

## COVID-19 AstraZeneca Vaccine Analysis Print (1)

Report Run Date: 21-Mar-2022  
Data Lock Date: 09-Mar-2022 18:30:05  
MedDRA Version: MedDRA 24.1

All suspected spontaneous reports from Scotland received between 01/01/2021 and 30/04/2021 for the COVID-19 vaccine AstraZeneca.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemias NEC</i></b>		
Anaemia	1	0
<b><i>Anaemias haemolytic NEC</i></b>		
Haemolytic anaemia	1	0
<b><i>Bleeding tendencies</i></b>		
Increased tendency to bruise	10	0
Spontaneous haematoma	1	0
<b><i>Coagulopathies</i></b>		
Antiphospholipid syndrome	1	0
Coagulopathy	2	0
Disseminated intravascular coagulation	5	0
<b><i>Eosinophilic disorders</i></b>		
Eosinophilia	1	0
<b><i>Haematological disorders</i></b>		
Blood disorder	1	0
Mast cell activation syndrome	2	0
Methaemoglobinaemia	1	0
<b><i>Haemolyses NEC</i></b>		
Haemolysis	1	0
<b><i>Leukocytoses NEC</i></b>		
Neutrophilia	2	0
<b><i>Leukopenias NEC</i></b>		
Leukopenia	1	0
Lymphopenia	1	0
<b><i>Lymphatic system disorders NEC</i></b>		
Lymph node pain	23	0
Lymphadenitis	1	0
Lymphadenopathy	275	0
<b><i>Marrow depression and hypoplastic anaemias</i></b>		
Pancytopenia	1	0
<b><i>Neutropenias</i></b>		
Agranulocytosis	2	0
Neutropenia	9	0
<b><i>Spleen disorders</i></b>		
Splenic infarction	1	0
Splenic varices	1	0
<b><i>Thrombocytopenias</i></b>		
Heparin-induced thrombocytopenia	2	0
Immune thrombocytopenia	16	0
Thrombocytopenia	51	0
<b><i>Thrombocytoses</i></b>		
Thrombocytosis	2	0
<b>Blood disorders SOC TOTAL</b>	<b>415</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 complete	2	0
<i><b>Cardiac disorders NEC</b></i>		
Acute cardiac event	1	1
Cardiac disorder	3	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Palpitations	236	0
<i><b>Cardiac valve disorders NEC</b></i>		
Heart valve incompetence	1	0
<i><b>Cardiomyopathies</b></i>		
Congestive cardiomyopathy	1	0
<i><b>Coronary artery disorders NEC</b></i>		
Coronary artery thrombosis	1	0
<i><b>Heart failures NEC</b></i>		
Cardiac failure	5	0
Cardiac failure acute	1	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute myocardial infarction	5	1
Angina pectoris	11	0
Angina unstable	3	0
Myocardial infarction	20	10
<i><b>Left ventricular failures</b></i>		
Acute left ventricular failure	1	0
<i><b>Myocardial disorders NEC</b></i>		
Cardiomegaly	2	0
Left ventricular dilatation	1	0
Left ventricular dysfunction	3	0
Myocardial injury	1	0
Ventricular hypertrophy	1	0
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	1	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	4	0
Bradycardia	4	0
Cardiac flutter	7	0
Extrasystoles	7	0
Heart alternation	1	0
Tachyarrhythmia	1	0
Tachycardia	54	0
<i><b>Right ventricular failures</b></i>		
Right ventricular failure	2	1
<i><b>Supraventricular arrhythmias</b></i>		
Atrial fibrillation	19	0
Atrial flutter	3	0
Sinus bradycardia	1	0
Sinus tachycardia	1	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Cardiac arrest	7	2
Ventricular extrasystoles	1	0
Ventricular tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>413</b>	<b>15</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	1	0
<i>Male reproductive tract disorders congenital</i>		
Micropenis	1	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear congestion	2	0
Ear discomfort	6	0
Ear pain	107	0
Ear swelling	1	0
Otorrhoea	1	0
<i>External ear disorders NEC</i>		
External ear pain	2	0
<i>Hearing losses</i>		
Deafness	16	0
Deafness bilateral	1	0
Deafness neurosensory	1	0
Deafness unilateral	2	0
Hypoacusis	4	0
Sudden hearing loss	3	0
<i>Hyperacusia</i>		
Hyperacusis	6	0
<i>Inner ear disorders NEC</i>		
Meniere's disease	2	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	7	0
Tinnitus	132	0
Vertigo	77	0
Vertigo labyrinthine	1	0
Vertigo positional	3	0
<b>Ear disorders SOC TOTAL</b>	<b>374</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis acute	1	0
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	3	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	2	0
Hyperthyroidism	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>7</b>	<b>0</b>

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<b>Eye disorders</b>		
<b><i>Amblyopic vision impairment</i></b>		
Amblyopia	1	0
<b><i>Choroid and vitreous haemorrhages and vascular disorders</i></b>		
Vitreous haemorrhage	1	0
<b><i>Choroid and vitreous structural change, deposit and degeneration</i></b>		
Chorioretinopathy	1	0
Vitreous detachment	2	0
Vitreous floaters	5	0
<b><i>Conjunctival and corneal bleeding and vascular disorders</i></b>		
Conjunctival haemorrhage	5	0
<b><i>Corneal structural change, deposit and degeneration</i></b>		
Corneal perforation	1	0
<b><i>Eyelid movement disorders</i></b>		
Blepharospasm	3	0
Excessive eye blinking	1	0
Eyelid ptosis	3	0
<b><i>Iris and uveal tract infections, irritations and inflammations</i></b>		
Uveitis	1	0
<b><i>Lacrimation disorders</i></b>		
Dry eye	13	0
Lacrimation increased	13	0
<b><i>Lid, lash and lacrimal infections, irritations and inflammations</i></b>		
Eyelid rash	1	0
Swelling of eyelid	4	0
<b><i>Lid, lash and lacrimal structural disorders</i></b>		
Eyelid thickening	1	0
Growth of eyelashes	1	0
<b><i>Ocular bleeding and vascular disorders NEC</i></b>		
Eye haemorrhage	5	0
<b><i>Ocular disorders NEC</i></b>		
Eye disorder	1	0
Eye pain	174	0
Eye swelling	28	0
Eyelid disorder	2	0
Eyelid pain	1	0
Eyelids pruritus	2	0
Ocular discomfort	4	0
Periorbital swelling	8	0
<b><i>Ocular infections, inflammations and associated manifestations</i></b>		
Eye allergy	1	0
Eye inflammation	1	0
Eye irritation	13	0
Eye pruritus	16	0
Ocular hyperaemia	18	0
<b><i>Ocular nerve and muscle disorders</i></b>		
Extraocular muscle paresis	1	0
Eye movement disorder	1	0
Gaze palsy	2	0
<b><i>Ocular sensation disorders</i></b>		
Abnormal sensation in eye	3	0
Asthenopia	18	0
Foreign body sensation in eyes	3	0
Photophobia	51	0

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<b>Eye disorders</b> Eye disorders cont'd		
<i><b>Pupil disorders</b></i>		
Mydriasis	1	0
<i><b>Retinal bleeding and vascular disorders (excl retinopathy)</b></i>		
Retinal vein occlusion	1	0
Retinal vein thrombosis	1	0
<i><b>Retinal structural change, deposit and degeneration</b></i>		
Retinal tear	1	0
<i><b>Visual colour distortions</b></i>		
Cyanopsia	1	0
<i><b>Visual disorders NEC</b></i>		
Diplopia	17	0
Metamorphopsia	2	0
Photopsia	19	0
Vision blurred	109	0
Visual brightness	1	0
<i><b>Visual field disorders</b></i>		
Visual field defect	1	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness	5	0
Night blindness	1	0
Visual acuity reduced	1	0
Visual impairment	33	0
<i><b>Visual pathway disorders</b></i>		
Optic nerve disorder	1	0
<b>Eye disorders SOC TOTAL</b>	<b>605</b>	<b>0</b>

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<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	3	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	1
Pancreatitis	1	0
Pancreatitis acute	1	0
<i>Anal and rectal pains</i>		
Proctalgia	1	0
<i>Anal and rectal signs and symptoms</i>		
Anal inflammation	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	1	0
<i>Colitis (excl infective)</i>		
Colitis	3	0
Colitis ulcerative	3	0
Crohn's disease	5	0
<i>Dental disorders NEC</i>		
Teething	1	0
<i>Dental pain and sensation disorders</i>		
Dental paraesthesia	1	0
Hyperaesthesia teeth	1	0
Hypoaesthesia teeth	1	0
Toothache	13	0
<i>Dental surface disorders</i>		
Tooth discolouration	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	515	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	36	0
Eructation	3	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
Faeces discoloured	3	0
Faeces soft	3	0
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	22	0
Flatulence	16	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	2	0
Gastric ulcer perforation	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	2	0
Reflux gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	235	0
Abdominal pain lower	12	0
Abdominal pain upper	221	0
Abdominal rigidity	7	0
Gastrointestinal pain	20	0

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Oesophageal pain	1	0
<b><i>Gastrointestinal atonic and hypomotility disorders NEC</i></b>		
Constipation	19	0
Gastrooesophageal reflux disease	8	0
<b><i>Gastrointestinal disorders NEC</i></b>		
Food poisoning	1	0
Gastrointestinal disorder	2	0
<b><i>Gastrointestinal dyskinetic disorders</i></b>		
Bowel movement irregularity	1	0
<b><i>Gastrointestinal inflammatory disorders NEC</i></b>		
Gastrointestinal tract irritation	1	0
Intestinal angioedema	1	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	79	0
Abdominal symptom	1	0
Acute abdomen	1	0
Anal incontinence	3	0
Breath odour	1	0
Dysphagia	13	0
Odynophagia	1	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Frequent bowel movements	1	0
Irritable bowel syndrome	2	0
Oesophageal spasm	1	0
<b><i>Gastrointestinal stenosis and obstruction NEC</i></b>		
Intestinal obstruction	1	0
Intussusception	1	0
<b><i>Gingival disorders, signs and symptoms NEC</i></b>		
Gingival blister	1	0
Gingival disorder	1	0
Gingival pain	15	0
Gingival swelling	3	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	7	0
<b><i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i></b>		
Haemorrhoids	4	0
<b><i>Inguinal hernias</i></b>		
Inguinal hernia	1	0
<b><i>Intestinal haemorrhages</i></b>		
Anal haemorrhage	1	0
Rectal haemorrhage	3	0
<b><i>Intestinal ulcers and perforation NEC</i></b>		
Intestinal perforation	1	0
<b><i>Malabsorption syndromes</i></b>		
Coeliac disease	1	0
<b><i>Nausea and vomiting symptoms</i></b>		
Acetonaemic vomiting	1	0
Discoloured vomit	2	0
Infantile spitting up	1	0
Infantile vomiting	1	0
Nausea	1845	0
Retching	15	0
Vomiting	612	0

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<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Vomiting projectile	9	0
<b>Non-site specific gastrointestinal haemorrhages</b>		
Gastrointestinal haemorrhage	1	0
Haematemesis	5	0
Haematochezia	2	0
<b>Oesophageal stenosis and obstruction</b>		
Oesophageal obstruction	1	0
<b>Oral dryness and saliva altered</b>		
Dry mouth	69	0
Lip dry	2	0
Salivary hypersecretion	2	0
<b>Oral soft tissue disorders NEC</b>		
Chapped lips	1	0
Cheilitis	3	0
Lip blister	3	0
<b>Oral soft tissue haemorrhages</b>		
Mouth haemorrhage	4	0
Oral blood blister	2	0
<b>Oral soft tissue infections</b>		
Angular cheilitis	1	0
<b>Oral soft tissue signs and symptoms</b>		
Anaesthesia oral	1	0
Burning mouth syndrome	4	0
Hypoaesthesia oral	31	0
Lip discolouration	1	0
Lip erythema	1	0
Lip exfoliation	1	0
Lip pain	3	0
Lip pruritus	2	0
Oral discomfort	6	0
Oral mucosal blistering	1	0
Oral mucosal eruption	3	0
Oral mucosal exfoliation	2	0
Oral pain	23	0
Paraesthesia oral	39	0
<b>Oral soft tissue swelling and oedema</b>		
Lip oedema	1	0
Lip swelling	52	0
Mouth swelling	4	0
Palatal oedema	1	0
Palatal swelling	1	0
<b>Peritoneal and retroperitoneal disorders</b>		
Ascites	1	0
<b>Salivary gland infections and inflammations</b>		
Noninfective sialoadenitis	1	0
<b>Stomatitis and ulceration</b>		
Aphthous ulcer	3	0
Lip ulceration	2	0
Mouth ulceration	41	0
Stomatitis	9	0
<b>Tongue disorders</b>		
Glossitis	1	0
Tongue disorder	1	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Trichoglossia	2	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	14	0
Swollen tongue	28	0
Tongue blistering	2	0
Tongue discomfort	1	0
Tongue dry	1	0
Tongue eruption	1	0
Tongue oedema	2	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>4187</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
Administration site haemorrhage	1	0
Administration site induration	1	0
Administration site pain	1	0
Administration site rash	2	0
Puncture site bruise	1	0
Puncture site pain	1	0
<b><i>Application and instillation site reactions</i></b>		
Application site acne	1	0
Application site bruise	1	0
Application site pain	5	0
Application site pruritus	2	0
Application site vesicles	1	0
Application site warmth	1	0
Instillation site warmth	2	0
<b><i>Asthenic conditions</i></b>		
Asthenia	232	0
Chronic fatigue syndrome	11	0
Decreased activity	1	0
Fatigue	2609	0
Malaise	605	0
Sluggishness	4	0
<b><i>Body temperature altered</i></b>		
Hyperthermia	2	0
Hypothermia	1	0
Temperature regulation disorder	1	0
<b><i>Complications associated with device NEC</i></b>		
Injury associated with device	1	0
<b><i>Death and sudden death</i></b>		
Death	15	15
Sudden death	2	2
<b><i>Febrile disorders</i></b>		
Hyperpyrexia	3	0
Pyrexia	2969	0
<b><i>Feelings and sensations NEC</i></b>		
Chills	2241	0
Feeling abnormal	132	0
Feeling cold	251	0
Feeling drunk	4	0
Feeling hot	92	0
Feeling jittery	4	0
Feeling of body temperature change	46	0
Hangover	8	0
Hunger	4	0
Sensation of foreign body	5	0
Temperature intolerance	4	0
Thirst	69	0
<b><i>Gait disturbances</i></b>		
Gait disturbance	25	0
Gait inability	13	0
Loss of control of legs	2	0
<b><i>General signs and symptoms NEC</i></b>		
Chronic disease	1	0

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<b>General disorders</b> General disorders cont'd		
Condition aggravated	16	0
Crepitations	1	0
Crying	12	0
Discharge	1	0
Energy increased	1	0
Exercise tolerance decreased	3	0
General physical health deterioration	2	0
Illness	285	0
Influenza like illness	435	0
Irritability postvaccinal	1	0
Local reaction	7	0
Multiple organ dysfunction syndrome	2	1
Peripheral swelling	299	0
Screaming	2	0
Secretion discharge	3	0
Swelling	141	0
Swelling face	51	0
Tissue discolouration	1	0
<b>Implant and catheter site reactions</b>		
Implant site discolouration	1	0
Implant site hypoaesthesia	1	0
Implant site warmth	1	0
<b>Inflammations</b>		
Inflammation	37	0
Systemic inflammatory response syndrome	1	0
<b>Injection site reactions</b>		
Injected limb mobility decreased	4	0
Injection site bruising	9	0
Injection site dryness	1	0
Injection site erythema	49	0
Injection site hypoaesthesia	2	0
Injection site inflammation	4	0
Injection site joint pain	2	0
Injection site mass	98	0
Injection site muscle weakness	1	0
Injection site oedema	3	0
Injection site pain	271	0
Injection site paraesthesia	2	0
Injection site pruritus	21	0
Injection site rash	22	0
Injection site reaction	9	0
Injection site swelling	18	0
Injection site urticaria	2	0
Injection site warmth	23	0
<b>Mass conditions NEC</b>		
Cyst	1	0
Mass	7	0
Nodule	1	0
<b>Mucosal findings abnormal</b>		
Mucosal inflammation	1	0
Mucosal pain	1	0
<b>Necrosis NEC</b>		
Necrosis	2	0

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<b>General disorders</b> General disorders cont'd		
<b><i>Oedema NEC</i></b>		
Oedema	5	0
Oedema peripheral	6	0
<b><i>Pain and discomfort NEC</i></b>		
Axillary pain	30	0
Chest discomfort	77	0
Chest pain	198	0
Discomfort	33	0
Facial discomfort	1	0
Facial pain	14	0
Non-cardiac chest pain	3	0
Pain	698	0
Tenderness	126	0
<b><i>Therapeutic and nontherapeutic responses</i></b>		
Diet failure	1	0
Drug ineffective	5	0
No reaction on previous exposure to drug	1	0
Therapeutic response unexpected	3	0
<b><i>Ulcers NEC</i></b>		
Ulcer	3	0
<b><i>Vaccination site reactions</i></b>		
Extensive swelling of vaccinated limb	2	0
Shoulder injury related to vaccine administration	2	0
Vaccination site bruising	10	0
Vaccination site erythema	37	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	10	0
Vaccination site inflammation	4	0
Vaccination site irritation	1	0
Vaccination site joint pain	4	0
Vaccination site mass	27	0
Vaccination site movement impairment	2	0
Vaccination site oedema	1	0
Vaccination site pain	110	0
Vaccination site pruritus	6	0
Vaccination site rash	14	0
Vaccination site reaction	2	0
Vaccination site scab	1	0
Vaccination site swelling	41	0
Vaccination site warmth	30	0
<b><i>Withdrawal and rebound effects</i></b>		
Withdrawal syndrome	7	0
<b>General disorders SOC TOTAL</b>	<b>12751</b>	<b>18</b>

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<b>Hepatic disorders</b>		
<i><b>Bile duct infections and inflammations</b></i>		
Biliary colic	2	0
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholecystitis	1	0
<i><b>Cholestasis and jaundice</b></i>		
Cholestasis	1	0
Jaundice	4	0
Jaundice cholestatic	2	0
<i><b>Hepatic and hepatobiliary disorders NEC</b></i>		
Liver disorder	1	0
<i><b>Hepatic enzymes and function abnormalities</b></i>		
Hepatic function abnormal	1	0
<i><b>Hepatic failure and associated disorders</b></i>		
Subacute hepatic failure	1	0
<i><b>Hepatic vascular disorders</b></i>		
Hepatic vein thrombosis	1	0
Portal vein thrombosis	2	0
Portosplenomesenteric venous thrombosis	1	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	3	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Hepatic necrosis	1	0
Hepatitis	3	0
Hepatitis acute	1	0
Liver injury	2	0
<b>Hepatic disorders SOC TOTAL</b>	<b>27</b>	<b>0</b>

# COVID-19 AstraZeneca Vaccine Analysis Print (1)

Report Run Date: 21-Mar-2022

Data Lock Date: 09-Mar-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	2	0
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Allergy to arthropod sting	1	0
Hypersensitivity	73	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	1	0
Drug hypersensitivity	7	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	30	0
Anaphylactic shock	5	0
Anaphylactoid reaction	1	0
<i>Atopic disorders</i>		
Seasonal allergy	3	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	3	0
Immune system disorder	1	0
Sensitisation	4	0
<b>Immune system disorders SOC TOTAL</b>	<b>133</b>	<b>0</b>

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Report Run Date: 21-Mar-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Appendicitis	2	0
Diarrhoea infectious	1	0
Diverticulitis	2	0
Gastroenteritis	4	0
<b><i>Bacterial infections NEC</i></b>		
Bacterial infection	1	0
Cellulitis	38	0
Folliculitis	1	0
Injection site cellulitis	1	0
Vaccination site cellulitis	2	0
<b><i>Borrelial infections</i></b>		
Erythema migrans	1	0
Lyme disease	1	0
<b><i>Candida infections</i></b>		
Candida infection	4	0
Oral candidiasis	3	0
Vulvovaginal candidiasis	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Meningitis	2	0
Myelitis	1	0
<b><i>Clostridia infections</i></b>		
Clostridium difficile colitis	1	0
<b><i>Coronavirus infections</i></b>		
COVID-19	8	0
Severe acute respiratory syndrome	1	0
Suspected COVID-19	2	0
<b><i>Coxiella infections</i></b>		
Q fever	8	0
<b><i>Dental and oral soft tissue infections</i></b>		
Abscess oral	1	0
Oral pustule	1	0
Parotitis	1	0
Pericoronitis	1	0
Tooth abscess	3	0
Tooth infection	1	0
<b><i>Ear infections</i></b>		
Ear infection	1	0
Labyrinthitis	13	0
Otitis media chronic	1	0
Otosalpingitis	1	0
<b><i>Ectoparasitic infestations</i></b>		
Trombidiasis	1	0
<b><i>Epstein-Barr viral infections</i></b>		
Infectious mononucleosis	3	0
<b><i>Escherichia infections</i></b>		
Escherichia sepsis	1	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	3	0
Eye infection	2	0
Hordeolum	4	0
<b><i>Female reproductive tract infections</i></b>		
Vaginal infection	1	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
<b><i>Fungal infections NEC</i></b>		
Vulvovaginal mycotic infection	1	0
<b><i>Hepatitis virus infections</i></b>		
Hepatitis E	1	0
<b><i>Hepatobiliary and spleen infections</i></b>		
Biliary sepsis	1	0
<b><i>Herpes viral infections</i></b>		
Genital herpes	3	0
Herpes ophthalmic	2	0
Herpes simplex	2	0
Herpes zoster	64	0
Herpes zoster oticus	1	0
Nasal herpes	2	0
Oral herpes	40	0
Varicella	1	0
<b><i>Infections NEC</i></b>		
Abscess limb	1	0
Infection	17	0
Infectious thyroiditis	1	0
Injection site infection	3	0
Localised infection	9	0
Vaccination site infection	2	0
<b><i>Influenza viral infections</i></b>		
Influenza	355	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Lower respiratory tract infection	8	0
Pneumonia	9	1
Pneumonia aspiration	2	0
<b><i>Male reproductive tract infections</i></b>		
Orchitis	1	0
<b><i>Mumps viral infections</i></b>		
Mumps	1	0
<b><i>Muscle and soft tissue infections</i></b>		
Soft tissue infection	1	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Neutropenic sepsis	1	0
Sepsis	7	0
Septic rash	1	0
<b><i>Skin structures and soft tissue infections</i></b>		
Dermatitis infected	1	0
Rash pustular	1	0
Skin infection	2	0
Subcutaneous abscess	1	0
Vaccination site pustule	1	0
<b><i>Staphylococcal infections</i></b>		
Furuncle	2	0
<b><i>Tinea infections</i></b>		
Body tinea	1	0
<b><i>Trypanosomal infections</i></b>		
African trypanosomiasis	1	0
<b><i>Upper respiratory tract infections</i></b>		
Chronic sinusitis	1	0
Laryngitis	1	0

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Report Run Date: 21-Mar-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Nasopharyngitis	84	0
Pharyngitis	1	0
Rhinitis	1	0
Sinusitis	16	0
Tonsillitis	3	0
<b>Urinary tract infections</b>		
Cystitis	5	0
Kidney infection	3	0
Urinary tract infection	14	0
<b>Viral infections NEC</b>		
Bronchitis viral	1	0
Gastroenteritis viral	4	0
Post viral fatigue syndrome	5	0
Sweating fever	50	0
Vestibular neuronitis	2	0
Viral diarrhoea	1	0
Viral infection	4	0
Viral pharyngitis	2	0
Viral rash	6	0
<b>Infections SOC TOTAL</b>	<b>875</b>	<b>1</b>

# COVID-19 AstraZeneca Vaccine Analysis Print (1)

Report Run Date: 21-Mar-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Abdomen crushing	1	0
Lip injury	1	0
Oral contusion	2	0
Splenic rupture	1	0
<b><i>Anaesthetic and allied procedural complications</i></b>		
Anaesthetic complication	1	0
<b><i>Cardiovascular injuries</i></b>		
Vascular injury	1	0
<b><i>Cerebral injuries NEC</i></b>		
Brain herniation	1	0
Subdural haemorrhage	1	0
<b><i>Chest and respiratory tract injuries NEC</i></b>		
Chest crushing	1	0
<b><i>Conditions caused by cold</i></b>		
Chillblains	4	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure via breast milk	5	0
Maternal exposure during breast feeding	40	0
Maternal exposure during pregnancy	9	0
<b><i>Eye injuries NEC</i></b>		
Eye contusion	3	0
Eye injury	1	0
Periorbital haemorrhage	1	0
<b><i>Fractures and dislocations NEC</i></b>		
Joint dislocation	1	0
<b><i>Gastrointestinal and hepatobiliary procedural complications</i></b>		
Procedural nausea	3	0
<b><i>Heat injuries (excl thermal burns)</i></b>		
Heat exhaustion	1	0
Heat oedema	2	0
Heat stroke	3	0
<b><i>Limb fractures and dislocations</i></b>		
Ankle fracture	1	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Medication error	1	0
<b><i>Muscle, tendon and ligament injuries</i></b>		
Epicondylitis	1	0
Ligament injury	1	0
Ligament sprain	1	0
Muscle injury	1	0
Muscle strain	3	0
<b><i>Nerve injuries NEC</i></b>		
Nerve injury	4	0
<b><i>Neurological and psychiatric procedural complications</i></b>		
Post lumbar puncture syndrome	1	0
<b><i>Non-occupational environmental exposures</i></b>		
Exposure to chemical pollution	1	0
<b><i>Non-site specific injuries NEC</i></b>		
Electric shock	2	0
Fall	9	0
Injury	1	0
Soft tissue injury	1	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Tissue injury	1	0
Wound	1	0
Wound haemorrhage	1	0
<b><i>Non-site specific procedural complications</i></b>		
Incision site pain	1	0
Injection related reaction	44	0
Post procedural complication	1	0
Procedural hypertension	1	0
<b><i>Pathways and sources of exposure</i></b>		
Exposure via unknown route	1	0
<b><i>Peripheral nerve injuries</i></b>		
Brachial plexus injury	1	0
Median nerve injury	1	0
Ulnar nerve injury	1	0
<b><i>Product administration errors and issues</i></b>		
Expired product administered	2	0
Product administered at inappropriate site	1	0
Product administered to patient of inappropriate age	1	0
Product administration error	1	0
Wrong product administered	1	0
<b><i>Product dispensing errors and issues</i></b>		
Product dispensing error	1	0
<b><i>Radiation injuries</i></b>		
Sunburn	3	0
<b><i>Respiratory tract and thoracic cavity procedural complications</i></b>		
Pulmonary oil microembolism	1	0
<b><i>Site specific injuries NEC</i></b>		
Head injury	1	0
Limb crushing injury	1	0
Limb injury	3	0
<b><i>Site specific procedural complications NEC</i></b>		
Axillary web syndrome	1	0
<b><i>Skin injuries NEC</i></b>		
Contusion	140	0
Skin abrasion	1	0
Skin injury	1	0
Skin wound	1	0
<b><i>Stoma complications</i></b>		
Stoma site rash	1	0
<b><i>Thermal burns</i></b>		
Airway burns	1	0
Burn of internal organs	1	0
Thermal burn	5	0
Thermal burns of eye	2	0
<b><i>Vaccination related complications</i></b>		
Vaccination complication	1	0
<b>Injuries SOC TOTAL</b>	<b>336</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Autoimmunity analyses</i></b>		
DNA antibody positive	1	0
<b><i>Blood counts NEC</i></b>		
Full blood count	2	0
Full blood count decreased	1	0
<b><i>Blood gas and acid base analyses</i></b>		
Blood gases	1	0
Blood pH	1	0
Oxygen saturation decreased	9	0
<b><i>Carbohydrate tolerance analyses (incl diabetes)</i></b>		
Blood glucose	1	0
Blood glucose abnormal	1	0
Blood glucose decreased	3	0
Blood glucose increased	9	0
<b><i>Cardiac auscultatory investigations</i></b>		
Cardiac murmur	1	0
Heart sounds	1	0
Heart sounds abnormal	1	0
<b><i>Cardiac function diagnostic procedures</i></b>		
Cardiac monitoring	1	0
Echocardiogram	1	0
Myocardial strain imaging	3	0
<b><i>Cardiac imaging procedures</i></b>		
Magnetic resonance imaging heart	1	0
<b><i>Central nervous system imaging procedures</i></b>		
Computerised tomogram head	1	0
Magnetic resonance imaging head	1	0
<b><i>Coagulation and bleeding analyses</i></b>		
Activated partial thromboplastin time prolonged	6	0
Blood fibrinogen decreased	1	0
Coagulation time prolonged	2	0
Fibrin D dimer decreased	1	0
Fibrin D dimer increased	2	0
International normalised ratio	1	0
International normalised ratio decreased	4	0
International normalised ratio increased	5	0
Prothrombin time prolonged	1	0
<b><i>ECG investigations</i></b>		
Cardiac telemetry	1	0
Electrocardiogram abnormal	1	0
<b><i>Foetal and neonatal diagnostic procedures</i></b>		
Foetal heart rate	1	0
<b><i>Heart rate and pulse investigations</i></b>		
Heart rate	55	0
Heart rate abnormal	3	0
Heart rate decreased	5	0
Heart rate increased	98	0
Heart rate irregular	7	0
Pulse abnormal	1	0
Sinus rhythm	1	0
<b><i>Imaging procedures NEC</i></b>		
Computerised tomogram	1	0
<b><i>Immunology analyses NEC</i></b>		

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Antibody test	1	0
Antibody test negative	1	0
Immunology test normal	1	0
<b>Investigations NEC</b>		
Blood test	4	0
Blood test abnormal	1	0
<b>Liver function analyses</b>		
Alanine aminotransferase increased	1	0
Hepatic enzyme increased	1	0
<b>Metabolism tests NEC</b>		
Blood ketone body	2	0
<b>Microbiology and serology tests NEC</b>		
Blood culture	1	0
<b>Mineral and electrolyte analyses</b>		
Blood iron	3	0
Blood iron decreased	1	0
Blood phosphorus decreased	1	0
Blood potassium decreased	1	0
Blood sodium	1	0
Blood sodium decreased	1	0
Serum ferritin	1	0
<b>Neurologic diagnostic procedures</b>		
Coma scale abnormal	2	0
Hoover's sign of leg paresis	1	0
Lumbar puncture	2	0
<b>Ophthalmic function diagnostic procedures</b>		
Intraocular pressure increased	1	0
<b>Physical examination procedures and organ system status</b>		
Body temperature	50	0
Body temperature abnormal	3	0
Body temperature decreased	6	0
Body temperature fluctuation	7	0
Body temperature increased	60	0
Dermatologic examination abnormal	1	0
Grip strength decreased	1	0
Lymph node palpable	1	0
Muscle strength abnormal	1	0
Respiratory rate decreased	2	0
Respiratory rate increased	5	0
Skin temperature	8	0
Weight decreased	14	0
Weight increased	1	0
<b>Pituitary analyses anterior</b>		
Blood corticotrophin	1	0
<b>Platelet analyses</b>		
Platelet count decreased	14	0
Platelet count increased	1	0
<b>Red blood cell analyses</b>		
Mean cell haemoglobin concentration	1	0
Mean cell volume abnormal	1	0
<b>Renal function analyses</b>		
Blood urea	1	0
<b>Reproductive hormone analyses</b>		

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Pregnancy test	1	0
<b>Respiratory and pulmonary function diagnostic procedures</b>		
Forced expiratory volume increased	1	0
Total lung capacity decreased	1	0
<b>Respiratory tract and thoracic imaging procedures</b>		
Chest X-ray	3	0
<b>Skeletal and cardiac muscle analyses</b>		
Myocardial necrosis marker	1	0
<b>Therapeutic drug monitoring analyses</b>		
Analgesic drug level	2	0
<b>Tissue enzyme analyses NEC</b>		
Blood lactate dehydrogenase	1	0
<b>Urinalysis NEC</b>		
Blood urine	1	0
Blood urine present	4	0
Urine analysis abnormal	1	0
Urine analysis normal	1	0
pH urine	1	0
pH urine increased	1	0
<b>Urinary tract function analyses NEC</b>		
Urine output	4	0
Urine output increased	1	0
<b>Vascular auscultatory investigations</b>		
Carotid bruit	1	0
<b>Vascular tests NEC (incl blood pressure)</b>		
Blood pressure decreased	2	0
Blood pressure increased	12	0
Blood pressure measurement	2	0
Blood pressure systolic increased	1	0
<b>Virus identification and serology</b>		
Coronavirus test	5	0
Herpes virus test	1	0
SARS-CoV-2 antibody test	1	0
SARS-CoV-2 antibody test negative	1	0
SARS-CoV-2 test negative	1	0
<b>Vitamin analyses</b>		
Blood folate	2	0
<b>White blood cell analyses</b>		
Lymphocyte count decreased	1	0
Mononuclear cell count abnormal	1	0
Neutrophil count decreased	2	0
White blood cell count	3	0
White blood cell count decreased	5	0
<b>Investigations SOC TOTAL</b>	<b>509</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	2	0
Decreased appetite	373	0
Food craving	2	0
Food refusal	2	0
Increased appetite	5	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	11	0
Diabetes mellitus inadequate control	1	0
Type 1 diabetes mellitus	3	0
<i><b>Diabetic complications NEC</b></i>		
Diabetic ketoacidosis	3	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	7	0
<i><b>Fat soluble vitamin deficiencies and disorders</b></i>		
Vitamin D deficiency	1	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	2	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	6	0
Feeding disorder	8	0
Food aversion	1	0
Poor feeding infant	1	0
Weight loss poor	1	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	13	0
Insulin resistance	1	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	3	0
<i><b>Iron deficiencies</b></i>		
Iron deficiency	1	0
<i><b>Metabolic acidoses (excl diabetic acidoses)</b></i>		
Metabolic acidosis	1	0
<i><b>Potassium imbalance</b></i>		
Hyperkalaemia	1	0
<i><b>Protein metabolism disorders NEC</b></i>		
Hypoalbuminaemia	1	0
<i><b>Sodium imbalance</b></i>		
Hyponatraemia	2	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	34	0
<i><b>Total fluid volume increased</b></i>		
Fluid retention	8	0
Hypervolaemia	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>495</b>	<b>0</b>

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Report Run Date: 21-Mar-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	17	0
Arthropathy	1	0
Autoimmune arthritis	1	0
Polyarthritis	1	0
Sacroiliitis	1	0
<b><i>Bone related signs and symptoms</i></b>		
Bone pain	78	0
Pain in jaw	35	0
Spinal pain	13	0
<b><i>Bursal disorders</i></b>		
Bursitis	2	0
<b><i>Cartilage disorders</i></b>		
Costochondritis	1	0
<b><i>Connective tissue disorders NEC</i></b>		
Polymyalgia rheumatica	1	0
<b><i>Epiphyseal disorders</i></b>		
Epiphyses premature fusion	1	0
<b><i>Extremity deformities</i></b>		
Finger deformity	1	0
<b><i>Joint related disorders NEC</i></b>		
Joint lock	3	0
Periarthritis	16	0
Rotator cuff syndrome	4	0
Temporomandibular joint syndrome	1	0
<b><i>Joint related signs and symptoms</i></b>		
Arthralgia	1115	0
Jaw clicking	1	0
Joint noise	1	0
Joint stiffness	26	0
Joint swelling	36	0
Joint warmth	5	0
<b><i>Lupus erythematosus (incl subtypes)</i></b>		
Systemic lupus erythematosus	3	0
<b><i>Muscle infections and inflammations</i></b>		
Myositis	3	0
<b><i>Muscle pains</i></b>		
Fibromyalgia	11	0
Myalgia	1620	0
Myofascial pain syndrome	3	0
<b><i>Muscle related signs and symptoms NEC</i></b>		
Muscle atrophy	1	0
Muscle fatigue	55	0
Muscle spasms	157	0
Muscle swelling	3	0
Muscle tightness	7	0
Muscle twitching	25	0
<b><i>Muscle tone abnormalities</i></b>		
Muscle rigidity	2	0
Trismus	2	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	122	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
Mobility decreased	9	0
Muscle contracture	1	0
Musculoskeletal stiffness	133	0
Weight bearing difficulty	1	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	279	0
Flank pain	3	0
Growing pains	1	0
Limb discomfort	97	0
Musculoskeletal chest pain	21	0
Musculoskeletal discomfort	6	0
Musculoskeletal pain	8	0
Neck pain	149	0
Pain in extremity	1034	0
Rheumatic disorder	2	0
<b><i>Myopathies</i></b>		
Compartment syndrome	1	0
Rhabdomyolysis	1	1
<b><i>Osteoarthropathies</i></b>		
Osteoarthritis	2	0
<b><i>Psoriatic arthropathies</i></b>		
Psoriatic arthropathy	2	0
<b><i>Rheumatoid arthropathies</i></b>		
Rheumatoid arthritis	6	0
<b><i>Soft tissue disorders NEC</i></b>		
Axillary mass	3	0
Groin pain	3	0
Neck mass	1	0
<b><i>Spondyloarthropathies</i></b>		
Ankylosing spondylitis	3	0
Arthritis reactive	2	0
<b><i>Tendon disorders</i></b>		
Tendon disorder	1	0
Tendon pain	4	0
Tendonitis	6	0
Trigger finger	4	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>5158</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i><b>Bone neoplasms malignant (excl sarcomas)</b></i>		
Bone cancer	1	0
<i><b>Breast and nipple neoplasms malignant</b></i>		
Breast cancer	2	0
<i><b>Cervix neoplasms malignant</b></i>		
Cervix carcinoma	1	0
<i><b>Endocrine neoplasms benign NEC</b></i>		
Pituitary tumour benign	1	0
<i><b>Hepatic neoplasms malignant</b></i>		
Hepatocellular carcinoma	1	0
<i><b>Leukaemias chronic lymphocytic</b></i>		
Chronic lymphocytic leukaemia	1	0
<i><b>Lymphomas unspecified NEC</b></i>		
Lymphoma	1	0
<i><b>Metastases to specified sites</b></i>		
Metastases to lung	1	1
<i><b>Ocular neoplasms benign</b></i>		
Eye naevus	1	0
<i><b>Plasma cell myelomas</b></i>		
Plasma cell myeloma	1	0
<i><b>Renal neoplasms malignant</b></i>		
Metastatic renal cell carcinoma	1	0
<i><b>Skin neoplasms benign</b></i>		
Haemangioma of skin	3	0
Skin papilloma	1	0
<i><b>Skin neoplasms malignant and unspecified (excl melanoma)</b></i>		
Skin cancer	1	0
<b>Neoplasms SOC TOTAL</b>	<b>17</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<b><i>Abnormal reflexes</i></b>		
Areflexia	6	0
Hyporeflexia	3	0
<b><i>Abnormal sleep-related events</i></b>		
Sleep paralysis	1	0
<b><i>Absence seizures</i></b>		
Petit mal epilepsy	1	0
<b><i>Acute polyneuropathies</i></b>		
Guillain-Barre syndrome	28	1
Miller Fisher syndrome	1	0
<b><i>Central nervous system haemorrhages and cerebrovascular accidents</i></b>		
Basal ganglia stroke	1	0
Carotid artery occlusion	1	0
Cerebellar stroke	1	0
Cerebral haematoma	1	0
Cerebral haemorrhage	5	1
Cerebral infarction	2	0
Cerebral thrombosis	2	1
Cerebrovascular accident	33	4
Embolic stroke	1	0
Haemorrhage intracranial	1	1
Haemorrhagic stroke	2	1
Intraventricular haemorrhage	1	0
Ischaemic stroke	8	1
Subarachnoid haemorrhage	4	0
<b><i>Central nervous system inflammatory disorders NEC</i></b>		
Neurosarcoidosis	1	0
<b><i>Central nervous system vascular disorders NEC</i></b>		
Cerebral small vessel ischaemic disease	1	0
Cerebrovascular disorder	1	0
<b><i>Cerebrovascular venous and sinus thrombosis</i></b>		
Cerebral venous sinus thrombosis	12	1
Cerebral venous thrombosis	3	0
Superior sagittal sinus thrombosis	1	1
<b><i>Chronic polyneuropathies</i></b>		
Demyelinating polyneuropathy	2	0
<b><i>Coma states</i></b>		
Coma	2	0
<b><i>Coordination and balance disturbances</i></b>		
Ataxia	2	0
Balance disorder	48	0
Coordination abnormal	4	0
Dysstasia	3	0
Nystagmus	1	0
<b><i>Cortical dysfunction NEC</i></b>		
Alexia	2	0
Aphasia	5	0
Neurologic neglect syndrome	2	0
<b><i>Cranial nerve disorders NEC</i></b>		
Cranial nerve paralysis	1	0
<b><i>Dementia (excl Alzheimer's type)</i></b>		
Dementia	1	0
<b><i>Demyelinating disorders NEC</i></b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Demyelination	1	0
<b><i>Disturbances in consciousness NEC</i></b>		
Altered state of consciousness	1	0
Depressed level of consciousness	4	0
Lethargy	242	0
Loss of consciousness	41	0
Somnolence	83	0
Syncope	113	0
<b><i>Dyskinesias and movement disorders NEC</i></b>		
Bradykinesia	1	0
Clumsiness	5	0
Dyskinesia	3	0
Fine motor skill dysfunction	2	0
Hyperkinesia	1	0
Hypokinesia	3	0
Motor dysfunction	2	0
Movement disorder	4	0
Psychomotor hyperactivity	2	0
<b><i>Dystonias</i></b>		
Dystonia	3	0
<b><i>Facial cranial nerve disorders</i></b>		
Bell's palsy	22	0
Facial nerve disorder	1	0
Facial paralysis	13	0
Facial paresis	10	0
<b><i>Generalised tonic-clonic seizures</i></b>		
Generalised tonic-clonic seizure	3	0
<b><i>Headaches NEC</i></b>		
Cervicogenic headache	1	0
Cluster headache	20	0
Cold-stimulus headache	2	0
Drug withdrawal headache	2	0
External compression headache	1	0
Headache	3931	0
Primary headache associated with sexual activity	1	0
Sinus headache	52	0
Tension headache	69	0
Thunderclap headache	3	0
Vascular headache	4	0
<b><i>Hydrocephalic conditions</i></b>		
Hydrocephalus	1	0
<b><i>Hypoglossal nerve disorders</i></b>		
Tongue paralysis	1	0
<b><i>Increased intracranial pressure disorders</i></b>		
Brain oedema	2	1
Intracranial pressure increased	3	0
<b><i>Intellectual disabilities</i></b>		
Intellectual disability	2	0
<b><i>Lumbar spinal cord and nerve root disorders</i></b>		
Sciatica	7	0
<b><i>Memory loss (excl dementia)</i></b>		
Amnesia	10	0
Memory impairment	14	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b><i>Mental impairment (excl dementia and memory loss)</i></b>		
Cognitive disorder	9	0
Disturbance in attention	39	0
Mental impairment	8	0
<b><i>Migraine headaches</i></b>		
Hemiplegic migraine	1	0
Migraine	312	0
Migraine with aura	25	0
Migraine without aura	3	0
Ophthalmic migraine	1	0
Retinal migraine	3	0
Typical aura without headache	1	0
<b><i>Mixed cranial nerve disorders</i></b>		
Bulbar palsy	1	0
<b><i>Mononeuropathies</i></b>		
Carpal tunnel syndrome	3	0
Mononeuropathy	1	0
Nerve compression	2	0
Ulnar neuritis	1	0
<b><i>Multiple sclerosis acute and progressive</i></b>		
Multiple sclerosis	4	0
Multiple sclerosis relapse	8	0
Uhthoff's phenomenon	1	0
<b><i>Muscle tone abnormal</i></b>		
Hypotonia	4	0
Stiff leg syndrome	2	0
<b><i>Myelitis (incl infective)</i></b>		
Myelitis transverse	1	0
<b><i>Narcolepsy and hypersomnia</i></b>		
Hypersomnia	11	0
<b><i>Nervous system disorders NEC</i></b>		
Nervous system disorder	2	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Dizziness	1094	0
Dizziness exertional	2	0
Dizziness postural	124	0
Drooling	1	0
Exaggerated startle response	1	0
Head discomfort	26	0
Myoclonus	2	0
Neurological symptom	6	0
Persistent postural-perceptual dizziness	1	0
Pleocytosis	1	0
Presyncope	32	0
Sensory overload	2	0
Unresponsive to stimuli	5	0
<b><i>Neuromuscular disorders NEC</i></b>		
Muscle contractions involuntary	1	0
Muscle spasticity	3	0
Neuromyotonia	1	0
<b><i>Olfactory nerve disorders</i></b>		
Anosmia	9	0
Hyposmia	2	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Parosmia	17	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	2	0
<b>Paraesthesias and dysaesthesias</b>		
Burning feet syndrome	3	0
Burning sensation	44	0
Dysaesthesia	1	0
Formication	2	0
Hyperaesthesia	18	0
Hypoaesthesia	259	0
Paraesthesia	418	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Diplegia	3	0
Hemiparesis	6	0
Hemiplegia	2	0
Monoparesis	7	0
Monoplegia	8	0
Paralysis	14	0
<b>Parkinson's disease and parkinsonism</b>		
Freezing phenomenon	15	0
Parkinson's disease	1	0
<b>Partial complex seizures</b>		
Dreamy state	2	0
<b>Peripheral neuropathies NEC</b>		
Neuropathy peripheral	7	0
Polyneuropathy	1	0
Small fibre neuropathy	1	0
<b>Seizures and seizure disorders NEC</b>		
Epilepsy	15	0
Febrile convulsion	1	0
Myoclonic epilepsy	1	0
Partial seizures	3	0
Seizure	60	0
Seizure anoxic	1	0
Seizure cluster	2	0
Status epilepticus	2	0
Tonic convulsion	2	0
<b>Sensory abnormalities NEC</b>		
Ageusia	54	0
Allodynia	3	0
Aura	3	0
Complex regional pain syndrome	1	0
Dysgeusia	103	0
Electric shock sensation	5	0
Hypogeusia	1	0
Loss of proprioception	1	0
Neuralgia	67	0
Restless arm syndrome	1	0
Restless legs syndrome	20	0
Sensory disturbance	6	0
Sensory loss	5	0
Taste disorder	22	0
<b>Sleep disturbances NEC</b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Sleep deficit	2	0
<b>Speech and language abnormalities</b>		
Dysarthria	23	0
Incoherent	1	0
Slow speech	2	0
Speech disorder	3	0
<b>Spinal cord and nerve root disorders NEC</b>		
Cauda equina syndrome	1	0
Radicular pain	1	0
Spinal cord disorder	1	0
<b>Structural brain disorders NEC</b>		
Brain injury	2	0
<b>Transient cerebrovascular events</b>		
Transient ischaemic attack	20	0
<b>Tremor (excl congenital)</b>		
Essential tremor	1	0
Head titubation	2	0
Tremor	570	0
<b>Trigeminal disorders</b>		
Trigeminal neuralgia	4	0
<b>Nervous system disorders SOC TOTAL</b>	<b>8480</b>	<b>13</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	3	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>6</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b><i>Device malfunction events NEC</i></b>		
Oversensing	4	0
Thrombosis in device	2	0
<b><i>Device physical property and chemical issues</i></b>		
Needle issue	1	0
<b>null SOC TOTAL</b>	<b>7</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Affect alterations NEC</i></b>		
Flat affect	1	0
Inappropriate affect	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	15	0
Anxiety	49	0
Nervousness	38	0
Stress	5	0
Tension	2	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit hyperactivity disorder	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	2	0
Impatience	1	0
Paranoia	3	0
<b><i>Bipolar disorders</i></b>		
Bipolar I disorder	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Mental fatigue	24	0
<b><i>Communications disorders</i></b>		
Communication disorder	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	96	0
Disorientation	40	0
<b><i>Deliria</i></b>		
Delirium	24	0
<b><i>Delusional symptoms</i></b>		
Delusion	1	0
<b><i>Depressive disorders</i></b>		
Agitated depression	1	0
Depression	17	0
Major depression	1	0
<b><i>Dissociative states</i></b>		
Dissociation	3	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Initial insomnia	2	0
Insomnia	139	0
Middle insomnia	6	0
Terminal insomnia	1	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	24	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	8	0
Emotional disorder	3	0
Emotional distress	3	0
Euphoric mood	2	0
Irritability	19	0
Mood altered	3	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	2	0
Fear of injection	1	0
Phobia	1	0
<b><i>Fluctuating mood symptoms</i></b>		

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Mood swings	5	0
<b>Hallucinations (excl sleep-related)</b>		
Hallucination	64	0
Hallucination, auditory	1	0
Hallucination, visual	2	0
Hallucinations, mixed	1	0
<b>Impulse control disorders</b>		
Impulse-control disorder	1	0
<b>Increased physical activity levels</b>		
Restlessness	22	0
<b>Mood alterations with depressive symptoms</b>		
Decreased interest	2	0
Depressed mood	31	0
Negative thoughts	1	0
Tearfulness	5	0
<b>Mood alterations with manic symptoms</b>		
Mania	2	0
<b>Mood disorders NEC</b>		
Listless	4	0
Substance-induced mood disorder	1	0
<b>Orgasmic disorders and disturbances</b>		
Orgasmic sensation decreased	1	0
<b>Panic attacks and disorders</b>		
Panic attack	12	0
<b>Parasomnias</b>		
Abnormal dreams	13	0
Abnormal sleep-related event	1	0
Exploding head syndrome	1	0
Nightmare	26	0
Sleep terror	5	0
<b>Perception disturbances NEC</b>		
Autoscopy	1	0
Deja vu	1	0
<b>Psychiatric elimination disorders</b>		
Enuresis	3	0
<b>Psychiatric symptoms NEC</b>		
Hypervigilance	2	0
<b>Psychotic disorder NEC</b>		
Psychotic disorder	2	0
<b>Sexual desire disorders</b>		
Libido decreased	2	0
Loss of libido	2	0
<b>Sleep disorders NEC</b>		
Sleep disorder	26	0
<b>Somatic symptom disorders</b>		
Conversion disorder	3	0
Habit cough	1	0
<b>Speech articulation and rhythm disturbances</b>		
Dysphemia	2	0
<b>Stereotypies and automatisms</b>		
Bruxism	1	0
Head banging	3	0
<b>Stress disorders</b>		

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Burnout syndrome	1	0
<b><i>Substance related and addictive disorders</i></b>		
Alcoholism	1	0
<b><i>Suicidal and self-injurious behaviour</i></b>		
Suicidal ideation	2	0
<b><i>Thinking disturbances</i></b>		
Bradyphrenia	5	0
Tachyphrenia	1	0
Thinking abnormal	1	0
<b><i>Tic disorders</i></b>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>803</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder discomfort	1	0
Bladder pain	3	0
Bladder spasm	1	0
Dysuria	4	0
Incontinence	8	0
Micturition urgency	7	0
Pollakiuria	16	0
Urinary incontinence	4	0
Urinary retention	5	0
<i><b>Bladder disorders NEC</b></i>		
Bladder dilatation	1	0
Bladder disorder	1	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
IgA nephropathy	2	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Bladder dysfunction	1	0
Hypertonic bladder	1	0
<i><b>Nephritis NEC</b></i>		
Nephritis	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	4	0
Chronic kidney disease	1	0
Renal failure	4	1
<i><b>Renal vascular and ischaemic conditions</b></i>		
Renal infarct	1	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	3	0
Haematuria	6	0
Proteinuria	2	0
Urine abnormality	1	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Haemorrhage urinary tract	3	0
Nocturia	4	0
Polyuria	1	0
Renal pain	55	0
Urinary tract pain	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>142</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	1	0
<i><b>Breast disorders NEC</b></i>		
Breast mass	5	0
<i><b>Breast infections and inflammations</b></i>		
Breast inflammation	1	0
<i><b>Breast signs and symptoms</b></i>		
Breast discomfort	1	0
Breast haemorrhage	1	0
Breast pain	15	0
Breast swelling	4	0
Breast tenderness	2	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Ejaculation failure	2	0
Erectile dysfunction	2	0
Organic erectile dysfunction	2	0
Retrograde ejaculation	1	0
<i><b>Fallopian tube and ovary infections and inflammations</b></i>		
Noninfective oophoritis	1	0
<i><b>Menopausal effects NEC</b></i>		
Artificial menopause	1	0
Premature menopause	1	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Postmenopausal haemorrhage	4	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Abnormal uterine bleeding	1	0
Dysmenorrhoea	9	0
Intermenstrual bleeding	10	0
Menstrual disorder	15	0
Menstruation irregular	12	0
Premenstrual pain	1	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	3	0
Hypomenorrhoea	5	0
Menstruation delayed	25	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	26	0
Polymenorrhoea	5	0
<i><b>Pelvis and broad ligament disorders NEC</b></i>		
Adnexa uteri pain	1	0
<i><b>Penile disorders NEC (excl erection and ejaculation)</b></i>		
Penile blister	2	0
Penis disorder	1	0
Peyronie's disease	2	0
<i><b>Prostate and seminal vesicles infections and inflammations</b></i>		
Prostatitis	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Pelvic pain	7	0
<i><b>Scrotal disorders NEC</b></i>		
Scrotal pain	2	0
<i><b>Sexual function and fertility disorders NEC</b></i>		
Dyspareunia	1	0
<i><b>Spermatogenesis and semen disorders</b></i>		

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
Reproductive & breast disorders cont'd		
Semen discolouration	1	0
<b><i>Testicular and epididymal disorders NEC</i></b>		
Testicular atrophy	1	0
Testicular pain	5	0
<b><i>Uterine disorders NEC</i></b>		
Uterine haemorrhage	2	0
<b><i>Vulvovaginal disorders NEC</i></b>		
Vaginal haemorrhage	21	0
<b><i>Vulvovaginal signs and symptoms</i></b>		
Vaginal discharge	1	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	1	0
Vulvovaginal rash	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>207</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	2	0
Dyspnoea	286	0
Dyspnoea at rest	1	0
Dyspnoea exertional	1	0
Hyperventilation	5	0
Hypopnoea	13	0
Irregular breathing	1	0
Mouth breathing	2	0
Respiration abnormal	5	0
Respiratory arrest	1	0
Tachypnoea	2	0
<i><b>Bronchial conditions NEC</b></i>		
Bronchiectasis	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Aspirin-exacerbated respiratory disease	1	0
Asthma	20	0
Asthmatic crisis	1	0
Bronchospasm	1	0
Chronic obstructive pulmonary disease	2	0
Wheezing	28	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Hypoxia	2	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	152	0
Haemoptysis	8	0
Productive cough	9	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
Lower respiratory tract congestion	1	0
Lung opacity	1	0
Pleuritic pain	1	0
Pulmonary haemorrhage	1	1
Pulmonary pain	14	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	23	0
Rhinitis allergic	1	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	110	0
Nasal crusting	1	0
Nasal dryness	2	0
Nasal oedema	1	0
Nasal pruritus	1	0
<i><b>Neonatal hypoxic conditions</b></i>		
Gasping syndrome	2	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Paranasal sinus inflammation	1	0
Sinonasal obstruction	1	0
Sinus congestion	6	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Emphysema	1	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Pulmonary cavitation	1	0
<b>Pharyngeal disorders (excl infections and neoplasms)</b>		
Pharyngeal hypoaesthesia	1	0
Pharyngeal paraesthesia	3	0
Pharyngeal swelling	10	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	2	0
<b>Pleural infections and inflammations</b>		
Pleurisy	3	0
<b>Pneumothorax and pleural effusions NEC</b>		
Pleural effusion	1	0
<b>Pulmonary oedemas</b>		
Acute pulmonary oedema	1	0
Pulmonary congestion	2	0
Pulmonary oedema	3	0
<b>Pulmonary thrombotic and embolic conditions</b>		
Pulmonary embolism	64	8
<b>Respiratory failures (excl neonatal)</b>		
Respiratory failure	2	0
<b>Respiratory signs and symptoms NEC</b>		
Diaphragmalgia	2	0
Respiratory symptom	1	0
<b>Respiratory tract disorders NEC</b>		
Aspiration	1	0
Chronic respiratory disease	1	0
Respiratory tract irritation	2	0
<b>Tracheal disorders (excl infections and neoplasms)</b>		
Tracheal pain	1	0
<b>Upper respiratory tract signs and symptoms</b>		
Aphonia	3	0
Catarrh	1	0
Dry throat	7	0
Dysphonia	9	0
Increased upper airway secretion	1	0
Nasal discomfort	8	0
Oropharyngeal blistering	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	191	0
Paranasal sinus discomfort	2	0
Rhinalgia	2	0
Rhinorrhoea	83	0
Sinus pain	28	0
Sneezing	19	0
Throat irritation	16	0
Throat tightness	8	0
Upper-airway cough syndrome	1	0
Yawning	5	0
<b>Respiratory disorders SOC TOTAL</b>	<b>1203</b>	<b>9</b>

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	6	0
Acne cystic	1	0
<b><i>Alopecias</i></b>		
Alopecia	6	0
Diffuse alopecia	1	0
Madarosis	1	0
<b><i>Angioedemas</i></b>		
Angioedema	19	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	89	0
Hyperhidrosis	507	0
Miliaria	17	0
Night sweats	68	0
<b><i>Bullous conditions</i></b>		
Blister	30	0
Blood blister	2	0
Dermatitis bullous	1	0
Erythema multiforme	3	0
Oedema blister	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	21	0
Pain of skin	56	0
Papule	5	0
Scab	2	0
Sensitive skin	28	0
Skin burning sensation	21	0
Skin discolouration	7	0
Skin discomfort	1	0
Skin disorder	3	0
Skin fissures	2	0
Skin indentation	1	0
Skin lesion	3	0
Skin necrosis	1	0
Skin odour abnormal	2	0
Skin plaque	1	0
Skin reaction	19	0
Skin sensitisation	1	0
Skin swelling	5	0
Skin tightness	3	0
Skin warm	30	0
Yellow skin	1	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	12	0
Dermatitis allergic	15	0
Dermatitis atopic	3	0
Dermatitis contact	1	0
Eczema	10	0
Eczema asteatotic	1	0
Skin irritation	6	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	3	0
Fixed eruption	1	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<b><i>Erythemas</i></b>		
Erythema	204	0
Palmar erythema	1	0
<b><i>Exfoliative conditions</i></b>		
Dermatitis exfoliative	1	0
Skin exfoliation	3	0
<b><i>Hyperpigmentation disorders</i></b>		
Solar lentigo	1	0
<b><i>Hypopigmentation disorders</i></b>		
Skin depigmentation	1	0
Skin hypopigmentation	1	0
Vitiligo	2	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Nail discolouration	2	0
Nail pitting	1	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	1	0
<b><i>Papulosquamous conditions</i></b>		
Lichen planus	1	0
Pityriasis rosea	1	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	8	0
<b><i>Pilar disorders NEC</i></b>		
Hair texture abnormal	1	0
Piloerection	8	0
Trichodynia	1	0
<b><i>Pruritus NEC</i></b>		
Pruritus	442	0
<b><i>Psoriatic conditions</i></b>		
Guttate psoriasis	4	0
Psoriasis	6	0
<b><i>Purpura and related conditions</i></b>		
Petechiae	14	0
Purpura	8	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	491	0
Rash erythematous	114	0
Rash macular	48	0
Rash maculo-papular	1	0
Rash morbilliform	2	0
Rash papular	30	0
Rash pruritic	112	0
Rash rubelliform	1	0
Rash vesicular	3	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Skin mass	4	0
<b><i>Skin and subcutaneous tissue ulcerations</i></b>		
Skin erosion	1	0
<b><i>Skin dystrophies</i></b>		
Skin wrinkling	1	0
<b><i>Skin haemorrhages</i></b>		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	2	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<i><b>Skin injuries and mechanical dermatoses</b></i>		
Needle track marks	1	0
<i><b>Skin preneoplastic conditions NEC</b></i>		
Actinic keratosis	1	0
Leukoplakia	1	0
<i><b>Skin vasculitides</b></i>		
Vasculitic rash	3	0
<i><b>Skin vasomotor conditions</b></i>		
Livedo reticularis	1	0
<i><b>Telangiectasia and related conditions</b></i>		
Spider naevus	1	0
<i><b>Urticarias</b></i>		
Cold urticaria	1	0
Solar urticaria	1	0
Urticaria	113	0
Urticaria chronic	1	0
Urticaria thermal	1	0
<b>Skin disorders SOC TOTAL</b>	<b>2665</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Social circumstances</b>		
<i>Disability issues</i>		
Bedridden	2	0
Dependence on oxygen therapy	1	0
Immobile	2	0
Immobilisation prolonged	1	0
Impaired work ability	1	0
Sight disability	1	0
<b>Social circumstances SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Dietary and nutritional therapies</i>		
Fluid replacement	1	0
<i>Facial therapeutic procedures</i>		
Face lift	1	0
<i>Fertility and fertilisation interventions female</i>		
Ovulation induction	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	1	0
<i>Immunisations</i>		
COVID-19 immunisation	8	0
Immunisation	4	0
<i>Nervous system therapeutic procedures NEC</i>		
Central nervous system stimulation	1	0
<i>Prophylactic procedures NEC</i>		
Anaphylaxis prophylaxis	1	0
<i>Therapeutic procedures NEC</i>		
Catheter placement	1	0
Hospitalisation	1	0
Injection	4	0
Localised alternating hot and cold therapy	2	0
Mass excision	2	0
Therapeutic hypothermia	2	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>30</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<b><i>Aortic aneurysms and dissections</i></b>		
Aortic aneurysm	3	0
<b><i>Aortic embolism and thrombosis</i></b>		
Aortic embolus	1	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	1	0
<b><i>Circulatory collapse and shock</i></b>		
Circulatory collapse	9	0
Shock	1	0
Shock symptom	2	0
<b><i>Haemorrhages NEC</i></b>		
Haematoma	9	0
Haemorrhage	22	0
Internal haemorrhage	1	0
<b><i>Lymphoedemas</i></b>		
Lymphoedema	2	0
<b><i>Non-site specific embolism and thrombosis</i></b>		
Arterial thrombosis	3	0
Embolism	15	0
Embolism arterial	1	0
Embolism venous	1	0
Thrombosis	51	2
Venous thrombosis	2	0
<b><i>Non-site specific necrosis and vascular insufficiency NEC</i></b>		
Arterial occlusive disease	2	0
Arteriosclerosis	1	0
Infarction	1	0
<b><i>Non-site specific vascular disorders NEC</i></b>		
Superficial vein prominence	1	0
Vascular pain	3	0
Vasodilatation	6	0
<b><i>Peripheral embolism and thrombosis</i></b>		
Blue toe syndrome	4	0
Deep vein thrombosis	38	0
Femoral artery embolism	1	0
Iliac artery embolism	1	0
Jugular vein thrombosis	2	0
Superficial vein thrombosis	2	0
Thrombophlebitis	7	0
<b><i>Peripheral vascular disorders NEC</i></b>		
Cyanosis	3	0
Erythromelalgia	1	0
Flushing	39	0
Hot flush	77	0
<b><i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i></b>		
Peripheral arterial occlusive disease	3	0
Peripheral artery occlusion	1	0
Peripheral coldness	69	0
Peripheral ischaemia	1	0
Poor peripheral circulation	1	0

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Reaction Name	Total	Fatal
<b>Vascular disorders</b> Vascular disorders cont'd		
Raynaud's phenomenon	5	0
<b>Phlebitis NEC</b>		
Phlebitis	2	0
Phlebitis superficial	1	0
<b>Site specific vascular disorders NEC</b>		
Pallor	8	0
<b>Varicose veins NEC</b>		
Varicose vein	2	0
<b>Vascular hypertensive disorders NEC</b>		
Hypertension	31	0
White coat hypertension	1	0
<b>Vascular hypotensive disorders</b>		
Capillary leak syndrome	1	0
Hypotension	16	0
Orthostatic hypotension	5	0
<b>Vasculitides NEC</b>		
Vasculitis	5	0
<b>Vascular disorders SOC TOTAL</b>	<b>467</b>	<b>2</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>40323</b>	<b>62</b>
<b>TOTAL REPORTS</b>	<b>10666</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>62</b>