

Case Series Drug Analysis Print

**Name: FOI 23/857 - COVID-19 Vaccine AstraZeneca Isle of Man
DAP**

Report Run Date: 29-Nov-2023
Data Lock Date: 21-Nov-2023 18:30:06
Earliest Reaction Date: 21-Mar-2020
MedDRA Version: MedDRA 26.1

FOI 23/857 - COVID-19 Vaccine AstraZeneca Isle of Man DAP: All spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the COVID-19 Vaccine AstraZeneca from the Isle of Man received up to and including 15/11/2023.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Coagulopathies</i>		
Antiphospholipid syndrome	1	0
<i>Haematological disorders</i>		
Mast cell activation syndrome	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	2	0
Lymphadenopathy	15	0
<i>Polycythaemia (excl rubra vera)</i>		
Stress polycythaemia	1	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	2	0
Blood disorders SOC TOTAL	22	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	13	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	3	0
Myocardial infarction	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Extrasystoles	2	0
Tachycardia	2	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	2	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
Cardiac disorders SOC TOTAL	25	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	7	0
<i>Hyperacusia</i>		
Hyperacusis	3	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	8	0
Vertigo	10	0
Vertigo positional	1	0
Ear disorders SOC TOTAL	29	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Adrenal gland disorders NEC</i>		
Haemorrhagic adrenal infarction	1	0
<i>Female gonadal function disorders</i>		
Polycystic ovarian syndrome	1	0
Endocrine disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	1	0
<i>Eyelid movement disorders</i>		
Eyelid ptosis	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iritis	1	0
<i>Ocular disorders NEC</i>		
Eye pain	11	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye pruritus	2	0
<i>Ocular sensation disorders</i>		
Asthenopia	2	0
Photophobia	3	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Dysmetropsia	1	0
Photopsia	2	0
Vision blurred	10	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	2	0
Visual impairment	3	0
Eye disorders SOC TOTAL	40	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Colitis (excl infective)</i>		
Crohn's disease	1	0
Inflammatory bowel disease	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	1	0
Hyperaesthesia teeth	1	0
Toothache	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	28	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	2	0
Eructation	1	0
<i>Faecal abnormalities NEC</i>		
Faeces hard	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
Flatulence	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	14	0
Abdominal pain lower	2	0
Abdominal pain upper	11	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
Intestinal dilatation	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	1	0
Dyschezia	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
Dysphagia	2	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	1	0
Mesenteric arterial occlusion	1	0
Mesenteric artery thrombosis	1	0
Visceral venous thrombosis	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	98	0
Retching	1	0
Vomiting	32	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	2	0
Lip dry	1	0
Salivary hypersecretion	1	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	2	0
<i>Oral soft tissue signs and symptoms</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Hypoaesthesia oral	4	0
Paraesthesia oral	4	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	1	0
Mouth ulceration	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	2	0
Swollen tongue	3	0
Tongue coated	1	0
Tongue discolouration	1	0
Tongue spasm	1	0
Gastrointestinal disorders SOC TOTAL	241	0

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	18	0
Fatigue	140	0
Malaise	28	0
<i>Complications associated with device NEC</i>		
Medical device site joint pain	1	0
<i>Febrile disorders</i>		
Pyrexia	123	0
<i>Feelings and sensations NEC</i>		
Chills	105	0
Feeling abnormal	7	0
Feeling cold	15	0
Feeling hot	6	0
Feeling of body temperature change	4	0
Hangover	2	0
Hunger	1	0
Temperature intolerance	1	0
Thirst	5	0
<i>Gait disturbances</i>		
Gait disturbance	2	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Illness	6	0
Influenza like illness	38	0
Local reaction	1	0
Peripheral swelling	21	0
Swelling	7	0
Swelling face	1	0
<i>Inflammations</i>		
Inflammation	5	0
<i>Injection site reactions</i>		
Injection site discharge	1	0
Injection site erythema	2	0
Injection site mass	2	0
Injection site pain	16	0
Injection site rash	1	0
Injection site scab	1	0
<i>Mass conditions NEC</i>		
Mass	1	0
<i>Oedema NEC</i>		
Oedema peripheral	2	0
<i>Pain and discomfort NEC</i>		
Axillary pain	1	0
Chest discomfort	2	0
Chest pain	18	0
Discomfort	5	0
Pain	40	0
Tenderness	2	0
<i>Therapeutic and nontherapeutic responses</i>		
Drug ineffective	1	0
<i>Vaccination site reactions</i>		
Vaccination site erythema	3	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site hypoaesthesia	1	0
Vaccination site mass	1	0
Vaccination site movement impairment	2	0
Vaccination site pain	1	0
Vaccination site swelling	1	0
Vaccination site warmth	2	0
General disorders SOC TOTAL	644	0

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis acute	1	0
<i>Obstructive bile duct disorders (excl neoplasms)</i>		
Sphincter of Oddi dysfunction	2	0
Hepatic disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	2	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
Sensitisation	1	0
Immune system disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Bacterial infection	1	0
<i>Candida infections</i>		
Vulvovaginal candidiasis	1	0
<i>Coronavirus infections</i>		
COVID-19	3	0
Suspected COVID-19	1	0
<i>Herpes viral infections</i>		
Herpes zoster	4	0
Oral herpes	2	0
<i>Infections NEC</i>		
Infection	5	0
Vaccination site infection	1	0
<i>Influenza viral infections</i>		
Influenza	35	0
<i>Lower respiratory tract and lung infections</i>		
Pneumonia	3	0
<i>Retroviral infections</i>		
HIV infection	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	9	0
Pharyngitis	1	0
Sinusitis	1	0
<i>Urinary tract infections</i>		
Urinary tract infection	1	0
<i>Viral infections NEC</i>		
Sweating fever	5	0
Viral infection	1	0
Infections SOC TOTAL	76	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	6	0
<i>Medication errors, product use errors and issues NEC</i>		
Inadequate aseptic technique in use of product	1	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle rupture	1	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	4	0
<i>Overdoses NEC</i>		
Intentional overdose	1	0
<i>Product prescribing errors and issues</i>		
Contraindicated product prescribed	1	0
<i>Site specific injuries NEC</i>		
Limb injury	1	0
<i>Skin injuries NEC</i>		
Contusion	4	0
Injuries SOC TOTAL	19	0

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Reaction Name	Total	Fatal
Investigations		
<i>Central nervous system imaging procedures</i>		
Magnetic resonance imaging head	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	3	0
Heart rate irregular	1	0
<i>Mineral and electrolyte analyses</i>		
Blood iron decreased	1	0
Blood iron increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	3	0
Body temperature decreased	2	0
Body temperature fluctuation	1	0
Body temperature increased	7	0
<i>Pituitary analyses anterior</i>		
Blood thyroid stimulating hormone increased	1	0
<i>Urinalysis NEC</i>		
Crystal urine	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure increased	1	0
<i>White blood cell analyses</i>		
White blood cell count	1	0
Investigations SOC TOTAL	24	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	13	0
<i>Total fluid volume decreased</i>		
Dehydration	4	0
<i>Total fluid volume increased</i>		
Fluid retention	1	0
Metabolic disorders SOC TOTAL	18	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	2	0
<i>Bone disorders NEC</i>		
Medial tibial stress syndrome	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	4	0
<i>Cartilage disorders</i>		
Costochondritis	1	0
<i>Joint related disorders NEC</i>		
Periarthritis	1	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	67	0
Joint stiffness	2	0
Joint swelling	6	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	63	0
Myofascial pain syndrome	1	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	4	0
Muscle spasms	11	0
Muscle tightness	1	0
Muscle twitching	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	6	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	3	0
Musculoskeletal stiffness	12	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	13	0
Limb discomfort	10	0
Musculoskeletal chest pain	1	0
Musculoskeletal discomfort	1	0
Neck pain	11	0
Pain in extremity	68	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
<i>Tendon disorders</i>		
Tendon pain	1	0
Tendonitis	2	0
Tenosynovitis	1	0
Muscle & tissue disorders SOC TOTAL	297	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	1	0
Neoplasms SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	4	1
<i>Coordination and balance disturbances</i>		
Balance disorder	1	0
Dysstasia	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	11	0
Loss of consciousness	3	0
Somnolence	4	0
Syncope	8	0
<i>Dyskinesias and movement disorders NEC</i>		
Movement disorder	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	3	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Cold-stimulus headache	1	0
Headache	231	0
Sinus headache	2	0
Tension headache	7	0
Thunderclap headache	1	0
<i>Memory loss (excl dementia)</i>		
Memory impairment	2	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	3	0
<i>Migraine headaches</i>		
Migraine	23	0
Migraine without aura	1	0
<i>Multiple sclerosis acute and progressive</i>		
Multiple sclerosis	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	64	0
Dizziness postural	4	0
Head discomfort	1	0
Neurological symptom	3	0
Presyncope	2	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	4	0
Formication	1	0
Hypoaesthesia	17	0
Paraesthesia	27	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	2	0

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Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Sensory abnormalities NEC</i>		
Ageusia	1	0
Dysgeusia	5	0
Neuralgia	1	0
Taste disorder	5	0
<i>Speech and language abnormalities</i>		
Dysarthria	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	5	0
<i>Tremor (excl congenital)</i>		
Tremor	35	0
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	493	1

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Reaction Name	Total	Fatal
<i>Device malfunction events NEC</i>		
Thrombosis in device	2	0
null SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Agitation	1	0
Anxiety	6	0
Stress	2	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Mental fatigue	2	0
<i>Confusion and disorientation</i>		
Confusional state	3	0
Disorientation	1	0
<i>Deliria</i>		
Delirium	2	0
<i>Depressive disorders</i>		
Depression	3	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	7	0
<i>Dyssomnias</i>		
Poor quality sleep	4	0
<i>Emotional and mood disturbances NEC</i>		
Anger	1	0
Irritability	2	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination, visual	1	0
<i>Increased physical activity levels</i>		
Restlessness	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
Tearfulness	1	0
<i>Mood disorders NEC</i>		
Listless	1	0
<i>Parasomnias</i>		
Abnormal dreams	2	0
Nightmare	3	0
<i>Somatic symptom disorders</i>		
Habit cough	1	0
<i>Stress disorders</i>		
Catastrophic reaction	1	0
Psychiatric disorders SOC TOTAL	47	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Pollakiuria	2	0
Urinary incontinence	1	0
<i>Bladder neoplasms</i>		
Bladder cyst	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	1	0
Renal & urinary disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	3	0
Breast tenderness	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Organic erectile dysfunction	1	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	1	0
Intermenstrual bleeding	1	0
Menstrual disorder	3	0
Menstruation irregular	5	0
Ovulation pain	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	2	0
Hypomenorrhoea	1	0
Menstruation delayed	5	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	10	0
Menometrorrhagia	1	0
Polymenorrhoea	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	1	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal burning sensation	1	0
Reproductive & breast disorders SOC TOTAL	41	0

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Name: FOI 23/857 - COVID-19 Vaccine AstraZeneca Isle of Man DAP

Report Run Date: 29-Nov-2023

Data Lock Date: 22-Nov-2023 18:30:06

Earliest Reaction Date: 21-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	21	0
Hypopnoea	2	0
<i>Bronchospasm and obstruction</i>		
Bronchospasm	1	0
Wheezing	2	0
<i>Coughing and associated symptoms</i>		
Cough	8	0
<i>Nasal disorders NEC</i>		
Epistaxis	7	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Tonsillar hypertrophy	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	5	0
<i>Upper respiratory tract signs and symptoms</i>		
Catarrh	1	0
Dry throat	1	0
Dysphonia	1	0
Oropharyngeal pain	9	0
Rhinorrhoea	2	0
Sinus pain	2	0
Sneezing	1	0
Throat irritation	2	0
Respiratory disorders SOC TOTAL	68	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Alopecias</i>		
Alopecia	1	0
<i>Angioedemas</i>		
Angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	3	0
Hyperhidrosis	27	0
Miliaria	1	0
Night sweats	4	0
<i>Bullous conditions</i>		
Blister	3	0
Erythema multiforme	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	1	0
Pain of skin	2	0
Papule	1	0
Skin burning sensation	2	0
Skin odour abnormal	1	0
Skin reaction	1	0
Skin warm	3	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	3	0
Eczema	1	0
<i>Erythemas</i>		
Erythema	9	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Pruritus NEC</i>		
Pruritus	26	0
<i>Purpura and related conditions</i>		
Purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	27	0
Rash erythematous	3	0
Rash macular	4	0
Rash pruritic	2	0
Rash vesicular	1	0
<i>Rosaceas</i>		
Rosacea	1	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	1	0
<i>Urticarias</i>		
Urticaria	6	0
Skin disorders SOC TOTAL	139	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Immunisations</i>		
COVID-19 immunisation	1	0
Immunisation	3	0
<i>Therapeutic procedures NEC</i>		
Catheter management	1	0
<i>Vascular therapeutic procedures NEC</i>		
Clamping of blood vessel	1	0
Surgical & medical procedures SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Aortic infections and inflammations</i>		
Aortitis	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	2	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
Haemorrhage	4	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	5	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	1	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	1	0
Deep vein thrombosis	4	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	1	0
Hot flush	14	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	7	0
Raynaud's phenomenon	1	0
<i>Vasculitides NEC</i>		
Vasculitis	2	0
Vascular disorders SOC TOTAL	46	0
TOTAL REACTIONS FOR DRUG	2298	1
TOTAL REPORTS	625	
TOTAL FATAL OUTCOME REPORTS		1