



# Case Series Drug Analysis Print

## Isle of Man - COVID-19 AstraZeneca

Report Run Date: 12-Nov-2021

Data Lock Date: 10-Nov-2021 18:30:19

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	1	0
Lymphadenopathy	14	0
<i>Polycythaemia (excl rubra vera)</i>		
Stress polycythaemia	1	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>17</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	12	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	3	0
<i>Rate and rhythm disorders NEC</i>		
Extrasystoles	1	0
Tachycardia	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	2	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>20</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pain	6	0
<i>Hyperacusia</i>		
Hyperacusis	3	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	8	0
Vertigo	9	0
Vertigo positional	1	0
<b>Ear disorders SOC TOTAL</b>	<b>27</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<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	7	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	2	0
Visual impairment	3	0
<b>Eye disorders SOC TOTAL</b>	<b>37</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<b><i>Abdominal findings abnormal</i></b>		
Gastrointestinal sounds abnormal	1	0
<b><i>Colitis (excl infective)</i></b>		
Crohn's disease	1	0
<b><i>Dental pain and sensation disorders</i></b>		
Dental discomfort	1	0
Hyperaesthesia teeth	1	0
Toothache	2	0
<b><i>Diarrhoea (excl infective)</i></b>		
Diarrhoea	27	0
<b><i>Dyspeptic signs and symptoms</i></b>		
Dyspepsia	2	0
Eructation	1	0
<b><i>Faecal abnormalities NEC</i></b>		
Faeces hard	1	0
<b><i>Flatulence, bloating and distension</i></b>		
Abdominal distension	1	0
Flatulence	2	0
<b><i>Gastrointestinal and abdominal pains (excl oral and throat)</i></b>		
Abdominal pain	12	0
Abdominal pain lower	1	0
Abdominal pain upper	11	0
Oesophageal pain	1	0
<b><i>Gastrointestinal atonic and hypomotility disorders NEC</i></b>		
Constipation	1	0
<b><i>Gastrointestinal dyskinetic disorders</i></b>		
Bowel movement irregularity	1	0
Change of bowel habit	1	0
Dyschezia	1	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	2	0
Dysphagia	2	0
<b><i>Gastrointestinal vascular occlusion and infarction</i></b>		
Mesenteric artery thrombosis	1	0
<b><i>Intestinal haemorrhages</i></b>		
Rectal haemorrhage	1	0
<b><i>Nausea and vomiting symptoms</i></b>		
Nausea	95	0
Retching	1	0
Vomiting	31	0
<b><i>Oral dryness and saliva altered</i></b>		
Dry mouth	2	0
Lip dry	1	0
Salivary hypersecretion	1	0
<b><i>Oral soft tissue disorders NEC</i></b>		
Chapped lips	2	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Hypoaesthesia oral	4	0
Paraesthesia oral	3	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	2	0
<b><i>Stomatitis and ulceration</i></b>		
Aphthous ulcer	1	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Mouth ulceration	1	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	2	0
Swollen tongue	3	0
Tongue coated	1	0
Tongue discolouration	1	0
Tongue spasm	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>227</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<b><i>Asthenic conditions</i></b>		
Asthenia	17	0
Fatigue	136	0
Malaise	28	0
<b><i>Complications associated with device NEC</i></b>		
Medical device site joint pain	1	0
<b><i>Febrile disorders</i></b>		
Pyrexia	121	0
<b><i>Feelings and sensations NEC</i></b>		
Chills	104	0
Feeling abnormal	6	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
<b><i>Gait disturbances</i></b>		
Gait disturbance	1	0
Loss of control of legs	1	0
<b><i>General signs and symptoms NEC</i></b>		
Illness	6	0
Influenza like illness	38	0
Local reaction	1	0
Peripheral swelling	21	0
Swelling	7	0
Swelling face	1	0
<b><i>Inflammations</i></b>		
Inflammation	6	0
<b><i>Injection site reactions</i></b>		
Injection site erythema	2	0
Injection site extravasation	1	0
Injection site mass	2	0
Injection site pain	15	0
Injection site rash	1	0
Injection site scab	1	0
<b><i>Mass conditions NEC</i></b>		
Mass	1	0
<b><i>Oedema NEC</i></b>		
Oedema peripheral	2	0
<b><i>Pain and discomfort NEC</i></b>		
Axillary pain	1	0
Chest discomfort	2	0
Chest pain	18	0
Discomfort	5	0
Pain	40	0
Tenderness	2	0
<b><i>Therapeutic and nontherapeutic responses</i></b>		
Drug ineffective	1	0
<b><i>Vaccination site reactions</i></b>		
Vaccination site erythema	3	0
Vaccination site hypoaesthesia	1	0



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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
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
<b>General disorders SOC TOTAL</b>	<b>634</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	1	0
<i>Obstructive bile duct disorders (excl neoplasms)</i>		
Sphincter of Oddi dysfunction	2	0
<b>Hepatic disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	3	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
<b>Immune system disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i>Coronavirus infections</i>		
COVID-19	2	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	2	0
<i>Retroviral infections</i>		
HIV infection	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	9	0
Sinusitis	1	0
<i>Urinary tract infections</i>		
Urinary tract infection	1	0
<i>Viral infections NEC</i>		
Sweating fever	4	0
<b>Infections SOC TOTAL</b>	<b>68</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	5	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
<b>Injuries SOC TOTAL</b>	<b>18</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i>Central nervous system imaging procedures</i>		
Magnetic resonance imaging head	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	3	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
<b>Investigations SOC TOTAL</b>	<b>23</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	12	0
<i>Total fluid volume decreased</i>		
Dehydration	4	0
<i>Total fluid volume increased</i>		
Fluid retention	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>17</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	2	0
<b><i>Bone disorders NEC</i></b>		
Medial tibial stress syndrome	1	0
<b><i>Bone related signs and symptoms</i></b>		
Bone pain	4	0
<b><i>Joint related disorders NEC</i></b>		
Temporomandibular joint syndrome	1	0
<b><i>Joint related signs and symptoms</i></b>		
Arthralgia	63	0
Joint stiffness	2	0
Joint swelling	5	0
<b><i>Muscle pains</i></b>		
Fibromyalgia	1	0
Myalgia	61	0
<b><i>Muscle related signs and symptoms NEC</i></b>		
Muscle fatigue	4	0
Muscle spasms	11	0
Muscle tightness	1	0
Muscle twitching	1	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	5	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Mobility decreased	2	0
Musculoskeletal stiffness	10	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	12	0
Limb discomfort	10	0
Musculoskeletal chest pain	1	0
Musculoskeletal discomfort	1	0
Neck pain	10	0
Pain in extremity	68	0
<b><i>Rheumatoid arthropathies</i></b>		
Rheumatoid arthritis	1	0
<b><i>Tendon disorders</i></b>		
Tendon pain	1	0
Tendonitis	2	0
Tenosynovitis	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>281</b>	<b>0</b>



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

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<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>		
Dysstasia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	11	0
Loss of consciousness	3	0
Somnolence	4	0
Syncope	8	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	3	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	227	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	2	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	61	0
Dizziness postural	4	0
Head discomfort	1	0
Neurological symptom	2	0
Presyncope	2	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	3	0
Hypoaesthesia	17	0
Paraesthesia	24	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	2	0
<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>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Transient ischaemic attack	4	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	33	0
<b><i>Trigeminal disorders</i></b>		
Trigeminal neuralgia	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>472</b>	<b>1</b>

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

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i><b>Anxiety symptoms</b></i>		
Agitation	1	0
Anxiety	5	0
Stress	2	0
<i><b>Cognitive and attention disorders and disturbances NEC</b></i>		
Mental fatigue	2	0
<i><b>Confusion and disorientation</b></i>		
Confusional state	3	0
Disorientation	1	0
<i><b>Deliria</b></i>		
Delirium	2	0
<i><b>Depressive disorders</b></i>		
Depression	2	0
<i><b>Disturbances in initiating and maintaining sleep</b></i>		
Insomnia	6	0
<i><b>Dyssomnias</b></i>		
Poor quality sleep	4	0
<i><b>Emotional and mood disturbances NEC</b></i>		
Anger	1	0
Irritability	2	0
<i><b>Fear symptoms and phobic disorders (incl social phobia)</b></i>		
Fear	1	0
<i><b>Hallucinations (excl sleep-related)</b></i>		
Hallucination, visual	1	0
<i><b>Increased physical activity levels</b></i>		
Restlessness	1	0
<i><b>Mood alterations with depressive symptoms</b></i>		
Depressed mood	1	0
Tearfulness	1	0
<i><b>Mood disorders NEC</b></i>		
Listless	1	0
<i><b>Parasomnias</b></i>		
Abnormal dreams	2	0
Nightmare	3	0
<i><b>Somatic symptom disorders</b></i>		
Habit cough	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>43</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Pollakiuria	2	0
Urinary incontinence	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast signs and symptoms</b></i>		
Breast pain	3	0
Breast tenderness	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Organic erectile dysfunction	1	0
<i><b>Menopausal effects NEC</b></i>		
Menopausal symptoms	1	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	1	0
Intermenstrual bleeding	1	0
Menstrual disorder	3	0
Menstruation irregular	3	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	2	0
Hypomenorrhoea	1	0
Menstruation delayed	3	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	10	0
Menometrorrhagia	1	0
Polymenorrhoea	1	0
<i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>		
Polycystic ovaries	1	0
<i><b>Ovarian and fallopian tube disorders NEC</b></i>		
Ovulation pain	1	0
<i><b>Pelvis and broad ligament disorders NEC</b></i>		
Adnexa uteri pain	1	0
<i><b>Scrotal disorders NEC</b></i>		
Scrotal pain	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	1	0
<i><b>Vulvovaginal signs and symptoms</b></i>		
Vulvovaginal burning sensation	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>38</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i>Breathing abnormalities</i>		
Dyspnoea	22	0
Hypopnoea	1	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
Oropharyngeal pain	9	0
Rhinorrhoea	2	0
Sinus pain	2	0
Sneezing	1	0
Throat irritation	2	0
<b>Respiratory disorders SOC TOTAL</b>	<b>67</b>	<b>0</b>



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Data Lock Date: 10-Nov-2021 18:30:19

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b>Angioedemas</b>		
Angioedema	1	0
<b>Apocrine and eccrine gland disorders</b>		
Cold sweat	3	0
Hyperhidrosis	27	0
Miliaria	1	0
Night sweats	4	0
<b>Bullous conditions</b>		
Blister	3	0
<b>Dermal and epidermal conditions NEC</b>		
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
<b>Dermatitis and eczema</b>		
Dermatitis allergic	3	0
Eczema	1	0
<b>Erythemas</b>		
Erythema	9	0
<b>Exfoliative conditions</b>		
Skin exfoliation	1	0
<b>Pruritus NEC</b>		
Pruritus	26	0
<b>Purpura and related conditions</b>		
Purpura	1	0
<b>Rashes, eruptions and exanthems NEC</b>		
Rash	26	0
Rash erythematous	2	0
Rash macular	4	0
Rash pruritic	2	0
Rash vesicular	1	0
<b>Rosaceas</b>		
Rosacea	1	0
<b>Skin haemorrhages</b>		
Haemorrhage subcutaneous	1	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	1	0
<b>Urticarias</b>		
Urticaria	6	0
<b>Skin disorders SOC TOTAL</b>	<b>134</b>	<b>0</b>

# Case Series Drug Analysis Print

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Surgical &amp; medical procedures</b>		
<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
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>6</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<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	3	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
<i>Vasculitides NEC</i>		
Vasculitis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>41</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>2188</b>	<b>1</b>
<b>TOTAL REPORTS</b>	<b>599</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>1</b>