

COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Data Lock Date: 14-Mar-2021 19:00:03

All UK spontaneous reports received between 4/01/21 and 14/03/21 for COVID-19 vaccine Oxford University/AstraZeneca

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia vitamin B12 deficiency	1	0
<i>Anaemias NEC</i>		
Anaemia	6	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	5	0
<i>Coagulopathies</i>		
Abnormal clotting factor	1	0
Antiphospholipid syndrome	2	0
Coagulopathy	4	0
<i>Eosinophilic disorders</i>		
Eosinophilia	5	0
<i>Haematological disorders</i>		
Bone marrow oedema	1	0
Mast cell activation syndrome	2	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	5	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	154	0
Lymphadenitis	11	0
Lymphadenopathy	1441	0
Lymphatic disorder	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Pancytopenia	4	0
<i>Neutropenias</i>		
Neutropenia	23	0
<i>Polycythaemia (excl rubra vera)</i>		
Stress polycythaemia	1	0
<i>Sickle cell trait and disorders</i>		
Sickle cell anaemia with crisis	2	0
<i>Spleen disorders</i>		
Spleen disorder	1	0
Splenic artery thrombosis	1	0
Splenic infarction	2	0
Splenomegaly	2	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	28	1
Thrombocytopenia	20	1
Thrombocytopenic purpura	3	0
<i>White blood cell abnormal findings NEC</i>		
White blood cell disorder	1	0
Blood disorders SOC TOTAL	1738	2

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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	3	0
Bundle branch block left	3	0
Long QT syndrome	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	2	1
Cardiac disorder	8	0
Cardiovascular disorder	1	0
Cardiovascular insufficiency	3	0
<i>Cardiac infections and inflammations NEC</i>		
Carditis	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	3	0
Palpitations	1763	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	1	1
<i>Cardiomyopathies</i>		
Cardiomyopathy	2	0
Congestive cardiomyopathy	4	0
<i>Heart failures NEC</i>		
Cardiac failure	10	4
Cardiac failure acute	1	0
Cardiogenic shock	1	1
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	6	2
Angina pectoris	41	0
Angina unstable	6	0
Arteriospasm coronary	1	0
Microvascular coronary artery disease	2	0
Myocardial infarction	48	14
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	2	0
<i>Noninfectious myocarditis</i>		
Myocarditis	3	1
<i>Noninfectious pericarditis</i>		
Pericarditis	7	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	3	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	43	0
Bradycardia	27	0
Cardiac flutter	47	0
Extrasystoles	21	0

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Postural orthostatic tachycardia syndrome	3	0
Tachyarrhythmia	8	0
Tachycardia	622	0
<i>Right ventricular failures</i>		
Right ventricular failure	1	1
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	9	0
Atrial fibrillation	78	0
Atrial flutter	10	0
Sinus arrhythmia	1	0
Sinus bradycardia	1	0
Sinus tachycardia	34	0
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	8	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	41	13
Ventricular arrhythmia	1	0
Ventricular extrasystoles	1	0
Ventricular fibrillation	1	0
Ventricular tachycardia	5	0
Cardiac disorders SOC TOTAL	2901	43

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	2	0
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	2	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	1	0
<i>Cerebral disorders congenital</i>		
Cerebral palsy	3	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogyrosis	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	21	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	2	0
Ear discomfort	24	0
Ear disorder	2	0
Ear haemorrhage	2	0
Ear pain	714	0
Ear pruritus	1	0
Ear swelling	20	0
Otorrhoea	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
External ear pain	5	0
Red ear syndrome	1	0
<i>Hearing disorders NEC</i>		
Auditory disorder	1	0
<i>Hearing losses</i>		
Deafness	46	0
Deafness bilateral	1	0
Deafness transitory	2	0
Deafness unilateral	7	0
Hypoacusis	46	0
Sudden hearing loss	8	0
<i>Hyperacusia</i>		
Hyperacusis	27	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	2	0
Meniere's disease	4	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	28	0
Phobic postural vertigo	1	0
Tinnitus	528	0
Vertigo	426	0
Vertigo labyrinthine	4	0
Vertigo positional	24	0
<i>Middle ear disorders NEC</i>		
Middle ear effusion	1	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	1	0
Ear disorders SOC TOTAL	1931	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	3	0
<i>Adrenal cortical hyperfunctions</i>		
Cushingoid	1	0
<i>Adrenal cortical hypofunctions</i>		
Adrenal insufficiency	9	0
Adrenocortical insufficiency acute	18	0
Glucocorticoid deficiency	1	0
<i>Adrenal gland disorders NEC</i>		
Adrenal haemorrhage	1	0
<i>Female gonadal function disorders</i>		
Ovulation delayed	1	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	3	0
<i>Thyroid disorders NEC</i>		
Thyroid mass	1	0
Thyroid pain	1	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
Thyrotoxic crisis	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	10	0
Endocrine disorders SOC TOTAL	51	0

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Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	1	0
<i>Cataract conditions</i>		
Cataract	4	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	4	0
Vitreous floaters	17	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	4	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	9	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	14	0
Eyelid ptosis	8	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	5	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	1	0
Iritis	1	0
Uveitis	5	0
<i>Lacrimation disorders</i>		
Dry eye	85	0
Lacrimation increased	71	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	5	0
Eyelid rash	2	0
Swelling of eyelid	21	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	5	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	2	0
Eye disorder	2	0
Eye oedema	2	0
Eye pain	1229	0
Eye swelling	165	0
Eye symptom	1	0
Eye ulcer	2	0
Eyelid disorder	1	0
Eyelid pain	1	0
Ocular discomfort	10	0
Periorbital oedema	7	0
Periorbital pain	3	0

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Eye disorders Eye disorders cont'd		
Periorbital swelling	28	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	8	0
Eye discharge	8	0
Eye inflammation	7	0
Eye irritation	76	0
Eye pruritus	93	0
Ocular hyperaemia	85	0
Ocular nerve and muscle disorders		
Extraocular muscle paresis	4	0
Eye movement disorder	8	0
Ocular sensation disorders		
Abnormal sensation in eye	10	0
Asthenopia	92	0
Eyelid sensory disorder	2	0
Foreign body sensation in eyes	12	0
Hypoaesthesia eye	4	0
Photophobia	384	0
Pupil disorders		
Miosis	3	0
Mydriasis	6	0
Pupils unequal	2	0
Refractive and accommodative disorders		
Altered visual depth perception	1	0
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	5	0
Scleritis	2	0
Structural change, deposit and degeneration of eye NEC		
Deposit eye	1	0
Endocrine ophthalmopathy	1	0
Visual colour distortions		
Chromatopsia	1	0
Xanthopsia	3	0
Visual disorders NEC		
Diplopia	60	0
Halo vision	4	0
Metamorphopsia	9	0
Photopsia	79	0
Vision blurred	477	0
Visual brightness	3	0
Visual snow syndrome	1	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	3	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Blindness	37	0
Blindness transient	2	0
Night blindness	2	0
Sudden visual loss	1	0
Visual acuity reduced	3	0
Visual impairment	138	0
Eye disorders SOC TOTAL	3369	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
Gastrointestinal sounds abnormal	4	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	1
Pancreatitis	13	0
Pancreatitis acute	2	0
Pancreatitis chronic	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	1	0
<i>Anal and rectal pains</i>		
Proctalgia	4	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	3	0
Anal pruritus	1	0
Anorectal discomfort	2	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	2	0
Tongue cyst	1	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	1	0
Colitis	7	0
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	25	0
Crohn's disease	27	0
Neutropenic colitis	1	0
Terminal ileitis	1	0
<i>Dental disorders NEC</i>		
Teething	9	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	3	0
Dental paraesthesia	3	0
Hyperaesthesia teeth	10	0
Toothache	105	0
<i>Dental surface disorders</i>		
Tooth discolouration	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	3594	0
Diarrhoea haemorrhagic	10	0
<i>Diverticula</i>		
Diverticulum	1	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	280	0
Epigastric discomfort	8	0
Eructation	31	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	5	0
Faecaloma	1	0
Faeces discoloured	12	0
Faeces hard	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Faeces pale	1	0
Faeces soft	6	0
Mucous stools	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	123	0
Flatulence	147	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	3	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	19	0
Reflux gastritis	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	1	0
Abdominal pain	1710	0
Abdominal pain lower	74	0
Abdominal pain upper	1828	0
Abdominal rigidity	16	0
Abdominal tenderness	7	0
Gastrointestinal pain	116	0
Oesophageal pain	3	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	127	0
Gastric dilatation	5	0
Gastrooesophageal reflux disease	59	0
Infrequent bowel movements	1	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
Functional gastrointestinal disorder	7	0
Gastric disorder	4	0
Gastrointestinal disorder	8	0
Neurogenic bowel	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	3	0
Dyschezia	2	0
Oesophageal achalasia	2	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Gastrointestinal tract irritation	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	564	0
Abdominal symptom	2	0
Acute abdomen	7	0
Anal incontinence	12	0
Breath odour	8	0
Dysphagia	57	1
Intestinal congestion	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	7	0
Frequent bowel movements	15	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Irritable bowel syndrome	25	0
Oesophageal spasm	2	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Mesenteric vein thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	8	0
Gingival discomfort	1	0
Gingival disorder	6	0
Gingival hypertrophy	1	0
Gingival oedema	1	0
Gingival pain	65	0
Gingival pruritus	1	0
Gingival swelling	16	0
Gingival ulceration	3	0
Noninfective gingivitis	6	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	21	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	6	0
Haemorrhoids thrombosed	1	0
<i>Inguinal hernias</i>		
Inguinal hernia	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	6	0
Mesenteric haemorrhage	1	0
Rectal haemorrhage	11	0
Small intestinal haemorrhage	9	0
<i>Large intestinal stenosis and obstruction</i>		
Large intestinal stenosis	1	0
<i>Malabsorption syndromes</i>		
Coeliac disease	3	0
<i>Nausea and vomiting symptoms</i>		
Acetonaemic vomiting	1	0
Discoloured vomit	10	0
Faecal vomiting	1	0
Nausea	14837	0
Regurgitation	1	0
Retching	127	0
Vomiting	5128	2
Vomiting projectile	69	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	6	1
Haematemesis	23	0
Haematochezia	18	0
Melaena	2	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	1	0
Oesophagitis	4	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	2	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Dry mouth	458	0
Lip dry	20	0
Saliva altered	2	0
Salivary hypersecretion	9	0
Oral soft tissue disorders NEC		
Chapped lips	4	0
Cheilitis	15	0
Chronic cheek biting	1	0
Enlarged uvula	2	0
Leukoplakia oral	1	0
Lip blister	14	0
Lip disorder	1	0
Oral disorder	5	0
Uvulitis	2	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	2	0
Oral blood blister	9	0
Oral soft tissue infections		
Angular cheilitis	2	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	3	0
Burning mouth syndrome	3	0
Coating in mouth	1	0
Hypoaesthesia oral	195	0
Lip erythema	3	0
Lip exfoliation	5	0
Lip pain	21	0
Lip pruritus	8	0
Odynophagia	8	0
Oral discomfort	27	0
Oral mucosal blistering	13	0
Oral mucosal eruption	8	0
Oral mucosal exfoliation	4	0
Oral mucosal roughening	2	0
Oral pain	126	0
Oral pruritus	8	0
Paraesthesia oral	298	0
Oral soft tissue swelling and oedema		
Lip oedema	4	0
Lip swelling	334	0
Mouth swelling	47	0
Oedema mouth	1	0
Palatal swelling	5	0
Rectal inflammations NEC		
Proctitis	1	0
Salivary gland disorders NEC		
Salivary gland pain	4	0
Salivary gland enlargements		
Parotid gland enlargement	4	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	1	0
Stomatitis and ulceration		
Apthous ulcer	20	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Lip ulceration	7	0
Mouth ulceration	211	0
Stomatitis	25	0
Tongue disorders		
Glossitis	8	0
Plicated tongue	1	0
Tongue disorder	13	0
Tongue geographic	1	0
Tongue ulceration	12	0
Trichoglossia	2	0
Tongue signs and symptoms		
Glossodynia	93	0
Scalloped tongue	2	0
Swollen tongue	186	0
Tongue blistering	10	0
Tongue coated	12	0
Tongue discolouration	8	0
Tongue discomfort	12	0
Tongue dry	6	0
Tongue eruption	1	0
Tongue exfoliation	1	0
Tongue movement disturbance	3	0
Tongue oedema	6	0
Tongue pruritus	1	0
Tongue rough	1	0
Tongue spasm	1	0
Tooth missing		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	31887	5

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	7	0
Administration site induration	1	0
Administration site mass	1	0
Administration site pain	23	0
Administration site rash	1	0
Administration site urticaria	1	0
Puncture site bruise	17	0
Puncture site haemorrhage	1	0
Puncture site pain	10	0
Puncture site reaction	2	0
Puncture site swelling	1	0
<i>Adverse effect absent</i>		
No adverse event	8	0
<i>Application and instillation site reactions</i>		
Application site bruise	6	0
Application site erythema	9	0
Application site joint pain	1	0
Application site pain	11	0
Application site pruritus	5	0
Application site swelling	2	0
Application site warmth	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	1817	3
Chronic fatigue syndrome	19	0
Fatigue	19351	0
Malaise	5106	3
Sluggishness	6	0
<i>Body temperature altered</i>		
Hyperthermia	5	0
Hypothermia	23	0
Temperature regulation disorder	8	0
<i>Complications associated with device NEC</i>		
Phantom shocks	2	0
<i>Death and sudden death</i>		
Brain death	1	1
Death	156	156
Sudden death	13	13
<i>Febrile disorders</i>		
Hyperpyrexia	28	0
Masked fever	1	0
Pyrexia	26545	0
<i>Feelings and sensations NEC</i>		
Chills	21037	0
Feeling abnormal	828	0
Feeling cold	2454	0
Feeling drunk	41	0
Feeling hot	883	0
Feeling jittery	13	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Feeling of body temperature change	443	0
Hangover	39	0
Hunger	13	0
Sensation of foreign body	13	0
Temperature intolerance	20	0
Thirst	554	0
Thirst decreased	3	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Decreased gait velocity	2	0
Gait disturbance	107	0
Gait inability	72	0
Loss of control of legs	12	0
General signs and symptoms NEC		
Apparent death	1	0
Chronic disease	1	0
Condition aggravated	56	0
Crying	67	0
Discharge	1	0
Energy increased	7	0
Exercise tolerance decreased	2	0
Foaming at mouth	2	0
General physical health deterioration	10	2
General symptom	6	0
Glassy eyes	1	0
High-pitched crying	1	0
Ill-defined disorder	1	0
Illness	2209	0
Induration	6	0
Influenza like illness	4247	1
Irritability postvaccinal	2	0
Local reaction	93	0
Moaning	5	0
Multiple organ dysfunction syndrome	2	0
Nonspecific reaction	1	0
Peripheral swelling	1829	0
Screaming	4	0
Secretion discharge	8	0
Swelling	800	0
Swelling face	310	0
Symptom recurrence	1	0
Implant and catheter site reactions		
Implant site hypoaesthesia	1	0
Implant site pain	2	0
Implant site rash	1	0
Implant site warmth	3	0
Inflammations		
Inflammation	179	0
Systemic inflammatory response syndrome	1	0
Infusion site reactions		
Infusion site bruising	1	0
Infusion site pain	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
 Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Infusion site warmth	2	0
Injection site reactions		
Injected limb mobility decreased	16	0
Injection site bruising	38	0
Injection site coldness	2	0
Injection site discolouration	2	0
Injection site discomfort	6	0
Injection site erythema	255	0
Injection site exfoliation	1	0
Injection site haemorrhage	1	0
Injection site hypoaesthesia	6	0
Injection site indentation	3	0
Injection site inflammation	27	0
Injection site injury	1	0
Injection site irritation	2	0
Injection site joint erythema	5	0
Injection site joint pain	22	0
Injection site mass	555	0
Injection site movement impairment	1	0
Injection site muscle weakness	1	0
Injection site nodule	1	0
Injection site oedema	16	0
Injection site pain	1893	0
Injection site papule	1	0
Injection site paraesthesia	8	0
Injection site pruritus	133	0
Injection site rash	109	0
Injection site reaction	52	0
Injection site scab	3	0
Injection site scar	2	0
Injection site swelling	87	0
Injection site urticaria	17	0
Injection site vesicles	4	0
Injection site warmth	167	0
Interactions		
Drug interaction	7	0
Inhibitory drug interaction	1	0
Mass conditions NEC		
Cyst	2	0
Mass	12	0
Nodule	2	0
Mucosal findings abnormal		
Mucosal disorder	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	1	0
Mucosal inflammation	2	0
Mucosal pain	1	0
Mucosal ulceration	1	0
Oedema mucosal	1	0
Oedema NEC		
Face oedema	12	0
Localised oedema	4	0
Oedema	7	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Oedema peripheral	16	0
<i>Pain and discomfort NEC</i>		
Axillary pain	185	0
Chest discomfort	701	0
Chest pain	1400	0
Discomfort	69	0
Facial discomfort	5	0
Facial pain	87	0
Inflammatory pain	6	0
Non-cardiac chest pain	13	0
Pain	5820	0
Tenderness	791	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	79	0
Adverse event	1	0
Adverse reaction	2	0
Diet failure	1	0
Drug ineffective	13	0
Drug intolerance	1	0
Inadequate analgesia	3	0
No reaction on previous exposure to drug	15	0
Therapeutic product effect decreased	1	0
Therapeutic response shortened	1	0
Therapeutic response unexpected	11	0
Treatment failure	3	0
Vaccine positive rechallenge	1	0
<i>Trophic disorders</i>		
Atrophy	1	0
Calcinosis	1	0
<i>Ulcers NEC</i>		
Ulcer	10	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	7	0
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	37	0
Vaccination site coldness	1	0
Vaccination site discharge	1	0
Vaccination site discolouration	3	0
Vaccination site discomfort	11	0
Vaccination site erythema	243	0
Vaccination site extravasation	1	0
Vaccination site granuloma	3	0
Vaccination site haemorrhage	2	0
Vaccination site hyperaesthesia	1	0
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	5	0
Vaccination site induration	26	0
Vaccination site inflammation	26	0
Vaccination site irritation	6	0
Vaccination site joint erythema	1	0
Vaccination site joint movement impairment	5	0
Vaccination site joint pain	26	0
Vaccination site joint swelling	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	1	0
Vaccination site mass	187	0
Vaccination site movement impairment	11	0
Vaccination site oedema	2	0
Vaccination site pain	685	0
Vaccination site papule	2	0
Vaccination site paraesthesia	5	0
Vaccination site pruritus	44	0
Vaccination site rash	59	0
Vaccination site reaction	10	0
Vaccination site swelling	192	0
Vaccination site urticaria	4	0
Vaccination site vesicles	3	0
Vaccination site warmth	133	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	2	0
Withdrawal syndrome	10	0
General disorders SOC TOTAL	104089	179

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021

Data Lock Date: 14-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	7	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	4	0
Cholelithiasis	3	0
<i>Cholestasis and jaundice</i>		
Jaundice	14	0
Jaundice cholestatic	1	0
Ocular icterus	1	0
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	20	0
Liver tenderness	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	3	0
Hepatitis acute	1	0
Liver injury	3	0
Hepatic disorders SOC TOTAL	60	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	6	0
<i>Allergic conditions NEC</i>		
Allergic oedema	9	0
Allergy to arthropod sting	1	0
Allergy to metals	1	0
Allergy to sting	1	0
Allergy to venom	1	0
Dust allergy	1	0
Hypersensitivity	396	0
Infusion related hypersensitivity reaction	2	0
Multiple allergies	5	0
Serum sickness	12	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>		
Allergic reaction to excipient	1	0
Allergy to chemicals	2	0
Allergy to vaccine	20	0
Drug hypersensitivity	26	0
Food allergy	2	0
Reaction to excipient	2	0
Reaction to preservatives	4	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	275	0
Anaphylactic shock	41	0
Anaphylactoid reaction	8	0
Anaphylactoid shock	2	0
<i>Atopic disorders</i>		
Seasonal allergy	10	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	3	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	7	0
Immune system disorder	6	0
Immunisation reaction	1	0
Pre-engraftment immune reaction	1	0
Sensitisation	12	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	1	0
Transplant rejection	1	0
Immune system disorders SOC TOTAL	871	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	3	0
Diverticulitis	2	0
Dysentery	1	0
Gastroenteritis	14	0
Gastrointestinal infection	2	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Arthritis bacterial	2	0
Bacterial infection	7	1
Cellulitis	185	1
Injection site cellulitis	4	0
Perichondritis	1	0
Pneumonia bacterial	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	6	0
<i>Candida infections</i>		
Anal candidiasis	1	0
Balanitis candida	1	0
Candida infection	17	0
Oral candidiasis	8	0
Skin candida	1	0
Vulvovaginal candidiasis	9	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	3	0
Meningitis	2	0
Myelitis	3	0
<i>Clostridia infections</i>		
Clostridium difficile colitis	1	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	2	0
COVID-19	186	13
COVID-19 pneumonia	7	3
Coronavirus infection	2	0
Severe acute respiratory syndrome	4	0
Suspected COVID-19	14	0
<i>Coxiella infections</i>		
Q fever	54	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	1	0
Gingival abscess	2	0
Gingivitis	6	0
Oral pustule	1	0
Parotitis	5	0
Pericoronitis	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Tongue abscess	2	0
Tooth abscess	1	0
Tooth infection	1	0
Ear infections		
Ear infection	10	0
Labyrinthitis	36	0
Otitis externa	1	0
Otitis media	1	0
Epstein-Barr viral infections		
Infectious mononucleosis	18	0
Escherichia infections		
Escherichia sepsis	1	0
Eye and eyelid infections		
Conjunctivitis	20	0
Eye infection	4	0
Eyelid infection	2	0
Hordeolum	7	0
Female reproductive tract infections		
Vaginal abscess	1	0
Vaginal infection	1	0
Flaviviral infections		
Yellow fever	1	0
Fungal infections NEC		
Fungal infection	3	0
Fungal skin infection	3	0
Severe asthma with fungal sensitisation	1	0
Tonsillitis fungal	1	0
Vulvovaginal mycotic infection	1	0
Hepatitis viral infections		
Hepatitis E	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	2	1
Herpes viral infections		
Genital herpes	8	0
Genital herpes simplex	1	0
Herpes ophthalmic	5	0
Herpes simplex	11	0
Herpes simplex reactivation	1	0
Herpes virus infection	4	0
Herpes zoster	229	0
Herpes zoster oticus	1	0
Nasal herpes	1	0
Ophthalmic herpes zoster	1	0
Oral herpes	223	0
Varicella	3	0
Infections NEC		
Abscess	6	0
Abscess limb	1	0
Catheter site infection	1	0
Coinfection	1	0
Genital abscess	1	0
Infected cyst	1	0
Infection	93	2

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Infection in an immunocompromised host	1	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	38	0
Lymph gland infection	1	0
Pathogen resistance	1	0
Respiratory tract infection	4	0
Vaccination site abscess	1	0
Vaccination site infection	10	0
Vestibulitis	1	0
<i>Influenza viral infections</i>		
H2N2 influenza	1	0
Influenza	2887	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	4	0
Infective exacerbation of bronchiectasis	1	0
Lower respiratory tract infection	52	2
Pneumonia	42	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	3	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	1	0
<i>Retroviral infections</i>		
Acquired immunodeficiency syndrome	1	0
HIV-associated neurocognitive disorder	1	0
<i>Salmonella infections</i>		
Typhoid fever	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Neutropenic sepsis	3	0
Sepsis	26	2
Sepsis syndrome	1	0
Septic rash	3	0
Septic shock	1	0
Urosepsis	2	1
Viraemia	2	0
<i>Skin structures and soft tissue infections</i>		
Dermatitis infected	1	0
Folliculitis	3	0
Infected dermal cyst	2	0
Pustule	1	0
Rash pustular	6	0
Skin infection	23	0
Subcutaneous abscess	3	0
Vaccination site pustule	1	0
<i>Staphylococcal infections</i>		
Furuncle	7	0
Staphylococcal scalded skin syndrome	1	0
Staphylococcal sepsis	1	1
<i>Streptococcal infections</i>		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
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
Chronic sinusitis	1	0
Laryngitis	5	0
Nasopharyngitis	580	0
Pharyngitis	8	0
Rhinitis	18	0
Sinusitis	68	0
Tonsillitis	20	0
Tracheitis	1	0
Upper respiratory tract infection	2	0
<i>Urinary tract infections</i>		
Cystitis	21	0
Kidney infection	10	0
Urinary tract infection	47	0
<i>Vascular infections</i>		
Infected lymphocele	1	0
Lymphangitis	3	0
<i>Viral infections NEC</i>		
Arthritis viral	1	0
Gastroenteritis viral	24	1
Pneumonia viral	2	1
Post viral fatigue syndrome	27	0
Sweating fever	357	0
Vestibular neuronitis	4	0
Viral diarrhoea	3	0
Viral infection	7	0
Viral labyrinthitis	1	0
Viral myocarditis	1	0
Viral pharyngitis	8	0
Viral rash	17	0
Viral sepsis	1	0
Infections SOC TOTAL	5679	41

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Abdomen crushing	1	0
Lip injury	1	0
Oral contusion	2	0
Palate injury	1	0
Splenic rupture	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	5	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	2	0
<i>Bone and joint injuries NEC</i>		
Bursa injury	1	0
Joint injury	1	0
<i>Cardiovascular injuries</i>		
Vascular injury	1	0
<i>Cerebral injuries NEC</i>		
Brain contusion	1	0
Concussion	1	0
Craniocerebral injury	1	0
Subdural haematoma	1	0
Subdural haemorrhage	1	0
<i>Chemical injuries</i>		
Chemical burn of skin	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	13	0
<i>Cranial nerve injuries</i>		
Optic nerve injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	2	0
Exposure via breast milk	7	0
Foetal exposure during pregnancy	15	0
Maternal exposure during breast feeding	238	0
Maternal exposure during pregnancy	72	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	5	0
Eye injury	3	0
Foreign body in eye	1	0
Periorbital haematoma	1	0
Superficial injury of eye	1	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural nausea	21	0
Procedural vomiting	5	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Heat injuries (excl thermal burns)</i>		
Heat exhaustion	2	0
Heat oedema	8	0
Heat stroke	3	0
<i>Limb fractures and dislocations</i>		
Ankle fracture	1	0
Clavicle fracture	3	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
Product use issue	1	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	4	0
Ligament sprain	2	0
Muscle injury	5	0
Muscle rupture	1	0
Muscle strain	5	0
Post-traumatic neck syndrome	1	0
Repetitive strain injury	1	0
Tendon rupture	2	0
<i>Nerve injuries NEC</i>		
Nerve injury	13	0
<i>Neurological and psychiatric procedural complications</i>		
Post lumbar puncture syndrome	5	0
Procedural dizziness	14	0
<i>Non-occupational environmental exposures</i>		
Exposure to chemical pollution	1	0
Exposure to extreme temperature	4	0
Exposure to noise	1	0
<i>Non-site specific injuries NEC</i>		
Arthropod bite	2	0
Arthropod sting	6	0
Electric shock	4	0
Fall	69	1
Inflammation of wound	3	0
Nervous system injury	1	0
Road traffic accident	1	0
Tissue injury	1	0
Traumatic shock	1	0
Wound complication	4	0
<i>Non-site specific procedural complications</i>		
Incision site pain	6	0
Infusion related reaction	12	0
Injection related reaction	395	0
Post procedural complication	23	0
Procedural pain	2	0
Suture related complication	1	0
<i>Occupational exposures</i>		

Case Series Drug Analysis Print

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Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
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	4	0
Product administration errors and issues		
Accidental overdose	2	0
Duplicate therapy error	1	0
Expired product administered	3	0
Extra dose administered	2	0
Inappropriate schedule of product administration	2	0
Incorrect dose administered	1	0
Incorrect route of product administration	2	0
Product administered at inappropriate site	1	0
Product administered to patient of inappropriate age	2	0
Product administration error	4	0
Wrong patient received product	1	0
Wrong product administered	1	0
Product confusion errors and issues		
Product label confusion	1	0
Product dispensing errors and issues		
Product dispensing error	3	0
Product monitoring errors and issues		
Product monitoring error	1	0
Product prescribing errors and issues		
Contraindicated product prescribed	1	0
Product storage errors and issues in the product use system		
Product storage error	1	0
Radiation injuries		
Sunburn	6	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Reproductive system and breast injuries		
Penile contusion	1	0
Reproductive tract and breast procedural complications		
Postmastectomy lymphoedema syndrome	1	0
Site specific injuries NEC		
Back injury	2	0
Central nervous system injury	1	0
Head injury	5	0
Limb crushing injury	1	0
Limb injury	27	0
Neck crushing	1	0
Skin injuries NEC		
Contusion	299	0
Scar	3	0
Skin abrasion	2	0
Skin injury	1	0
Skin wound	3	0
Spinal cord injuries NEC		

Case Series Drug Analysis Print

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Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Spinal cord injury sacral	1	0
<i>Stoma complications</i>		
Gastrointestinal stoma complication	2	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	15	0
Thermal burns of eye	19	0
<i>Underdoses NEC</i>		
Intentional underdose	1	0
<i>Vaccination related complications</i>		
Vaccination complication	42	0
Vaccination failure	4	0
Injuries SOC TOTAL	1518	1

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

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 lactic acid	1	0
Blood pH	2	0
Blood pH increased	4	0
Oxygen consumption	1	0
Oxygen saturation	14	0
Oxygen saturation decreased	84	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	13	0
Blood glucose abnormal	6	0
Blood glucose decreased	20	0
Blood glucose fluctuation	11	0
Blood glucose increased	91	0
Glycosylated haemoglobin increased	2	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	5	0
Heart sounds	4	0
Heart sounds abnormal	2	0
<i>Cardiac function diagnostic procedures</i>		
Myocardial strain	1	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	2	0
Magnetic resonance imaging brain	35	0
<i>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	11	0
International normalised ratio increased	22	0
<i>ECG investigations</i>		
Electrocardiogram T wave inversion	1	0
Electrocardiogram abnormal	2	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

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Gastrointestinal function diagnostic procedures</i>		
Gastrointestinal stoma output increased	1	0
Swallow study	1	0
<i>Gastrointestinal, pancreatic and APUD hormone analyses</i>		
Blood gastrin	1	0
Blood gastrin normal	1	0
Blood insulin	4	0
Blood insulin decreased	1	0
Blood insulin increased	2	0
<i>Haematological analyses NEC</i>		
Blood viscosity increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	405	0
Heart rate abnormal	16	0
Heart rate decreased	24	0
Heart rate increased	792	0
Heart rate irregular	61	0
Maximum heart rate	2	0
Maximum heart rate decreased	1	0
Orthostatic heart rate response increased	1	0
Pulse abnormal	8	0
Pulse absent	2	0
Sinus rhythm	2	0
<i>Imaging procedures NEC</i>		
Computerised tomogram	1	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin E increased	2	0
<i>Immunology analyses NEC</i>		
Immunology test	2	0
Immunology test normal	1	0
<i>Immunology skin tests NEC</i>		
Allergy alert test	1	0
<i>Investigations NEC</i>		
Blood test	7	0
Blood test abnormal	1	0
Investigation	1	0
Polymerase chain reaction positive	1	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	2	0
Aspartate aminotransferase increased	2	0
Bile output	2	0
Blood bilirubin increased	1	0
Gamma-glutamyltransferase increased	2	0
Hepatic enzyme increased	1	0
Liver function test	1	0
Liver function test abnormal	5	0
Transaminases increased	2	0
<i>Metabolism tests NEC</i>		
Blood ketone body	7	0
Ubiquinone	2	0
<i>Mineral and electrolyte analyses</i>		
Blood phosphorus decreased	1	0
Blood phosphorus increased	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood potassium decreased	1	0
Blood potassium increased	1	0
Blood sodium decreased	1	0
Sweat test	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	2	0
Physical examination procedures and organ system status		
Body surface area	1	0
Body temperature	502	0
Body temperature abnormal	35	0
Body temperature decreased	60	0
Body temperature fluctuation	73	0
Body temperature increased	573	0
Breath sounds abnormal	2	0
Grip strength	2	0
Grip strength decreased	9	0
Head lag	4	0
Lymph node palpable	1	0
Male genital examination abnormal	1	0
Muscle strength abnormal	1	0
Neurological examination	1	0
Respiratory rate	5	0
Respiratory rate decreased	7	0
Respiratory rate increased	31	0
Skin temperature	82	0
Temperature difference of extremities	2	0
Urological examination	1	0
Weight decreased	46	0
Weight increased	2	0
Pituitary analyses anterior		
Blood thyroid stimulating hormone increased	1	0
Platelet analyses		
Platelet count decreased	9	0
Protein analyses NEC		
C-reactive protein abnormal	1	0
C-reactive protein increased	3	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	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Forced expiratory volume decreased	1	0
Forced expiratory volume increased	7	0
Forced expiratory volume normal	1	0
Maximal voluntary ventilation	1	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	3	0
Pulmonary function test	1	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	8	0
Analgesic drug level therapeutic	1	0
Anticoagulation drug level above therapeutic	2	0
Anticoagulation drug level below therapeutic	2	0
Thyroid analyses		
Thyroxine abnormal	1	0
Tissue enzyme analyses NEC		
Lactate dehydrogenase urine increased	1	0
Toxicology laboratory analyses		
Blood heavy metal test	1	0
Urinalysis NEC		
Blood urine	6	0
Blood urine present	7	0
Cells in urine	1	0
Protein urine present	1	0
Red blood cells urine	1	0
Urine analysis	1	0
Urine analysis abnormal	4	0
Urine analysis normal	1	0
pH urine	6	0
pH urine decreased	1	0
pH urine increased	2	0
Urinary tract function analyses NEC		
Urine output	21	0
Urine output decreased	4	0
Urine output increased	5	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	1	0
Blood pressure decreased	27	0
Blood pressure increased	96	0
Blood pressure measurement	25	0
Blood pressure systolic increased	2	0
Virus identification and serology		
Coronavirus test	15	0
HIV antibody negative	1	0
Herpes virus test	1	0
SARS-CoV-2 antibody test negative	4	0
SARS-CoV-2 antibody test positive	1	0
SARS-CoV-2 test	12	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
 Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
SARS-CoV-2 test false negative	1	0
SARS-CoV-2 test false positive	1	0
SARS-CoV-2 test negative	5	0
SARS-CoV-2 test positive	34	0
Viral test	1	0
Vitamin analyses		
Vitamin B12 decreased	1	0
Water and electrolyte analyses NEC		
Volume blood	1	0
White blood cell analyses		
Lymphocyte count	1	0
Lymphocyte count decreased	1	0
Neutrophil count	1	0
Neutrophil count decreased	2	0
White blood cell count	6	0
White blood cell count decreased	4	0
White blood cell count increased	3	0
Investigations SOC TOTAL	3541	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	9	0
Decreased appetite	3091	0
Diet refusal	1	0
Food craving	6	0
Food refusal	22	0
Hyperphagia	2	0
Hypophagia	13	0
Increased appetite	18	0
Salt craving	1	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	2	0
Tetany	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	25	0
Diabetes mellitus inadequate control	16	0
Increased insulin requirement	1	0
Type 1 diabetes mellitus	7	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	10	2
Diabetic ketosis	3	0
<i>Disorders of purine metabolism</i>		
Gout	24	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	10	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	11	0
Abnormal weight gain	2	0
Cachexia	1	0
Feeding disorder	47	0
Food aversion	27	0
Poor feeding infant	1	0
Starvation	1	0
Underweight	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	72	0
Insulin resistance	3	0
Metabolic syndrome	1	0
<i>Hyperlipidaemias NEC</i>		
Hyperlipidaemia	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hyperinsulinaemic hypoglycaemia	1	0
Hypoglycaemia	43	0
Hypoglycaemia unawareness	2	0
<i>Iron deficiencies</i>		
Iron deficiency	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021

Data Lock Date: 14-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		
<i>Magnesium metabolism disorders</i>		
Hypomagnesaemia	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Ketoacidosis	1	0
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>		
Hypernatraemia	1	0
Hyponatraemia	7	0
Hyponatraemic syndrome	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	264	0
Hypovolaemia	1	0
<i>Total fluid volume increased</i>		
Fluid overload	2	0
Fluid retention	17	0
Metabolic disorders SOC TOTAL	3788	2

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	86	0
Arthropathy	6	0
Autoimmune arthritis	1	0
Palindromic rheumatism	1	0
Polyarthritis	4	0
Rheumatic fever	1	0
Sacroiliitis	3	0
<i>Bone disorders NEC</i>		
Medial tibial stress syndrome	4	0
Osteitis	3	0
<i>Bone related signs and symptoms</i>		
Bone pain	427	0
Pain in jaw	190	0
Spinal pain	88	0
<i>Bursal disorders</i>		
Bursitis	15	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	6	0
<i>Connective tissue disorders NEC</i>		
Mixed connective tissue disease	1	0
Morphoea	1	0
Polymyalgia rheumatica	13	0
Reynold's syndrome	2	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	15	0
Patellofemoral pain syndrome	1	0
Periarthritis	33	0
Rotator cuff syndrome	8	0
Temporomandibular joint syndrome	3	0
<i>Joint related signs and symptoms</i>		
Arthralgia	9253	0
Jaw clicking	1	0
Joint effusion	1	0
Joint noise	5	0
Joint stiffness	142	0
Joint swelling	154	0
Joint warmth	10	0
<i>Ligament disorders</i>		
Ligament pain	1	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	7	0
<i>Metabolic bone disorders</i>		
Osteopenia	1	0
Osteoporosis	3	0
<i>Muscle infections and inflammations</i>		
Myositis	4	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
 Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Polymyositis	1	0
Muscle pains		
Fibromyalgia	58	0
Myalgia	12206	0
Myofascial pain syndrome	5	0
Muscle related signs and symptoms NEC		
Muscle discomfort	3	0
Muscle disorder	1	0
Muscle fatigue	362	0
Muscle haemorrhage	1	0
Muscle mass	3	0
Muscle oedema	2	0
Muscle spasms	832	0
Muscle swelling	10	0
Muscle tightness	48	0
Muscle twitching	129	0
Muscle tone abnormalities		
Muscle rigidity	21	0
Nuchal rigidity	4	0
Torticollis	4	0
Trismus	26	0
Muscle weakness conditions		
Muscular weakness	657	0
Musculoskeletal and connective tissue conditions NEC		
Infantile back arching	1	0
Limb mass	2	0
Mastication disorder	1	0
Mobility decreased	51	0
Muscle contracture	1	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	708	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	2172	0
Flank pain	26	0
Growing pains	3	0
Limb discomfort	716	0
Musculoskeletal chest pain	150	0
Musculoskeletal discomfort	38	0
Musculoskeletal pain	23	0
Neck pain	995	0
Pain in extremity	6597	0
Rheumatic disorder	3	0
Myopathies		
Myopathy	1	0
Rhabdomyolysis	5	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	8	0

Case Series Drug Analysis Print

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Report Run Date: 22-Mar-2021
 Earliest Reaction Date: 03-Feb-1921

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 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Spinal osteoarthritis	1	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	9	0
<i>Rheumatoid arthropathies</i>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	40	0
Still's disease	2	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	12	0
Groin pain	52	0
Neck mass	3	0
Soft tissue mass	1	0
Soft tissue swelling	2	0
<i>Spine and neck deformities</i>		
Scoliosis	1	0
Spinal stenosis	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	10	0
Arthritis reactive	8	0
<i>Synovial disorders</i>		
Synovial cyst	1	0
Synovitis	3	0
<i>Tendon disorders</i>		
Tendon pain	3	0
Tendonitis	6	0
Trigger finger	4	0
Muscle & tissue disorders SOC TOTAL	36540	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Neoplasms		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	3	0
Breast cancer stage III	1	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	2	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	3	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	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>Neoplasms unspecified malignancy and site unspecified NEC</i>		
Neoplasm recurrence	1	0
<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>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	1	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>Salivary gland neoplasms malignant</i>		
Salivary gland cancer stage III	1	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	29	1

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

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	11	0
<i>Absence seizures</i>		
Petit mal epilepsy	7	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	36	1
Miller Fisher syndrome	2	0
<i>Auditory nerve disorders</i>		
Acoustic neuritis	1	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	3	0
Orthostatic intolerance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	1
Brain stem stroke	1	0
Cerebellar stroke	1	0
Cerebral haematoma	1	0
Cerebral haemorrhage	10	3
Cerebral infarction	4	1
Cerebral thrombosis	1	1
Cerebrovascular accident	85	7
Embolic stroke	1	0
Haemorrhage intracranial	5	0
Haemorrhagic stroke	4	1
Ischaemic stroke	12	0
Lacunar stroke	1	0
Subarachnoid haemorrhage	3	0
<i>Central nervous system inflammatory disorders NEC</i>		
Central nervous system inflammation	3	0
Neurosarcoidosis	1	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebral congestion	1	0
Cerebral small vessel ischaemic disease	1	0
Cerebrovascular disorder	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	4	0
Superior sagittal sinus thrombosis	1	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervicobrachial syndrome	2	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	5	0
<i>Coordination and balance disturbances</i>		
Ataxia	6	0
Balance disorder	280	0
Cerebellar ataxia	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Coordination abnormal	32	0
Dysstasia	32	0
Nystagmus	6	0
Cortical dysfunction NEC		
Aphasia	21	0
Dyslexia	1	0
Dyspraxia	1	0
Neurologic neglect syndrome	1	0
Cranial nerve disorders NEC		
Cranial nerve disorder	1	0
Dementia (excl Alzheimer's type)		
Dementia	8	0
Frontotemporal dementia	1	0
Senile dementia	1	0
Vascular dementia	3	0
Demyelinating disorders NEC		
Demyelination	3	0
Disturbances in consciousness NEC		
Altered state of consciousness	5	0
Consciousness fluctuating	3	0
Depressed level of consciousness	25	0
Lethargy	1906	0
Loss of consciousness	304	0
Sedation	5	0
Somnolence	643	1
Stupor	3	0
Syncope	783	0
Disturbances in sleep phase rhythm		
Advanced sleep phase	1	0
Circadian rhythm sleep disorder	1	0
Dyskinesias and movement disorders NEC		
Akathisia	7	0
Bradykinesia	6	0
Clumsiness	9	0
Dyskinesia	36	0
Extrapyramidal disorder	11	0
Fine motor skill dysfunction	3	0
Hyperkinesia	1	0
Hypokinesia	13	0
Motor dysfunction	4	0
Movement disorder	20	0
Psychomotor hyperactivity	15	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	2	0
Eye movement disorders		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Illrd nerve paralysis	1	0
Facial cranial nerve disorders		
Facial nerve disorder	2	0
Facial paralysis	117	0
Facial paresis	24	0
Facial spasm	8	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	24	0
Headaches NEC		
Cervicogenic headache	1	0
Cluster headache	217	0
Cold-stimulus headache	12	0
Drug withdrawal headache	6	0
Exertional headache	3	0
External compression headache	2	0
Headache	33494	0
Medication overuse headache	3	0
New daily persistent headache	2	0
Occipital neuralgia	3	0
Post-traumatic headache	1	0
Primary headache associated with sexual activity	2	0
Sinus headache	299	0
Tension headache	499	0
Thunderclap headache	9	0
Vascular headache	23	0
Hypoglossal nerve disorders		
Tongue paralysis	2	0
Increased intracranial pressure disorders		
Brain compression	1	0
Brain oedema	3	0
Intracranial pressure increased	2	0
Intellectual disabilities		
Intellectual disability	4	0
Lumbar spinal cord and nerve root disorders		
Sciatica	25	0
Memory loss (excl dementia)		
Amnesia	58	0
Memory impairment	56	0
Transient global amnesia	4	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	30	1
Disturbance in attention	156	0
Mental impairment	33	0
Migraine headaches		
Basilar migraine	1	0
Hemiplegic migraine	5	0
Migraine	2377	0
Migraine with aura	77	0
Migraine without aura	18	0
Retinal migraine	12	0
Status migrainosus	1	0
Typical aura without headache	6	0
Vestibular migraine	3	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	4	0
Diabetic mononeuropathy	1	0
Nerve compression	3	0
Peroneal nerve palsy	2	0
Ulnar nerve palsy	1	0
Ulnar neuritis	1	0
<i>Multiple sclerosis acute and progressive</i>		
Band sensation	1	0
Multiple sclerosis	24	0
Multiple sclerosis relapse	18	0
Uhthoff's phenomenon	2	0
<i>Muscle tone abnormal</i>		
Hypotonia	8	0
Serotonin syndrome	1	0
Stiff leg syndrome	2	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	10	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	56	0
Narcolepsy	8	0
<i>Nervous system cysts and polyps</i>		
Pineal gland cyst	1	0
<i>Nervous system disorders NEC</i>		
Cerebral disorder	1	0
Nervous system disorder	7	0
Psychomotor skills impaired	2	0
<i>Neurologic visual problems NEC</i>		
Tunnel vision	6	0
Visual field defect	4	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	7996	0
Dizziness exertional	35	0
Dizziness postural	906	1
Drooling	3	0
Exaggerated startle response	3	0
Head discomfort	126	0
Hyporesponsive to stimuli	1	0
Infant irritability	1	0
Myoclonus	9	0
Neurological symptom	31	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	3	0
Presyncope	224	0
Sensory overload	3	0
Unresponsive to stimuli	33	0
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	9	0
Muscle spasticity	7	0
Neuromuscular pain	2	0
Neuromyopathy	2	0
Neuromyotonia	1	0
<i>Neuromuscular junction dysfunction</i>		

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Report Run Date: 22-Mar-2021
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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Myasthenia gravis	2	0
Myasthenia gravis crisis	1	0
Olfactory nerve disorders		
Anosmia	87	0
Hyposmia	5	0
Parosmia	120	0
Optic nerve disorders NEC		
Optic neuritis	5	0
Paraesthesias and dysaesthesias		
Anaesthesia	2	0
Burning feet syndrome	7	0
Burning sensation	178	0
Dysaesthesia	4	0
Formication	12	0
Hemianaesthesia	2	0
Hyperaesthesia	103	0
Hypoaesthesia	1225	0
Lhermitte's sign	1	0
Paraesthesia	2175	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	12	0
Hemiparesis	18	0
Hemiplegia	4	0
Monoparesis	13	0
Monoplegia	38	0
Paralysis	86	0
Paraparesis	2	0
Paraplegia	1	0
Paresis	2	0
Peripheral nerve palsy	1	0
Postictal paralysis	1	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	65	0
Parkinson's disease	9	0
Parkinsonism	6	0
Reduced facial expression	1	0
Partial complex seizures		
Dreamy state	5	0
Focal dyscognitive seizures	2	0
Temporal lobe epilepsy	1	0
Partial simple seizures NEC		
Simple partial seizures	2	0
Peripheral neuropathies NEC		
Neuritis	1	0
Neuropathy peripheral	49	0
Polyneuropathy	3	0
Seizures and seizure disorders NEC		
Alcoholic seizure	1	0
Atonic seizures	5	0
Clonic convulsion	4	0
Epilepsy	78	0
Febrile convulsion	36	0
Migraine-triggered seizure	1	0

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Report Run Date: 22-Mar-2021

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Myoclonic epilepsy	2	0
Partial seizures	21	0
Psychogenic seizure	3	0
Seizure	351	2
Seizure anoxic	1	0
Seizure cluster	3	0
Seizure like phenomena	2	0
Status epilepticus	6	1
Tonic convulsion	13	0
Sensory abnormalities NEC		
Ageusia	383	0
Allodynia	26	0
Aura	2	0
Central pain syndrome	1	0
Complex regional pain syndrome	4	0
Dysgeusia	633	0
Hypogeusia	2	0
Loss of proprioception	2	0
Neuralgia	343	0
Persistent genital arousal disorder	1	0
Phantom limb syndrome	9	0
Post herpetic neuralgia	2	0
Restless arm syndrome	5	0
Restless legs syndrome	123	0
Sensory disturbance	19	0
Sensory loss	34	0
Taste disorder	188	0
Sleep disturbances NEC		
Microsleep	1	0
Poor quality sleep	264	0
Sleep deficit	17	0
Speech and language abnormalities		
Dysarthria	76	1
Incoherent	2	0
Language disorder	2	0
Slow speech	5	0
Speech disorder	14	0
Spinal cord and nerve root disorders NEC		
Cauda equina syndrome	1	0
Myelopathy	2	0
Radiculitis brachial	1	0
Radiculopathy	1	0
Structural brain disorders NEC		
Brain injury	1	0
Transient cerebrovascular events		
Transient ischaemic attack	58	0
Tremor (excl congenital)		
Action tremor	1	0
Essential tremor	2	0
Head titubation	5	0
Intention tremor	1	0
Resting tremor	3	0
Tremor	5003	1

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Trigeminal disorders</i>		
Facial neuralgia	5	0
Numb chin syndrome	1	0
Trigeminal neuralgia	19	0
Nervous system disorders SOC TOTAL	63660	23

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	9	0
<i>Foetal position and presentation abnormalities</i>		
Face presentation	1	0
<i>Labour onset and length abnormalities</i>		
Precipitate labour	1	0
Premature labour	2	0
Premature rupture of membranes	1	0
<i>Maternal complications of pregnancy NEC</i>		
Hyperemesis gravidarum	2	0
Morning sickness	16	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	2	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	3	0
Pregnancy conditions SOC TOTAL	37	0

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Reaction Name	Total	Fatal
<i>Device electrical issues</i>		
Device electrical impedance issue	1	0
<i>Device incompatibility issues</i>		
Patient-device incompatibility	1	0
<i>Device issues NEC</i>		
Device issue	1	0
<i>Device malfunction events NEC</i>		
Oversensing	9	0
Stent malfunction	1	0
Thrombosis in device	4	0
Undersensing	1	0
<i>Device physical property and chemical issues</i>		
Needle issue	1	0
<i>Product label issues</i>		
Product label issue	1	0
<i>Product physical issues</i>		
Product taste abnormal	2	0
<i>Product quality issues NEC</i>		
Product origin unknown	1	0
null SOC TOTAL	23	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	2	0
Breath holding	1	0
Staring	1	0
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	2	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
Constricted affect	2	0
Flat affect	2	0
Inappropriate affect	1	0
<i>Amnesic symptoms</i>		
Paramnesia	2	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	71	0
Anxiety	246	0
Nervousness	286	0
Stress	3	0
Tension	13	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	4	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	2	0
Asocial behaviour	1	0
Indifference	1	0
Paranoia	10	0
Personality change	1	0
Social avoidant behaviour	1	0
Soliloquy	1	0
Violence-related symptom	2	0
<i>Bipolar disorders</i>		
Bipolar I disorder	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	6	0
Mental fatigue	133	0
<i>Communications disorders</i>		
Mutism	2	0
<i>Confusion and disorientation</i>		
Confusional state	675	0
Disorientation	274	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	221	0
<i>Delusional symptoms</i>		
Delusion	14	0
<i>Depressive disorders</i>		
Agitated depression	1	0
Depression	126	0
Depression suicidal	2	0
Major depression	7	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	4	0
Dissociation	14	0
Dissociative disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	10	0
Insomnia	1195	0
Middle insomnia	22	0
Terminal insomnia	1	0
<i>Dyssomnias</i>		
Dyssomnia	1	0
<i>Eating disorders NEC</i>		
Eating disorder	2	0
<i>Emotional and mood disturbances NEC</i>		
Anger	17	0
Emotional disorder	37	0
Emotional distress	20	0
Euphoric mood	19	0
Frustration tolerance decreased	2	0
Irritability	83	0
Mood altered	15	0
<i>Factitious disorders</i>		
Factitious disorder	3	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Agoraphobia	1	0
Fear	7	0
Fear of death	4	0
Fear of disease	1	0
Fear of eating	1	0
Fear of falling	1	0
Phonophobia	2	0
<i>Fluctuating mood symptoms</i>		
Mood swings	11	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	398	0
Hallucination, auditory	8	0
Hallucination, olfactory	1	0
Hallucination, tactile	1	0
Hallucination, visual	19	0
Hallucinations, mixed	3	0
<i>Impulse control disorders</i>		
Impulse-control disorder	2	0
Impulsive behaviour	1	0
<i>Increased physical activity levels</i>		
Restlessness	181	0
<i>Mental disorders NEC</i>		
Mental disorder	3	0
Mental status changes	1	0
<i>Mood alterations with depressive symptoms</i>		
Anhedonia	2	0
Decreased interest	5	0
Depressed mood	149	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Feeling of despair	5	0
Negative thoughts	4	0
Sense of a foreshortened future	1	0
Tearfulness	33	0
Mood alterations with manic symptoms		
Mania	7	0
Mood disorders NEC		
Apathy	14	0
Listless	61	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	1	0
Obsessive-compulsive disorders and symptoms		
Obsessive thoughts	1	0
Orgasmic disorders and disturbances		
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0
Panic attacks and disorders		
Limited symptom panic attack	1	0
Panic attack	78	0
Panic disorder	1	0
Panic reaction	11	0
Parasomnias		
Abnormal dreams	138	0
Confusional arousal	2	0
Exploding head syndrome	4	0
Nightmare	158	0
Rapid eye movements sleep abnormal	2	0
Sleep talking	9	0
Sleep terror	21	0
Sleep-related eating disorder	1	0
Somnambulism	1	0
Perception disturbances NEC		
Autoscopy	9	0
Derealisation	5	0
Flashback	1	0
Illusion	4	0
Time perception altered	4	0
Psychiatric elimination disorders		
Enuresis	14	0
Psychiatric symptoms NEC		
Hypervigilance	4	0
Psychiatric symptom	1	0
Psychological trauma	1	0
Psychotic disorder NEC		
Psychotic disorder	9	0
Schizophrenia NEC		
Schizophrenia	1	0
Sexual arousal disorders		
Disturbance in sexual arousal	1	0
Sexual desire disorders		
Libido decreased	1	0
Libido increased	1	0
Loss of libido	6	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Sleep disorders NEC</i>		
Sleep disorder	124	0
Sleep disorder due to general medical condition, insomnia type	1	0
<i>Somatic symptom disorders</i>		
Conversion disorder	2	0
Habit cough	16	0
Somatic symptom disorder	1	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	1	0
Logorrhoea	2	0
Pedantic speech	1	0
Verbigeration	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	5	0
Lack of spontaneous speech	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	11	0
Head banging	16	0
Waxy flexibility	1	0
<i>Stress disorders</i>		
Acute stress disorder	2	0
Burnout syndrome	2	0
Hyperarousal	2	0
Post-traumatic stress disorder	7	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	20	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	22	0
Intrusive thoughts	2	0
Morbid thoughts	1	0
Tachyphrenia	11	0
Thinking abnormal	6	0
Thought blocking	1	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	5253	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	3	0
Bladder irritation	2	0
Bladder pain	13	0
Bladder spasm	1	0
Dysuria	31	0
Incontinence	31	0
Micturition frequency decreased	1	0
Micturition urgency	50	0
Mixed incontinence	1	0
Pollakiuria	113	0
Urethral pain	1	0
Urge incontinence	1	0
Urinary hesitation	3	0
Urinary incontinence	45	0
Urinary retention	26	0
Urine flow decreased	2	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	4	0
Urinary bladder haemorrhage	1	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
Nephrotic syndrome	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	3	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	14	0
Anuria	1	0
Chronic kidney disease	4	0
Oliguria	4	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	37	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Glycosuria	1	0
Haematuria	8	0
Proteinuria	2	0
Urine abnormality	6	0
Urine odour abnormal	14	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	2	0
Nocturia	5	0
Polyuria	15	0
Renal colic	1	0
Renal pain	350	0
Urinary tract pain	2	0
Renal & urinary disorders SOC TOTAL	826	1

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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 infections and inflammations</i>		
Nipple inflammation	1	0
<i>Breast signs and symptoms</i>		
Breast discomfort	1	0
Breast oedema	1	0
Breast pain	78	0
Breast swelling	3	0
Breast tenderness	10	0
Nipple pain	5	0
Nipple swelling	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation failure	1	0
Erectile dysfunction	11	0
Organic erectile dysfunction	1	0
Painful erection	1	0
Retrograde ejaculation	1	0
Spontaneous penile erection	1	0
<i>Lactation disorders</i>		
Suppressed lactation	2	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	4	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	2	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	21	0
Menstrual disorder	26	0
Menstruation irregular	25	0
Metrorrhagia	12	0
Premenstrual pain	3	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	4	0
Hypomenorrhoea	13	0
Menstruation delayed	27	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	47	0
Polymenorrhoea	6	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Polycystic ovaries	1	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Premature ovulation	1	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 and scrotal infections and inflammations</i>		
Balanoposthitis	1	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile blister	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Penile oedema	2	0
Penis disorder	2	0
Peyronie's disease	1	0
Prostate and seminal vesicles infections and inflammations		
Prostatitis	1	0
Reproductive tract disorders NEC (excl neoplasms)		
Female genital tract fistula	1	0
Genital blister	1	0
Genital haemorrhage	2	0
Genital hyperaesthesia	1	0
Genital ulceration	4	0
Reproductive tract signs and symptoms NEC		
Genital burning sensation	1	0
Genital discomfort	3	0
Pelvic discomfort	2	0
Pelvic pain	34	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
Spermatogenesis and semen disorders		
Haemospermia	1	0
Testicular and epididymal disorders NEC		
Testicular pain	22	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	69	0
Vulval haemorrhage	3	0
Vulval ulceration	1	0
Vulvovaginal signs and symptoms		
Vaginal discharge	8	0
Vaginal lesion	3	0
Vulval oedema	1	0
Vulvovaginal burning sensation	2	0
Vulvovaginal pain	7	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	3	0
Reproductive & breast disorders SOC TOTAL	515	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	4	0
Dyspnoea	1920	2
Dyspnoea at rest	3	0
Dyspnoea exertional	7	0
Hyperventilation	33	0
Hypopnoea	84	0
Irregular breathing	11	0
Mouth breathing	4	0
Orthopnoea	2	0
Respiration abnormal	46	1
Respiratory arrest	6	0
Respiratory distress	3	0
Sleep apnoea syndrome	7	0
Tachypnoea	24	0
<i>Bronchial conditions NEC</i>		
Bronchiectasis	6	0
<i>Bronchospasm and obstruction</i>		
Asthma	150	0
Asthma late onset	1	0
Asthmatic crisis	3	0
Bronchospasm	10	0
Chronic obstructive pulmonary disease	12	2
Cough variant asthma	3	0
Obstructive airways disorder	2	0
Reversible airways obstruction	1	0
Wheezing	208	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	24	0
<i>Coughing and associated symptoms</i>		
Allergic cough	1	0
Cough	1359	0
Haemoptysis	15	0
Productive cough	54	0
Sputum discoloured	3	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Reflux laryngitis	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Laryngeal oedema	2	0
Laryngospasm	1	0
Stridor	12	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Pneumonia aspiration	7	3
Pneumonitis	3	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	10	0
Lower respiratory tract congestion	2	0
Lung opacity	1	0
Pleuritic pain	6	0
Pulmonary haemorrhage	1	0
Pulmonary pain	65	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Nasal congestion and inflammations</i>		
Nasal congestion	167	0
Nasal inflammation	3	0
Rhinitis allergic	4	0
Rhinitis perennial	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	314	0
Nasal crusting	1	0
Nasal cyst	1	0
Nasal disorder	1	0
Nasal dryness	22	0
Nasal odour	2	0
Nasal oedema	6	0
Nasal pruritus	2	0
Nasal ulcer	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Paranasal sinus haemorrhage	2	0
Paranasal sinus inflammation	1	0
Sinonasal obstruction	4	0
Sinus congestion	17	0
Sinus disorder	2	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	9	0
Pharyngeal oedema	4	0
Pharyngeal paraesthesia	11	0
Pharyngeal swelling	83	0
Pharyngeal ulceration	5	0
Tonsillar erythema	2	0
Tonsillar hypertrophy	21	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	2	0
Pneumothorax	2	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	1	0
<i>Pulmonary oedemas</i>		
Acute pulmonary oedema	1	0
Pulmonary congestion	7	0
Pulmonary oedema	5	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	64	6
Pulmonary infarction	1	1
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	2	0
<i>Respiratory signs and symptoms NEC</i>		

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Diaphragmalgia	3	0
Painful respiration	2	0
Respiratory symptom	5	0
Suffocation feeling	2	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	3	2
Lung disorder	2	0
Respiratory tract congestion	3	0
Respiratory tract irritation	3	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	1	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal fistula	1	0
Tracheal pain	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	25	0
Catarrh	23	0
Choking	6	0
Choking sensation	5	0
Dry throat	104	0
Dysphonia	44	0
Increased upper airway secretion	1	0
Increased viscosity of upper respiratory secretion	5	0
Laryngeal pain	1	0
Nasal discomfort	34	0
Oropharyngeal blistering	3	0
Oropharyngeal discomfort	8	0
Oropharyngeal pain	1616	0
Paranasal sinus discomfort	13	0
Rhinalgia	11	0
Rhinorrhoea	669	0
Sinus pain	183	0
Sneezing	164	0
Throat clearing	2	0
Throat irritation	79	0
Throat lesion	1	0
Throat tightness	62	0
Upper-airway cough syndrome	9	0
Yawning	30	0
Respiratory disorders SOC TOTAL	8024	17

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	8	0
Acne cystic	1	0
<i>Alopecias</i>		
Alopecia	19	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	110	0
Circumoral oedema	1	0
Idiopathic angioedema	2	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	1	0
Cold sweat	735	0
Hyperhidrosis	4062	0
Miliaria	53	0
Night sweats	733	0
Sweat discolouration	1	0
Sweat gland disorder	1	0
<i>Bullous conditions</i>		
Blister	89	0
Blood blister	6	0
Dermatitis bullous	3	0
Erythema multiforme	6	0
Oedema blister	1	0
Pemphigoid	2	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<i>Connective tissue disorders</i>		
Subacute cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	94	0
Macule	3	0
Pain of skin	399	0
Papule	14	0
Peau d'orange	1	0
Scab	5	0
Scar pain	4	0
Sensitive skin	252	0
Skin burning sensation	209	0
Skin discolouration	26	0
Skin disorder	7	0
Skin fissures	1	0
Skin fragility	1	0
Skin induration	3	0
Skin lesion	3	0
Skin necrosis	1	0
Skin odour abnormal	14	0
Skin reaction	82	0
Skin sensitisation	37	0
Skin swelling	31	0
Skin texture abnormal	1	0
Skin tightness	4	0
Skin warm	196	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Sticky skin	1	0
Yellow skin	11	0
<i>Dermatitis and eczema</i>		
Dermatitis	57	0
Dermatitis allergic	90	0
Dermatitis atopic	5	0
Dermatitis contact	1	0
Dermatitis diaper	1	0
Dyshidrotic eczema	1	0
Eczema	35	0
Eczema asteatotic	2	0
Eczema nummular	1	0
Perioral dermatitis	1	0
Rebound eczema	1	0
Seborrhoeic dermatitis	1	0
Skin irritation	44	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	13	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	1177	0
Palmar erythema	2	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	2	0
Exfoliative rash	4	0
Skin exfoliation	24	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Granuloma annulare	1	0
<i>Hyperpigmentation disorders</i>		
Solar lentigo	1	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	1	0
Vitiligo	2	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 pigmentation	1	0
Nail pitting	1	0
Onychoclasia	1	0
<i>Panniculitides</i>		
Erythema nodosum	3	0
<i>Papulosquamous conditions</i>		
Lichen planus	3	0
Pityriasis rosea	4	0
Pityriasis rubra pilaris	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	62	0
Polymorphic light eruption	1	0
<i>Pigmentation changes NEC</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Pigmentation disorder	1	0
Pilar disorders NEC		
Hair growth abnormal	1	0
Piloerection	37	0
Trichodynia	3	0
Pruritus NEC		
Itching scar	1	0
Pruritus	2229	0
Pruritus allergic	1	0
Psoriatic conditions		
Guttate psoriasis	4	0
Psoriasis	31	0
Pustular psoriasis	1	0
Purpura and related conditions		
Ecchymosis	1	0
Henoch-Schonlein purpura	2	0
Petechiae	23	0
Purpura	11	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	3	0
Rash	2198	0
Rash erythematous	691	0
Rash macular	185	0
Rash maculo-papular	20	0
Rash morbilliform	4	0
Rash papular	115	0
Rash pruritic	529	0
Rash vesicular	18	0
Systemic lupus erythematosus rash	2	0
Rosaceas		
Rosacea	4	0
Sebaceous gland disorders		
Seborrhoea	1	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	3	0
Skin mass	7	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	12	0
Skin ulcer	4	0
Skin cysts and polyps		
Dermal cyst	3	0
Skin haemorrhages		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	3	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	1	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	2	0
Needle track marks	2	0
Skin vasculitides		
Cutaneous vasculitis	1	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	8	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Skin vasomotor conditions</i>		
Livedo reticularis	14	0
<i>Urticarias</i>		
Cold urticaria	1	0
Idiopathic urticaria	2	0
Urticaria	678	0
Urticaria chronic	3	0
Urticaria papular	1	0
Urticaria thermal	2	0
Urticarial vasculitis	1	0
Skin disorders SOC TOTAL	15656	0

Case Series Drug Analysis Print

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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	34	0
Disability	1	0
Immobile	14	0
Impaired driving ability	2	0
Impaired work ability	4	0
Loss of personal independence in daily activities	1	0
Sight disability	4	0
<i>Employment issues</i>		
Retirement	3	0
<i>Non-occupational and unspecified environmental problems</i>		
Food contamination	1	0
<i>Pregnancy related circumstances</i>		
Breast feeding	2	0
<i>Social issues NEC</i>		
Contraindication to medical treatment	1	0
Contraindication to vaccination	2	0
Convalescent	1	0
Impaired quality of life	1	0
<i>Tobacco use</i>		
Tobacco user	1	0
Social circumstances SOC TOTAL	73	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	2	0
<i>Blood and blood product treatment</i>		
Photopheresis	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	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	18	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	2	0
<i>Immunisations</i>		
COVID-19 immunisation	65	1
Immunisation	40	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	11	0
Limb operation	3	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	2	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>Spine and spinal cord therapeutic procedures</i>		
Spinal operation	1	0
<i>Therapeutic procedures NEC</i>		
Anaphylaxis treatment	1	0
Bed rest	9	0
Fatigue management	1	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Hospitalisation	4	0
Injection	17	0
Localised alternating hot and cold therapy	5	0
Mass excision	2	0
Smoking cessation therapy	1	0
Specialist consultation	1	0
Therapeutic hypothermia	2	0
Therapy change	1	0
<i>Uterine therapeutic procedures</i>		
Endometrial ablation	1	0
Surgical & medical procedures SOC TOTAL	208	1

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	1	0
Hypertensive emergency	1	0
Hypertensive urgency	1	0
Malignant hypertension	1	0
Tyramine reaction	1	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	1	0
<i>Aortic aneurysms and dissections</i>		
Aortic aneurysm	2	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	1	0
Aortic thrombosis	1	1
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	10	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	4	0
Labile blood pressure	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	32	1
Neurogenic shock	3	0
Peripheral circulatory failure	1	0
Shock	19	0
Shock symptom	4	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	15	0
Haemorrhage	39	1
Internal haemorrhage	2	0
<i>Lymphoedemas</i>		
Lymphoedema	20	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	3	0
Embolism venous	1	0
Thrombophlebitis migrans	1	0
Thrombosis	55	4
Venous thrombosis	4	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial spasm	1	0
Arteriosclerosis	1	0
Ischaemia	1	0
<i>Non-site specific vascular disorders NEC</i>		
Neovascularisation	1	0
Vascular pain	11	0
Vasodilatation	8	0
Vein rupture	1	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	3	0
Deep vein thrombosis	66	1
Pelvic venous thrombosis	1	0
Thrombophlebitis	4	0
Thrombophlebitis superficial	3	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	37	0
Erythromelalgia	1	0
Flushing	295	0
Hot flush	769	0
Peripheral vascular disorder	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Ischaemic limb pain	2	0
Peripheral coldness	478	0
Poor peripheral circulation	6	0
Raynaud's phenomenon	32	0
<i>Phlebitis NEC</i>		
Phlebitis	6	0
<i>Site specific vascular disorders NEC</i>		
Pallor	165	0
Plethoric face	1	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicophlebitis	1	0
Varicose vein	4	0
<i>Vascular hypertensive disorders NEC</i>		
Diastolic hypertension	1	0
Hypertension	176	0
Systolic hypertension	1	0
White coat hypertension	2	0
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	2	0
Hypotension	190	0
Orthostatic hypotension	18	0
<i>Vasculitides NEC</i>		
Diffuse vasculitis	1	1
MAGIC syndrome	3	1
Vasculitis	11	0
Vascular disorders SOC TOTAL	2532	10
TOTAL REACTIONS FOR DRUG	294820	326
TOTAL REPORTS	78223	
TOTAL FATAL OUTCOME REPORTS		326