

COVID-19 Moderna Vaccine Analysis Print

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All UK spontaneous reports received up to 14/07/21 for COVID-19 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: 15-Jul-2021
 Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 14-Jul-2021 18:30:32
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	2	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	1	0
Spontaneous haematoma	1	0
<i>Haematological disorders</i>		
Blood disorder	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	88	0
Lymphadenitis	8	0
Lymphadenopathy	473	0
<i>Neutropenias</i>		
Neutropenia	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	2	0
Thrombocytopenia	6	0
Blood disorders SOC TOTAL	584	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	4	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	167	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	7	0
Myocardial infarction	9	0
<i>Mitral valvular disorders</i>		
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	1	0
Ventricular hypertrophy	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	17	0
<i>Noninfectious pericarditis</i>		
Pericarditis	20	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	4	0
Bradycardia	6	0
Cardiac flutter	14	0
Extrasystoles	5	0
Tachycardia	19	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Atrial flutter	1	0
Atrial tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	2	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	282	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
Congenital disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	4	0
Ear discomfort	2	0
Ear disorder	1	0
Ear pain	60	0
Ear swelling	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
<i>Hearing losses</i>		
Deafness	9	0
Deafness transitory	1	0
Deafness unilateral	4	0
Hypoacusis	8	0
Sudden hearing loss	2	0
<i>Hyperacusia</i>		
Hyperacusis	4	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	6	0
Tinnitus	110	0
Vertigo	77	0
Vertigo positional	1	0
Ear disorders SOC TOTAL	292	0

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Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	2	0
Premature menarche	1	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	2	0
Ovulation delayed	2	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Pituitary haemorrhage	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
Endocrine disorders SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	1	0
<i>Cataract conditions</i>		
Cataract	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	1	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	6	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Uveitis	2	0
<i>Lacrimation disorders</i>		
Dry eye	5	0
Lacrimation increased	3	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	6	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	1	0
<i>Ocular disorders NEC</i>		
Eye pain	62	0
Eye swelling	24	0
Periorbital oedema	2	0
Periorbital swelling	3	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	2	0
Eye irritation	3	0
Eye pruritus	10	0
Ocular hyperaemia	11	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	4	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Asthenopia	2	0
Hypoaesthesia eye	1	0
Photophobia	17	0
<i>Optic disc abnormalities NEC</i>		
Optic discs blurred	1	0
Papilloedema	1	0
<i>Optic nerve bleeding and vascular disorders</i>		
Optic ischaemic neuropathy	1	0
<i>Orbital infections, inflammations and irritations</i>		
Orbital myositis	1	0
<i>Pupil disorders</i>		
Mydriasis	2	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
Retinal vein occlusion	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	4	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Exophthalmos	1	0
<i>Visual colour distortions</i>		

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Eye disorders Eye disorders cont'd		
Cyanopsia	1	0
Visual disorders NEC		
Diplopia	8	0
Metamorphopsia	1	0
Photopsia	3	0
Vision blurred	93	0
Visual impairment and blindness (excl colour blindness)		
Blindness	6	0
Blindness transient	1	0
Visual acuity reduced	1	0
Visual impairment	11	0
Eye disorders SOC TOTAL	307	0

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Gastrointestinal disorders		
<i>Anal and rectal pains</i>		
Proctalgia	1	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
<i>Colitis (excl infective)</i>		
Colitis ulcerative	1	0
Crohn's disease	3	0
Inflammatory bowel disease	1	0
<i>Dental pain and sensation disorders</i>		
Hyperaesthesia teeth	4	0
Toothache	7	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	255	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	25	0
Epigastric discomfort	1	0
Eructation	3	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	3	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	14	0
Flatulence	9	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	1	0
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	86	0
Abdominal pain lower	4	0
Abdominal pain upper	178	0
Abdominal rigidity	1	0
Abdominal tenderness	1	0
Gastrointestinal pain	6	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	10	0
Gastrooesophageal reflux disease	5	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
Gastric disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
Gastrointestinal motility disorder	1	0
<i>Gastrointestinal fistulae</i>		
Fistula of small intestine	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	34	0
Anal incontinence	2	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Breath odour	3	0
Dysphagia	9	0
Odynophagia	2	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	3	0
Irritable bowel syndrome	3	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	2	0
Gingival swelling	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	2	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	3	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	969	0
Retching	3	0
Vomiting	300	0
Vomiting projectile	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
Haematochezia	3	0
Melaena	1	0
Upper gastrointestinal haemorrhage	2	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0
Dry mouth	33	0
Lip dry	4	0
Saliva altered	1	0
Salivary hypersecretion	5	0
<i>Oral soft tissue disorders NEC</i>		
Cheilitis	1	0
Enlarged uvula	1	0
Lip blister	2	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	1	0
Oral blood blister	2	0
<i>Oral soft tissue signs and symptoms</i>		
Coating in mouth	1	0
Hypoaesthesia oral	28	0
Lip discolouration	1	0
Lip pain	2	0
Lip pruritus	1	0
Oral discomfort	2	0
Oral mucosal roughening	1	0
Oral pain	6	0
Oral pruritus	1	0
Paraesthesia oral	48	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	45	0
Mouth swelling	7	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Peptic ulcers and perforation</i>		
Peptic ulcer haemorrhage	1	0
<i>Salivary gland enlargements</i>		
Submaxillary gland enlargement	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	3	0
Lip ulceration	1	0
Mouth ulceration	27	0
Stomatitis	2	0
<i>Tongue disorders</i>		
Glossitis	2	0
Tongue disorder	4	0
Tongue haemorrhage	1	0
Tongue ulceration	2	0
<i>Tongue signs and symptoms</i>		
Glossodynia	10	0
Swollen tongue	26	0
Tongue blistering	1	0
Tongue coated	1	0
Tongue discolouration	1	0
Tongue discomfort	2	0
Tongue dry	2	0
Tongue movement disturbance	1	0
<i>Tooth missing</i>		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	2260	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site lymphadenopathy	1	0
Administration site pain	1	0
Puncture site bruise	3	0
<i>Application and instillation site reactions</i>		
Application site bruise	1	0
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>Asthenic conditions</i>		
Asthenia	97	0
Fatigue	1370	0
Malaise	221	0
<i>Death and sudden death</i>		
Death	4	4
<i>Febrile disorders</i>		
Pyrexia	1112	1
<i>Feelings and sensations NEC</i>		
Chills	611	0
Feeling abnormal	104	0
Feeling cold	50	0
Feeling drunk	7	0
Feeling hot	112	0
Feeling jittery	3	0
Feeling of body temperature change	24	0
Hangover	6	0
Hunger	7	0
Sensation of blood flow	1	0
Sensation of foreign body	2	0
Temperature intolerance	6	0
Thirst	26	0
<i>Gait disturbances</i>		
Gait disturbance	9	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	4	0
Crying	15	0
Discharge	1	0
Energy increased	1	0
Exercise tolerance decreased	4	0
Illness	101	0
Induration	5	0
Influenza like illness	120	0
Irritability postvaccinal	1	0
Local reaction	10	0
Peripheral swelling	795	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Screaming	2	0
Swelling	414	0
Swelling face	47	0
Implant and catheter site reactions		
Implant site warmth	3	0
Inflamations		
Inflammation	48	0
Soft tissue inflammation	1	0
Infusion site reactions		
Infusion site mass	1	0
Infusion site pain	3	0
Infusion site urticaria	2	0
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	4	0
Injection site bruising	7	0
Injection site discolouration	1	0
Injection site erythema	87	0
Injection site haemorrhage	2	0
Injection site hypersensitivity	4	0
Injection site hypoaesthesia	4	0
Injection site indentation	1	0
Injection site inflammation	5	0
Injection site irritation	1	0
Injection site joint erythema	3	0
Injection site mass	85	0
Injection site oedema	1	0
Injection site pain	210	0
Injection site paraesthesia	1	0
Injection site pruritus	69	0
Injection site rash	120	0
Injection site reaction	8	0
Injection site swelling	36	0
Injection site urticaria	38	0
Injection site vesicles	1	0
Injection site warmth	39	0
Interactions		
Alcohol interaction	1	0
Mass conditions NEC		
Cyst	4	0
Mass	12	0
Nodule	2	0
Mucosal findings abnormal		
Enanthema	1	0
Mucosal discolouration	1	0
Mucosal pain	1	0
Oedema NEC		
Face oedema	1	0
Localised oedema	1	0
Oedema	2	0
Oedema peripheral	2	0
Pain and discomfort NEC		
Axillary pain	259	0

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General disorders General disorders cont'd		
Chest discomfort	87	0
Chest pain	185	0
Discomfort	38	0
Facial pain	8	0
Pain	656	0
Tenderness	77	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	11	0
Drug ineffective	6	0
Drug intolerance	1	0
Inadequate analgesia	1	0
Therapeutic response unexpected	2	0
Vaccination failure	1	0
Ulcers NEC		
Ulcer	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Vaccination site bruising	10	0
Vaccination site discolouration	1	0
Vaccination site discomfort	6	0
Vaccination site eczema	1	0
Vaccination site erythema	180	0
Vaccination site haemorrhage	1	0
Vaccination site hypoaesthesia	3	0
Vaccination site induration	13	0
Vaccination site inflammation	6	0
Vaccination site irritation	1	0
Vaccination site joint erythema	2	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	2	0
Vaccination site mass	42	0
Vaccination site movement impairment	5	0
Vaccination site oedema	1	0
Vaccination site pain	154	0
Vaccination site papule	2	0
Vaccination site pruritus	45	0
Vaccination site rash	87	0
Vaccination site reaction	2	0
Vaccination site swelling	106	0
Vaccination site urticaria	6	0
Vaccination site warmth	83	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	1	0
General disorders SOC TOTAL	8229	5

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Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	3	0
<i>Cholestasis and jaundice</i>		
Jaundice cholestatic	2	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	1	0
Hepatic disorders SOC TOTAL	6	0

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Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	3	0
Allergy to animal	1	0
Hypersensitivity	127	0
Infusion related hypersensitivity reaction	5	0
Multiple allergies	1	0
Type IV hypersensitivity reaction	10	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	4	0
Drug hypersensitivity	3	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	21	0
Anaphylactic shock	3	0
Anaphylactoid reaction	2	0
<i>Atopic disorders</i>		
Seasonal allergy	8	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	15	0
Immune-mediated adverse reaction	1	0
Sensitisation	1	0
Immune system disorders SOC TOTAL	207	0

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Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	1	0
Diverticulitis	1	0
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Application site cellulitis	1	0
Bacterial infection	2	0
Cellulitis	40	0
Injection site cellulitis	2	0
Skin bacterial infection	1	0
Vaccination site cellulitis	1	0
<i>Breast infections</i>		
Breast abscess	1	0
<i>Candida infections</i>		
Candida infection	2	0
Oral candidiasis	1	0
Vulvovaginal candidiasis	7	0
<i>Cardiac infections</i>		
Endocarditis	1	0
<i>Central nervous system and spinal infections</i>		
Central nervous system infection	1	0
Meningitis	2	0
<i>Coronavirus infections</i>		
COVID-19	23	0
COVID-19 pneumonia	1	0
Suspected COVID-19	1	0
<i>Coxiella infections</i>		
Q fever	2	0
<i>Ear infections</i>		
Ear infection	2	0
Labyrinthitis	2	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	8	0
Hordeolum	1	0
<i>Female reproductive tract infections</i>		
Vaginal infection	1	0
<i>Flaviviral infections</i>		
Dengue fever	1	0
<i>Fungal infections NEC</i>		
Fungal skin infection	1	0
<i>Herpes viral infections</i>		
Genital herpes	4	0
Herpes zoster	24	0
Oral herpes	17	0
<i>Infections NEC</i>		
Abscess limb	1	0
Abscess rupture	1	0
Infection	41	0
Injection site infection	1	0
Localised infection	8	0
Respiratory tract infection	1	0

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Infections Infections cont'd		
Vaccination site infection	2	0
Vestibulitis	1	0
<i>Infectious disorders carrier</i>		
SARS-CoV-2 carrier	2	0
<i>Infectious transmissions</i>		
Secondary transmission	2	0
<i>Influenza viral infections</i>		
Influenza	87	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	2	0
Lower respiratory tract infection	12	0
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	6	0
Pyoderma	1	0
Rash pustular	3	0
Skin infection	7	0
<i>Staphylococcal infections</i>		
Furuncle	1	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	78	0
Peritonsillar abscess	1	0
Rhinitis	1	0
Sinusitis	3	0
Tonsillitis	7	0
<i>Urinary tract infections</i>		
Cystitis	1	0
Kidney infection	1	0
Urinary tract infection	8	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Post viral fatigue syndrome	1	0
Sweating fever	9	0
Viral infection	1	0
Viral pharyngitis	2	0
Viral rash	3	0
Infections SOC TOTAL	462	1

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Reaction Name	Total	Fatal
Injuries		
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
<i>Cardiovascular injuries</i>		
Heart injury	1	0
<i>Cerebral injuries NEC</i>		
Concussion	2	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	5	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	1	0
Foetal exposure during pregnancy	3	0
Maternal exposure during breast feeding	185	0
Maternal exposure during pregnancy	84	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	1	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat oedema	1	0
Heat stroke	6	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	3	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	3	0
Wrong schedule	1	0
Wrong technique in device usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	1	0
Muscle injury	1	0
Muscle strain	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	4	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	3	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	1	0
<i>Non-site specific injuries NEC</i>		
Arthropod bite	3	0
Bite	1	0
Electric shock	3	0
Fall	6	0
Wound complication	1	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	1	0
Procedural pain	1	0
<i>Poisoning and toxicity</i>		
Toxicity to various agents	1	0
<i>Product administration errors and issues</i>		
Expired product administered	4	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Inappropriate schedule of product administration	3	0
Incorrect dose administered	1	0
Incorrect route of product administration	1	0
Product administered at inappropriate site	1	0
Wrong product administered	1	0
Product dispensing errors and issues		
Product dispensing error	1	0
Radiation injuries		
Sunburn	4	0
Site specific injuries NEC		
Head injury	5	0
Limb injury	9	0
Skin injuries NEC		
Contusion	94	0
Scar	5	0
Scratch	1	0
Skin injury	1	0
Skin wound	1	0
Subcutaneous haematoma	2	0
Stoma complications		
Stoma site oedema	1	0
Thermal burns		
Thermal burn	3	0
Vaccination related complications		
Vaccination complication	1	0
Injuries SOC TOTAL	468	0

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Reaction Name	Total	Fatal
Investigations		
Adrenal medulla tests		
Norepinephrine increased	2	0
Blood counts NEC		
Blood count abnormal	1	0
Blood gas and acid base analyses		
Oxygen consumption decreased	1	0
Oxygen saturation decreased	3	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose increased	1	0
Coagulation and bleeding analyses		
Fibrin D dimer increased	1	0
ECG investigations		
Electrocardiogram ST segment elevation	1	0
Electrocardiogram T wave inversion	2	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	1	0
Fungus identification and serology		
Fungal test	1	0
Heart rate and pulse investigations		
Heart rate	34	0
Heart rate abnormal	2	0
Heart rate decreased	3	0
Heart rate increased	61	0
Heart rate irregular	10	0
Investigations NEC		
Blood test abnormal	2	0
Liver function analyses		
Alanine aminotransferase increased	2	0
Aspartate aminotransferase	1	0
Blood bilirubin increased	1	0
Liver function test abnormal	3	0
Liver function test increased	1	0
Mineral and electrolyte analyses		
Blood iron decreased	2	0
Blood magnesium decreased	1	0
Blood potassium decreased	1	0
Ophthalmic function diagnostic procedures		
Visual tracking test abnormal	1	0
Physical examination procedures and organ system status		
Body temperature	20	0
Body temperature abnormal	1	0
Body temperature decreased	3	0
Body temperature fluctuation	6	0
Body temperature increased	16	0
Grip strength	1	0
Grip strength decreased	1	0
Lymph node palpable	1	0
Product residue present	1	0
Respiratory rate	1	0
Respiratory rate increased	5	0
Skin temperature	3	0
Temperature difference of extremities	1	0
Weight decreased	4	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Weight increased	4	0
<i>Pituitary analyses anterior</i>		
Blood thyroid stimulating hormone increased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	5	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	1	0
<i>Red blood cell analyses</i>		
Haemoglobin E	1	0
Haemoglobin decreased	1	0
<i>Reproductive hormone analyses</i>		
Pregnancy test	1	0
<i>Urinalysis NEC</i>		
Blood urine present	1	0
Protein urine	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	6	0
Blood pressure diastolic increased	1	0
Blood pressure increased	5	0
Blood pressure measurement	2	0
<i>Virus identification and serology</i>		
Coronavirus test	3	0
SARS-CoV-2 antibody test	2	0
SARS-CoV-2 test	4	0
SARS-CoV-2 test negative	1	0
SARS-CoV-2 test positive	2	0
<i>White blood cell analyses</i>		
White blood cell count decreased	1	0
Investigations SOC TOTAL	249	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	70	0
Food craving	1	0
Food refusal	1	0
Hyperphagia	3	0
Increased appetite	2	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	2	0
Type 1 diabetes mellitus	1	0
Type 2 diabetes mellitus	1	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	2	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	1	0
Food intolerance	1	0
<i>General nutritional disorders NEC</i>		
Abnormal weight gain	3	0
Feeding disorder	6	0
Neonatal insufficient breast milk syndrome	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	3	0
<i>Total fluid volume decreased</i>		
Dehydration	17	0
<i>Total fluid volume increased</i>		
Fluid retention	6	0
Metabolic disorders SOC TOTAL	123	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	5	0
Arthropathy	1	0
Autoimmune arthritis	1	0
<i>Bone disorders NEC</i>		
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	15	0
Pain in jaw	24	0
Spinal pain	2	0
<i>Bursal disorders</i>		
Bursitis	3	0
<i>Cartilage disorders</i>		
Costochondritis	4	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	1	0
Reynold's syndrome	1	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc protrusion	1	0
<i>Joint related disorders NEC</i>		
Joint lock	2	0
Periarthritis	7	0
Rotator cuff syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	402	0
Joint noise	1	0
Joint stiffness	16	0
Joint swelling	20	0
Joint vibration	1	0
Joint warmth	1	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
<i>Muscle infections and inflammations</i>		
Myositis	4	0
<i>Muscle pains</i>		
Fibromyalgia	3	0
Myalgia	658	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	19	0
Muscle haemorrhage	1	0
Muscle spasms	108	0
Muscle swelling	5	0
Muscle tightness	11	0
Muscle twitching	27	0
Myosclerosis	1	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	1	0
Nuchal rigidity	1	0
Trismus	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	40	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Muscle contracture	1	0
Musculoskeletal stiffness	125	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Dupuytren's contracture	1	0
Fasciitis	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	139	0
Flank pain	1	0
Limb discomfort	129	0
Musculoskeletal chest pain	4	0
Musculoskeletal discomfort	4	0
Musculoskeletal pain	1	0
Neck pain	73	0
Pain in extremity	1212	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	15	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>Synovial disorders</i>		
Synovial cyst	2	0
<i>Tendon disorders</i>		
Trigger finger	2	0
Muscle & tissue disorders SOC TOTAL	3114	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Lymphomas unspecified NEC</i>		
Lymphoma	1	0
<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
Skin papilloma	2	0
<i>Small intestinal neoplasms malignant</i>		
Small intestine adenocarcinoma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	2	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	2	1
Cerebrovascular accident	5	0
Haemorrhage intracranial	1	0
Ischaemic stroke	1	0
Subarachnoid haemorrhage	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	1	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	14	0
Coordination abnormal	1	0
Dysstasia	2	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	4	0
Lethargy	107	0
Loss of consciousness	68	0
Somnolence	71	0
Stupor	1	0
Syncope	361	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	1	0
Clumsiness	2	0
Dyskinesia	2	0
Fine motor delay	1	0
Fine motor skill dysfunction	1	0
Hyperkinesia	1	0
Hypokinesia	2	0
Movement disorder	2	0
Psychomotor hyperactivity	1	0
<i>Eye movement disorders</i>		
IVth nerve paresis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	16	0
Facial paralysis	15	0
Facial paresis	1	0
Facial spasm	2	0
<i>Glossopharyngeal nerve disorders</i>		
Glossopharyngeal neuralgia	1	0
<i>Headaches NEC</i>		
Cluster headache	15	0
Cold-stimulus headache	1	0
Drug withdrawal headache	1	0
Headache	1470	0
New daily persistent headache	1	0
Sinus headache	15	0
Tension headache	28	0
Thunderclap headache	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Vascular headache	2	0
Increased intracranial pressure disorders		
Intracranial pressure increased	1	0
Lumbar spinal cord and nerve root disorders		
Sciatica	1	0
Memory loss (excl dementia)		
Amnesia	8	0
Memory impairment	9	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	4	0
Disturbance in attention	23	0
Mental impairment	2	0
Migraine headaches		
Hemiplegic migraine	1	0
Migraine	162	0
Migraine with aura	15	0
Migraine without aura	1	0
Retinal migraine	1	0
Mononeuropathies		
Cubital tunnel syndrome	1	0
Mononeuritis	1	0
Muscle tone abnormal		
Hypotonia	1	0
Narcolepsy and hypersomnia		
Hypersomnia	3	0
Nervous system disorders NEC		
Nervous system disorder	1	0
Neurologic visual problems NEC		
Tunnel vision	3	0
Neurological signs and symptoms NEC		
Dizziness	949	0
Dizziness postural	30	0
Drooling	2	0
Head discomfort	19	0
Neurological symptom	2	0
Persistent postural-perceptual dizziness	1	0
Presyncope	80	0
Unresponsive to stimuli	5	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	1	0
Muscle spasticity	1	0
Olfactory nerve disorders		
Anosmia	5	0
Parosmia	7	0
Optic nerve disorders NEC		
Optic neuritis	1	0
Paraesthesias and dysaesthesias		
Burning sensation	35	0
Formication	1	0
Hemianaesthesia	1	0
Hyperaesthesia	15	0
Hypoaesthesia	179	0
Paraesthesia	269	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	3	0
Hemiplegia	1	0
Monoparesis	5	0
Monoplegia	7	0
Paralysis	3	0
Paresis	1	0
<i>Parkinson's disease and parkinsonism</i>		
Reduced facial expression	1	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	4	0
<i>Seizures and seizure disorders NEC</i>		
Febrile convulsion	2	0
Partial seizures	2	0
Psychogenic seizure	1	0
Seizure	43	0
Status epilepticus	24	0
Tonic clonic movements	2	0
Tonic convulsion	1	0
<i>Sensory abnormalities NEC</i>		
Ageusia	15	0
Dysgeusia	79	0
Electric shock sensation	2	0
Hypogeusia	1	0
Neuralgia	17	0
Post herpetic neuralgia	2	0
Restless legs syndrome	13	0
Sensory disturbance	4	0
Sensory loss	3	0
Taste disorder	11	0
Vibratory sense increased	1	0
<i>Sleep disturbances NEC</i>		
Sleep deficit	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	9	0
Incoherent	2	0
Slow speech	1	0
Speech disorder	3	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	5	0
<i>Tremor (excl congenital)</i>		
Tremor	95	0
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	4433	1

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	14	0
<i>Foetal complications NEC</i>		
Foetal disorder	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	1	0
<i>Maternal complications of labour NEC</i>		
Uterine hypertonus	1	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	1	0
Ectopic pregnancy	3	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	6	0
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	1	0
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	29	0

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device expulsion	1	0
Device leakage	1	0
<i>Product quality issues NEC</i>		
Product quality issue	1	0
null SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
Flat affect	3	0
<i>Anxiety symptoms</i>		
Agitation	5	0
Anxiety	86	0
Nervousness	14	0
Stress	4	0
Tension	3	0
<i>Behaviour and socialisation disturbances</i>		
Paranoia	3	0
Personality change	1	0
Social avoidant behaviour	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
Mental fatigue	15	0
<i>Confusion and disorientation</i>		
Confusional state	40	0
Disorientation	19	0
<i>Deliria</i>		
Delirium	9	0
<i>Depressive disorders</i>		
Depression	20	0
Depression suicidal	2	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Dissociation	4	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	68	0
Middle insomnia	2	0
Terminal insomnia	5	0
<i>Dyssomnias</i>		
Poor quality sleep	19	0
<i>Eating disorders NEC</i>		
Binge eating	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	6	0
Emotional disorder	7	0
Emotional distress	6	0
Euphoric mood	6	0
Irritability	11	0
Mood altered	3	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear of death	1	0
Fear of injection	5	0
Phobia	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	7	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	21	0
Hallucination, auditory	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Hallucination, visual	1	0
Increased physical activity levels		
Restlessness	17	0
Mental disorders NEC		
Mental disorder	1	0
Mood alterations with depressive symptoms		
Depressed mood	18	0
Feeling of despair	2	0
Tearfulness	2	0
Mood alterations with manic symptoms		
Mania	3	0
Mood disorders NEC		
Apathy	3	0
Listless	1	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	1	0
Orgasmic disorders and disturbances		
Orgasm abnormal	1	0
Orgasmic sensation decreased	1	0
Panic attacks and disorders		
Panic attack	17	0
Panic reaction	3	0
Parasomnias		
Abnormal dreams	12	0
Nightmare	12	0
Sleep terror	1	0
Somnambulism	1	0
Perception disturbances NEC		
Autoscopy	2	0
Derealisation	1	0
Psychiatric elimination disorders		
Enuresis	2	0
Psychiatric symptoms NEC		
Psychiatric symptom	1	0
Psychological trauma	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic disorder	1	0
Sexual desire disorders		
Libido decreased	2	0
Libido increased	1	0
Sleep disorders NEC		
Sleep disorder	11	0
Somatic symptom disorders		
Conversion disorder	1	0
Habit cough	2	0
Speech articulation and rhythm disturbances		
Dysphemia	1	0
Stress disorders		
Post-traumatic stress disorder	1	0
Substance related and addictive disorders		
Alcoholism	1	0
Suicidal and self-injurious behaviour		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Suicidal behaviour	1	0
Suicidal ideation	4	0
Suicide attempt	1	0
Thinking disturbances		
Bradyphrenia	3	0
Intrusive thoughts	1	0
Tachyphrenia	1	0
Thinking abnormal	3	0
Psychiatric disorders SOC TOTAL	544	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	2	0
Dysuria	5	0
Incontinence	1	0
Micturition urgency	2	0
Pollakiuria	10	0
Urinary incontinence	2	0
Urinary retention	1	0
Urine flow decreased	1	0
<i>Renal failure and impairment</i>		
Oliguria	1	0
Renal impairment	1	0
<i>Urinary abnormalities</i>		
Chromaturia	5	0
Haematuria	2	0
Urine abnormality	1	0
Urine odour abnormal	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	3	0
Renal pain	15	0
Renal & urinary disorders SOC TOTAL	53	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	2	0
<i>Breast disorders NEC</i>		
Breast enlargement	2	0
Breast mass	4	0
Fibrocystic breast disease	1	0
<i>Breast signs and symptoms</i>		
Breast discomfort	1	0
Breast pain	28	0
Breast swelling	3	0
Breast tenderness	1	0
Nipple swelling	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation failure	1	0
Erectile dysfunction	2	0
Organic erectile dysfunction	1	0
Painful ejaculation	1	0
<i>Lactation disorders</i>		
Lactation disorder	1	0
Lactation puerperal increased	1	0
Suppressed lactation	1	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	4	0
Premature menopause	2	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	13	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	133	0
Intermenstrual bleeding	75	0
Menstrual discomfort	1	0
Menstrual disorder	135	0
Menstruation irregular	219	0
Premenstrual headache	1	0
Premenstrual pain	3	0
Premenstrual syndrome	4	0
Withdrawal bleed	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	30	0
Hypomenorrhoea	42	0
Menstruation delayed	255	0
Oligomenorrhoea	10	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	370	0
Menometrorrhagia	2	0
Polymenorrhoea	46	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	1	0
Polycystic ovaries	1	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation pain	5	0
Premature ovulation	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	3	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penis disorder	1	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	1	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital haemorrhage	2	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	6	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular mass	1	0
Testicular pain	4	0
Testicular swelling	1	0
<i>Uterine disorders NEC</i>		
Endometriosis	5	0
Uterine haemorrhage	5	0
<i>Uterine tone disorders</i>		
Uterine spasm	6	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vaginal cyst	1	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	96	0
Vulval haemorrhage	2	0
<i>Vulvovaginal signs and symptoms</i>		
Labia enlarged	1	0
Vaginal discharge	4	0
Vulvovaginal discomfort	1	0
Vulvovaginal pain	2	0
Reproductive & breast disorders SOC TOTAL	1551	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	184	0
Dyspnoea exertional	2	0
Hyperventilation	2	0
Hypopnoea	4	0
Hypoventilation	1	0
Respiration abnormal	6	0
Respiratory distress	1	0
Sleep apnoea syndrome	1	0
Tachypnoea	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	13	0
Wheezing	23	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	110	0
Haemoptysis	1	0
Productive cough	11	0
Sputum discoloured	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Reflux laryngitis	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	12	0
Pulmonary haemorrhage	1	0
Pulmonary pain	4	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	14	0
<i>Nasal disorders NEC</i>		
Epistaxis	51	0
Nasal oedema	1	0
Nasal pruritus	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	2	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal hypoaesthesia	2	0
Pharyngeal oedema	1	0
Pharyngeal paraesthesia	2	0
Pharyngeal swelling	25	0
Tonsillar hypertrophy	3	0
<i>Pleural infections and inflammations</i>		
Pleurisy	1	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	1	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	1	0
Pulmonary oedema	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Pulmonary embolism	7	0
<i>Respiratory signs and symptoms NEC</i>		
Diaphragmalgia	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	5	0
Catarrh	1	0
Dry throat	10	0
Dysphonia	2	0
Increased viscosity of upper respiratory secretion	1	0
Nasal discomfort	2	0
Oropharyngeal discomfort	2	0
Oropharyngeal pain	142	0
Paranasal sinus discomfort	5	0
Rhinalgia	1	0
Rhinorrhoea	32	0
Sinus pain	14	0
Sneezing	8	0
Throat irritation	12	0
Throat tightness	16	0
Upper-airway cough syndrome	1	0
Yawning	1	0
Respiratory disorders SOC TOTAL	752	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	9	0
<i>Alopecias</i>		
Alopecia	11	0
Alopecia areata	1	0
<i>Angioedemas</i>		
Angioedema	13	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	73	0
Hyperhidrosis	198	0
Miliaria	34	0
Night sweats	37	0
<i>Bullous conditions</i>		
Blister	25	0
Blister rupture	1	0
Dermatitis bullous	1	0
Erythema multiforme	8	0
Stevens-Johnson syndrome	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	33	0
Pain of skin	19	0
Papule	9	0
Scab	1	0
Scar pain	1	0
Sensitive skin	29	0
Skin burning sensation	17	0
Skin discolouration	8	0
Skin induration	5	0
Skin lesion	16	0
Skin reaction	59	0
Skin sensitisation	4	0
Skin swelling	11	0
Skin tightness	3	0
Skin warm	102	0
Yellow skin	2	0
<i>Dermatitis and eczema</i>		
Dermatitis	14	0
Dermatitis allergic	57	0
Dermatitis atopic	3	0
Dermatitis contact	2	0
Dyshidrotic eczema	7	0
Eczema	17	0
Skin irritation	12	0
<i>Dermatitis ascribed to specific agent</i>		
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	533	0
<i>Exfoliative conditions</i>		
Skin exfoliation	4	0
<i>Hyperpigmentation disorders</i>		
Skin hyperpigmentation	1	0
Solar lentigo	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Onychoclasia	1	0
Papulosquamous conditions		
Lichen planus	1	0
Pityriasis rosea	2	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	9	0
Pilar disorders NEC		
Piloerection	3	0
Pruritus NEC		
Itching scar	2	0
Pruritus	1187	0
Psoriatic conditions		
Guttate psoriasis	1	0
Psoriasis	7	0
Purpura and related conditions		
Petechiae	6	0
Purpura	5	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	1	0
Rash	1350	0
Rash erythematous	551	0
Rash macular	76	0
Rash maculo-papular	1	0
Rash morbilliform	4	0
Rash papular	101	0
Rash pruritic	320	0
Rash vesicular	4	0
Rosaceas		
Rosacea	2	0
Scaly conditions		
Pityriasis	1	0
Sebaceous gland disorders		
Seborrhoea	1	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	2	0
Skin mass	3	0
Skin and subcutaneous tissue ulcerations		
Skin ulcer	1	0
Skin cysts and polyps		
Dermal cyst	2	0
Skin haemorrhages		
Skin haemorrhage	1	0
Skin hypoplasias and atrophies		
Skin atrophy	2	0
Skin injuries and mechanical dermatoses		
Needle track marks	1	0
Skin vasomotor conditions		
Livedo reticularis	1	0
Telangiectasia and related conditions		
Spider naevus	1	0
Urticarias		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Urticaria	175	0
Urticaria cholinergic	1	0
Skin disorders SOC TOTAL	5211	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menopause	3	0
<i>Disability issues</i>		
Bedridden	1	0
Immobile	1	0
Impaired driving ability	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
Social circumstances SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	1	0
<i>Immunisations</i>		
COVID-19 immunisation	8	0
Immunisation	7	0
<i>Joint therapeutic procedures</i>		
Joint stabilisation	1	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	2	0
<i>Therapeutic procedures NEC</i>		
Botulinum toxin injection	1	0
Hospitalisation	1	0
Injection	3	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	27	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive urgency	1	0
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	1	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	3	0
Haemorrhage	74	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	3	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	0
Thrombosis	36	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arteriosclerosis	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	3	0
Vasodilatation	1	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	2	0
Deep vein thrombosis	7	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	3	0
Flushing	16	0
Hot flush	87	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	21	0
Raynaud's phenomenon	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	38	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	35	0
Prehypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	36	0
Orthostatic hypotension	2	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	381	0
TOTAL REACTIONS FOR DRUG	29606	7
TOTAL REPORTS	10109	
TOTAL FATAL OUTCOME REPORTS		7