

COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 11-Feb-2021
Data Lock Date: 10-Feb-2021 19:00:04

All UK spontaneous reports received between 4/01/21 and 07/02/21 for
COVID-19 vaccine Oxford University/AstraZeneca

Case Series Drug Analysis Print

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Report Run Date: 11-Feb-2021
Earliest Reaction Date: 06-Jan-2001

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	1	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	1	0
<i>Coagulopathies</i>		
Coagulopathy	1	0
<i>Eosinophilic disorders</i>		
Eosinophilia	1	0
<i>Haematological disorders</i>		
Bone marrow oedema	1	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	1	0
<i>Leukopenias NEC</i>		
Leukopenia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	28	0
Lymphadenitis	5	0
Lymphadenopathy	306	0
<i>Marrow depression and hypoplastic anaemias</i>		
Pancytopenia	1	0
<i>Neutropenias</i>		
Neutropenia	10	0
<i>Purpuras (excl thrombocytopenic)</i>		
Purpura non-thrombocytopenic	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	2	0
Thrombocytopenia	4	0
<i>White blood cell abnormal findings NEC</i>		
White blood cell disorder	1	0
Blood disorders SOC TOTAL	367	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	2	1
Cardiac disorder	2	0
Cardiovascular insufficiency	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	1	0
Palpitations	375	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	10	0
Myocardial infarction	7	3
<i>Noninfectious pericarditis</i>		
Pericarditis	1	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	5	0
Bradycardia	10	0
Cardiac flutter	7	0
Extrasystoles	4	0
Tachyarrhythmia	1	0
Tachycardia	211	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	2	0
Atrial fibrillation	7	0
Atrial flutter	2	0
Sinus arrhythmia	1	0
Sinus tachycardia	9	0
Supraventricular tachycardia	4	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	10	6
Ventricular extrasystoles	1	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	676	10

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cerebral disorders congenital</i>		
Cerebral palsy	1	0
<i>Pulmonary and bronchial disorders congenital</i>		
Cystic fibrosis	1	0
Congenital disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	7	0
Ear pain	142	0
Ear swelling	8	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
External ear pain	1	0
<i>Hearing losses</i>		
Deafness	8	0
Deafness transitory	2	0
Deafness unilateral	1	0
Hypoacusis	11	0
Sudden hearing loss	2	0
<i>Hyperacusia</i>		
Hyperacusis	8	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	5	0
Tinnitus	85	0
Vertigo	87	0
Vertigo positional	7	0
Ear disorders SOC TOTAL	375	0

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Endocrine disorders		
<i>Adrenal cortical hypofunctions</i>		
Adrenal insufficiency	1	0
Adrenocortical insufficiency acute	5	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	1	0
Endocrine disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	2	0
<i>Eyelid movement disorders</i>		
Blepharospasm	3	0
Eyelid ptosis	1	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	12	0
Lacrimation increased	15	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Erythema of eyelid	1	0
Eyelid oedema	1	0
Swelling of eyelid	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye pain	308	0
Eye swelling	42	0
Eye symptom	1	0
Ocular discomfort	2	0
Periorbital oedema	3	0
Periorbital swelling	8	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye irritation	14	0
Eye pruritus	14	0
Ocular hyperaemia	19	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	3	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	3	0
Asthenopia	16	0
Foreign body sensation in eyes	2	0
Photophobia	99	0
<i>Pupil disorders</i>		
Miosis	1	0
Mydriasis	2	0
Pupils unequal	2	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal vascular thrombosis	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Vitreoretinal traction syndrome	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	1	0
<i>Visual colour distortions</i>		
Chromatopsia	1	0
<i>Visual disorders NEC</i>		
Diplopia	10	0
Metamorphopsia	1	0
Photopsia	14	0
Vision blurred	79	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Visual snow syndrome	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	13	0
Blindness transient	2	0
Night blindness	1	0
Sudden visual loss	1	0
Visual acuity reduced	1	0
Visual impairment	32	0
Eye disorders SOC TOTAL	738	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	1
Pancreatitis	2	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	1	0
<i>Colitis (excl infective)</i>		
Colitis	1	0
Colitis ischaemic	1	0
Colitis ulcerative	2	0
Crohn's disease	2	0
<i>Dental disorders NEC</i>		
Teething	3	0
<i>Dental pain and sensation disorders</i>		
Dental paraesthesia	1	0
Hyperaesthesia teeth	2	0
Toothache	19	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	866	0
Diarrhoea haemorrhagic	2	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	57	0
Epigastric discomfort	2	0
Eructation	4	0
<i>Faecal abnormalities NEC</i>		
Faecaloma	1	0
Faeces discoloured	2	0
Faeces soft	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	17	0
Flatulence	35	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	2	0
<i>Gastritis (excl infective)</i>		
Gastritis	5	0
Reflux gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	425	0
Abdominal pain lower	13	0
Abdominal pain upper	421	0
Abdominal rigidity	4	0
Abdominal tenderness	1	0
Gastrointestinal pain	32	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	22	0
Gastric dilatation	3	0
Gastrooesophageal reflux disease	14	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	1	0
Gastric disorder	1	0
Gastrointestinal disorder	3	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	124	0
Acute abdomen	1	0
Anal incontinence	1	0
Dysphagia	17	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	2	0
Frequent bowel movements	2	0
Irritable bowel syndrome	4	0
Oesophageal spasm	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	3	0
Gingival oedema	1	0
Gingival pain	18	0
Gingival pruritus	1	0
Gingival swelling	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	3	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	4	0
Small intestinal haemorrhage	3	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	2	0
Nausea	3966	0
Retching	32	0
Vomiting	1474	2
Vomiting projectile	11	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
Haematochezia	7	0
Melaena	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	110	0
Lip dry	3	0
Saliva altered	1	0
Salivary hypersecretion	6	0
<i>Oral soft tissue disorders NEC</i>		
Cheilitis	4	0
Lip blister	4	0
Lip disorder	1	0
<i>Oral soft tissue haemorrhages</i>		
Oral blood blister	1	0
<i>Oral soft tissue signs and symptoms</i>		
Anaesthesia oral	1	0
Hypoaesthesia oral	43	0
Lip pain	7	0
Lip pruritus	4	0
Odynophagia	1	0
Oral discomfort	8	0
Oral mucosal blistering	2	0
Oral pain	27	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oral pruritus	2	0
Paraesthesia oral	75	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	88	0
Mouth swelling	10	0
Palatal swelling	2	0
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland pain	2	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	3	0
Mouth ulceration	22	0
Stomatitis	2	0
<i>Tongue disorders</i>		
Glossitis	1	0
Plicated tongue	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	15	0
Scalloped tongue	1	0
Swollen tongue	42	0
Tongue blistering	4	0
Tongue discolouration	2	0
Tongue discomfort	1	0
Tongue dry	3	0
Tongue eruption	1	0
Tongue oedema	2	0
Tongue pruritus	1	0
Tongue spasm	1	0
Gastrointestinal disorders SOC TOTAL	8160	3

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	2	0
Administration site pain	5	0
Administration site urticaria	1	0
Puncture site bruise	4	0
Puncture site pain	1	0
Puncture site reaction	1	0
<i>Adverse effect absent</i>		
No adverse event	4	0
<i>Application and instillation site reactions</i>		
Application site bruise	2	0
Application site erythema	2	0
Application site pain	3	0
<i>Asthenic conditions</i>		
Asthenia	462	1
Chronic fatigue syndrome	3	0
Fatigue	4728	0
Malaise	1250	2
Sluggishness	2	0
<i>Body temperature altered</i>		
Hyperthermia	1	0
Hypothermia	8	0
Temperature regulation disorder	3	0
<i>Complications associated with device NEC</i>		
Phantom shocks	1	0
<i>Death and sudden death</i>		
Death	88	88
Sudden death	8	8
<i>Febrile disorders</i>		
Hyperpyrexia	13	0
Masked fever	1	0
Pyrexia	7552	0
<i>Feelings and sensations NEC</i>		
Chills	5298	0
Feeling abnormal	196	0
Feeling cold	598	0
Feeling drunk	4	0
Feeling hot	208	0
Feeling jittery	2	0
Feeling of body temperature change	135	0
Hangover	3	0
Hunger	5	0
Sensation of foreign body	5	0
Temperature intolerance	4	0
Thirst	148	0
Thirst decreased	2	0
<i>Fibrosis NEC</i>		
Fibrosis	1	0
<i>Gait disturbances</i>		
Gait disturbance	30	0
Gait inability	20	0
Loss of control of legs	4	0
<i>General signs and symptoms NEC</i>		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Condition aggravated	8	0
Crying	13	0
Energy increased	1	0
General physical health deterioration	5	1
General symptom	1	0
Illness	588	0
Influenza like illness	1095	0
Local reaction	31	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	411	0
Secretion discharge	2	0
Swelling	206	0
Swelling face	68	0
Implant and catheter site reactions		
Implant site warmth	2	0
Inflamations		
Inflammation	35	0
Infusion site reactions		
Infusion site bruising	1	0
Infusion site pain	1	0
Injection site reactions		
Injected limb mobility decreased	3	0
Injection site bruising	3	0
Injection site coldness	1	0
Injection site erythema	51	0
Injection site hypoaesthesia	3	0
Injection site indentation	1	0
Injection site inflammation	10	0
Injection site joint erythema	1	0
Injection site joint pain	7	0
Injection site mass	129	0
Injection site oedema	5	0
Injection site pain	441	0
Injection site papule	1	0
Injection site paraesthesia	1	0
Injection site pruritus	28	0
Injection site rash	22	0
Injection site reaction	12	0
Injection site swelling	18	0
Injection site urticaria	3	0
Injection site warmth	40	0
Interactions		
Drug interaction	1	0
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	2	0
Oedema	1	0

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General disorders General disorders cont'd		
Oedema peripheral	6	0
<i>Pain and discomfort NEC</i>		
Axillary pain	35	0
Chest discomfort	188	0
Chest pain	331	0
Discomfort	18	0
Facial discomfort	2	0
Facial pain	22	0
Inflammatory pain	2	0
Non-cardiac chest pain	3	0
Pain	1727	0
Tenderness	176	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	129	0
Adverse event	1	0
Adverse reaction	5	0
Drug ineffective	6	0
No reaction on previous exposure to drug	6	0
Therapeutic product effect decreased	1	0
Therapeutic response unexpected	1	0
Vaccine positive rechallenge	1	0
<i>Ulcers NEC</i>		
Ulcer	1	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	2	0
Vaccination site bruising	6	0
Vaccination site discomfort	2	0
Vaccination site erythema	52	0
Vaccination site induration	6	0
Vaccination site inflammation	6	0
Vaccination site irritation	1	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	8	0
Vaccination site joint swelling	1	0
Vaccination site mass	42	0
Vaccination site movement impairment	2	0
Vaccination site pain	160	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	11	0
Vaccination site rash	9	0
Vaccination site reaction	2	0
Vaccination site swelling	37	0
Vaccination site vesicles	1	0
Vaccination site warmth	23	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	2	0
General disorders SOC TOTAL	27110	100

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Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	2	0
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	3	0
Hepatic disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Allergy to sting	1	0
Hypersensitivity	71	0
Multiple allergies	1	0
Serum sickness	5	0
Serum sickness-like reaction	4	0
Type III immune complex mediated reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	7	0
Drug hypersensitivity	6	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	56	0
Anaphylactic shock	2	0
Anaphylactoid reaction	2	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	4	0
Immune system disorder	1	0
Sensitisation	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	165	0

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Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	1	0
Gastroenteritis	2	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Arthritis bacterial	1	0
Bacterial infection	3	1
Cellulitis	63	1
Vaccination site cellulitis	3	0
<i>Breast infections</i>		
Mastitis	2	0
<i>Candida infections</i>		
Oral candidiasis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
Myelitis	1	0
<i>Coronavirus infections</i>		
COVID-19	82	9
Suspected COVID-19	5	0
<i>Coxiella infections</i>		
Q fever	12	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	1	0
Gingival abscess	2	0
Gingivitis	1	0
Oral pustule	1	0
<i>Ear infections</i>		
Ear infection	1	0
Labyrinthitis	4	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	5	0
Eye infection	1	0
Eyelid infection	1	0
<i>Fungal infections NEC</i>		
Fungal infection	1	0
<i>Herpes viral infections</i>		
Genital herpes simplex	1	0
Herpes simplex	2	0
Herpes zoster	33	0
Oral herpes	34	0
Varicella	1	0
<i>Infections NEC</i>		
Abscess	2	0
Abscess limb	1	0
Infection	19	1
Injection site infection	2	0
Localised infection	9	0
Vaccination site infection	3	0
<i>Infectious transmissions</i>		
Secondary transmission	1	0
<i>Influenza viral infections</i>		

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Infections Infections cont'd		
H2N2 influenza	1	0
Influenza	715	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	13	1
Pneumonia	8	3
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	14	1
Urosepsis	2	1
<i>Skin structures and soft tissue infections</i>		
Skin infection	6	0
<i>Staphylococcal infections</i>		
Furuncle	1	0
Staphylococcal scalded skin syndrome	1	0
<i>Streptococcal infections</i>		
Erysipelas	1	0
<i>Tuberculous infections</i>		
Tuberculosis	1	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	1	0
Laryngitis	3	0
Nasopharyngitis	120	0
Pharyngitis	3	0
Rhinitis	7	0
Sinusitis	10	0
Tonsillitis	7	0
<i>Urinary tract infections</i>		
Cystitis	4	0
Kidney infection	3	0
Urinary tract infection	9	0
<i>Vascular infections</i>		
Infected lymphocele	1	0
<i>Viral infections NEC</i>		
Gastroenteritis viral	8	0
Post viral fatigue syndrome	3	0
Sweating fever	82	0
Vestibular neuronitis	1	0
Viral infection	1	0
Viral pharyngitis	1	0
Viral rash	3	0
Viral sepsis	1	0
Infections SOC TOTAL	1339	18

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 11-Feb-2021
Earliest Reaction Date: 06-Jan-2001

Data Lock Date: 10-Feb-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries		
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
<i>Conditions caused by cold</i>		
Chillblains	2	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	1	0
Foetal exposure during pregnancy	3	0
Maternal exposure during breast feeding	3	0
Maternal exposure during pregnancy	12	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	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural nausea	6	0
<i>Heat injuries (excl thermal burns)</i>		
Heat exhaustion	1	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	1	0
Vaccination error	1	0
<i>Muscle, tendon and ligament injuries</i>		
Ligament sprain	1	0
Muscle strain	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	3	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	3	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	1	0
Electric shock	1	0
Fall	23	0
Inflammation of wound	1	0
Wound complication	1	0
<i>Non-site specific procedural complications</i>		
Infusion related reaction	4	0
Injection related reaction	90	0
Post procedural complication	6	0
<i>Overdoses NEC</i>		
Intentional overdose	1	0
<i>Product administration errors and issues</i>		
Extra dose administered	1	0
Inappropriate schedule of product administration	1	0
Product administered to patient of inappropriate age	1	0
Product administration error	2	0
<i>Product dispensing errors and issues</i>		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 11-Feb-2021
 Earliest Reaction Date: 06-Jan-2001

Data Lock Date: 10-Feb-2021 19:00:04
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Product dispensing error	1	0
Site specific injuries NEC		
Limb crushing injury	1	0
Limb injury	1	0
Skin injuries NEC		
Contusion	56	0
Skin injury	1	0
Thermal burns		
Burn of internal organs	1	0
Thermal burn	1	0
Thermal burns of eye	2	0
Underdoses NEC		
Intentional underdose	1	0
Vaccination related complications		
Vaccination complication	12	0
Injuries SOC TOTAL	259	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 11-Feb-2021
Earliest Reaction Date: 06-Jan-2001

Data Lock Date: 10-Feb-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol increased	1	0
<i>Autoimmunity analyses</i>		
Cold agglutinins positive	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen saturation	7	0
Oxygen saturation decreased	29	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	3	0
Blood glucose abnormal	1	0
Blood glucose decreased	3	0
Blood glucose fluctuation	2	0
Blood glucose increased	10	0
Glycosylated haemoglobin increased	1	0
<i>Central nervous system imaging procedures</i>		
Magnetic resonance imaging brain	14	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker decreased	1	0
<i>Coagulation and bleeding analyses</i>		
International normalised ratio decreased	2	0
International normalised ratio increased	6	0
<i>Gastrointestinal function diagnostic procedures</i>		
Gastrointestinal stoma output increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	73	0
Heart rate abnormal	4	0
Heart rate decreased	6	0
Heart rate increased	164	0
Heart rate irregular	12	0
Maximum heart rate decreased	1	0
Orthostatic heart rate response increased	1	0
Pulse abnormal	2	0
<i>Immunology skin tests NEC</i>		
Allergy alert test	1	0
<i>Investigations NEC</i>		
Blood test	1	0
<i>Metabolism tests NEC</i>		
Blood ketone body	2	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	152	0
Body temperature abnormal	15	0
Body temperature decreased	18	0
Body temperature fluctuation	24	0
Body temperature increased	172	0
Breath sounds abnormal	1	0
Grip strength decreased	2	0
Head lag	2	0
Respiratory rate decreased	4	0
Respiratory rate increased	10	0
Skin temperature	25	0
Weight decreased	9	0
<i>Platelet analyses</i>		
Platelet count decreased	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 11-Feb-2021
 Earliest Reaction Date: 06-Jan-2001

Data Lock Date: 10-Feb-2021 19:00:04
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Red blood cell analyses</i>		
Haemoglobin	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Forced expiratory volume	1	0
Peak expiratory flow rate	1	0
<i>Therapeutic drug monitoring analyses</i>		
Analgesic drug level	4	0
Anticoagulation drug level below therapeutic	2	0
<i>Urinalysis NEC</i>		
Blood urine	2	0
Blood urine present	3	0
Cells in urine	1	0
pH urine	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output	6	0
Urine output decreased	3	0
Urine output increased	2	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	9	0
Blood pressure increased	22	0
Blood pressure measurement	5	0
<i>Virus identification and serology</i>		
Coronavirus test	1	0
SARS-CoV-2 antibody test negative	2	0
SARS-CoV-2 test	6	0
SARS-CoV-2 test negative	1	0
SARS-CoV-2 test positive	10	0
Investigations SOC TOTAL	868	0

Case Series Drug Analysis Print

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Report Run Date: 11-Feb-2021
Earliest Reaction Date: 06-Jan-2001

Data Lock Date: 10-Feb-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	791	0
Diet refusal	1	0
Food refusal	5	0
Hyperphagia	1	0
Hypophagia	3	0
Increased appetite	5	0
Salt craving	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	2	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	2	1
<i>Disorders of purine metabolism</i>		
Gout	3	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	1	0
<i>Fluid intake increased</i>		
Polydipsia	3	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Food intolerance	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Abnormal weight gain	1	0
Feeding disorder	12	0
Food aversion	6	0
Starvation	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	8	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	8	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Ketosis	1	0
<i>Potassium imbalance</i>		
Hyperkalaemia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	60	0
<i>Total fluid volume increased</i>		
Fluid retention	1	0
Metabolic disorders SOC TOTAL	922	1

Case Series Drug Analysis Print

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Report Run Date: 11-Feb-2021
Earliest Reaction Date: 06-Jan-2001

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	16	0
<i>Bone related signs and symptoms</i>		
Bone pain	113	0
Pain in jaw	42	0
Spinal pain	19	0
<i>Bursal disorders</i>		
Bursitis	1	0
<i>Cartilage disorders</i>		
Costochondritis	1	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	2	0
<i>Extremity deformities</i>		
Hand deformity	1	0
Limb deformity	1	0
<i>Joint related disorders NEC</i>		
Joint lock	3	0
Patellofemoral pain syndrome	1	0
Periarthritis	5	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	2273	0
Joint noise	3	0
Joint stiffness	28	0
Joint swelling	29	0
Joint warmth	2	0
<i>Metabolic bone disorders</i>		
Osteopenia	1	0
<i>Muscle infections and inflammations</i>		
Myositis	2	0
<i>Muscle pains</i>		
Fibromyalgia	8	0
Myalgia	3217	0
Myofascial pain syndrome	2	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle disorder	1	0
Muscle fatigue	82	0
Muscle mass	1	0
Muscle oedema	1	0
Muscle spasms	201	0
Muscle swelling	5	0
Muscle tightness	13	0
Muscle twitching	27	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	7	0
Nuchal rigidity	2	0
Trismus	10	0
<i>Muscle weakness conditions</i>		
Muscular weakness	159	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Limb mass	1	0
Mobility decreased	13	0
Musculoskeletal stiffness	169	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 11-Feb-2021
 Earliest Reaction Date: 06-Jan-2001

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Connective tissue inflammation	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	616	0
Flank pain	9	0
Growing pains	1	0
Limb discomfort	169	0
Musculoskeletal chest pain	39	0
Musculoskeletal discomfort	7	0
Musculoskeletal pain	7	0
Neck pain	259	0
Pain in extremity	1484	0
<i>Myopathies</i>		
Myopathy	1	0
Rhabdomyolysis	1	0
<i>Osteoarthropathies</i>		
Osteoarthritis	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	2	0
Still's disease	1	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	3	0
Groin pain	8	0
Neck mass	1	0
Soft tissue mass	1	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	1	0
<i>Synovial disorders</i>		
Synovitis	1	0
<i>Tendon disorders</i>		
Tendon pain	2	0
Tendonitis	1	0
Muscle & tissue disorders SOC TOTAL	9079	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 11-Feb-2021

Data Lock Date: 10-Feb-2021 19:00:04

Earliest Reaction Date: 06-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Neoplasms		
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 11-Feb-2021
Earliest Reaction Date: 06-Jan-2001

Data Lock Date: 10-Feb-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	2	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Alzheimer's disease (incl subtypes)</i>		
Dementia Alzheimer's type	1	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem stroke	1	0
Cerebral haemorrhage	6	1
Cerebrovascular accident	22	6
Embolic stroke	1	0
Haemorrhage intracranial	1	1
Haemorrhagic stroke	2	0
Ischaemic stroke	2	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebrovascular disorder	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	2	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervicobrachial syndrome	1	0
<i>Coma states</i>		
Coma	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	2	0
Balance disorder	92	0
Coordination abnormal	9	0
Dysstasia	8	0
<i>Cortical dysfunction NEC</i>		
Aphasia	6	0
<i>Dementia (excl Alzheimer's type)</i>		
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	8	0
Lethargy	488	0
Loss of consciousness	55	0
Sedation	1	0
Somnolence	171	0
Syncope	193	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	3	0
Bradykinesia	2	0
Clumsiness	4	0
Dyskinesia	5	0
Extrapyramidal disorder	1	0
Hypokinesia	1	0
Motor dysfunction	1	0
Movement disorder	1	0
Psychomotor hyperactivity	4	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 11-Feb-2021
Earliest Reaction Date: 06-Jan-2001

Data Lock Date: 10-Feb-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Dystonias</i>		
Dystonia	1	0
Dystonic tremor	1	0
<i>Encephalitis NEC</i>		
Noninfective encephalitis	1	0
<i>Eye movement disorders</i>		
IIIrd nerve paralysis	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	26	0
Facial paresis	5	0
Facial spasm	4	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	4	0
<i>Headaches NEC</i>		
Cluster headache	55	0
Cold-stimulus headache	2	0
Drug withdrawal headache	2	0
Exertional headache	1	0
External compression headache	1	0
Headache	8797	0
Medication overuse headache	1	0
Sinus headache	64	0
Tension headache	130	0
Thunderclap headache	2	0
Vascular headache	4	0
<i>Hypoglossal nerve disorders</i>		
Tongue paralysis	1	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0
Intracranial pressure increased	1	0
<i>Intellectual disabilities</i>		
Intellectual disability	2	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	4	0
<i>Memory loss (excl dementia)</i>		
Amnesia	14	0
Memory impairment	7	0
Transient global amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	8	0
Disturbance in attention	38	0
Mental impairment	9	0
<i>Migraine headaches</i>		
Hemiplegic migraine	1	0
Migraine	562	0
Migraine with aura	14	0
Migraine without aura	3	0
Retinal migraine	1	0
<i>Mononeuropathies</i>		
Nerve compression	1	0
Peroneal nerve palsy	1	0
Ulnar nerve palsy	1	0
<i>Multiple sclerosis acute and progressive</i>		

Case Series Drug Analysis Print

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Report Run Date: 11-Feb-2021
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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Multiple sclerosis	3	0
Multiple sclerosis relapse	1	0
Muscle tone abnormal		
Hypotonia	1	0
Myelitis (incl infective)		
Myelitis transverse	3	0
Narcolepsy and hypersomnia		
Hypersomnia	15	0
Narcolepsy	2	0
Nervous system disorders NEC		
Nervous system disorder	3	0
Neurologic visual problems NEC		
Tunnel vision	1	0
Visual field defect	1	0
Neurological signs and symptoms NEC		
Dizziness	2026	1
Dizziness exertional	7	0
Dizziness postural	206	0
Drooling	1	0
Exaggerated startle response	1	0
Head discomfort	40	0
Infant irritability	1	0
Myoclonus	3	0
Neurological symptom	10	0
Persistent postural-perceptual dizziness	1	0
Presyncope	67	0
Unresponsive to stimuli	14	1
Neuromuscular disorders NEC		
Muscle contractions involuntary	4	0
Muscle spasticity	2	0
Neuromuscular pain	1	0
Olfactory nerve disorders		
Anosmia	24	0
Hyposmia	1	0
Parosmia	29	0
Optic nerve disorders NEC		
Optic neuritis	1	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	2	0
Burning sensation	35	0
Formication	7	0
Hemianaesthesia	1	0
Hyperaesthesia	40	0
Hypoaesthesia	284	0
Lhermitte's sign	1	0
Paraesthesia	510	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	5	0
Hemiparesis	6	0
Monoparesis	4	0
Monoplegia	6	0
Paralysis	15	0
Paraplegia	1	0

Case Series Drug Analysis Print

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Report Run Date: 11-Feb-2021
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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	19	0
Parkinson's disease	3	0
Parkinsonism	3	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	8	0
<i>Seizures and seizure disorders NEC</i>		
Clonic convulsion	1	0
Epilepsy	15	0
Febrile convulsion	9	0
Partial seizures	2	0
Seizure	81	1
Seizure anoxic	1	0
Seizure like phenomena	1	0
Status epilepticus	1	0
Tonic convulsion	2	0
<i>Sensory abnormalities NEC</i>		
Ageusia	73	0
Allodynia	8	0
Aura	1	0
Dysgeusia	153	0
Hypogeusia	1	0
Neuralgia	71	0
Phantom limb syndrome	3	0
Post herpetic neuralgia	1	0
Restless arm syndrome	1	0
Restless legs syndrome	46	0
Sensory disturbance	7	0
Sensory loss	9	0
Taste disorder	42	0
<i>Sleep disturbances NEC</i>		
Poor quality sleep	58	0
Sleep deficit	6	0
<i>Speech and language abnormalities</i>		
Dysarthria	20	0
Incoherent	1	0
Slow speech	1	0
Speech disorder	3	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	9	0
<i>Tremor (excl congenital)</i>		
Essential tremor	1	0
Head titubation	1	0
Intention tremor	1	0
Resting tremor	1	0
Tremor	1202	1
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	4	0
Nervous system disorders SOC TOTAL	16135	12

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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	2	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	3	0
<i>Unintended pregnancies</i>		
Pregnancy with implant contraceptive	1	0
Pregnancy conditions SOC TOTAL	11	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	4	0
Stent malfunction	1	0
<i>Product physical issues</i>		
Product taste abnormal	1	0
null SOC TOTAL	7	0

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Affect alterations NEC</i>		
Constricted affect	1	0
Inappropriate affect	1	0
<i>Amnesic symptoms</i>		
Paramnesia	2	0
<i>Anxiety symptoms</i>		
Agitation	22	0
Anxiety	48	0
Nervousness	65	0
Stress	1	0
Tension	7	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	2	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	2	0
Mental fatigue	22	0
<i>Communications disorders</i>		
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	179	0
Disorientation	72	0
<i>Deliria</i>		
Delirium	61	0
<i>Delusional symptoms</i>		
Delusion	3	0
<i>Depressive disorders</i>		
Depression	14	0
Major depression	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	1	0
Dissociation	3	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	313	0
Middle insomnia	2	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	4	0
Emotional disorder	9	0
Emotional distress	1	0
Euphoric mood	3	0
Frustration tolerance decreased	1	0
Irritability	25	0
Mood altered	4	0
<i>Factitious disorders</i>		
Factitious disorder	2	0

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Earliest Reaction Date: 06-Jan-2001

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Agoraphobia	1	0
Fear	1	0
Fear of disease	1	0
Fear of falling	1	0
Phonophobia	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	104	0
Hallucination, auditory	1	0
Hallucination, visual	6	0
Hallucinations, mixed	1	0
<i>Increased physical activity levels</i>		
Restlessness	47	0
<i>Mental disorders NEC</i>		
Mental disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Anhedonia	2	0
Decreased interest	3	0
Depressed mood	19	0
Feeling of despair	2	0
Negative thoughts	1	0
Sense of a foreshortened future	1	0
Tearfulness	10	0
<i>Mood alterations with manic symptoms</i>		
Mania	1	0
<i>Mood disorders NEC</i>		
Apathy	3	0
Listless	8	0
<i>Panic attacks and disorders</i>		
Panic attack	14	0
Panic reaction	2	0
<i>Parasomnias</i>		
Abnormal dreams	35	0
Confusional arousal	1	0
Exploding head syndrome	1	0
Nightmare	45	0
Sleep talking	2	0
Sleep terror	3	0
Somnambulism	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	3	0
Illusion	3	0
<i>Psychiatric elimination disorders</i>		
Enuresis	1	0
<i>Psychiatric symptoms NEC</i>		
Psychological trauma	1	0
<i>Psychotic disorder NEC</i>		
Psychotic disorder	3	0
<i>Sexual desire disorders</i>		
Loss of libido	1	0
<i>Sleep disorders NEC</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Sleep disorder	42	0
<i>Somatic symptom disorders</i>		
Conversion disorder	1	0
Habit cough	3	0
Somatic symptom disorder	1	0
<i>Speech and language usage disturbances</i>		
Logorrhoea	1	0
<i>Speech articulation and rhythm disturbances</i>		
Lack of spontaneous speech	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	2	0
Head banging	3	0
<i>Stress disorders</i>		
Hyperarousal	1	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	4	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	6	0
Tachyphrenia	4	0
Thinking abnormal	3	0
Thought blocking	1	0
Psychiatric disorders SOC TOTAL	1287	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	1	0
Bladder pain	3	0
Dysuria	7	0
Incontinence	6	0
Micturition urgency	12	0
Pollakiuria	40	0
Urinary hesitation	2	0
Urinary incontinence	10	0
Urinary retention	5	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	1	0
<i>Bladder infections and inflammations</i>		
Cystitis interstitial	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	4	0
Chronic kidney disease	1	0
Oliguria	1	0
Renal failure	1	0
Renal injury	1	0
<i>Structural and obstructive urethral disorders (excl congenital)</i>		
Urethral spasm	1	0
<i>Urinary abnormalities</i>		
Chromaturia	7	0
Haematuria	2	0
Urine abnormality	2	0
Urine odour abnormal	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	1	0
Nocturia	1	0
Polyuria	4	0
Renal pain	86	0
Renal & urinary disorders SOC TOTAL	207	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	17	0
Breast swelling	1	0
Breast tenderness	3	0
Nipple pain	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	1	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	8	0
Menstrual disorder	4	0
Menstruation irregular	4	0
Metrorrhagia	2	0
Premenstrual pain	1	0
<i>Menstruation with decreased bleeding</i>		
Hypomenorrhoea	3	0
Menstruation delayed	4	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	11	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penis disorder	1	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Female genital tract fistula	1	0
Genital blister	1	0
Genital ulceration	2	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital burning sensation	1	0
Pelvic pain	14	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	1	0
Scrotal swelling	1	0
<i>Sexual function and fertility disorders NEC</i>		
Sexual dysfunction	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	5	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	18	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	3	0
Vaginal lesion	2	0
Vulvovaginal pain	3	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	123	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	467	2
Dyspnoea at rest	1	0
Dyspnoea exertional	2	0
Hyperventilation	7	0
Hypopnoea	21	0
Irregular breathing	2	0
Mouth breathing	1	0
Orthopnoea	1	0
Respiration abnormal	10	0
Respiratory arrest	2	0
Respiratory distress	1	0
Sleep apnoea syndrome	2	0
Tachypnoea	13	0
<i>Bronchospasm and obstruction</i>		
Asthma	23	0
Bronchospasm	2	0
Chronic obstructive pulmonary disease	3	1
Obstructive airways disorder	1	0
Wheezing	50	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	11	0
<i>Coughing and associated symptoms</i>		
Cough	302	0
Haemoptysis	3	0
Productive cough	10	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	3	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonia aspiration	2	1
Pneumonitis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	2	0
Pleuritic pain	1	0
Pulmonary pain	14	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	37	0
<i>Nasal disorders NEC</i>		
Epistaxis	73	0
Nasal dryness	4	0
Nasal odour	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Paranasal sinus haemorrhage	1	0
Sinonasal obstruction	1	0
Sinus congestion	3	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Oropharyngeal swelling	1	0
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	1	0
Pharyngeal oedema	1	0
Pharyngeal paraesthesia	5	0
Pharyngeal swelling	18	0
Tonsillar erythema	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Tonsillar hypertrophy	7	0
<i>Pleural infections and inflammations</i>		
Pleurisy	1	0
<i>Pulmonary oedemas</i>		
Acute pulmonary oedema	1	0
Pulmonary congestion	1	0
Pulmonary oedema	3	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	3	0
<i>Respiratory signs and symptoms NEC</i>		
Respiratory symptom	3	0
Suffocation feeling	1	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	2	1
Lung disorder	2	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	5	0
Catarrh	2	0
Choking	1	0
Dry throat	28	0
Dysphonia	5	0
Nasal discomfort	5	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	357	0
Paranasal sinus discomfort	1	0
Rhinalgia	3	0
Rhinorrhoea	115	0
Sinus pain	31	0
Sneezing	22	0
Throat clearing	1	0
Throat irritation	20	0
Throat tightness	13	0
Upper-airway cough syndrome	3	0
Yawning	5	0
Respiratory disorders SOC TOTAL	1748	5

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	2	0
<i>Alopecias</i>		
Alopecia	1	0
<i>Angioedemas</i>		
Angioedema	33	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	211	0
Hyperhidrosis	1061	0
Miliaria	7	0
Night sweats	195	0
Sweat discolouration	1	0
Sweat gland disorder	1	0
<i>Bullous conditions</i>		
Blister	22	0
Blood blister	1	0
Erythema multiforme	3	0
Pemphigoid	1	0
Stevens-Johnson syndrome	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	11	0
Macule	1	0
Pain of skin	110	0
Papule	1	0
Scab	2	0
Scar pain	1	0
Sensitive skin	60	0
Skin burning sensation	52	0
Skin discolouration	8	0
Skin disorder	1	0
Skin fissures	1	0
Skin odour abnormal	1	0
Skin reaction	24	0
Skin sensitisation	10	0
Skin swelling	6	0
Skin tightness	1	0
Skin warm	47	0
Sticky skin	1	0
Yellow skin	3	0
<i>Dermatitis and eczema</i>		
Dermatitis	17	0
Dermatitis allergic	19	1
Eczema	4	0
Eczema asteatotic	1	0
Skin irritation	11	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	6	0
<i>Erythemas</i>		
Erythema	274	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	0
Skin exfoliation	7	0
<i>Lipodystrophies</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Lipohypertrophy	1	0
Panniculitides		
Erythema nodosum	1	0
Papulosquamous conditions		
Lichen planus	1	0
Pityriasis rosea	1	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	20	0
Pilar disorders NEC		
Piloerection	9	0
Pruritus NEC		
Pruritus	438	0
Psoriatic conditions		
Psoriasis	3	0
Purpura and related conditions		
Petechiae	4	0
Purpura	1	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	1	0
Rash	470	0
Rash erythematous	121	0
Rash macular	31	0
Rash maculo-papular	6	0
Rash papular	18	0
Rash pruritic	85	0
Rash vesicular	1	0
Systemic lupus erythematosus rash	1	0
Rosaceas		
Rosacea	1	0
Skin and subcutaneous conditions NEC		
Skin mass	1	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	3	0
Skin ulcer	1	0
Skin haemorrhages		
Skin haemorrhage	1	0
Skin injuries and mechanical dermatoses		
Needle track marks	1	0
Skin vasculitides		
Vasculitic rash	1	0
Skin vasomotor conditions		
Livedo reticularis	3	0
Urticarias		
Urticaria	174	0
Skin disorders SOC TOTAL	3620	1

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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	8	0
Immobile	4	0
Impaired driving ability	1	0
Impaired work ability	2	0
Sight disability	1	0
Social circumstances SOC TOTAL	17	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Cardiac therapeutic procedures NEC</i>		
Pericardial excision	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis against gastrointestinal ulcer	1	0
Prophylaxis of nausea and vomiting	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	2	0
<i>Immunisations</i>		
COVID-19 immunisation	14	0
Immunisation	10	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	4	0
Limb operation	1	0
<i>Muscle therapeutic procedures</i>		
Muscle relaxant therapy	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	1	0
Hospitalisation	1	0
Injection	4	0
Localised alternating hot and cold therapy	1	0
Mass excision	1	0
Surgical & medical procedures SOC TOTAL	45	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Tyramine reaction	1	0
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	4	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	9	0
Shock	6	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	3	0
Haemorrhage	9	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	0
Thrombosis	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	1	0
Vasodilatation	2	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	2	0
Thrombophlebitis superficial	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	13	0
Flushing	67	0
Hot flush	201	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Ischaemic limb pain	2	0
Peripheral coldness	100	0
Raynaud's phenomenon	5	0
<i>Site specific vascular disorders NEC</i>		
Pallor	59	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	59	0
<i>Vascular hypotensive disorders</i>		
Hypotension	55	0
Orthostatic hypotension	3	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	607	0
TOTAL REACTIONS FOR DRUG	73883	150
TOTAL REPORTS	20428	
TOTAL FATAL OUTCOME REPORTS		150