

COVID-19 Moderna Vaccine Analysis Print

All UK spontaneous reports received up to and including 15/09/21 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: 16-Sep-2021

Data Lock Date: 15-Sep-2021 18:31:25

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	4	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	3	0
Spontaneous haematoma	1	0
<i>Coagulopathies</i>		
Antiphospholipid syndrome	1	0
Coagulopathy	1	0
<i>Haematological disorders</i>		
Blood disorder	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	130	0
Lymphadenitis	10	0
Lymphadenopathy	765	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	4	0
Thrombocytopenia	18	0
Thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	942	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	6	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	2	0
Palpitations	352	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	18	0
Myocardial infarction	13	0
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	2	0
<i>Noninfectious myocarditis</i>		
Myocarditis	64	0
<i>Noninfectious pericarditis</i>		
Pericarditis	40	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	8	0
Bradycardia	8	0
Cardiac fibrillation	1	0
Cardiac flutter	34	0
Extrasystoles	14	0
Tachycardia	35	0
Tachycardia foetal	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	2	0
Atrial flutter	1	0
Atrial tachycardia	1	0
Sinus arrhythmia	1	0
Sinus tachycardia	2	0
Supraventricular tachycardia	2	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	3	0
Ventricular extrasystoles	1	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	618	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	1	0
<i>Cerebellar disorders congenital</i>		
Hereditary ataxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>Male reproductive tract disorders congenital</i>		
Micropenis	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
Congenital disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	5	0
Ear discomfort	3	0
Ear disorder	1	0
Ear pain	110	0
Ear swelling	2	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	3	0
Red ear syndrome	1	0
<i>Hearing losses</i>		
Deafness	17	0
Deafness transitory	1	0
Deafness unilateral	4	0
Hypoacusis	17	0
Sudden hearing loss	6	0
<i>Hyperacusia</i>		
Hyperacusis	5	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	12	0
Tinnitus	168	0
Vertigo	125	0
Vertigo positional	2	0
Ear disorders SOC TOTAL	484	0

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Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	2	0
Premature menarche	3	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	4	0
Ovulation delayed	8	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Pituitary haemorrhage	1	0
<i>Thyroid disorders NEC</i>		
Goitre	3	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	2	0
Endocrine disorders SOC TOTAL	25	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>		
Chorioretinopathy	1	0
Vitreous floaters	6	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	2	0
<i>Eyelid movement disorders</i>		
Blepharospasm	16	0
Eyelid ptosis	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Uveitis	4	0
<i>Lacrimation disorders</i>		
Dry eye	14	0
Lacrimation increased	5	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid rash	1	0
Swelling of eyelid	7	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye pain	117	0
Eye swelling	37	0
Ocular discomfort	4	0
Periorbital oedema	2	0
Periorbital swelling	9	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	2	0
Eye inflammation	1	0
Eye irritation	9	0
Eye pruritus	15	0
Ocular hyperaemia	17	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	5	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Asthenopia	7	0
Foreign body sensation in eyes	1	0
Hypoaesthesia eye	1	0
Photophobia	48	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	3	0
<i>Refractive and accommodative disorders</i>		

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Eye disorders Eye disorders cont'd		
Accommodation disorder	1	0
Astigmatism	2	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
Retinal vein occlusion	1	0
<i>Retinopathies NEC</i>		
Acute zonal occult outer retinopathy	1	0
Serous retinopathy	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>		
Cyanopsia	1	0
<i>Visual disorders NEC</i>		
Diplopia	14	0
Halo vision	1	0
Metamorphopsia	1	0
Photopsia	6	0
Vision blurred	153	0
<i>Visual field disorders</i>		
Visual field defect	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	15	0
Blindness transient	3	0
Blindness unilateral	1	0
Visual acuity reduced	2	0
Visual impairment	24	0
Eye disorders SOC TOTAL	578	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Anal and rectal pains</i>		
Proctalgia	3	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
Anorectal discomfort	1	0
<i>Colitis (excl infective)</i>		
Colitis	2	0
Colitis ulcerative	3	0
Crohn's disease	7	0
Inflammatory bowel disease	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Teething	1	0
Tooth disorder	1	0
<i>Dental pain and sensation disorders</i>		
Dental paraesthesia	1	0
Hyperaesthesia teeth	4	0
Toothache	12	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	450	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	49	0
Epigastric discomfort	1	0
Eructation	6	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	5	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	34	0
Flatulence	15	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	1	0
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	135	0
Abdominal pain lower	11	0
Abdominal pain upper	310	0
Abdominal rigidity	1	0
Abdominal tenderness	2	0
Gastrointestinal pain	11	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	20	0
Gastrooesophageal reflux disease	12	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
Gastric disorder	1	0
Stomach mass	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	1	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	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	57	0
Anal incontinence	3	0
Breath odour	4	0
Dysphagia	16	0
Odynophagia	6	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Frequent bowel movements	4	0
Irritable bowel syndrome	6	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	6	0
Gingival swelling	4	0
Noninfective gingivitis	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	5	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	2	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	1	0
Rectal haemorrhage	7	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	1843	0
Retching	12	0
Vomiting	631	0
Vomiting projectile	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
Haematochezia	4	0
Melaena	1	0
Upper gastrointestinal haemorrhage	2	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Dry mouth	50	0
Lip dry	4	0
Saliva altered	2	0
Salivary hypersecretion	6	0
Oral soft tissue disorders NEC		
Chapped lips	1	0
Cheilitis	1	0
Enlarged uvula	1	0
Lip blister	2	0
Lip disorder	1	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	2	0
Oral blood blister	2	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	1	0
Coating in mouth	2	0
Hypoaesthesia oral	39	0
Lip discolouration	1	0
Lip pain	3	0
Lip pruritus	1	0
Oral discomfort	3	0
Oral mucosal roughening	1	0
Oral pain	9	0
Oral pruritus	1	0
Paraesthesia oral	62	0
Oral soft tissue swelling and oedema		
Lip swelling	73	0
Mouth swelling	9	0
Peptic ulcers and perforation		
Peptic ulcer haemorrhage	2	0
Rectal inflammations NEC		
Proctitis	1	0
Salivary gland disorders NEC		
Salivary gland pain	1	0
Salivary gland enlargements		
Submaxillary gland enlargement	1	0
Stomatitis and ulceration		
Aphthous ulcer	3	0
Lip ulceration	2	0
Mouth ulceration	42	0
Stomatitis	3	0
Tongue disorders		
Glossitis	2	0
Tongue disorder	4	0
Tongue haemorrhage	1	0
Tongue ulceration	4	0
Tongue signs and symptoms		
Glossodynia	14	0
Swollen tongue	38	0
Tongue blistering	1	0
Tongue coated	2	0
Tongue discolouration	2	0
Tongue discomfort	2	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tongue dry	2	0
Tongue movement disturbance	1	0
Tongue oedema	1	0
<i>Tooth missing</i>		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	4150	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site extravasation	1	0
Administration site lymphadenopathy	1	0
Administration site pain	2	0
Puncture site bruise	5	0
Puncture site pain	1	0
<i>Application and instillation site reactions</i>		
Application site bruise	1	0
Application site burn	1	0
Application site erythema	6	0
Application site joint erythema	1	0
Application site pain	1	0
Application site pruritus	9	0
Application site rash	1	0
Application site swelling	2	0
Application site vesicles	4	0
Application site warmth	1	0
Instillation site erythema	1	0
Instillation site warmth	2	0
<i>Asthenic conditions</i>		
Asthenia	209	0
Chronic fatigue syndrome	2	0
Fatigue	2418	0
Malaise	404	0
<i>Death and sudden death</i>		
Death	7	7
<i>Febrile disorders</i>		
Pyrexia	2714	1
<i>Feelings and sensations NEC</i>		
Chills	1470	0
Feeling abnormal	216	0
Feeling cold	100	0
Feeling drunk	11	0
Feeling hot	167	0
Feeling jittery	8	0
Feeling of body temperature change	48	0
Hangover	12	0
Hunger	12	0
Sensation of blood flow	1	0
Sensation of foreign body	4	0
Temperature intolerance	16	0
Thirst	47	0
<i>Gait disturbances</i>		
Gait disturbance	16	0
Gait inability	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	11	0
Crying	21	0
Discharge	3	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	4	0
Foaming at mouth	2	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Illness	225	0
Induration	7	0
Influenza like illness	267	0
Irritability postvaccinal	1	0
Local reaction	12	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	1144	0
Screaming	3	0
Secretion discharge	2	0
Swelling	603	0
Swelling face	70	0
Implant and catheter site reactions		
Implant site warmth	3	0
Inflamations		
Inflammation	75	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	1	0
Infusion site reactions		
Infusion site erythema	1	0
Infusion site mass	1	0
Infusion site pain	4	0
Infusion site pruritus	1	0
Infusion site urticaria	2	0
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	4	0
Injection site bruising	9	0
Injection site discolouration	1	0
Injection site erythema	108	0
Injection site haemorrhage	3	0
Injection site hypersensitivity	6	0
Injection site hypoaesthesia	5	0
Injection site indentation	2	0
Injection site inflammation	9	0
Injection site irritation	1	0
Injection site joint erythema	4	0
Injection site mass	108	0
Injection site oedema	2	0
Injection site pain	354	0
Injection site paraesthesia	1	0
Injection site plaque	1	0
Injection site pruritus	81	0
Injection site rash	150	0
Injection site reaction	13	0
Injection site swelling	49	0
Injection site urticaria	43	0
Injection site vesicles	1	0
Injection site warmth	52	0
Interactions		
Alcohol interaction	1	0
Drug interaction	1	0

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General disorders General disorders cont'd		
<i>Mass conditions NEC</i>		
Cyst	4	0
Mass	16	0
Nodule	3	0
<i>Mucosal findings abnormal</i>		
Enanthema	1	0
Mucosal discolouration	1	0
Mucosal pain	1	0
<i>Oedema NEC</i>		
Face oedema	2	0
Localised oedema	1	0
Oedema	4	0
Oedema peripheral	6	0
<i>Pain and discomfort NEC</i>		
Axillary pain	386	0
Chest discomfort	156	0
Chest pain	420	0
Discomfort	71	0
Facial pain	13	0
Inflammatory pain	1	0
Non-cardiac chest pain	2	0
Pain	1220	0
Tenderness	103	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	7	0
Drug ineffective	10	0
Drug intolerance	1	0
Immediate post-injection reaction	1	0
Inadequate analgesia	3	0
No reaction on previous exposure to drug	2	0
Therapeutic product effect decreased	1	0
Therapeutic response unexpected	2	0
Vaccination failure	1	0
<i>Ulcers NEC</i>		
Ulcer	2	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	3	0
Vaccination site bruising	11	0
Vaccination site discolouration	1	0
Vaccination site discomfort	6	0
Vaccination site eczema	1	0
Vaccination site erythema	207	0
Vaccination site haemorrhage	2	0
Vaccination site hypoaesthesia	3	0
Vaccination site induration	14	0
Vaccination site inflammation	7	0
Vaccination site irritation	1	0
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	2	0
Vaccination site joint pain	2	0
Vaccination site mass	48	0
Vaccination site movement impairment	7	0

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General disorders General disorders cont'd		
Vaccination site oedema	1	0
Vaccination site pain	188	0
Vaccination site papule	2	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	53	0
Vaccination site rash	110	0
Vaccination site reaction	2	0
Vaccination site scar	1	0
Vaccination site swelling	130	0
Vaccination site urticaria	7	0
Vaccination site vesicles	1	0
Vaccination site warmth	91	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	4	0
General disorders SOC TOTAL	14755	9

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Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	4	0
<i>Cholestasis and jaundice</i>		
Jaundice cholestatic	2	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	1	0
Hepatic steatosis	1	0
Liver injury	1	0
Hepatic disorders SOC TOTAL	11	0

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Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	4	0
Allergy to animal	1	0
Allergy to metals	1	0
Hypersensitivity	183	0
Infusion related hypersensitivity reaction	10	0
Multiple allergies	1	0
Type IV hypersensitivity reaction	12	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	6	0
Drug hypersensitivity	3	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	33	0
Anaphylactic shock	4	0
Anaphylactoid reaction	2	0
<i>Atopic disorders</i>		
Seasonal allergy	14	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	2	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	28	0
Immune-mediated adverse reaction	1	0
Sensitisation	3	0
Systemic immune activation	1	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	312	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	3	0
Diverticulitis	2	0
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Application site cellulitis	1	0
Bacterial infection	2	0
Cellulitis	48	0
Folliculitis	1	0
Injection site cellulitis	2	0
Skin bacterial infection	1	0
Vaccination site cellulitis	1	0
<i>Breast infections</i>		
Breast abscess	1	0
Mastitis	2	0
<i>Candida infections</i>		
Candida infection	4	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
Myelitis	1	0
<i>Coronavirus infections</i>		
COVID-19	60	0
COVID-19 pneumonia	2	0
Suspected COVID-19	1	0
<i>Coxiella infections</i>		
Q fever	2	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	1	0
Tooth abscess	1	0
Tooth infection	1	0
<i>Ear infections</i>		
Ear infection	3	0
Labyrinthitis	2	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	9	0
Eye infection	1	0
Eyelid boil	1	0
Hordeolum	1	0
<i>Female reproductive tract infections</i>		
Vaginal infection	1	0
<i>Flaviviral infections</i>		
Dengue fever	2	0
Encephalitis Japanese B	1	0
<i>Fungal infections NEC</i>		

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Fungal infection	2	0
Fungal skin infection	2	0
Overgrowth fungal	1	1
<i>Fusobacterium infections</i>		
Necrotising ulcerative gingivostomatitis	1	0
<i>Herpes viral infections</i>		
Genital herpes	6	0
Herpes ophthalmic	1	0
Herpes simplex	1	0
Herpes zoster	40	0
Herpes zoster oticus	1	0
Ophthalmic herpes simplex	1	0
Oral herpes	35	0
Varicella	1	0
<i>Infections NEC</i>		
Abscess limb	1	0
Abscess rupture	1	0
Infection	52	0
Injection site infection	1	0
Localised infection	11	0
Respiratory tract infection	1	0
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	208	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	3	0
Lower respiratory tract infection	15	0
Pneumonia	8	0
<i>Male reproductive tract infections</i>		
Orchitis	1	0
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Nematode infections</i>		
Enterobiasis	1	0
<i>Rabies viral infections</i>		
Rabies	1	1
<i>Rubella viral infections</i>		
Rubella	2	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
Septic shock	1	0
Urosepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Impetigo	2	0
Pustule	8	0
Pyoderma	1	0
Rash pustular	3	0
Skin infection	8	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Staphylococcal infections</i>		
Furuncle	4	0
<i>Tinea infections</i>		
Body tinea	3	0
Tinea infection	1	0
<i>Tuberculous infections</i>		
Disseminated Bacillus Calmette-Guerin infection	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	1	0
Nasopharyngitis	146	0
Peritonsillar abscess	1	0
Pharyngitis	2	0
Rhinitis	2	0
Sinusitis	7	0
Tonsillitis	10	0
Upper respiratory tract infection	1	0
<i>Urinary tract infections</i>		
Cystitis	5	0
Kidney infection	1	0
Urinary tract infection	17	0
<i>Vascular infections</i>		
Lymphangitis	2	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Gastroenteritis viral	1	0
Meningitis viral	1	0
Post viral fatigue syndrome	3	0
Sweating fever	24	0
Viral infection	1	0
Viral labyrinthitis	1	0
Viral pharyngitis	2	0
Viral rash	4	0
Infections SOC TOTAL	847	2

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Oral contusion	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Anaesthetic and allied procedural complications</i>		
Anaesthetic complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
<i>Cardiovascular injuries</i>		
Heart injury	1	0
Vascular injury	1	0
<i>Cerebral injuries NEC</i>		
Concussion	6	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	7	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	1	0
Foetal exposure during pregnancy	5	0
Maternal exposure during breast feeding	328	0
Maternal exposure during pregnancy	158	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	2	0
Heat stroke	6	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	4	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	4	0
Wrong schedule	1	0
Wrong technique in device usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	2	0
Muscle injury	1	0
Muscle strain	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	8	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	4	0
Fall	15	0
Injury	1	0
Wound complication	2	0
Wound haemorrhage	1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Non-site specific procedural complications</i>		
Injection related reaction	3	0
Procedural pain	1	0
<i>Off label uses</i>		
Off label use	1	0
<i>Overdoses NEC</i>		
Overdose	6	0
<i>Peripheral nerve injuries</i>		
Sciatic nerve injury	1	0
<i>Poisoning and toxicity</i>		
Toxicity to various agents	1	0
<i>Product administration errors and issues</i>		
Expired product administered	6	0
Inappropriate schedule of product administration	7	0
Incorrect dose administered	1	0
Incorrect route of product administration	1	0
Poor quality product administered	1	0
Product administered at inappropriate site	1	0
Product dose omission issue	2	0
Wrong product administered	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Radiation injuries</i>		
Sunburn	9	0
<i>Site specific injuries NEC</i>		
Head injury	5	0
Limb injury	14	0
<i>Skin injuries NEC</i>		
Contusion	164	0
Scar	9	0
Scratch	1	0
Skin injury	1	0
Skin wound	1	0
Subcutaneous haematoma	2	0
<i>Stoma complications</i>		
Stoma site oedema	1	0
<i>Thermal burns</i>		
Burn oesophageal	1	0
Cold burn	1	0
Thermal burn	6	0
Thermal burns of eye	1	0
<i>Vaccination related complications</i>		
Vaccination complication	3	0
Injuries SOC TOTAL	828	0

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal medulla tests</i>		
Norepinephrine increased	2	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Campylobacter test positive	1	0
<i>Blood counts NEC</i>		
Blood count abnormal	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen consumption decreased	1	0
Oxygen saturation decreased	3	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	1	0
Blood glucose increased	2	0
<i>Cardiac auscultatory investigations</i>		
Heart sounds	3	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	1	0
<i>Coagulation and bleeding analyses</i>		
Fibrin D dimer increased	1	0
<i>ECG investigations</i>		
Electrocardiogram P wave abnormal	1	0
Electrocardiogram ST segment elevation	1	0
Electrocardiogram ST-T segment abnormal	1	0
Electrocardiogram T wave inversion	2	0
Electrocardiogram abnormal	1	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	3	0
<i>Fertility analyses</i>		
Semen analysis abnormal	1	0
<i>Fungus identification and serology</i>		
Fungal test	1	0
<i>Gastrointestinal and abdominal imaging procedures</i>		
X-ray with contrast upper gastrointestinal tract	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	75	0
Heart rate abnormal	5	0
Heart rate decreased	5	0
Heart rate increased	119	0
Heart rate irregular	20	0
Heart rate variability decreased	1	0
<i>Investigations NEC</i>		
Blood test abnormal	3	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	4	0
Aspartate aminotransferase	2	0
Blood bilirubin increased	1	0
Liver function test abnormal	5	0
Liver function test increased	1	0
<i>Mineral and electrolyte analyses</i>		
Blood iron decreased	2	0
Blood magnesium decreased	1	0
Blood potassium decreased	2	0
Serum ferritin increased	1	0
<i>Neurologic diagnostic procedures</i>		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Coma scale abnormal	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Visual tracking test abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	36	0
Body temperature abnormal	2	0
Body temperature decreased	3	0
Body temperature fluctuation	11	0
Body temperature increased	37	0
Grip strength	1	0
Grip strength decreased	1	0
Lymph node palpable	1	0
Palpatory finding abnormal	1	0
Product residue present	1	0
Respiratory rate	2	0
Respiratory rate decreased	2	0
Respiratory rate increased	6	0
Skin temperature	8	0
Temperature difference of extremities	1	0
Weight decreased	10	0
Weight increased	6	0
<i>Pituitary analyses anterior</i>		
Blood thyroid stimulating hormone increased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	7	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	4	0
<i>Red blood cell analyses</i>		
Haemoglobin E	1	0
Haemoglobin decreased	1	0
<i>Renal function analyses</i>		
Blood creatinine increased	1	0
<i>Reproductive hormone analyses</i>		
Pregnancy test	1	0
<i>Reproductive organ and breast histopathology procedures</i>		
Smear cervix	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Forced expiratory volume increased	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Troponin T increased	1	0
Troponin increased	1	0
<i>Therapeutic drug monitoring analyses</i>		
Analgesic drug level	3	0
<i>Tissue enzyme analyses NEC</i>		
Blood lactate dehydrogenase increased	1	0
<i>Urinalysis NEC</i>		
Blood urine present	5	0
Protein urine	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output	3	0
Urine output decreased	1	0
<i>Urinary tract imaging procedures</i>		
Bladder scan	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	1	0
Blood pressure decreased	6	0
Blood pressure diastolic increased	1	0
Blood pressure increased	8	0
Blood pressure measurement	3	0
<i>Virus identification and serology</i>		
Coronavirus test	4	0
SARS-CoV-2 antibody test	2	0
SARS-CoV-2 test	4	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	2	0
<i>Vitamin analyses</i>		
Blood folate decreased	1	0
<i>White blood cell analyses</i>		
Neutrophil count	1	0
White blood cell count	1	0
White blood cell count decreased	1	0
White blood cell count increased	1	0
Investigations SOC TOTAL	481	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	149	0
Food craving	1	0
Food refusal	1	0
Hyperphagia	5	0
Hypophagia	1	0
Increased appetite	6	0
Salt craving	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	1	0
Diabetes mellitus inadequate control	2	0
Type 1 diabetes mellitus	1	0
Type 2 diabetes mellitus	1	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	2	0
<i>Disorders of purine metabolism</i>		
Gout	8	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	2	0
<i>General nutritional disorders NEC</i>		
Abnormal weight gain	5	0
Feeding disorder	18	0
Food aversion	3	0
Neonatal insufficient breast milk syndrome	3	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	5	0
<i>Potassium imbalance</i>		
Hypokalaemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	39	0
<i>Total fluid volume increased</i>		
Fluid retention	8	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	269	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	11	0
Arthritis enteropathic	1	0
Arthropathy	4	0
Autoimmune arthritis	1	0
<i>Bone disorders NEC</i>		
Jaw cyst	1	0
Jaw disorder	1	0
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	30	0
Bone swelling	1	0
Pain in jaw	35	0
Spinal pain	7	0
<i>Bursal disorders</i>		
Bursitis	7	0
<i>Cartilage disorders</i>		
Costochondritis	8	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	2	0
<i>Joint related disorders NEC</i>		
Joint lock	3	0
Periarthritis	15	0
Rotator cuff syndrome	3	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	842	0
Joint noise	2	0
Joint stiffness	31	0
Joint swelling	28	0
Joint vibration	1	0
Joint warmth	2	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
<i>Muscle infections and inflammations</i>		
Myositis	5	0
<i>Muscle pains</i>		
Fibromyalgia	6	0
Myalgia	1321	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	2	0
Muscle discomfort	1	0
Muscle fatigue	42	0
Muscle haemorrhage	1	0
Muscle spasms	227	0
Muscle swelling	7	0
Muscle tightness	17	0
Muscle twitching	44	0
Myosclerosis	1	0
<i>Muscle tone abnormalities</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Muscle rigidity	2	0
Nuchal rigidity	1	0
Trismus	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	82	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Growth retardation	1	0
Mastication disorder	1	0
Mobility decreased	4	0
Muscle contracture	1	0
Musculoskeletal stiffness	205	0
<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>		
Facial asymmetry	1	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	304	0
Flank pain	6	0
Limb discomfort	191	0
Musculoskeletal chest pain	15	0
Musculoskeletal discomfort	7	0
Musculoskeletal pain	1	0
Neck pain	151	0
Pain in extremity	1820	0
<i>Myopathies</i>		
Rhabdomyolysis	1	0
<i>Osteoarthropathies</i>		
Osteoarthritis	2	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	4	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	23	0
Groin pain	9	0
Neck mass	3	0
Soft tissue swelling	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	2	0
Arthritis reactive	3	0
Axial spondyloarthritis	1	0
<i>Synovial disorders</i>		
Synovial cyst	3	0
<i>Tendon disorders</i>		
Tendon pain	1	0
Trigger finger	2	0
Muscle & tissue disorders SOC TOTAL	5568	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma stage III	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	1	0
<i>Leukaemias NEC</i>		
Leukaemia	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	4	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>		
Anogenital warts	1	0
Haemangioma of skin	3	0
Skin papilloma	3	0
<i>Small intestinal neoplasms malignant</i>		
Small intestine adenocarcinoma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	20	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	2	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	3	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	0
Cerebral haemorrhage	2	1
Cerebral infarction	2	0
Cerebrovascular accident	8	1
Haemorrhage intracranial	1	0
Intracranial haematoma	1	0
Ischaemic stroke	1	0
Subarachnoid haemorrhage	2	0
<i>Central nervous system inflammatory disorders NEC</i>		
Central nervous system inflammation	1	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebral congestion	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	23	0
Coordination abnormal	1	0
Dysstasia	4	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	7	0
Lethargy	192	0
Loss of consciousness	113	0
Somnolence	119	0
Stupor	1	0
Syncope	560	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	2	0
Clumsiness	2	0
Dyskinesia	5	0
Extrapyramidal disorder	1	0
Fine motor delay	1	0
Fine motor skill dysfunction	1	0
Foetal movement disorder	1	0
Hyperkinesia	1	0
Hypokinesia	5	0
Movement disorder	5	0
Psychomotor hyperactivity	1	0
<i>Eye movement disorders</i>		
IVth nerve paresis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	33	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Facial paralysis	24	0
Facial paresis	2	0
Facial spasm	4	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	1	0
Glossopharyngeal nerve disorders		
Glossopharyngeal neuralgia	1	0
Headaches NEC		
Cluster headache	27	0
Cold-stimulus headache	3	0
Drug withdrawal headache	1	0
Headache	3003	0
New daily persistent headache	1	0
Occipital neuralgia	1	0
Sinus headache	34	0
Tension headache	57	0
Thunderclap headache	1	0
Vascular headache	2	0
Increased intracranial pressure disorders		
Idiopathic intracranial hypertension	1	0
Intracranial pressure increased	2	0
Lumbar spinal cord and nerve root disorders		
Sciatica	2	0
Memory loss (excl dementia)		
Amnesia	16	0
Memory impairment	16	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	9	0
Disturbance in attention	44	0
Mental impairment	4	0
Migraine headaches		
Hemiplegic migraine	2	0
Migraine	332	0
Migraine with aura	27	0
Migraine without aura	2	0
Retinal migraine	2	0
Typical aura without headache	1	0
Vestibular migraine	2	0
Mononeuropathies		
Carpal tunnel syndrome	1	0
Cubital tunnel syndrome	1	0
Mononeuritis	2	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Muscle tone abnormal		
Hypotonia	3	0
Stiff leg syndrome	2	0
Myelitis (incl infective)		
Myelitis transverse	1	0
Narcolepsy and hypersomnia		
Hypersomnia	10	0
Narcolepsy	2	0
Nervous system disorders NEC		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Nervous system disorder	2	0
Neurologic visual problems NEC		
Tunnel vision	5	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Dizziness	1550	0
Dizziness exertional	2	0
Dizziness postural	64	0
Drooling	2	0
Head discomfort	30	0
Inability to crawl	1	0
Neurological symptom	4	0
Persistent postural-perceptual dizziness	1	0
Presyncope	130	0
Unresponsive to stimuli	9	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	2	0
Muscle spasticity	2	0
Olfactory nerve disorders		
Anosmia	15	0
Parosmia	11	0
Optic nerve disorders NEC		
Optic neuritis	3	0
Paraesthesias and dysaesthesias		
Burning sensation	49	0
Formication	2	0
Hemianaesthesia	1	0
Hyperaesthesia	27	0
Hypoaesthesia	307	0
Paraesthesia	437	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	5	0
Hemiplegia	4	0
Monoparesis	9	0
Monoplegia	11	0
Paralysis	11	0
Paresis	1	0
Parkinson's disease and parkinsonism		
Reduced facial expression	1	0
Peripheral neuropathies NEC		
Neuritis	1	0
Neuropathy peripheral	6	0
Polyneuropathy	1	0
Seizures and seizure disorders NEC		
Epilepsy	6	0
Febrile convulsion	3	0
Partial seizures	2	0
Psychogenic seizure	1	0
Seizure	96	0
Status epilepticus	24	0
Tonic clonic movements	2	0
Tonic convulsion	2	0
Sensory abnormalities NEC		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Ageusia	31	0
Allodynia	1	0
Complex regional pain syndrome	1	0
Dysgeusia	102	0
Electric shock sensation	2	0
Hypogeusia	1	0
Neuralgia	41	0
Post herpetic neuralgia	2	0
Restless legs syndrome	22	0
Sensory disturbance	7	0
Sensory loss	10	0
Taste disorder	16	0
Vibratory sense increased	1	0
Sleep disturbances NEC		
Sleep deficit	1	0
Speech and language abnormalities		
Dysarthria	18	0
Incoherent	5	0
Slow speech	3	0
Speech disorder	8	0
Spinal cord and nerve root disorders NEC		
Radiculopathy	1	0
Transient cerebrovascular events		
Transient ischaemic attack	6	0
Tremor (excl congenital)		
Tremor	188	0
Trigeminal disorders		
Facial neuralgia	1	0
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	8068	2

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	31	1
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	3	0
<i>Maternal complications of labour NEC</i>		
Uterine hypertonus	2	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	1	0
Ectopic pregnancy	2	0
Morning sickness	2	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	1	0
Pregnancy	6	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	1	1
<i>Unintended pregnancies</i>		
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	52	2

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device expulsion	1	0
Device leakage	1	0
<i>Device malfunction events NEC</i>		
Thrombosis in device	1	0
<i>Product contamination and sterility issues</i>		
Product contamination physical	8	0
<i>Product quality issues NEC</i>		
Product impurity	1	0
Product quality issue	1	0
null SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	2	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
Flat affect	3	0
Inappropriate affect	1	0
<i>Anxiety symptoms</i>		
Agitation	10	0
Anxiety	142	0
Nervousness	23	0
Stress	13	0
Tension	6	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	2	0
<i>Behaviour and socialisation disturbances</i>		
Disinhibition	1	0
Paranoia	4	0
Personality change	1	0
Social avoidant behaviour	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
Mental fatigue	27	0
<i>Confusion and disorientation</i>		
Confusional state	75	0
Disorientation	32	0
<i>Deliria</i>		
Delirium	14	0
<i>Delusional disorders</i>		
Alice in wonderland syndrome	1	0
<i>Delusional symptoms</i>		
Delusion	1	0
<i>Depressive disorders</i>		
Depression	43	0
Depression suicidal	2	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	1	0
Dissociation	8	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	2	0
Insomnia	163	0
Middle insomnia	9	0
Terminal insomnia	9	0
<i>Dyssomnias</i>		
Poor quality sleep	35	0
<i>Eating disorders NEC</i>		
Binge eating	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	7	0
Emotional disorder	13	0
Emotional distress	7	0
Euphoric mood	7	0
Irritability	30	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Mood altered	8	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	2	0
Fear of death	2	0
Fear of injection	7	0
Phobia	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	10	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	48	0
Hallucination, auditory	2	0
Hallucination, visual	1	0
Somatic hallucination	1	0
<i>Increased physical activity levels</i>		
Restlessness	30	0
<i>Mental disorders NEC</i>		
Mental disorder	3	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	44	0
Feeling of despair	2	0
Tearfulness	2	0
<i>Mood alterations with manic symptoms</i>		
Mania	3	0
<i>Mood disorders NEC</i>		
Apathy	5	0
Listless	2	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	1	0
<i>Orgasmic disorders and disturbances</i>		
Orgasm abnormal	1	0
Orgasmic sensation decreased	1	0
<i>Panic attacks and disorders</i>		
Limited symptom panic attack	1	0
Panic attack	33	0
Panic reaction	7	0
<i>Parasomnias</i>		
Abnormal dreams	20	0
Nightmare	22	0
Sleep talking	1	0
Sleep terror	1	0
Somnambulism	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	3	0
Derealisation	2	0
Illusion	1	0
<i>Psychiatric elimination disorders</i>		
Enuresis	7	0
<i>Psychiatric symptoms NEC</i>		
Psychiatric symptom	1	0
Psychological trauma	1	0
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
Psychotic disorder	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Sexual desire disorders</i>		
Libido decreased	3	0
Libido increased	1	0
Loss of libido	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	19	0
<i>Somatic symptom disorders</i>		
Conversion disorder	2	0
Habit cough	4	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	3	0
Lack of spontaneous speech	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	1	0
Head banging	1	0
<i>Stress disorders</i>		
Post-traumatic stress disorder	1	0
<i>Substance related and addictive disorders</i>		
Alcoholism	1	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	1	0
Suicidal behaviour	2	0
Suicidal ideation	5	0
Suicide attempt	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	3	0
Intrusive thoughts	1	0
Tachyphrenia	1	0
Thinking abnormal	3	0
Psychiatric disorders SOC TOTAL	1035	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	4	0
Dysuria	6	0
Incontinence	2	0
Micturition urgency	4	0
Pollakiuria	15	0
Urethral pain	1	0
Urinary incontinence	6	0
Urinary retention	1	0
Urinary straining	1	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
Urinary bladder haemorrhage	2	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
IgA nephropathy	2	0
<i>Renal failure and impairment</i>		
Acute kidney injury	4	0
Oliguria	1	0
Renal impairment	1	0
<i>Urinary abnormalities</i>		
Chromaturia	8	0
Haematuria	1	0
Urine abnormality	4	0
Urine odour abnormal	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	5	0
Renal pain	40	0
Renal & urinary disorders SOC TOTAL	112	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	3	0
<i>Breast disorders NEC</i>		
Breast enlargement	3	0
Breast mass	8	0
Fibrocystic breast disease	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	1	0
<i>Breast signs and symptoms</i>		
Breast discomfort	1	0
Breast pain	56	0
Breast swelling	6	0
Breast tenderness	7	0
Nipple swelling	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Ejaculation failure	2	0
Erectile dysfunction	5	0
Nocturnal emission	1	0
Organic erectile dysfunction	6	0
Painful ejaculation	1	0
<i>Gender disorders</i>		
Feminisation acquired	1	0
<i>Lactation disorders</i>		
Galactorrhoea	1	0
Lactation puerperal increased	2	0
Suppressed lactation	4	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	6	0
Premature menopause	2	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	8	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	226	0
Intermenstrual bleeding	116	0
Menstrual discomfort	1	0
Menstrual disorder	214	0
Menstruation irregular	334	0
Premenstrual dysphoric disorder	1	0
Premenstrual headache	2	0
Premenstrual pain	9	0
Premenstrual syndrome	10	0
Withdrawal bleed	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	55	0
Hypomenorrhoea	66	0
Menstruation delayed	437	0
Oligomenorrhoea	14	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	577	0
Menometrorrhagia	5	0
Polymenorrhoea	81	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Ovarian cyst	3	0
Polycystic ovaries	2	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation pain	12	0
Premature ovulation	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	9	0
Pelvic haemorrhage	2	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penis disorder	2	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
Genital paraesthesia	1	0
Genital ulceration	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	13	0
Pruritus genital	1	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	2	0
Varicocele	1	0
<i>Sexual function and fertility disorders NEC</i>		
Infertility	3	0
Sexual dysfunction	1	0
<i>Spermatogenesis and semen disorders</i>		
Haemospermia	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	1	0
Testicular mass	1	0
Testicular pain	8	0
Testicular swelling	2	0
<i>Uterine disorders NEC</i>		
Endometriosis	8	0
Uterine haemorrhage	5	0
Uterine pain	1	0
<i>Uterine tone disorders</i>		
Uterine spasm	11	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vaginal cyst	1	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	159	0
Vulval haemorrhage	5	0
<i>Vulvovaginal signs and symptoms</i>		
Labia enlarged	1	0
Vaginal discharge	11	0
Vulvovaginal burning sensation	2	0
Vulvovaginal discomfort	1	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Reproductive & breast disorders SOC TOTAL	2558	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	380	0
Dyspnoea exertional	3	0
Hyperventilation	4	0
Hypopnoea	9	0
Hypoventilation	1	0
Irregular breathing	1	0
Respiration abnormal	8	0
Respiratory arrest	1	1
Respiratory distress	1	0
Sleep apnoea syndrome	1	0
Tachypnoea	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	25	0
Asthma late onset	1	0
Wheezing	36	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Allergic cough	1	0
Cough	193	0
Productive cough	16	0
Sputum discoloured	2	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 inflammatory and immunologic conditions</i>		
Pneumonitis	2	0
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	13	0
Pulmonary haemorrhage	1	0
Pulmonary pain	9	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	24	0
<i>Nasal disorders NEC</i>		
Epistaxis	80	0
Nasal oedema	1	0
Nasal pruritus	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	5	0
Sinus disorder	1	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	2	0
Pharyngeal oedema	2	0
Pharyngeal paraesthesia	2	0
Pharyngeal swelling	36	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Tonsillar erythema	1	0
Tonsillar hypertrophy	8	0
<i>Pleural infections and inflammations</i>		
Pleurisy	4	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	1	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	1	0
Pulmonary oedema	2	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	18	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	1	0
<i>Respiratory signs and symptoms NEC</i>		
Diaphragmalgia	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	1	0
Respiratory tract irritation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	6	0
Catarrh	1	0
Choking	1	0
Dry throat	15	0
Dysphonia	6	0
Increased viscosity of upper respiratory secretion	2	0
Nasal discomfort	3	0
Oropharyngeal blistering	1	0
Oropharyngeal discomfort	3	0
Oropharyngeal pain	234	0
Paranasal sinus discomfort	5	0
Rhinalgia	2	0
Rhinorrhoea	62	0
Sinus pain	27	0
Sneezing	15	0
Throat irritation	20	0
Throat tightness	32	0
Upper-airway cough syndrome	1	0
Yawning	4	0
Respiratory disorders SOC TOTAL	1351	1

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	19	0
<i>Alopecias</i>		
Alopecia	22	0
Alopecia areata	4	0
Alopecia totalis	1	0
<i>Angioedemas</i>		
Angioedema	21	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	142	0
Hidradenitis	1	0
Hyperhidrosis	433	0
Miliaria	46	0
Night sweats	89	0
<i>Bullous conditions</i>		
Blister	38	0
Blister rupture	1	0
Blood blister	1	0
Dermatitis bullous	1	0
Erythema multiforme	10	0
Pemphigoid	1	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	51	0
Pain of skin	49	0
Papule	17	0
Scab	4	0
Scar pain	2	0
Sensitive skin	72	0
Skin burning sensation	32	0
Skin discolouration	17	0
Skin induration	6	0
Skin lesion	20	0
Skin reaction	75	0
Skin sensitisation	9	0
Skin swelling	12	0
Skin tightness	4	0
Skin warm	145	0
Yellow skin	2	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	1	0
Dermatitis	17	0
Dermatitis allergic	72	0
Dermatitis atopic	7	0
Dermatitis contact	5	0
Dyshidrotic eczema	8	0
Eczema	29	0
Eczema nummular	2	0
Neurodermatitis	1	0
Skin irritation	17	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	707	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	1
Exfoliative rash	2	0
Skin exfoliation	9	0
<i>Hyperpigmentation disorders</i>		
Ephelides	1	0
Skin hyperpigmentation	1	0
Solar lentigo	1	0
<i>Hypopigmentation disorders</i>		
Vitiligo	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Onychoclasia	1	0
<i>Panniculitides</i>		
Erythema nodosum	3	0
<i>Papulosquamous conditions</i>		
Lichen planus	2	0
Pityriasis rosea	4	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	13	0
<i>Pilar disorders NEC</i>		
Piloerection	8	0
<i>Pruritus NEC</i>		
Itching scar	3	0
Pruritus	1527	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
Psoriasis	15	0
<i>Purpura and related conditions</i>		
Petechiae	14	0
Purpura	7	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	1	0
Rash	1784	0
Rash erythematous	712	0
Rash macular	116	0
Rash maculo-papular	1	0
Rash morbilliform	4	0
Rash papular	127	0
Rash pruritic	404	0
Rash vesicular	4	0
<i>Rosaceas</i>		
Rosacea	2	0
<i>Scaly conditions</i>		
Pityriasis	1	0
<i>Sebaceous gland disorders</i>		
Seborrhoea	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Cutaneous symptom	3	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin mass	4	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	1	0
Skin ulcer	2	0
Skin cysts and polyps		
Dermal cyst	5	0
Skin dystrophies		
Keloid scar	1	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 vasculitides		
Cutaneous vasculitis	2	0
Skin vasomotor conditions		
Livedo reticularis	3	0
Telangiectasia and related conditions		
Spider naevus	1	0
Urticarias		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	1	0
Urticaria	248	0
Urticaria cholinergic	1	0
Urticaria chronic	1	0
Skin disorders SOC TOTAL	7267	1

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 16-Sep-2021

Data Lock Date: 15-Sep-2021 18:31:25

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menopause	4	0
<i>Disability issues</i>		
Bedridden	3	0
Immobile	2	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	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	4	0
Social circumstances SOC TOTAL	18	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

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>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	1	0
<i>Immunisations</i>		
COVID-19 immunisation	12	0
Immunisation	17	0
<i>Joint therapeutic procedures</i>		
Joint stabilisation	1	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	3	0
<i>Therapeutic procedures NEC</i>		
Bed rest	2	0
Botulinum toxin injection	1	0
Hospitalisation	1	0
Injection	14	0
Interchange of vaccine products	1	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	57	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

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>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	1	0
Neurogenic shock	1	0
Shock	2	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	4	0
Haemorrhage	131	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	6	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	2	0
Embolism venous	1	0
Thrombosis	37	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arteriosclerosis	1	0
Peripheral venous disease	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	5	0
Vasodilatation	2	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	2	0
Deep vein thrombosis	10	0
Thrombophlebitis	1	0
Thrombophlebitis superficial	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	4	0
Flushing	25	0
Hot flush	160	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	32	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	56	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	46	0
Prehypertension	1	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 16-Sep-2021

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Hypotension	56	0
Orthostatic hypotension	5	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	609	0
TOTAL REACTIONS FOR DRUG	51034	17
TOTAL REPORTS	15916	
TOTAL FATAL OUTCOME REPORTS		17