

COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 09-Mar-2021
Data Lock Date: 08-Mar-2021 19:00:03

All UK spontaneous reports received between 4/01/21 and 28/02/21 for
COVID-19 vaccine Oxford University/AstraZeneca

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 09-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 08-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	4	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	2	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	3	0
<i>Coagulopathies</i>		
Coagulopathy	2	0
<i>Eosinophilic disorders</i>		
Eosinophilia	4	0
<i>Haematological disorders</i>		
Bone marrow oedema	1	0
Mast cell activation syndrome	1	0
Mastocytosis	1	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	2	0
<i>Leukocytoses NEC</i>		
Lymphocytosis	1	0
<i>Leukopenias NEC</i>		
Leukopenia	3	0
Lymphopenia	3	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	93	0
Lymphadenitis	10	0
Lymphadenopathy	904	0
Lymphatic disorder	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Pancytopenia	3	0
<i>Neutropenias</i>		
Neutropenia	17	0
<i>Sickle cell trait and disorders</i>		
Sickle cell anaemia with crisis	2	0
<i>Spleen disorders</i>		
Spleen disorder	1	0
Splenic infarction	1	0
Splenomegaly	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	22	1
Thrombocytopenia	12	0
Thrombocytopenic purpura	1	0
<i>White blood cell abnormal findings NEC</i>		
White blood cell disorder	1	0
Blood disorders SOC TOTAL	1098	1

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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
Long QT syndrome	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	2	1
Cardiac disorder	4	0
Cardiovascular disorder	1	0
Cardiovascular insufficiency	3	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	1	0
Palpitations	1130	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	1	1
<i>Cardiomyopathies</i>		
Cardiomyopathy	1	0
Congestive cardiomyopathy	3	0
<i>Heart failures NEC</i>		
Cardiac failure	6	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	25	0
Angina unstable	3	0
Microvascular coronary artery disease	2	0
Myocardial infarction	25	12
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
Left ventricular dysfunction	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	1	0
<i>Noninfectious pericarditis</i>		
Pericarditis	4	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	3	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	30	0
Bradycardia	21	0
Cardiac flutter	30	0
Extrasystoles	15	0
Postural orthostatic tachycardia syndrome	3	0
Tachyarrhythmia	4	0
Tachycardia	456	0
<i>Right ventricular failures</i>		

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Right ventricular failure	1	1
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	4	0
Atrial fibrillation	49	0
Atrial flutter	7	0
Sinus arrhythmia	1	0
Sinus tachycardia	18	0
Supraventricular tachycardia	5	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	33	13
Ventricular arrhythmia	1	0
Ventricular extrasystoles	1	0
Ventricular fibrillation	1	0
Ventricular tachycardia	4	0
Cardiac disorders SOC TOTAL	1922	39

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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	3	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	5	0
<i>Pulmonary and bronchial disorders congenital</i>		
Cystic fibrosis	3	0
Congenital disorders SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	14	0
Ear haemorrhage	2	0
Ear pain	453	0
Ear swelling	14	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	30	0
Deafness bilateral	1	0
Deafness transitory	2	0
Deafness unilateral	4	0
Hypoacusis	30	0
Sudden hearing loss	6	0
<i>Hyperacusia</i>		
Hyperacusis	19	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	17	0
Tinnitus	320	0
Vertigo	274	0
Vertigo labyrinthine	3	0
Vertigo positional	16	0
Ear disorders SOC TOTAL	1217	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	1	0
<i>Adrenal cortical hypofunctions</i>		
Adrenal insufficiency	7	0
Adrenocortical insufficiency acute	16	0
Glucocorticoid deficiency	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	7	0
Endocrine disorders SOC TOTAL	36	0

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Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	1	0
<i>Cataract conditions</i>		
Cataract	2	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	9	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	2	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	3	0
<i>Eyelid movement disorders</i>		
Blepharospasm	8	0
Eyelid ptosis	5	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	3	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iritis	1	0
Uveitis	2	0
<i>Lacrimation disorders</i>		
Dry eye	44	0
Lacrimation increased	38	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 oedema	2	0
Swelling of eyelid	12	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	2	0
<i>Ocular disorders NEC</i>		
Eye disorder	2	0
Eye oedema	2	0
Eye pain	794	0
Eye swelling	108	0
Eye symptom	1	0
Ocular discomfort	7	0
Periorbital oedema	6	0
Periorbital pain	2	0
Periorbital swelling	21	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	6	0
Eye discharge	5	0
Eye inflammation	4	0
Eye irritation	42	0
Eye pruritus	62	0
Ocular hyperaemia	57	0
<i>Ocular nerve and muscle disorders</i>		
Extraocular muscle paresis	4	0
Eye movement disorder	7	0

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Eye disorders Eye disorders cont'd		
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	4	0
Asthenopia	60	0
Eyelid sensory disorder	2	0
Foreign body sensation in eyes	10	0
Hypoaesthesia eye	3	0
Photophobia	261	0
<i>Pupil disorders</i>		
Miosis	2	0
Mydriasis	5	0
Pupils unequal	2	0
<i>Refractive and accommodative disorders</i>		
Hypermetropia	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal aneurysm	1	0
Retinal vascular thrombosis	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Macular detachment	1	0
Neovascular age-related macular degeneration	2	0
Vitreoretinal traction syndrome	1	0
<i>Retinopathies NEC</i>		
Acute macular outer retinopathy	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	2	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Endocrine ophthalmopathy	1	0
<i>Visual colour distortions</i>		
Chromatopsia	1	0
Xanthopsia	1	0
<i>Visual disorders NEC</i>		
Diplopia	40	0
Halo vision	3	0
Metamorphopsia	5	0
Photopsia	58	0
Vision blurred	282	0
Visual brightness	1	0
Visual snow syndrome	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Amaurosis fugax	1	0
Blindness	28	0
Blindness transient	2	0
Night blindness	2	0
Sudden visual loss	1	0
Visual acuity reduced	3	0
Visual impairment	90	0
Eye disorders SOC TOTAL	2150	0

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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	9	0
Pancreatitis acute	2	0
<i>Anal and rectal pains</i>		
Proctalgia	1	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
<i>Colitis (excl infective)</i>		
Autoimmune colitis	1	0
Colitis	4	0
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	19	0
Crohn's disease	16	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	7	0
Toothache	76	0
<i>Dental surface disorders</i>		
Tooth discolouration	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	2517	0
Diarrhoea haemorrhagic	7	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	197	0
Epigastric discomfort	6	0
Eructation	20	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	5	0
Faecaloma	1	0
Faeces discoloured	5	0
Faeces hard	1	0
Faeces pale	1	0
Faeces soft	4	0
Mucous stools	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	73	0
Flatulence	89	0
<i>Gastric and oesophageal haemorrhages</i>		

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gastric haemorrhage	1	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	15	0
Reflux gastritis	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	1158	0
Abdominal pain lower	51	0
Abdominal pain upper	1212	0
Abdominal rigidity	14	0
Abdominal tenderness	5	0
Gastrointestinal pain	80	0
Oesophageal pain	2	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	79	0
Gastric dilatation	3	0
Gastrooesophageal reflux disease	44	0
Infrequent bowel movements	1	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	4	0
Gastric disorder	4	0
Gastrointestinal disorder	7	0
Neurogenic bowel	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	3	0
Dyschezia	1	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	374	0
Abdominal symptom	2	0
Acute abdomen	5	0
Anal incontinence	8	0
Breath odour	5	0
Dysphagia	42	1
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	6	0
Frequent bowel movements	9	0
Irritable bowel syndrome	21	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	7	0
Gingival discomfort	1	0
Gingival disorder	4	0
Gingival oedema	1	0
Gingival pain	46	0
Gingival pruritus	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
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	3	0
<i>Inguinal hernias</i>		
Inguinal hernia	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	2	0
Rectal haemorrhage	8	0
Small intestinal haemorrhage	7	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	10498	0
Regurgitation	1	0
Retching	93	0
Vomiting	3777	2
Vomiting projectile	43	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	4	1
Haematemesis	12	0
Haematochezia	14	0
Melaena	2	0
<i>Oesophagitis (excl infective)</i>		
Oesophagitis	2	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	313	0
Lip dry	12	0
Saliva altered	1	0
Salivary hypersecretion	9	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	2	0
Cheilitis	11	0
Enlarged uvula	2	0
Leukoplakia oral	1	0
Lip blister	9	0
Lip disorder	1	0
Oral disorder	1	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	1	0
Oral blood blister	4	0
<i>Oral soft tissue signs and symptoms</i>		
Anaesthesia oral	2	0
Burning mouth syndrome	1	0
Hypoaesthesia oral	112	0
Lip erythema	2	0
Lip exfoliation	4	0

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Gastrointestinal disorders		
Lip pain	17	0
Lip pruritus	8	0
Odynophagia	4	0
Oral discomfort	17	0
Oral mucosal blistering	8	0
Oral mucosal eruption	3	0
Oral mucosal exfoliation	4	0
Oral mucosal roughening	1	0
Oral pain	84	0
Oral pruritus	4	0
Paraesthesia oral	199	0
Oral soft tissue swelling and oedema		
Lip oedema	2	0
Lip swelling	228	0
Mouth swelling	35	0
Oedema mouth	1	0
Palatal swelling	4	0
Rectal inflammations NEC		
Proctitis	1	0
Salivary gland disorders NEC		
Salivary gland pain	2	0
Salivary gland enlargements		
Parotid gland enlargement	3	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	1	0
Stomatitis and ulceration		
Apthous ulcer	10	0
Lip ulceration	4	0
Mouth ulceration	119	0
Stomatitis	16	0
Tongue disorders		
Glossitis	6	0
Plicated tongue	1	0
Tongue disorder	5	0
Tongue ulceration	3	0
Trichoglossia	2	0
Tongue signs and symptoms		
Glossodynia	61	0
Scalloped tongue	2	0
Swollen tongue	127	0
Tongue blistering	6	0
Tongue coated	9	0
Tongue discolouration	4	0
Tongue discomfort	7	0
Tongue dry	6	0
Tongue eruption	1	0
Tongue exfoliation	1	0
Tongue movement disturbance	1	0
Tongue oedema	6	0
Tongue pruritus	1	0
Tongue rough	1	0
Tongue spasm	1	0
Tooth missing		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	22336	5

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	5	0
Administration site pain	14	0
Administration site urticaria	1	0
Puncture site bruise	11	0
Puncture site pain	7	0
Puncture site reaction	1	0
<i>Adverse effect absent</i>		
No adverse event	7	0
<i>Application and instillation site reactions</i>		
Application site bruise	4	0
Application site erythema	6	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 warmth	6	0
<i>Asthenic conditions</i>		
Asthenia	1247	3
Chronic fatigue syndrome	9	0
Fatigue	13202	0
Malaise	3631	3
Sluggishness	3	0
<i>Body temperature altered</i>		
Hyperthermia	5	0
Hypothermia	19	0
Temperature regulation disorder	6	0
<i>Complications associated with device NEC</i>		
Phantom shocks	1	0
<i>Death and sudden death</i>		
Brain death	1	1
Death	134	134
Sudden death	9	9
<i>Febrile disorders</i>		
Hyperpyrexia	25	0
Masked fever	1	0
Pyrexia	18640	1
<i>Feelings and sensations NEC</i>		
Chills	14442	0
Feeling abnormal	558	0
Feeling cold	1688	0
Feeling drunk	19	0
Feeling hot	628	0
Feeling jittery	8	0
Feeling of body temperature change	319	0
Hangover	25	0
Hunger	9	0
Sensation of foreign body	7	0
Temperature intolerance	12	0
Thirst	402	0
Thirst decreased	3	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Fibrosis NEC</i>		
Fibrosis	1	0
<i>Gait disturbances</i>		
Decreased gait velocity	1	0
Gait disturbance	78	0
Gait inability	52	0
Loss of control of legs	10	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	42	0
Crying	42	0
Discharge	1	0
Energy increased	2	0
Exercise tolerance decreased	2	0
Foaming at mouth	2	0
General physical health deterioration	7	2
General symptom	4	0
Illness	1514	0
Induration	5	0
Influenza like illness	3006	0
Local reaction	74	0
Moaning	3	0
Multiple organ dysfunction syndrome	2	0
Nonspecific reaction	1	0
Peripheral swelling	1172	0
Screaming	3	0
Secretion discharge	6	0
Swelling	530	0
Swelling face	211	0
Symptom recurrence	1	0
<i>Implant and catheter site reactions</i>		
Implant site pain	1	0
Implant site rash	1	0
Implant site warmth	3	0
<i>Inflammations</i>		
Inflammation	120	0
<i>Infusion site reactions</i>		
Infusion site bruising	1	0
Infusion site pain	2	0
Infusion site warmth	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	12	0
Injection site bruising	22	0
Injection site coldness	1	0
Injection site discolouration	1	0
Injection site discomfort	3	0
Injection site erythema	176	0
Injection site haemorrhage	1	0
Injection site hypoaesthesia	4	0
Injection site indentation	2	0
Injection site inflammation	21	0
Injection site injury	1	0
Injection site irritation	2	0
Injection site joint erythema	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 09-Mar-2021

Data Lock Date: 08-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 joint pain	16	0
Injection site mass	344	0
Injection site muscle weakness	1	0
Injection site nodule	1	0
Injection site oedema	9	0
Injection site pain	1248	0
Injection site papule	1	0
Injection site paraesthesia	6	0
Injection site pruritus	90	0
Injection site rash	72	0
Injection site reaction	35	0
Injection site scab	1	0
Injection site scar	2	0
Injection site swelling	51	0
Injection site urticaria	9	0
Injection site vesicles	2	0
Injection site warmth	106	0
Interactions		
Drug interaction	5	0
Inhibitory drug interaction	1	0
Mass conditions NEC		
Cyst	1	0
Mass	8	0
Nodule	1	0
Mucosal findings abnormal		
Mucosal disorder	1	0
Mucosal haemorrhage	1	0
Mucosal inflammation	2	0
Mucosal pain	1	0
Oedema NEC		
Face oedema	6	0
Localised oedema	4	0
Oedema	4	0
Oedema peripheral	9	0
Pain and discomfort NEC		
Axillary pain	103	0
Chest discomfort	468	0
Chest pain	887	0
Discomfort	53	0
Facial discomfort	4	0
Facial pain	63	0
Inflammatory pain	4	0
Non-cardiac chest pain	8	0
Pain	4018	0
Tenderness	509	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	17	0
Diet failure	1	0
Drug ineffective	11	0
Drug intolerance	1	0
Inadequate analgesia	1	0
No reaction on previous exposure to drug	10	0
Therapeutic product effect decreased	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 09-Mar-2021
 Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 08-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Therapeutic response shortened	1	0
Therapeutic response unexpected	7	0
Treatment failure	2	0
Vaccine positive rechallenge	1	0
Ulcers NEC		
Ulcer	5	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	7	0
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	24	0
Vaccination site discolouration	2	0
Vaccination site discomfort	5	0
Vaccination site erythema	172	0
Vaccination site extravasation	1	0
Vaccination site granuloma	3	0
Vaccination site haemorrhage	1	0
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	2	0
Vaccination site induration	20	0
Vaccination site inflammation	18	0
Vaccination site irritation	4	0
Vaccination site joint erythema	1	0
Vaccination site joint movement impairment	5	0
Vaccination site joint pain	20	0
Vaccination site joint swelling	1	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	1	0
Vaccination site mass	128	0
Vaccination site movement impairment	7	0
Vaccination site oedema	2	0
Vaccination site pain	490	0
Vaccination site papule	2	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	25	0
Vaccination site rash	42	0
Vaccination site reaction	8	0
Vaccination site swelling	143	0
Vaccination site urticaria	1	0
Vaccination site vesicles	1	0
Vaccination site warmth	89	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	4	0
General disorders SOC TOTAL	71732	153

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 09-Mar-2021

Data Lock Date: 08-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	2	0
Cholelithiasis	3	0
<i>Cholestasis and jaundice</i>		
Jaundice	7	0
Ocular icterus	1	0
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	11	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	1	0
Hepatic disorders SOC TOTAL	29	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 09-Mar-2021

Data Lock Date: 08-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

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	5	0
Allergy to metals	1	0
Allergy to sting	1	0
Allergy to venom	1	0
Hypersensitivity	243	0
Infusion related hypersensitivity reaction	2	0
Multiple allergies	5	0
Serum sickness	9	0
Serum sickness-like reaction	7	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	14	0
Drug hypersensitivity	18	0
Food allergy	1	0
Reaction to excipient	2	0
Reaction to preservatives	4	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	173	0
Anaphylactic shock	14	0
Anaphylactoid reaction	5	0
Anaphylactoid shock	2	0
<i>Atopic disorders</i>		
Seasonal allergy	6	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	6	0
Immune system disorder	3	0
Immunisation reaction	1	0
Sensitisation	8	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
<i>Transplant rejections</i>		
Transplant rejection	1	0
Immune system disorders SOC TOTAL	542	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 09-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 08-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	1	0
Dysentery	1	0
Gastroenteritis	8	0
Gastrointestinal infection	1	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Arthritis bacterial	2	0
Bacterial infection	5	1
Cellulitis	140	1
Injection site cellulitis	2	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	4	0
<i>Candida infections</i>		
Balanitis candida	1	0
Candida infection	8	0
Oral candidiasis	6	0
Skin candida	1	0
Vulvovaginal candidiasis	5	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	152	11
COVID-19 pneumonia	4	3
Coronavirus infection	1	0
Severe acute respiratory syndrome	3	0
Suspected COVID-19	12	0
<i>Coxiella infections</i>		
Q fever	35	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	2	0
Tooth abscess	1	0
<i>Ear infections</i>		
Ear infection	5	0
Labyrinthitis	22	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 09-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 08-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	9	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	12	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
<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	4	0
Genital herpes simplex	1	0
Herpes ophthalmic	2	0
Herpes simplex	7	0
Herpes simplex reactivation	1	0
Herpes virus infection	2	0
Herpes zoster	150	0
Ophthalmic herpes zoster	1	0
Oral herpes	136	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	65	2
Injection site infection	4	0
Localised infection	22	0
Lymph gland infection	1	0
Pathogen resistance	1	0
Respiratory tract infection	2	0
Vaccination site infection	9	0
<i>Influenza viral infections</i>		
H2N2 influenza	1	0
Influenza	1962	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	2	0
Infective exacerbation of bronchiectasis	1	0
Lower respiratory tract infection	40	2
Pneumonia	31	11
<i>Male reproductive tract infections</i>		
Orchitis	1	0
<i>Mumps viral infections</i>		
Mumps	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 09-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 08-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Phleboviral infections</i>		
Severe fever with thrombocytopenia syndrome	2	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Neutropenic sepsis	2	0
Sepsis	24	2
Septic rash	1	0
Septic shock	1	0
Urosepsis	2	1
<i>Skin structures and soft tissue infections</i>		
Folliculitis	2	0
Infected dermal cyst	1	0
Pustule	1	0
Rash pustular	5	0
Skin infection	12	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	1	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	382	0
Pharyngitis	5	0
Rhinitis	13	0
Sinusitis	43	0
Tonsillitis	14	0
Upper respiratory tract infection	2	0
<i>Urinary tract infections</i>		
Cystitis	14	0
Kidney infection	9	0
Urinary tract infection	29	0
<i>Vascular infections</i>		
Infected lymphocele	1	0
Lymphangitis	2	0
<i>Viral infections NEC</i>		
Arthritis viral	1	0
Gastroenteritis viral	17	1
Pneumonia viral	2	1
Post viral fatigue syndrome	18	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 09-Mar-2021

Data Lock Date: 08-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Sweating fever	233	0
Vestibular neuronitis	2	0
Viral diarrhoea	2	0
Viral infection	4	0
Viral labyrinthitis	1	0
Viral myocarditis	1	0
Viral pharyngitis	7	0
Viral rash	8	0
Viral sepsis	1	0
Infections SOC TOTAL	3839	38

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 09-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 08-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
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
<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 via breast milk	4	0
Foetal exposure during pregnancy	7	0
Maternal exposure during breast feeding	55	0
Maternal exposure during pregnancy	45	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	14	0
Procedural vomiting	2	0
<i>Heat injuries (excl thermal burns)</i>		
Heat exhaustion	2	0
Heat oedema	4	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	2	0
Lower limb fracture	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Device use issue	1	0
Medication error	2	0
Vaccination error	1	0
Wrong drug	1	0
Wrong technique in product usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	3	0
Ligament sprain	1	0
Muscle injury	2	0

Case Series Drug Analysis Print

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Report Run Date: 09-Mar-2021

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Muscle rupture	1	0
Muscle strain	2	0
Post-traumatic neck syndrome	1	0
Tendon rupture	2	0
<i>Nerve injuries NEC</i>		
Nerve injury	8	0
<i>Neurological and psychiatric procedural complications</i>		
Post lumbar puncture syndrome	5	0
Procedural dizziness	10	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	3	0
Exposure to noise	1	0
<i>Non-site specific injuries NEC</i>		
Arthropod bite	2	0
Arthropod sting	3	0
Electric shock	2	0
Fall	53	1
Inflammation of wound	1	0
Nervous system injury	1	0
Road traffic accident	1	0
Tissue injury	1	0
Wound complication	1	0
<i>Non-site specific procedural complications</i>		
Incision site pain	5	0
Infusion related reaction	7	0
Injection related reaction	303	0
Post procedural complication	16	0
Procedural pain	1	0
Suture related complication	1	0
<i>Occupational exposures</i>		
Occupational exposure to product	1	0
<i>Overdoses NEC</i>		
Overdose	3	0
<i>Peripheral nerve injuries</i>		
Ulnar nerve injury	1	0
<i>Poisoning and toxicity</i>		
Alcohol poisoning	1	0
Toxicity to various agents	3	0
<i>Product administration errors and issues</i>		
Accidental overdose	2	0
Duplicate therapy error	1	0
Expired product administered	2	0
Extra dose administered	2	0
Incorrect route of product administration	2	0
Product administered to patient of inappropriate age	2	0
Product administration error	4	0
Wrong product administered	1	0
<i>Product confusion errors and issues</i>		
Product label confusion	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Product monitoring errors and issues</i>		
Product monitoring error	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 09-Mar-2021
 Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 08-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Product prescribing errors and issues</i>		
Contraindicated product prescribed	1	0
<i>Radiation injuries</i>		
Sunburn	2	0
<i>Reproductive tract and breast procedural complications</i>		
Postmastectomy lymphoedema syndrome	1	0
<i>Site specific injuries NEC</i>		
Back injury	1	0
Head injury	3	0
Limb crushing injury	1	0
Limb injury	13	0
Neck crushing	1	0
<i>Skin injuries NEC</i>		
Contusion	187	0
Scar	1	0
Skin abrasion	2	0
Skin injury	1	0
Skin wound	2	0
<i>Spinal cord injuries NEC</i>		
Spinal cord injury sacral	1	0
<i>Stoma complications</i>		
Gastrointestinal stoma complication	1	0
<i>Thermal burns</i>		
Burn of internal organs	3	0
Burn oral cavity	1	0
Burns second degree	1	0
Cold burn	1	0
Thermal burn	8	0
Thermal burns of eye	10	0
<i>Underdoses NEC</i>		
Intentional underdose	1	0
<i>Vaccination related complications</i>		
Vaccination complication	29	0
Vaccination failure	2	0
Injuries SOC TOTAL	916	1

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 09-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 08-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	1	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 increased	3	0
Oxygen saturation	11	0
Oxygen saturation decreased	71	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	9	0
Blood glucose abnormal	4	0
Blood glucose decreased	16	0
Blood glucose fluctuation	7	0
Blood glucose increased	62	0
Glycosylated haemoglobin increased	2	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	2	0
Heart sounds	3	0
Heart sounds abnormal	1	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	2	0
Magnetic resonance imaging brain	27	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	5	0
International normalised ratio increased	17	0
<i>ECG investigations</i>		
Electrocardiogram T wave inversion	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>		
Blood gastrin normal	1	0
Blood insulin	4	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 09-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 08-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood insulin increased	1	0
Heart rate and pulse investigations		
Heart rate	250	0
Heart rate abnormal	9	0
Heart rate decreased	16	0
Heart rate increased	542	0
Heart rate irregular	42	0
Maximum heart rate	1	0
Maximum heart rate decreased	1	0
Orthostatic heart rate response increased	1	0
Pulse abnormal	5	0
Pulse absent	2	0
Sinus rhythm	1	0
Imaging procedures NEC		
Computerised tomogram	1	0
Immunoglobulin analyses		
Blood immunoglobulin E increased	1	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	3	0
Transaminases increased	2	0
Metabolism tests NEC		
Blood ketone body	5	0
Ubiquinone	1	0
Mineral and electrolyte analyses		
Blood phosphorus 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		
Body surface area	1	0
Body temperature	356	0
Body temperature abnormal	26	0
Body temperature decreased	46	0
Body temperature fluctuation	50	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 09-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 08-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Body temperature increased	413	0
Breath sounds abnormal	2	0
Grip strength	2	0
Grip strength decreased	5	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	23	0
Skin temperature	56	0
Temperature difference of extremities	1	0
Urological examination	1	0
Weight decreased	26	0
Weight increased	1	0
Platelet analyses		
Platelet count decreased	6	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
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
Therapeutic drug monitoring analyses		
Analgesic drug level	5	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		
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

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Protein urine present	1	0
Urine analysis abnormal	1	0
pH urine	3	0
pH urine decreased	1	0
pH urine increased	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output	13	0
Urine output decreased	3	0
Urine output increased	4	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	1	0
Blood pressure decreased	20	0
Blood pressure increased	69	0
Blood pressure measurement	17	0
Blood pressure systolic increased	1	0
<i>Virus identification and serology</i>		
Coronavirus test	10	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	4	0
SARS-CoV-2 test positive	15	0
<i>White blood cell analyses</i>		
Neutrophil count decreased	1	0
White blood cell count	3	0
White blood cell count decreased	3	0
White blood cell count increased	2	0
Investigations SOC TOTAL	2436	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	3	0
Decreased appetite	2182	0
Diet refusal	1	0
Food craving	5	0
Food refusal	15	0
Hyperphagia	2	0
Hypophagia	11	0
Increased appetite	12	0
Salt craving	1	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	2	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	13	0
Diabetes mellitus inadequate control	9	0
Increased insulin requirement	1	0
Type 1 diabetes mellitus	4	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	5	2
Diabetic ketosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	14	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	3	0
<i>Fluid intake increased</i>		
Polydipsia	8	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Food intolerance	4	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	8	0
Abnormal weight gain	2	0
Cachexia	1	0
Feeding disorder	34	0
Food aversion	21	0
Starvation	1	0
Underweight	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	47	0
Insulin resistance	2	0
<i>Hyperlipidaemias NEC</i>		
Hyperlipidaemia	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hyperinsulinaemic hypoglycaemia	1	0
Hypoglycaemia	29	0
Hypoglycaemia unawareness	1	0
<i>Iron deficiencies</i>		
Iron deficiency	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Ketosis	1	0
Metabolic acidosis	1	0
<i>Potassium imbalance</i>		

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Hyperkalaemia	1	0
Sodium imbalance		
Hyponatraemia	7	0
Total fluid volume decreased		
Dehydration	176	0
Hypovolaemia	1	0
Total fluid volume increased		
Fluid overload	1	0
Fluid retention	9	0
Metabolic disorders SOC TOTAL	2644	2

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	49	0
Arthropathy	2	0
Autoimmune arthritis	1	0
Palindromic rheumatism	1	0
Polyarthritis	2	0
Sacroiliitis	1	0
<i>Bone disorders NEC</i>		
Medial tibial stress syndrome	1	0
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	299	0
Pain in jaw	118	0
Spinal pain	59	0
<i>Bursal disorders</i>		
Bursitis	7	0
<i>Cartilage disorders</i>		
Costochondritis	3	0
<i>Connective tissue disorders NEC</i>		
Morphoea	1	0
Polymyalgia rheumatica	8	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	19	0
Rotator cuff syndrome	5	0
Temporomandibular joint syndrome	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	6317	0
Joint noise	4	0
Joint stiffness	94	0
Joint swelling	93	0
Joint warmth	6	0
<i>Ligament disorders</i>		
Ligament pain	1	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	4	0
<i>Metabolic bone disorders</i>		
Osteopenia	1	0
Osteoporosis	1	0
<i>Muscle infections and inflammations</i>		
Myositis	2	0
<i>Muscle pains</i>		
Fibromyalgia	34	0
Myalgia	8308	0
Myofascial pain syndrome	3	0
<i>Muscle related signs and symptoms NEC</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Muscle discomfort	1	0
Muscle disorder	1	0
Muscle fatigue	255	0
Muscle mass	3	0
Muscle oedema	2	0
Muscle spasms	554	0
Muscle swelling	7	0
Muscle tightness	32	0
Muscle twitching	82	0
Muscle tone abnormalities		
Muscle rigidity	16	0
Nuchal rigidity	2	0
Torticollis	2	0
Trismus	19	0
Muscle weakness conditions		
Muscular weakness	471	0
Musculoskeletal and connective tissue conditions NEC		
Infantile back arching	1	0
Limb mass	2	0
Mobility decreased	40	0
Musculoskeletal stiffness	470	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	1499	0
Flank pain	21	0
Growing pains	3	0
Limb discomfort	463	0
Musculoskeletal chest pain	99	0
Musculoskeletal discomfort	22	0
Musculoskeletal pain	21	0
Neck pain	674	0
Pain in extremity	4297	0
Rheumatic disorder	3	0
Myopathies		
Myopathy	1	0
Rhabdomyolysis	4	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	8	0
Psoriatic arthropathies		
Psoriatic arthropathy	8	0
Rheumatoid arthropathies		
Rheumatoid arthritis	23	0
Still's disease	2	0
Soft tissue disorders NEC		
Axillary mass	6	0
Groin pain	28	0
Neck mass	1	0
Soft tissue mass	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Soft tissue swelling	1	0
<i>Spine and neck deformities</i>		
Spinal stenosis	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	3	0
Arthritis reactive	3	0
<i>Synovial disorders</i>		
Synovitis	2	0
<i>Tendon disorders</i>		
Tendon pain	2	0
Tendonitis	5	0
Trigger finger	2	0
Muscle & tissue disorders SOC TOTAL	24631	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	2	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	3	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>		
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	18	1

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	3	0
Hyporeflexia	3	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	7	0
<i>Absence seizures</i>		
Petit mal epilepsy	4	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	19	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	7	1
Cerebral infarction	1	0
Cerebral thrombosis	1	1
Cerebrovascular accident	41	6
Embolic stroke	1	0
Haemorrhage intracranial	3	0
Haemorrhagic stroke	4	1
Ischaemic stroke	9	0
Subarachnoid haemorrhage	1	0
<i>Central nervous system inflammatory disorders NEC</i>		
Central nervous system inflammation	2	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	1	0
<i>Coma states</i>		
Coma	4	0
<i>Coordination and balance disturbances</i>		
Ataxia	5	0
Balance disorder	209	0
Cerebellar ataxia	1	0
Coordination abnormal	20	0
Dysstasia	23	0
Nystagmus	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	16	0
Dyspraxia	1	0
Neurologic neglect syndrome	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	6	0
Frontotemporal dementia	1	0
Senile dementia	1	0
Vascular dementia	3	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	3	0
Consciousness fluctuating	3	0
Depressed level of consciousness	22	0
Lethargy	1344	0
Loss of consciousness	209	0
Sedation	4	0
Somnolence	470	1
Syncope	559	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	6	0
Bradykinesia	6	0
Clumsiness	8	0
Dyskinesia	19	0
Extrapyramidal disorder	8	0
Fine motor skill dysfunction	1	0
Hypokinesia	8	0
Motor dysfunction	2	0
Movement disorder	15	0
Psychomotor hyperactivity	9	0
<i>Dystonias</i>		
Dystonia	4	0
Dystonic tremor	2	0
<i>Encephalitis NEC</i>		
Noninfective encephalitis	2	0
<i>Encephalopathies NEC</i>		
Encephalopathy	1	0
<i>Encephalopathies toxic and metabolic</i>		
Hepatic encephalopathy	1	0
<i>Eye movement disorders</i>		
IIIrd nerve paralysis	1	0
<i>Facial cranial nerve disorders</i>		
Facial nerve disorder	1	0
Facial paralysis	73	0
Facial paresis	15	0
Facial spasm	7	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	15	0
<i>Headaches NEC</i>		
Cervicogenic headache	1	0
Cluster headache	160	0
Cold-stimulus headache	8	0
Drug withdrawal headache	5	0
Exertional headache	3	0
External compression headache	2	0
Headache	23454	0
Medication overuse headache	2	0
New daily persistent headache	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Occipital neuralgia	1	0
Post-traumatic headache	1	0
Primary headache associated with sexual activity	2	0
Sinus headache	216	0
Tension headache	356	0
Thunderclap headache	7	0
Vascular headache	17	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Brain oedema	2	0
Intracranial pressure increased	2	0
Intellectual disabilities		
Intellectual disability	3	0
Lumbar spinal cord and nerve root disorders		
Sciatica	17	0
Memory loss (excl dementia)		
Amnesia	37	0
Memory impairment	32	0
Transient global amnesia	2	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	21	1
Disturbance in attention	93	0
Mental impairment	21	0
Migraine headaches		
Hemiplegic migraine	2	0
Migraine	1520	0
Migraine with aura	48	0
Migraine without aura	9	0
Retinal migraine	7	0
Status migrainosus	1	0
Typical aura without headache	4	0
Vestibular migraine	2	0
Mononeuropathies		
Carpal tunnel syndrome	2	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	17	0
Multiple sclerosis relapse	8	0
Muscle tone abnormal		
Hypotonia	7	0
Stiff leg syndrome	2	0
Myelitis (incl infective)		
Myelitis transverse	6	0
Narcolepsy and hypersomnia		
Hypersomnia	41	0
Narcolepsy	6	0
Nervous system cysts and polyps		

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Pineal gland cyst	1	0
<i>Nervous system disorders NEC</i>		
Cerebral disorder	1	0
Nervous system disorder	6	0
Psychomotor skills impaired	2	0
<i>Neurologic visual problems NEC</i>		
Tunnel vision	3	0
Visual field defect	4	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	5513	0
Dizziness exertional	27	0
Dizziness postural	622	1
Drooling	1	0
Exaggerated startle response	2	0
Head discomfort	91	0
Hyporesponsive to stimuli	1	0
Infant irritability	1	0
Myoclonus	5	0
Neurological symptom	19	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	2	0
Presyncope	172	0
Sensory overload	1	0
Unresponsive to stimuli	28	0
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	9	0
Muscle spasticity	4	0
Neuromuscular pain	1	0
<i>Neuromuscular junction dysfunction</i>		
Myasthenia gravis	1	0
Myasthenia gravis crisis	1	0
<i>Olfactory nerve disorders</i>		
Anosmia	52	0
Hyposmia	4	0
Parosmia	92	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	6	0
<i>Paraesthesias and dysaesthesias</i>		
Anaesthesia	2	0
Burning feet syndrome	5	0
Burning sensation	127	0
Dysaesthesia	3	0
Formication	9	0
Hemianaesthesia	2	0
Hyperaesthesia	74	0
Hypoaesthesia	751	0
Lhermitte's sign	1	0
Paraesthesia	1413	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	10	0
Hemiparesis	13	0
Hemiplegia	4	0
Monoparesis	7	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Monoplegia	24	0
Paralysis	49	0
Paraparesis	2	0
Paraplegia	1	0
Paresis	1	0
Peripheral nerve palsy	1	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	47	0
Parkinson's disease	8	0
Parkinsonism	6	0
Reduced facial expression	1	0
Partial complex seizures		
Dreamy state	3	0
Focal dyscognitive seizures	1	0
Partial simple seizures NEC		
Simple partial seizures	2	0
Peripheral neuropathies NEC		
Neuropathy peripheral	33	0
Seizures and seizure disorders NEC		
Alcoholic seizure	1	0
Atonic seizures	2	0
Clonic convulsion	1	0
Epilepsy	50	0
Febrile convulsion	25	0
Partial seizures	10	0
Psychogenic seizure	1	0
Seizure	241	2
Seizure anoxic	1	0
Seizure cluster	2	0
Seizure like phenomena	2	0
Status epilepticus	3	1
Tonic convulsion	8	0
Sensory abnormalities NEC		
Ageusia	235	0
Allodynia	16	0
Aura	2	0
Central pain syndrome	1	0
Complex regional pain syndrome	2	0
Dysgeusia	424	0
Hypogeusia	1	0
Loss of proprioception	2	0
Neuralgia	216	0
Phantom limb syndrome	8	0
Post herpetic neuralgia	2	0
Restless arm syndrome	4	0
Restless legs syndrome	81	0
Sensory disturbance	15	0
Sensory loss	19	0
Taste disorder	118	0
Sleep disturbances NEC		
Poor quality sleep	173	0
Sleep deficit	11	0
Speech and language abnormalities		

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Dysarthria	51	1
Incoherent	2	0
Language disorder	1	0
Slow speech	3	0
Speech disorder	9	0
Spinal cord and nerve root disorders NEC		
Myelopathy	2	0
Radiculopathy	1	0
Structural brain disorders NEC		
Brain injury	1	0
Transient cerebrovascular events		
Transient ischaemic attack	25	0
Tremor (excl congenital)		
Action tremor	1	0
Essential tremor	1	0
Head titubation	5	0
Intention tremor	1	0
Resting tremor	3	0
Tremor	3492	1
Trigeminal disorders		
Facial neuralgia	4	0
Trigeminal neuralgia	10	0
Nervous system disorders SOC TOTAL	43951	19

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	4	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	11	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	1	0
Pregnancy conditions SOC TOTAL	20	0

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Reaction Name	Total	Fatal
<i>Device incompatibility issues</i>		
Patient-device incompatibility	1	0
<i>Device malfunction events NEC</i>		
Oversensing	7	0
Stent malfunction	1	0
Undersensing	1	0
<i>Product physical issues</i>		
Product taste abnormal	1	0
null SOC TOTAL	11	0

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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	52	0
Anxiety	151	0
Nervousness	201	0
Stress	2	0
Tension	10	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	6	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	4	0
Mental fatigue	84	0
<i>Communications disorders</i>		
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	486	0
Disorientation	186	0
<i>Deliria</i>		
Delirium	158	0
<i>Delusional symptoms</i>		
Delusion	6	0
<i>Depressive disorders</i>		
Agitated depression	1	0
Depression	77	0
Major depression	4	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>		
Initial insomnia	9	0
Insomnia	810	0
Middle insomnia	12	0

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Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 08-Mar-2021 19:00:03
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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Terminal insomnia	1	0
Dyssomnias		
Dyssomnia	1	0
Eating disorders NEC		
Eating disorder	1	0
Emotional and mood disturbances NEC		
Anger	10	0
Emotional disorder	25	0
Emotional distress	11	0
Euphoric mood	9	0
Frustration tolerance decreased	2	0
Irritability	57	0
Mood altered	9	0
Factitious disorders		
Factitious disorder	3	0
Fear symptoms and phobic disorders (incl social phobia)		
Agoraphobia	1	0
Fear	4	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	285	0
Hallucination, auditory	4	0
Hallucination, visual	14	0
Hallucinations, mixed	2	0
Impulse control disorders		
Impulse-control disorder	2	0
Increased physical activity levels		
Restlessness	127	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	90	0
Feeling of despair	3	0
Negative thoughts	2	0
Sense of a foreshortened future	1	0
Tearfulness	27	0
Mood alterations with manic symptoms		
Mania	3	0
Mood disorders NEC		
Apathy	11	0
Listless	43	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	1	0
Obsessive-compulsive disorders and symptoms		
Obsessive thoughts	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Panic attacks and disorders</i>		
Panic attack	36	0
Panic reaction	6	0
<i>Parasomnias</i>		
Abnormal dreams	98	0
Confusional arousal	2	0
Exploding head syndrome	2	0
Nightmare	111	0
Rapid eye movements sleep abnormal	1	0
Sleep talking	7	0
Sleep terror	11	0
Sleep-related eating disorder	1	0
Somnambulism	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	6	0
Derealisation	2	0
Illusion	3	0
Time perception altered	2	0
<i>Psychiatric elimination disorders</i>		
Enuresis	9	0
<i>Psychiatric symptoms NEC</i>		
Hypervigilance	2	0
Psychiatric symptom	1	0
Psychological trauma	1	0
<i>Psychotic disorder NEC</i>		
Psychotic disorder	8	0
<i>Sexual desire disorders</i>		
Libido decreased	1	0
Libido increased	1	0
Loss of libido	3	0
<i>Sleep disorders NEC</i>		
Sleep disorder	87	0
Sleep disorder due to general medical condition, insomnia type	1	0
<i>Somatic symptom disorders</i>		
Conversion disorder	1	0
Habit cough	6	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>		
Bruxism	8	0
Head banging	11	0
Waxy flexibility	1	0
<i>Stress disorders</i>		
Acute stress disorder	1	0
Burnout syndrome	1	0
Hyperarousal	1	0
Post-traumatic stress disorder	5	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<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>		
Intentional self-injury	1	0
Suicidal ideation	9	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	12	0
Intrusive thoughts	1	0
Tachyphrenia	7	0
Thinking abnormal	4	0
Thought blocking	1	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	3554	0

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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	20	0
Incontinence	21	0
Micturition frequency decreased	1	0
Micturition urgency	35	0
Mixed incontinence	1	0
Pollakiuria	79	0
Urethral pain	1	0
Urinary hesitation	3	0
Urinary incontinence	29	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	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Anti-glomerular basement membrane disease	1	0
IgA nephropathy	1	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	1	0
Hypertonic bladder	3	0
Loss of bladder sensation	3	0
Neurogenic bladder	1	0
<i>Nephritis NEC</i>		
Nephritis	2	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	11	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	18	0
Haematuria	6	0
Proteinuria	1	0
Urine abnormality	3	0
Urine odour abnormal	9	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	1	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Nocturia	4	0
Polyuria	14	0
Renal colic	1	0
Renal pain	236	0
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	563	1

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Breast enlargement	1	0
Breast mass	3	0
<i>Breast signs and symptoms</i>		
Breast discomfort	1	0
Breast oedema	1	0
Breast pain	51	0
Breast swelling	2	0
Breast tenderness	8	0
Nipple pain	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation failure	1	0
Erectile dysfunction	4	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	2	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	12	0
Menstrual disorder	14	0
Menstruation irregular	11	0
Metrorrhagia	6	0
Premenstrual pain	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	2	0
Hypomenorrhoea	7	0
Menstruation delayed	11	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	21	0
Polymenorrhoea	3	0
<i>Pelvic prolapse conditions</i>		
Vaginal prolapse	1	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
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>		
Genital burning sensation	1	0
Genital discomfort	1	0
Pelvic discomfort	1	0
Pelvic pain	21	0
Pruritus genital	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Scrotal disorders NEC		
Scrotal pain	1	0
Scrotal swelling	2	0
Sexual function and fertility disorders NEC		
Sexual dysfunction	1	0
Testicular and epididymal disorders NEC		
Testicular pain	12	0
Testicular swelling	2	0
Uterine disorders NEC		
Endometriosis	1	0
Uterine haemorrhage	2	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	46	0
Vulvovaginal signs and symptoms		
Vaginal discharge	5	0
Vaginal lesion	3	0
Vulval oedema	1	0
Vulvovaginal pain	4	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	2	0
Reproductive & breast disorders SOC TOTAL	297	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	3	0
Dyspnoea	1289	2
Dyspnoea at rest	3	0
Dyspnoea exertional	5	0
Hyperventilation	17	0
Hypopnoea	54	0
Irregular breathing	6	0
Mouth breathing	2	0
Orthopnoea	1	0
Respiration abnormal	28	0
Respiratory arrest	6	0
Respiratory distress	3	0
Sleep apnoea syndrome	4	0
Tachypnoea	22	0
<i>Bronchial conditions NEC</i>		
Bronchiectasis	4	0
<i>Bronchospasm and obstruction</i>		
Asthma	104	0
Asthma late onset	1	0
Asthmatic crisis	1	0
Bronchospasm	8	0
Chronic obstructive pulmonary disease	12	2
Cough variant asthma	3	0
Obstructive airways disorder	1	0
Reversible airways obstruction	1	0
Wheezing	146	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	22	0
<i>Coughing and associated symptoms</i>		
Cough	899	0
Haemoptysis	11	0
Productive cough	35	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	1	0
Laryngospasm	1	0
Stridor	7	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Pneumonia aspiration	7	3
Pneumonitis	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	7	0
Pleuritic pain	4	0
Pulmonary haemorrhage	1	0
Pulmonary pain	43	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	114	0
Nasal inflammation	2	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Rhinitis allergic	3	0
Rhinitis perennial	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	205	0
Nasal disorder	1	0
Nasal dryness	15	0
Nasal odour	2	0
Nasal oedema	3	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	1	0
Sinus congestion	12	0
Sinus disorder	1	0
<i>Parenchymal lung disorders NEC</i>		
Idiopathic pulmonary fibrosis	1	0
Lung consolidation	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	6	0
Pharyngeal swelling	50	0
Pharyngeal ulceration	1	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	16	0
Tonsillar inflammation	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	2	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
Pulmonary congestion	6	0
Pulmonary oedema	4	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	13	1
Pulmonary infarction	1	1
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	2	0
<i>Respiratory signs and symptoms NEC</i>		
Respiratory symptom	4	0
Suffocation feeling	2	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	3	2
Lung disorder	2	0
Respiratory tract congestion	2	0
Respiratory tract irritation	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	1	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal pain	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	20	0
Catarrh	10	0
Choking	6	0
Choking sensation	3	0
Dry throat	77	0
Dysphonia	32	0
Increased viscosity of upper respiratory secretion	3	0
Nasal discomfort	19	0
Oropharyngeal blistering	2	0
Oropharyngeal discomfort	5	0
Oropharyngeal pain	1091	0
Paranasal sinus discomfort	3	0
Rhinalgia	8	0
Rhinorrhoea	427	0
Sinus pain	112	0
Sneezing	115	0
Throat clearing	2	0
Throat irritation	56	0
Throat lesion	1	0
Throat tightness	38	0
Upper-airway cough syndrome	5	0
Yawning	21	0
Respiratory disorders SOC TOTAL	5323	11

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	3	0
<i>Alopecias</i>		
Alopecia	12	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	79	0
Circumoral oedema	1	0
Idiopathic angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	1	0
Cold sweat	510	0
Hyperhidrosis	2772	0
Miliaria	33	0
Night sweats	493	0
Sweat discolouration	1	0
Sweat gland disorder	1	0
<i>Bullous conditions</i>		
Blister	61	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	56	0
Macule	1	0
Pain of skin	281	0
Papule	9	0
Peau d'orange	1	0
Scab	2	0
Scar pain	4	0
Sensitive skin	161	0
Skin burning sensation	138	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	7	0
Skin reaction	59	0
Skin sensitisation	25	0
Skin swelling	20	0
Skin texture abnormal	1	0
Skin tightness	3	0
Skin warm	131	0
Sticky skin	1	0
Yellow skin	8	0
<i>Dermatitis and eczema</i>		
Dermatitis	38	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Dermatitis allergic	60	0
Dermatitis atopic	3	0
Dermatitis contact	1	0
Dermatitis diaper	1	0
Dyshidrotic eczema	1	0
Eczema	19	0
Eczema asteatotic	2	0
Eczema nummular	1	0
Perioral dermatitis	1	0
Rebound eczema	1	0
Seborrhoeic dermatitis	1	0
Skin irritation	35	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	9	0
Fixed eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	825	0
Palmar erythema	2	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	0
Exfoliative rash	2	0
Skin exfoliation	16	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Granuloma annulare	1	0
<i>Hypopigmentation disorders</i>		
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
Onychoclasia	1	0
<i>Panniculitides</i>		
Erythema nodosum	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
Pityriasis rosea	2	0
Pityriasis rubra pilaris	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	41	0
<i>Pilar disorders NEC</i>		
Hair growth abnormal	1	0
Piloerection	22	0
Trichodynia	2	0
<i>Pruritus NEC</i>		
Itching scar	1	0
Pruritus	1490	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
Psoriasis	21	0
Pustular psoriasis	1	0
<i>Purpura and related conditions</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Ecchymosis	1	0
Henoch-Schonlein purpura	2	0
Petechiae	17	0
Purpura	8	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	2	0
Rash	1417	0
Rash erythematous	455	0
Rash macular	116	0
Rash maculo-papular	16	0
Rash morbilliform	3	0
Rash papular	78	0
Rash pruritic	334	0
Rash vesicular	12	0
Systemic lupus erythematosus rash	2	0
<i>Rosaceas</i>		
Rosacea	3	0
<i>Skin and subcutaneous conditions NEC</i>		
Cutaneous symptom	2	0
Skin mass	3	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin erosion	9	0
Skin ulcer	3	0
<i>Skin cysts and polyps</i>		
Dermal cyst	1	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	4	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	8	0
<i>Urticarias</i>		
Idiopathic urticaria	2	0
Urticaria	460	0
Urticaria chronic	3	0
Urticaria papular	1	0
Urticarial vasculitis	1	0
Skin disorders SOC TOTAL	10507	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Dietary and nutritional issues</i>		
Inadequate diet	1	0
<i>Disability issues</i>		
Bedridden	25	0
Disability	1	0
Immobile	8	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>Social issues NEC</i>		
Impaired quality of life	1	0
<i>Tobacco use</i>		
Tobacco user	1	0
Social circumstances SOC TOTAL	48	0

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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	12	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	2	0
<i>Immunisations</i>		
COVID-19 immunisation	50	1
Immunisation	31	0
<i>Joint therapeutic procedures</i>		
Hip surgery	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	1	0
<i>Small intestine therapeutic procedures</i>		
Ileostomy	1	0
<i>Therapeutic procedures NEC</i>		
Bed rest	5	0
Fatigue management	1	0
Hospitalisation	3	0
Injection	13	0
Localised alternating hot and cold therapy	2	0
Mass excision	2	0
Therapeutic hypothermia	2	0
Therapy change	1	0
<i>Uterine therapeutic procedures</i>		
Endometrial ablation	1	0
Surgical & medical procedures SOC TOTAL	151	1

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 09-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 08-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	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	9	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	16	0
Shock symptom	3	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	8	0
Haemorrhage	20	1
<i>Lymphoedemas</i>		
Lymphoedema	15	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
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	6	0
Vasodilatation	4	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	2	0
Deep vein thrombosis	14	0
Pelvic venous thrombosis	1	0
Thrombophlebitis	1	0
Thrombophlebitis superficial	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	26	0
Erythromelalgia	1	0
Flushing	205	0
Hot flush	504	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Ischaemic limb pain	2	0
Peripheral coldness	296	0
Poor peripheral circulation	3	0
Raynaud's phenomenon	20	0
<i>Phlebitis NEC</i>		
Phlebitis	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	131	0
Plethoric face	1	0
<i>Varicose veins NEC</i>		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 09-Mar-2021

Data Lock Date: 08-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Spider vein	1	0
Varicophlebitis	1	0
Varicose vein	1	0
<i>Vascular hypertensive disorders NEC</i>		
Diastolic hypertension	1	0
Hypertension	126	0
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	2	0
Hypotension	142	0
Orthostatic hypotension	13	0
<i>Vasculitides NEC</i>		
MAGIC syndrome	3	1
Vasculitis	9	0
Vascular disorders SOC TOTAL	1635	3
TOTAL REACTIONS FOR DRUG	201622	275
TOTAL REPORTS	54180	
TOTAL FATAL OUTCOME REPORTS		275