety related reaction | 1 | 0 |
| Nervousness | 599 | 0 |
| Procedural anxiety | 1 | 0 |
| Stress | 162 | 0 |
| Tension | 72 | 0 |
| <i>Attention deficit and disruptive behaviour disorders</i> | | |
| Attention deficit hyperactivity disorder | 20 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Aggression | 17 | 0 |
| Antisocial behaviour | 2 | 0 |
| Asocial behaviour | 1 | 0 |
| Attention-seeking behaviour | 1 | 0 |
| Aversion | 1 | 0 |
| Disinhibition | 2 | 0 |
| Homicidal ideation | 1 | 0 |
| Impatience | 2 | 0 |
| Indifference | 10 | 0 |
| Paranoia | 42 | 0 |
| Personality change | 10 | 0 |
| Social avoidant behaviour | 6 | 0 |
| Soliloquy | 3 | 0 |
| Violence-related symptom | 3 | 0 |
| <i>Bipolar disorders</i> | | |
| Bipolar I disorder | 8 | 0 |
| Bipolar disorder | 6 | 0 |
| <i>Cognitive and attention disorders and disturbances NEC</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders ^{Psychiatric disorders cont'd} | | |
| Change in sustained attention | 1 | 0 |
| Daydreaming | 16 | 0 |
| Distractibility | 2 | 0 |
| Mental fatigue | 488 | 0 |
| Communications disorders | | |
| Communication disorder | 8 | 0 |
| Mutism | 6 | 0 |
| Speech sound disorder | 2 | 0 |
| Confusion and disorientation | | |
| Confusional state | 2167 | 0 |
| Disorientation | 736 | 0 |
| Decreased physical activity levels | | |
| Catatonia | 3 | 0 |
| Deliria | | |
| Delirium | 483 | 0 |
| Delirium febrile | 3 | 0 |
| Delusional disorders | | |
| Alice in wonderland syndrome | 3 | 0 |
| Delusional symptoms | | |
| Delusion | 54 | 0 |
| Delusion of parasitosis | 3 | 0 |
| Mixed delusion | 1 | 0 |
| Thought withdrawal | 1 | 0 |
| Dementia NEC | | |
| Pseudodementia | 1 | 0 |
| Depressive disorders | | |
| Agitated depression | 4 | 0 |
| Childhood depression | 1 | 0 |
| Depression | 683 | 0 |
| Depression suicidal | 16 | 0 |
| Major depression | 24 | 0 |
| Menopausal depression | 2 | 0 |
| Mixed anxiety and depressive disorder | 2 | 0 |
| Dissociative states | | |
| Depersonalisation/derealisation disorder | 20 | 0 |
| Dissociation | 77 | 0 |
| Dissociative amnesia | 1 | 0 |
| Dissociative disorder | 2 | 0 |
| Disturbances in initiating and maintaining sleep | | |
| Initial insomnia | 42 | 0 |
| Insomnia | 3117 | 0 |
| Middle insomnia | 72 | 0 |
| Terminal insomnia | 27 | 0 |
| Dyssomnias | | |
| Dyssomnia | 5 | 0 |
| Poor quality sleep | 666 | 0 |
| Eating disorders NEC | | |
| Binge eating | 1 | 0 |
| Eating disorder | 18 | 0 |
| Pica | 1 | 0 |
| Selective eating disorder | 2 | 0 |
| Emotional and mood disturbances NEC | | |
| Anger | 90 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders ^{Psychiatric disorders cont'd} | | |
| Dysphoria | 2 | 0 |
| Emotional disorder | 102 | 0 |
| Emotional distress | 84 | 0 |
| Emotional poverty | 2 | 0 |
| Euphoric mood | 70 | 0 |
| Frustration tolerance decreased | 15 | 0 |
| Irritability | 319 | 0 |
| Mood altered | 89 | 0 |
| Factitious disorders | | |
| Factitious disorder | 4 | 0 |
| Fear symptoms and phobic disorders (incl social phobia) | | |
| Acrophobia | 2 | 0 |
| Agoraphobia | 4 | 0 |
| Fear | 66 | 0 |
| Fear of death | 18 | 0 |
| Fear of disease | 2 | 0 |
| Fear of eating | 1 | 0 |
| Fear of falling | 5 | 0 |
| Fear of injection | 2 | 0 |
| Fear of open spaces | 1 | 0 |
| Fear-related avoidance of activities | 2 | 0 |
| Performance fear | 1 | 0 |
| Phobia | 3 | 0 |
| Phonophobia | 4 | 0 |
| Social anxiety disorder | 1 | 0 |
| Social fear | 1 | 0 |
| Thanatophobia | 1 | 0 |
| Fluctuating mood symptoms | | |
| Mood swings | 139 | 0 |
| Hallucinations (excl sleep-related) | | |
| Hallucination | 936 | 0 |
| Hallucination, auditory | 48 | 0 |
| Hallucination, olfactory | 14 | 0 |
| Hallucination, tactile | 1 | 0 |
| Hallucination, visual | 57 | 0 |
| Hallucinations, mixed | 9 | 0 |
| Somatic hallucination | 1 | 0 |
| Impulse control disorders | | |
| Clinomania | 1 | 0 |
| Impulse-control disorder | 2 | 0 |
| Impulsive behaviour | 2 | 0 |
| Intermittent explosive disorder | 1 | 0 |
| Increased physical activity levels | | |
| Restlessness | 489 | 0 |
| Infancy, childhood and adolescence psychiatric disorders NEC | | |
| Emotional disorder of childhood | 1 | 0 |
| Learning disorders | | |
| Reading disorder | 1 | 0 |
| Mental disorders NEC | | |
| Mental disorder | 28 | 0 |
| Mental status changes | 5 | 0 |
| Mental disorders due to a general medical condition NEC | | |
| Mental disorder due to a general medical condition | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders ^{Psychiatric disorders cont'd} | | |
| Neuropsychiatric symptoms | 2 | 0 |
| <i>Mood alterations with depressive symptoms</i> | | |
| Anhedonia | 4 | 0 |
| Decreased interest | 17 | 0 |
| Depressed mood | 694 | 0 |
| Depressive symptom | 2 | 0 |
| Feeling guilty | 1 | 0 |
| Feeling of despair | 19 | 0 |
| Negative thoughts | 10 | 0 |
| Sense of a foreshortened future | 3 | 0 |
| Tearfulness | 104 | 0 |
| <i>Mood alterations with manic symptoms</i> | | |
| Hypomania | 1 | 0 |
| Mania | 31 | 0 |
| <i>Mood disorders NEC</i> | | |
| Affective disorder | 4 | 0 |
| Apathy | 76 | 0 |
| Laziness | 2 | 0 |
| Listless | 124 | 0 |
| Mood disorder due to a general medical condition | 1 | 0 |
| Substance-induced mood disorder | 1 | 0 |
| <i>Narcolepsy and associated conditions</i> | | |
| Hypnagogic hallucination | 4 | 0 |
| Sleep attacks | 2 | 0 |
| <i>Obsessive-compulsive disorders and symptoms</i> | | |
| Body dysmorphic disorder | 2 | 0 |
| Compulsive shopping | 2 | 0 |
| Dermatillomania | 2 | 0 |
| Obsessive thoughts | 3 | 0 |
| Obsessive-compulsive disorder | 2 | 0 |
| Obsessive-compulsive symptom | 1 | 0 |
| <i>Orgasmic disorders and disturbances</i> | | |
| Anorgasmia | 6 | 0 |
| Female orgasmic disorder | 1 | 0 |
| Orgasm abnormal | 1 | 0 |
| Orgasmic sensation decreased | 4 | 0 |
| Premature ejaculation | 3 | 0 |
| <i>Panic attacks and disorders</i> | | |
| Limited symptom panic attack | 1 | 0 |
| Panic attack | 347 | 0 |
| Panic disorder | 9 | 0 |
| Panic reaction | 41 | 0 |
| <i>Paraphilias and paraphilic disorders</i> | | |
| Fetishism | 2 | 0 |
| <i>Parasomnias</i> | | |
| Abnormal dreams | 369 | 0 |
| Abnormal sleep-related event | 2 | 0 |
| Confusional arousal | 3 | 0 |
| Exploding head syndrome | 7 | 0 |
| Nightmare | 461 | 0 |
| Parasomnia | 1 | 0 |
| Rapid eye movements sleep abnormal | 4 | 0 |
| Sleep inertia | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Sleep talking | 16 | 0 |
| Sleep terror | 60 | 0 |
| Sleep-related eating disorder | 2 | 0 |
| Somnambulism | 11 | 0 |
| Perception disturbances NEC | | |
| Autoscopy | 27 | 0 |
| Deja vu | 4 | 0 |
| Delusional perception | 2 | 0 |
| Derealisation | 16 | 0 |
| Flashback | 2 | 0 |
| Illusion | 12 | 0 |
| Imperception | 1 | 0 |
| Jamais vu | 1 | 0 |
| Near death experience | 1 | 0 |
| Pseudohallucination | 1 | 0 |
| Time perception altered | 5 | 0 |
| Pervasive developmental disorders NEC | | |
| Autism spectrum disorder | 4 | 0 |
| Psychiatric elimination disorders | | |
| Enuresis | 60 | 0 |
| Psychiatric symptoms NEC | | |
| Decreased eye contact | 2 | 0 |
| Helplessness | 3 | 0 |
| Hypervigilance | 12 | 0 |
| Psychiatric symptom | 11 | 0 |
| Psychological trauma | 5 | 0 |
| Psychotic disorder NEC | | |
| Acute psychosis | 6 | 0 |
| Psychotic behaviour | 2 | 0 |
| Psychotic disorder | 45 | 0 |
| Psychotic symptom | 1 | 0 |
| Rebound psychosis | 1 | 0 |
| Schizoaffective and schizophreniform disorders | | |
| Schizoaffective disorder | 1 | 0 |
| Schizophrenia NEC | | |
| Schizophrenia | 1 | 0 |
| Sexual arousal disorders | | |
| Disturbance in sexual arousal | 5 | 0 |
| Sexual desire disorders | | |
| Excessive masturbation | 1 | 0 |
| Hypersexuality | 1 | 0 |
| Libido decreased | 24 | 0 |
| Libido disorder | 1 | 0 |
| Libido increased | 9 | 0 |
| Loss of libido | 53 | 0 |
| Sexual dysfunction NEC | | |
| Genito-pelvic pain/penetration disorder | 1 | 0 |
| Sleep disorders NEC | | |
| Sleep disorder | 436 | 1 |
| Sleep disorder due to a general medical condition | 1 | 0 |
| Sleep disorder due to general medical condition, insomnia type | 3 | 0 |
| Somatic symptom disorders | | |
| Conversion disorder | 32 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Habit cough | 39 | 0 |
| Illness anxiety disorder | 1 | 0 |
| Psychogenic tremor | 2 | 0 |
| Somatic symptom disorder | 1 | 0 |
| <i>Speech and language usage disturbances</i> | | |
| Disorganised speech | 21 | 0 |
| Logorrhoea | 3 | 0 |
| Pedantic speech | 1 | 0 |
| Poverty of speech | 1 | 0 |
| Verbigeration | 1 | 0 |
| <i>Speech articulation and rhythm disturbances</i> | | |
| Dysphemia | 36 | 0 |
| Lack of spontaneous speech | 3 | 0 |
| <i>Stereotypies and automatisms</i> | | |
| Bruxism | 35 | 0 |
| Head banging | 47 | 0 |
| Waxy flexibility | 2 | 0 |
| <i>Stress disorders</i> | | |
| Acute stress disorder | 2 | 0 |
| Burnout syndrome | 14 | 0 |
| Hyperarousal | 3 | 0 |
| Post-traumatic stress disorder | 15 | 0 |
| <i>Substance related and addictive disorders</i> | | |
| Alcohol abuse | 2 | 0 |
| Alcohol use disorder | 3 | 0 |
| Alcoholic hangover | 1 | 0 |
| Alcoholism | 3 | 0 |
| Dependence | 2 | 0 |
| Drug abuse | 1 | 0 |
| Drug dependence | 1 | 0 |
| Nicotine dependence | 1 | 0 |
| Substance abuse | 2 | 0 |
| <i>Suicidal and self-injurious behaviour</i> | | |
| Completed suicide | 5 | 4 |
| Intentional self-injury | 9 | 0 |
| Self-injurious ideation | 3 | 0 |
| Suicidal behaviour | 4 | 0 |
| Suicidal ideation | 118 | 0 |
| Suicide attempt | 31 | 0 |
| Suicide threat | 1 | 0 |
| <i>Thinking disturbances</i> | | |
| Bradyphrenia | 91 | 0 |
| Confabulation | 1 | 0 |
| Illogical thinking | 1 | 0 |
| Impaired reasoning | 3 | 0 |
| Intrusive thoughts | 6 | 0 |
| Morbid thoughts | 5 | 0 |
| Tachyphrenia | 23 | 0 |
| Thinking abnormal | 31 | 0 |
| Thought blocking | 6 | 0 |
| <i>Tic disorders</i> | | |
| Secondary tic | 2 | 0 |
| Tic | 21 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|--------------|----------|
| Psychiatric disorders ^{Psychiatric disorders cont'd} | | |
| Psychiatric disorders SOC TOTAL | 17834 | 5 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Renal & urinary disorders | | |
| <i>Bladder and urethral symptoms</i> | | |
| Bladder discomfort | 8 | 0 |
| Bladder irritation | 7 | 0 |
| Bladder pain | 64 | 0 |
| Bladder spasm | 1 | 0 |
| Dysuria | 88 | 0 |
| Incontinence | 87 | 0 |
| Micturition disorder | 4 | 0 |
| Micturition frequency decreased | 1 | 0 |
| Micturition urgency | 102 | 0 |
| Mixed incontinence | 1 | 0 |
| Pollakiuria | 297 | 0 |
| Stress urinary incontinence | 1 | 0 |
| Urethral pain | 6 | 0 |
| Urge incontinence | 2 | 0 |
| Urinary hesitation | 7 | 0 |
| Urinary incontinence | 127 | 0 |
| Urinary retention | 98 | 0 |
| Urine flow decreased | 22 | 0 |
| <i>Bladder disorders NEC</i> | | |
| Bladder dilatation | 1 | 0 |
| Bladder disorder | 22 | 0 |
| Bladder prolapse | 1 | 0 |
| Urinary bladder haemorrhage | 17 | 1 |
| Urinary bladder rupture | 1 | 0 |
| <i>Bladder infections and inflammations</i> | | |
| Cystitis haemorrhagic | 1 | 0 |
| Cystitis interstitial | 10 | 0 |
| Cystitis noninfective | 3 | 0 |
| Lupus cystitis | 1 | 0 |
| <i>Genital and urinary tract disorders NEC</i> | | |
| Urinary tract disorder | 12 | 0 |
| Urogenital haemorrhage | 1 | 0 |
| <i>Glomerulonephritis and nephrotic syndrome</i> | | |
| Anti-glomerular basement membrane disease | 1 | 0 |
| Focal segmental glomerulosclerosis | 2 | 0 |
| Glomerulonephritis | 1 | 0 |
| Glomerulonephritis membranoproliferative | 1 | 0 |
| Glomerulonephritis membranous | 1 | 0 |
| Glomerulonephritis minimal lesion | 5 | 0 |
| IgA nephropathy | 5 | 0 |
| Nephrotic syndrome | 18 | 0 |
| <i>Myoneurogenic bladder disorders</i> | | |
| Atonic urinary bladder | 1 | 0 |
| Automatic bladder | 1 | 0 |
| Bladder dysfunction | 13 | 0 |
| Hypertonic bladder | 16 | 0 |
| Loss of bladder sensation | 13 | 0 |
| Neurogenic bladder | 4 | 0 |
| <i>Nephritis NEC</i> | | |
| Lupus nephritis | 2 | 0 |
| Nephritis | 7 | 0 |
| Tubulointerstitial nephritis | 7 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Renal & urinary disorders | | |
| <i>Renal & urinary disorders cont'd</i> | | |
| <i>Nephropathies and tubular disorders NEC</i> | | |
| Nephropathy | 2 | 0 |
| <i>Renal disorders NEC</i> | | |
| Oedematous kidney | 1 | 0 |
| Renal disorder | 14 | 0 |
| Renal haemorrhage | 3 | 0 |
| <i>Renal failure and impairment</i> | | |
| Acute kidney injury | 69 | 1 |
| Anuria | 5 | 0 |
| Chronic kidney disease | 10 | 0 |
| End stage renal disease | 1 | 0 |
| Oliguria | 11 | 0 |
| Renal failure | 45 | 2 |
| Renal impairment | 28 | 0 |
| Renal injury | 7 | 0 |
| <i>Renal hypertension and related conditions</i> | | |
| Hypertensive nephropathy | 1 | 0 |
| <i>Renal lithiasis</i> | | |
| Nephrolithiasis | 22 | 0 |
| <i>Renal obstructive disorders</i> | | |
| Hydronephrosis | 1 | 0 |
| <i>Renal structural abnormalities and trauma</i> | | |
| Kidney enlargement | 1 | 0 |
| Renal atrophy | 2 | 0 |
| <i>Renal vascular and ischaemic conditions</i> | | |
| Renal artery occlusion | 2 | 0 |
| Renal artery thrombosis | 1 | 0 |
| Renal cortical necrosis | 1 | 0 |
| Renal embolism | 1 | 0 |
| Renal infarct | 17 | 1 |
| Renal ischaemia | 1 | 0 |
| Renal tubular injury | 1 | 0 |
| Renal vascular thrombosis | 2 | 0 |
| Renal vasculitis | 2 | 0 |
| Renal vein embolism | 1 | 0 |
| Renal vein occlusion | 3 | 0 |
| Renal vein thrombosis | 9 | 0 |
| <i>Structural and obstructive urethral disorders (excl congenital)</i> | | |
| Urethral spasm | 1 | 0 |
| Urethral stenosis | 1 | 0 |
| <i>Ureteric disorders NEC</i> | | |
| Ureteral disorder | 2 | 0 |
| <i>Urinary abnormalities</i> | | |
| Chromaturia | 108 | 0 |
| Glycosuria | 1 | 0 |
| Haematuria | 1 | 0 |
| Haematuria | 63 | 0 |
| Microalbuminuria | 1 | 0 |
| Proteinuria | 12 | 0 |
| Urine abnormality | 21 | 0 |
| Urine odour abnormal | 21 | 0 |
| <i>Urinary tract signs and symptoms NEC</i> | | |
| Costovertebral angle tenderness | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Renal & urinary disorders | | |
| Renal & urinary disorders cont'd | | |
| Haemorrhage urinary tract | 59 | 0 |
| Nocturia | 22 | 0 |
| Polyuria | 33 | 0 |
| Renal colic | 4 | 0 |
| Renal pain | 941 | 0 |
| Urinary tract discomfort | 2 | 0 |
| Urinary tract pain | 15 | 0 |
| Renal & urinary disorders SOC TOTAL | 2664 | 5 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Reproductive & breast disorders | | |
| <i>Benign and malignant breast neoplasms</i> | | |
| Breast cyst | 12 | 0 |
| <i>Breast disorders NEC</i> | | |
| Anisomastia | 1 | 0 |
| Breast disorder | 4 | 0 |
| Breast enlargement | 11 | 0 |
| Breast mass | 72 | 0 |
| Gynaecomastia | 9 | 0 |
| Mammary duct ectasia | 1 | 0 |
| Nipple disorder | 1 | 0 |
| <i>Breast infections and inflammations</i> | | |
| Breast inflammation | 4 | 0 |
| Nipple inflammation | 1 | 0 |
| <i>Breast signs and symptoms</i> | | |
| Breast discharge | 9 | 0 |
| Breast discolouration | 1 | 0 |
| Breast discomfort | 12 | 0 |
| Breast engorgement | 6 | 0 |
| Breast haemorrhage | 1 | 0 |
| Breast induration | 1 | 0 |
| Breast oedema | 1 | 0 |
| Breast pain | 491 | 0 |
| Breast swelling | 71 | 0 |
| Breast tenderness | 77 | 0 |
| Nipple exudate bloody | 1 | 0 |
| Nipple pain | 38 | 0 |
| Nipple swelling | 4 | 0 |
| <i>Cervix disorders NEC</i> | | |
| Cervical friability | 1 | 0 |
| Cervix haemorrhage uterine | 1 | 0 |
| Ectropion of cervix | 1 | 0 |
| <i>Cervix neoplasms</i> | | |
| Cervical polyp | 1 | 0 |
| <i>Erection and ejaculation conditions and disorders</i> | | |
| Ejaculation delayed | 2 | 0 |
| Ejaculation disorder | 4 | 0 |
| Ejaculation failure | 5 | 0 |
| Erectile dysfunction | 94 | 0 |
| Erection increased | 7 | 0 |
| Organic erectile dysfunction | 20 | 0 |
| Painful ejaculation | 1 | 0 |
| Painful erection | 2 | 0 |
| Priapism | 3 | 0 |
| Retrograde ejaculation | 4 | 0 |
| Spontaneous penile erection | 2 | 0 |
| <i>Fallopian tube and ovary infections and inflammations</i> | | |
| Noninfective oophoritis | 1 | 0 |
| <i>Lactation disorders</i> | | |
| Galactorrhoea | 3 | 0 |
| Galactostasis | 2 | 0 |
| Lactation disorder | 2 | 0 |
| Lactation puerperal increased | 6 | 0 |
| Suppressed lactation | 27 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Menopausal effects NEC | | |
| Artificial menopause | 2 | 0 |
| Menopausal disorder | 3 | 0 |
| Menopausal symptoms | 61 | 0 |
| Menopause delayed | 5 | 0 |
| Premature menopause | 48 | 0 |
| Menopausal effects on the genitourinary tract | | |
| Atrophic vulvovaginitis | 1 | 0 |
| Postmenopausal haemorrhage | 299 | 0 |
| Menstruation and uterine bleeding NEC | | |
| Abnormal uterine bleeding | 7 | 0 |
| Abnormal withdrawal bleeding | 5 | 0 |
| Dysmenorrhoea | 1386 | 0 |
| Intermenstrual bleeding | 681 | 0 |
| Menstrual discomfort | 14 | 0 |
| Menstrual disorder | 1478 | 0 |
| Menstruation irregular | 2243 | 0 |
| Premenstrual dysphoric disorder | 6 | 0 |
| Premenstrual headache | 9 | 0 |
| Premenstrual pain | 82 | 0 |
| Premenstrual syndrome | 53 | 0 |
| Retrograde menstruation | 4 | 0 |
| Withdrawal bleed | 13 | 0 |
| Menstruation with decreased bleeding | | |
| Amenorrhoea | 583 | 0 |
| Hypomenorrhoea | 422 | 0 |
| Menstruation delayed | 3164 | 0 |
| Oligomenorrhoea | 115 | 0 |
| Menstruation with increased bleeding | | |
| Heavy menstrual bleeding | 4558 | 0 |
| Menometrorrhagia | 17 | 0 |
| Polymenorrhoea | 672 | 0 |
| Ovarian and fallopian tube cysts and neoplasms | | |
| Ovarian cyst | 28 | 0 |
| Ovarian cyst ruptured | 2 | 0 |
| Polycystic ovaries | 41 | 0 |
| Ovarian and fallopian tube disorders NEC | | |
| Fallopian tube spasm | 1 | 0 |
| Ovarian adhesion | 1 | 0 |
| Ovarian enlargement | 2 | 0 |
| Ovarian failure | 2 | 0 |
| Ovarian haemorrhage | 5 | 0 |
| Ovarian hyperstimulation syndrome | 1 | 0 |
| Ovarian necrosis | 1 | 0 |
| Ovarian oedema | 1 | 0 |
| Ovarian vein thrombosis | 2 | 0 |
| Ovulation pain | 55 | 0 |
| Premature ovulation | 8 | 0 |
| Pelvic prolapse conditions | | |
| Vaginal prolapse | 2 | 0 |
| Pelvis and broad ligament disorders NEC | | |
| Adnexa uteri pain | 43 | 0 |
| Pelvic haematoma | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Pelvic haemorrhage | 27 | 0 |
| Pelvic organ prolapse | 1 | 0 |
| <i>Penile and scrotal infections and inflammations</i> | | |
| Balanoposthitis | 4 | 0 |
| <i>Penile disorders NEC (excl erection and ejaculation)</i> | | |
| Penile blister | 6 | 0 |
| Penile burning sensation | 1 | 0 |
| Penile curvature | 4 | 0 |
| Penile discharge | 4 | 0 |
| Penile erosion | 1 | 0 |
| Penile exfoliation | 1 | 0 |
| Penile haemorrhage | 7 | 0 |
| Penile oedema | 3 | 0 |
| Penile pain | 2 | 0 |
| Penile size reduced | 2 | 0 |
| Penis disorder | 10 | 0 |
| Peyronie's disease | 4 | 0 |
| <i>Prostate and seminal vesicles infections and inflammations</i> | | |
| Prostatitis | 6 | 0 |
| <i>Prostatic neoplasms and hypertrophy</i> | | |
| Benign prostatic hyperplasia | 2 | 0 |
| <i>Prostatic signs, symptoms and disorders NEC</i> | | |
| Prostatic pain | 1 | 0 |
| Prostatism | 1 | 0 |
| Prostatomegaly | 3 | 0 |
| <i>Reproductive tract disorders NEC (excl neoplasms)</i> | | |
| Female genital tract fistula | 1 | 0 |
| Genital blister | 5 | 0 |
| Genital dysaesthesia | 1 | 0 |
| Genital haemorrhage | 31 | 0 |
| Genital hyperaesthesia | 1 | 0 |
| Genital hypoaesthesia | 2 | 0 |
| Genital lesion | 2 | 0 |
| Genital paraesthesia | 5 | 0 |
| Genital ulceration | 13 | 0 |
| Perineal disorder | 2 | 0 |
| Varicose veins pelvic | 1 | 0 |
| <i>Reproductive tract infections and inflammations NEC</i> | | |
| Genital tract inflammation | 2 | 0 |
| <i>Reproductive tract neoplasms NEC</i> | | |
| Genital cyst | 2 | 0 |
| <i>Reproductive tract signs and symptoms NEC</i> | | |
| Genital burning sensation | 8 | 0 |
| Genital discomfort | 3 | 0 |
| Genital erythema | 1 | 0 |
| Genital pain | 3 | 0 |
| Genital rash | 6 | 0 |
| Genital swelling | 2 | 0 |
| Pelvic discomfort | 4 | 0 |
| Pelvic pain | 174 | 0 |
| Perineal pain | 2 | 0 |
| Pruritus genital | 9 | 0 |
| <i>Scrotal disorders NEC</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Scrotal dermatitis | 1 | 0 |
| Scrotal oedema | 1 | 0 |
| Scrotal pain | 19 | 0 |
| Scrotal swelling | 6 | 0 |
| Varicocele | 1 | 0 |
| Sexual function and fertility disorders NEC | | |
| Dyspareunia | 7 | 0 |
| Female sexual dysfunction | 1 | 0 |
| Infertility | 11 | 0 |
| Infertility female | 6 | 0 |
| Infertility male | 3 | 0 |
| Male sexual dysfunction | 2 | 0 |
| Sexual dysfunction | 14 | 0 |
| Spermatogenesis and semen disorders | | |
| Aspermia | 2 | 0 |
| Haemospermia | 17 | 0 |
| Semen discolouration | 2 | 0 |
| Testicular and epididymal disorders NEC | | |
| Testicular atrophy | 1 | 0 |
| Testicular disorder | 8 | 0 |
| Testicular mass | 1 | 0 |
| Testicular oedema | 2 | 0 |
| Testicular pain | 110 | 0 |
| Testicular retraction | 3 | 0 |
| Testicular swelling | 24 | 0 |
| Testis discomfort | 6 | 0 |
| Testicular and epididymal infections and inflammations | | |
| Orchitis noninfective | 1 | 0 |
| Testicular and epididymal neoplasms | | |
| Epididymal cyst | 1 | 0 |
| Testicular cyst | 1 | 0 |
| Uterine disorders NEC | | |
| Adenomyosis | 14 | 0 |
| Endometrial hyperplasia | 1 | 0 |
| Endometrial thickening | 2 | 0 |
| Endometriosis | 84 | 0 |
| Metrorrhoea | 1 | 0 |
| Uterine enlargement | 2 | 0 |
| Uterine haemorrhage | 71 | 0 |
| Uterine pain | 10 | 0 |
| Uterine neoplasms | | |
| Uterine cyst | 1 | 0 |
| Uterine polyp | 4 | 0 |
| Uterine tone disorders | | |
| Uterine spasm | 23 | 0 |
| Vaginal and vulval infections and inflammations | | |
| Vulvovaginal inflammation | 2 | 0 |
| Vulvovaginal cysts and neoplasms | | |
| Bartholin's cyst | 2 | 0 |
| Vaginal cyst | 15 | 0 |
| Vulva cyst | 1 | 0 |
| Vulvovaginal disorders NEC | | |
| Vaginal disorder | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|--------------|----------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Vaginal haemorrhage | 1286 | 0 |
| Vaginal ulceration | 7 | 0 |
| Vulval disorder | 3 | 0 |
| Vulval haemorrhage | 33 | 0 |
| Vulval ulceration | 7 | 0 |
| Vulvovaginal disorder | 1 | 0 |
| Vulvovaginal ulceration | 2 | 0 |
| <i>Vulvovaginal signs and symptoms</i> | | |
| Clitoral engorgement | 1 | 0 |
| Coital bleeding | 7 | 0 |
| Enlarged clitoris | 1 | 0 |
| Labia enlarged | 2 | 0 |
| Vaginal discharge | 88 | 0 |
| Vaginal lesion | 7 | 0 |
| Vaginal odour | 5 | 0 |
| Vulval oedema | 1 | 0 |
| Vulvovaginal burning sensation | 10 | 0 |
| Vulvovaginal discomfort | 8 | 0 |
| Vulvovaginal dryness | 12 | 0 |
| Vulvovaginal erythema | 1 | 0 |
| Vulvovaginal pain | 37 | 0 |
| Vulvovaginal pruritus | 12 | 0 |
| Vulvovaginal rash | 2 | 0 |
| Vulvovaginal swelling | 7 | 0 |
| Reproductive & breast disorders SOC TOTAL | 19540 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Apnoea | 13 | 0 |
| Apnoeic attack | 1 | 0 |
| Cheyne-Stokes respiration | 2 | 0 |
| Dyspnoea | 7597 | 0 |
| Dyspnoea at rest | 15 | 0 |
| Dyspnoea exertional | 59 | 0 |
| Dyspnoea paroxysmal nocturnal | 1 | 0 |
| Grunting | 2 | 0 |
| Hyperventilation | 100 | 0 |
| Hypopnoea | 230 | 0 |
| Hypoventilation | 1 | 0 |
| Irregular breathing | 26 | 0 |
| Mouth breathing | 8 | 0 |
| Orthopnoea | 3 | 0 |
| Respiration abnormal | 107 | 0 |
| Respiratory arrest | 27 | 0 |
| Respiratory distress | 12 | 0 |
| Respiratory fatigue | 7 | 0 |
| Sleep apnoea syndrome | 32 | 0 |
| Tachypnoea | 37 | 0 |
| <i>Bronchial conditions NEC</i> | | |
| Bronchial haemorrhage | 1 | 0 |
| Bronchial secretion retention | 1 | 0 |
| Bronchial wall thickening | 1 | 0 |
| Bronchiectasis | 16 | 0 |
| <i>Bronchospasm and obstruction</i> | | |
| Aspirin-exacerbated respiratory disease | 1 | 0 |
| Asthma | 624 | 0 |
| Asthma exercise induced | 4 | 0 |
| Asthma late onset | 3 | 0 |
| Asthma-chronic obstructive pulmonary disease overlap syndrome | 2 | 0 |
| Asthmatic crisis | 5 | 0 |
| Bronchial oedema | 1 | 0 |
| Bronchitis chronic | 2 | 0 |
| Bronchospasm | 18 | 0 |
| Chronic obstructive pulmonary disease | 51 | 4 |
| Cough variant asthma | 9 | 0 |
| Obstructive airways disorder | 2 | 0 |
| Reversible airways obstruction | 1 | 0 |
| Wheezing | 634 | 0 |
| <i>Conditions associated with abnormal gas exchange</i> | | |
| Asphyxia | 3 | 0 |
| Hypercapnia | 1 | 0 |
| Hypoxia | 70 | 1 |
| <i>Coughing and associated symptoms</i> | | |
| Allergic cough | 8 | 0 |
| Cough | 3964 | 0 |
| Haemoptysis | 144 | 0 |
| Productive cough | 207 | 0 |
| Sputum discoloured | 15 | 0 |
| Sputum increased | 3 | 0 |
| Sputum retention | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| <i>Diaphragmatic disorders</i> | | |
| Diaphragmatic paralysis | 1 | 0 |
| Diaphragmatic spasm | 2 | 0 |
| <i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i> | | |
| Reflux laryngitis | 4 | 0 |
| Vocal cord disorder | 5 | 0 |
| Vocal cord dysfunction | 6 | 0 |
| Vocal cord thickening | 2 | 0 |
| <i>Laryngeal spasm, oedema and obstruction</i> | | |
| Epiglottic oedema | 1 | 0 |
| Laryngeal oedema | 3 | 0 |
| Laryngospasm | 3 | 0 |
| Stridor | 21 | 0 |
| <i>Lower respiratory tract inflammatory and immunologic conditions</i> | | |
| Alveolitis | 2 | 0 |
| Autoimmune lung disease | 1 | 0 |
| Eosinophilic pneumonia | 2 | 0 |
| Hypersensitivity pneumonitis | 1 | 0 |
| Pneumonitis | 34 | 1 |
| Pulmonary sarcoidosis | 2 | 0 |
| Pulmonary vasculitis | 1 | 0 |
| <i>Lower respiratory tract signs and symptoms</i> | | |
| Hiccups | 47 | 0 |
| Lower respiratory tract congestion | 4 | 0 |
| Lung opacity | 7 | 0 |
| Pleuritic pain | 48 | 0 |
| Pulmonary haemorrhage | 7 | 1 |
| Pulmonary pain | 232 | 0 |
| Rales | 2 | 0 |
| <i>Mediastinal disorders</i> | | |
| Pulmonary hilum mass | 1 | 0 |
| <i>Nasal congestion and inflammations</i> | | |
| Nasal congestion | 470 | 0 |
| Nasal inflammation | 8 | 0 |
| Rhinitis allergic | 27 | 0 |
| Rhinitis perennial | 1 | 0 |
| <i>Nasal disorders NEC</i> | | |
| Epistaxis | 2264 | 0 |
| Intranasal hypoaesthesia | 1 | 0 |
| Nasal crusting | 6 | 0 |
| Nasal cyst | 2 | 0 |
| Nasal disorder | 7 | 0 |
| Nasal dryness | 70 | 0 |
| Nasal mucosal discolouration | 1 | 0 |
| Nasal odour | 2 | 0 |
| Nasal oedema | 16 | 0 |
| Nasal polyps | 1 | 0 |
| Nasal pruritus | 12 | 0 |
| Nasal septum deviation | 1 | 0 |
| Nasal septum perforation | 1 | 0 |
| Nasal ulcer | 4 | 0 |
| <i>Neonatal hypoxic conditions</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| Gasping syndrome | 2 | 0 |
| <i>Paranasal sinus disorders (excl infections and neoplasms)</i> | | |
| Allergic sinusitis | 2 | 0 |
| Paranasal sinus haemorrhage | 5 | 0 |
| Paranasal sinus hypersecretion | 1 | 0 |
| Paranasal sinus inflammation | 4 | 0 |
| Sinonasal obstruction | 12 | 0 |
| Sinus congestion | 90 | 0 |
| Sinus disorder | 17 | 0 |
| Sinus polyp | 3 | 0 |
| <i>Parenchymal lung disorders NEC</i> | | |
| Atelectasis | 8 | 0 |
| Cystic lung disease | 1 | 0 |
| Emphysema | 5 | 0 |
| Idiopathic pulmonary fibrosis | 3 | 0 |
| Interstitial lung disease | 9 | 2 |
| Lung consolidation | 9 | 0 |
| Lung cyst | 1 | 0 |
| Lung induration | 1 | 0 |
| Lung infiltration | 2 | 0 |
| Pulmonary alveolar haemorrhage | 1 | 0 |
| Pulmonary calcification | 1 | 0 |
| Pulmonary cavitation | 3 | 0 |
| Pulmonary fibrosis | 10 | 0 |
| <i>Pharyngeal disorders (excl infections and neoplasms)</i> | | |
| Oropharyngeal swelling | 2 | 0 |
| Pharyngeal erythema | 5 | 0 |
| Pharyngeal haemorrhage | 1 | 0 |
| Pharyngeal hypoaesthesia | 40 | 0 |
| Pharyngeal inflammation | 1 | 0 |
| Pharyngeal oedema | 14 | 0 |
| Pharyngeal paraesthesia | 36 | 0 |
| Pharyngeal swelling | 294 | 0 |
| Pharyngeal ulceration | 15 | 0 |
| Tonsillar disorder | 1 | 0 |
| Tonsillar erythema | 7 | 0 |
| Tonsillar haemorrhage | 1 | 0 |
| Tonsillar hypertrophy | 65 | 0 |
| Tonsillar inflammation | 4 | 0 |
| Tonsillar ulcer | 2 | 0 |
| Tonsillolith | 1 | 0 |
| <i>Pleural conditions NEC</i> | | |
| Pleural thickening | 1 | 0 |
| <i>Pleural infections and inflammations</i> | | |
| Lupus pleurisy | 2 | 0 |
| Pleurisy | 53 | 0 |
| <i>Pneumothorax and pleural effusions NEC</i> | | |
| Haemothorax | 1 | 0 |
| Pleural effusion | 48 | 1 |
| Pneumothorax | 11 | 0 |
| Pneumothorax spontaneous | 1 | 0 |
| <i>Pulmonary hypertension</i> | | |
| Pulmonary hypertension | 6 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| <i>Pulmonary oedemas</i> | | |
| Acute lung injury | 1 | 0 |
| Acute pulmonary oedema | 3 | 0 |
| Acute respiratory distress syndrome | 1 | 0 |
| Pulmonary congestion | 22 | 0 |
| Pulmonary oedema | 40 | 1 |
| <i>Pulmonary thrombotic and embolic conditions</i> | | |
| Pulmonary artery thrombosis | 2 | 0 |
| Pulmonary embolism | 1671 | 110 |
| Pulmonary infarction | 15 | 1 |
| Pulmonary thrombosis | 26 | 5 |
| Pulmonary venous thrombosis | 4 | 0 |
| <i>Respiratory failures (excl neonatal)</i> | | |
| Acute respiratory failure | 3 | 1 |
| Respiratory failure | 27 | 3 |
| <i>Respiratory signs and symptoms NEC</i> | | |
| Allergic respiratory symptom | 11 | 0 |
| Diaphragmalgia | 15 | 0 |
| Nasal flaring | 1 | 0 |
| Painful respiration | 9 | 0 |
| Pleural rub | 1 | 0 |
| Respiratory symptom | 24 | 0 |
| Suffocation feeling | 5 | 0 |
| Use of accessory respiratory muscles | 2 | 0 |
| <i>Respiratory tract disorders NEC</i> | | |
| Aspiration | 10 | 2 |
| Chronic respiratory disease | 2 | 1 |
| Lung disorder | 10 | 0 |
| Pulmonary mass | 9 | 0 |
| Respiratory disorder | 9 | 0 |
| Respiratory tract congestion | 10 | 0 |
| Respiratory tract haemorrhage | 2 | 0 |
| Respiratory tract irritation | 10 | 0 |
| Respiratory tract oedema | 3 | 0 |
| <i>Thoracic musculoskeletal disorders</i> | | |
| Respiratory muscle weakness | 2 | 0 |
| <i>Tracheal disorders (excl infections and neoplasms)</i> | | |
| Tracheal fistula | 1 | 0 |
| Tracheal pain | 4 | 0 |
| <i>Upper respiratory tract signs and symptoms</i> | | |
| Aphonia | 116 | 0 |
| Catarrh | 67 | 0 |
| Choking | 21 | 0 |
| Choking sensation | 12 | 0 |
| Dry throat | 260 | 0 |
| Dysphonia | 171 | 0 |
| Increased upper airway secretion | 4 | 0 |
| Increased viscosity of upper respiratory secretion | 21 | 0 |
| Laryngeal pain | 1 | 0 |
| Nasal discharge discolouration | 2 | 0 |
| Nasal discomfort | 113 | 0 |
| Nasal obstruction | 2 | 0 |
| Oropharyngeal blistering | 27 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|--------------|------------|
| Respiratory disorders Respiratory disorders cont'd | | |
| Oropharyngeal discomfort | 38 | 0 |
| Oropharyngeal pain | 4209 | 0 |
| Oropharyngeal plaque | 1 | 0 |
| Paranasal sinus discomfort | 78 | 0 |
| Rhinalgia | 35 | 0 |
| Rhinorrhoea | 1674 | 0 |
| Sinus pain | 605 | 0 |
| Sneezing | 518 | 0 |
| Snoring | 5 | 0 |
| Throat clearing | 7 | 0 |
| Throat irritation | 216 | 0 |
| Throat lesion | 1 | 0 |
| Throat tightness | 228 | 0 |
| Upper airway obstruction | 1 | 0 |
| Upper respiratory tract congestion | 1 | 0 |
| Upper-airway cough syndrome | 26 | 0 |
| Yawning | 71 | 0 |
| <i>Vascular pulmonary disorders NEC</i> | | |
| Pulmonary artery occlusion | 1 | 0 |
| Pulmonary vascular disorder | 1 | 0 |
| Respiratory disorders SOC TOTAL | 28695 | 135 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Skin disorders | | |
| <i>Acnes</i> | | |
| Acne | 148 | 0 |
| Acne cystic | 11 | 0 |
| Dermatitis acneiform | 11 | 0 |
| <i>Alopecias</i> | | |
| Alopecia | 431 | 0 |
| Alopecia areata | 45 | 0 |
| Alopecia scarring | 2 | 0 |
| Alopecia totalis | 2 | 0 |
| Alopecia universalis | 3 | 0 |
| Androgenetic alopecia | 2 | 0 |
| Diffuse alopecia | 5 | 0 |
| Hypotrichosis | 1 | 0 |
| Madarosis | 6 | 0 |
| <i>Angioedemas</i> | | |
| Angioedema | 354 | 0 |
| Circumoral oedema | 2 | 0 |
| Idiopathic angioedema | 3 | 0 |
| <i>Apocrine and eccrine gland disorders</i> | | |
| Anhidrosis | 2 | 0 |
| Cold sweat | 1720 | 0 |
| Hidradenitis | 3 | 0 |
| Hyperhidrosis | 9231 | 0 |
| Hypohidrosis | 6 | 0 |
| Miliaria | 222 | 0 |
| Night sweats | 1916 | 0 |
| Sweat discolouration | 3 | 0 |
| Sweat gland disorder | 1 | 0 |
| <i>Bullous conditions</i> | | |
| Autoimmune blistering disease | 1 | 0 |
| Blister | 633 | 0 |
| Blister rupture | 7 | 0 |
| Blood blister | 114 | 0 |
| Bullous haemorrhagic dermatosis | 1 | 0 |
| Dermatitis bullous | 17 | 0 |
| Dermatitis herpetiformis | 2 | 0 |
| Erythema multiforme | 39 | 0 |
| Linear IgA disease | 1 | 0 |
| Oedema blister | 1 | 0 |
| Pemphigoid | 35 | 0 |
| Pemphigus | 8 | 0 |
| Stevens-Johnson syndrome | 7 | 0 |
| Toxic epidermal necrolysis | 2 | 0 |
| <i>Connective tissue disorders</i> | | |
| Chronic cutaneous lupus erythematosus | 1 | 0 |
| Cutaneous lupus erythematosus | 3 | 0 |
| Dermatomyositis | 4 | 0 |
| Subacute cutaneous lupus erythematosus | 1 | 0 |
| <i>Dermal and epidermal conditions NEC</i> | | |
| Acute febrile neutrophilic dermatosis | 3 | 0 |
| Dermatosis | 1 | 0 |
| Dry skin | 454 | 0 |
| Macule | 13 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|-------------------------------------|-------|-------|
| Skin disorders | | |
| Skin disorders cont'd | | |
| Myxoid cyst | 1 | 0 |
| Neutrophilic dermatosis | 1 | 0 |
| Pain of skin | 939 | 0 |
| Papule | 126 | 0 |
| Scab | 28 | 0 |
| Scar pain | 18 | 0 |
| Sensitive skin | 594 | 0 |
| Skin burning sensation | 582 | 0 |
| Skin discolouration | 216 | 0 |
| Skin discomfort | 6 | 0 |
| Skin disorder | 44 | 0 |
| Skin fissures | 15 | 0 |
| Skin fragility | 3 | 0 |
| Skin indentation | 17 | 0 |
| Skin induration | 17 | 0 |
| Skin laxity | 1 | 0 |
| Skin lesion | 61 | 0 |
| Skin necrosis | 7 | 0 |
| Skin odour abnormal | 51 | 0 |
| Skin plaque | 3 | 0 |
| Skin reaction | 274 | 0 |
| Skin sensitisation | 90 | 0 |
| Skin swelling | 100 | 0 |
| Skin texture abnormal | 2 | 0 |
| Skin tightness | 42 | 0 |
| Skin warm | 583 | 0 |
| Skin weeping | 10 | 0 |
| Sticky skin | 9 | 0 |
| Target skin lesion | 2 | 0 |
| Transient acantholytic dermatosis | 2 | 0 |
| Yellow skin | 33 | 0 |
| <i>Dermatitis and eczema</i> | | |
| Autoimmune dermatitis | 2 | 0 |
| Dermatitis | 191 | 0 |
| Dermatitis allergic | 318 | 0 |
| Dermatitis atopic | 40 | 0 |
| Dermatitis contact | 35 | 0 |
| Dermatitis diaper | 3 | 0 |
| Dyshidrotic eczema | 21 | 0 |
| Eczema | 364 | 0 |
| Eczema asteatotic | 19 | 0 |
| Eczema nummular | 5 | 0 |
| Eczema weeping | 2 | 0 |
| Hand dermatitis | 7 | 0 |
| Intertrigo | 3 | 0 |
| Neurodermatitis | 2 | 0 |
| Perioral dermatitis | 5 | 0 |
| Prurigo | 1 | 0 |
| Rebound eczema | 1 | 0 |
| Seborrhoeic dermatitis | 11 | 0 |
| Skin irritation | 158 | 0 |
| Stasis dermatitis | 7 | 0 |
| Urticarial dermatitis | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| <i>Dermatitis ascribed to specific agent</i> | | |
| Drug eruption | 37 | 0 |
| Drug reaction with eosinophilia and systemic symptoms | 13 | 0 |
| Fixed eruption | 8 | 0 |
| Palmar-plantar erythrodysesthesia syndrome | 3 | 0 |
| <i>Erythemas</i> | | |
| Erythema | 3388 | 0 |
| Erythema ab igne | 1 | 0 |
| Palmar erythema | 7 | 0 |
| Plantar erythema | 3 | 0 |
| <i>Exfoliative conditions</i> | | |
| Dermatitis exfoliative | 2 | 0 |
| Dermatitis exfoliative generalised | 9 | 0 |
| Exfoliative rash | 19 | 0 |
| Skin exfoliation | 182 | 0 |
| <i>Granulomatous and deep cutaneous inflammatory conditions</i> | | |
| Granuloma annulare | 9 | 0 |
| Granuloma skin | 1 | 0 |
| <i>Hyperkeratoses</i> | | |
| Hyperkeratosis | 2 | 0 |
| <i>Hyperpigmentation disorders</i> | | |
| Chloasma | 2 | 0 |
| Ephelides | 1 | 0 |
| Melanoderma | 2 | 0 |
| Skin hyperpigmentation | 10 | 0 |
| Solar lentigo | 7 | 0 |
| <i>Hypertrichoses</i> | | |
| Hypertrichosis | 4 | 0 |
| <i>Hypopigmentation disorders</i> | | |
| Skin depigmentation | 10 | 0 |
| Skin hypopigmentation | 3 | 0 |
| Vitiligo | 35 | 0 |
| <i>Lipodystrophies</i> | | |
| Lipoatrophy | 2 | 0 |
| Lipohypertrophy | 2 | 0 |
| Progressive facial hemiatrophy | 1 | 0 |
| <i>Nail and nail bed conditions (excl infections and infestations)</i> | | |
| Anonychia | 1 | 0 |
| Ingrowing nail | 2 | 0 |
| Nail bed bleeding | 2 | 0 |
| Nail bed disorder | 2 | 0 |
| Nail bed inflammation | 1 | 0 |
| Nail bed tenderness | 2 | 0 |
| Nail discolouration | 16 | 0 |
| Nail disorder | 3 | 0 |
| Nail growth abnormal | 2 | 0 |
| Nail hypertrophy | 1 | 0 |
| Nail necrosis | 1 | 0 |
| Nail pigmentation | 2 | 0 |
| Nail pitting | 1 | 0 |
| Nail ridging | 8 | 0 |
| Onychalgia | 6 | 0 |
| Onychoclasia | 9 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Onycholysis | 4 | 0 |
| Onychomadesis | 5 | 0 |
| Splinter haemorrhages | 6 | 0 |
| <i>Panniculitides</i> | | |
| Erythema nodosum | 37 | 0 |
| Panniculitis | 4 | 0 |
| <i>Papulosquamous conditions</i> | | |
| Erythema annulare | 2 | 0 |
| Lichen planus | 36 | 0 |
| Lichen sclerosus | 8 | 0 |
| Lichen striatus | 1 | 0 |
| Parapsoriasis | 2 | 0 |
| Pityriasis lichenoides et varioliformis acuta | 1 | 0 |
| Pityriasis rosea | 67 | 0 |
| Pityriasis rubra pilaris | 2 | 0 |
| <i>Photosensitivity and photodermatosis conditions</i> | | |
| Photodermatosis | 2 | 0 |
| Photosensitivity reaction | 171 | 0 |
| Polymorphic light eruption | 6 | 0 |
| Solar dermatitis | 1 | 0 |
| <i>Pigmentation changes NEC</i> | | |
| Pigmentation disorder | 17 | 0 |
| <i>Pilar disorders NEC</i> | | |
| Hair colour changes | 14 | 0 |
| Hair disorder | 1 | 0 |
| Hair growth abnormal | 7 | 0 |
| Hair texture abnormal | 12 | 0 |
| Piloerection | 101 | 0 |
| Pseudofolliculitis | 2 | 0 |
| Trichodynia | 7 | 0 |
| Trichorrhexis | 6 | 0 |
| <i>Pruritus NEC</i> | | |
| Itching scar | 5 | 0 |
| Pruritus | 8286 | 0 |
| Pruritus allergic | 1 | 0 |
| Senile pruritus | 1 | 0 |
| <i>Psoriatic conditions</i> | | |
| Dermatitis psoriasiform | 2 | 0 |
| Erythrodermic psoriasis | 1 | 0 |
| Guttate psoriasis | 29 | 0 |
| Nail psoriasis | 1 | 0 |
| Palmoplantar pustulosis | 2 | 0 |
| Psoriasis | 237 | 0 |
| Pustular psoriasis | 6 | 0 |
| <i>Purpura and related conditions</i> | | |
| Ecchymosis | 5 | 0 |
| Henoch-Schonlein purpura | 18 | 0 |
| Petechiae | 374 | 0 |
| Purpura | 146 | 0 |
| <i>Pustular conditions</i> | | |
| Acute generalised exanthematous pustulosis | 1 | 0 |
| Rash follicular | 4 | 0 |
| <i>Rashes, eruptions and exanthems NEC</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Butterfly rash | 8 | 0 |
| Nodular rash | 1 | 0 |
| Rash | 9095 | 0 |
| Rash erythematous | 2254 | 0 |
| Rash macular | 771 | 0 |
| Rash maculo-papular | 69 | 0 |
| Rash morbilliform | 49 | 0 |
| Rash papular | 572 | 0 |
| Rash pruritic | 1959 | 0 |
| Rash rubelliform | 1 | 0 |
| Rash scarlatiniform | 2 | 0 |
| Rash vesicular | 104 | 0 |
| Systemic lupus erythematosus rash | 9 | 0 |
| Rosaceas | | |
| Erythematotelangiectatic rosacea | 3 | 0 |
| Granulomatous rosacea | 1 | 0 |
| Papulopustular rosacea | 1 | 0 |
| Rosacea | 48 | 0 |
| Scaly conditions | | |
| Dandruff | 1 | 0 |
| Pityriasis | 13 | 0 |
| Sebaceous gland disorders | | |
| Sebaceous glands overactivity | 1 | 0 |
| Seborrhoea | 15 | 0 |
| Skin and subcutaneous conditions NEC | | |
| Cellulite | 3 | 0 |
| Cutaneous symptom | 11 | 0 |
| Skin discharge | 1 | 0 |
| Skin mass | 44 | 0 |
| Skin and subcutaneous tissue ulcerations | | |
| Diabetic foot | 2 | 0 |
| Diabetic ulcer | 1 | 0 |
| Ischaemic skin ulcer | 1 | 0 |
| Pyoderma gangrenosum | 3 | 0 |
| Skin erosion | 57 | 0 |
| Skin ulcer | 35 | 0 |
| Vasculitic ulcer | 1 | 0 |
| Skin cysts and polyps | | |
| Dermal cyst | 23 | 0 |
| Skin dystrophies | | |
| Keloid scar | 3 | 0 |
| Skin wrinkling | 4 | 0 |
| Skin haemorrhages | | |
| Haemorrhage subcutaneous | 21 | 0 |
| Mucocutaneous haemorrhage | 3 | 0 |
| Skin haemorrhage | 50 | 0 |
| Skin hyperplasias and hypertrophies | | |
| Skin hypertrophy | 3 | 0 |
| Skin hypoplasias and atrophies | | |
| Skin atrophy | 12 | 0 |
| Skin striae | 13 | 0 |
| Skin injuries and mechanical dermatoses | | |
| Decubitus ulcer | 5 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|--------------|----------|
| Skin disorders Skin disorders cont'd | | |
| Needle track marks | 3 | 0 |
| Skin preneoplastic conditions NEC | | |
| Actinic keratosis | 3 | 0 |
| Leukoplakia | 1 | 0 |
| Skin vascular conditions NEC | | |
| Angiodermatitis | 1 | 0 |
| Haemangioma-thrombocytopenia syndrome | 1 | 0 |
| Skin oedema | 3 | 0 |
| Skin vasculitides | | |
| Capillaritis | 1 | 0 |
| Cutaneous vasculitis | 14 | 0 |
| Hypersensitivity vasculitis | 4 | 0 |
| Nodular vasculitis | 1 | 0 |
| Vasculitic rash | 29 | 0 |
| Skin vasomotor conditions | | |
| Livedo reticularis | 60 | 0 |
| Telangiectasia and related conditions | | |
| Spider naevus | 5 | 0 |
| Telangiectasia | 5 | 0 |
| Urticarias | | |
| Chronic spontaneous urticaria | 6 | 0 |
| Cold urticaria | 10 | 0 |
| Idiopathic urticaria | 10 | 0 |
| Mechanical urticaria | 8 | 0 |
| Solar urticaria | 1 | 0 |
| Urticaria | 2574 | 0 |
| Urticaria chronic | 49 | 0 |
| Urticaria contact | 3 | 0 |
| Urticaria papular | 3 | 0 |
| Urticaria pigmentosa | 1 | 0 |
| Urticaria thermal | 7 | 0 |
| Urticarial vasculitis | 5 | 0 |
| Skin disorders SOC TOTAL | 52095 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Social circumstances | | |
| <i>Age related issues</i> | | |
| Childhood | 1 | 0 |
| Menarche | 3 | 0 |
| Menopause | 71 | 0 |
| Postmenopause | 18 | 0 |
| <i>Alcohol product use</i> | | |
| Alcoholic | 4 | 0 |
| <i>Crime victims</i> | | |
| Victim of abuse | 1 | 0 |
| <i>Criminal activity</i> | | |
| Chemical submission | 1 | 0 |
| Verbal abuse | 1 | 0 |
| <i>Dependents</i> | | |
| Sick relative | 1 | 0 |
| <i>Dietary and nutritional issues</i> | | |
| Inadequate diet | 1 | 0 |
| Kosher diet | 1 | 0 |
| <i>Disability issues</i> | | |
| Bedridden | 100 | 0 |
| Breast prosthesis user | 2 | 0 |
| Dependence on oxygen therapy | 1 | 0 |
| Disability | 8 | 0 |
| Hearing aid user | 2 | 0 |
| Hearing disability | 1 | 0 |
| Housebound | 2 | 0 |
| Immobile | 57 | 0 |
| Immobilisation prolonged | 4 | 0 |
| Impaired driving ability | 4 | 0 |
| Impaired work ability | 31 | 0 |
| Loss of personal independence in daily activities | 11 | 0 |
| Mental disability | 1 | 0 |
| Paralytic disability | 1 | 0 |
| Physical disability | 3 | 0 |
| Sight disability | 23 | 0 |
| Sitting disability | 3 | 0 |
| Walking aid user | 2 | 0 |
| Walking disability | 8 | 0 |
| Wheelchair user | 2 | 0 |
| <i>Educational issues</i> | | |
| Educational problem | 1 | 0 |
| Illiteracy | 3 | 0 |
| <i>Employment issues</i> | | |
| Job dissatisfaction | 2 | 0 |
| Retirement | 5 | 0 |
| Stress at work | 1 | 0 |
| Unemployment | 1 | 0 |
| <i>Family and partner issues</i> | | |
| Homosexual parent | 1 | 0 |
| Partner stress | 1 | 0 |
| <i>Non-occupational and unspecified environmental problems</i> | | |
| Food contamination | 1 | 0 |
| Water pollution | 4 | 0 |
| <i>Pregnancy related circumstances</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Social circumstances <small>Social circumstances cont'd</small> | | |
| Breast feeding | 8 | 0 |
| Sexuality issues | | |
| Anal sex | 1 | 0 |
| Homosexuality | 1 | 0 |
| Social issues NEC | | |
| Blood donor | 2 | 0 |
| Contraindication to medical treatment | 1 | 0 |
| Contraindication to vaccination | 2 | 0 |
| Convalescent | 1 | 0 |
| Hair dye user | 1 | 0 |
| Impaired quality of life | 5 | 0 |
| Refusal of vaccination | 3 | 0 |
| Tanning | 2 | 0 |
| Tattoo | 1 | 0 |
| Tobacco use | | |
| Non-tobacco user | 6 | 0 |
| Tobacco user | 2 | 0 |
| Social circumstances SOC TOTAL | 425 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Surgical & medical procedures | | |
| <i>Anaesthesia and allied procedures</i> | | |
| Local anaesthesia | 3 | 0 |
| Nerve block | 5 | 0 |
| <i>Analgesia supportive care</i> | | |
| Analgesic therapy | 1 | 0 |
| <i>Antiinfective therapies</i> | | |
| Antibiotic therapy | 2 | 0 |
| COVID-19 treatment | 7 | 0 |
| <i>Arterial therapeutic procedures (excl aortic)</i> | | |
| Cerebral revascularisation | 1 | 0 |
| Coronary artery bypass | 2 | 0 |
| <i>Autonomic nerve therapeutic procedures</i> | | |
| Vagotomy | 3 | 0 |
| <i>Biliary tract and gallbladder therapeutic procedures</i> | | |
| Cholecystectomy | 2 | 0 |
| Cholelithotomy | 1 | 0 |
| <i>Blood and blood product treatment</i> | | |
| Photopheresis | 1 | 0 |
| Transfusion | 1 | 0 |
| <i>Breast therapeutic procedures NEC</i> | | |
| Axillary lymphadenectomy | 1 | 0 |
| <i>Bronchial and pulmonary therapeutic procedures</i> | | |
| Airway secretion clearance therapy | 1 | 0 |
| Antitussive therapy | 1 | 0 |
| <i>Cardiac device therapeutic procedures</i> | | |
| Cardiac pacemaker insertion | 2 | 0 |
| Pacemaker generated rhythm | 1 | 0 |
| <i>Cardiac therapeutic procedures NEC</i> | | |
| Pericardial excision | 2 | 0 |
| <i>Cardiac valve therapeutic procedures</i> | | |
| Aortic valve replacement | 1 | 0 |
| Heart valve replacement | 1 | 0 |
| <i>Chemotherapies</i> | | |
| Chemotherapy toxicity attenuation | 1 | 0 |
| <i>Contraceptive methods female</i> | | |
| Contraception | 3 | 0 |
| Contraceptive diaphragm | 3 | 0 |
| Intrauterine contraception | 1 | 0 |
| Oral contraception | 2 | 0 |
| <i>Corneal and scleral therapeutic procedures</i> | | |
| Corneal transplant | 1 | 0 |
| <i>Dental and gingival therapeutic procedures</i> | | |
| Dental care | 1 | 0 |
| Tooth extraction | 2 | 0 |
| Tooth restoration | 4 | 0 |
| <i>Dietary and nutritional therapies</i> | | |
| Fluid replacement | 1 | 0 |
| Gluten free diet | 1 | 0 |
| Medical diet | 6 | 0 |
| Mineral supplementation | 1 | 0 |
| Nothing by mouth order | 8 | 0 |
| <i>External ear therapeutic procedures</i> | | |
| Cerumen removal | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Surgical & medical procedures | | |
| <i>Surgical & medical procedures cont'd</i> | | |
| <i>Eye therapeutic procedures NEC</i> | | |
| Eye irrigation | 3 | 0 |
| <i>Facial therapeutic procedures</i> | | |
| Face lift | 3 | 0 |
| <i>Fallopian tube therapeutic procedures</i> | | |
| Fallopian tube operation | 1 | 0 |
| <i>Fascial and bursal therapeutic procedures</i> | | |
| Bursa removal | 1 | 0 |
| <i>Fertility and fertilisation interventions female</i> | | |
| Ovulation induction | 2 | 0 |
| <i>Gastric therapeutic procedures</i> | | |
| Antacid therapy | 1 | 0 |
| <i>Gastrointestinal therapeutic procedures NEC</i> | | |
| Intestinal resection | 1 | 0 |
| Prophylaxis against gastrointestinal ulcer | 1 | 0 |
| Prophylaxis of nausea and vomiting | 28 | 0 |
| <i>Gynaecological therapeutic procedures NEC</i> | | |
| Gynaecological disorder prophylaxis | 1 | 0 |
| Menstrual cycle management | 4 | 0 |
| <i>Haematological therapeutic procedures NEC</i> | | |
| Anticoagulant therapy | 2 | 0 |
| Haemofiltration | 1 | 0 |
| Thrombosis prophylaxis | 2 | 0 |
| <i>Head, neck and oral cavity therapeutic procedures NEC</i> | | |
| Neck lift | 1 | 0 |
| <i>Hormonal therapeutic procedures NEC</i> | | |
| Hormone replacement therapy | 7 | 0 |
| Hormone therapy | 9 | 0 |
| Steroid therapy | 1 | 0 |
| <i>Immunisations</i> | | |
| COVID-19 immunisation | 221 | 0 |
| Immunisation | 116 | 0 |
| Influenza immunisation | 1 | 0 |
| Tuberculosis immunisation | 1 | 0 |
| <i>Induced abortions</i> | | |
| Abortion induced | 3 | 0 |
| <i>Iris and ciliary body therapeutic procedures</i> | | |
| Pupil constriction procedure | 1 | 0 |
| <i>Joint therapeutic procedures</i> | | |
| Hip surgery | 1 | 0 |
| Joint dislocation reduction | 1 | 0 |
| Joint injection | 6 | 0 |
| Joint stabilisation | 2 | 0 |
| Knee operation | 2 | 0 |
| Shoulder operation | 2 | 0 |
| <i>Large intestine therapeutic procedures</i> | | |
| Appendectomy | 8 | 0 |
| Colectomy | 2 | 0 |
| <i>Limb therapeutic procedures</i> | | |
| Arm amputation | 1 | 0 |
| Foot amputation | 1 | 0 |
| Leg amputation | 5 | 0 |
| Limb immobilisation | 28 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Surgical & medical procedures | | |
| <i>Surgical & medical procedures cont'd</i> | | |
| Limb operation | 13 | 0 |
| Limb reattachment surgery | 1 | 0 |
| Toe amputation | 5 | 0 |
| Mastectomies | | |
| Breast conserving surgery | 2 | 0 |
| Muscle therapeutic procedures | | |
| Muscle relaxant therapy | 3 | 0 |
| Nail therapeutic procedures | | |
| Nail operation | 2 | 0 |
| Nasal therapeutic procedures | | |
| Nasal irrigation | 1 | 0 |
| Nervous system therapeutic procedures NEC | | |
| Central nervous system stimulation | 3 | 0 |
| Multiple sclerosis relapse prophylaxis | 1 | 0 |
| Neurological rehabilitation | 1 | 0 |
| Orbit and globe therapeutic procedures | | |
| Eye muscle operation | 1 | 0 |
| Patient positioning | | |
| Prone position | 1 | 0 |
| Peripheral nerve therapeutic procedures | | |
| Carpal tunnel decompression | 1 | 0 |
| Phototherapies | | |
| UV light therapy | 1 | 0 |
| Prophylactic procedures NEC | | |
| Anaphylaxis prophylaxis | 3 | 0 |
| Reproductive system disorder prophylaxis | 1 | 0 |
| Psychiatric therapies | | |
| Antidepressant therapy | 1 | 0 |
| Psychotherapy | 1 | 0 |
| Renal therapeutic procedures | | |
| Dialysis | 1 | 0 |
| Respiratory tract therapeutic procedures NEC | | |
| Respiratory therapy | 1 | 0 |
| Skin and subcutaneous tissue therapeutic procedures NEC | | |
| Dermal filler injection | 1 | 0 |
| Skin lesion excisions | | |
| Skin neoplasm excision | 1 | 0 |
| Tattoo excision | 1 | 0 |
| Skull and brain therapeutic procedures | | |
| Brain operation | 2 | 0 |
| Small intestine therapeutic procedures | | |
| Ileostomy | 3 | 0 |
| Spine and spinal cord therapeutic procedures | | |
| Spinal operation | 1 | 0 |
| Testicular and scrotal therapeutic procedures | | |
| Testes exploration | 1 | 0 |
| Therapeutic procedures NEC | | |
| Anaphylaxis treatment | 4 | 0 |
| Antiallergic therapy | 1 | 0 |
| Bed rest | 24 | 0 |
| Catheter management | 4 | 0 |
| Catheter placement | 2 | 0 |
| Continuous passive motion machine therapy | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Surgical & medical procedures | | |
| <i>Surgical & medical procedures cont'd</i> | | |
| Fatigue management | 1 | 0 |
| Heat therapy | 3 | 0 |
| Hospitalisation | 31 | 0 |
| Immobilisation bandage | 1 | 0 |
| Injection | 53 | 0 |
| Interchange of vaccine products | 34 | 0 |
| Localised alternating hot and cold therapy | 6 | 0 |
| Magnetic therapy | 1 | 0 |
| Manipulation | 1 | 0 |
| Mass excision | 10 | 0 |
| Medication dilution | 3 | 0 |
| Occupational therapy | 1 | 0 |
| Physical fitness training | 4 | 0 |
| Physiotherapy | 1 | 0 |
| Product used for unknown indication | 2 | 0 |
| Promotion of wound healing | 1 | 0 |
| Self-medication | 1 | 0 |
| Smoking cessation therapy | 1 | 0 |
| Specialist consultation | 1 | 0 |
| Stoma care | 1 | 0 |
| Surgery | 2 | 0 |
| Therapeutic hypothermia | 2 | 0 |
| Therapy change | 2 | 0 |
| Transgender operation | 1 | 0 |
| Tumour excision | 1 | 0 |
| Wound treatment | 1 | 0 |
| <i>Tonsillar therapeutic procedures</i> | | |
| Tonsillectomy | 1 | 0 |
| <i>Tracheal therapeutic procedures</i> | | |
| Tracheostomy | 1 | 0 |
| <i>Tumour vaccine therapies</i> | | |
| Tumour vaccine therapy | 1 | 0 |
| <i>Uterine therapeutic procedures</i> | | |
| Endometrial ablation | 6 | 0 |
| Hysterectomy | 1 | 0 |
| <i>Vascular therapeutic procedures NEC</i> | | |
| Clamping of blood vessel | 1 | 0 |
| Thrombectomy | 3 | 0 |
| Thromboembolectomy | 1 | 0 |
| Thrombolysis | 2 | 0 |
| Vascular graft | 1 | 0 |
| <i>Venous therapeutic procedures</i> | | |
| Phlebotomy | 2 | 0 |
| Surgical & medical procedures SOC TOTAL | 823 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Vascular disorders | | |
| <i>Accelerated and malignant hypertension</i> | | |
| Accelerated hypertension | 1 | 0 |
| Hypertensive crisis | 15 | 0 |
| Hypertensive emergency | 2 | 0 |
| Hypertensive urgency | 4 | 0 |
| Malignant hypertension | 6 | 0 |
| Tyramine reaction | 1 | 0 |
| <i>Aneurysms and dissections non-site specific</i> | | |
| Aneurysm | 13 | 1 |
| Aneurysm ruptured | 1 | 0 |
| Artery dissection | 4 | 0 |
| Venous aneurysm | 1 | 0 |
| <i>Aortic aneurysms and dissections</i> | | |
| Acute aortic syndrome | 1 | 0 |
| Aortic aneurysm | 7 | 0 |
| Aortic aneurysm rupture | 1 | 1 |
| Aortic dissection | 4 | 1 |
| Aortic intramural haematoma | 1 | 0 |
| Penetrating aortic ulcer | 1 | 0 |
| <i>Aortic embolism and thrombosis</i> | | |
| Aortic embolus | 25 | 1 |
| Aortic thrombosis | 12 | 2 |
| <i>Aortic infections and inflammations</i> | | |
| Aortitis | 2 | 0 |
| <i>Aortic necrosis and vascular insufficiency</i> | | |
| Aortic occlusion | 1 | 0 |
| Aortic stenosis | 3 | 0 |
| <i>Arterial infections and inflammations</i> | | |
| Arteritis | 5 | 0 |
| Giant cell arteritis | 59 | 0 |
| <i>Blood pressure disorders NEC</i> | | |
| Blood pressure fluctuation | 25 | 0 |
| Labile blood pressure | 4 | 0 |
| <i>Bruising, ecchymosis and purpura</i> | | |
| Achenbach syndrome | 10 | 0 |
| <i>Circulatory collapse and shock</i> | | |
| Circulatory collapse | 131 | 2 |
| Distributive shock | 2 | 0 |
| Hypoperfusion | 2 | 0 |
| Hypovolaemic shock | 1 | 0 |
| Neurogenic shock | 10 | 0 |
| Peripheral circulatory failure | 4 | 0 |
| Shock | 57 | 1 |
| Shock haemorrhagic | 1 | 0 |
| Shock symptom | 6 | 0 |
| <i>Haemorrhages NEC</i> | | |
| Bloody discharge | 16 | 0 |
| Haematoma | 113 | 0 |
| Haemorrhage | 1433 | 2 |
| Internal haemorrhage | 31 | 0 |
| Venous haemorrhage | 9 | 0 |
| <i>Lymphangiopathies</i> | | |
| Lymphangiopathy | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Vascular disorders Vascular disorders cont'd | | |
| Lymphocele | 2 | 0 |
| Lymphorrhoea | 1 | 0 |
| Lymphoedemas | | |
| Lymphoedema | 75 | 0 |
| Non-site specific embolism and thrombosis | | |
| Air embolism | 1 | 0 |
| Arterial thrombosis | 31 | 1 |
| Atheroembolism | 1 | 0 |
| Embolism | 255 | 3 |
| Embolism arterial | 3 | 0 |
| Embolism venous | 13 | 1 |
| Microembolism | 3 | 0 |
| Paradoxical embolism | 1 | 0 |
| Post thrombotic syndrome | 4 | 0 |
| Thrombophlebitis migrans | 2 | 0 |
| Thrombosis | 1834 | 39 |
| Venous thrombosis | 36 | 0 |
| Non-site specific necrosis and vascular insufficiency NEC | | |
| Arterial occlusive disease | 16 | 0 |
| Arterial spasm | 2 | 0 |
| Arterial stenosis | 1 | 0 |
| Arteriosclerosis | 7 | 0 |
| Haemorrhagic infarction | 1 | 0 |
| Infarction | 14 | 0 |
| Ischaemia | 15 | 0 |
| Peripheral venous disease | 11 | 0 |
| Vascular compression | 2 | 0 |
| Vascular occlusion | 3 | 0 |
| Vasospasm | 13 | 0 |
| Non-site specific vascular disorders NEC | | |
| Angiopathy | 5 | 0 |
| Arterial rupture | 1 | 0 |
| Capillary disorder | 1 | 0 |
| Capillary fragility | 11 | 0 |
| Collateral circulation | 1 | 0 |
| Haemodynamic instability | 4 | 0 |
| Hyperaemia | 2 | 0 |
| Neovascularisation | 1 | 0 |
| Superficial vein prominence | 7 | 0 |
| Vascular fragility | 1 | 0 |
| Vascular pain | 136 | 0 |
| Vascular rupture | 2 | 0 |
| Vascular wall discolouration | 1 | 0 |
| Vasodilatation | 122 | 0 |
| Vein collapse | 2 | 0 |
| Vein discolouration | 8 | 0 |
| Vein disorder | 25 | 0 |
| Vein rupture | 17 | 0 |
| Peripheral aneurysms and dissections | | |
| Peripheral artery aneurysm | 2 | 0 |
| Peripheral embolism and thrombosis | | |
| Axillary vein thrombosis | 1 | 0 |
| Blue toe syndrome | 39 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Vascular disorders <small>Vascular disorders cont'd</small> | | |
| Deep vein thrombosis | 1256 | 9 |
| Femoral artery embolism | 2 | 0 |
| Iliac artery embolism | 2 | 0 |
| Jugular vein thrombosis | 27 | 0 |
| Pelvic venous thrombosis | 24 | 1 |
| Peripheral artery thrombosis | 18 | 0 |
| Peripheral embolism | 10 | 0 |
| Peripheral vein thrombus extension | 1 | 0 |
| Subclavian artery embolism | 2 | 0 |
| Subclavian artery thrombosis | 1 | 0 |
| Subclavian vein thrombosis | 4 | 0 |
| Superficial vein thrombosis | 69 | 0 |
| Thrombophlebitis | 141 | 0 |
| Venous thrombosis limb | 6 | 0 |
| Peripheral vascular disorders NEC | | |
| Cyanosis | 110 | 0 |
| Erythromelalgia | 7 | 0 |
| Flushing | 705 | 0 |
| Hot flush | 2196 | 0 |
| Peripheral vascular disorder | 7 | 0 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | | |
| Dry gangrene | 2 | 0 |
| Extremity necrosis | 3 | 0 |
| Iliac artery occlusion | 2 | 0 |
| Intermittent claudication | 7 | 0 |
| Ischaemic limb pain | 5 | 0 |
| Jugular vein occlusion | 2 | 0 |
| Peripheral arterial occlusive disease | 5 | 0 |
| Peripheral artery occlusion | 9 | 0 |
| Peripheral coldness | 1309 | 0 |
| Peripheral ischaemia | 34 | 2 |
| Poor peripheral circulation | 57 | 0 |
| Raynaud's phenomenon | 151 | 0 |
| Phlebitis NEC | | |
| Phlebitis | 62 | 0 |
| Phlebitis superficial | 13 | 0 |
| Site specific embolism and thrombosis NEC | | |
| Brachiocephalic vein thrombosis | 1 | 0 |
| Site specific necrosis and vascular insufficiency NEC | | |
| Superior vena cava syndrome | 1 | 0 |
| Site specific vascular disorders NEC | | |
| Aortic dilatation | 1 | 0 |
| Aortic rupture | 1 | 0 |
| Pallor | 424 | 0 |
| Plethoric face | 1 | 0 |
| Varicose veins NEC | | |
| Bleeding varicose vein | 2 | 0 |
| Spider vein | 21 | 0 |
| Varicophlebitis | 10 | 0 |
| Varicose ulceration | 1 | 0 |
| Varicose vein | 153 | 0 |
| Varicose vein ruptured | 1 | 0 |
| Vascular hypertensive disorders NEC | | |

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|---------------|-------------|
| Vascular disorders <small>Vascular disorders cont'd</small> | | |
| Diastolic hypertension | 5 | 0 |
| Essential hypertension | 1 | 0 |
| Hypertension | 1010 | 0 |
| Labile hypertension | 1 | 0 |
| Systolic hypertension | 3 | 0 |
| Venous hypertension | 4 | 0 |
| White coat hypertension | 12 | 0 |
| <i>Vascular hypotensive disorders</i> | | |
| Capillary leak syndrome | 14 | 0 |
| Diastolic hypotension | 1 | 0 |
| Hypotension | 545 | 0 |
| Orthostatic hypotension | 48 | 0 |
| <i>Vascular malformations and acquired anomalies</i> | | |
| Arteriovenous fistula | 1 | 0 |
| <i>Vasculitides NEC</i> | | |
| Behcet's syndrome | 3 | 0 |
| Diffuse vasculitis | 2 | 1 |
| Granulomatosis with polyangiitis | 1 | 0 |
| MAGIC syndrome | 3 | 1 |
| Vasculitis | 107 | 2 |
| <i>Vena caval embolism and thrombosis</i> | | |
| Vena cava thrombosis | 6 | 1 |
| Vascular disorders SOC TOTAL | 13395 | 72 |
| TOTAL REACTIONS FOR DRUG | 846131 | 1138 |
| TOTAL REPORTS | 238641 | |
| TOTAL FATAL OUTCOME REPORTS | | 1138 |