

## Case Series Drug Analysis Print

**Name: All FOI 23/980 - AZ vaccine batch number 4120Z003**

Report Run Date: 09-Jan-2024  
Data Lock Date: 07-Jan-2024 18:30:05  
Earliest Reaction Date: 18-Mar-2020  
MedDRA Version: MedDRA 26.1

All FOI 23/980 - AZ vaccine batch number 4120Z003: All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the COVID-19 Vaccine AstraZeneca batch number 4120Z003 received up to and including 07/01/2024.

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Anaemia deficiencies</b></i>		
Anaemia vitamin B12 deficiency	1	0
Iron deficiency anaemia	1	0
Pernicious anaemia	1	0
<i><b>Anaemias NEC</b></i>		
Anaemia	6	0
<i><b>Anaemias haemolytic NEC</b></i>		
Haemolytic anaemia	1	0
<i><b>Bleeding tendencies</b></i>		
Increased tendency to bruise	3	0
Spontaneous haemorrhage	1	0
<i><b>Coagulopathies</b></i>		
Hypercoagulation	1	0
<i><b>Lymphatic system disorders NEC</b></i>		
Lymph node pain	9	0
Lymphadenopathy	100	0
<i><b>Neutropenias</b></i>		
Neutropenia	1	0
<i><b>Platelet disorders NEC</b></i>		
Platelet disorder	1	0
<i><b>Polycythaemia (excl rubra vera)</b></i>		
Polycythaemia	1	0
<i><b>Spleen disorders</b></i>		
Splenic thrombosis	1	0
<i><b>Thrombocytopenias</b></i>		
Heparin-induced thrombocytopenia	1	0
Immune thrombocytopenia	3	0
Thrombocytopenia	19	0
Thrombosis with thrombocytopenia syndrome	3	0
Thrombotic thrombocytopenic purpura	1	0
<b>Blood disorders SOC TOTAL</b>	<b>155</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block	2	0
Bundle branch block	1	0
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	3	0
Intracardiac thrombus	1	0
<i><b>Cardiac hypertensive complications</b></i>		
Hypertensive heart disease	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Palpitations	96	0
<i><b>Cardiac valve disorders NEC</b></i>		
Heart valve incompetence	1	0
<i><b>Coronary artery disorders NEC</b></i>		
Coronary artery occlusion	1	0
Coronary artery thrombosis	6	1
<i><b>Heart failures NEC</b></i>		
Cardiac failure	2	0
Cardiac failure acute	1	0
Cardiac failure congestive	1	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute myocardial infarction	4	0
Angina pectoris	8	0
Myocardial infarction	8	1
Myocardial ischaemia	1	0
<i><b>Myocardial disorders NEC</b></i>		
Right ventricular dilatation	1	0
<i><b>Noninfectious myocarditis</b></i>		
Myocarditis	4	0
Myopericarditis	1	0
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	4	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	4	0
Cardiac fibrillation	1	0
Cardiac flutter	9	0
Extrasystoles	3	0
Postural orthostatic tachycardia syndrome	5	0
Tachyarrhythmia	1	0
Tachycardia	32	0
<i><b>Supraventricular arrhythmias</b></i>		
Arrhythmia supraventricular	1	0
Atrial fibrillation	5	0
Sinus tachycardia	1	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Cardiac arrest	5	3
<b>Cardiac disorders SOC TOTAL</b>	<b>214</b>	<b>5</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	1	0
<i>Cardiac valve disorders congenital</i>		
Bicuspid aortic valve	1	0
<i>Central nervous system disorders congenital NEC</i>		
Brain malformation	1	0
<i>Connective tissue disorders congenital</i>		
Hypermobility syndrome	1	0
<i>Gene mutations and other alterations NEC</i>		
Tuberous sclerosis complex	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear discomfort	5	0
Ear disorder	1	0
Ear haemorrhage	2	0
Ear pain	37	0
<i><b>Eustachian tube disorders</b></i>		
Eustachian tube obstruction	2	0
<i><b>Hearing losses</b></i>		
Deafness	7	0
Deafness unilateral	1	0
Hypoacusis	4	0
Sudden hearing loss	3	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	10	0
<i><b>Inner ear disorders NEC</b></i>		
Meniere's disease	1	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	4	0
Phobic postural vertigo	1	0
Tinnitus	104	0
Vertigo	48	0
Vertigo positional	3	0
<b>Ear disorders SOC TOTAL</b>	<b>233</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Adrenal cortical hyperfunctions</i>		
Cushingoid	1	0
<i>Adrenal gland disorders NEC</i>		
Adrenal mass	1	0
<i>Female gonadal function disorders</i>		
Ovulation delayed	1	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	1	0
<i>Thyroid disorders NEC</i>		
Thyroid mass	1	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	2	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	2	0
<b>Endocrine disorders SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Amblyopic vision impairment</b></i>		
Amblyopia	2	0
<i><b>Cataract conditions</b></i>		
Cataract	2	0
<i><b>Choroid and vitreous haemorrhages and vascular disorders</b></i>		
Vitreous haemorrhage	2	0
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Vitreous detachment	2	0
Vitreous floaters	11	0
<i><b>Colour blindness (incl acquired)</b></i>		
Dyschromatopsia	1	0
<i><b>Conjunctival and corneal bleeding and vascular disorders</b></i>		
Conjunctival haemorrhage	2	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	7	0
Eyelid ptosis	4	0
<i><b>Glaucomas (excl congenital)</b></i>		
Glaucoma	2	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Iridocyclitis	1	0
Uveitis	3	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	13	0
Lacrimation increased	7	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Blepharitis	2	0
Eyelid cyst	1	0
Swelling of eyelid	3	0
<i><b>Lid, lash and lacrimal structural disorders</b></i>		
Lagophthalmos	1	0
<i><b>Ocular bleeding and vascular disorders NEC</b></i>		
Eye haemorrhage	3	0
Ophthalmic vein thrombosis	1	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	3	0
Eye pain	61	0
Eye swelling	13	0
Eyelid pain	1	0
Ocular discomfort	7	0
Periorbital oedema	2	0
Periorbital swelling	2	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye allergy	1	0
Eye inflammation	3	0
Eye irritation	5	0
Eye pruritus	6	0
Limbal swelling	1	0
Ocular hyperaemia	14	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	1	0
Ocular myasthenia	1	0
Ophthalmoplegia	1	0
<i><b>Ocular sensation disorders</b></i>		

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Asthenopia	6	0
Foreign body sensation in eyes	1	0
Hypoaesthesia eye	1	0
Photophobia	24	0
<b>Optic disc abnormalities NEC</b>		
Optic disc drusen	1	0
<b>Pupil disorders</b>		
Miosis	1	0
Mydriasis	1	0
Pupil fixed	2	0
Pupillary reflex impaired	1	0
<b>Refractive and accommodative disorders</b>		
Altered visual depth perception	1	0
Myopia	1	0
<b>Retinal bleeding and vascular disorders (excl retinopathy)</b>		
Retinal artery occlusion	1	0
Retinal ischaemia	1	0
Retinal vein thrombosis	1	0
Retinal vessel avulsion	1	0
<b>Retinal structural change, deposit and degeneration</b>		
Retinal detachment	1	0
Retinal tear	1	0
Retinal toxicity	1	0
<b>Retinopathies NEC</b>		
Diabetic retinopathy	1	0
Retinal exudates	1	0
<b>Scleral infections, irritations and inflammations</b>		
Episcleritis	1	0
<b>Visual colour distortions</b>		
Xanthopsia	1	0
<b>Visual disorders NEC</b>		
Diplopia	9	0
Metamorphopsia	1	0
Photopsia	11	0
Scintillating scotoma	2	0
Vision blurred	89	0
Visual brightness	1	0
<b>Visual field disorders</b>		
Visual field defect	1	0
<b>Visual impairment and blindness (excl colour blindness)</b>		
Blindness	10	0
Blindness transient	1	0
Blindness unilateral	6	0
Visual acuity reduced	2	0
Visual impairment	29	0
<b>Eye disorders SOC TOTAL</b>	<b>405</b>	<b>0</b>



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<b>Gastrointestinal disorders</b>		
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Anal and rectal ulcers and perforation</i>		
Anal ulcer	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	1	0
<i>Colitis (excl infective)</i>		
Colitis	1	0
Colitis ulcerative	2	0
Crohn's disease	2	0
Inflammatory bowel disease	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	1	0
Dental paraesthesia	1	0
Hyperaesthesia teeth	5	0
Toothache	5	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	129	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	15	0
Eructation	6	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	2	0
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	16	0
Flatulence	5	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	92	0
Abdominal pain lower	2	0
Abdominal pain upper	92	0
Abdominal rigidity	2	0
Abdominal tenderness	1	0
Gastrointestinal pain	2	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	11	0
Gastric dilatation	1	0
Gastrooesophageal reflux disease	6	0
Impaired gastric emptying	1	0
Infrequent bowel movements	1	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	1	0
Gastrointestinal disorder	3	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
Dyschezia	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Duodenitis	1	0

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	26	0
Anal incontinence	1	0
Dysphagia	6	0
Odynophagia	1	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Frequent bowel movements	1	0
Irritable bowel syndrome	4	0
<b><i>Gastrointestinal stenosis and obstruction NEC</i></b>		
Intestinal obstruction	1	0
<b><i>Gastrointestinal vascular occlusion and infarction</i></b>		
Intestinal ischaemia	1	0
Thrombosis mesenteric vessel	1	0
<b><i>Gingival disorders, signs and symptoms NEC</i></b>		
Gingival blister	1	0
Gingival swelling	1	0
Noninfective gingivitis	1	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	6	0
<b><i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i></b>		
Haemorrhoidal haemorrhage	1	0
<b><i>Intestinal haemorrhages</i></b>		
Anal haemorrhage	1	0
Rectal haemorrhage	4	0
<b><i>Intestinal ulcers and perforation NEC</i></b>		
Intestinal perforation	1	0
<b><i>Malabsorption syndromes</i></b>		
Steatorrhoea	1	0
<b><i>Nausea and vomiting symptoms</i></b>		
Discoloured vomit	1	0
Nausea	583	0
Retching	2	0
Vomiting	215	0
Vomiting projectile	2	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Gastrointestinal haemorrhage	1	0
Haematemesis	2	0
<b><i>Oesophagitis (excl infective)</i></b>		
Oesophagitis	1	0
<b><i>Oral dryness and saliva altered</i></b>		
Dry mouth	29	0
Saliva altered	1	0
Salivary hypersecretion	6	0
<b><i>Oral soft tissue disorders NEC</i></b>		
Cheilitis	1	0
Enlarged uvula	1	0
Oral disorder	1	0
<b><i>Oral soft tissue haemorrhages</i></b>		
Mouth haemorrhage	2	0
Oral blood blister	1	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Burning mouth syndrome	1	0
Hypoaesthesia oral	17	0

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Lip discolouration	1	0
Lip pain	4	0
Oral discomfort	6	0
Oral mucosal blistering	1	0
Oral mucosal exfoliation	1	0
Oral pain	6	0
Oral pruritus	1	0
Paraesthesia oral	27	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	27	0
Mouth swelling	6	0
<b><i>Pancreatic disorders NEC</i></b>		
Pancreatic failure	1	0
<b><i>Stomatitis and ulceration</i></b>		
Aphthous ulcer	1	0
Lip ulceration	1	0
Mouth ulceration	24	0
Stomatitis	3	0
<b><i>Tongue disorders</i></b>		
Tongue geographic	1	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	6	0
Swollen tongue	18	0
Tongue blistering	1	0
Tongue coated	2	0
Tongue discolouration	1	0
Tongue discomfort	1	0
Tongue dry	1	0
Tongue erythema	1	0
Tongue oedema	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>1485</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
Puncture site bruise	4	0
Puncture site pain	1	0
<b><i>Application and instillation site reactions</i></b>		
Application site bruise	1	0
Application site erythema	1	0
Application site rash	2	0
Application site wound	1	0
<b><i>Asthenic conditions</i></b>		
Asthenia	96	0
Chronic fatigue syndrome	12	0
Fatigue	936	0
Malaise	229	0
<b><i>Body temperature altered</i></b>		
Hypothermia	1	0
Temperature regulation disorder	2	0
<b><i>Death and sudden death</i></b>		
Death	3	3
Sudden death	1	1
<b><i>Febrile disorders</i></b>		
Pyrexia	761	0
<b><i>Feelings and sensations NEC</i></b>		
Chills	655	0
Feeling abnormal	55	0
Feeling cold	76	0
Feeling drunk	3	0
Feeling hot	63	0
Feeling jittery	2	0
Feeling of body temperature change	22	0
Hangover	6	0
Hunger	3	0
Temperature intolerance	2	0
Thirst	26	0
Thirst decreased	1	0
<b><i>Fibrosis NEC</i></b>		
Fibrosis	1	0
<b><i>Gait disturbances</i></b>		
Gait disturbance	13	0
Gait inability	7	0
<b><i>General signs and symptoms NEC</i></b>		
Condition aggravated	6	0
Critical illness	1	0
Crying	8	0
Energy increased	1	0
General physical health deterioration	1	0
Glassy eyes	1	0
Ill-defined disorder	1	0
Illness	53	0
Influenza like illness	173	0
Local reaction	3	0
Peripheral swelling	114	0
Swelling	56	0
Swelling face	29	0

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<b>General disorders</b> General disorders cont'd		
Unevaluable event	1	0
<b>Implant and catheter site reactions</b>		
Implant site urticaria	1	0
Implant site warmth	1	0
<b>Inflammations</b>		
Inflammation	30	0
Systemic inflammatory response syndrome	1	0
<b>Injection site reactions</b>		
Injected limb mobility decreased	1	0
Injection site bruising	2	0
Injection site discomfort	1	0
Injection site erythema	9	0
Injection site haemorrhage	2	0
Injection site indentation	1	0
Injection site inflammation	4	0
Injection site injury	1	0
Injection site mass	22	0
Injection site necrosis	1	0
Injection site pain	91	0
Injection site papule	1	0
Injection site pruritus	4	0
Injection site rash	9	0
Injection site reaction	7	0
Injection site swelling	8	0
Injection site urticaria	2	0
Injection site warmth	6	0
<b>Interactions</b>		
Inhibitory drug interaction	1	0
<b>Mass conditions NEC</b>		
Mass	6	0
<b>Oedema NEC</b>		
Oedema	3	0
Oedema peripheral	4	0
<b>Pain and discomfort NEC</b>		
Axillary pain	12	0
Chest discomfort	54	0
Chest pain	116	0
Discomfort	30	0
Facial pain	7	0
Inflammatory pain	2	0
Pain	354	0
Tenderness	38	0
Visceral pain	1	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	2	0
Drug ineffective	10	0
Inadequate analgesia	1	0
Therapeutic product ineffective	1	0
Therapeutic response unexpected	7	0
Vaccination failure	1	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	2	0

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<b>General disorders</b> General disorders cont'd		
Vaccination site bruising	2	0
Vaccination site discolouration	3	0
Vaccination site erythema	12	0
Vaccination site induration	2	0
Vaccination site inflammation	2	0
Vaccination site mass	14	0
Vaccination site movement impairment	7	0
Vaccination site pain	61	0
Vaccination site papule	1	0
Vaccination site pruritus	1	0
Vaccination site rash	3	0
Vaccination site reaction	1	0
Vaccination site scar	1	0
Vaccination site swelling	8	0
Vaccination site urticaria	1	0
Vaccination site vesicles	2	0
Vaccination site warmth	5	0
<b><i>Withdrawal and rebound effects</i></b>		
Withdrawal syndrome	1	0
<b>General disorders SOC TOTAL</b>	<b>4419</b>	<b>4</b>

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<b>Hepatic disorders</b>		
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholecystitis	2	0
<i><b>Cholestasis and jaundice</b></i>		
Jaundice	2	0
<i><b>Gallbladder disorders NEC</b></i>		
Gallbladder disorder	1	0
<i><b>Hepatic and hepatobiliary disorders NEC</b></i>		
Liver disorder	1	0
<i><b>Hepatic failure and associated disorders</b></i>		
Hepatic failure	1	0
<i><b>Hepatic vascular disorders</b></i>		
Budd-Chiari syndrome	1	0
Portal hypertension	1	0
Portal vein thrombosis	4	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	1	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Hepatic steatosis	2	0
Hepatitis	1	0
Hepatitis acute	1	0
Liver injury	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>19</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Hypersensitivity	51	0
Multiple allergies	1	0
Type IV hypersensitivity reaction	2	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergy to vaccine	1	0
Contrast media reaction	1	0
Drug hypersensitivity	1	0
Food allergy	1	0
Reaction to excipient	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	26	0
Anaphylactic shock	3	0
Anaphylactoid reaction	1	0
<i><b>Atopic disorders</b></i>		
Seasonal allergy	1	0
<i><b>Autoimmune disorders NEC</b></i>		
Autoimmune disorder	3	0
<i><b>Immune and associated conditions NEC</b></i>		
Bacille Calmette-Guerin scar reactivation	1	0
Immune system disorder	1	0
<i><b>Immunodeficiency disorders NEC</b></i>		
Immunodeficiency	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>96</b>	<b>0</b>



## Case Series Drug Analysis Print

**Name: All FOI 23/980 - AZ vaccine batch number 4120Z003**

Report Run Date: 09-Jan-2024

Data Lock Date: 07-Jan-2024 18:30:05

Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Appendicitis	2	0
<b><i>Bacterial infections NEC</i></b>		
Acinetobacter infection	1	0
Cellulitis	10	0
<b><i>Bone and joint infections</i></b>		
Arthritis infective	1	0
<b><i>Breast infections</i></b>		
Mastitis	1	0
<b><i>Candida infections</i></b>		
Candida infection	2	0
Oral candidiasis	3	0
Vulvovaginal candidiasis	2	0
<b><i>Cardiac infections</i></b>		
Endocarditis	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Brain abscess	1	0
Cavernous sinus thrombosis	1	0
Meningitis	1	0
Myelitis	1	0
Spinal cord abscess	1	0
<b><i>Coronavirus infections</i></b>		
COVID-19	53	0
COVID-19 pneumonia	4	0
Post-acute COVID-19 syndrome	3	0
<b><i>Corynebacteria infections</i></b>		
Diphtheria	1	0
<b><i>Dental and oral soft tissue infections</i></b>		
Oral pustule	1	0
Parotitis	1	0
<b><i>Ear infections</i></b>		
Ear infection	3	0
Labyrinthitis	11	0
Otitis media	1	0
<b><i>Epstein-Barr viral infections</i></b>		
Infectious mononucleosis	1	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	2	0
Hordeolum	2	0
<b><i>Female reproductive tract infections</i></b>		
Vaginal infection	1	0
<b><i>Herpes viral infections</i></b>		
Genital herpes	1	0
Herpes simplex	1	0
Herpes zoster	26	0
Nasal herpes	1	0
Oral herpes	8	0
<b><i>Infections NEC</i></b>		
Infection	11	0
Injection site infection	1	0
Localised infection	2	0
<b><i>Influenza viral infections</i></b>		
Influenza	131	0

## Case Series Drug Analysis Print

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Report Run Date: 09-Jan-2024

Data Lock Date: 07-Jan-2024 18:30:05

Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	2	0
Lower respiratory tract infection	11	0
Pneumonia	7	0
Pneumonia aspiration	1	0
<b><i>Muscle and soft tissue infections</i></b>		
Soft tissue infection	1	0
<b><i>Rubella viral infections</i></b>		
Rubella	1	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	1	0
<b><i>Serratia infections</i></b>		
Serratia infection	1	0
<b><i>Skin structures and soft tissue infections</i></b>		
Impetigo	1	0
Skin infection	3	0
<b><i>Streptococcal infections</i></b>		
Scarlet fever	1	0
Streptococcal bacteraemia	1	0
<b><i>Treponema infections</i></b>		
Pinta	1	0
<b><i>Upper respiratory tract infections</i></b>		
Chronic sinusitis	2	0
Laryngitis	1	0
Nasopharyngitis	44	0
Peritonsillar abscess	1	0
Pharyngitis	2	0
Rhinitis	2	0
Sinusitis	14	0
Tonsillitis	2	0
Upper respiratory tract infection	1	0
<b><i>Urinary tract infections</i></b>		
Cystitis	1	0
Kidney infection	1	0
Pyelonephritis	1	0
Renal abscess	1	0
Urinary tract infection	6	0
<b><i>Vascular infections</i></b>		
Infected varicose vein	1	0
<b><i>Viral infections NEC</i></b>		
Gastroenteritis viral	2	0
Pleurisy viral	1	0
Sweating fever	11	0
Viral infection	2	0
Viral labyrinthitis	1	0
Viral myocarditis	1	0
Viral pharyngitis	1	0
Viral rash	1	0
Viral tonsillitis	1	0
<b>Infections SOC TOTAL</b>	<b>427</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 09-Jan-2024

Data Lock Date: 07-Jan-2024 18:30:05

Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Oral contusion	1	0
<b><i>Cerebral injuries NEC</i></b>		
Brain contusion	2	0
Extradural haematoma	1	0
<b><i>Chemical injuries</i></b>		
Chemical burn of skin	1	0
<b><i>Chest and respiratory tract injuries NEC</i></b>		
Chest crushing	1	0
Chest injury	1	0
<b><i>Conditions caused by cold</i></b>		
Chillblains	2	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure via breast milk	3	0
Maternal exposure during breast feeding	25	0
Maternal exposure during pregnancy	9	0
<b><i>Eye injuries NEC</i></b>		
Eye injury	1	0
<b><i>Intentional product use issues</i></b>		
Intentional dose omission	3	0
<b><i>Limb fractures and dislocations</i></b>		
Clavicle fracture	2	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Circumstance or information capable of leading to medication error	1	0
Medication error	4	0
Wrong drug	1	0
<b><i>Muscle, tendon and ligament injuries</i></b>		
Epicondylitis	2	0
Muscle injury	1	0
Tendon rupture	2	0
<b><i>Nerve injuries NEC</i></b>		
Nerve injury	5	0
<b><i>Non-site specific injuries NEC</i></b>		
Arthropod sting	1	0
Electric shock	3	0
Fall	6	0
Wound complication	1	0
Wound haemorrhage	1	0
<b><i>Non-site specific procedural complications</i></b>		
Injection related reaction	5	0
<b><i>Off label uses</i></b>		
Off label use	5	0
<b><i>Overdoses NEC</i></b>		
Overdose	1	0
<b><i>Poisoning and toxicity</i></b>		
Toxicity to various agents	1	0
<b><i>Product administration errors and issues</i></b>		
Contraindicated product administered	1	0
Inappropriate schedule of product administration	6	0
Incomplete course of vaccination	6	0
Incorrect dose administered	1	0
Incorrect route of product administration	3	0
Product administered at inappropriate site	1	0

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MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Product dose omission issue	2	0
<b><i>Product storage errors and issues in the product use system</i></b>		
Product storage error	1	0
<b><i>Site specific injuries NEC</i></b>		
Limb injury	11	0
<b><i>Skin injuries NEC</i></b>		
Contusion	103	0
Scar	2	0
Scratch	1	0
Skin injury	1	0
Skin laceration	1	0
<b><i>Spinal fractures and dislocations</i></b>		
Spinal compression fracture	1	0
<b><i>Thermal burns</i></b>		
Burn oral cavity	1	0
Thermal burns of eye	1	0
<b><i>Vaccination related complications</i></b>		
Immunisation reaction	3	0
Post vaccination syndrome	3	0
<b>Injuries SOC TOTAL</b>	<b>241</b>	<b>0</b>

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Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Autoimmunity analyses</i></b>		
Antinuclear antibody	1	0
Antinuclear antibody positive	2	0
Rheumatoid factor increased	1	0
<b><i>Blood gas and acid base analyses</i></b>		
Oxygen saturation decreased	6	0
Oxygen saturation normal	1	0
<b><i>Bone marrow and immune tissue imaging procedures</i></b>		
Scan lymph nodes	1	0
<b><i>Carbohydrate tolerance analyses (incl diabetes)</i></b>		
Blood glucose decreased	1	0
Blood glucose increased	1	0
<b><i>Cardiac auscultatory investigations</i></b>		
Cardiac murmur	2	0
<b><i>Cardiac function diagnostic procedures</i></b>		
Myocardial strain imaging	1	0
<b><i>Chemistry analyses NEC</i></b>		
Histamine abnormal	1	0
Inflammatory marker increased	1	0
<b><i>Coagulation and bleeding analyses</i></b>		
Activated partial thromboplastin time prolonged	3	0
Fibrin D dimer increased	2	0
International normalised ratio abnormal	1	0
International normalised ratio increased	2	0
<b><i>ECG investigations</i></b>		
Electrocardiogram T wave inversion	1	0
<b><i>Endocrine analyses and imaging NEC</i></b>		
Hormone level abnormal	4	0
<b><i>Haematological analyses NEC</i></b>		
Red blood cell sedimentation rate	1	0
<b><i>Heart rate and pulse investigations</i></b>		
Heart rate	22	0
Heart rate abnormal	4	0
Heart rate decreased	6	0
Heart rate increased	47	0
Heart rate irregular	5	0
Pulse abnormal	1	0
<b><i>Hepatobiliary function diagnostic procedures</i></b>		
Alanine aminotransferase increased	1	0
Hepatic enzyme abnormal	1	0
Liver function test abnormal	1	0
<b><i>Immunology skin tests NEC</i></b>		
Skin test positive	1	0
<b><i>Investigations NEC</i></b>		
Blood test	2	0
Blood test abnormal	5	0
<b><i>Metabolism tests NEC</i></b>		
Ubiquinone	1	0
<b><i>Mineral and electrolyte analyses</i></b>		
Blood iron	1	0
Blood iron increased	1	0
Serum ferritin decreased	1	0
<b><i>Mycobacteria identification and serology</i></b>		

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MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Interferon gamma release assay positive	1	0
<b>Neurologic diagnostic procedures</b>		
Coma scale abnormal	2	0
Lumbar puncture	1	0
<b>Physical examination procedures and organ system status</b>		
Body temperature	11	0
Body temperature abnormal	1	0
Body temperature decreased	1	0
Body temperature fluctuation	4	0
Body temperature increased	24	0
Breath sounds abnormal	1	0
Grip strength decreased	5	0
Respiratory rate	1	0
Respiratory rate decreased	1	0
Respiratory rate increased	1	0
Skin temperature	1	0
Temperature difference of extremities	1	0
Weight decreased	5	0
<b>Pituitary analyses anterior</b>		
Blood thyroid stimulating hormone increased	1	0
<b>Platelet analyses</b>		
Platelet count decreased	12	0
<b>Red blood cell analyses</b>		
Haemoglobin decreased	1	0
<b>Renal function analyses</b>		
Glomerular filtration rate decreased	1	0
<b>Reproductive hormone analyses</b>		
Blood oestrogen increased	2	0
Dihydrotestosterone decreased	1	0
<b>Respiratory and pulmonary function diagnostic procedures</b>		
Pulmonary function test decreased	1	0
<b>Respiratory tract and thoracic histopathology procedures</b>		
Sputum abnormal	1	0
<b>Respiratory tract and thoracic imaging procedures</b>		
Chest X-ray	1	0
<b>Skeletal and cardiac muscle analyses</b>		
Troponin increased	1	0
<b>Urinalysis NEC</b>		
Blood urine present	4	0
<b>Urinary tract function analyses NEC</b>		
Urine output decreased	1	0
<b>Vascular tests NEC (incl blood pressure)</b>		
Blood pressure abnormal	3	0
Blood pressure decreased	2	0
Blood pressure diastolic increased	1	0
Blood pressure increased	11	0
Blood pressure measurement	3	0
Blood pressure orthostatic decreased	1	0
Blood pressure systolic increased	1	0
<b>Virus identification and serology</b>		
SARS-CoV-2 antibody test negative	2	0
SARS-CoV-2 test	1	0
<b>White blood cell analyses</b>		

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Report Run Date: 09-Jan-2024

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Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Eosinophil count	1	0
Eosinophil count abnormal	1	0
Lymphocyte count decreased	1	0
<b>Investigations SOC TOTAL</b>	<b>249</b>	<b>0</b>

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	3	0
Decreased appetite	99	0
Increased appetite	1	0
<i><b>Calcium metabolism disorders</b></i>		
Hypercalcaemia	1	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	2	0
Diabetes mellitus inadequate control	1	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	2	0
<i><b>Elevated cholesterol</b></i>		
Hypercholesterolaemia	1	0
<i><b>Fat soluble vitamin deficiencies and disorders</b></i>		
Vitamin D deficiency	1	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Alcohol intolerance	1	0
Food intolerance	3	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal weight gain	1	0
Feeding disorder	7	0
Food aversion	1	0
Poor feeding infant	1	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	1	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	2	0
Postprandial hypoglycaemia	1	0
<i><b>Iron excess</b></i>		
Haemochromatosis	1	0
<i><b>Metabolic acidoses (excl diabetic acidoses)</b></i>		
Hyperlactacidaemia	1	0
Metabolic acidosis	1	0
<i><b>Mixed acid-base disorders</b></i>		
Acidosis	1	0
<i><b>Potassium imbalance</b></i>		
Hypokalaemia	1	0
<i><b>Sodium imbalance</b></i>		
Hyponatraemia	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	8	0
<b>Metabolic disorders SOC TOTAL</b>	<b>143</b>	<b>0</b>



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Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	18	0
Arthropathy	1	0
<i><b>Bone disorders NEC</b></i>		
Enostosis	1	0
Jaw disorder	1	0
Osteitis	1	0
Osteosclerosis	2	0
Spinal disorder	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	13	0
Bone swelling	1	0
Pain in jaw	17	0
Spinal pain	7	0
<i><b>Bursal disorders</b></i>		
Bursitis	5	0
<i><b>Cartilage disorders</b></i>		
Costochondritis	5	0
<i><b>Connective tissue disorders NEC</b></i>		
Connective tissue disorder	1	0
Morphoea	2	0
Polymyalgia rheumatica	2	0
Reynold's syndrome	2	0
<i><b>Epiphyseal disorders</b></i>		
Epiphyses premature fusion	1	0
<i><b>Extremity deformities</b></i>		
Limb deformity	1	0
<i><b>Intervertebral disc disorders NEC</b></i>		
Intervertebral disc protrusion	2	0
<i><b>Joint related disorders NEC</b></i>		
Joint destruction	1	0
Joint laxity	1	0
Joint lock	2	0
Periarthritis	7	0
Rotator cuff syndrome	3	0
Temporomandibular joint syndrome	4	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	424	0
Joint noise	2	0
Joint range of motion decreased	2	0
Joint stiffness	16	0
Joint swelling	21	0
Joint warmth	1	0
<i><b>Lupus erythematosus (incl subtypes)</b></i>		
Systemic lupus erythematosus	2	0
<i><b>Muscle infections and inflammations</b></i>		
Myositis	1	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	7	0
Myalgia	495	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle fatigue	19	0
Muscle mass	1	0

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MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
Muscle spasms	60	0
Muscle swelling	1	0
Muscle tightness	6	0
Muscle twitching	17	0
<b><i>Muscle tone abnormalities</i></b>		
Nuchal rigidity	1	0
Trismus	1	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	61	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Limb mass	1	0
Mobility decreased	4	0
Musculoskeletal stiffness	56	0
Weight bearing difficulty	1	0
<b><i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i></b>		
Facial asymmetry	1	0
<b><i>Musculoskeletal and connective tissue infections and inflammations NEC</i></b>		
Connective tissue inflammation	1	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	100	0
Flank pain	2	0
Limb discomfort	51	0
Musculoskeletal chest pain	14	0
Musculoskeletal discomfort	5	0
Musculoskeletal pain	5	0
Neck pain	85	0
Pain in extremity	452	0
<b><i>Myopathies</i></b>		
Muscle necrosis	1	0
<b><i>Osteoarthropathies</i></b>		
Osteoarthritis	7	0
<b><i>Rheumatoid arthropathies</i></b>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	3	0
<b><i>Soft tissue disorders NEC</i></b>		
Axillary mass	4	0
Groin pain	4	0
Soft tissue swelling	1	0
<b><i>Spondyloarthropathies</i></b>		
Ankylosing spondylitis	1	0
Arthritis reactive	3	0
Axial spondyloarthritis	1	0
<b><i>Synovial disorders</i></b>		
Synovial cyst	1	0
Synovitis	1	0
<b><i>Tendon disorders</i></b>		
Tendon pain	2	0
Tendonitis	3	0
Tenosynovitis	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>2052</b>	<b>0</b>

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i><b>Aural neoplasms benign</b></i>		
Cholesterol granuloma	1	0
<i><b>Breast and nipple neoplasms malignant</b></i>		
Breast cancer	2	0
Breast cancer male	1	0
<i><b>Colorectal neoplasms malignant</b></i>		
Colon cancer	1	0
<i><b>Leiomyosarcomas</b></i>		
Pleomorphic leiomyosarcoma	1	0
<i><b>Lip and oral cavity neoplasms benign</b></i>		
Papillary cystadenoma lymphomatosum	1	0
<i><b>Lymphomas unspecified NEC</b></i>		
Lymphoma	1	0
<i><b>Neoplasms unspecified malignancy and site unspecified NEC</b></i>		
Neoplasm recurrence	1	0
<i><b>Nervous system neoplasms unspecified malignancy NEC</b></i>		
Brain neoplasm	1	0
<i><b>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</b></i>		
Pancreatic carcinoma	1	0
<i><b>Paraneoplastic syndromes NEC</b></i>		
Paraneoplastic syndrome	1	0
<i><b>Skin neoplasms benign</b></i>		
Haemangioma of skin	1	0
<i><b>Uterine neoplasms benign</b></i>		
Uterine leiomyoma	1	0
<i><b>Uterine neoplasms malignant NEC</b></i>		
Uterine cancer	1	0
<b>Neoplasms SOC TOTAL</b>	<b>15</b>	<b>0</b>

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MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Abnormal reflexes</b></i>		
Hyporeflexia	1	0
Poor sucking reflex	1	0
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	1	0
<i><b>Acute polyneuropathies</b></i>		
Guillain-Barre syndrome	8	0
Miller Fisher syndrome	1	0
<i><b>Central nervous system haemorrhages and cerebrovascular accidents</b></i>		
Basilar artery thrombosis	1	0
Carotid artery thrombosis	1	0
Cerebellar infarction	1	0
Cerebellar stroke	1	0
Cerebral artery embolism	1	0
Cerebral artery thrombosis	1	0
Cerebral haematoma	1	0
Cerebral haemorrhage	4	0
Cerebral infarction	1	0
Cerebral thrombosis	3	0
Cerebral vascular occlusion	1	0
Cerebrovascular accident	28	0
Haemorrhagic cerebellar infarction	1	0
Haemorrhagic stroke	1	0
Haemorrhagic transformation stroke	1	1
Ischaemic stroke	3	0
Middle cerebral artery stroke	2	1
Subarachnoid haemorrhage	6	0
Thrombotic stroke	2	0
<i><b>Central nervous system vascular disorders NEC</b></i>		
Cerebral amyloid angiopathy	1	0
Cerebral microhaemorrhage	1	0
Cerebrovascular insufficiency	1	0
<i><b>Cerebrovascular venous and sinus thrombosis</b></i>		
Cerebral venous sinus thrombosis	5	2
Superior sagittal sinus thrombosis	2	0
<i><b>Coordination and balance disturbances</b></i>		
Ataxia	1	0
Balance disorder	27	0
Coordination abnormal	3	0
Dysstasia	2	0
<i><b>Cortical dysfunction NEC</b></i>		
Aphasia	4	0
Visuospatial deficit	1	0
<i><b>Demyelinating disorders NEC</b></i>		
Demyelination	1	0
<i><b>Disturbances in consciousness NEC</b></i>		
Altered state of consciousness	1	0
Depressed level of consciousness	4	0
Lethargy	94	0
Loss of consciousness	30	0
Somnolence	33	0
Syncope	62	0
<i><b>Dyskinesias and movement disorders NEC</b></i>		

## Case Series Drug Analysis Print

**Name: All FOI 23/980 - AZ vaccine batch number 4120Z003**

Report Run Date: 09-Jan-2024

Data Lock Date: 07-Jan-2024 18:30:05

Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Bradykinesia	1	0
Clumsiness	1	0
Dyskinesia	3	0
Extrapyramidal disorder	1	0
Hyperkinesia	1	0
Hypokinesia	5	0
Motor dysfunction	1	0
Movement disorder	4	0
<b>Eye movement disorders</b>		
Vlth nerve paralysis	1	0
<b>Facial cranial nerve disorders</b>		
Bell's palsy	13	0
Facial paralysis	8	0
Facial paresis	4	0
Facial spasm	3	0
<b>Generalised tonic-clonic seizures</b>		
Generalised tonic-clonic seizure	3	0
<b>Headaches NEC</b>		
Cluster headache	10	0
Cold-stimulus headache	3	0
Headache	1447	0
Medication overuse headache	1	0
Occipital neuralgia	2	0
Primary headache associated with sexual activity	1	0
Primary stabbing headache	5	0
Sinus headache	20	0
Tension headache	37	0
Thunderclap headache	2	0
Vascular headache	3	0
<b>Increased intracranial pressure disorders</b>		
Brain oedema	4	0
<b>Lumbar spinal cord and nerve root disorders</b>		
Lumbar radiculopathy	1	0
Sciatica	3	0
<b>Memory loss (excl dementia)</b>		
Amnesia	13	0
Memory impairment	11	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	9	0
Disturbance in attention	24	0
Judgement impaired	2	0
Mental impairment	1	0
<b>Migraine headaches</b>		
Hemiplegic migraine	2	0
Migraine	161	0
Migraine with aura	10	0
Migraine without aura	2	0
Retinal migraine	4	0
Status migrainosus	1	0
Vestibular migraine	1	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	2	0
Nerve compression	2	0

## Case Series Drug Analysis Print

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Report Run Date: 09-Jan-2024

Data Lock Date: 07-Jan-2024 18:30:05

Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Peroneal nerve palsy	1	0
<b>Multiple sclerosis acute and progressive</b>		
Band sensation	1	0
<b>Muscle tone abnormal</b>		
Serotonin syndrome	1	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	8	0
<b>Narcolepsy and hypersomnia</b>		
Hypersomnia	3	0
<b>Nervous system cysts and polyps</b>		
Cerebral cyst	1	0
<b>Nervous system disorders NEC</b>		
Central nervous system lesion	1	0
Nervous system disorder	1	0
<b>Neurologic visual problems NEC</b>		
Hemianopia	1	0
<b>Neurological signs and symptoms NEC</b>		
Brain fog	25	0
Dizziness	429	0
Dizziness exertional	2	0
Dizziness postural	44	0
Head discomfort	29	0
Meningism	1	0
Neurological symptom	3	0
Presyncope	15	0
Unresponsive to stimuli	3	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	4	0
<b>Olfactory nerve disorders</b>		
Anosmia	4	0
Parosmia	10	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	4	0
<b>Paraesthesias and dysaesthesias</b>		
Burning feet syndrome	1	0
Burning sensation	25	0
Formication	2	0
Hyperaesthesia	4	0
Hypoaesthesia	185	0
Paraesthesia	277	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Diplegia	2	0
Hemiparesis	4	0
Hemiplegia	3	0
Monoparesis	7	0
Monoplegia	2	0
Paralysis	3	0
Paraparesis	1	0
Spinal cord paralysis	1	0
<b>Parkinson's disease and parkinsonism</b>		
Freezing phenomenon	2	0
Parkinson's disease	1	0
<b>Peripheral neuropathies NEC</b>		

## Case Series Drug Analysis Print

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Report Run Date: 09-Jan-2024

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Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Neuralgic amyotrophy	1	0
Neuropathy peripheral	9	0
Small fibre neuropathy	1	0
<b>Seizures and seizure disorders NEC</b>		
Clonic convulsion	1	0
Epilepsy	3	0
Febrile convulsion	5	0
Seizure	25	0
Tonic convulsion	2	0
<b>Sensory abnormalities NEC</b>		
Ageusia	13	0
Allodynia	1	0
Aura	1	0
Dysgeusia	60	0
Electric shock sensation	2	0
Neuralgia	36	0
Post herpetic neuralgia	1	0
Restless legs syndrome	4	0
Sensory disturbance	7	0
Sensory loss	9	0
Sensory overload	1	0
Taste disorder	16	0
<b>Sleep disturbances NEC</b>		
Sleep deficit	1	0
<b>Speech and language abnormalities</b>		
Dysarthria	10	0
Incoherent	1	0
Slow speech	2	0
Speech disorder	5	0
<b>Spinal cord and nerve root disorders NEC</b>		
Myelopathy	1	0
<b>Structural brain disorders NEC</b>		
Cerebral mass effect	2	0
<b>Transient cerebrovascular events</b>		
Transient ischaemic attack	6	0
<b>Tremor (excl congenital)</b>		
Head titubation	2	0
Postural tremor	1	0
Tremor	164	0
<b>Trigeminal disorders</b>		
Trigeminal neuralgia	3	0
<b>Nervous system disorders SOC TOTAL</b>	<b>3685</b>	<b>4</b>

## Case Series Drug Analysis Print

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Report Run Date: 09-Jan-2024

Data Lock Date: 07-Jan-2024 18:30:05

Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	3	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>4</b>	<b>0</b>



# Case Series Drug Analysis Print

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Report Run Date: 09-Jan-2024

Data Lock Date: 07-Jan-2024 18:30:05

Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b><i>Device issues NEC</i></b>		
Device issue	1	0
<b><i>Device malfunction events NEC</i></b>		
Thrombosis in device	1	0
<b><i>Product packaging issues</i></b>		
Product container issue	1	0
<b>null SOC TOTAL</b>	<b>3</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 09-Jan-2024

Data Lock Date: 07-Jan-2024 18:30:05

Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	2	0
Staring	1	0
<b><i>Affect alterations NEC</i></b>		
Constricted affect	1	0
Inappropriate affect	1	0
<b><i>Amnesic symptoms</i></b>		
Paramnesia	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	10	0
Anxiety	28	0
Nervousness	12	0
Stress	7	0
Tension	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Paranoia	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Daydreaming	2	0
Mental fatigue	11	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	28	0
Disorientation	11	0
<b><i>Deliria</i></b>		
Delirium	11	0
<b><i>Delusional symptoms</i></b>		
Delusion	2	0
<b><i>Depressive disorders</i></b>		
Depression	17	0
Depression suicidal	1	0
<b><i>Dissociative states</i></b>		
Depersonalisation/derealisation disorder	1	0
Dissociation	4	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Initial insomnia	1	0
Insomnia	48	0
Middle insomnia	1	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	11	0
<b><i>Eating disorders NEC</i></b>		
Binge eating	1	0
Eating disorder	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	4	0
Emotional disorder	2	0
Emotional distress	4	0
Euphoric mood	3	0
Irritability	5	0
Mood altered	2	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	3	0
Fear of death	2	0
Fear of falling	1	0
Fear of open spaces	1	0

## Case Series Drug Analysis Print

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Report Run Date: 09-Jan-2024

Data Lock Date: 07-Jan-2024 18:30:05

Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Phonophobia	1	0
<b>Fluctuating mood symptoms</b>		
Mood swings	2	0
<b>Hallucinations (excl sleep-related)</b>		
Hallucination	10	0
<b>Increased physical activity levels</b>		
Restlessness	12	0
<b>Mental disorders NEC</b>		
Mental disorder	1	0
<b>Mood alterations with depressive symptoms</b>		
Depressed mood	15	0
Feeling of despair	1	0
Tearfulness	2	0
<b>Mood alterations with manic symptoms</b>		
Mania	3	0
<b>Mood disorders NEC</b>		
Listless	2	0
<b>Panic attacks and disorders</b>		
Panic attack	6	0
<b>Parasomnias</b>		
Abnormal dreams	8	0
Nightmare	8	0
Sleep terror	1	0
<b>Perception disturbances NEC</b>		
Autoscopy	2	0
Deja vu	1	0
<b>Personality disorders NEC</b>		
Personality disorder	1	0
<b>Psychiatric elimination disorders</b>		
Enuresis	1	0
<b>Psychiatric symptoms NEC</b>		
Abulia	1	0
<b>Sexual desire disorders</b>		
Libido increased	1	0
Loss of libido	1	0
<b>Sleep disorders NEC</b>		
Sleep disorder	7	0
<b>Somatic symptom disorders</b>		
Conversion disorder	4	0
<b>Stereotypies and automatisms</b>		
Bruxism	2	0
<b>Suicidal and self-injurious behaviour</b>		
Intentional self-injury	1	0
Suicidal ideation	6	0
<b>Thinking disturbances</b>		
Bradyphrenia	6	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>349</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 09-Jan-2024

Data Lock Date: 07-Jan-2024 18:30:05

Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder discomfort	1	0
Bladder irritation	2	0
Dysuria	2	0
Incontinence	4	0
Micturition urgency	1	0
Mixed incontinence	1	0
Pollakiuria	5	0
Urinary incontinence	6	0
<i><b>Bladder disorders NEC</b></i>		
Bladder disorder	1	0
Urinary bladder haemorrhage	1	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Glomerulonephritis minimal lesion	1	0
Nephrotic syndrome	1	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Bladder dysfunction	1	0
Hypertonic bladder	1	0
Loss of bladder sensation	1	0
<i><b>Renal disorders NEC</b></i>		
Renal disorder	1	0
<i><b>Renal failure and impairment</b></i>		
Renal failure	2	0
Renal injury	1	0
<i><b>Renal lithiasis</b></i>		
Nephrolithiasis	1	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	2	0
Haematuria	3	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Haemorrhage urinary tract	3	0
Nocturia	2	0
Polyuria	1	0
Renal colic	1	0
Renal pain	16	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>62</b>	<b>0</b>

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Report Run Date: 09-Jan-2024

Data Lock Date: 07-Jan-2024 18:30:05

Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	2	0
<i><b>Breast signs and symptoms</b></i>		
Breast pain	11	0
Breast swelling	1	0
Breast tenderness	2	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Erectile dysfunction	4	0
<i><b>Menopausal effects NEC</b></i>		
Menopausal symptoms	3	0
Premature menopause	2	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Postmenopausal haemorrhage	12	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Abnormal withdrawal bleeding	1	0
Dysmenorrhoea	32	0
Intermenstrual bleeding	20	0
Menstrual discomfort	1	0
Menstrual disorder	40	0
Menstruation irregular	42	0
Ovulation pain	1	0
Premenstrual pain	3	0
Premenstrual syndrome	1	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	17	0
Hypomenorrhoea	12	0
Menstruation delayed	61	0
Oligomenorrhoea	4	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	104	0
Menometrorrhagia	1	0
Polymenorrhoea	11	0
<i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>		
Ovarian cyst	1	0
<i><b>Reproductive tract disorders NEC (excl neoplasms)</b></i>		
Genital haemorrhage	2	0
Genital ulceration	2	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Pelvic pain	1	0
<i><b>Sexual function and fertility disorders NEC</b></i>		
Infertility male	1	0
<i><b>Testicular and epididymal disorders NEC</b></i>		
Testicular pain	3	0
<i><b>Uterine disorders NEC</b></i>		
Uterine haemorrhage	3	0
<i><b>Uterine tone disorders</b></i>		
Uterine spasm	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	25	0
Vulval ulceration	1	0
<i><b>Vulvovaginal signs and symptoms</b></i>		
Vaginal discharge	1	0
Vulvovaginal pain	1	0

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Report Run Date: 09-Jan-2024

Data Lock Date: 07-Jan-2024 18:30:05

Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>430</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: All FOI 23/980 - AZ vaccine batch number 4120Z003**

Report Run Date: 09-Jan-2024

Data Lock Date: 07-Jan-2024 18:30:05

Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Cheyne-Stokes respiration	1	0
Dyspnoea	149	0
Dyspnoea at rest	1	0
Dyspnoea paroxysmal nocturnal	1	0
Hyperventilation	3	0
Hypopnoea	6	0
Respiration abnormal	2	0
Sleep apnoea syndrome	1	0
Tachypnoea	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	14	0
Bronchospasm	1	0
Wheezing	8	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Asphyxia	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	74	0
Haemoptysis	2	0
Productive cough	5	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Stridor	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	2	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	12	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	46	0
Nasal cyst	1	0
Nasal dryness	3	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinonasal obstruction	1	0
Sinus congestion	2	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Pulmonary fibrosis	2	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	2	0
Pharyngeal oedema	1	0
Pharyngeal swelling	11	0
Tonsillar hypertrophy	2	0
<i><b>Pleural infections and inflammations</b></i>		
Pleurisy	1	0
<i><b>Pulmonary oedemas</b></i>		
Pulmonary congestion	1	0
<i><b>Pulmonary thrombotic and embolic conditions</b></i>		
Pulmonary embolism	30	1
Pulmonary thrombosis	1	0
<i><b>Respiratory failures (excl neonatal)</b></i>		
Respiratory failure	1	0
<i><b>Respiratory signs and symptoms NEC</b></i>		
Allergic respiratory symptom	1	0
<i><b>Respiratory tract disorders NEC</b></i>		

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Data Lock Date: 07-Jan-2024 18:30:05

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MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Lung disorder	2	0
Pulmonary mass	1	0
Respiratory tract oedema	1	0
<b><i>Thoracic musculoskeletal disorders</i></b>		
Respiratory muscle weakness	1	0
<b><i>Upper respiratory tract signs and symptoms</i></b>		
Aphonia	3	0
Catarrh	2	0
Dry throat	3	0
Dysphonia	7	0
Increased viscosity of upper respiratory secretion	2	0
Nasal discomfort	2	0
Oropharyngeal discomfort	5	0
Oropharyngeal pain	76	0
Paranasal sinus discomfort	4	0
Rhinalgia	5	0
Rhinorrhoea	37	0
Sinus pain	18	0
Sneezing	11	0
Throat irritation	1	0
Throat tightness	7	0
<b>Respiratory disorders SOC TOTAL</b>	<b>580</b>	<b>1</b>



## Case Series Drug Analysis Print

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Report Run Date: 09-Jan-2024

Data Lock Date: 07-Jan-2024 18:30:05

Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	4	0
Dermatitis acneiform	1	0
<b><i>Alopecias</i></b>		
Alopecia	12	0
Alopecia scarring	1	0
<b><i>Angioedemas</i></b>		
Angioedema	14	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	33	0
Hyperhidrosis	141	0
Miliaria	3	0
Night sweats	36	0
<b><i>Bullous conditions</i></b>		
Blister	18	0
Blood blister	5	0
Erythema multiforme	1	0
Pemphigus	2	0
Stevens-Johnson syndrome	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	12	0
Pain of skin	11	0
Papule	4	0
Scab	2	0
Sensitive skin	15	0
Skin burning sensation	15	0
Skin discolouration	8	0
Skin discomfort	1	0
Skin fissures	1	0
Skin indentation	1	0
Skin induration	1	0
Skin odour abnormal	1	0
Skin reaction	2	0
Skin sensitisation	1	0
Skin swelling	2	0
Skin warm	12	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	5	0
Dermatitis allergic	7	0
Dermatitis atopic	1	0
Eczema	10	0
Intertrigo	1	0
Skin irritation	5	0
Stasis dermatitis	1	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug reaction with eosinophilia and systemic symptoms	1	0
<b><i>Erythemas</i></b>		
Erythema	80	0
Erythema ab igne	1	0
<b><i>Exfoliative conditions</i></b>		
Skin exfoliation	2	0
<b><i>Granulomatous and deep cutaneous inflammatory conditions</i></b>		
Granuloma annulare	2	0

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Report Run Date: 09-Jan-2024

Data Lock Date: 07-Jan-2024 18:30:05

Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<b><i>Hyperpigmentation disorders</i></b>		
Solar lentigo	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Nail disorder	1	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	1	0
<b><i>Papulosquamous conditions</i></b>		
Lichen planus	2	0
Pityriasis rosea	5	0
<b><i>Photosensitivity and photodermatitis conditions</i></b>		
Photosensitivity reaction	3	0
<b><i>Pilar disorders NEC</i></b>		
Hair growth abnormal	1	0
Hair texture abnormal	1	0
Piloerection	2	0
<b><i>Pruritus NEC</i></b>		
Pruritus	194	0
<b><i>Psoriatic conditions</i></b>		
Psoriasis	5	0
<b><i>Purpura and related conditions</i></b>		
Henoch-Schonlein purpura	1	0
Petechiae	17	0
Purpura	4	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	226	0
Rash erythematous	64	0
Rash macular	19	0
Rash morbilliform	1	0
Rash papular	19	0
Rash pruritic	41	0
Rash scarlatiniform	1	0
Rash vesicular	4	0
<b><i>Rosaceas</i></b>		
Rosacea	1	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Cutaneous symptom	1	0
Skin mass	1	0
<b><i>Skin and subcutaneous tissue ulcerations</i></b>		
Skin erosion	3	0
Skin ulcer	1	0
<b><i>Skin haemorrhages</i></b>		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	3	0
<b><i>Skin vascular conditions NEC</i></b>		
Haemangioma-thrombocytopenia syndrome	1	0
Skin oedema	1	0
<b><i>Skin vasomotor conditions</i></b>		
Livedo reticularis	3	0
<b><i>Urticarias</i></b>		
Cold urticaria	1	0
Mechanical urticaria	1	0
Urticaria	71	0
Urticaria chronic	1	0

# Case Series Drug Analysis Print

Name: All FOI 23/980 - AZ vaccine batch number 4120Z003

Report Run Date: 09-Jan-2024

Data Lock Date: 07-Jan-2024 18:30:05

Earliest Reaction Date: 18-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<b>Skin disorders SOC TOTAL</b>	<b>1180</b>	<b>0</b>

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Age related issues</i>		
Childhood	1	0
Menopause	3	0
<i>Disability issues</i>		
Bedridden	4	0
Disability	1	0
Immobile	1	0
Impaired work ability	5	0
Sight disability	1	0
Sitting disability	1	0
<b>Social circumstances SOC TOTAL</b>	<b>17</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Adrenal gland therapeutic procedures</i>		
Adrenalectomy	1	0
<i>Anaesthesia and allied procedures</i>		
Nerve block	1	0
<i>Contraceptive methods female</i>		
Intrauterine contraception	1	0
<i>Immunisations</i>		
COVID-19 immunisation	6	0
<i>Joint therapeutic procedures</i>		
Joint injection	1	0
<i>Therapeutic procedures NEC</i>		
Hospitalisation	3	0
Injection	1	0
Interchange of vaccine products	9	0
Lesion excision	1	0
Manipulation	1	0
Physical fitness training	1	0
Rest regimen	1	0
<i>Vascular therapeutic procedures NEC</i>		
Thrombectomy	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>28</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<b><i>Accelerated and malignant hypertension</i></b>		
Hypertensive crisis	2	0
<b><i>Aneurysms and dissections non-site specific</i></b>		
Aneurysm	4	0
<b><i>Aortic embolism and thrombosis</i></b>		
Aortic embolus	2	0
Aortic thrombosis	1	0
<b><i>Arterial infections and inflammations</i></b>		
Giant cell arteritis	1	0
<b><i>Blood pressure disorders NEC</i></b>		
Blood pressure fluctuation	2	0
<b><i>Bruising, ecchymosis and purpura</i></b>		
Achenbach syndrome	1	0
<b><i>Circulatory collapse and shock</i></b>		
Circulatory collapse	2	0
Shock	5	0
<b><i>Haemorrhages NEC</i></b>		
Bloody discharge	1	0
Haematoma	2	0
Haemorrhage	39	0
Internal haemorrhage	2	0
<b><i>Lymphoedemas</i></b>		
Lymphoedema	3	0
<b><i>Non-site specific embolism and thrombosis</i></b>		
Arterial thrombosis	4	0
Embolism	5	0
Microembolism	1	0
Thrombosis	48	0
Venous thrombosis	2	0
<b><i>Non-site specific necrosis and vascular insufficiency NEC</i></b>		
Arterial occlusive disease	1	0
Arteriosclerosis	1	1
Infarction	1	0
Ischaemia	1	0
Vasospasm	1	0
<b><i>Non-site specific vascular disorders NEC</i></b>		
Capillary fragility	2	0
Vascular pain	7	0
Vasodilatation	4	0
Vein disorder	1	0
<b><i>Peripheral embolism and thrombosis</i></b>		
Blue toe syndrome	1	0
Deep vein thrombosis	22	0
Peripheral artery thrombosis	1	0
Peripheral embolism	1	0
Subclavian artery embolism	1	0
Superficial vein thrombosis	2	0
Thrombophlebitis	2	0
<b><i>Peripheral vascular disorders NEC</i></b>		
Cyanosis	5	0
Flushing	23	0
Hot flush	42	0
<b><i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i></b>		

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Reaction Name	Total	Fatal
<b>Vascular disorders</b> <small>Vascular disorders cont'd</small>		
Peripheral coldness	44	0
Peripheral ischaemia	2	0
Poor peripheral circulation	2	0
<b><i>Phlebitis NEC</i></b>		
Phlebitis	2	0
Phlebitis superficial	1	0
<b><i>Site specific vascular disorders NEC</i></b>		
Pallor	11	0
<b><i>Varicose veins NEC</i></b>		
Varicose vein	3	0
<b><i>Vascular hypertensive disorders NEC</i></b>		
Hypertension	33	0
Systolic hypertension	1	0
<b><i>Vascular hypotensive disorders</i></b>		
Capillary leak syndrome	1	0
Hypotension	10	0
<b><i>Vasculitides NEC</i></b>		
Granulomatosis with polyangiitis	1	0
Vasculitis	4	0
<b>Vascular disorders SOC TOTAL</b>	<b>361</b>	<b>1</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>16866</b>	<b>15</b>
<b>TOTAL REPORTS</b>	<b>4496</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>15</b>