

## COVID-19 Moderna vaccine analysis print

Report Run Date: 01-Jul-2021  
Data Lock Date: 30-Jun-2021 18:30:05

All UK spontaneous reports received between 9/12/20 and 30/06/21 for Moderna vaccine analysis print.

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.

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 01-Jul-2021

Data Lock Date: 30-Jun-2021 18:30:05

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemias NEC</i></b>		
Anaemia	2	0
<b><i>Bleeding tendencies</i></b>		
Increased tendency to bruise	1	0
<b><i>Lymphatic system disorders NEC</i></b>		
Lymph node pain	72	0
Lymphadenitis	6	0
Lymphadenopathy	363	0
<b><i>Neutropenias</i></b>		
Neutropenia	1	0
<b><i>Thrombocytopenias</i></b>		
Immune thrombocytopenia	2	0
Thrombocytopenia	6	0
<b>Blood disorders SOC TOTAL</b>	<b>453</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	1	0
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	3	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Palpitations	104	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Angina pectoris	4	0
Myocardial infarction	5	0
<i><b>Mitral valvular disorders</b></i>		
Mitral valve prolapse	1	0
<i><b>Myocardial disorders NEC</b></i>		
Cardiomegaly	1	0
Ventricular hypertrophy	1	0
<i><b>Noninfectious myocarditis</b></i>		
Myocarditis	7	0
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	6	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	2	0
Bradycardia	5	0
Cardiac flutter	5	0
Extrasystoles	3	0
Tachycardia	16	0
<i><b>Supraventricular arrhythmias</b></i>		
Atrial fibrillation	1	0
Atrial flutter	1	0
Atrial tachycardia	1	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Cardiac arrest	2	0
<b>Cardiac disorders SOC TOTAL</b>	<b>169</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Congenital disorders</b>		
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	1	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		
Craniosynostosis	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear congestion	3	0
Ear discomfort	2	0
Ear disorder	1	0
Ear pain	49	0
<i><b>Eustachian tube disorders</b></i>		
Eustachian tube obstruction	1	0
<i><b>External ear disorders NEC</b></i>		
Excessive cerumen production	1	0
<i><b>Hearing losses</b></i>		
Deafness	4	0
Deafness transitory	1	0
Deafness unilateral	4	0
Hypoacusis	5	0
Sudden hearing loss	1	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	3	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	5	0
Tinnitus	87	0
Vertigo	57	0
Vertigo positional	1	0
<b>Ear disorders SOC TOTAL</b>	<b>225</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Endocrine disorders</b>		
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	2	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	2	0
Ovulation delayed	1	0
<i>Thyroid disorders NEC</i>		
Goitre	2	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<b><i>Amblyopic vision impairment</i></b>		
Amblyopia	1	0
<b><i>Cataract conditions</i></b>		
Cataract	1	0
<b><i>Conjunctival and corneal bleeding and vascular disorders</i></b>		
Conjunctival haemorrhage	1	0
<b><i>Eyelid movement disorders</i></b>		
Blepharospasm	5	0
<b><i>Lacrimation disorders</i></b>		
Dry eye	4	0
Lacrimation increased	3	0
<b><i>Lid, lash and lacrimal infections, irritations and inflammations</i></b>		
Swelling of eyelid	6	0
<b><i>Ocular bleeding and vascular disorders NEC</i></b>		
Eye haematoma	1	0
<b><i>Ocular disorders NEC</i></b>		
Eye pain	46	0
Eye swelling	19	0
Periorbital oedema	1	0
Periorbital swelling	2	0
<b><i>Ocular infections, inflammations and associated manifestations</i></b>		
Eye allergy	2	0
Eye irritation	3	0
Eye pruritus	6	0
Ocular hyperaemia	9	0
<b><i>Ocular nerve and muscle disorders</i></b>		
Eye movement disorder	4	0
<b><i>Ocular sensation disorders</i></b>		
Abnormal sensation in eye	1	0
Asthenopia	1	0
Hypoaesthesia eye	1	0
Photophobia	9	0
<b><i>Optic disc abnormalities NEC</i></b>		
Optic discs blurred	1	0
<b><i>Optic nerve bleeding and vascular disorders</i></b>		
Optic ischaemic neuropathy	1	0
<b><i>Orbital infections, inflammations and irritations</i></b>		
Orbital myositis	1	0
<b><i>Pupil disorders</i></b>		
Mydriasis	2	0
<b><i>Retinal bleeding and vascular disorders (excl retinopathy)</i></b>		
Retinal haemorrhage	1	0
<b><i>Scleral infections, irritations and inflammations</i></b>		
Episcleritis	4	0
<b><i>Structural change, deposit and degeneration of eye NEC</i></b>		
Exophthalmos	1	0
<b><i>Visual colour distortions</i></b>		
Cyanopsia	1	0
<b><i>Visual disorders NEC</i></b>		
Diplopia	5	0
Metamorphopsia	1	0
Photopsia	2	0
Vision blurred	67	0

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<b>Eye disorders</b> Eye disorders cont'd		
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	5	0
Blindness transient	1	0
Visual impairment	7	0
<b>Eye disorders SOC TOTAL</b>	<b>226</b>	<b>0</b>



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<b>Gastrointestinal disorders</b>		
<i><b>Anal and rectal signs and symptoms</b></i>		
Anal pruritus	1	0
<i><b>Colitis (excl infective)</b></i>		
Colitis ulcerative	1	0
Crohn's disease	3	0
Inflammatory bowel disease	1	0
<i><b>Dental pain and sensation disorders</b></i>		
Hyperaesthesia teeth	2	0
Toothache	6	0
<i><b>Dental pulp disorders</b></i>		
Dental pulp disorder	1	0
<i><b>Diarrhoea (excl infective)</b></i>		
Diarrhoea	197	0
Diarrhoea haemorrhagic	1	0
<i><b>Dyspeptic signs and symptoms</b></i>		
Dyspepsia	17	0
Epigastric discomfort	1	0
<i><b>Faecal abnormalities NEC</b></i>		
Faeces discoloured	2	0
<i><b>Flatulence, bloating and distension</b></i>		
Abdominal distension	9	0
Flatulence	7	0
<i><b>Gastric ulcers and perforation</b></i>		
Gastric ulcer	1	0
Gastritis erosive	1	0
<i><b>Gastritis (excl infective)</b></i>		
Gastritis	1	0
<i><b>Gastrointestinal and abdominal pains (excl oral and throat)</b></i>		
Abdominal pain	61	0
Abdominal pain lower	2	0
Abdominal pain upper	129	0
Abdominal tenderness	1	0
Gastrointestinal pain	6	0
<i><b>Gastrointestinal atonic and hypomotility disorders NEC</b></i>		
Constipation	7	0
Gastrooesophageal reflux disease	3	0
<i><b>Gastrointestinal disorders NEC</b></i>		
Food poisoning	1	0
Gastric disorder	1	0
<i><b>Gastrointestinal dyskinetic disorders</b></i>		
Change of bowel habit	1	0
<i><b>Gastrointestinal mucosal dystrophies and secretion disorders</b></i>		
Hyperchlorhydria	1	0
<i><b>Gastrointestinal signs and symptoms NEC</b></i>		
Abdominal discomfort	22	0
Anal incontinence	2	0
Breath odour	2	0
Dysphagia	5	0
Odynophagia	2	0
<i><b>Gastrointestinal spastic and hypermotility disorders</b></i>		
Frequent bowel movements	1	0
Irritable bowel syndrome	1	0
<i><b>Gingival disorders, signs and symptoms NEC</b></i>		

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Gingival pain	1	0
Gingival swelling	1	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	1	0
<b><i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i></b>		
Haemorrhoids	1	0
<b><i>Intestinal haemorrhages</i></b>		
Rectal haemorrhage	3	0
<b><i>Nausea and vomiting symptoms</i></b>		
Discoloured vomit	1	0
Nausea	698	0
Retching	1	0
Vomiting	201	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Haematemesis	1	0
Haematochezia	2	0
Melaena	1	0
<b><i>Oral dryness and saliva altered</i></b>		
Dry mouth	29	0
Lip dry	4	0
Saliva altered	1	0
Salivary hypersecretion	4	0
<b><i>Oral soft tissue disorders NEC</i></b>		
Enlarged uvula	1	0
Lip blister	2	0
<b><i>Oral soft tissue haemorrhages</i></b>		
Mouth haemorrhage	1	0
Oral blood blister	2	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Coating in mouth	1	0
Hypoaesthesia oral	24	0
Lip discolouration	1	0
Lip pain	2	0
Lip pruritus	1	0
Oral discomfort	2	0
Oral mucosal roughening	1	0
Oral pain	5	0
Oral pruritus	1	0
Paraesthesia oral	42	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	36	0
Mouth swelling	6	0
<b><i>Peptic ulcers and perforation</i></b>		
Peptic ulcer haemorrhage	1	0
<b><i>Salivary gland enlargements</i></b>		
Submaxillary gland enlargement	1	0
<b><i>Stomatitis and ulceration</i></b>		
Aphthous ulcer	3	0
Lip ulceration	1	0
Mouth ulceration	20	0
Stomatitis	2	0
<b><i>Tongue disorders</i></b>		
Glossitis	1	0

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<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Tongue disorder	3	0
Tongue ulceration	2	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	8	0
Swollen tongue	22	0
Tongue blistering	1	0
Tongue coated	1	0
Tongue discomfort	2	0
Tongue dry	2	0
Tongue movement disturbance	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>1649</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Administration site reactions NEC</b></i>		
Administration site lymphadenopathy	1	0
Administration site pain	1	0
Puncture site bruise	2	0
<i><b>Application and instillation site reactions</b></i>		
Application site burn	1	0
Application site erythema	3	0
Application site joint erythema	1	0
Application site pain	1	0
Application site pruritus	7	0
Application site rash	1	0
Application site swelling	1	0
Application site vesicles	3	0
Application site warmth	1	0
Instillation site warmth	2	0
<i><b>Asthenic conditions</b></i>		
Asthenia	63	0
Fatigue	1026	0
Malaise	157	0
<i><b>Death and sudden death</b></i>		
Death	3	3
<i><b>Febrile disorders</b></i>		
Pyrexia	716	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	394	0
Feeling abnormal	74	0
Feeling cold	39	0
Feeling drunk	6	0
Feeling hot	85	0
Feeling jittery	2	0
Feeling of body temperature change	19	0
Hangover	5	0
Hunger	4	0
Sensation of blood flow	1	0
Sensation of foreign body	1	0
Temperature intolerance	1	0
Thirst	22	0
<i><b>Gait disturbances</b></i>		
Gait disturbance	5	0
Gait inability	1	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	3	0
Crying	12	0
Developmental delay	1	0
Exercise tolerance decreased	3	0
Illness	71	0
Induration	5	0
Influenza like illness	77	0
Irritability postvaccinal	1	0
Local reaction	10	0
Peripheral swelling	637	0
Screaming	3	0
Swelling	317	0

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<b>General disorders</b> General disorders cont'd		
Swelling face	42	0
<b>Implant and catheter site reactions</b>		
Implant site warmth	2	0
<b>Inflamations</b>		
Inflammation	40	0
Soft tissue inflammation	1	0
<b>Infusion site reactions</b>		
Infusion site mass	1	0
Infusion site pain	3	0
Infusion site urticaria	2	0
Infusion site warmth	1	0
<b>Injection site reactions</b>		
Injected limb mobility decreased	2	0
Injection site bruising	7	0
Injection site discolouration	1	0
Injection site erythema	71	0
Injection site haemorrhage	1	0
Injection site hypersensitivity	4	0
Injection site hypoaesthesia	2	0
Injection site indentation	1	0
Injection site inflammation	5	0
Injection site joint erythema	1	0
Injection site mass	65	0
Injection site oedema	1	0
Injection site pain	158	0
Injection site paraesthesia	1	0
Injection site pruritus	55	0
Injection site rash	98	0
Injection site reaction	6	0
Injection site swelling	25	0
Injection site urticaria	30	0
Injection site warmth	32	0
<b>Interactions</b>		
Alcohol interaction	1	0
<b>Mass conditions NEC</b>		
Cyst	3	0
Mass	12	0
Nodule	2	0
<b>Mucosal findings abnormal</b>		
Mucosal discolouration	1	0
Mucosal pain	1	0
<b>Oedema NEC</b>		
Localised oedema	1	0
Oedema	2	0
Oedema peripheral	2	0
<b>Pain and discomfort NEC</b>		
Axillary pain	195	0
Chest discomfort	61	0
Chest pain	115	0
Discomfort	27	0
Facial pain	6	0
Pain	467	0
Tenderness	59	0

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<b>General disorders</b> General disorders cont'd		
<i><b>Therapeutic and nontherapeutic responses</b></i>		
Adverse drug reaction	43	0
Adverse reaction	1	0
Drug ineffective	3	0
Drug intolerance	1	0
No reaction on previous exposure to drug	1	0
Therapeutic response unexpected	1	0
Vaccination failure	1	0
<i><b>Ulcers NEC</b></i>		
Ulcer	1	0
<i><b>Vaccination site reactions</b></i>		
Vaccination site bruising	10	0
Vaccination site discolouration	1	0
Vaccination site discomfort	6	0
Vaccination site eczema	1	0
Vaccination site erythema	158	0
Vaccination site haemorrhage	1	0
Vaccination site hypoaesthesia	3	0
Vaccination site induration	12	0
Vaccination site inflammation	6	0
Vaccination site joint erythema	1	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	2	0
Vaccination site mass	33	0
Vaccination site movement impairment	2	0
Vaccination site oedema	1	0
Vaccination site pain	121	0
Vaccination site papule	2	0
Vaccination site pruritus	37	0
Vaccination site rash	73	0
Vaccination site reaction	1	0
Vaccination site swelling	88	0
Vaccination site urticaria	6	0
Vaccination site warmth	64	0
<i><b>Withdrawal and rebound effects</b></i>		
Drug withdrawal syndrome	1	0
<b>General disorders SOC TOTAL</b>	<b>6085</b>	<b>3</b>

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<b>Hepatic disorders</b>		
<i>Bile duct infections and inflammations</i>		
Biliary colic	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Allergic oedema	3	0
Allergy to animal	1	0
Hypersensitivity	93	0
Infusion related hypersensitivity reaction	4	0
Type IV hypersensitivity reaction	7	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergy to vaccine	3	0
Drug hypersensitivity	2	0
Reaction to excipient	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	20	0
Anaphylactic shock	3	0
Anaphylactoid reaction	1	0
<i><b>Atopic disorders</b></i>		
Seasonal allergy	6	0
<i><b>Autoimmune disorders NEC</b></i>		
Autoimmune disorder	1	0
<i><b>Immune and associated conditions NEC</b></i>		
Bacille Calmette-Guerin scar reactivation	11	0
Immune-mediated adverse reaction	1	0
Sensitisation	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>158</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Diverticulitis	1	0
<b><i>Bacterial infections NEC</i></b>		
Application site cellulitis	1	0
Bacterial infection	1	0
Cellulitis	28	0
Injection site cellulitis	2	0
Skin bacterial infection	1	0
<b><i>Breast infections</i></b>		
Breast abscess	1	0
<b><i>Candida infections</i></b>		
Candida infection	2	0
Vulvovaginal candidiasis	7	0
<b><i>Cardiac infections</i></b>		
Endocarditis	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Central nervous system infection	1	0
Meningitis	2	0
<b><i>Coronavirus infections</i></b>		
COVID-19	13	0
Suspected COVID-19	1	0
<b><i>Coxiella infections</i></b>		
Q fever	2	0
<b><i>Ear infections</i></b>		
Ear infection	2	0
Labyrinthitis	2	0
<b><i>Epstein-Barr viral infections</i></b>		
Infectious mononucleosis	2	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	7	0
Hordeolum	1	0
<b><i>Fungal infections NEC</i></b>		
Fungal skin infection	1	0
<b><i>Herpes viral infections</i></b>		
Genital herpes	2	0
Herpes zoster	20	0
Oral herpes	11	0
<b><i>Infections NEC</i></b>		
Abscess limb	1	0
Abscess rupture	1	0
Infection	33	0
Localised infection	5	0
Respiratory tract infection	1	0
Vaccination site infection	2	0
Vestibulitis	1	0
<b><i>Infectious disorders carrier</i></b>		
SARS-CoV-2 carrier	2	0
<b><i>Infectious transmissions</i></b>		
Secondary transmission	1	0
<b><i>Influenza viral infections</i></b>		
Influenza	53	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Lower respiratory tract infection	6	0

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<b>Infections</b> Infections cont'd		
Pneumonia	4	0
<i>Rabies viral infections</i>		
Rabies	1	1
<i>Rubella viral infections</i>		
Rubella	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
Urosepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Pustule	5	0
Rash pustular	3	0
Skin infection	6	0
<i>Tinea infections</i>		
Body tinea	1	0
<i>Tuberculous infections</i>		
Disseminated Bacillus Calmette-Guerin infection	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	1	0
Nasopharyngitis	59	0
Peritonsillar abscess	1	0
Rhinitis	1	0
Sinusitis	3	0
Tonsillitis	4	0
<i>Urinary tract infections</i>		
Cystitis	1	0
Urinary tract infection	6	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Post viral fatigue syndrome	1	0
Sweating fever	6	0
Viral infection	1	0
Viral pharyngitis	2	0
Viral rash	3	0
<b>Infections SOC TOTAL</b>	<b>332</b>	<b>1</b>

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 01-Jul-2021  
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 30-Jun-2021 18:30:05  
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Accidental exposures to product</i></b>		
Accidental exposure to product	1	0
<b><i>Atmospheric pressure injuries</i></b>		
Barotrauma	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	1	0
Foetal exposure during pregnancy	2	0
Maternal exposure during breast feeding	152	0
Maternal exposure during pregnancy	67	0
<b><i>Exposures to agents or circumstances NEC</i></b>		
Exposure to SARS-CoV-2	1	0
<b><i>Heat injuries (excl thermal burns)</i></b>		
Heat oedema	1	0
Heat stroke	1	0
<b><i>Limb fractures and dislocations</i></b>		
Clavicle fracture	1	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Medication error	1	0
Wrong schedule	1	0
Wrong technique in device usage process	1	0
<b><i>Muscle, tendon and ligament injuries</i></b>		
Epicondylitis	1	0
Muscle injury	1	0
Muscle strain	1	0
<b><i>Nerve injuries NEC</i></b>		
Nerve injury	2	0
<b><i>Neurological and psychiatric procedural complications</i></b>		
Procedural dizziness	2	0
<b><i>Non-occupational environmental exposures</i></b>		
Exposure to extreme temperature	1	0
<b><i>Non-site specific injuries NEC</i></b>		
Arthropod bite	2	0
Bite	1	0
Fall	5	0
Wound complication	1	0
<b><i>Non-site specific procedural complications</i></b>		
Injection related reaction	1	0
Procedural pain	1	0
<b><i>Poisoning and toxicity</i></b>		
Toxicity to various agents	1	0
<b><i>Product administration errors and issues</i></b>		
Expired product administered	2	0
Inappropriate schedule of product administration	1	0
Incorrect dose administered	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	4	0

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Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
<i><b>Site specific injuries NEC</b></i>		
Head injury	4	0
Limb injury	6	0
<i><b>Skin injuries NEC</b></i>		
Contusion	75	0
Scar	2	0
Scratch	1	0
Skin injury	1	0
Skin wound	1	0
Subcutaneous haematoma	2	0
<i><b>Stoma complications</b></i>		
Stoma site oedema	1	0
<i><b>Thermal burns</b></i>		
Thermal burn	3	0
<b>Injuries SOC TOTAL</b>	<b>362</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Adrenal medulla tests</b></i>		
Norepinephrine increased	1	0
<i><b>Blood gas and acid base analyses</b></i>		
Oxygen saturation decreased	3	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose increased	1	0
<i><b>Coagulation and bleeding analyses</b></i>		
Fibrin D dimer increased	1	0
<i><b>ECG investigations</b></i>		
Electrocardiogram T wave inversion	1	0
<i><b>Endocrine analyses and imaging NEC</b></i>		
Hormone level abnormal	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate	24	0
Heart rate abnormal	1	0
Heart rate decreased	2	0
Heart rate increased	36	0
Heart rate irregular	5	0
<i><b>Investigations NEC</b></i>		
Blood test abnormal	1	0
<i><b>Liver function analyses</b></i>		
Alanine aminotransferase increased	1	0
Blood bilirubin increased	1	0
Liver function test abnormal	2	0
Liver function test increased	1	0
<i><b>Mineral and electrolyte analyses</b></i>		
Blood iron decreased	1	0
Blood magnesium decreased	1	0
Blood potassium decreased	1	0
<i><b>Ophthalmic function diagnostic procedures</b></i>		
Visual tracking test abnormal	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature	14	0
Body temperature decreased	3	0
Body temperature fluctuation	4	0
Body temperature increased	11	0
Grip strength	1	0
Grip strength decreased	1	0
Lymph node palpable	1	0
Respiratory rate	1	0
Respiratory rate increased	4	0
Skin temperature	3	0
Weight decreased	3	0
Weight increased	4	0
<i><b>Pituitary analyses anterior</b></i>		
Blood thyroid stimulating hormone increased	1	0
<i><b>Platelet analyses</b></i>		
Platelet count decreased	5	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	1	0
<i><b>Red blood cell analyses</b></i>		
Haemoglobin decreased	1	0
<i><b>Reproductive hormone analyses</b></i>		

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Pregnancy test	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output	2	0
<i>Urinary tract imaging procedures</i>		
Bladder scan	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	3	0
Blood pressure diastolic increased	1	0
Blood pressure increased	3	0
Blood pressure measurement	2	0
<i>Virus identification and serology</i>		
Coronavirus test	3	0
SARS-CoV-2 antibody test	1	0
SARS-CoV-2 test	4	0
SARS-CoV-2 test negative	2	0
<i>White blood cell analyses</i>		
White blood cell count decreased	1	0
<b>Investigations SOC TOTAL</b>	<b>168</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	46	0
Increased appetite	2	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	1	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	2	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	1	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal weight gain	3	0
Feeding disorder	2	0
Neonatal insufficient breast milk syndrome	1	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	3	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	14	0
<i><b>Total fluid volume increased</b></i>		
Fluid retention	5	0
<b>Metabolic disorders SOC TOTAL</b>	<b>80</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	4	0
Arthropathy	1	0
Autoimmune arthritis	1	0
<i><b>Bone disorders NEC</b></i>		
Osteitis	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	11	0
Pain in jaw	20	0
Spinal pain	2	0
<i><b>Bursal disorders</b></i>		
Bursitis	3	0
<i><b>Cartilage disorders</b></i>		
Costochondritis	3	0
<i><b>Connective tissue disorders NEC</b></i>		
Reynold's syndrome	1	0
<i><b>Joint related disorders NEC</b></i>		
Joint lock	1	0
Periarthritis	7	0
Rotator cuff syndrome	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	280	0
Joint noise	1	0
Joint stiffness	13	0
Joint swelling	13	0
Joint vibration	1	0
Joint warmth	1	0
<i><b>Lupus erythematosus (incl subtypes)</b></i>		
Lupus-like syndrome	1	0
<i><b>Muscle infections and inflammations</b></i>		
Myositis	3	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	1	0
Myalgia	470	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle fatigue	16	0
Muscle haemorrhage	1	0
Muscle spasms	70	0
Muscle swelling	5	0
Muscle tightness	8	0
Muscle twitching	21	0
Myosclerosis	1	0
<i><b>Muscle tone abnormalities</b></i>		
Nuchal rigidity	1	0
Trismus	2	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	34	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Mobility decreased	1	0
Musculoskeletal stiffness	95	0
<i><b>Musculoskeletal and connective tissue infections and inflammations NEC</b></i>		
Dupuytren's contracture	1	0
Fasciitis	1	0



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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	96	0
Flank pain	1	0
Limb discomfort	104	0
Musculoskeletal chest pain	2	0
Musculoskeletal discomfort	3	0
Neck pain	55	0
Pain in extremity	979	0
<i>Myopathies</i>		
Rhabdomyolysis	1	0
<i>Osteoarthropathies</i>		
Osteoarthritis	1	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	13	0
Groin pain	3	0
Neck mass	1	0
Soft tissue swelling	1	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	1	0
Axial spondyloarthritis	1	0
<i>Tendon disorders</i>		
Trigger finger	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>2362</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Mediastinal neoplasms malignancy unspecified NEC</i>		
Good syndrome	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	2	0
<i>Skin neoplasms benign</i>		
Haemangioma of skin	1	0
<i>Small intestinal neoplasms malignant</i>		
Small intestine adenocarcinoma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>6</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	2	1
Cerebrovascular accident	3	0
Haemorrhage intracranial	1	0
Ischaemic stroke	1	0
Subarachnoid haemorrhage	1	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	12	0
Coordination abnormal	1	0
Dysstasia	2	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	3	0
Lethargy	81	0
Loss of consciousness	49	0
Somnolence	57	0
Syncope	235	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	2	0
Dyskinesia	1	0
Fine motor delay	1	0
Fine motor skill dysfunction	1	0
Hyperkinesia	1	0
Hypokinesia	1	0
Movement disorder	2	0
Psychomotor hyperactivity	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	11	0
Facial paralysis	12	0
Facial paresis	1	0
<i>Glossopharyngeal nerve disorders</i>		
Glossopharyngeal neuralgia	1	0
<i>Headaches NEC</i>		
Cluster headache	10	0
Cold-stimulus headache	1	0
Drug withdrawal headache	1	0
Headache	1051	0
New daily persistent headache	1	0
Sinus headache	12	0
Tension headache	22	0
Thunderclap headache	1	0
Vascular headache	2	0
<i>Increased intracranial pressure disorders</i>		
Intracranial pressure increased	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	6	0
Memory impairment	8	0
<i>Mental impairment (excl dementia and memory loss)</i>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Cognitive disorder	4	0
Disturbance in attention	19	0
Mental impairment	2	0
<b>Migraine headaches</b>		
Hemiplegic migraine	1	0
Migraine	118	0
Migraine with aura	11	0
Retinal migraine	1	0
<b>Mononeuropathies</b>		
Cubital tunnel syndrome	1	0
Mononeuritis	1	0
<b>Neurologic visual problems NEC</b>		
Tunnel vision	2	0
<b>Neurological signs and symptoms NEC</b>		
Dizziness	689	0
Dizziness postural	25	0
Drooling	2	0
Head discomfort	14	0
Neurological symptom	1	0
Persistent postural-perceptual dizziness	1	0
Presyncope	53	0
Unresponsive to stimuli	4	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	1	0
<b>Olfactory nerve disorders</b>		
Anosmia	4	0
Parosmia	5	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	26	0
Formication	1	0
Hyperaesthesia	14	0
Hypoaesthesia	137	0
Paraesthesia	217	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Hemiparesis	3	0
Hemiplegia	1	0
Monoparesis	5	0
Monoplegia	6	0
Paralysis	1	0
Paresis	1	0
<b>Parkinson's disease and parkinsonism</b>		
Reduced facial expression	1	0
<b>Peripheral neuropathies NEC</b>		
Neuropathy peripheral	2	0
<b>Seizures and seizure disorders NEC</b>		
Febrile convulsion	2	0
Partial seizures	1	0
Psychogenic seizure	1	0
Seizure	28	0
Status epilepticus	23	0
Tonic convulsion	1	0
<b>Sensory abnormalities NEC</b>		
Ageusia	12	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Dysgeusia	65	0
Electric shock sensation	1	0
Neuralgia	11	0
Post herpetic neuralgia	2	0
Restless legs syndrome	9	0
Sensory disturbance	3	0
Sensory loss	2	0
Taste disorder	10	0
<b>Sleep disturbances NEC</b>		
Sleep deficit	1	0
<b>Speech and language abnormalities</b>		
Dysarthria	8	0
Incoherent	2	0
Slow speech	1	0
Speech disorder	2	0
<b>Structural brain disorders NEC</b>		
Intracranial mass	1	1
<b>Transient cerebrovascular events</b>		
Transient ischaemic attack	5	0
<b>Tremor (excl congenital)</b>		
Tremor	63	0
<b>Trigeminal disorders</b>		
Trigeminal neuralgia	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>3231</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	9	0
<i>Maternal complications of labour NEC</i>		
Uterine hypertonus	1	0
<i>Maternal complications of pregnancy NEC</i>		
Ectopic pregnancy	2	0
Ectopic pregnancy with contraceptive device	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	4	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	1	0
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	1	0
Unintended pregnancy	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>21</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<i>Device issues NEC</i>		
Device expulsion	1	0
Device leakage	1	0
<b>null SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	1	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	1	0
Flat affect	2	0
<b><i>Anxiety symptoms</i></b>		
Agitation	3	0
Anxiety	58	0
Nervousness	11	0
Stress	1	0
Tension	2	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Paranoia	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Distractibility	1	0
Mental fatigue	13	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	29	0
Disorientation	14	0
<b><i>Deliria</i></b>		
Delirium	4	0
<b><i>Depressive disorders</i></b>		
Depression	15	0
Depression suicidal	2	0
Mixed anxiety and depressive disorder	1	0
<b><i>Dissociative states</i></b>		
Dissociation	4	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	47	0
Middle insomnia	1	0
Terminal insomnia	4	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	11	0
<b><i>Eating disorders NEC</i></b>		
Binge eating	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	5	0
Emotional disorder	7	0
Emotional distress	5	0
Euphoric mood	5	0
Irritability	9	0
Mood altered	2	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear of injection	3	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	3	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	15	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	13	0
<b><i>Mental disorders NEC</i></b>		
Mental disorder	1	0
<b><i>Mood alterations with depressive symptoms</i></b>		



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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Depressed mood	15	0
Feeling of despair	2	0
Tearfulness	1	0
<b>Mood alterations with manic symptoms</b>		
Mania	2	0
<b>Mood disorders NEC</b>		
Apathy	3	0
Listless	1	0
<b>Narcolepsy and associated conditions</b>		
Hypnagogic hallucination	1	0
<b>Panic attacks and disorders</b>		
Panic attack	14	0
Panic reaction	2	0
<b>Parasomnias</b>		
Abnormal dreams	9	0
Nightmare	9	0
Sleep terror	1	0
Somnambulism	1	0
<b>Perception disturbances NEC</b>		
Autoscopy	2	0
<b>Psychiatric elimination disorders</b>		
Enuresis	1	0
<b>Psychiatric symptoms NEC</b>		
Psychiatric symptom	1	0
<b>Psychotic disorder NEC</b>		
Acute psychosis	1	0
Psychotic disorder	1	0
<b>Sexual desire disorders</b>		
Libido decreased	2	0
Libido increased	1	0
<b>Sleep disorders NEC</b>		
Sleep disorder	5	0
<b>Somatic symptom disorders</b>		
Conversion disorder	1	0
Habit cough	1	0
<b>Speech articulation and rhythm disturbances</b>		
Dysphemia	1	0
<b>Stress disorders</b>		
Post-traumatic stress disorder	1	0
<b>Substance related and addictive disorders</b>		
Alcoholism	1	0
<b>Suicidal and self-injurious behaviour</b>		
Suicidal behaviour	1	0
Suicidal ideation	4	0
<b>Thinking disturbances</b>		
Bradyphrenia	3	0
Intrusive thoughts	1	0
Thinking abnormal	2	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>386</b>	<b>0</b>

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 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Bladder pain	2	0
Dysuria	3	0
Incontinence	1	0
Micturition urgency	1	0
Pollakiuria	6	0
Urinary incontinence	2	0
Urinary retention	1	0
Urine flow decreased	1	0
<i>Renal failure and impairment</i>		
Renal impairment	1	0
<i>Urinary abnormalities</i>		
Chromaturia	4	0
Haematuria	2	0
Urine odour abnormal	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	2	0
Renal pain	12	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>39</b>	<b>0</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 enlargement	2	0
Breast mass	3	0
Fibrocystic breast disease	1	0
<i><b>Breast signs and symptoms</b></i>		
Breast discomfort	1	0
Breast pain	19	0
Breast swelling	1	0
Nipple swelling	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Ejaculation failure	1	0
Erectile dysfunction	2	0
Painful ejaculation	1	0
<i><b>Lactation disorders</b></i>		
Lactation disorder	1	0
Lactation puerperal increased	1	0
<i><b>Menopausal effects NEC</b></i>		
Menopausal symptoms	4	0
Premature menopause	1	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Postmenopausal haemorrhage	9	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	99	0
Intermenstrual bleeding	56	0
Menstrual discomfort	1	0
Menstrual disorder	100	0
Menstruation irregular	170	0
Premenstrual headache	1	0
Premenstrual pain	1	0
Premenstrual syndrome	4	0
Withdrawal bleed	2	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	16	0
Hypomenorrhoea	33	0
Menstruation delayed	179	0
Oligomenorrhoea	9	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	283	0
Menometrorrhagia	2	0
Polymenorrhoea	34	0
<i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>		
Ovarian cyst	1	0
Polycystic ovaries	1	0
<i><b>Ovarian and fallopian tube disorders NEC</b></i>		
Ovulation pain	4	0
Premature ovulation	1	0
<i><b>Pelvis and broad ligament disorders NEC</b></i>		
Adnexa uteri pain	3	0
<i><b>Penile disorders NEC (excl erection and ejaculation)</b></i>		
Penis disorder	1	0
<i><b>Prostate and seminal vesicles infections and inflammations</b></i>		

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Prostatitis	1	0
<b><i>Prostatic signs, symptoms and disorders NEC</i></b>		
Prostatic pain	1	0
<b><i>Reproductive tract disorders NEC (excl neoplasms)</i></b>		
Genital haemorrhage	1	0
<b><i>Reproductive tract signs and symptoms NEC</i></b>		
Pelvic pain	3	0
<b><i>Testicular and epididymal disorders NEC</i></b>		
Testicular mass	1	0
Testicular pain	4	0
Testicular swelling	1	0
<b><i>Uterine disorders NEC</i></b>		
Endometriosis	2	0
Uterine haemorrhage	3	0
<b><i>Uterine tone disorders</i></b>		
Uterine spasm	3	0
<b><i>Vulvovaginal cysts and neoplasms</i></b>		
Vaginal cyst	1	0
Vulva cyst	1	0
<b><i>Vulvovaginal disorders NEC</i></b>		
Vaginal haemorrhage	75	0
Vulval haemorrhage	2	0
<b><i>Vulvovaginal signs and symptoms</i></b>		
Labia enlarged	1	0
Vaginal discharge	3	0
Vulvovaginal discomfort	1	0
Vulvovaginal pain	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>1155</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	132	0
Dyspnoea exertional	1	0
Hyperventilation	2	0
Hypopnoea	1	0
Hypoventilation	1	0
Respiration abnormal	4	0
Respiratory distress	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	11	0
Wheezing	17	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Hypoxia	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	85	0
Haemoptysis	1	0
Productive cough	8	0
Sputum discoloured	1	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Reflux laryngitis	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	12	0
Pulmonary haemorrhage	1	0
Pulmonary pain	3	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	11	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	38	0
Nasal oedema	1	0
Nasal pruritus	1	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	2	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Interstitial lung disease	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal hypoaesthesia	1	0
Pharyngeal oedema	1	0
Pharyngeal paraesthesia	2	0
Pharyngeal swelling	20	0
Tonsillar hypertrophy	3	0
<i><b>Pleural infections and inflammations</b></i>		
Pleurisy	1	0
<i><b>Pulmonary hypertensions</b></i>		
Pulmonary hypertension	1	0
<i><b>Pulmonary oedemas</b></i>		
Pulmonary congestion	1	0
Pulmonary oedema	1	0
<i><b>Pulmonary thrombotic and embolic conditions</b></i>		
Pulmonary embolism	4	0
<i><b>Respiratory signs and symptoms NEC</b></i>		
Diaphragmalgia	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
Aphonia	4	0
Catarrh	1	0
Dry throat	10	0
Dysphonia	1	0
Increased viscosity of upper respiratory secretion	1	0
Nasal discomfort	2	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	115	0
Paranasal sinus discomfort	3	0
Rhinalgia	1	0
Rhinorrhoea	23	0
Sinus pain	11	0
Sneezing	5	0
Throat irritation	10	0
Throat tightness	11	0
Upper-airway cough syndrome	1	0
Yawning	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>574</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	4	0
<b><i>Alopecias</i></b>		
Alopecia	7	0
Alopecia areata	1	0
<b><i>Angioedemas</i></b>		
Angioedema	12	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	49	0
Hyperhidrosis	110	0
Miliaria	27	0
Night sweats	25	0
<b><i>Bullous conditions</i></b>		
Blister	19	0
Blister rupture	1	0
Dermatitis bullous	1	0
Erythema multiforme	7	0
Stevens-Johnson syndrome	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	24	0
Pain of skin	17	0
Papule	9	0
Sensitive skin	20	0
Skin burning sensation	16	0
Skin discolouration	5	0
Skin induration	5	0
Skin lesion	14	0
Skin reaction	49	0
Skin sensitisation	2	0
Skin swelling	8	0
Skin tightness	2	0
Skin warm	87	0
Yellow skin	2	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	11	0
Dermatitis allergic	47	0
Dermatitis atopic	3	0
Dermatitis contact	2	0
Dyshidrotic eczema	4	0
Eczema	14	0
Skin irritation	10	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Palmar-plantar erythrodysesthesia syndrome	1	0
<b><i>Erythemas</i></b>		
Erythema	434	0
<b><i>Exfoliative conditions</i></b>		
Skin exfoliation	4	0
<b><i>Hyperpigmentation disorders</i></b>		
Skin hyperpigmentation	1	0
Solar lentigo	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Onychoclasia	1	0
<b><i>Papulosquamous conditions</i></b>		

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Lichen planus	1	0
Pityriasis rosea	1	0
<b>Photosensitivity and photodermatosis conditions</b>		
Photosensitivity reaction	6	0
<b>Pilar disorders NEC</b>		
Piloerection	2	0
<b>Pruritus NEC</b>		
Itching scar	1	0
Pruritus	1009	0
<b>Psoriatic conditions</b>		
Psoriasis	6	0
<b>Purpura and related conditions</b>		
Petechiae	5	0
Purpura	3	0
<b>Rashes, eruptions and exanthems NEC</b>		
Butterfly rash	1	0
Rash	1072	0
Rash erythematous	453	0
Rash macular	61	0
Rash morbilliform	3	0
Rash papular	83	0
Rash pruritic	277	0
Rash vesicular	2	0
<b>Rosaceas</b>		
Rosacea	2	0
<b>Scaly conditions</b>		
Pityriasis	1	0
<b>Sebaceous gland disorders</b>		
Seborrhoea	1	0
<b>Skin and subcutaneous conditions NEC</b>		
Cutaneous symptom	1	0
Skin mass	3	0
<b>Skin and subcutaneous tissue ulcerations</b>		
Skin ulcer	1	0
<b>Skin cysts and polyps</b>		
Dermal cyst	2	0
<b>Skin hypoplasias and atrophies</b>		
Skin atrophy	1	0
<b>Skin injuries and mechanical dermatoses</b>		
Needle track marks	1	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	1	0
<b>Telangiectasia and related conditions</b>		
Spider naevus	1	0
<b>Urticarias</b>		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	1	0
Urticaria	139	0
<b>Skin disorders SOC TOTAL</b>	<b>4199</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Age related issues</i>		
Menopause	3	0
<i>Disability issues</i>		
Immobile	1	0
Sight disability	1	0
<i>Employment issues</i>		
Retirement	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Water pollution	1	0
<i>Pregnancy related circumstances</i>		
Breast feeding	4	0
<i>Social issues NEC</i>		
Exercise lack of	1	0
<b>Social circumstances SOC TOTAL</b>	<b>12</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i><b>Analgesia supportive care</b></i>		
Analgesic therapy	1	0
<i><b>Breast therapeutic procedures NEC</b></i>		
Axillary lymphadenectomy	1	0
<i><b>Dietary and nutritional therapies</b></i>		
Medical diet	1	0
<i><b>Immunisations</b></i>		
COVID-19 immunisation	5	0
Immunisation	1	0
<i><b>Joint therapeutic procedures</b></i>		
Joint stabilisation	1	0
<i><b>Skin and subcutaneous tissue therapeutic procedures NEC</b></i>		
Dermal filler injection	1	0
<i><b>Therapeutic procedures NEC</b></i>		
Injection	1	0
Polypectomy	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>13</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Accelerated and malignant hypertension</i>		
Hypertensive urgency	1	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	1	0
Haemorrhage	53	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	2	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	0
Thrombosis	15	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	1	0
Vasodilatation	1	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	2	0
Deep vein thrombosis	4	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	2	0
Flushing	12	0
Hot flush	64	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	15	0
<i>Site specific vascular disorders NEC</i>		
Pallor	27	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	26	0
Prehypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	31	0
Orthostatic hypotension	2	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>269</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>22191</b>	<b>6</b>
<b>TOTAL REPORTS</b>	<b>7853</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>6</b>