

COVID-19 vaccine Oxford University/AstraZeneca analysis print

Report Run Date: 22-Feb-2021
Data Lock Date: 19-Feb-2021 19:00:04

All UK spontaneous reports received between 4/01/21 and 14/02/21 for COVID-19 vaccine Oxford University/AstraZeneca

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

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

Data Lock Date: 19-Feb-2021 19:00:04
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Blood disorders		
Anaemias NEC		
Anaemia	1	0
Anaemias haemolytic NEC		
Haemolytic anaemia	1	0
Anaemias haemolytic immune		
Autoimmune haemolytic anaemia	1	0
Bleeding tendencies		
Increased tendency to bruise	1	0
Coagulopathies		
Coagulopathy	1	0
Eosinophilic disorders		
Eosinophilia	2	0
Haematological disorders		
Bone marrow oedema	1	0
Methaemoglobinaemia	1	0
Haemolyses NEC		
Haemolysis	1	0
Leukocytoses NEC		
Lymphocytosis	1	0
Leukopenias NEC		
Leukopenia	2	0
Lymphatic system disorders NEC		
Lymph node pain	53	0
Lymphadenitis	6	0
Lymphadenopathy	476	0
Marrow depression and hypoplastic anaemias		
Pancytopenia	1	0
Neutropenias		
Neutropenia	14	0
Spleen disorders		
Spleen disorder	1	0
Splenomegaly	1	0
Thrombocytopenias		
Immune thrombocytopenia	6	0
Thrombocytopenia	4	0
Thrombocytopenic purpura	1	0
White blood cell abnormal findings NEC		
White blood cell disorder	1	0
Blood disorders SOC TOTAL	577	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	3	0
Cardiovascular insufficiency	2	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	1	0
Palpitations	604	0
<i>Heart failures NEC</i>		
Cardiac failure	2	0
Cardiac failure acute	1	0
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	1	0
Angina pectoris	11	0
Angina unstable	1	0
Myocardial infarction	14	6
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>Noninfectious pericarditis</i>		
Pericarditis	2	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	18	0
Bradycardia	13	0
Cardiac flutter	11	0
Extrasystoles	8	0
Tachyarrhythmia	2	0
Tachycardia	285	0
<i>Right ventricular failures</i>		
Right ventricular failure	1	1
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	4	0
Atrial fibrillation	25	0
Atrial flutter	3	0
Sinus arrhythmia	1	0
Sinus tachycardia	10	0
Supraventricular tachycardia	5	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	20	10
Ventricular arrhythmia	1	0
Ventricular extrasystoles	1	0
Ventricular fibrillation	1	0
Ventricular tachycardia	2	0
Cardiac disorders SOC TOTAL	1069	22

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cerebral disorders congenital</i>		
Cerebral palsy	2	0
<i>Peripheral nervous system disorders congenital NEC</i>		
Paroxysmal extreme pain disorder	2	0
<i>Pulmonary and bronchial disorders congenital</i>		
Cystic fibrosis	2	0
Congenital disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	10	0
Ear pain	235	0
Ear swelling	9	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	18	0
Deafness bilateral	1	0
Deafness transitory	2	0
Deafness unilateral	1	0
Hypoacusis	17	0
Sudden hearing loss	5	0
<i>Hyperacusia</i>		
Hyperacusis	10	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	12	0
Tinnitus	136	0
Vertigo	145	0
Vertigo labyrinthine	1	0
Vertigo positional	11	0
Ear disorders SOC TOTAL	617	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Adrenal cortical hypofunctions</i>		
Adrenal insufficiency	2	0
Adrenocortical insufficiency acute	6	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	1	0
<i>Thyroid disorders NEC</i>		
Thyroid pain	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	4	0
Endocrine disorders SOC TOTAL	14	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	3	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	1	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	3	0
Eyelid ptosis	2	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>		
Uveitis	1	0
<i>Lacrimation disorders</i>		
Dry eye	22	0
Lacrimation increased	22	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Erythema of eyelid	1	0
Eyelid oedema	1	0
Swelling of eyelid	5	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye pain	466	0
Eye swelling	61	0
Eye symptom	1	0
Ocular discomfort	3	0
Periorbital oedema	3	0
Periorbital swelling	13	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	5	0
Eye inflammation	1	0
Eye irritation	28	0
Eye pruritus	24	0
Ocular hyperaemia	30	0
<i>Ocular nerve and muscle disorders</i>		
Extraocular muscle paresis	2	0
Eye movement disorder	5	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	3	0
Asthenopia	27	0
Eyelid sensory disorder	1	0
Foreign body sensation in eyes	4	0
Hypoaesthesia eye	2	0
Photophobia	146	0
<i>Pupil disorders</i>		
Miosis	1	0
Mydriasis	3	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Pupils unequal	2	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal aneurysm	1	0
Retinal vascular thrombosis	1	0
Retinal structural change, deposit and degeneration		
Vitreoretinal traction syndrome	1	0
Scleral infections, irritations and inflammations		
Episcleritis	2	0
Visual colour distortions		
Chromatopsia	1	0
Xanthopsia	1	0
Visual disorders NEC		
Diplopia	18	0
Halo vision	1	0
Metamorphopsia	3	0
Photopsia	22	0
Vision blurred	134	0
Visual snow syndrome	1	0
Visual impairment and blindness (excl colour blindness)		
Blindness	16	0
Blindness transient	2	0
Night blindness	1	0
Sudden visual loss	1	0
Visual acuity reduced	3	0
Visual impairment	50	0
Eye disorders SOC TOTAL	1157	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
Gastrointestinal sounds abnormal	1	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	1
Pancreatitis	4	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
<i>Colitis (excl infective)</i>		
Colitis	1	0
Colitis ischaemic	1	0
Colitis ulcerative	7	0
Crohn's disease	7	0
<i>Dental disorders NEC</i>		
Teething	3	0
<i>Dental pain and sensation disorders</i>		
Dental paraesthesia	2	0
Hyperaesthesia teeth	5	0
Toothache	44	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1423	0
Diarrhoea haemorrhagic	3	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	104	0
Epigastric discomfort	3	0
Eructation	10	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
Faecaloma	1	0
Faeces discoloured	3	0
Faeces soft	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	36	0
Flatulence	51	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	1	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	2	0
<i>Gastritis (excl infective)</i>		
Gastritis	6	0
Reflux gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	651	0
Abdominal pain lower	25	0
Abdominal pain upper	672	0
Abdominal rigidity	6	0
Abdominal tenderness	3	0
Gastrointestinal pain	53	0
Oesophageal pain	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	35	0
Gastric dilatation	3	0
Gastrooesophageal reflux disease	22	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	2	0
Gastric disorder	1	0
Gastrointestinal disorder	6	0
Neurogenic bowel	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Gastrointestinal tract irritation	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	210	0
Acute abdomen	2	0
Anal incontinence	3	0
Breath odour	1	0
Dysphagia	27	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	3	0
Frequent bowel movements	4	0
Irritable bowel syndrome	9	0
Oesophageal spasm	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	5	0
Gingival oedema	1	0
Gingival pain	29	0
Gingival pruritus	1	0
Gingival swelling	4	0
Noninfective gingivitis	3	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	5	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	8	0
Small intestinal haemorrhage	3	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	3	0
Nausea	6036	0
Retching	54	0
Vomiting	2306	2
Vomiting projectile	19	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	2	0
Haematochezia	9	0
Melaena	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	177	0
Lip dry	9	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Saliva altered	1	0
Salivary hypersecretion	8	0
Oral soft tissue disorders NEC		
Chapped lips	1	0
Cheilitis	6	0
Enlarged uvula	1	0
Lip blister	4	0
Lip disorder	1	0
Oral soft tissue haemorrhages		
Oral blood blister	2	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	1	0
Burning mouth syndrome	1	0
Hypoaesthesia oral	64	0
Lip erythema	1	0
Lip pain	11	0
Lip pruritus	7	0
Odynophagia	1	0
Oral discomfort	10	0
Oral mucosal blistering	5	0
Oral mucosal eruption	1	0
Oral pain	41	0
Oral pruritus	2	0
Paraesthesia oral	107	0
Oral soft tissue swelling and oedema		
Lip oedema	1	0
Lip swelling	128	0
Mouth swelling	21	0
Oedema mouth	1	0
Palatal swelling	3	0
Rectal inflammations NEC		
Proctitis	1	0
Salivary gland disorders NEC		
Salivary gland pain	2	0
Salivary gland enlargements		
Parotid gland enlargement	1	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	1	0
Stomatitis and ulceration		
Aphthous ulcer	5	0
Lip ulceration	2	0
Mouth ulceration	51	0
Stomatitis	8	0
Tongue disorders		
Glossitis	2	0
Plicated tongue	1	0
Tongue disorder	2	0
Trichoglossia	2	0
Tongue signs and symptoms		
Glossodynia	27	0
Scalloped tongue	1	0
Swollen tongue	64	0
Tongue blistering	4	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tongue coated	3	0
Tongue discolouration	3	0
Tongue discomfort	4	0
Tongue dry	6	0
Tongue eruption	1	0
Tongue movement disturbance	1	0
Tongue oedema	3	0
Tongue pruritus	1	0
Tongue spasm	1	0
Gastrointestinal disorders SOC TOTAL	12776	3

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Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site bruise	3	0
Administration site pain	9	0
Administration site urticaria	1	0
Puncture site bruise	5	0
Puncture site pain	2	0
Puncture site reaction	1	0
Adverse effect absent		
No adverse event	5	0
Application and instillation site reactions		
Application site bruise	2	0
Application site erythema	3	0
Application site joint pain	1	0
Application site pain	4	0
Application site pruritus	1	0
Instillation site warmth	2	0
Asthenic conditions		
Asthenia	734	3
Chronic fatigue syndrome	5	0
Fatigue	7321	0
Malaise	1996	2
Sluggishness	3	0
Body temperature altered		
Hyperthermia	3	0
Hypothermia	12	0
Temperature regulation disorder	4	0
Complications associated with device NEC		
Phantom shocks	1	0
Death and sudden death		
Cardiac death	1	1
Death	111	111
Sudden death	8	8
Febrile disorders		
Hyperpyrexia	17	0
Masked fever	1	0
Pyrexia	11113	0
Feelings and sensations NEC		
Chills	8363	0
Feeling abnormal	302	0
Feeling cold	1019	0
Feeling drunk	5	0
Feeling hot	333	0
Feeling jittery	4	0
Feeling of body temperature change	178	0
Hangover	11	0
Hunger	5	0
Sensation of foreign body	6	0
Temperature intolerance	5	0
Thirst	240	0
Thirst decreased	3	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Gait disturbance	42	0
Gait inability	35	0
Loss of control of legs	6	0
General signs and symptoms NEC		
Condition aggravated	20	0
Crying	18	0
Energy increased	1	0
Foaming at mouth	1	0
General physical health deterioration	5	1
General symptom	1	0
Illness	908	0
Induration	1	0
Influenza like illness	1762	0
Local reaction	50	0
Moaning	1	0
Multiple organ dysfunction syndrome	2	0
Peripheral swelling	639	0
Screaming	1	0
Secretion discharge	4	0
Swelling	305	0
Swelling face	110	0
Implant and catheter site reactions		
Implant site warmth	2	0
Inflammations		
Inflammation	65	0
Infusion site reactions		
Infusion site bruising	1	0
Infusion site pain	2	0
Injection site reactions		
Injected limb mobility decreased	6	0
Injection site bruising	10	0
Injection site coldness	1	0
Injection site discomfort	1	0
Injection site erythema	83	0
Injection site hypoaesthesia	3	0
Injection site indentation	2	0
Injection site inflammation	14	0
Injection site joint erythema	1	0
Injection site joint pain	11	0
Injection site mass	185	0
Injection site oedema	6	0
Injection site pain	655	0
Injection site papule	1	0
Injection site paraesthesia	2	0
Injection site pruritus	43	0
Injection site rash	32	0
Injection site reaction	17	0
Injection site swelling	27	0
Injection site urticaria	3	0
Injection site vesicles	2	0
Injection site warmth	55	0
Interactions		
Drug interaction	1	0

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General disorders General disorders cont'd		
Mass conditions NEC		
Mass	3	0
Mucosal findings abnormal		
Mucosal inflammation	1	0
Mucosal pain	1	0
Oedema NEC		
Face oedema	2	0
Localised oedema	3	0
Oedema	1	0
Oedema peripheral	6	0
Pain and discomfort NEC		
Axillary pain	48	0
Chest discomfort	268	0
Chest pain	505	1
Discomfort	31	0
Facial discomfort	3	0
Facial pain	32	0
Inflammatory pain	3	0
Non-cardiac chest pain	5	0
Pain	2463	0
Tenderness	284	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	116	0
Adverse event	1	1
Adverse reaction	6	0
Diet failure	1	0
Drug ineffective	9	0
Drug intolerance	1	0
No reaction on previous exposure to drug	6	0
Therapeutic product effect decreased	1	0
Therapeutic response unexpected	3	0
Treatment failure	2	0
Vaccine positive rechallenge	1	0
Ulcers NEC		
Ulcer	3	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	2	0
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	11	0
Vaccination site discolouration	1	0
Vaccination site discomfort	2	0
Vaccination site erythema	89	0
Vaccination site extravasation	1	0
Vaccination site granuloma	2	0
Vaccination site haemorrhage	1	0
Vaccination site induration	12	0
Vaccination site inflammation	10	0
Vaccination site irritation	1	0
Vaccination site joint movement impairment	2	0
Vaccination site joint pain	14	0
Vaccination site joint swelling	1	0
Vaccination site mass	64	0
Vaccination site movement impairment	3	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site pain	263	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	14	0
Vaccination site rash	15	0
Vaccination site reaction	5	0
Vaccination site swelling	72	0
Vaccination site urticaria	1	0
Vaccination site vesicles	1	0
Vaccination site warmth	37	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	3	0
General disorders SOC TOTAL	41429	127

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	3	0
<i>Cholecystitis and cholelithiasis</i>		
Cholelithiasis	1	0
<i>Cholestasis and jaundice</i>		
Jaundice	2	0
Ocular icterus	1	0
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	5	0
Hepatic disorders SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	2	0
Allergy to sting	1	0
Hypersensitivity	110	0
Multiple allergies	1	0
Serum sickness	6	0
Serum sickness-like reaction	7	0
Type III immune complex mediated reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	9	0
Drug hypersensitivity	10	0
Reaction to excipient	1	0
Reaction to preservatives	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	97	0
Anaphylactic shock	4	0
Anaphylactoid reaction	3	0
Anaphylactoid shock	1	0
<i>Atopic disorders</i>		
Seasonal allergy	2	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	5	0
Immune system disorder	2	0
Sensitisation	3	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	270	0

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Earliest Reaction Date: 03-Feb-1921Data Lock Date: 19-Feb-2021 19:00:04
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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	1	0
Gastroenteritis	4	0
Gastrointestinal infection	1	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Arthritis bacterial	1	0
Bacterial infection	4	1
Cellulitis	84	1
Vaccination site cellulitis	3	0
<i>Bone and joint infections</i>		
Intervertebral discitis	1	0
<i>Breast infections</i>		
Mastitis	2	0
<i>Candida infections</i>		
Candida infection	3	0
Oral candidiasis	3	0
Vulvovaginal candidiasis	2	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
Myelitis	1	0
<i>Clostridia infections</i>		
Clostridium difficile colitis	1	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	1	0
COVID-19	108	10
COVID-19 pneumonia	2	1
Severe acute respiratory syndrome	2	0
Suspected COVID-19	8	0
<i>Coxiella infections</i>		
Q fever	19	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	1	0
Gingival abscess	2	0
Gingivitis	2	0
Oral pustule	1	0
Tooth abscess	1	0
<i>Ear infections</i>		
Ear infection	2	0
Labyrinthitis	9	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	3	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	6	0
Eye infection	1	0
Eyelid infection	2	0
Hordeolum	1	0
<i>Fungal infections NEC</i>		
Fungal infection	1	0
<i>Herpes viral infections</i>		
Genital herpes	2	0
Genital herpes simplex	1	0
Herpes simplex	4	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Herpes zoster	56	0
Ophthalmic herpes zoster	1	0
Oral herpes	69	0
Varicella	1	0
Infections NEC		
Abscess	3	0
Abscess limb	1	0
Infection	27	1
Injection site infection	3	0
Localised infection	11	0
Vaccination site infection	6	0
Influenza viral infections		
H2N2 influenza	1	0
Influenza	1157	0
Lower respiratory tract and lung infections		
Lower respiratory tract infection	18	1
Pneumonia	13	5
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		
Sepsis	15	2
Urosepsis	2	1
Skin structures and soft tissue infections		
Folliculitis	1	0
Rash pustular	1	0
Skin infection	8	0
Subcutaneous abscess	1	0
Staphylococcal infections		
Furuncle	1	0
Staphylococcal scalded skin syndrome	1	0
Streptococcal infections		
Erysipelas	1	0
Tuberculous infections		
Tuberculosis	1	0
Upper respiratory tract infections		
Acute sinusitis	1	0
Laryngitis	3	0
Nasopharyngitis	214	0
Pharyngitis	5	0
Rhinitis	8	0
Sinusitis	23	0
Tonsillitis	9	0
Urinary tract infections		
Cystitis	6	0
Kidney infection	5	0
Urinary tract infection	16	0
Vascular infections		

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Infected lymphocele	1	0
Viral infections NEC		
Gastroenteritis viral	10	0
Post viral fatigue syndrome	5	0
Sweating fever	127	0
Vestibular neuronitis	1	0
Viral infection	3	0
Viral pharyngitis	1	0
Viral rash	3	0
Viral sepsis	1	0
Infections SOC TOTAL	2138	23

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Oral contusion	1	0
Splenic rupture	1	0
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
<i>Cerebral injuries NEC</i>		
Subdural haematoma	1	0
<i>Conditions caused by cold</i>		
Chillblains	2	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	2	0
Foetal exposure during pregnancy	2	0
Maternal exposure during breast feeding	5	0
Maternal exposure during pregnancy	19	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	2	0
Eye injury	2	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural nausea	9	0
Procedural vomiting	2	0
<i>Heat injuries (excl thermal burns)</i>		
Heat exhaustion	1	0
Heat oedema	2	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Device use issue	1	0
Medication error	2	0
Vaccination error	1	0
Wrong technique in product usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Ligament sprain	1	0
Muscle strain	1	0
Tendon rupture	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	5	0
<i>Neurological and psychiatric procedural complications</i>		
Post lumbar puncture syndrome	4	0
Procedural dizziness	7	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	1	0
Exposure to noise	1	0
<i>Non-site specific injuries NEC</i>		
Arthropod bite	2	0
Arthropod sting	1	0
Electric shock	1	0
Fall	32	0
Inflammation of wound	1	0
Road traffic accident	1	0
Wound complication	1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Non-site specific procedural complications</i>		
Incision site pain	2	0
Infusion related reaction	7	0
Injection related reaction	168	0
Post procedural complication	11	0
Suture related complication	1	0
<i>Occupational exposures</i>		
Occupational exposure to product	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Peripheral nerve injuries</i>		
Ulnar nerve injury	1	0
<i>Poisoning and toxicity</i>		
Toxicity to various agents	1	0
<i>Product administration errors and issues</i>		
Expired product administered	2	0
Extra dose administered	1	0
Inappropriate schedule of product administration	1	0
Product administered to patient of inappropriate age	1	0
Product administration error	3	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Radiation injuries</i>		
Sunburn	1	0
<i>Site specific injuries NEC</i>		
Head injury	1	0
Limb crushing injury	1	0
Limb injury	4	0
<i>Skin injuries NEC</i>		
Contusion	91	0
Skin injury	1	0
<i>Stoma complications</i>		
Gastrointestinal stoma complication	1	0
<i>Thermal burns</i>		
Burn of internal organs	1	0
Burns second degree	1	0
Thermal burn	4	0
Thermal burns of eye	5	0
<i>Underdoses NEC</i>		
Intentional underdose	1	0
<i>Vaccination related complications</i>		
Vaccination complication	19	0
Injuries SOC TOTAL	454	0

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Reaction Name	Total	Fatal
Investigations		
Adrenal cortex tests		
Cortisol increased	1	0
Autoimmunity analyses		
Cold agglutinins positive	1	0
Blood gas and acid base analyses		
Blood pH increased	2	0
Oxygen saturation	9	0
Oxygen saturation decreased	44	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose	4	0
Blood glucose abnormal	2	0
Blood glucose decreased	5	0
Blood glucose fluctuation	2	0
Blood glucose increased	22	0
Glycosylated haemoglobin increased	1	0
Central nervous system imaging procedures		
Computerised tomogram head	2	0
Magnetic resonance imaging brain	19	0
Chemistry analyses NEC		
Inflammatory marker decreased	1	0
Inflammatory marker increased	1	0
Coagulation and bleeding analyses		
Coagulation time prolonged	1	0
International normalised ratio decreased	4	0
International normalised ratio increased	8	0
Faecal analyses NEC		
Faecal calprotectin increased	1	0
Fertility analyses		
Semen volume decreased	1	0
Gastrointestinal and abdominal imaging procedures		
Computerised tomogram abdomen	1	0
Gastrointestinal function diagnostic procedures		
Gastrointestinal stoma output increased	1	0
Gastrointestinal, pancreatic and APUD hormone analyses		
Blood gastrin normal	1	0
Blood insulin	1	0
Heart rate and pulse investigations		
Heart rate	113	0
Heart rate abnormal	5	0
Heart rate decreased	8	0
Heart rate increased	282	0
Heart rate irregular	19	0
Maximum heart rate	1	0
Maximum heart rate decreased	1	0
Orthostatic heart rate response increased	1	0
Pulse abnormal	2	0
Pulse absent	1	0
Sinus rhythm	1	0
Imaging procedures NEC		
Computerised tomogram	1	0
Immunology skin tests NEC		
Allergy alert test	1	0
Investigations NEC		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood test	4	0
Liver function analyses		
Alanine aminotransferase increased	1	0
Aspartate aminotransferase increased	1	0
Liver function test abnormal	1	0
Transaminases increased	1	0
Metabolism tests NEC		
Blood ketone body	2	0
Ubiquinone	1	0
Mineral and electrolyte analyses		
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	227	0
Body temperature abnormal	20	0
Body temperature decreased	27	0
Body temperature fluctuation	34	0
Body temperature increased	248	0
Breath sounds abnormal	1	0
Grip strength decreased	2	0
Head lag	2	0
Respiratory rate	2	0
Respiratory rate decreased	5	0
Respiratory rate increased	15	0
Skin temperature	35	0
Weight decreased	15	0
Platelet analyses		
Platelet count decreased	3	0
Protein analyses NEC		
C-reactive protein abnormal	1	0
Red blood cell analyses		
Haematocrit	1	0
Haemoglobin	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
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	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 below therapeutic	2	0
Tissue enzyme analyses NEC		
Lactate dehydrogenase urine increased	1	0
Urinalysis NEC		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood urine	2	0
Blood urine present	3	0
Cells in urine	1	0
Protein urine present	1	0
pH urine	1	0
pH urine decreased	1	0
Urinary tract function analyses NEC		
Urine output	8	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	15	0
Blood pressure increased	39	0
Blood pressure measurement	6	0
Blood pressure systolic increased	1	0
Virus identification and serology		
Coronavirus test	4	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	10	0
White blood cell analyses		
White blood cell count decreased	2	0
White blood cell count increased	1	0
Investigations SOC TOTAL	1359	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	1233	0
Diet refusal	1	0
Food craving	2	0
Food refusal	12	0
Hyperphagia	1	0
Hypophagia	9	0
Increased appetite	8	0
Salt craving	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	3	0
Diabetes mellitus inadequate control	2	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	3	2
<i>Disorders of purine metabolism</i>		
Gout	5	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	3	0
<i>Fluid intake increased</i>		
Polydipsia	5	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Food intolerance	3	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	3	0
Abnormal weight gain	2	0
Cachexia	1	0
Feeding disorder	21	0
Food aversion	9	0
Starvation	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	20	0
<i>Hyperlipidaemias NEC</i>		
Hyperlipidaemia	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hyperinsulinaemic hypoglycaemia	1	0
Hypoglycaemia	10	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	100	0
<i>Total fluid volume increased</i>		
Fluid retention	4	0
Metabolic disorders SOC TOTAL	1473	2

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	28	0
Arthropathy	1	0
Polyarthritis	1	0
Sacroiliitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	178	0
Pain in jaw	65	0
Spinal pain	30	0
<i>Bursal disorders</i>		
Bursitis	2	0
<i>Cartilage disorders</i>		
Costochondritis	1	0
<i>Connective tissue disorders NEC</i>		
Morphoea	1	0
Polymyalgia rheumatica	5	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	6	0
Patellofemoral pain syndrome	1	0
Periarthritis	8	0
Rotator cuff syndrome	1	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	3603	0
Joint noise	3	0
Joint stiffness	45	0
Joint swelling	41	0
Joint warmth	2	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Metabolic bone disorders</i>		
Osteopenia	1	0
<i>Muscle infections and inflammations</i>		
Myositis	2	0
<i>Muscle pains</i>		
Fibromyalgia	13	0
Myalgia	4819	0
Myofascial pain syndrome	3	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle disorder	1	0
Muscle fatigue	145	0
Muscle mass	3	0
Muscle oedema	1	0
Muscle spasms	327	0
Muscle swelling	5	0
Muscle tightness	20	0
Muscle twitching	46	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	11	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders cont'd		
Muscle & tissue disorders		
Nuchal rigidity	2	0
Torticollis	1	0
Trismus	13	0
Muscle weakness conditions		
Muscular weakness	255	0
Musculoskeletal and connective tissue conditions NEC		
Limb mass	1	0
Mobility decreased	21	0
Musculoskeletal stiffness	269	0
Weight bearing difficulty	1	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Connective tissue inflammation	1	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	911	0
Flank pain	13	0
Growing pains	3	0
Limb discomfort	257	0
Musculoskeletal chest pain	54	0
Musculoskeletal discomfort	13	0
Musculoskeletal pain	12	0
Neck pain	388	0
Pain in extremity	2329	0
Rheumatic disorder	1	0
Myopathies		
Myopathy	1	0
Rhabdomyolysis	2	0
Osteoarthropathies		
Osteoarthritis	4	0
Psoriatic arthropathies		
Psoriatic arthropathy	3	0
Rheumatoid arthropathies		
Rheumatoid arthritis	8	0
Still's disease	2	0
Soft tissue disorders NEC		
Axillary mass	4	0
Groin pain	17	0
Neck mass	1	0
Soft tissue mass	1	0
Spondyloarthropathies		
Ankylosing spondylitis	1	0
Arthritis reactive	2	0
Synovial disorders		
Synovitis	2	0
Tendon disorders		
Tendon pain	2	0
Tendonitis	1	0
Trigger finger	1	0
Muscle & tissue disorders SOC TOTAL	14022	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	1	0
<i>Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)</i>		
Lymphoproliferative disorder in remission	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	1	1
<i>Oncologic complications and emergencies</i>		
Cancer fatigue	1	0
<i>Plasma cell myelomas</i>		
Plasma cell myeloma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	7	1

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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	2	0
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	4	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 haemorrhage	7	1
Cerebral infarction	2	1
Cerebrovascular accident	32	6
Embolic stroke	1	0
Haemorrhage intracranial	1	1
Haemorrhagic stroke	2	0
Ischaemic stroke	5	0
Subarachnoid haemorrhage	1	0
<i>Central nervous system inflammatory disorders NEC</i>		
Central nervous system inflammation	1	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebral small vessel ischaemic disease	1	0
Cerebrovascular disorder	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	2	0
Superior sagittal sinus thrombosis	1	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervicobrachial syndrome	1	0
<i>Coma states</i>		
Coma	2	0
<i>Coordination and balance disturbances</i>		
Ataxia	3	0
Balance disorder	126	0
Coordination abnormal	17	0
Dysstasia	12	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	7	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	3	0
Senile dementia	1	0
Vascular dementia	2	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	2	0
Consciousness fluctuating	2	0
Depressed level of consciousness	13	0
Lethargy	786	0
Loss of consciousness	114	0
Sedation	2	0
Somnolence	272	1

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Syncope	325	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	3	0
Bradykinesia	4	0
Clumsiness	6	0
Dyskinesia	13	0
Extrapyramidal disorder	4	0
Hypokinesia	3	0
Motor dysfunction	1	0
Movement disorder	4	0
Psychomotor hyperactivity	7	0
<i>Dystonias</i>		
Dystonia	2	0
Dystonic tremor	1	0
<i>Encephalitis NEC</i>		
Noninfective encephalitis	2	0
<i>Eye movement disorders</i>		
Illi nerve paralysis	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	35	0
Facial paresis	9	0
Facial spasm	4	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	6	0
<i>Headaches NEC</i>		
Cervicogenic headache	1	0
Cluster headache	88	0
Cold-stimulus headache	3	0
Drug withdrawal headache	3	0
Exertional headache	2	0
External compression headache	1	0
Headache	13690	0
Medication overuse headache	2	0
New daily persistent headache	1	0
Primary headache associated with sexual activity	2	0
Sinus headache	118	0
Tension headache	195	0
Thunderclap headache	4	0
Vascular headache	9	0
<i>Hypoglossal nerve disorders</i>		
Tongue paralysis	1	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	2	0
Intracranial pressure increased	1	0
<i>Intellectual disabilities</i>		
Intellectual disability	2	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	8	0
<i>Memory loss (excl dementia)</i>		
Amnesia	21	0
Memory impairment	17	0
Transient global amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Cognitive disorder	10	0
Disturbance in attention	52	0
Mental impairment	11	0
Migraine headaches		
Hemiplegic migraine	1	0
Migraine	848	0
Migraine with aura	28	0
Migraine without aura	3	0
Retinal migraine	3	0
Status migrainosus	1	0
Mononeuropathies		
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	5	0
Multiple sclerosis relapse	4	0
Muscle tone abnormal		
Hypotonia	3	0
Myelitis (incl infective)		
Myelitis transverse	5	0
Narcolepsy and hypersomnia		
Hypersomnia	27	0
Narcolepsy	2	0
Nervous system disorders NEC		
Cerebral disorder	1	0
Nervous system disorder	4	0
Psychomotor skills impaired	2	0
Neurologic visual problems NEC		
Tunnel vision	2	0
Visual field defect	2	0
Neurological signs and symptoms NEC		
Dizziness	3117	0
Dizziness exertional	9	0
Dizziness postural	331	0
Drooling	1	0
Exaggerated startle response	1	0
Head discomfort	58	0
Infant irritability	1	0
Myoclonus	5	0
Neurological symptom	11	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	2	0
Presyncope	96	0
Unresponsive to stimuli	18	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	6	0
Muscle spasticity	3	0
Neuromuscular pain	1	0
Olfactory nerve disorders		
Anosmia	32	0
Hyposmia	3	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Feb-2021

Data Lock Date: 19-Feb-2021 19:00:04

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Parosmia	54	0
Optic nerve disorders NEC		
Optic neuritis	2	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	4	0
Burning sensation	62	0
Dysaesthesia	2	0
Formication	7	0
Hemianaesthesia	1	0
Hyperaesthesia	46	0
Hypoaesthesia	421	0
Lhermitte's sign	1	0
Paraesthesia	758	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	6	0
Hemiparesis	9	0
Hemiplegia	1	0
Monoparesis	6	0
Monoplegia	12	0
Paralysis	29	0
Paraparesis	2	0
Paraplegia	1	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	26	0
Parkinson's disease	3	0
Parkinsonism	3	0
Reduced facial expression	1	0
Partial complex seizures		
Dreamy state	2	0
Peripheral neuropathies NEC		
Neuropathy peripheral	14	0
Seizures and seizure disorders NEC		
Atonic seizures	1	0
Clonic convulsion	1	0
Epilepsy	28	0
Febrile convulsion	15	0
Partial seizures	4	0
Seizure	137	1
Seizure anoxic	1	0
Seizure like phenomena	1	0
Status epilepticus	3	0
Tonic convulsion	4	0
Sensory abnormalities NEC		
Ageusia	116	0
Allodynia	8	0
Aura	1	0
Central pain syndrome	1	0
Dysgeusia	232	0
Hypogeusia	1	0
Neuralgia	109	0
Phantom limb syndrome	6	0
Post herpetic neuralgia	2	0
Restless arm syndrome	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Restless legs syndrome	51	0
Sensory disturbance	9	0
Sensory loss	14	0
Taste disorder	63	0
Sleep disturbances NEC		
Poor quality sleep	92	0
Sleep deficit	7	0
Speech and language abnormalities		
Dysarthria	34	0
Incoherent	2	0
Slow speech	3	0
Speech disorder	4	0
Structural brain disorders NEC		
Brain injury	1	1
Transient cerebrovascular events		
Transient ischaemic attack	19	0
Tremor (excl congenital)		
Action tremor	1	0
Essential tremor	1	0
Head titubation	3	0
Intention tremor	1	0
Resting tremor	2	0
Tremor	2038	1
Trigeminal disorders		
Facial neuralgia	1	0
Trigeminal neuralgia	7	0
Nervous system disorders SOC TOTAL	25251	14

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	3	0
<i>Labour onset and length abnormalities</i>		
Premature labour	1	0
Premature rupture of membranes	1	0
<i>Maternal complications of pregnancy NEC</i>		
Morning sickness	7	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	2	0
<i>Unintended pregnancies</i>		
Pregnancy with implant contraceptive	2	0
Pregnancy conditions SOC TOTAL	16	0

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<i>Device incompatibility issues</i>		
Patient-device incompatibility	1	0
<i>Device malfunction events NEC</i>		
Oversensing	6	0
Stent malfunction	1	0
Undersensing	1	0
<i>Product physical issues</i>		
Product taste abnormal	1	0
null SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	1	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	35	0
Anxiety	75	0
Nervousness	111	0
Stress	2	0
Tension	8	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	2	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	39	0
<i>Communications disorders</i>		
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	279	0
Disorientation	112	0
<i>Deliria</i>		
Delirium	97	0
<i>Delusional symptoms</i>		
Delusion	3	0
<i>Depressive disorders</i>		
Depression	27	0
Major depression	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	3	0
Dissociation	3	0
Dissociative disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	3	0
Insomnia	447	0
Middle insomnia	7	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	4	0
Emotional disorder	12	0
Emotional distress	2	0
Euphoric mood	4	0

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Frustration tolerance decreased	2	0
Irritability	35	0
Mood altered	5	0
Factitious disorders		
Factitious disorder	3	0
Fear symptoms and phobic disorders (incl social phobia)		
Agoraphobia	1	0
Fear	2	0
Fear of death	2	0
Fear of disease	1	0
Fear of falling	1	0
Phonophobia	1	0
Fluctuating mood symptoms		
Mood swings	3	0
Hallucinations (excl sleep-related)		
Hallucination	157	0
Hallucination, auditory	3	0
Hallucination, visual	7	0
Hallucinations, mixed	1	0
Increased physical activity levels		
Restlessness	74	0
Mental disorders NEC		
Mental disorder	2	0
Mental status changes	1	0
Mood alterations with depressive symptoms		
Anhedonia	2	0
Decreased interest	3	0
Depressed mood	31	0
Feeling of despair	2	0
Negative thoughts	1	0
Sense of a foreshortened future	1	0
Tearfulness	16	0
Mood alterations with manic symptoms		
Mania	3	0
Mood disorders NEC		
Apathy	4	0
Listless	18	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	1	0
Obsessive-compulsive disorders and symptoms		
Obsessive thoughts	1	0
Panic attacks and disorders		
Panic attack	20	0
Panic reaction	4	0
Parasomnias		
Abnormal dreams	53	0
Confusional arousal	2	0
Exploding head syndrome	1	0
Nightmare	62	0
Sleep talking	3	0
Sleep terror	5	0
Somnambulism	1	0
Perception disturbances NEC		

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Autoscopy	4	0
Derealisation	1	0
Illusion	3	0
Time perception altered	1	0
Psychiatric elimination disorders		
Enuresis	6	0
Psychiatric symptoms NEC		
Hypervigilance	2	0
Psychological trauma	1	0
Psychotic disorder NEC		
Psychotic disorder	4	0
Sexual desire disorders		
Loss of libido	1	0
Sleep disorders NEC		
Sleep disorder	60	0
Somatic symptom disorders		
Conversion disorder	1	0
Habit cough	3	0
Somatic symptom disorder	1	0
Speech and language usage disturbances		
Logorrhoea	1	0
Speech articulation and rhythm disturbances		
Lack of spontaneous speech	1	0
Stereotypies and automatisms		
Bruxism	2	0
Head banging	5	0
Stress disorders		
Acute stress disorder	1	0
Burnout syndrome	1	0
Hyperarousal	1	0
Post-traumatic stress disorder	2	0
Substance related and addictive disorders		
Drug dependence	1	0
Suicidal and self-injurious behaviour		
Intentional self-injury	1	0
Suicidal ideation	4	0
Suicide threat	1	0
Thinking disturbances		
Bradyphrenia	7	0
Intrusive thoughts	1	0
Tachyphrenia	4	0
Thinking abnormal	3	0
Thought blocking	1	0
Psychiatric disorders SOC TOTAL	1957	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	1	0
Bladder pain	6	0
Dysuria	10	0
Incontinence	11	0
Micturition frequency decreased	1	0
Micturition urgency	22	0
Pollakiuria	50	0
Urinary hesitation	2	0
Urinary incontinence	17	0
Urinary retention	12	0
Urine flow decreased	2	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	2	0
<i>Bladder infections and inflammations</i>		
Cystitis interstitial	1	0
<i>Myoneurogenic bladder disorders</i>		
Hypertonic bladder	1	0
Loss of bladder sensation	2	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	8	0
Chronic kidney disease	1	0
Oliguria	2	0
Renal failure	2	0
Renal injury	1	0
<i>Structural and obstructive urethral disorders (excl congenital)</i>		
Urethral spasm	1	0
<i>Urinary abnormalities</i>		
Chromaturia	9	0
Haematuria	4	0
Proteinuria	1	0
Urine abnormality	2	0
Urine odour abnormal	4	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	1	0
Nocturia	1	0
Polyuria	7	0
Renal colic	1	0
Renal pain	127	0
Renal & urinary disorders SOC TOTAL	317	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Breast enlargement	1	0
Breast mass	2	0
<i>Breast signs and symptoms</i>		
Breast oedema	1	0
Breast pain	21	0
Breast swelling	1	0
Breast tenderness	5	0
Nipple pain	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	1	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	1	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	9	0
Menstrual disorder	6	0
Menstruation irregular	4	0
Metrorrhagia	3	0
Premenstrual pain	1	0
<i>Menstruation with decreased bleeding</i>		
Hypomenorrhoea	3	0
Menstruation delayed	5	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	15	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile oedema	1	0
Penis disorder	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
Pelvic pain	15	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
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	7	0
<i>Uterine disorders NEC</i>		
Uterine pain	1	0
<i>Uterine tone disorders</i>		
Uterine spasm	2	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	26	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	4	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Vaginal lesion	2	0
Vulvovaginal pain	4	0
Vulvovaginal rash	1	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	157	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	717	3
Dyspnoea at rest	1	0
Dyspnoea exertional	4	0
Hyperventilation	9	0
Hypopnoea	37	0
Irregular breathing	3	0
Mouth breathing	1	0
Orthopnoea	1	0
Respiration abnormal	16	0
Respiratory arrest	3	0
Respiratory distress	2	0
Sleep apnoea syndrome	3	0
Tachypnoea	16	0
<i>Bronchial conditions NEC</i>		
Bronchiectasis	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	52	0
Bronchospasm	6	0
Chronic obstructive pulmonary disease	10	2
Obstructive airways disorder	1	0
Wheezing	82	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	17	0
<i>Coughing and associated symptoms</i>		
Cough	487	0
Haemoptysis	8	0
Productive cough	19	0
Sputum discoloured	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	4	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	4	0
Pleuritic pain	1	0
Pulmonary pain	20	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	59	0
Nasal inflammation	2	0
Rhinitis allergic	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	124	0
Nasal dryness	6	0
Nasal odour	1	0
Nasal pruritus	2	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Paranasal sinus haemorrhage	1	0
Paranasal sinus inflammation	1	0
Sinonasal obstruction	1	0
Sinus congestion	4	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Pharyngeal disorders (excl infections and neoplasms)		
Oropharyngeal swelling	1	0
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	4	0
Pharyngeal oedema	1	0
Pharyngeal paraesthesia	5	0
Pharyngeal swelling	25	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	9	0
Pleural infections and inflammations		
Pleurisy	1	0
Pneumothorax and pleural effusions NEC		
Pneumothorax	1	0
Pulmonary oedemas		
Acute pulmonary oedema	1	0
Pulmonary congestion	2	0
Pulmonary oedema	3	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	8	0
Pulmonary infarction	1	1
Respiratory signs and symptoms NEC		
Respiratory symptom	3	0
Suffocation feeling	1	0
Respiratory tract disorders NEC		
Aspiration	3	2
Lung disorder	2	0
Upper respiratory tract signs and symptoms		
Aphonia	11	0
Catarrh	2	0
Choking	4	0
Choking sensation	2	0
Dry throat	49	0
Dysphonia	14	0
Nasal discomfort	12	0
Oropharyngeal discomfort	4	0
Oropharyngeal pain	582	0
Paranasal sinus discomfort	2	0
Rhinalgia	4	0
Rhinorrhoea	213	0
Sinus pain	54	0
Sneezing	55	0
Throat clearing	1	0
Throat irritation	30	0
Throat tightness	22	0
Upper-airway cough syndrome	3	0
Yawning	15	0
Respiratory disorders SOC TOTAL	2888	11

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders		
Acnes		
Acne	2	0
Alopecias		
Alopecia	6	0
Madarosis	1	0
Angioedemas		
Angioedema	54	0
Apocrine and eccrine gland disorders		
Anhidrosis	1	0
Cold sweat	310	0
Hyperhidrosis	1557	0
Miliaria	17	0
Night sweats	284	0
Sweat discolouration	1	0
Sweat gland disorder	1	0
Bullous conditions		
Blister	30	0
Blood blister	1	0
Erythema multiforme	4	0
Pemphigoid	1	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
Dermal and epidermal conditions NEC		
Dry skin	26	0
Macule	1	0
Pain of skin	154	0
Papule	4	0
Peau d'orange	1	0
Scab	2	0
Scar pain	1	0
Sensitive skin	89	0
Skin burning sensation	78	0
Skin discolouration	10	0
Skin disorder	2	0
Skin fissures	1	0
Skin odour abnormal	3	0
Skin reaction	30	0
Skin sensitisation	13	0
Skin swelling	7	0
Skin tightness	1	0
Skin warm	70	0
Sticky skin	1	0
Yellow skin	4	0
Dermatitis and eczema		
Dermatitis	23	0
Dermatitis allergic	29	0
Eczema	8	0
Eczema asteatotic	1	0
Skin irritation	21	0
Dermatitis ascribed to specific agent		
Drug eruption	7	0
Erythemas		
Erythema	455	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	0
Exfoliative rash	1	0
Skin exfoliation	8	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	24	0
<i>Pilar disorders NEC</i>		
Hair growth abnormal	1	0
Piloerection	12	0
Trichodynia	2	0
<i>Pruritus NEC</i>		
Pruritus	713	0
<i>Psoriatic conditions</i>		
Psoriasis	4	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	1	0
Petechiae	8	0
Purpura	3	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	1	0
Rash	753	0
Rash erythematous	201	0
Rash macular	55	0
Rash maculo-papular	7	0
Rash papular	42	0
Rash pruritic	145	0
Rash vesicular	3	0
Systemic lupus erythematosus rash	1	0
<i>Rosaceas</i>		
Rosacea	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Cutaneous symptom	1	0
Skin mass	1	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin erosion	6	0
Skin ulcer	2	0
<i>Skin haemorrhages</i>		
Skin haemorrhage	1	0
<i>Skin injuries and mechanical dermatoses</i>		
Needle track marks	1	0
<i>Skin vasculitides</i>		
Hypersensitivity vasculitis	1	0
Vasculitic rash	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	4	0
<i>Urticarias</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Urticaria	264	0
Urticaria chronic	2	0
Urticarial vasculitis	1	0
Skin disorders SOC TOTAL	5590	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Dietary and nutritional issues</i>		
Inadequate diet	1	0
<i>Disability issues</i>		
Bedridden	14	0
Immobile	7	0
Impaired driving ability	1	0
Impaired work ability	2	0
Sight disability	2	0
<i>Social issues NEC</i>		
Impaired quality of life	1	0
Social circumstances SOC TOTAL	28	0

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Data Lock Date: 19-Feb-2021 19:00:04

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Cardiac therapeutic procedures NEC</i>		
Pericardial excision	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	3	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	2	0
<i>Immunisations</i>		
COVID-19 immunisation	26	0
Immunisation	19	0
<i>Joint therapeutic procedures</i>		
Hip surgery	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	5	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	2	0
Hospitalisation	3	0
Injection	6	0
Localised alternating hot and cold therapy	2	0
Mass excision	1	0
Surgical & medical procedures SOC TOTAL	78	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 22-Feb-2021
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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	6	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	16	0
Neurogenic shock	2	0
Shock	10	0
Shock symptom	1	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	5	0
Haemorrhage	14	1
<i>Lymphoedemas</i>		
Lymphoedema	5	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	0
Thrombosis	1	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arteriosclerosis	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	1	0
Vasodilatation	2	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	1	0
Deep vein thrombosis	7	0
Thrombophlebitis superficial	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	19	0
Flushing	127	0
Hot flush	280	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Ischaemic limb pain	2	0
Peripheral coldness	168	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	6	0
<i>Site specific vascular disorders NEC</i>		
Pallor	93	0
<i>Varicose veins NEC</i>		
Varicophlebitis	1	0
Varicose vein	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	83	0
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	1	0
Hypotension	81	0
Orthostatic hypotension	6	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
<i>Vasculitides NEC</i>		
MAGIC syndrome	1	0
Vasculitis	2	0
Vascular disorders SOC TOTAL	952	1
TOTAL REACTIONS FOR DRUG	114625	205
TOTAL REPORTS	31427	
TOTAL FATAL OUTCOME REPORTS		205