

COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Data Lock Date: 07-Mar-2021 19:00:03

All UK spontaneous reports received between 4/01/21 and 07/03/21 for COVID-19 vaccine Oxford University/AstraZeneca

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Blood disorders		
Anaemias NEC		
Anaemia	6	0
Anaemias haemolytic NEC		
Haemolytic anaemia	2	0
Anaemias haemolytic immune		
Autoimmune haemolytic anaemia	1	0
Bleeding tendencies		
Increased tendency to bruise	3	0
Coagulopathies		
Antiphospholipid syndrome	1	0
Coagulopathy	2	0
Eosinophilic disorders		
Eosinophilia	4	0
Haematological disorders		
Bone marrow oedema	1	0
Mast cell activation syndrome	1	0
Mastocytosis	1	0
Methaemoglobinaemia	1	0
Haemolyses NEC		
Haemolysis	2	0
Leukocytoses NEC		
Lymphocytosis	1	0
Leukopenias NEC		
Leukopenia	3	0
Lymphopenia	4	0
Lymphatic system disorders NEC		
Lymph node pain	104	0
Lymphadenitis	10	0
Lymphadenopathy	1065	0
Lymphatic disorder	1	0
Marrow depression and hypoplastic anaemias		
Pancytopenia	3	0
Neutropenias		
Neutropenia	20	0
Sickle cell trait and disorders		
Sickle cell anaemia with crisis	2	0
Spleen disorders		
Spleen disorder	1	0
Splenic artery thrombosis	1	0
Splenic infarction	2	0
Splenomegaly	1	0
Thrombocytopenias		
Immune thrombocytopenia	25	1
Thrombocytopenia	15	0
Thrombocytopenic purpura	3	0
White blood cell abnormal findings NEC		
White blood cell disorder	1	0
Blood disorders SOC TOTAL	1287	1

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Cardiac disorders		
<i>Aortic valvular disorders</i>		
Aortic valve stenosis	1	0
<i>Cardiac conduction disorders</i>		
Atrioventricular block	2	0
Bundle branch block left	1	0
Long QT syndrome	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	2	1
Cardiac disorder	5	0
Cardiovascular disorder	1	0
Cardiovascular insufficiency	3	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	1	0
Palpitations	1318	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	1	1
<i>Cardiomyopathies</i>		
Cardiomyopathy	2	0
Congestive cardiomyopathy	3	0
<i>Heart failures NEC</i>		
Cardiac failure	8	3
Cardiac failure acute	1	0
Cardiogenic shock	1	1
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	5	2
Angina pectoris	28	0
Angina unstable	4	0
Arteriospasm coronary	1	0
Microvascular coronary artery disease	2	0
Myocardial infarction	27	11
Myocardial ischaemia	6	3
Prinzmetal angina	1	0
<i>Left ventricular failures</i>		
Left ventricular failure	1	1
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	2	0
<i>Noninfectious pericarditis</i>		
Pericarditis	7	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	3	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	31	0
Bradycardia	21	0
Cardiac flutter	32	0
Extrasystoles	17	0
Postural orthostatic tachycardia syndrome	3	0
Tachyarrhythmia	5	0
Tachycardia	500	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
<i>Right ventricular failures</i>		
Right ventricular failure	1	1
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	5	0
Atrial fibrillation	60	0
Atrial flutter	7	0
Sinus arrhythmia	1	0
Sinus bradycardia	1	0
Sinus tachycardia	23	0
Supraventricular tachycardia	7	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	38	13
Ventricular arrhythmia	1	0
Ventricular extrasystoles	1	0
Ventricular fibrillation	1	0
Ventricular tachycardia	4	0
Cardiac disorders SOC TOTAL	2200	38

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	1	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	1	0
<i>Cerebral disorders congenital</i>		
Cerebral palsy	5	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogyposis	1	0
<i>Neurological disorders congenital NEC</i>		
Familial periodic paralysis	1	0
<i>Pancreatic disorders congenital</i>		
Hereditary pancreatitis	1	0
<i>Peripheral nervous system disorders congenital NEC</i>		
Paroxysmal extreme pain disorder	6	0
<i>Pulmonary and bronchial disorders congenital</i>		
Cystic fibrosis	3	0
Congenital disorders SOC TOTAL	19	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	1	0
Ear discomfort	17	0
Ear disorder	1	0
Ear haemorrhage	2	0
Ear pain	525	0
Ear swelling	15	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
External ear pain	2	0
Red ear syndrome	1	0
<i>Hearing disorders NEC</i>		
Auditory disorder	1	0
<i>Hearing losses</i>		
Deafness	35	0
Deafness bilateral	1	0
Deafness transitory	2	0
Deafness unilateral	5	0
Hypoacusis	38	0
Sudden hearing loss	6	0
<i>Hyperacusia</i>		
Hyperacusis	21	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	2	0
Meniere's disease	3	0
Vestibular disorder	1	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	22	0
Phobic postural vertigo	1	0
Tinnitus	376	0
Vertigo	323	0
Vertigo labyrinthine	3	0
Vertigo positional	17	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	1	0
Ear disorders SOC TOTAL	1424	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	1	0
<i>Adrenal cortical hyperfunctions</i>		
Cushingoid	1	0
<i>Adrenal cortical hypofunctions</i>		
Adrenal insufficiency	9	0
Adrenocortical insufficiency acute	16	0
Glucocorticoid deficiency	1	0
<i>Adrenal gland disorders NEC</i>		
Adrenal haemorrhage	1	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	3	0
<i>Thyroid disorders NEC</i>		
Thyroid pain	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	9	0
Endocrine disorders SOC TOTAL	42	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	1	0
<i>Cataract conditions</i>		
Cataract	3	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Vitreous haemorrhage	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	2	0
Vitreous floaters	11	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	2	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	3	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	9	0
Eyelid ptosis	5	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	1	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	4	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iritis	1	0
Uveitis	3	0
<i>Lacrimation disorders</i>		
Dry eye	60	0
Lacrimation increased	49	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	1	0
Erythema of eyelid	2	0
Eyelid cyst	1	0
Eyelid oedema	2	0
Swelling of eyelid	13	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	2	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	1	0
Eye disorder	2	0
Eye oedema	2	0
Eye pain	925	0
Eye swelling	126	0
Eye symptom	1	0
Eyelid pain	1	0
Ocular discomfort	9	0
Periorbital oedema	7	0
Periorbital pain	2	0
Periorbital swelling	23	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	6	0
Eye discharge	6	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eye inflammation	4	0
Eye irritation	54	0
Eye pruritus	71	0
Ocular hyperaemia	65	0
Ocular nerve and muscle disorders		
Extraocular muscle paresis	4	0
Eye movement disorder	7	0
Ocular sensation disorders		
Abnormal sensation in eye	7	0
Asthenopia	65	0
Eyelid sensory disorder	2	0
Foreign body sensation in eyes	11	0
Hypoaesthesia eye	3	0
Photophobia	298	0
Pupil disorders		
Miosis	3	0
Mydriasis	5	0
Pupils unequal	2	0
Refractive and accommodative disorders		
Hypermetropia	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal aneurysm	1	0
Retinal vascular thrombosis	1	0
Retinal structural change, deposit and degeneration		
Macular detachment	1	0
Neovascular age-related macular degeneration	2	0
Vitreoretinal traction syndrome	1	0
Retinopathies NEC		
Acute macular outer retinopathy	2	0
Scleral infections, irritations and inflammations		
Episcleritis	4	0
Structural change, deposit and degeneration of eye NEC		
Deposit eye	1	0
Endocrine ophthalmopathy	1	0
Visual colour distortions		
Chromatopsia	1	0
Xanthopsia	1	0
Visual disorders NEC		
Diplopia	45	0
Halo vision	4	0
Metamorphopsia	8	0
Photopsia	60	0
Vision blurred	333	0
Visual brightness	1	0
Visual snow syndrome	1	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	1	0
Blindness	30	0
Blindness transient	2	0
Night blindness	2	0
Sudden visual loss	1	0
Visual acuity reduced	3	0
Visual impairment	101	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eye disorders SOC TOTAL	2499	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
Gastrointestinal sounds abnormal	2	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	1
Pancreatitis	10	0
Pancreatitis acute	2	0
<i>Anal and rectal pains</i>		
Proctalgia	2	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	2	0
Anal pruritus	1	0
Anorectal discomfort	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	1	0
Tongue cyst	1	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	1	0
Colitis	4	0
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	22	0
Crohn's disease	20	0
Terminal ileitis	1	0
<i>Dental disorders NEC</i>		
Teething	6	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	2	0
Dental paraesthesia	2	0
Hyperaesthesia teeth	8	0
Toothache	88	0
<i>Dental surface disorders</i>		
Tooth discolouration	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	2827	0
Diarrhoea haemorrhagic	8	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	220	0
Epigastric discomfort	6	0
Eructation	24	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	4	0
Faecaloma	1	0
Faeces discoloured	6	0
Faeces hard	1	0
Faeces pale	1	0
Faeces soft	5	0
Mucous stools	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	86	0
Flatulence	102	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	2	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	3	0
Gastric ulcer perforation	1	0
<i>Gastritis (excl infective)</i>		
Chronic gastritis	1	0
Gastritis	16	0
Reflux gastritis	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	1328	0
Abdominal pain lower	56	0
Abdominal pain upper	1384	0
Abdominal rigidity	14	0
Abdominal tenderness	5	0
Gastrointestinal pain	90	0
Oesophageal pain	2	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	92	0
Gastric dilatation	3	0
Gastrooesophageal reflux disease	48	0
Infrequent bowel movements	1	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	5	0
Gastric disorder	4	0
Gastrointestinal disorder	8	0
Neurogenic bowel	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	3	0
Dyschezia	2	0
Oesophageal achalasia	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Gastrointestinal tract irritation	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	423	0
Abdominal symptom	2	0
Acute abdomen	7	0
Anal incontinence	8	0
Breath odour	5	0
Dysphagia	43	1
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	7	0
Frequent bowel movements	10	0
Irritable bowel syndrome	22	0
Oesophageal spasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	8	0
Gingival discomfort	1	0
Gingival disorder	5	0
Gingival oedema	1	0
Gingival pain	54	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gingival pruritus	1	0
Gingival swelling	11	0
Gingival ulceration	1	0
Noninfective gingivitis	6	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	9	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	5	0
<i>Inguinal hernias</i>		
Inguinal hernia	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	4	0
Rectal haemorrhage	9	0
Small intestinal haemorrhage	7	0
<i>Large intestinal stenosis and obstruction</i>		
Large intestinal stenosis	1	0
<i>Malabsorption syndromes</i>		
Coeliac disease	2	0
<i>Nausea and vomiting symptoms</i>		
Acetonaemic vomiting	1	0
Discoloured vomit	7	0
Faecal vomiting	1	0
Nausea	11768	0
Regurgitation	1	0
Retching	106	0
Vomiting	4207	2
Vomiting projectile	53	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	5	1
Haematemesis	15	0
Haematochezia	14	0
Melaena	2	0
<i>Oesophagitis (excl infective)</i>		
Oesophagitis	3	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	346	0
Lip dry	15	0
Saliva altered	1	0
Salivary hypersecretion	9	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	3	0
Cheilitis	13	0
Enlarged uvula	2	0
Leukoplakia oral	1	0
Lip blister	10	0
Lip disorder	1	0
Oral disorder	2	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	2	0
Oral blood blister	7	0
<i>Oral soft tissue infections</i>		
Angular cheilitis	2	0
<i>Oral soft tissue signs and symptoms</i>		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Anaesthesia oral	3	0
Burning mouth syndrome	2	0
Hypoaesthesia oral	135	0
Lip erythema	2	0
Lip exfoliation	5	0
Lip pain	19	0
Lip pruritus	8	0
Odynophagia	4	0
Oral discomfort	20	0
Oral mucosal blistering	8	0
Oral mucosal eruption	3	0
Oral mucosal exfoliation	4	0
Oral mucosal roughening	1	0
Oral pain	106	0
Oral pruritus	5	0
Paraesthesia oral	230	0
<i>Oral soft tissue swelling and oedema</i>		
Lip oedema	3	0
Lip swelling	262	0
Mouth swelling	42	0
Oedema mouth	1	0
Palatal swelling	4	0
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland pain	3	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	4	0
<i>Salivary gland infections and inflammations</i>		
Noninfective sialoadenitis	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	13	0
Lip ulceration	5	0
Mouth ulceration	149	0
Stomatitis	19	0
<i>Tongue disorders</i>		
Glossitis	7	0
Plicated tongue	1	0
Tongue disorder	9	0
Tongue ulceration	6	0
Trichoglossia	2	0
<i>Tongue signs and symptoms</i>		
Glossodynia	75	0
Scalloped tongue	2	0
Swollen tongue	148	0
Tongue blistering	8	0
Tongue coated	9	0
Tongue discolouration	6	0
Tongue discomfort	8	0
Tongue dry	6	0
Tongue eruption	1	0
Tongue exfoliation	1	0
Tongue movement disturbance	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tongue oedema	6	0
Tongue pruritus	1	0
Tongue rough	1	0
Tongue spasm	1	0
<i>Tooth missing</i>		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	25163	5

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	6	0
Administration site induration	1	0
Administration site pain	16	0
Administration site urticaria	1	0
Puncture site bruise	13	0
Puncture site pain	9	0
Puncture site reaction	2	0
Puncture site swelling	1	0
<i>Adverse effect absent</i>		
No adverse event	7	0
<i>Application and instillation site reactions</i>		
Application site bruise	5	0
Application site erythema	7	0
Application site joint pain	1	0
Application site pain	7	0
Application site pruritus	4	0
Application site swelling	1	0
Instillation site discomfort	1	0
Instillation site pain	1	0
Instillation site pruritus	1	0
Instillation site warmth	7	0
<i>Asthenic conditions</i>		
Asthenia	1416	3
Chronic fatigue syndrome	12	0
Fatigue	14921	0
Malaise	4059	3
Sluggishness	5	0
<i>Body temperature altered</i>		
Hyperthermia	5	0
Hypothermia	21	0
Temperature regulation disorder	6	0
<i>Complications associated with device NEC</i>		
Phantom shocks	2	0
<i>Death and sudden death</i>		
Brain death	1	1
Death	14F	14F
Sudden death	12	12
<i>Febrile disorders</i>		
Hyperpyrexia	26	0
Masked fever	1	0
Pyrexia	20918	1
<i>Feelings and sensations NEC</i>		
Chills	16299	0
Feeling abnormal	632	0
Feeling cold	1884	0
Feeling drunk	22	0
Feeling hot	699	0
Feeling jittery	10	0
Feeling of body temperature change	355	0
Hangover	27	0
Hunger	9	0
Sensation of foreign body	9	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Temperature intolerance	15	0
Thirst	444	0
Thirst decreased	3	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Decreased gait velocity	1	0
Gait disturbance	88	0
Gait inability	56	0
Loss of control of legs	11	0
General signs and symptoms NEC		
Condition aggravated	48	0
Crying	50	0
Discharge	1	0
Energy increased	3	0
Exercise tolerance decreased	2	0
Foaming at mouth	2	0
General physical health deterioration	7	2
General symptom	5	0
Glassy eyes	1	0
Illness	1729	0
Induration	5	0
Influenza like illness	3343	1
Irritability postvaccinal	1	0
Local reaction	82	0
Moaning	4	0
Multiple organ dysfunction syndrome	2	0
Nonspecific reaction	1	0
Peripheral swelling	1365	0
Screaming	4	0
Secretion discharge	6	0
Swelling	618	0
Swelling face	240	0
Symptom recurrence	1	0
Implant and catheter site reactions		
Implant site pain	1	0
Implant site rash	1	0
Implant site warmth	3	0
Inflammations		
Inflammation	136	0
Systemic inflammatory response syndrome	1	0
Infusion site reactions		
Infusion site bruising	1	0
Infusion site pain	2	0
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	13	0
Injection site bruising	26	0
Injection site coldness	1	0
Injection site discolouration	1	0
Injection site discomfort	3	0
Injection site erythema	203	0
Injection site haemorrhage	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site hypoaesthesia	4	0
Injection site indentation	2	0
Injection site inflammation	23	0
Injection site injury	1	0
Injection site irritation	2	0
Injection site joint erythema	3	0
Injection site joint pain	17	0
Injection site mass	407	0
Injection site muscle weakness	1	0
Injection site nodule	1	0
Injection site oedema	12	0
Injection site pain	1435	0
Injection site papule	1	0
Injection site paraesthesia	6	0
Injection site pruritus	103	0
Injection site rash	87	0
Injection site reaction	41	0
Injection site scab	3	0
Injection site scar	2	0
Injection site swelling	63	0
Injection site urticaria	11	0
Injection site vesicles	4	0
Injection site warmth	129	0
Interactions		
Drug interaction	5	0
Inhibitory drug interaction	1	0
Mass conditions NEC		
Cyst	2	0
Mass	10	0
Nodule	1	0
Mucosal findings abnormal		
Mucosal disorder	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	1	0
Mucosal inflammation	2	0
Mucosal pain	1	0
Oedema NEC		
Face oedema	8	0
Localised oedema	4	0
Oedema	4	0
Oedema peripheral	11	0
Pain and discomfort NEC		
Axillary pain	123	0
Chest discomfort	538	0
Chest pain	1011	0
Discomfort	57	0
Facial discomfort	4	0
Facial pain	67	0
Inflammatory pain	6	0
Non-cardiac chest pain	9	0
Pain	4505	0
Tenderness	589	0
Therapeutic and nontherapeutic responses		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Adverse drug reaction	107	0
Diet failure	1	0
Drug ineffective	11	0
Drug intolerance	1	0
Inadequate analgesia	1	0
No reaction on previous exposure to drug	13	0
Therapeutic product effect decreased	1	0
Therapeutic response shortened	1	0
Therapeutic response unexpected	8	0
Treatment failure	2	0
Vaccine positive rechallenge	1	0
Ulcers NEC		
Ulcer	8	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	7	0
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	26	0
Vaccination site discolouration	2	0
Vaccination site discomfort	8	0
Vaccination site erythema	188	0
Vaccination site extravasation	1	0
Vaccination site granuloma	3	0
Vaccination site haemorrhage	1	0
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	3	0
Vaccination site induration	20	0
Vaccination site inflammation	21	0
Vaccination site irritation	4	0
Vaccination site joint erythema	1	0
Vaccination site joint movement impairment	5	0
Vaccination site joint pain	21	0
Vaccination site joint swelling	1	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	1	0
Vaccination site mass	148	0
Vaccination site movement impairment	7	0
Vaccination site oedema	2	0
Vaccination site pain	525	0
Vaccination site papule	2	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	31	0
Vaccination site rash	48	0
Vaccination site reaction	9	0
Vaccination site swelling	157	0
Vaccination site urticaria	3	0
Vaccination site vesicles	2	0
Vaccination site warmth	98	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	2	0
Withdrawal syndrome	5	0
General disorders SOC TOTAL	80954	163

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	3	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	3	0
Cholelithiasis	3	0
<i>Cholestasis and jaundice</i>		
Jaundice	12	0
Ocular icterus	1	0
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	12	0
Liver tenderness	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	3	0
Hepatitis acute	1	0
Liver injury	1	0
Hepatic disorders SOC TOTAL	41	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	5	0
<i>Allergic conditions NEC</i>		
Allergic oedema	6	0
Allergy to metals	1	0
Allergy to sting	1	0
Allergy to venom	1	0
Dust allergy	1	0
Hypersensitivity	280	0
Infusion related hypersensitivity reaction	2	0
Multiple allergies	5	0
Serum sickness	9	0
Serum sickness-like reaction	8	0
Type III immune complex mediated reaction	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to chemicals	1	0
Allergy to vaccine	17	0
Drug hypersensitivity	21	0
Food allergy	1	0
Reaction to excipient	2	0
Reaction to preservatives	4	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	206	0
Anaphylactic shock	20	0
Anaphylactoid reaction	6	0
Anaphylactoid shock	2	0
<i>Atopic disorders</i>		
Seasonal allergy	8	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	7	0
Immune system disorder	4	0
Immunisation reaction	1	0
Sensitisation	9	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
<i>Transplant rejections</i>		
Transplant rejection	1	0
Immune system disorders SOC TOTAL	633	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	2	0
Diverticulitis	2	0
Dysentery	1	0
Gastroenteritis	11	0
Gastrointestinal infection	2	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Arthritis bacterial	2	0
Bacterial infection	5	1
Cellulitis	154	1
Injection site cellulitis	3	0
Perichondritis	1	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	9	0
<i>Bone and joint infections</i>		
Intervertebral discitis	1	0
<i>Bordetella infections</i>		
Pertussis	1	0
<i>Borrelial infections</i>		
Erythema migrans	1	0
<i>Breast infections</i>		
Mastitis	5	0
<i>Candida infections</i>		
Balanitis candida	1	0
Candida infection	10	0
Oral candidiasis	6	0
Skin candida	1	0
Vulvovaginal candidiasis	6	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	2	0
Myelitis	2	0
<i>Clostridia infections</i>		
Clostridium difficile colitis	1	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	2	0
COVID-19	166	12
COVID-19 pneumonia	7	3
Coronavirus infection	1	0
Severe acute respiratory syndrome	4	0
Suspected COVID-19	12	0
<i>Coxiella infections</i>		
Q fever	40	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	1	0
Gingival abscess	2	0
Gingivitis	4	0
Oral pustule	1	0
Parotitis	3	0
Pericoronitis	1	0
Tooth abscess	1	0
Tooth infection	1	0
<i>Ear infections</i>		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Ear infection	8	0
Labyrinthitis	24	0
Otitis externa	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	10	0
<i>Escherichia infections</i>		
Escherichia sepsis	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	13	0
Eye infection	2	0
Eyelid infection	2	0
Hordeolum	4	0
<i>Female reproductive tract infections</i>		
Vaginal abscess	1	0
<i>Fungal infections NEC</i>		
Fungal infection	3	0
Fungal skin infection	2	0
Tonsillitis fungal	1	0
<i>Hepatitis viral infections</i>		
Hepatitis E	1	0
<i>Hepatobiliary and spleen infections</i>		
Biliary sepsis	2	1
<i>Herpes viral infections</i>		
Genital herpes	5	0
Genital herpes simplex	1	0
Herpes ophthalmic	3	0
Herpes simplex	9	0
Herpes simplex reactivation	1	0
Herpes virus infection	2	0
Herpes zoster	177	0
Herpes zoster oticus	1	0
Ophthalmic herpes zoster	1	0
Oral herpes	159	0
Varicella	3	0
<i>Infections NEC</i>		
Abscess	5	0
Abscess limb	1	0
Catheter site infection	1	0
Coinfection	1	0
Genital abscess	1	0
Infected cyst	1	0
Infection	74	2
Injection site infection	5	0
Localised infection	29	0
Lymph gland infection	1	0
Pathogen resistance	1	0
Respiratory tract infection	3	0
Vaccination site abscess	1	0
Vaccination site infection	9	0
Vestibulitis	1	0
<i>Influenza viral infections</i>		
H2N2 influenza	1	0
Influenza	2231	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	2	0
Infective exacerbation of bronchiectasis	1	0
Lower respiratory tract infection	43	2
Pneumonia	36	12
<i>Male reproductive tract infections</i>		
Orchitis	1	0
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Phleboviral infections</i>		
Severe fever with thrombocytopenia syndrome	2	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	1	0
<i>Salmonella infections</i>		
Typhoid fever	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Neutropenic sepsis	2	0
Sepsis	24	2
Septic rash	2	0
Septic shock	1	0
Urosepsis	2	1
<i>Skin structures and soft tissue infections</i>		
Dermatitis infected	1	0
Folliculitis	3	0
Infected dermal cyst	1	0
Injection site pustule	1	0
Pustule	1	0
Rash pustular	5	0
Skin infection	14	0
Subcutaneous abscess	2	0
<i>Staphylococcal infections</i>		
Furuncle	3	0
Staphylococcal scalded skin syndrome	1	0
Staphylococcal sepsis	1	1
<i>Streptococcal infections</i>		
Cellulitis streptococcal	1	0
Erysipelas	1	0
Pharyngitis streptococcal	2	0
<i>Tinea infections</i>		
Body tinea	2	0
Tinea cruris	1	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	2	0
<i>Tuberculous infections</i>		
Tuberculosis	1	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	1	0
Laryngitis	5	0
Nasopharyngitis	436	0
Pharyngitis	6	0
Rhinitis	15	0
Sinusitis	46	0
Tonsillitis	15	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
 Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Upper respiratory tract infection	2	0
Urinary tract infections		
Cystitis	17	0
Kidney infection	10	0
Urinary tract infection	36	0
Vascular infections		
Infected lymphocele	1	0
Lymphangitis	3	0
Viral infections NEC		
Arthritis viral	1	0
Gastroenteritis viral	18	1
Pneumonia viral	2	1
Post viral fatigue syndrome	20	0
Sweating fever	274	0
Vestibular neuronitis	2	0
Viral diarrhoea	3	0
Viral infection	5	0
Viral labyrinthitis	1	0
Viral myocarditis	1	0
Viral pharyngitis	7	0
Viral rash	12	0
Viral sepsis	1	0
Infections SOC TOTAL	4382	40

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Abdomen crushing	1	0
Lip injury	1	0
Oral contusion	1	0
Palate injury	1	0
Splenic rupture	1	0
<i>Anaesthetic and allied procedural complications</i>		
Delayed recovery from anaesthesia	1	0
Sedation complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
Hypobarism	1	0
<i>Bone and joint injuries NEC</i>		
Bursa injury	1	0
<i>Cerebral injuries NEC</i>		
Brain contusion	1	0
Cranio-cerebral injury	1	0
Subdural haematoma	1	0
Subdural haemorrhage	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	10	0
<i>Cranial nerve injuries</i>		
Optic nerve injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	1	0
Exposure via breast milk	5	0
Foetal exposure during pregnancy	9	0
Maternal exposure during breast feeding	109	0
Maternal exposure during pregnancy	48	0
Maternal exposure timing unspecified	1	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	3	0
<i>Eye injuries NEC</i>		
Eye contusion	4	0
Eye injury	2	0
Periorbital haematoma	1	0
Superficial injury of eye	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural nausea	17	0
Procedural vomiting	3	0
<i>Heat injuries (excl thermal burns)</i>		
Heat exhaustion	2	0
Heat oedema	7	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	2	0
Lower limb fracture	1	0
Patella fracture	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Device use issue	1	0
Medication error	3	0
Vaccination error	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Wrong drug	1	0
Wrong technique in product usage process	1	0
Muscle, tendon and ligament injuries		
Epicondylitis	3	0
Ligament sprain	1	0
Muscle injury	4	0
Muscle rupture	1	0
Muscle strain	2	0
Post-traumatic neck syndrome	1	0
Tendon rupture	2	0
Nerve injuries NEC		
Nerve injury	9	0
Neurological and psychiatric procedural complications		
Post lumbar puncture syndrome	5	0
Procedural dizziness	11	0
Non-occupational environmental exposures		
Exposure to chemical pollution	1	0
Exposure to extreme temperature	3	0
Exposure to noise	1	0
Non-site specific injuries NEC		
Arthropod bite	2	0
Arthropod sting	3	0
Electric shock	2	0
Fall	57	1
Inflammation of wound	3	0
Nervous system injury	1	0
Road traffic accident	1	0
Tissue injury	1	0
Wound complication	1	0
Non-site specific procedural complications		
Incision site pain	5	0
Infusion related reaction	8	0
Injection related reaction	330	0
Post procedural complication	20	0
Procedural pain	1	0
Suture related complication	1	0
Occupational exposures		
Occupational exposure to product	1	0
Overdoses NEC		
Overdose	4	0
Peripheral nerve injuries		
Ulnar nerve injury	1	0
Poisoning and toxicity		
Alcohol poisoning	2	0
Toxicity to various agents	3	0
Product administration errors and issues		
Accidental overdose	2	0
Duplicate therapy error	1	0
Expired product administered	2	0
Extra dose administered	2	0
Inappropriate schedule of product administration	2	0
Incorrect route of product administration	2	0
Product administered to patient of inappropriate age	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
 Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Product administration error	4	0
Wrong product administered	1	0
Product confusion errors and issues		
Product label confusion	1	0
Product dispensing errors and issues		
Product dispensing error	2	0
Product monitoring errors and issues		
Product monitoring error	1	0
Product prescribing errors and issues		
Contraindicated product prescribed	1	0
Radiation injuries		
Sunburn	2	0
Reproductive system and breast injuries		
Penile contusion	1	0
Reproductive tract and breast procedural complications		
Postmastectomy lymphoedema syndrome	1	0
Site specific injuries NEC		
Back injury	2	0
Head injury	3	0
Limb crushing injury	1	0
Limb injury	19	0
Neck crushing	1	0
Skin injuries NEC		
Contusion	217	0
Scar	1	0
Skin abrasion	2	0
Skin injury	1	0
Skin wound	2	0
Spinal cord injuries NEC		
Spinal cord injury sacral	1	0
Stoma complications		
Gastrointestinal stoma complication	1	0
Thermal burns		
Burn of internal organs	3	0
Burn oral cavity	1	0
Burns second degree	1	0
Cold burn	1	0
Thermal burn	10	0
Thermal burns of eye	13	0
Underdoses NEC		
Intentional underdose	1	0
Vaccination related complications		
Vaccination complication	34	0
Vaccination failure	3	0
Injuries SOC TOTAL	1086	1

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	1	0
Cortisol increased	1	0
<i>Adrenal medulla tests</i>		
Norepinephrine increased	2	0
<i>Autoimmunity analyses</i>		
Cold agglutinins positive	1	0
<i>Blood counts NEC</i>		
Full blood count decreased	1	0
<i>Blood gas and acid base analyses</i>		
Blood pH	1	0
Blood pH increased	3	0
Oxygen saturation	12	0
Oxygen saturation decreased	73	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	10	0
Blood glucose abnormal	5	0
Blood glucose decreased	17	0
Blood glucose fluctuation	9	0
Blood glucose increased	73	0
Glycosylated haemoglobin increased	2	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	2	0
Heart sounds	4	0
Heart sounds abnormal	2	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	2	0
Magnetic resonance imaging brain	29	0
<i>Chemistry analyses NEC</i>		
Histamine level increased	1	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	2	0
<i>Coagulation and bleeding analyses</i>		
Coagulation time	1	0
Coagulation time prolonged	1	0
Fibrin D dimer increased	1	0
International normalised ratio decreased	7	0
International normalised ratio increased	18	0
<i>ECG investigations</i>		
Electrocardiogram T wave inversion	1	0
Electrocardiogram abnormal	1	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	1	0
<i>Faecal analyses NEC</i>		
Faecal calprotectin increased	1	0
<i>Fertility analyses</i>		
Semen volume decreased	1	0
<i>Gastrointestinal and abdominal imaging procedures</i>		
Computerised tomogram abdomen	1	0
<i>Gastrointestinal function diagnostic procedures</i>		
Gastrointestinal stoma output increased	1	0
Swallow study	1	0
<i>Gastrointestinal, pancreatic and APUD hormone analyses</i>		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood gastrin normal	1	0
Blood insulin	4	0
Blood insulin decreased	1	0
Blood insulin increased	1	0
Heart rate and pulse investigations		
Heart rate	294	0
Heart rate abnormal	12	0
Heart rate decreased	19	0
Heart rate increased	617	0
Heart rate irregular	47	0
Maximum heart rate	1	0
Maximum heart rate decreased	1	0
Orthostatic heart rate response increased	1	0
Pulse abnormal	7	0
Pulse absent	2	0
Sinus rhythm	1	0
Imaging procedures NEC		
Computerised tomogram	1	0
Immunoglobulin analyses		
Blood immunoglobulin E increased	2	0
Immunology analyses NEC		
Immunology test	1	0
Immunology test normal	1	0
Immunology skin tests NEC		
Allergy alert test	1	0
Investigations NEC		
Blood test	4	0
Polymerase chain reaction positive	1	0
Liver function analyses		
Alanine aminotransferase increased	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin increased	1	0
Gamma-glutamyltransferase increased	1	0
Hepatic enzyme increased	1	0
Liver function test abnormal	5	0
Transaminases increased	2	0
Metabolism tests NEC		
Blood ketone body	6	0
Ubiquinone	1	0
Mineral and electrolyte analyses		
Blood phosphorus decreased	1	0
Blood phosphorus increased	1	0
Blood potassium increased	1	0
Blood sodium decreased	1	0
Musculoskeletal and soft tissue tests NEC		
Swollen joint count increased	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	1	0
Lumbar puncture	1	0
Ophthalmic function diagnostic procedures		
Intraocular pressure increased	1	0
Intraocular pressure test	1	0
Physical examination procedures and organ system status		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Body surface area	1	0
Body temperature	401	0
Body temperature abnormal	31	0
Body temperature decreased	49	0
Body temperature fluctuation	59	0
Body temperature increased	462	0
Breath sounds abnormal	2	0
Grip strength	2	0
Grip strength decreased	6	0
Head lag	3	0
Lymph node palpable	1	0
Male genital examination abnormal	1	0
Respiratory rate	3	0
Respiratory rate decreased	7	0
Respiratory rate increased	26	0
Skin temperature	69	0
Temperature difference of extremities	1	0
Urological examination	1	0
Weight decreased	30	0
Weight increased	1	0
Platelet analyses		
Platelet count decreased	8	0
Protein analyses NEC		
C-reactive protein abnormal	1	0
C-reactive protein increased	2	0
Red blood cell analyses		
Haematocrit	2	0
Haemoglobin	2	0
Mean cell volume abnormal	1	0
Renal function analyses		
Blood creatinine decreased	1	0
Blood creatinine increased	1	0
Reproductive hormone analyses		
Pregnancy test	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume	1	0
Forced expiratory volume increased	5	0
Forced expiratory volume normal	1	0
Maximal voluntary ventilation	1	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	2	0
Respiratory tract and thoracic imaging procedures		
Computerised tomogram thorax	1	0
Laryngoscopy	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	1	0
Myocardial necrosis marker increased	1	0
Therapeutic drug monitoring analyses		
Analgesic drug level	6	0
Analgesic drug level therapeutic	1	0
Anticoagulation drug level above therapeutic	2	0
Anticoagulation drug level below therapeutic	2	0
Tissue enzyme analyses NEC		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Lactate dehydrogenase urine increased	1	0
Toxicology laboratory analyses		
Blood heavy metal test	1	0
Urinalysis NEC		
Blood urine	4	0
Blood urine present	5	0
Cells in urine	1	0
Protein urine present	1	0
Urine analysis abnormal	2	0
Urine analysis normal	1	0
pH urine	4	0
pH urine decreased	1	0
pH urine increased	1	0
Urinary tract function analyses NEC		
Urine output	13	0
Urine output decreased	3	0
Urine output increased	4	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	1	0
Blood pressure decreased	21	0
Blood pressure increased	81	0
Blood pressure measurement	19	0
Blood pressure systolic increased	1	0
Virus identification and serology		
Coronavirus test	12	0
SARS-CoV-2 antibody test negative	4	0
SARS-CoV-2 antibody test positive	1	0
SARS-CoV-2 test	10	0
SARS-CoV-2 test false negative	1	0
SARS-CoV-2 test negative	5	0
SARS-CoV-2 test positive	16	0
Viral test	1	0
White blood cell analyses		
Neutrophil count	1	0
Neutrophil count decreased	2	0
White blood cell count	4	0
White blood cell count decreased	3	0
White blood cell count increased	2	0
Investigations SOC TOTAL	2767	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	3	0
Decreased appetite	2424	0
Diet refusal	1	0
Food craving	5	0
Food refusal	16	0
Hyperphagia	2	0
Hypophagia	12	0
Increased appetite	14	0
Salt craving	1	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	2	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	19	0
Diabetes mellitus inadequate control	10	0
Increased insulin requirement	1	0
Type 1 diabetes mellitus	5	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	7	2
Diabetic ketosis	2	0
<i>Disorders of purine metabolism</i>		
Gout	16	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	4	0
<i>Fluid intake increased</i>		
Polydipsia	8	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Food intolerance	4	0
Gluten sensitivity	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	9	0
Abnormal weight gain	2	0
Cachexia	1	0
Feeding disorder	35	0
Food aversion	23	0
Starvation	1	0
Underweight	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	54	0
Insulin resistance	2	0
<i>Hyperlipidaemias NEC</i>		
Hyperlipidaemia	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hyperinsulinaemic hypoglycaemia	1	0
Hypoglycaemia	34	0
Hypoglycaemia unawareness	1	0
<i>Iron deficiencies</i>		
Iron deficiency	1	0
<i>Magnesium metabolism disorders</i>		
Hypomagnesaemia	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Ketosis	1	0
Metabolic acidosis	1	0
<i>Phosphorus metabolism disorders</i>		
Hypophosphataemia	1	0
<i>Potassium imbalance</i>		
Hyperkalaemia	1	0
Hypokalaemia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	7	0
Hyponatraemic syndrome	1	0
<i>Total fluid volume decreased</i>		
Dehydration	200	0
Hypovolaemia	1	0
<i>Total fluid volume increased</i>		
Fluid overload	2	0
Fluid retention	11	0
Metabolic disorders SOC TOTAL	2952	2

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	58	0
Arthropathy	3	0
Autoimmune arthritis	1	0
Palindromic rheumatism	1	0
Polyarthritis	3	0
Rheumatic fever	1	0
Sacroiliitis	3	0
<i>Bone disorders NEC</i>		
Medial tibial stress syndrome	1	0
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	340	0
Pain in jaw	137	0
Spinal pain	68	0
<i>Bursal disorders</i>		
Bursitis	8	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	4	0
<i>Connective tissue disorders NEC</i>		
Mixed connective tissue disease	1	0
Morphoea	1	0
Polymyalgia rheumatica	9	0
Reynold's syndrome	1	0
<i>Extremity deformities</i>		
Hand deformity	1	0
Limb deformity	1	0
<i>Joint related disorders NEC</i>		
Joint laxity	1	0
Joint lock	9	0
Patellofemoral pain syndrome	1	0
Periarthritis	24	0
Rotator cuff syndrome	5	0
Temporomandibular joint syndrome	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	7130	0
Joint noise	5	0
Joint stiffness	104	0
Joint swelling	111	0
Joint warmth	7	0
<i>Ligament disorders</i>		
Ligament pain	1	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	5	0
<i>Metabolic bone disorders</i>		
Osteopenia	1	0
Osteoporosis	1	0
<i>Muscle infections and inflammations</i>		
Myositis	3	0
<i>Muscle pains</i>		
Fibromyalgia	41	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Myalgia	9393	0
Myofascial pain syndrome	3	0
Muscle related signs and symptoms NEC		
Muscle discomfort	1	0
Muscle disorder	1	0
Muscle fatigue	283	0
Muscle mass	3	0
Muscle oedema	2	0
Muscle spasms	635	0
Muscle swelling	7	0
Muscle tightness	39	0
Muscle twitching	98	0
Muscle tone abnormalities		
Muscle rigidity	16	0
Nuchal rigidity	2	0
Torticollis	4	0
Trismus	21	0
Muscle weakness conditions		
Muscular weakness	527	0
Musculoskeletal and connective tissue conditions NEC		
Infantile back arching	1	0
Limb mass	2	0
Mobility decreased	46	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	535	0
Somatic dysfunction	1	0
Weight bearing difficulty	2	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Connective tissue inflammation	1	0
Dactylitis	1	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	1698	0
Flank pain	23	0
Growing pains	3	0
Limb discomfort	532	0
Musculoskeletal chest pain	111	0
Musculoskeletal discomfort	26	0
Musculoskeletal pain	21	0
Neck pain	764	0
Pain in extremity	4915	0
Rheumatic disorder	3	0
Myopathies		
Myopathy	1	0
Rhabdomyolysis	5	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	8	0
Spinal osteoarthritis	1	0
Psoriatic arthropathies		
Psoriatic arthropathy	9	0
Rheumatoid arthropathies		
Rheumatoid arthritis	31	0
Still's disease	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Soft tissue disorders NEC</i>		
Axillary mass	9	0
Groin pain	36	0
Neck mass	1	0
Soft tissue mass	1	0
Soft tissue swelling	2	0
<i>Spine and neck deformities</i>		
Spinal stenosis	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	7	0
Arthritis reactive	4	0
<i>Synovial disorders</i>		
Synovitis	2	0
<i>Tendon disorders</i>		
Tendon pain	2	0
Tendonitis	5	0
Trigger finger	3	0
Muscle & tissue disorders SOC TOTAL	27948	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Neoplasms		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	2	0
Breast cancer stage III	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	3	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	1	0
<i>Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)</i>		
Lymphoproliferative disorder in remission	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	1	1
<i>Ocular neoplasms benign</i>		
Eye naevus	1	0
<i>Oesophageal neoplasms malignant</i>		
Oesophageal squamous cell carcinoma	1	0
<i>Oncologic complications and emergencies</i>		
Cancer fatigue	2	0
<i>Plasma cell myelomas</i>		
Plasma cell myeloma	1	0
<i>Renal neoplasms malignant</i>		
Clear cell renal cell carcinoma	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	2	0
<i>Skin neoplasms benign</i>		
Melanocytic naevus	1	0
Skin papilloma	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	21	1

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	2	0
Hyporeflexia	3	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	8	0
<i>Absence seizures</i>		
Petit mal epilepsy	5	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	25	1
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	2	0
Orthostatic intolerance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	1
Brain stem stroke	1	0
Cerebral haematoma	1	0
Cerebral haemorrhage	8	1
Cerebral infarction	1	0
Cerebral thrombosis	1	1
Cerebrovascular accident	49	6
Embolic stroke	1	0
Haemorrhage intracranial	4	0
Haemorrhagic stroke	4	1
Ischaemic stroke	10	0
Subarachnoid haemorrhage	2	0
<i>Central nervous system inflammatory disorders NEC</i>		
Central nervous system inflammation	2	0
Neurosarcoidosis	1	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebral small vessel ischaemic disease	1	0
Cerebrovascular disorder	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	3	0
Superior sagittal sinus thrombosis	1	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervicobrachial syndrome	1	0
<i>Choreiform movements</i>		
Chorea	1	0
Sydenham's chorea	1	0
<i>Chronic polyneuropathies</i>		
Diabetic neuropathy	2	0
<i>Coma states</i>		
Coma	4	0
<i>Coordination and balance disturbances</i>		
Ataxia	5	0
Balance disorder	233	0
Cerebellar ataxia	1	0
Coordination abnormal	22	0
Dysstasia	25	0
Nystagmus	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	19	0
Dyspraxia	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Neurologic neglect syndrome	1	0
Dementia (excl Alzheimer's type)		
Dementia	7	0
Frontotemporal dementia	1	0
Senile dementia	1	0
Vascular dementia	3	0
Demyelinating disorders NEC		
Demyelination	2	0
Disturbances in consciousness NEC		
Altered state of consciousness	3	0
Consciousness fluctuating	3	0
Depressed level of consciousness	24	0
Lethargy	1518	0
Loss of consciousness	234	0
Sedation	4	0
Somnolence	517	1
Stupor	1	0
Syncope	627	0
Dyskinesias and movement disorders NEC		
Akathisia	6	0
Bradykinesia	6	0
Clumsiness	9	0
Dyskinesia	25	0
Extrapyramidal disorder	9	0
Fine motor skill dysfunction	1	0
Hyperkinesia	1	0
Hypokinesia	10	0
Motor dysfunction	3	0
Movement disorder	17	0
Psychomotor hyperactivity	9	0
Dystonias		
Dystonia	5	0
Dystonic tremor	2	0
Encephalitis NEC		
Noninfective encephalitis	2	0
Encephalopathies NEC		
Autoimmune encephalopathy	1	0
Encephalopathy	1	0
Encephalopathies toxic and metabolic		
Hepatic encephalopathy	1	0
Eye movement disorders		
IIIrd nerve paralysis	1	0
Facial cranial nerve disorders		
Facial nerve disorder	2	0
Facial paralysis	86	0
Facial paresis	16	0
Facial spasm	7	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	18	0
Headaches NEC		
Cervicogenic headache	1	0
Cluster headache	174	0
Cold-stimulus headache	9	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Drug withdrawal headache	5	0
Exertional headache	3	0
External compression headache	2	0
Headache	26331	1
Medication overuse headache	3	0
New daily persistent headache	1	0
Occipital neuralgia	1	0
Post-traumatic headache	1	0
Primary headache associated with sexual activity	2	0
Sinus headache	237	0
Tension headache	399	0
Thunderclap headache	8	0
Vascular headache	18	0
Hypoglossal nerve disorders		
Tongue paralysis	2	0
Increased intracranial pressure disorders		
Brain oedema	3	0
Intracranial pressure increased	2	0
Intellectual disabilities		
Intellectual disability	4	0
Lumbar spinal cord and nerve root disorders		
Sciatica	19	0
Memory loss (excl dementia)		
Amnesia	48	0
Memory impairment	43	0
Transient global amnesia	2	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	24	1
Disturbance in attention	110	0
Mental impairment	22	0
Migraine headaches		
Hemiplegic migraine	3	0
Migraine	1756	0
Migraine with aura	56	0
Migraine without aura	11	0
Retinal migraine	10	0
Status migrainosus	1	0
Typical aura without headache	5	0
Vestibular migraine	2	0
Mononeuropathies		
Carpal tunnel syndrome	4	0
Diabetic mononeuropathy	1	0
Nerve compression	2	0
Peroneal nerve palsy	1	0
Ulnar nerve palsy	1	0
Ulnar neuritis	1	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	20	0
Multiple sclerosis relapse	9	0
Uhthoff's phenomenon	1	0
Muscle tone abnormal		
Hypotonia	7	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Stiff leg syndrome	2	0
Myelitis (incl infective)		
Myelitis transverse	7	0
Narcolepsy and hypersomnia		
Hypersomnia	44	0
Narcolepsy	6	0
Nervous system cysts and polyps		
Pineal gland cyst	1	0
Nervous system disorders NEC		
Cerebral disorder	1	0
Nervous system disorder	7	0
Psychomotor skills impaired	2	0
Neurologic visual problems NEC		
Tunnel vision	3	0
Visual field defect	4	0
Neurological signs and symptoms NEC		
Dizziness	6265	0
Dizziness exertional	31	0
Dizziness postural	707	1
Drooling	1	0
Exaggerated startle response	3	0
Head discomfort	101	0
Hyporesponsive to stimuli	1	0
Infant irritability	1	0
Myoclonus	6	0
Neurological symptom	24	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	3	0
Presyncope	189	0
Sensory overload	1	0
Unresponsive to stimuli	29	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	9	0
Muscle spasticity	6	0
Neuromuscular pain	2	0
Neuromyopathy	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	1	0
Myasthenia gravis crisis	1	0
Olfactory nerve disorders		
Anosmia	62	0
Hyposmia	4	0
Parosmia	100	0
Optic nerve disorders NEC		
Optic neuritis	7	0
Paraesthesias and dysaesthesias		
Anaesthesia	2	0
Burning feet syndrome	5	0
Burning sensation	141	0
Dysaesthesia	3	0
Formication	11	0
Hemianaesthesia	2	0
Hyperaesthesia	86	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Hypoaesthesia	873	0
Lhermitte's sign	1	0
Paraesthesia	1626	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	10	0
Hemiparesis	13	0
Hemiplegia	4	0
Monoparesis	11	0
Monoplegia	28	0
Paralysis	63	0
Paraparesis	2	0
Paraplegia	1	0
Paresis	1	0
Peripheral nerve palsy	1	0
Postictal paralysis	1	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	49	0
Parkinson's disease	8	0
Parkinsonism	6	0
Reduced facial expression	1	0
<i>Partial complex seizures</i>		
Dreamy state	4	0
Focal dyscognitive seizures	1	0
<i>Partial simple seizures NEC</i>		
Simple partial seizures	2	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	40	0
Polyneuropathy	1	0
<i>Seizures and seizure disorders NEC</i>		
Alcoholic seizure	1	0
Atonic seizures	3	0
Clonic convulsion	3	0
Epilepsy	57	0
Febrile convulsion	27	0
Myoclonic epilepsy	1	0
Partial seizures	14	0
Psychogenic seizure	1	0
Seizure	278	2
Seizure anoxic	1	0
Seizure cluster	3	0
Seizure like phenomena	2	0
Status epilepticus	5	1
Tonic convulsion	9	0
<i>Sensory abnormalities NEC</i>		
Ageusia	270	0
Allodynia	21	0
Aura	2	0
Central pain syndrome	1	0
Complex regional pain syndrome	2	0
Dysgeusia	491	0
Hypogeusia	1	0
Loss of proprioception	1	0
Neuralgia	251	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Phantom limb syndrome	8	0
Post herpetic neuralgia	2	0
Restless arm syndrome	5	0
Restless legs syndrome	92	0
Sensory disturbance	15	0
Sensory loss	25	0
Taste disorder	136	0
<i>Sleep disturbances NEC</i>		
Poor quality sleep	206	0
Sleep deficit	11	0
<i>Speech and language abnormalities</i>		
Dysarthria	56	1
Incoherent	2	0
Language disorder	1	0
Slow speech	3	0
Speech disorder	10	0
<i>Spinal cord and nerve root disorders NEC</i>		
Myelopathy	2	0
Radiculitis brachial	1	0
Radiculopathy	1	0
<i>Structural brain disorders NEC</i>		
Brain injury	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	28	0
<i>Tremor (excl congenital)</i>		
Action tremor	1	0
Essential tremor	2	0
Head titubation	5	0
Intention tremor	1	0
Resting tremor	3	0
Tremor	3941	1
<i>Trigeminal disorders</i>		
Facial neuralgia	4	0
Trigeminal neuralgia	13	0
Nervous system disorders SOC TOTAL	49655	20

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	5	0
<i>Foetal position and presentation abnormalities</i>		
Face presentation	1	0
<i>Labour onset and length abnormalities</i>		
Precipitate labour	1	0
Premature labour	1	0
Premature rupture of membranes	1	0
<i>Maternal complications of pregnancy NEC</i>		
Hyperemesis gravidarum	1	0
Morning sickness	12	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
<i>Stillbirth and foetal death</i>		
Stillbirth	1	0
Pregnancy conditions SOC TOTAL	25	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<i>Device incompatibility issues</i>		
Patient-device incompatibility	1	0
<i>Device malfunction events NEC</i>		
Oversensing	8	0
Stent malfunction	1	0
Undersensing	1	0
<i>Device physical property and chemical issues</i>		
Needle issue	1	0
<i>Product physical issues</i>		
Product taste abnormal	1	0
<i>Product quality issues NEC</i>		
Product origin unknown	1	0
null SOC TOTAL	14	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
Breath holding	1	0
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	2	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
Constricted affect	1	0
Flat affect	1	0
Inappropriate affect	1	0
<i>Amnesic symptoms</i>		
Paramnesia	2	0
<i>Anxiety symptoms</i>		
Agitation	56	0
Anxiety	178	0
Nervousness	231	0
Stress	2	0
Tension	11	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	3	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	2	0
Asocial behaviour	1	0
Indifference	1	0
Paranoia	8	0
Personality change	1	0
Social avoidant behaviour	1	0
Soliloquy	1	0
Violence-related symptom	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	5	0
Mental fatigue	100	0
<i>Communications disorders</i>		
Mutism	2	0
<i>Confusion and disorientation</i>		
Confusional state	546	0
Disorientation	215	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	175	0
<i>Delusional symptoms</i>		
Delusion	7	0
<i>Depressive disorders</i>		
Agitated depression	1	0
Depression	90	0
Depression suicidal	1	0
Major depression	5	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	4	0
Dissociation	8	0
Dissociative disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Initial insomnia	9	0
Insomnia	907	0
Middle insomnia	13	0
Terminal insomnia	1	0
Dyssomnias		
Dyssomnia	1	0
Eating disorders NEC		
Eating disorder	1	0
Emotional and mood disturbances NEC		
Anger	12	0
Emotional disorder	31	0
Emotional distress	16	0
Euphoric mood	14	0
Frustration tolerance decreased	2	0
Irritability	66	0
Mood altered	11	0
Factitious disorders		
Factitious disorder	3	0
Fear symptoms and phobic disorders (incl social phobia)		
Agoraphobia	1	0
Fear	5	0
Fear of death	2	0
Fear of disease	1	0
Fear of falling	1	0
Phonophobia	1	0
Fluctuating mood symptoms		
Mood swings	7	0
Hallucinations (excl sleep-related)		
Hallucination	313	0
Hallucination, auditory	4	0
Hallucination, visual	16	0
Hallucinations, mixed	2	0
Impulse control disorders		
Impulse-control disorder	2	0
Impulsive behaviour	1	0
Increased physical activity levels		
Restlessness	141	0
Mental disorders NEC		
Mental disorder	3	0
Mental status changes	1	0
Mood alterations with depressive symptoms		
Anhedonia	2	0
Decreased interest	4	0
Depressed mood	110	0
Feeling of despair	4	0
Negative thoughts	3	0
Sense of a foreshortened future	1	0
Tearfulness	27	0
Mood alterations with manic symptoms		
Mania	5	0
Mood disorders NEC		
Apathy	12	0
Listless	46	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	1	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive thoughts	1	0
<i>Orgasmic disorders and disturbances</i>		
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0
<i>Panic attacks and disorders</i>		
Limited symptom panic attack	1	0
Panic attack	51	0
Panic reaction	7	0
<i>Parasomnias</i>		
Abnormal dreams	109	0
Confusional arousal	2	0
Exploding head syndrome	2	0
Nightmare	125	0
Rapid eye movements sleep abnormal	1	0
Sleep talking	8	0
Sleep terror	13	0
Sleep-related eating disorder	1	0
Somnambulism	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	6	0
Derealisation	3	0
Illusion	4	0
Time perception altered	2	0
<i>Psychiatric elimination disorders</i>		
Enuresis	11	0
<i>Psychiatric symptoms NEC</i>		
Hypervigilance	3	0
Psychiatric symptom	1	0
Psychological trauma	1	0
<i>Psychotic disorder NEC</i>		
Psychotic disorder	9	0
<i>Sexual desire disorders</i>		
Libido decreased	1	0
Libido increased	1	0
Loss of libido	5	0
<i>Sleep disorders NEC</i>		
Sleep disorder	100	0
Sleep disorder due to general medical condition, insomnia type	1	0
<i>Somatic symptom disorders</i>		
Conversion disorder	1	0
Habit cough	14	0
Somatic symptom disorder	1	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	1	0
Logorrhoea	2	0
Pedantic speech	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	4	0
Lack of spontaneous speech	1	0
<i>Stereotypies and automatisms</i>		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Bruxism	9	0
Head banging	12	0
Waxy flexibility	1	0
<i>Stress disorders</i>		
Acute stress disorder	2	0
Burnout syndrome	1	0
Hyperarousal	1	0
Post-traumatic stress disorder	5	0
<i>Substance related and addictive disorders</i>		
Alcohol abuse	1	0
Drug dependence	1	0
Substance abuse	1	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	1	0
Intentional self-injury	1	0
Suicidal ideation	12	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	13	0
Intrusive thoughts	2	0
Tachyphrenia	7	0
Thinking abnormal	5	0
Thought blocking	1	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	4046	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	1	0
Bladder irritation	1	0
Bladder pain	9	0
Bladder spasm	1	0
Dysuria	22	0
Incontinence	24	0
Micturition frequency decreased	1	0
Micturition urgency	38	0
Mixed incontinence	1	0
Pollakiuria	85	0
Urethral pain	1	0
Urinary hesitation	3	0
Urinary incontinence	33	0
Urinary retention	19	0
Urine flow decreased	2	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	4	0
<i>Bladder infections and inflammations</i>		
Cystitis interstitial	2	0
Cystitis noninfective	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Anti-glomerular basement membrane disease	1	0
IgA nephropathy	1	0
<i>Myoneurogenic bladder disorders</i>		
Automatic bladder	1	0
Bladder dysfunction	1	0
Hypertonic bladder	4	0
Loss of bladder sensation	4	0
Neurogenic bladder	1	0
<i>Nephritis NEC</i>		
Nephritis	2	0
Tubulointerstitial nephritis	1	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	1	0
<i>Renal disorders NEC</i>		
Renal disorder	2	0
<i>Renal failure and impairment</i>		
Acute kidney injury	13	0
Anuria	1	0
Chronic kidney disease	4	0
Oliguria	3	0
Renal failure	3	1
Renal impairment	1	0
Renal injury	1	0
<i>Structural and obstructive urethral disorders (excl congenital)</i>		
Urethral spasm	1	0
<i>Urinary abnormalities</i>		
Chromaturia	21	0
Haematuria	7	0
Proteinuria	1	0
Urine abnormality	4	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Urine odour abnormal	9	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	1	0
Nocturia	5	0
Polyuria	15	0
Renal colic	1	0
Renal pain	281	0
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	641	1

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	1	0
<i>Breast disorders NEC</i>		
Breast enlargement	1	0
Breast mass	4	0
<i>Breast signs and symptoms</i>		
Breast discomfort	1	0
Breast oedema	1	0
Breast pain	61	0
Breast swelling	3	0
Breast tenderness	8	0
Nipple pain	3	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation failure	1	0
Erectile dysfunction	8	0
Organic erectile dysfunction	1	0
Retrograde ejaculation	1	0
<i>Lactation disorders</i>		
Suppressed lactation	2	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	3	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	15	0
Menstrual disorder	15	0
Menstruation irregular	14	0
Metrorrhagia	9	0
Premenstrual pain	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	2	0
Hypomenorrhoea	8	0
Menstruation delayed	14	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	25	0
Polymenorrhoea	4	0
<i>Pelvic prolapse conditions</i>		
Vaginal prolapse	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	1	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile blister	1	0
Penile oedema	2	0
Penis disorder	1	0
Peyronie's disease	1	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	1	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Female genital tract fistula	1	0
Genital blister	1	0
Genital haemorrhage	2	0
Genital ulceration	3	0
<i>Reproductive tract signs and symptoms NEC</i>		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Genital burning sensation	1	0
Genital discomfort	1	0
Pelvic discomfort	1	0
Pelvic pain	26	0
Pruritus genital	1	0
Scrotal disorders NEC		
Scrotal pain	1	0
Scrotal swelling	2	0
Sexual function and fertility disorders NEC		
Female sexual dysfunction	1	0
Sexual dysfunction	1	0
Testicular and epididymal disorders NEC		
Testicular pain	13	0
Testicular swelling	3	0
Uterine disorders NEC		
Endometriosis	1	0
Uterine haemorrhage	3	0
Uterine pain	1	0
Uterine tone disorders		
Uterine spasm	3	0
Vaginal and vulval infections and inflammations		
Vulvovaginal inflammation	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	51	0
Vulvovaginal signs and symptoms		
Vaginal discharge	7	0
Vaginal lesion	3	0
Vulval oedema	1	0
Vulvovaginal pain	5	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	2	0
Reproductive & breast disorders SOC TOTAL	354	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	4	0
Dyspnoea	1470	2
Dyspnoea at rest	3	0
Dyspnoea exertional	5	0
Hyperventilation	18	0
Hypopnoea	60	0
Irregular breathing	7	0
Mouth breathing	2	0
Orthopnoea	1	0
Respiration abnormal	32	0
Respiratory arrest	6	0
Respiratory distress	3	0
Sleep apnoea syndrome	4	0
Tachypnoea	23	0
<i>Bronchial conditions NEC</i>		
Bronchiectasis	4	0
<i>Bronchospasm and obstruction</i>		
Asthma	113	0
Asthma late onset	1	0
Asthmatic crisis	1	0
Bronchospasm	9	0
Chronic obstructive pulmonary disease	12	2
Cough variant asthma	3	0
Obstructive airways disorder	2	0
Reversible airways obstruction	1	0
Wheezing	169	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	22	0
<i>Coughing and associated symptoms</i>		
Cough	1033	0
Haemoptysis	12	0
Productive cough	36	0
Sputum discoloured	2	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Reflux laryngitis	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Laryngeal oedema	2	0
Laryngospasm	1	0
Stridor	9	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Pneumonia aspiration	7	3
Pneumonitis	3	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	8	0
Pleuritic pain	4	0
Pulmonary haemorrhage	1	0
Pulmonary pain	46	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	127	0
Nasal inflammation	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Rhinitis allergic	4	0
Rhinitis perennial	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	224	0
Nasal cyst	1	0
Nasal disorder	1	0
Nasal dryness	16	0
Nasal odour	2	0
Nasal oedema	4	0
Nasal pruritus	2	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Paranasal sinus haemorrhage	1	0
Paranasal sinus inflammation	1	0
Sinonasal obstruction	2	0
Sinus congestion	13	0
Sinus disorder	2	0
<i>Parenchymal lung disorders NEC</i>		
Idiopathic pulmonary fibrosis	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Oropharyngeal swelling	1	0
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	6	0
Pharyngeal oedema	2	0
Pharyngeal paraesthesia	7	0
Pharyngeal swelling	61	0
Pharyngeal ulceration	1	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	18	0
Tonsillar inflammation	2	0
<i>Pleural infections and inflammations</i>		
Lupus pleurisy	1	0
Pleurisy	4	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
Pneumothorax	1	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	1	0
<i>Pulmonary oedemas</i>		
Acute pulmonary oedema	1	0
Acute respiratory distress syndrome	1	0
Pulmonary congestion	6	0
Pulmonary oedema	4	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	16	2
Pulmonary infarction	1	1
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	2	0
<i>Respiratory signs and symptoms NEC</i>		
Diaphragmalgia	1	0
Painful respiration	1	0
Respiratory symptom	5	0
Suffocation feeling	2	0
<i>Respiratory tract disorders NEC</i>		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Aspiration	3	2
Lung disorder	2	0
Respiratory tract congestion	2	0
Respiratory tract irritation	1	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	1	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal fistula	1	0
Tracheal pain	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	21	0
Catarrh	15	0
Choking	6	0
Choking sensation	3	0
Dry throat	83	0
Dysphonia	34	0
Increased viscosity of upper respiratory secretion	5	0
Nasal discomfort	22	0
Oropharyngeal blistering	2	0
Oropharyngeal discomfort	5	0
Oropharyngeal pain	1230	0
Paranasal sinus discomfort	8	0
Rhinalgia	9	0
Rhinorrhoea	491	0
Sinus pain	131	0
Sneezing	129	0
Throat clearing	2	0
Throat irritation	63	0
Throat lesion	1	0
Throat tightness	45	0
Upper-airway cough syndrome	7	0
Yawning	24	0
Respiratory disorders SOC TOTAL	6040	12

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	5	0
<i>Alopecias</i>		
Alopecia	14	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	92	0
Circumoral oedema	1	0
Idiopathic angioedema	2	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	1	0
Cold sweat	573	0
Hyperhidrosis	3159	0
Miliaria	38	0
Night sweats	573	0
Sweat discolouration	1	0
Sweat gland disorder	1	0
<i>Bullous conditions</i>		
Blister	71	0
Blood blister	2	0
Dermatitis bullous	2	0
Erythema multiforme	5	0
Pemphigoid	2	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	64	0
Macule	2	0
Pain of skin	309	0
Papule	9	0
Peau d'orange	1	0
Scab	3	0
Scar pain	4	0
Sensitive skin	184	0
Skin burning sensation	163	0
Skin discolouration	17	0
Skin disorder	6	0
Skin fissures	1	0
Skin fragility	1	0
Skin induration	3	0
Skin lesion	2	0
Skin necrosis	1	0
Skin odour abnormal	10	0
Skin reaction	68	0
Skin sensitisation	29	0
Skin swelling	24	0
Skin texture abnormal	1	0
Skin tightness	3	0
Skin warm	154	0
Sticky skin	1	0
Yellow skin	10	0
<i>Dermatitis and eczema</i>		
Dermatitis	44	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Dermatitis allergic	68	0
Dermatitis atopic	4	0
Dermatitis contact	1	0
Dermatitis diaper	1	0
Dyshidrotic eczema	1	0
Eczema	22	0
Eczema asteatotic	2	0
Eczema nummular	1	0
Perioral dermatitis	1	0
Rebound eczema	1	0
Seborrhoeic dermatitis	1	0
Skin irritation	38	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	11	0
Fixed eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	942	0
Palmar erythema	2	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	0
Exfoliative rash	2	0
Skin exfoliation	20	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Granuloma annulare	1	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	1	0
Vitiligo	1	0
<i>Lipodystrophies</i>		
Lipohypertrophy	2	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail bed tenderness	1	0
Nail discolouration	2	0
Nail pitting	1	0
Onychoclasia	1	0
<i>Panniculitides</i>		
Erythema nodosum	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	2	0
Pityriasis rosea	3	0
Pityriasis rubra pilaris	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	46	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pilar disorders NEC</i>		
Hair growth abnormal	1	0
Piloerection	24	0
Trichodynia	2	0
<i>Pruritus NEC</i>		
Itching scar	1	0
Pruritus	1733	0
Pruritus allergic	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
Psoriasis	24	0
Pustular psoriasis	1	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
Henoch-Schonlein purpura	2	0
Petechiae	20	0
Purpura	8	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	2	0
Rash	1662	0
Rash erythematous	518	0
Rash macular	134	0
Rash maculo-papular	16	0
Rash morbilliform	3	0
Rash papular	88	0
Rash pruritic	397	0
Rash vesicular	15	0
Systemic lupus erythematosus rash	2	0
<i>Rosaceas</i>		
Rosacea	3	0
<i>Skin and subcutaneous conditions NEC</i>		
Cutaneous symptom	3	0
Skin mass	5	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin erosion	11	0
Skin ulcer	3	0
<i>Skin cysts and polyps</i>		
Dermal cyst	2	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	2	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	1	0
<i>Skin injuries and mechanical dermatoses</i>		
Decubitus ulcer	1	0
Needle track marks	2	0
<i>Skin vasculitides</i>		
Cutaneous vasculitis	1	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	7	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	8	0
<i>Urticarias</i>		
Idiopathic urticaria	2	0
Urticaria	524	0
Urticaria chronic	3	0
Urticaria papular	1	0
Urticaria thermal	1	0
Urticularial vasculitis	1	0
Skin disorders SOC TOTAL	12083	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Dietary and nutritional issues</i>		
Inadequate diet	1	0
<i>Disability issues</i>		
Bedridden	27	0
Disability	1	0
Immobile	9	0
Impaired driving ability	1	0
Impaired work ability	3	0
Loss of personal independence in daily activities	1	0
Sight disability	4	0
<i>Employment issues</i>		
Retirement	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	1	0
<i>Social issues NEC</i>		
Impaired quality of life	1	0
<i>Tobacco use</i>		
Tobacco user	1	0
Social circumstances SOC TOTAL	52	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Nerve block	1	0
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Antiinfective therapies</i>		
COVID-19 treatment	1	0
<i>Cardiac device therapeutic procedures</i>		
Pacemaker generated rhythm	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Pericardial excision	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	1	0
<i>Facial therapeutic procedures</i>		
Face lift	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis against gastrointestinal ulcer	1	0
Prophylaxis of nausea and vomiting	13	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	2	0
<i>Immunisations</i>		
COVID-19 immunisation	58	1
Immunisation	33	0
<i>Joint therapeutic procedures</i>		
Hip surgery	1	0
Joint injection	1	0
<i>Large intestine therapeutic procedures</i>		
Appendectomy	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	9	0
Limb operation	1	0
Limb reattachment surgery	1	0
<i>Muscle therapeutic procedures</i>		
Muscle relaxant therapy	1	0
<i>Nervous system therapeutic procedures NEC</i>		
Central nervous system stimulation	1	0
<i>Patient positioning</i>		
Prone position	1	0
<i>Prophylactic procedures NEC</i>		
Anaphylaxis prophylaxis	2	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	1	0
<i>Small intestine therapeutic procedures</i>		
Ileostomy	1	0
<i>Therapeutic procedures NEC</i>		
Bed rest	6	0
Fatigue management	1	0
Hospitalisation	4	0
Injection	14	0
Localised alternating hot and cold therapy	3	0
Mass excision	2	0
Smoking cessation therapy	1	0
Therapeutic hypothermia	2	0
Therapy change	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
<i>Uterine therapeutic procedures</i>		
Endometrial ablation	1	0
Surgical & medical procedures SOC TOTAL	170	1

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	1	0
Hypertensive emergency	1	0
Hypertensive urgency	1	0
Tyramine reaction	1	0
<i>Aortic aneurysms and dissections</i>		
Aortic aneurysm	2	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	10	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	2	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	28	1
Neurogenic shock	3	0
Shock	17	0
Shock symptom	4	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	11	0
Haemorrhage	23	1
Internal haemorrhage	1	0
<i>Lymphoedemas</i>		
Lymphoedema	16	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	0
Thrombosis	3	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arteriosclerosis	1	0
Ischaemia	1	0
<i>Non-site specific vascular disorders NEC</i>		
Neovascularisation	1	0
Vascular pain	7	0
Vasodilatation	7	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	2	0
Deep vein thrombosis	15	0
Pelvic venous thrombosis	1	0
Thrombophlebitis	1	0
Thrombophlebitis superficial	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	28	0
Erythromelalgia	1	0
Flushing	234	0
Hot flush	575	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Ischaemic limb pain	2	0
Peripheral coldness	333	0
Poor peripheral circulation	3	0
Raynaud's phenomenon	24	0
<i>Phlebitis NEC</i>		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Phlebitis	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	137	0
Plethoric face	1	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicophlebitis	1	0
Varicose vein	1	0
<i>Vascular hypertensive disorders NEC</i>		
Diastolic hypertension	1	0
Hypertension	146	0
Systolic hypertension	1	0
White coat hypertension	2	0
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	2	0
Hypotension	156	0
Orthostatic hypotension	14	0
<i>Vasculitides NEC</i>		
MAGIC syndrome	3	1
Vasculitis	10	0
Vascular disorders SOC TOTAL	1843	3
TOTAL REACTIONS FOR DRUG	228337	289
TOTAL REPORTS	61304	
TOTAL FATAL OUTCOME REPORTS		289