

COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021
Data Lock Date: 24-Feb-2021 19:00:03

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

Case Series Drug Analysis Print

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Report Run Date: 25-Feb-2021
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Blood disorders		
Anaemias NEC		
Anaemia	2	0
Anaemias haemolytic NEC		
Haemolytic anaemia	2	0
Anaemias haemolytic immune		
Autoimmune haemolytic anaemia	1	0
Bleeding tendencies		
Increased tendency to bruise	1	0
Coagulopathies		
Coagulopathy	2	0
Eosinophilic disorders		
Eosinophilia	3	0
Haematological disorders		
Bone marrow oedema	1	0
Methaemoglobinaemia	1	0
Haemolyses NEC		
Haemolysis	2	0
Leukocytoses NEC		
Lymphocytosis	1	0
Leukopenias NEC		
Leukopenia	2	0
Lymphopenia	2	0
Lymphatic system disorders NEC		
Lymph node pain	69	0
Lymphadenitis	8	0
Lymphadenopathy	657	0
Lymphatic disorder	1	0
Marrow depression and hypoplastic anaemias		
Pancytopenia	2	0
Neutropenias		
Neutropenia	16	0
Sickle cell trait and disorders		
Sickle cell anaemia with crisis	1	0
Spleen disorders		
Spleen disorder	1	0
Splenomegaly	1	0
Thrombocytopenias		
Immune thrombocytopenia	16	0
Thrombocytopenia	5	0
Thrombocytopenic purpura	1	0
White blood cell abnormal findings NEC		
White blood cell disorder	1	0
Blood disorders SOC TOTAL	799	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Aortic valvular disorders</i>		
Aortic valve stenosis	1	0
<i>Cardiac conduction disorders</i>		
Atrioventricular block	2	0
Long QT syndrome	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	2	1
Cardiac disorder	4	0
Cardiovascular insufficiency	2	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	1	0
Palpitations	882	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	1	0
Congestive cardiomyopathy	1	0
<i>Heart failures NEC</i>		
Cardiac failure	5	2
Cardiac failure acute	1	0
Cardiogenic shock	1	0
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	2	1
Angina pectoris	18	0
Angina unstable	2	0
Microvascular coronary artery disease	1	0
Myocardial infarction	18	10
Myocardial ischaemia	5	2
<i>Left ventricular failures</i>		
Left ventricular failure	1	1
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	1	0
<i>Noninfectious pericarditis</i>		
Pericarditis	4	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	22	0
Bradycardia	20	0
Cardiac flutter	23	0
Extrasystoles	10	0
Tachyarrhythmia	4	0
Tachycardia	382	0
<i>Right ventricular failures</i>		
Right ventricular failure	1	1
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	4	0
Atrial fibrillation	38	0
Atrial flutter	4	0
Sinus arrhythmia	1	0
Sinus tachycardia	13	0
Supraventricular tachycardia	5	0

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Cardiac disorders Cardiac disorders cont'd		
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	24	11
Ventricular arrhythmia	1	0
Ventricular extrasystoles	1	0
Ventricular fibrillation	1	0
Ventricular tachycardia	2	0
Cardiac disorders SOC TOTAL	1516	30

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	1	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	1	0
<i>Cerebral disorders congenital</i>		
Cerebral palsy	2	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	4	0
<i>Pulmonary and bronchial disorders congenital</i>		
Cystic fibrosis	3	0
Congenital disorders SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	11	0
Ear haemorrhage	1	0
Ear pain	337	0
Ear swelling	10	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
External ear pain	1	0
Red ear syndrome	1	0
<i>Hearing disorders NEC</i>		
Auditory disorder	1	0
<i>Hearing losses</i>		
Deafness	25	0
Deafness bilateral	1	0
Deafness transitory	2	0
Deafness unilateral	2	0
Hypoacusis	22	0
Sudden hearing loss	5	0
<i>Hyperacusia</i>		
Hyperacusis	16	0
<i>Inner ear disorders NEC</i>		
Meniere's disease	2	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	15	0
Tinnitus	218	0
Vertigo	203	0
Vertigo labyrinthine	3	0
Vertigo positional	14	0
Ear disorders SOC TOTAL	891	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Adrenal cortical hypofunctions</i>		
Adrenal insufficiency	5	0
Adrenocortical insufficiency acute	11	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	3	0
<i>Thyroid disorders NEC</i>		
Thyroid pain	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	4	0
Endocrine disorders SOC TOTAL	24	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Cataract conditions</i>		
Cataract	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	5	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	1	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	2	0
<i>Eyelid movement disorders</i>		
Blepharospasm	4	0
Eyelid ptosis	4	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iritis	1	0
Uveitis	2	0
<i>Lacrimation disorders</i>		
Dry eye	31	0
Lacrimation increased	28	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	1	0
Erythema of eyelid	2	0
Eyelid oedema	1	0
Swelling of eyelid	10	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	2	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye oedema	1	0
Eye pain	620	0
Eye swelling	83	0
Eye symptom	1	0
Ocular discomfort	5	0
Periorbital oedema	5	0
Periorbital pain	1	0
Periorbital swelling	18	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	6	0
Eye discharge	2	0
Eye inflammation	3	0
Eye irritation	33	0
Eye pruritus	39	0
Ocular hyperaemia	43	0
<i>Ocular nerve and muscle disorders</i>		
Extraocular muscle paresis	3	0
Eye movement disorder	5	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	4	0
Asthenopia	42	0
Eyelid sensory disorder	2	0
Foreign body sensation in eyes	8	0

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Eye disorders Eye disorders cont'd		
Hypoaesthesia eye	3	0
Photophobia	202	0
<i>Pupil disorders</i>		
Miosis	2	0
Mydriasis	3	0
Pupils unequal	2	0
<i>Refractive and accommodative disorders</i>		
Hypermetropia	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal aneurysm	1	0
Retinal vascular thrombosis	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Neovascular age-related macular degeneration	1	0
Vitreoretinal traction syndrome	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	2	0
<i>Visual colour distortions</i>		
Chromatopsia	1	0
Xanthopsia	1	0
<i>Visual disorders NEC</i>		
Diplopia	29	0
Halo vision	1	0
Metamorphopsia	4	0
Photopsia	38	0
Vision blurred	200	0
Visual brightness	1	0
Visual snow syndrome	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	23	0
Blindness transient	2	0
Night blindness	2	0
Sudden visual loss	1	0
Visual acuity reduced	3	0
Visual impairment	65	0
Eye disorders SOC TOTAL	1613	0

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Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
Gastrointestinal sounds abnormal	2	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	1
Pancreatitis	5	0
Pancreatitis acute	1	0
<i>Anal and rectal pains</i>		
Proctalgia	1	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	2	0
Anal pruritus	1	0
Anorectal discomfort	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	1	0
<i>Colitis (excl infective)</i>		
Colitis	4	0
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	10	0
Crohn's disease	10	0
<i>Dental disorders NEC</i>		
Teething	5	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	2	0
Dental paraesthesia	2	0
Hyperaesthesia teeth	7	0
Toothache	60	0
<i>Dental surface disorders</i>		
Tooth discolouration	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1975	0
Diarrhoea haemorrhagic	5	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	152	0
Epigastric discomfort	4	0
Eructation	15	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	2	0
Faecaloma	1	0
Faeces discoloured	4	0
Faeces soft	4	0
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	57	0
Flatulence	71	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	1	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	3	0
<i>Gastritis (excl infective)</i>		
Gastritis	11	0
Reflux gastritis	2	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	904	0
Abdominal pain lower	40	0
Abdominal pain upper	935	0
Abdominal rigidity	11	0
Abdominal tenderness	4	0
Gastrointestinal pain	72	0
Oesophageal pain	2	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	48	0
Gastric dilatation	3	0
Gastrooesophageal reflux disease	31	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	2	0
Gastric disorder	2	0
Gastrointestinal disorder	7	0
Neurogenic bowel	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
Dyschezia	1	0
Oesophageal achalasia	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Gastrointestinal tract irritation	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	295	0
Abdominal symptom	1	0
Acute abdomen	3	0
Anal incontinence	4	0
Breath odour	5	0
Dysphagia	34	1
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	4	0
Frequent bowel movements	5	0
Irritable bowel syndrome	15	0
Oesophageal spasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	6	0
Gingival discomfort	1	0
Gingival disorder	1	0
Gingival oedema	1	0
Gingival pain	37	0
Gingival pruritus	1	0
Gingival swelling	9	0
Noninfective gingivitis	5	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	8	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	2	0
<i>Inguinal hernias</i>		
Inguinal hernia	1	0
<i>Intestinal haemorrhages</i>		

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Anal haemorrhage	1	0
Rectal haemorrhage	8	0
Small intestinal haemorrhage	6	0
Malabsorption syndromes		
Coeliac disease	1	0
Nausea and vomiting symptoms		
Discoloured vomit	5	0
Nausea	8291	0
Regurgitation	1	0
Retching	70	0
Vomiting	3044	2
Vomiting projectile	34	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	2	1
Haematemesis	7	0
Haematochezia	11	0
Melaena	1	0
Oesophagitis (excl infective)		
Oesophagitis	1	0
Oral dryness and saliva altered		
Dry mouth	251	0
Lip dry	11	0
Saliva altered	1	0
Salivary hypersecretion	8	0
Oral soft tissue disorders NEC		
Chapped lips	2	0
Cheilitis	9	0
Enlarged uvula	2	0
Lip blister	7	0
Lip disorder	1	0
Oral disorder	1	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	1	0
Oral blood blister	3	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	1	0
Burning mouth syndrome	1	0
Hypoaesthesia oral	94	0
Lip erythema	1	0
Lip exfoliation	3	0
Lip pain	17	0
Lip pruritus	8	0
Odynophagia	1	0
Oral discomfort	15	0
Oral mucosal blistering	7	0
Oral mucosal eruption	3	0
Oral mucosal exfoliation	2	0
Oral mucosal roughening	1	0
Oral pain	62	0
Oral pruritus	2	0
Paraesthesia oral	145	0
Oral soft tissue swelling and oedema		
Lip oedema	1	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Lip swelling	184	0
Mouth swelling	31	0
Oedema mouth	1	0
Palatal swelling	4	0
Rectal inflammations NEC		
Proctitis	1	0
Salivary gland disorders NEC		
Salivary gland pain	2	0
Salivary gland enlargements		
Parotid gland enlargement	2	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	1	0
Stomatitis and ulceration		
Apthous ulcer	6	0
Lip ulceration	4	0
Mouth ulceration	77	0
Stomatitis	11	0
Tongue disorders		
Glossitis	3	0
Plicated tongue	1	0
Tongue disorder	3	0
Tongue ulceration	1	0
Trichoglossia	2	0
Tongue signs and symptoms		
Glossodynia	45	0
Scalloped tongue	2	0
Swollen tongue	102	0
Tongue blistering	6	0
Tongue coated	6	0
Tongue discolouration	3	0
Tongue discomfort	6	0
Tongue dry	6	0
Tongue eruption	1	0
Tongue movement disturbance	1	0
Tongue oedema	4	0
Tongue pruritus	1	0
Tongue rough	1	0
Tongue spasm	1	0
Tooth missing		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	17597	5

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	5	0
Administration site pain	13	0
Administration site urticaria	1	0
Puncture site bruise	7	0
Puncture site pain	5	0
Puncture site reaction	1	0
<i>Adverse effect absent</i>		
No adverse event	5	0
<i>Application and instillation site reactions</i>		
Application site bruise	3	0
Application site erythema	4	0
Application site joint pain	1	0
Application site pain	6	0
Application site pruritus	3	0
Instillation site discomfort	1	0
Instillation site pain	1	0
Instillation site warmth	4	0
<i>Asthenic conditions</i>		
Asthenia	986	3
Chronic fatigue syndrome	6	0
Fatigue	10206	0
Malaise	2869	3
Sluggishness	3	0
<i>Body temperature altered</i>		
Hyperthermia	4	0
Hypothermia	18	0
Temperature regulation disorder	4	0
<i>Complications associated with device NEC</i>		
Phantom shocks	1	0
<i>Death and sudden death</i>		
Death	128	128
Sudden death	9	9
<i>Febrile disorders</i>		
Hyperpyrexia	22	0
Masked fever	1	0
Pyrexia	14850	1
<i>Feelings and sensations NEC</i>		
Chills	11454	0
Feeling abnormal	394	0
Feeling cold	1374	0
Feeling drunk	10	0
Feeling hot	476	0
Feeling jittery	6	0
Feeling of body temperature change	246	0
Hangover	18	0
Hunger	7	0
Sensation of foreign body	7	0
Temperature intolerance	10	0
Thirst	319	0
Thirst decreased	3	0
<i>Fibrosis NEC</i>		
Fibrosis	1	0

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General disorders General disorders cont'd		
<i>Gait disturbances</i>		
Decreased gait velocity	1	0
Gait disturbance	59	0
Gait inability	44	0
Loss of control of legs	9	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	31	0
Crying	31	0
Energy increased	1	0
Exercise tolerance decreased	1	0
Foaming at mouth	2	0
General physical health deterioration	5	1
General symptom	2	0
Illness	1212	0
Induration	3	0
Influenza like illness	2401	0
Local reaction	66	0
Moaning	2	0
Multiple organ dysfunction syndrome	2	0
Nonspecific reaction	1	0
Peripheral swelling	888	0
Screaming	1	0
Secretion discharge	5	0
Swelling	408	0
Swelling face	159	0
<i>Implant and catheter site reactions</i>		
Implant site warmth	2	0
<i>Inflammations</i>		
Inflammation	88	0
<i>Infusion site reactions</i>		
Infusion site bruising	1	0
Infusion site pain	2	0
Infusion site warmth	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	10	0
Injection site bruising	15	0
Injection site coldness	1	0
Injection site discolouration	1	0
Injection site discomfort	2	0
Injection site erythema	120	0
Injection site haemorrhage	1	0
Injection site hypoaesthesia	3	0
Injection site indentation	2	0
Injection site inflammation	15	0
Injection site irritation	1	0
Injection site joint erythema	2	0
Injection site joint pain	13	0
Injection site mass	253	0
Injection site oedema	7	0
Injection site pain	943	0
Injection site papule	1	0
Injection site paraesthesia	2	0
Injection site pruritus	66	0

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General disorders General disorders cont'd		
Injection site rash	50	0
Injection site reaction	26	0
Injection site swelling	41	0
Injection site urticaria	7	0
Injection site vesicles	2	0
Injection site warmth	79	0
Interactions		
Drug interaction	4	0
Mass conditions NEC		
Cyst	1	0
Mass	5	0
Nodule	1	0
Mucosal findings abnormal		
Mucosal disorder	1	0
Mucosal inflammation	2	0
Mucosal pain	1	0
Oedema NEC		
Face oedema	4	0
Localised oedema	4	0
Oedema	2	0
Oedema peripheral	7	0
Pain and discomfort NEC		
Axillary pain	70	0
Chest discomfort	351	0
Chest pain	682	1
Discomfort	42	0
Facial discomfort	3	0
Facial pain	49	0
Inflammatory pain	4	0
Non-cardiac chest pain	6	0
Pain	3221	0
Tenderness	398	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	7	0
Adverse event	1	0
Diet failure	1	0
Drug ineffective	12	0
Drug intolerance	1	0
No reaction on previous exposure to drug	9	0
Therapeutic product effect decreased	1	0
Therapeutic response unexpected	4	0
Treatment failure	2	0
Vaccine positive rechallenge	1	0
Ulcers NEC		
Ulcer	3	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	4	0
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	17	0
Vaccination site discolouration	1	0
Vaccination site discomfort	4	0
Vaccination site erythema	125	0
Vaccination site extravasation	1	0

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 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site granuloma	3	0
Vaccination site haemorrhage	1	0
Vaccination site hypersensitivity	1	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	14	0
Vaccination site inflammation	13	0
Vaccination site irritation	3	0
Vaccination site joint erythema	1	0
Vaccination site joint movement impairment	3	0
Vaccination site joint pain	17	0
Vaccination site joint swelling	1	0
Vaccination site mass	89	0
Vaccination site movement impairment	5	0
Vaccination site oedema	1	0
Vaccination site pain	363	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	18	0
Vaccination site rash	24	0
Vaccination site reaction	7	0
Vaccination site swelling	106	0
Vaccination site urticaria	1	0
Vaccination site vesicles	1	0
Vaccination site warmth	58	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	3	0
General disorders SOC TOTAL	56377	146

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	3	0
<i>Cholecystitis and cholelithiasis</i>		
Cholelithiasis	2	0
<i>Cholestasis and jaundice</i>		
Jaundice	6	0
Ocular icterus	1	0
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	9	0
Hepatic disorders SOC TOTAL	22	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 24-Feb-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	3	0
<i>Allergic conditions NEC</i>		
Allergic oedema	4	0
Allergy to sting	1	0
Hypersensitivity	175	0
Infusion related hypersensitivity reaction	1	0
Multiple allergies	3	0
Serum sickness	8	0
Serum sickness-like reaction	7	0
Type III immune complex mediated reaction	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	13	0
Drug hypersensitivity	15	0
Food allergy	1	0
Reaction to excipient	1	0
Reaction to preservatives	4	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	137	0
Anaphylactic shock	8	0
Anaphylactoid reaction	4	0
Anaphylactoid shock	1	0
<i>Atopic disorders</i>		
Seasonal allergy	5	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	6	0
Immune system disorder	2	0
Immunisation reaction	1	0
Sensitisation	5	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
<i>Transplant rejections</i>		
Transplant rejection	1	0
Immune system disorders SOC TOTAL	410	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 24-Feb-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	1	0
Diverticulitis	1	0
Dysentery	1	0
Gastroenteritis	4	0
Gastrointestinal infection	1	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Arthritis bacterial	2	0
Bacterial infection	5	1
Cellulitis	104	1
Injection site cellulitis	1	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	4	0
<i>Bone and joint infections</i>		
Intervertebral discitis	1	0
<i>Bordetella infections</i>		
Pertussis	1	0
<i>Breast infections</i>		
Mastitis	2	0
<i>Candida infections</i>		
Candida infection	5	0
Oral candidiasis	3	0
Skin candida	1	0
Vulvovaginal candidiasis	4	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	2	0
Myelitis	2	0
<i>Clostridia infections</i>		
Clostridium difficile colitis	1	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	2	0
COVID-19	129	10
COVID-19 pneumonia	4	4
Severe acute respiratory syndrome	2	0
Suspected COVID-19	11	0
<i>Coxiella infections</i>		
Q fever	28	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	1	0
Gingival abscess	2	0
Gingivitis	4	0
Oral pustule	1	0
Parotitis	1	0
Tooth abscess	1	0
<i>Ear infections</i>		
Ear infection	4	0
Labyrinthitis	17	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	6	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	8	0
Eye infection	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 24-Feb-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Eyelid infection	2	0
Hordeolum	2	0
Female reproductive tract infections		
Vaginal abscess	1	0
Fungal infections NEC		
Fungal infection	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	1	1
Herpes viral infections		
Genital herpes	4	0
Genital herpes simplex	1	0
Herpes simplex	6	0
Herpes virus infection	1	0
Herpes zoster	97	0
Ophthalmic herpes zoster	1	0
Oral herpes	109	0
Varicella	3	0
Infections NEC		
Abscess	3	0
Abscess limb	1	0
Infection	44	2
Injection site infection	3	0
Localised infection	15	0
Respiratory tract infection	1	0
Vaccination site infection	7	0
Influenza viral infections		
H2N2 influenza	1	0
Influenza	1604	0
Lower respiratory tract and lung infections		
Bronchitis	1	0
Infective exacerbation of bronchiectasis	1	0
Lower respiratory tract infection	27	1
Pneumonia	22	9
Male reproductive tract infections		
Orchitis	1	0
Mumps viral infections		
Mumps	1	0
Phleboviral infections		
Severe fever with thrombocytopenia syndrome	2	0
Pneumocystis infections		
Pneumocystis jirovecii pneumonia	1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Neutropenic sepsis	1	0
Sepsis	19	2
Urosepsis	2	1
Skin structures and soft tissue infections		
Folliculitis	2	0
Pustule	1	0
Rash pustular	2	0
Skin infection	11	0
Subcutaneous abscess	2	0
Staphylococcal infections		
Furuncle	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Staphylococcal scalded skin syndrome	1	0
<i>Streptococcal infections</i>		
Cellulitis streptococcal	1	0
Erysipelas	1	0
<i>Tinea infections</i>		
Body tinea	1	0
Tinea cruris	1	0
<i>Tuberculous infections</i>		
Tuberculosis	1	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	1	0
Laryngitis	5	0
Nasopharyngitis	303	0
Pharyngitis	5	0
Rhinitis	11	0
Sinusitis	34	0
Tonsillitis	11	0
Upper respiratory tract infection	1	0
<i>Urinary tract infections</i>		
Cystitis	10	0
Kidney infection	8	0
Urinary tract infection	21	0
<i>Vascular infections</i>		
Infected lymphocele	1	0
Lymphangitis	2	0
<i>Viral infections NEC</i>		
Arthritis viral	1	0
Gastroenteritis viral	15	1
Pneumonia viral	1	0
Post viral fatigue syndrome	12	0
Sweating fever	177	0
Vestibular neuronitis	2	0
Viral diarrhoea	1	0
Viral infection	3	0
Viral myocarditis	1	0
Viral pharyngitis	3	0
Viral rash	4	0
Viral sepsis	1	0
Infections SOC TOTAL	3016	32

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 24-Feb-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Oral contusion	1	0
Palate injury	1	0
Splenic rupture	1	0
<i>Anaesthetic and allied procedural complications</i>		
Sedation complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
<i>Cerebral injuries NEC</i>		
Subdural haematoma	1	0
Subdural haemorrhage	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	7	0
<i>Cranial nerve injuries</i>		
Optic nerve injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	3	0
Foetal exposure during pregnancy	2	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	9	0
Maternal exposure during pregnancy	30	0
Maternal exposure timing unspecified	1	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	2	0
<i>Eye injuries NEC</i>		
Eye contusion	3	0
Eye injury	2	0
Superficial injury of eye	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural nausea	12	0
Procedural vomiting	2	0
<i>Heat injuries (excl thermal burns)</i>		
Heat exhaustion	2	0
Heat oedema	3	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	2	0
<i>Medication errors, product use errors and issues NEC</i>		
Device use issue	1	0
Medication error	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	3	0
Ligament sprain	1	0
Muscle injury	1	0
Muscle rupture	1	0
Muscle strain	1	0
Tendon rupture	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	6	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Neurological and psychiatric procedural complications		
Post lumbar puncture syndrome	4	0
Procedural dizziness	7	0
Non-occupational environmental exposures		
Exposure to extreme temperature	3	0
Exposure to noise	1	0
Non-site specific injuries NEC		
Arthropod bite	2	0
Arthropod sting	2	0
Electric shock	2	0
Fall	41	1
Inflammation of wound	1	0
Road traffic accident	1	0
Wound complication	1	0
Non-site specific procedural complications		
Incision site pain	4	0
Infusion related reaction	7	0
Injection related reaction	252	0
Post procedural complication	15	0
Suture related complication	1	0
Occupational exposures		
Occupational exposure to product	1	0
Overdoses NEC		
Overdose	1	0
Peripheral nerve injuries		
Ulnar nerve injury	1	0
Poisoning and toxicity		
Alcohol poisoning	1	0
Toxicity to various agents	2	0
Product administration errors and issues		
Accidental overdose	1	0
Duplicate therapy error	1	0
Expired product administered	2	0
Extra dose administered	1	0
Inappropriate schedule of product administration	1	0
Incorrect route of product administration	1	0
Product administered to patient of inappropriate age	1	0
Product administration error	3	0
Product confusion errors and issues		
Product label confusion	1	0
Product dispensing errors and issues		
Product dispensing error	1	0
Radiation injuries		
Sunburn	1	0
Reproductive tract and breast procedural complications		
Postmastectomy lymphoedema syndrome	1	0
Site specific injuries NEC		
Back injury	1	0
Head injury	1	0
Limb crushing injury	1	0
Limb injury	7	0
Neck crushing	1	0
Skin injuries NEC		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Contusion	134	0
Skin abrasion	1	0
Skin injury	1	0
Skin wound	1	0
Spinal cord injuries NEC		
Spinal cord injury sacral	1	0
Stoma complications		
Gastrointestinal stoma complication	1	0
Thermal burns		
Burn of internal organs	3	0
Burn oral cavity	1	0
Burns second degree	1	0
Cold burn	1	0
Thermal burn	8	0
Thermal burns of eye	6	0
Underdoses NEC		
Intentional underdose	1	0
Vaccination related complications		
Vaccination complication	21	0
Vaccination failure	1	0
Injuries SOC TOTAL	668	1

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-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 increased	1	0
<i>Adrenal medulla tests</i>		
Norepinephrine increased	1	0
<i>Autoimmunity analyses</i>		
Cold agglutinins positive	1	0
<i>Blood gas and acid base analyses</i>		
Blood pH increased	3	0
Oxygen saturation	10	0
Oxygen saturation decreased	59	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	6	0
Blood glucose abnormal	3	0
Blood glucose decreased	7	0
Blood glucose fluctuation	4	0
Blood glucose increased	40	0
Glycosylated haemoglobin increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
Heart sounds	1	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	2	0
Magnetic resonance imaging brain	23	0
<i>Chemistry analyses NEC</i>		
Histamine level increased	1	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	1	0
<i>Coagulation and bleeding analyses</i>		
Coagulation time prolonged	1	0
Fibrin D dimer increased	1	0
International normalised ratio decreased	5	0
International normalised ratio increased	12	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	1	0
<i>Faecal analyses NEC</i>		
Faecal calprotectin increased	1	0
<i>Fertility analyses</i>		
Semen volume decreased	1	0
<i>Gastrointestinal and abdominal imaging procedures</i>		
Computerised tomogram abdomen	1	0
<i>Gastrointestinal function diagnostic procedures</i>		
Gastrointestinal stoma output increased	1	0
Swallow study	1	0
<i>Gastrointestinal, pancreatic and APUD hormone analyses</i>		
Blood gastrin normal	1	0
Blood insulin	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	183	0
Heart rate abnormal	8	0
Heart rate decreased	11	0
Heart rate increased	417	0
Heart rate irregular	32	0
Maximum heart rate	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 24-Feb-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Maximum heart rate decreased	1	0
Orthostatic heart rate response increased	1	0
Pulse abnormal	3	0
Pulse absent	2	0
Sinus rhythm	1	0
Imaging procedures NEC		
Computerised tomogram	1	0
Immunology analyses NEC		
Immunology test	1	0
Immunology test normal	1	0
Immunology skin tests NEC		
Allergy alert test	1	0
Investigations NEC		
Blood test	4	0
Liver function analyses		
Alanine aminotransferase increased	1	0
Aspartate aminotransferase increased	1	0
Hepatic enzyme increased	1	0
Liver function test abnormal	2	0
Transaminases increased	2	0
Metabolism tests NEC		
Blood ketone body	3	0
Ubiquinone	1	0
Mineral and electrolyte analyses		
Blood phosphorus increased	1	0
Blood sodium decreased	1	0
Neurologic diagnostic procedures		
Lumbar puncture	1	0
Ophthalmic function diagnostic procedures		
Intraocular pressure increased	1	0
Intraocular pressure test	1	0
Physical examination procedures and organ system status		
Body temperature	286	0
Body temperature abnormal	21	0
Body temperature decreased	34	0
Body temperature fluctuation	41	0
Body temperature increased	327	0
Breath sounds abnormal	1	0
Grip strength	1	0
Grip strength decreased	3	0
Head lag	3	0
Respiratory rate	2	0
Respiratory rate decreased	6	0
Respiratory rate increased	20	0
Skin temperature	45	0
Weight decreased	19	0
Weight increased	1	0
Platelet analyses		
Platelet count decreased	5	0
Protein analyses NEC		
C-reactive protein abnormal	1	0
C-reactive protein increased	1	0
Red blood cell analyses		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 24-Feb-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Haematocrit	2	0
Haemoglobin	2	0
Mean cell volume abnormal	1	0
Renal function analyses		
Blood creatinine decreased	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume	1	0
Forced expiratory volume increased	2	0
Forced expiratory volume normal	1	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	1	0
Respiratory tract and thoracic imaging procedures		
Computerised tomogram thorax	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	1	0
Therapeutic drug monitoring analyses		
Analgesic drug level	5	0
Analgesic drug level therapeutic	1	0
Anticoagulation drug level above therapeutic	1	0
Anticoagulation drug level below therapeutic	2	0
Tissue enzyme analyses NEC		
Lactate dehydrogenase urine increased	1	0
Urinalysis NEC		
Blood urine	2	0
Blood urine present	5	0
Cells in urine	1	0
Protein urine present	1	0
Urine analysis abnormal	1	0
pH urine	3	0
pH urine decreased	1	0
pH urine increased	1	0
Urinary tract function analyses NEC		
Urine output	11	0
Urine output decreased	3	0
Urine output increased	4	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	1	0
Blood pressure decreased	17	0
Blood pressure increased	57	0
Blood pressure measurement	11	0
Blood pressure systolic increased	1	0
Virus identification and serology		
Coronavirus test	8	0
SARS-CoV-2 antibody test negative	3	0
SARS-CoV-2 antibody test positive	1	0
SARS-CoV-2 test	8	0
SARS-CoV-2 test false negative	1	0
SARS-CoV-2 test negative	2	0
SARS-CoV-2 test positive	12	0
White blood cell analyses		
White blood cell count	2	0
White blood cell count decreased	2	0
White blood cell count increased	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Investigations SOC TOTAL	1878	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 24-Feb-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	1710	0
Diet refusal	1	0
Food craving	3	0
Food refusal	14	0
Hyperphagia	2	0
Hypophagia	10	0
Increased appetite	9	0
Salt craving	1	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	2	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	7	0
Diabetes mellitus inadequate control	6	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	3	2
<i>Disorders of purine metabolism</i>		
Gout	8	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	3	0
<i>Fluid intake increased</i>		
Polydipsia	7	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Food intolerance	4	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	6	0
Abnormal weight gain	2	0
Cachexia	1	0
Feeding disorder	26	0
Food aversion	16	0
Starvation	1	0
Underweight	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	35	0
Insulin resistance	1	0
<i>Hyperlipidaemias NEC</i>		
Hyperlipidaemia	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hyperinsulinaemic hypoglycaemia	1	0
Hypoglycaemia	17	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Ketosis	1	0
Metabolic acidosis	1	0
<i>Potassium imbalance</i>		
Hyperkalaemia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	4	0
<i>Total fluid volume decreased</i>		
Dehydration	140	0
<i>Total fluid volume increased</i>		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-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		
Fluid overload	1	0
Fluid retention	8	0
Metabolic disorders SOC TOTAL	2057	2

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 24-Feb-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	36	0
Arthropathy	1	0
Autoimmune arthritis	1	0
Palindromic rheumatism	1	0
Polyarthritis	1	0
Sacroiliitis	1	0
<i>Bone disorders NEC</i>		
Medial tibial stress syndrome	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	235	0
Pain in jaw	93	0
Spinal pain	39	0
<i>Bursal disorders</i>		
Bursitis	4	0
<i>Cartilage disorders</i>		
Costochondritis	2	0
<i>Connective tissue disorders NEC</i>		
Morphoea	1	0
Polymyalgia rheumatica	6	0
Reynold's syndrome	1	0
<i>Extremity deformities</i>		
Hand deformity	1	0
Limb deformity	1	0
<i>Joint related disorders NEC</i>		
Joint laxity	1	0
Joint lock	7	0
Patellofemoral pain syndrome	1	0
Periarthritis	14	0
Rotator cuff syndrome	2	0
Temporomandibular joint syndrome	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	4984	0
Joint noise	3	0
Joint stiffness	66	0
Joint swelling	68	0
Joint warmth	5	0
<i>Ligament disorders</i>		
Ligament pain	1	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	1	0
<i>Metabolic bone disorders</i>		
Osteopenia	1	0
Osteoporosis	1	0
<i>Muscle infections and inflammations</i>		
Myositis	2	0
<i>Muscle pains</i>		
Fibromyalgia	23	0
Myalgia	6537	0
Myofascial pain syndrome	3	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle discomfort	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 24-Feb-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Muscle disorder	1	0
Muscle fatigue	202	0
Muscle mass	3	0
Muscle oedema	1	0
Muscle spasms	433	0
Muscle swelling	5	0
Muscle tightness	27	0
Muscle twitching	57	0
Muscle tone abnormalities		
Muscle rigidity	13	0
Nuchal rigidity	2	0
Torticollis	2	0
Trismus	15	0
Muscle weakness conditions		
Muscular weakness	358	0
Musculoskeletal and connective tissue conditions NEC		
Limb mass	2	0
Mobility decreased	33	0
Musculoskeletal stiffness	367	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	1203	0
Flank pain	19	0
Growing pains	3	0
Limb discomfort	365	0
Musculoskeletal chest pain	70	0
Musculoskeletal discomfort	19	0
Musculoskeletal pain	19	0
Neck pain	529	0
Pain in extremity	3260	0
Rheumatic disorder	3	0
Myopathies		
Myopathy	1	0
Rhabdomyolysis	2	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	6	0
Psoriatic arthropathies		
Psoriatic arthropathy	7	0
Rheumatoid arthropathies		
Rheumatoid arthritis	13	0
Still's disease	2	0
Soft tissue disorders NEC		
Axillary mass	5	0
Groin pain	24	0
Neck mass	1	0
Soft tissue mass	1	0
Spine and neck deformities		
Spinal stenosis	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	1	0
Arthritis reactive	2	0
<i>Synovial disorders</i>		
Synovitis	2	0
<i>Tendon disorders</i>		
Tendon pain	2	0
Tendonitis	3	0
Trigger finger	2	0
Muscle & tissue disorders SOC TOTAL	19241	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Neoplasms		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	2	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>Oesophageal neoplasms malignant</i>		
Oesophageal squamous cell carcinoma	1	0
<i>Oncologic complications and emergencies</i>		
Cancer fatigue	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	1	0
<i>Skin neoplasms benign</i>		
Anogenital warts	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	13	1

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Report Run Date: 25-Feb-2021
Earliest Reaction Date: 03-Feb-1921

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Hyporeflexia	1	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	4	0
<i>Absence seizures</i>		
Petit mal epilepsy	3	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	6	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	2	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	1
Brain stem stroke	1	0
Cerebral haematoma	1	0
Cerebral haemorrhage	6	1
Cerebral infarction	2	1
Cerebrovascular accident	35	6
Embolic stroke	1	0
Haemorrhage intracranial	4	0
Haemorrhagic stroke	3	1
Ischaemic stroke	6	0
Subarachnoid haemorrhage	1	0
<i>Central nervous system inflammatory disorders NEC</i>		
Central nervous system inflammation	2	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebral small vessel ischaemic disease	1	0
Cerebrovascular disorder	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	3	0
Cerebral venous thrombosis	1	0
Superior sagittal sinus thrombosis	1	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervicobrachial syndrome	1	0
<i>Chronic polyneuropathies</i>		
Diabetic neuropathy	1	0
<i>Coma states</i>		
Coma	3	0
<i>Coordination and balance disturbances</i>		
Ataxia	4	0
Balance disorder	165	0
Cerebellar ataxia	1	0
Coordination abnormal	18	0
Dysstasia	16	0
Nystagmus	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	15	0
Neurologic neglect syndrome	1	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	4	0
Senile dementia	1	0
Vascular dementia	3	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	2	0

Case Series Drug Analysis Print

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Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Consciousness fluctuating	2	0
Depressed level of consciousness	16	0
Lethargy	1062	0
Loss of consciousness	159	0
Sedation	4	0
Somnolence	372	1
Syncope	425	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	6	0
Bradykinesia	5	0
Clumsiness	7	0
Dyskinesia	13	0
Extrapyramidal disorder	6	0
Hypokinesia	8	0
Motor dysfunction	2	0
Movement disorder	6	0
Psychomotor hyperactivity	8	0
<i>Dystonias</i>		
Dystonia	4	0
Dystonic tremor	2	0
<i>Encephalitis NEC</i>		
Noninfective encephalitis	2	0
<i>Encephalopathies NEC</i>		
Encephalopathy	1	0
<i>Eye movement disorders</i>		
IIIrd nerve paralysis	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	53	0
Facial paresis	11	0
Facial spasm	4	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	11	0
<i>Headaches NEC</i>		
Cervicogenic headache	1	0
Cluster headache	135	0
Cold-stimulus headache	4	0
Drug withdrawal headache	4	0
Exertional headache	2	0
External compression headache	1	0
Headache	18703	0
Medication overuse headache	2	0
New daily persistent headache	1	0
Occipital neuralgia	1	0
Post-traumatic headache	1	0
Primary headache associated with sexual activity	2	0
Sinus headache	166	0
Tension headache	281	0
Thunderclap headache	4	0
Vascular headache	15	0
<i>Hypoglossal nerve disorders</i>		
Tongue paralysis	1	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	2	0

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Report Run Date: 25-Feb-2021

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Intracranial pressure increased	1	0
Intellectual disabilities		
Intellectual disability	2	0
Lumbar spinal cord and nerve root disorders		
Sciatica	14	0
Memory loss (excl dementia)		
Amnesia	31	0
Memory impairment	25	0
Transient global amnesia	2	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	16	0
Disturbance in attention	71	0
Mental impairment	16	0
Migraine headaches		
Hemiplegic migraine	2	0
Migraine	1169	0
Migraine with aura	38	0
Migraine without aura	7	0
Retinal migraine	7	0
Status migrainosus	1	0
Typical aura without headache	4	0
Mononeuropathies		
Diabetic mononeuropathy	1	0
Nerve compression	2	0
Peroneal nerve palsy	1	0
Ulnar nerve palsy	1	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	13	0
Multiple sclerosis relapse	6	0
Muscle tone abnormal		
Hypotonia	3	0
Myelitis (incl infective)		
Myelitis transverse	6	0
Narcolepsy and hypersomnia		
Hypersomnia	38	0
Narcolepsy	3	0
Nervous system disorders NEC		
Cerebral disorder	1	0
Nervous system disorder	5	0
Psychomotor skills impaired	2	0
Neurologic visual problems NEC		
Tunnel vision	2	0
Visual field defect	4	0
Neurological signs and symptoms NEC		
Dizziness	4288	0
Dizziness exertional	16	0
Dizziness postural	489	1
Drooling	1	0
Exaggerated startle response	1	0
Head discomfort	79	0
Hyporesponsive to stimuli	1	0
Infant irritability	1	0

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Myoclonus	5	0
Neurological symptom	15	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	2	0
Presyncope	136	0
Unresponsive to stimuli	21	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	7	0
Muscle spasticity	3	0
Neuromuscular pain	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	1	0
Olfactory nerve disorders		
Anosmia	41	0
Hyposmia	4	0
Parosmia	71	0
Optic nerve disorders NEC		
Optic neuritis	4	0
Paraesthesias and dysaesthesias		
Anaesthesia	1	0
Burning feet syndrome	5	0
Burning sensation	89	0
Dysaesthesia	3	0
Formication	7	0
Hemianaesthesia	2	0
Hyperaesthesia	54	0
Hypoaesthesia	563	0
Lhermitte's sign	1	0
Paraesthesia	1066	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	9	0
Hemiparesis	11	0
Hemiplegia	4	0
Monoparesis	7	0
Monoplegia	19	0
Paralysis	39	0
Paraparesis	2	0
Paraplegia	1	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	38	0
Parkinson's disease	6	0
Parkinsonism	4	0
Reduced facial expression	1	0
Partial complex seizures		
Dreamy state	2	0
Focal dyscognitive seizures	1	0
Partial simple seizures NEC		
Simple partial seizures	1	0
Peripheral neuropathies NEC		
Neuropathy peripheral	24	0
Seizures and seizure disorders NEC		
Alcoholic seizure	1	0
Atonic seizures	1	0

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Clonic convulsion	1	0
Epilepsy	36	0
Febrile convulsion	22	0
Partial seizures	8	0
Seizure	182	1
Seizure anoxic	1	0
Seizure cluster	1	0
Seizure like phenomena	1	0
Status epilepticus	4	0
Tonic convulsion	5	0
Sensory abnormalities NEC		
Ageusia	179	0
Allodynia	12	0
Aura	2	0
Central pain syndrome	1	0
Complex regional pain syndrome	2	0
Dysgeusia	328	0
Hypogeusia	1	0
Neuralgia	173	0
Phantom limb syndrome	6	0
Post herpetic neuralgia	2	0
Restless arm syndrome	2	0
Restless legs syndrome	64	0
Sensory disturbance	12	0
Sensory loss	14	0
Taste disorder	93	0
Sleep disturbances NEC		
Poor quality sleep	124	0
Sleep deficit	9	0
Speech and language abnormalities		
Dysarthria	42	0
Incoherent	2	0
Slow speech	3	0
Speech disorder	5	0
Spinal cord and nerve root disorders NEC		
Myelopathy	1	0
Radiculopathy	1	0
Structural brain disorders NEC		
Brain injury	1	0
Transient cerebrovascular events		
Transient ischaemic attack	22	0
Tremor (excl congenital)		
Action tremor	1	0
Essential tremor	1	0
Head titubation	5	0
Intention tremor	1	0
Resting tremor	3	0
Tremor	2788	1
Trigeminal disorders		
Facial neuralgia	3	0
Trigeminal neuralgia	8	0
Nervous system disorders SOC TOTAL	34656	14

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	4	0
<i>Labour onset and length abnormalities</i>		
Precipitate labour	1	0
Premature labour	1	0
Premature rupture of membranes	1	0
<i>Maternal complications of pregnancy NEC</i>		
Hyperemesis gravidarum	1	0
Morning sickness	9	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	2	0
Pregnancy conditions SOC TOTAL	19	0

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

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	2	0
<i>Affect alterations NEC</i>		
Constricted affect	1	0
Flat affect	1	0
Inappropriate affect	1	0
<i>Amnesic symptoms</i>		
Paramnesia	2	0
<i>Anxiety symptoms</i>		
Agitation	41	0
Anxiety	118	0
Nervousness	157	0
Stress	2	0
Tension	9	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	3	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	2	0
Indifference	1	0
Paranoia	3	0
Social avoidant behaviour	1	0
Soliloquy	1	0
Violence-related symptom	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	3	0
Mental fatigue	64	0
<i>Communications disorders</i>		
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	382	0
Disorientation	157	0
<i>Deliria</i>		
Delirium	127	0
<i>Delusional symptoms</i>		
Delusion	4	0
<i>Depressive disorders</i>		
Agitated depression	1	0
Depression	50	0
Major depression	3	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	3	0
Dissociation	5	0
Dissociative disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	7	0
Insomnia	640	0
Middle insomnia	10	0
Terminal insomnia	1	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	6	0
Emotional disorder	19	0

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Emotional distress	6	0
Euphoric mood	7	0
Frustration tolerance decreased	2	0
Irritability	48	0
Mood altered	5	0
Factitious disorders		
Factitious disorder	3	0
Fear symptoms and phobic disorders (incl social phobia)		
Agoraphobia	1	0
Fear	3	0
Fear of death	2	0
Fear of disease	1	0
Fear of falling	1	0
Phonophobia	1	0
Fluctuating mood symptoms		
Mood swings	4	0
Hallucinations (excl sleep-related)		
Hallucination	227	0
Hallucination, auditory	3	0
Hallucination, visual	13	0
Hallucinations, mixed	2	0
Increased physical activity levels		
Restlessness	101	0
Mental disorders NEC		
Mental disorder	2	0
Mental status changes	1	0
Mood alterations with depressive symptoms		
Anhedonia	2	0
Decreased interest	4	0
Depressed mood	60	0
Feeling of despair	3	0
Negative thoughts	2	0
Sense of a foreshortened future	1	0
Tearfulness	20	0
Mood alterations with manic symptoms		
Mania	3	0
Mood disorders NEC		
Apathy	7	0
Listless	34	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	1	0
Obsessive-compulsive disorders and symptoms		
Obsessive thoughts	1	0
Panic attacks and disorders		
Panic attack	29	0
Panic reaction	5	0
Parasomnias		
Abnormal dreams	71	0
Confusional arousal	2	0
Exploding head syndrome	1	0
Nightmare	87	0
Rapid eye movements sleep abnormal	1	0
Sleep talking	4	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Sleep terror	9	0
Sleep-related eating disorder	1	0
Somnambulism	1	0
Perception disturbances NEC		
Autoscopy	6	0
Derealisation	2	0
Illusion	3	0
Time perception altered	2	0
Psychiatric elimination disorders		
Enuresis	8	0
Psychiatric symptoms NEC		
Hypervigilance	2	0
Psychological trauma	1	0
Psychotic disorder NEC		
Psychotic disorder	5	0
Sexual desire disorders		
Loss of libido	2	0
Sleep disorders NEC		
Sleep disorder	70	0
Somatic symptom disorders		
Conversion disorder	1	0
Habit cough	5	0
Somatic symptom disorder	1	0
Speech and language usage disturbances		
Logorrhoea	2	0
Speech articulation and rhythm disturbances		
Dysphemia	1	0
Lack of spontaneous speech	1	0
Stereotypies and automatisms		
Bruxism	4	0
Head banging	5	0
Stress disorders		
Acute stress disorder	1	0
Burnout syndrome	1	0
Hyperarousal	1	0
Post-traumatic stress disorder	3	0
Substance related and addictive disorders		
Alcohol abuse	1	0
Drug dependence	1	0
Substance abuse	1	0
Suicidal and self-injurious behaviour		
Intentional self-injury	1	0
Suicidal ideation	8	0
Suicide threat	1	0
Thinking disturbances		
Bradyphrenia	11	0
Intrusive thoughts	1	0
Tachyphrenia	4	0
Thinking abnormal	3	0
Thought blocking	1	0
Psychiatric disorders SOC TOTAL	2773	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	1	0
Bladder pain	8	0
Bladder spasm	1	0
Dysuria	17	0
Incontinence	17	0
Micturition frequency decreased	1	0
Micturition urgency	30	0
Mixed incontinence	1	0
Pollakiuria	69	0
Urinary hesitation	3	0
Urinary incontinence	21	0
Urinary retention	15	0
Urine flow decreased	2	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	3	0
<i>Bladder infections and inflammations</i>		
Cystitis interstitial	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
IgA nephropathy	1	0
<i>Myoneurogenic bladder disorders</i>		
Hypertonic bladder	2	0
Loss of bladder sensation	3	0
Neurogenic bladder	1	0
<i>Nephritis NEC</i>		
Nephritis	1	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	1	0
<i>Renal disorders NEC</i>		
Renal disorder	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	11	0
Chronic kidney disease	2	0
Oliguria	3	0
Renal failure	3	1
Renal injury	1	0
<i>Structural and obstructive urethral disorders (excl congenital)</i>		
Urethral spasm	1	0
<i>Urinary abnormalities</i>		
Chromaturia	13	0
Haematuria	5	0
Proteinuria	1	0
Urine abnormality	2	0
Urine odour abnormal	6	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	1	0
Nocturia	2	0
Polyuria	11	0
Renal colic	1	0
Renal pain	189	0
Renal & urinary disorders SOC TOTAL	453	1

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Breast enlargement	1	0
Breast mass	3	0
<i>Breast signs and symptoms</i>		
Breast oedema	1	0
Breast pain	37	0
Breast swelling	1	0
Breast tenderness	8	0
Nipple pain	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation failure	1	0
Erectile dysfunction	3	0
Organic erectile dysfunction	1	0
Retrograde ejaculation	1	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	2	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	11	0
Menstrual disorder	8	0
Menstruation irregular	7	0
Metrorrhagia	4	0
Premenstrual pain	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	2	0
Hypomenorrhoea	6	0
Menstruation delayed	10	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	18	0
Polymenorrhoea	2	0
<i>Pelvic prolapse conditions</i>		
Vaginal prolapse	1	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile oedema	1	0
Penis disorder	1	0
Peyronie's disease	1	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	1	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Female genital tract fistula	1	0
Genital blister	1	0
Genital ulceration	3	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital burning sensation	1	0
Genital discomfort	1	0
Pelvic discomfort	1	0
Pelvic pain	16	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	1	0
Scrotal swelling	2	0
<i>Sexual function and fertility disorders NEC</i>		
Sexual dysfunction	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021

Data Lock Date: 24-Feb-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	10	0
Testicular swelling	1	0
<i>Uterine disorders NEC</i>		
Uterine haemorrhage	1	0
Uterine pain	1	0
<i>Uterine tone disorders</i>		
Uterine spasm	3	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	34	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	4	0
Vaginal lesion	3	0
Vulvovaginal pain	4	0
Vulvovaginal rash	1	0
Vulvovaginal swelling	2	0
Reproductive & breast disorders SOC TOTAL	229	0

Case Series Drug Analysis Print

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Report Run Date: 25-Feb-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 24-Feb-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	969	2
Dyspnoea at rest	1	0
Dyspnoea exertional	5	0
Hyperventilation	12	0
Hypopnoea	45	0
Irregular breathing	3	0
Mouth breathing	1	0
Orthopnoea	1	0
Respiration abnormal	21	0
Respiratory arrest	6	0
Respiratory distress	3	0
Sleep apnoea syndrome	3	0
Tachypnoea	19	0
<i>Bronchial conditions NEC</i>		
Bronchiectasis	3	0
<i>Bronchospasm and obstruction</i>		
Asthma	76	0
Bronchospasm	6	0
Chronic obstructive pulmonary disease	12	2
Cough variant asthma	1	0
Obstructive airways disorder	1	0
Wheezing	116	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	18	0
<i>Coughing and associated symptoms</i>		
Cough	684	0
Haemoptysis	10	0
Productive cough	24	0
Sputum discoloured	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	5	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonia aspiration	5	3
Pneumonitis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	6	0
Pleuritic pain	4	0
Pulmonary pain	32	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	90	0
Nasal inflammation	2	0
Rhinitis allergic	1	0
Rhinitis perennial	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	169	0
Nasal disorder	1	0
Nasal dryness	12	0
Nasal odour	2	0
Nasal oedema	1	0
Nasal pruritus	2	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 24-Feb-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Paranasal sinus haemorrhage	1	0
Paranasal sinus inflammation	1	0
Sinonasal obstruction	1	0
Sinus congestion	9	0
Sinus disorder	1	0
<i>Parenchymal lung disorders NEC</i>		
Pulmonary toxicity	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Oropharyngeal swelling	1	0
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	4	0
Pharyngeal oedema	1	0
Pharyngeal paraesthesia	6	0
Pharyngeal swelling	39	0
Pharyngeal ulceration	1	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	11	0
Tonsillar inflammation	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
Pneumothorax	1	0
<i>Pulmonary oedemas</i>		
Acute pulmonary oedema	1	0
Pulmonary congestion	3	0
Pulmonary oedema	3	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	11	0
Pulmonary infarction	1	1
<i>Respiratory signs and symptoms NEC</i>		
Respiratory symptom	4	0
Suffocation feeling	2	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	3	2
Lung disorder	2	0
Respiratory tract congestion	1	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal pain	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	17	0
Catarrh	4	0
Choking	6	0
Choking sensation	3	0
Dry throat	63	0
Dysphonia	24	0
Increased viscosity of upper respiratory secretion	2	0
Nasal discomfort	16	0
Oropharyngeal discomfort	5	0
Oropharyngeal pain	824	0
Paranasal sinus discomfort	3	0
Rhinalgia	5	0
Rhinorrhoea	335	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Sinus pain	77	0
Sneezing	89	0
Throat clearing	2	0
Throat irritation	41	0
Throat tightness	30	0
Upper-airway cough syndrome	4	0
Yawning	18	0
Respiratory disorders SOC TOTAL	4059	10

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 25-Feb-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 24-Feb-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	2	0
<i>Alopecias</i>		
Alopecia	9	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	60	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	1	0
Cold sweat	400	0
Hyperhidrosis	2107	0
Miliaria	22	0
Night sweats	386	0
Sweat discolouration	1	0
Sweat gland disorder	1	0
<i>Bullous conditions</i>		
Blister	46	0
Blood blister	2	0
Dermatitis bullous	2	0
Erythema multiforme	5	0
Pemphigoid	1	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	42	0
Macule	1	0
Pain of skin	214	0
Papule	7	0
Peau d'orange	1	0
Scab	2	0
Scar pain	3	0
Sensitive skin	121	0
Skin burning sensation	105	0
Skin discolouration	16	0
Skin disorder	5	0
Skin fissures	1	0
Skin fragility	1	0
Skin lesion	1	0
Skin necrosis	1	0
Skin odour abnormal	5	0
Skin reaction	42	0
Skin sensitisation	18	0
Skin swelling	15	0
Skin texture abnormal	1	0
Skin tightness	2	0
Skin warm	97	0
Sticky skin	1	0
Yellow skin	7	0
<i>Dermatitis and eczema</i>		
Dermatitis	30	0
Dermatitis allergic	44	0
Dermatitis atopic	1	0
Dyshidrotic eczema	1	0

Case Series Drug Analysis Print

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Report Run Date: 25-Feb-2021
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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Eczema	10	0
Eczema asteatotic	1	0
Eczema nummular	1	0
Perioral dermatitis	1	0
Rebound eczema	1	0
Seborrhoeic dermatitis	1	0
Skin irritation	28	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	9	0
Fixed eruption	1	0
<i>Erythemas</i>		
Erythema	618	0
Palmar erythema	2	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	0
Exfoliative rash	2	0
Skin exfoliation	13	0
<i>Lipodystrophies</i>		
Lipohypertrophy	1	0
<i>Panniculitides</i>		
Erythema nodosum	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
Pityriasis rosea	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	32	0
<i>Pilar disorders NEC</i>		
Hair growth abnormal	1	0
Piloerection	15	0
Trichodynia	2	0
<i>Pruritus NEC</i>		
Itching scar	1	0
Pruritus	1066	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
Psoriasis	11	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
Henoch-Schonlein purpura	1	0
Petechiae	13	0
Purpura	6	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	2	0
Rash	1083	0
Rash erythematous	322	0
Rash macular	73	0
Rash maculo-papular	11	0
Rash papular	56	0
Rash pruritic	244	0
Rash vesicular	7	0
Systemic lupus erythematosus rash	1	0
<i>Rosaceas</i>		
Rosacea	3	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		
<i>Skin and subcutaneous conditions NEC</i>		
Cutaneous symptom	1	0
Skin mass	2	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin erosion	8	0
Skin ulcer	3	0
<i>Skin cysts and polyps</i>		
Dermal cyst	1	0
<i>Skin haemorrhages</i>		
Skin haemorrhage	1	0
<i>Skin injuries and mechanical dermatoses</i>		
Decubitus ulcer	1	0
Needle track marks	1	0
<i>Skin vasculitides</i>		
Cutaneous vasculitis	1	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	4	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	7	0
<i>Urticarias</i>		
Idiopathic urticaria	2	0
Urticaria	357	0
Urticaria chronic	2	0
Urticaria papular	1	0
Urticularial vasculitis	1	0
Skin disorders SOC TOTAL	7872	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	21	0
Disability	1	0
Immobile	7	0
Impaired driving ability	1	0
Impaired work ability	2	0
Sight disability	3	0
<i>Employment issues</i>		
Retirement	1	0
<i>Social issues NEC</i>		
Impaired quality of life	1	0
<i>Tobacco use</i>		
Tobacco user	1	0
Social circumstances SOC TOTAL	39	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Antiinfective therapies</i>		
COVID-19 treatment	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	9	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	3	0
<i>Immunisations</i>		
COVID-19 immunisation	39	1
Immunisation	27	0
<i>Joint therapeutic procedures</i>		
Hip surgery	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	6	0
Limb operation	1	0
<i>Muscle therapeutic procedures</i>		
Muscle relaxant therapy	1	0
<i>Nervous system therapeutic procedures NEC</i>		
Central nervous system stimulation	1	0
<i>Patient positioning</i>		
Prone position	1	0
<i>Small intestine therapeutic procedures</i>		
Ileostomy	1	0
<i>Therapeutic procedures NEC</i>		
Bed rest	4	0
Hospitalisation	2	0
Injection	10	0
Localised alternating hot and cold therapy	2	0
Mass excision	1	0
Therapy change	1	0
<i>Uterine therapeutic procedures</i>		
Endometrial ablation	1	0
Surgical & medical procedures SOC TOTAL	117	1

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive emergency	1	0
Hypertensive urgency	1	0
Tyramine reaction	1	0
<i>Aortic aneurysms and dissections</i>		
Aortic aneurysm	1	0
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	7	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	23	0
Neurogenic shock	2	0
Shock	14	0
Shock symptom	3	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	6	0
Haemorrhage	17	1
<i>Lymphoedemas</i>		
Lymphoedema	10	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	0
Thrombosis	3	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arteriosclerosis	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	4	0
Vasodilatation	3	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	1	0
Deep vein thrombosis	12	0
Pelvic venous thrombosis	1	0
Thrombophlebitis superficial	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	22	0
Erythromelalgia	1	0
Flushing	163	0
Hot flush	372	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Ischaemic limb pain	2	0
Peripheral coldness	233	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	13	0
<i>Site specific vascular disorders NEC</i>		
Pallor	113	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicophlebitis	1	0
Varicose vein	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	104	0
<i>Vascular hypotensive disorders</i>		

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Capillary leak syndrome	2	0
Hypotension	114	0
Orthostatic hypotension	9	0
<i>Vasculitides NEC</i>		
MAGIC syndrome	1	0
Vasculitis	5	0
Vascular disorders SOC TOTAL	1274	1
TOTAL REACTIONS FOR DRUG	157637	244
TOTAL REPORTS	42917	
TOTAL FATAL OUTCOME REPORTS		244