

COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 29-Jul-2021
Data Lock Date: 28-Jul-2021 18:30:14

All UK spontaneous reports received up to and including 28/07/2021 for COVID-19 vaccine Moderna

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: 29-Jul-2021

Data Lock Date: 28-Jul-2021 18:30:14

Earliest Reaction Date: 15-Oct-1958

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	3	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	1	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	102	0
Lymphadenitis	9	0
Lymphadenopathy	553	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	3	0
Thrombocytopenia	11	0
Thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	690	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	5	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	2	0
Palpitations	228	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
Cardiac failure congestive	1	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	9	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	25	0
<i>Noninfectious pericarditis</i>		
Pericarditis	22	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	5	0
Bradycardia	7	0
Cardiac flutter	18	0
Extrasystoles	6	0
Tachycardia	21	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	3	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	370	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	72	0
Ear swelling	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	3	0
<i>Hearing losses</i>		
Deafness	12	0
Deafness transitory	1	0
Deafness unilateral	4	0
Hypoacusis	10	0
Sudden hearing loss	4	0
<i>Hyperacusia</i>		
Hyperacusis	4	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	7	0
Tinnitus	126	0
Vertigo	88	0
Vertigo positional	2	0
Ear disorders SOC TOTAL	342	0

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Reaction Name	Total	Fatal
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	4	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	15	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	2	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	10	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Uveitis	2	0
<i>Lacrimation disorders</i>		
Dry eye	6	0
Lacrimation increased	4	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	79	0
Eye swelling	26	0
Periorbital oedema	2	0
Periorbital swelling	4	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	2	0
Eye inflammation	1	0
Eye irritation	3	0
Eye pruritus	11	0
Ocular hyperaemia	12	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	3	0
Hypoaesthesia eye	1	0
Photophobia	19	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>Retinopathies NEC</i>		
Acute zonal occult outer retinopathy	1	0
Serous retinopathy	1	0

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Eye disorders Eye disorders cont'd		
<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	10	0
Metamorphopsia	1	0
Photopsia	3	0
Vision blurred	107	0
<i>Visual field disorders</i>		
Visual field defect	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	10	0
Blindness transient	1	0
Blindness unilateral	1	0
Visual acuity reduced	1	0
Visual impairment	14	0
Eye disorders SOC TOTAL	368	0

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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	1	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
<i>Colitis (excl infective)</i>		
Colitis	1	0
Colitis ulcerative	2	0
Crohn's disease	4	0
Inflammatory bowel disease	1	0
<i>Dental pain and sensation disorders</i>		
Dental paraesthesia	1	0
Hyperaesthesia teeth	4	0
Toothache	9	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	309	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	32	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	19	0
Flatulence	11	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	1	0
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	95	0
Abdominal pain lower	5	0
Abdominal pain upper	215	0
Abdominal rigidity	1	0
Abdominal tenderness	1	0
Gastrointestinal pain	6	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	14	0
Gastrooesophageal reflux disease	7	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
Gastric disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	1	0
Gastrointestinal motility disorder	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oesophageal achalasia	1	0
Gastrointestinal fistulae		
Fistula of small intestine	1	0
Gastrointestinal mucosal dystrophies and secretion disorders		
Hyperchlorhydria	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	41	0
Anal incontinence	2	0
Breath odour	3	0
Dysphagia	12	0
Odynophagia	2	0
Gastrointestinal spastic and hypermotility disorders		
Frequent bowel movements	3	0
Irritable bowel syndrome	5	0
Gastrointestinal stenosis and obstruction NEC		
Intestinal obstruction	1	0
Gastrointestinal vascular malformations		
Gastric antral vascular ectasia	1	0
Gingival disorders, signs and symptoms NEC		
Gingival pain	3	0
Gingival swelling	4	0
Gingival haemorrhages		
Gingival bleeding	4	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)		
Haemorrhoids	1	0
Intestinal haemorrhages		
Rectal haemorrhage	6	0
Nausea and vomiting symptoms		
Discoloured vomit	1	0
Nausea	1164	0
Retching	6	0
Vomiting	365	0
Vomiting projectile	1	0
Non-site specific gastrointestinal haemorrhages		
Haematemesis	1	0
Haematochezia	4	0
Melaena	1	0
Upper gastrointestinal haemorrhage	1	0
Oral dryness and saliva altered		
Aptyalism	1	0
Dry mouth	38	0
Lip dry	4	0
Saliva altered	1	0
Salivary hypersecretion	5	0
Oral soft tissue disorders NEC		
Cheilitis	1	0
Enlarged uvula	1	0
Lip blister	2	0
Lip disorder	1	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	1	0
Oral blood blister	2	0
Oral soft tissue signs and symptoms		

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Coating in mouth	2	0
Hypoaesthesia oral	32	0
Lip discolouration	1	0
Lip pain	2	0
Lip pruritus	1	0
Oral discomfort	2	0
Oral mucosal roughening	1	0
Oral pain	7	0
Oral pruritus	1	0
Paraesthesia oral	58	0
Oral soft tissue swelling and oedema		
Lip swelling	50	0
Mouth swelling	9	0
Peptic ulcers and perforation		
Peptic ulcer haemorrhage	1	0
Salivary gland enlargements		
Submaxillary gland enlargement	1	0
Stomatitis and ulceration		
Aphthous ulcer	3	0
Lip ulceration	1	0
Mouth ulceration	32	0
Stomatitis	2	0
Tongue disorders		
Glossitis	2	0
Tongue disorder	4	0
Tongue haemorrhage	1	0
Tongue ulceration	3	0
Tongue signs and symptoms		
Glossodynia	11	0
Swollen tongue	30	0
Tongue blistering	1	0
Tongue coated	2	0
Tongue discolouration	1	0
Tongue discomfort	2	0
Tongue dry	2	0
Tongue movement disturbance	1	0
Tooth missing		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	2718	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	4	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	4	0
Application site joint erythema	1	0
Application site pain	1	0
Application site pruritus	8	0
Application site rash	1	0
Application site swelling	2	0
Application site vesicles	3	0
Application site warmth	1	0
Instillation site warmth	2	0
<i>Asthenic conditions</i>		
Asthenia	119	0
Fatigue	1657	0
Malaise	268	0
<i>Death and sudden death</i>		
Death	4	4
<i>Febrile disorders</i>		
Pyrexia	1489	1
<i>Feelings and sensations NEC</i>		
Chills	798	0
Feeling abnormal	132	0
Feeling cold	57	0
Feeling drunk	8	0
Feeling hot	122	0
Feeling jittery	6	0
Feeling of body temperature change	26	0
Hangover	7	0
Hunger	9	0
Sensation of blood flow	1	0
Sensation of foreign body	2	0
Temperature intolerance	10	0
Thirst	35	0
<i>Gait disturbances</i>		
Gait disturbance	11	0
Gait inability	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	4	0
Crying	18	0
Discharge	2	0
Energy increased	1	0
Exercise tolerance decreased	4	0
Illness	121	0
Induration	5	0
Influenza like illness	162	0
Irritability postvaccinal	1	0
Local reaction	11	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Perforation	1	0
Peripheral swelling	895	0
Screaming	2	0
Swelling	465	0
Swelling face	53	0
Implant and catheter site reactions		
Implant site warmth	3	0
Inflammations		
Inflammation	55	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	9	0
Injection site discolouration	1	0
Injection site erythema	89	0
Injection site haemorrhage	3	0
Injection site hypersensitivity	5	0
Injection site hypoaesthesia	4	0
Injection site indentation	1	0
Injection site inflammation	6	0
Injection site irritation	1	0
Injection site joint erythema	3	0
Injection site mass	94	0
Injection site oedema	2	0
Injection site pain	251	0
Injection site paraesthesia	1	0
Injection site plaque	1	0
Injection site pruritus	71	0
Injection site rash	133	0
Injection site reaction	10	0
Injection site swelling	40	0
Injection site urticaria	42	0
Injection site vesicles	1	0
Injection site warmth	45	0
Interactions		
Alcohol interaction	1	0
Drug interaction	1	0
Mass conditions NEC		
Cyst	4	0
Mass	14	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

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General disorders General disorders cont'd		
Oedema	2	0
Oedema peripheral	2	0
Pain and discomfort NEC		
Axillary pain	291	0
Chest discomfort	102	0
Chest pain	232	0
Discomfort	47	0
Facial pain	9	0
Pain	805	0
Tenderness	81	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	29	0
Drug ineffective	8	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
Shoulder injury related to vaccine administration	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	188	0
Vaccination site haemorrhage	1	0
Vaccination site hypoaesthesia	3	0
Vaccination site induration	14	0
Vaccination site inflammation	6	0
Vaccination site irritation	1	0
Vaccination site joint erythema	3	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	166	0
Vaccination site papule	2	0
Vaccination site pruritus	50	0
Vaccination site rash	91	0
Vaccination site reaction	2	0
Vaccination site swelling	112	0
Vaccination site urticaria	6	0
Vaccination site vesicles	1	0
Vaccination site warmth	87	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	2	0
General disorders SOC TOTAL	9871	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
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	1	0
Hepatic disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	3	0
Allergy to animal	1	0
Hypersensitivity	140	0
Infusion related hypersensitivity reaction	5	0
Multiple allergies	1	0
Type IV hypersensitivity reaction	11	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	5	0
Drug hypersensitivity	3	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	23	0
Anaphylactic shock	3	0
Anaphylactoid reaction	2	0
<i>Atopic disorders</i>		
Seasonal allergy	10	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	19	0
Cytokine release syndrome	1	0
Immune-mediated adverse reaction	1	0
Sensitisation	2	0
Immune system disorders SOC TOTAL	232	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	2	0
Diverticulitis	1	0
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Application site cellulitis	1	0
Bacterial infection	2	0
Cellulitis	44	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	1	0
<i>Candida infections</i>		
Candida infection	3	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	33	0
COVID-19 pneumonia	1	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 infection	1	0
<i>Ear infections</i>		
Ear infection	2	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	8	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>		
Fungal infection	1	0
Fungal skin infection	1	0
<i>Fusobacterium infections</i>		

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Infections		
Infections cont'd		
Necrotising ulcerative gingivostomatitis	1	0
Herpes viral infections		
Genital herpes	5	0
Herpes zoster	27	0
Ophthalmic herpes simplex	1	0
Oral herpes	22	0
Varicella	1	0
Infections NEC		
Abscess limb	1	0
Abscess rupture	1	0
Infection	45	0
Injection site infection	1	0
Localised infection	8	0
Respiratory tract infection	1	0
Vaccination site infection	2	0
Vestibulitis	1	0
Infectious disorders carrier		
SARS-CoV-2 carrier	2	0
Infectious transmissions		
Secondary transmission	2	0
Influenza viral infections		
Influenza	114	0
Lower respiratory tract and lung infections		
Bronchitis	2	0
Lower respiratory tract infection	13	0
Pneumonia	6	0
Nematode infections		
Enterobiasis	1	0
Rabies viral infections		
Rabies	1	1
Rubella viral infections		
Rubella	1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Sepsis	1	0
Urosepsis	1	0
Skin structures and soft tissue infections		
Impetigo	1	0
Pustule	6	0
Pyoderma	1	0
Rash pustular	3	0
Skin infection	8	0
Staphylococcal infections		
Furuncle	2	0
Tinea infections		
Body tinea	2	0
Tuberculous infections		
Disseminated Bacillus Calmette-Guerin infection	1	0
Upper respiratory tract infections		
Laryngitis	1	0
Nasopharyngitis	90	0
Peritonsillar abscess	1	0
Rhinitis	1	0
Sinusitis	4	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 29-Jul-2021

Data Lock Date: 28-Jul-2021 18:30:14

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Tonsillitis	9	0
Upper respiratory tract infection	1	0
Urinary tract infections		
Cystitis	2	0
Kidney infection	1	0
Urinary tract infection	11	0
Vascular infections		
Lymphangitis	1	0
Viral infections NEC		
Conjunctivitis viral	1	0
Post viral fatigue syndrome	2	0
Sweating fever	12	0
Viral infection	1	0
Viral pharyngitis	2	0
Viral rash	3	0
Infections SOC TOTAL	563	1

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 29-Jul-2021
Earliest Reaction Date: 15-Oct-1958

Data Lock Date: 28-Jul-2021 18:30:14
MedDRA Version: MedDRA 24.0

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	3	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	6	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	1	0
Foetal exposure during pregnancy	4	0
Maternal exposure during breast feeding	225	0
Maternal exposure during pregnancy	104	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	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	5	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	9	0
Wound complication	2	0
Wound haemorrhage	1	0
<i>Non-site specific procedural complications</i>		

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Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 29-Jul-2021

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Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Injection related reaction	1	0
Procedural pain	1	0
Overdoses NEC		
Overdose	3	0
Poisoning and toxicity		
Toxicity to various agents	1	0
Product administration errors and issues		
Expired product administered	4	0
Inappropriate schedule of product administration	5	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
Wrong product administered	1	0
Product dispensing errors and issues		
Product dispensing error	1	0
Radiation injuries		
Sunburn	6	0
Site specific injuries NEC		
Head injury	5	0
Limb injury	10	0
Skin injuries NEC		
Contusion	121	0
Scar	7	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	3	0
Injuries SOC TOTAL	581	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal medulla tests</i>		
Norepinephrine increased	2	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	1	0
<i>Cardiac auscultatory investigations</i>		
Heart sounds	2	0
<i>Coagulation and bleeding analyses</i>		
Fibrin D dimer increased	1	0
<i>ECG investigations</i>		
Electrocardiogram T wave inversion	2	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	2	0
<i>Fungus identification and serology</i>		
Fungal test	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	50	0
Heart rate abnormal	3	0
Heart rate decreased	3	0
Heart rate increased	76	0
Heart rate irregular	11	0
<i>Investigations NEC</i>		
Blood test abnormal	2	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	3	0
Aspartate aminotransferase	1	0
Blood bilirubin increased	1	0
Liver function test abnormal	3	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	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	26	0
Body temperature abnormal	1	0
Body temperature decreased	3	0
Body temperature fluctuation	7	0
Body temperature increased	21	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	6	0
Skin temperature	6	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Temperature difference of extremities	1	0
Weight decreased	8	0
Weight increased	5	0
Pituitary analyses anterior		
Blood thyroid stimulating hormone increased	1	0
Platelet analyses		
Platelet count decreased	5	0
Protein analyses NEC		
C-reactive protein increased	1	0
Red blood cell analyses		
Haemoglobin E	1	0
Haemoglobin decreased	1	0
Renal function analyses		
Blood creatinine increased	1	0
Reproductive hormone analyses		
Pregnancy test	1	0
Therapeutic drug monitoring analyses		
Analgesic drug level	1	0
Urinalysis NEC		
Blood urine present	2	0
Protein urine	1	0
Urinary tract function analyses NEC		
Urine output	2	0
Urinary tract imaging procedures		
Bladder scan	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure decreased	6	0
Blood pressure diastolic increased	1	0
Blood pressure increased	6	0
Blood pressure measurement	2	0
Virus identification and serology		
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
White blood cell analyses		
Neutrophil count	1	0
White blood cell count decreased	1	0
Investigations SOC TOTAL	312	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	1	0
Decreased appetite	83	0
Food craving	1	0
Food refusal	1	0
Hyperphagia	3	0
Hypophagia	1	0
Increased appetite	3	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	2	0
Diabetes mellitus inadequate control	1	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	1	0
<i>General nutritional disorders NEC</i>		
Abnormal weight gain	3	0
Feeding disorder	8	0
Food aversion	1	0
Neonatal insufficient breast milk syndrome	2	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	4	0
<i>Total fluid volume decreased</i>		
Dehydration	20	0
<i>Total fluid volume increased</i>		
Fluid retention	7	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	157	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	7	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	21	0
Pain in jaw	26	0
Spinal pain	2	0
<i>Bursal disorders</i>		
Bursitis	4	0
<i>Cartilage disorders</i>		
Costochondritis	5	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	3	0
Periarthritis	10	0
Rotator cuff syndrome	1	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	514	0
Joint noise	1	0
Joint stiffness	18	0
Joint swelling	24	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	4	0
Myalgia	820	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	26	0
Muscle haemorrhage	1	0
Muscle spasms	141	0
Muscle swelling	5	0
Muscle tightness	11	0
Muscle twitching	33	0
Myosclerosis	1	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	2	0
Nuchal rigidity	1	0
Trismus	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	48	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Growth retardation	1	0
Mastication disorder	1	0
Mobility decreased	2	0
Muscle contracture	1	0
Musculoskeletal stiffness	146	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	176	0
Flank pain	2	0
Limb discomfort	144	0
Musculoskeletal chest pain	7	0
Musculoskeletal discomfort	5	0
Musculoskeletal pain	1	0
Neck pain	95	0
Pain in extremity	1383	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	16	0
Groin pain	4	0
Neck mass	1	0
Soft tissue swelling	1	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	3	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	3746	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	1	0
<i>Leukaemias NEC</i>		
Leukaemia	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	3	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	1	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	15	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
Cerebral infarction	1	0
Cerebrovascular accident	7	0
Haemorrhage intracranial	1	0
Ischaemic stroke	1	0
Subarachnoid haemorrhage	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	16	0
Coordination abnormal	1	0
Dysstasia	2	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	6	0
Lethargy	129	0
Loss of consciousness	76	0
Somnolence	82	0
Stupor	1	0
Syncope	431	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	1	0
Clumsiness	2	0
Dyskinesia	5	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	26	0
Facial paralysis	17	0
Facial paresis	2	0
Facial spasm	2	0
<i>Glossopharyngeal nerve disorders</i>		
Glossopharyngeal neuralgia	1	0
<i>Headaches NEC</i>		
Cluster headache	20	0
Cold-stimulus headache	2	0
Drug withdrawal headache	1	0
Headache	1830	0
New daily persistent headache	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Occipital neuralgia	1	0
Sinus headache	19	0
Tension headache	36	0
Thunderclap headache	1	0
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	12	0
Memory impairment	10	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	6	0
Disturbance in attention	28	0
Mental impairment	2	0
Migraine headaches		
Hemiplegic migraine	2	0
Migraine	197	0
Migraine with aura	18	0
Migraine without aura	2	0
Retinal migraine	1	0
Vestibular migraine	1	0
Mononeuropathies		
Cubital tunnel syndrome	1	0
Mononeuritis	1	0
Muscle tone abnormal		
Hypotonia	2	0
Narcolepsy and hypersomnia		
Hypersomnia	7	0
Nervous system disorders NEC		
Nervous system disorder	1	0
Neurologic visual problems NEC		
Tunnel vision	3	0
Neurological signs and symptoms NEC		
Dizziness	1115	0
Dizziness exertional	1	0
Dizziness postural	42	0
Drooling	2	0
Head discomfort	21	0
Neurological symptom	3	0
Persistent postural-perceptual dizziness	1	0
Presyncope	93	0
Unresponsive to stimuli	6	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	2	0
Muscle spasticity	1	0
Olfactory nerve disorders		
Anosmia	6	0
Parosmia	8	0
Optic nerve disorders NEC		
Optic neuritis	2	0
Paraesthesias and dysaesthesias		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Burning sensation	38	0
Formication	1	0
Hemianaesthesia	1	0
Hyperaesthesia	17	0
Hypoaesthesia	224	0
Paraesthesia	323	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	4	0
Hemiplegia	2	0
Monoparesis	5	0
Monoplegia	9	0
Paralysis	9	0
Paresis	1	0
Parkinson's disease and parkinsonism		
Reduced facial expression	1	0
Peripheral neuropathies NEC		
Neuropathy peripheral	5	0
Polyneuropathy	1	0
Seizures and seizure disorders NEC		
Febrile convulsion	3	0
Partial seizures	2	0
Psychogenic seizure	1	0
Seizure	55	0
Status epilepticus	24	0
Tonic clonic movements	2	0
Tonic convulsion	1	0
Sensory abnormalities NEC		
Ageusia	19	0
Dysgeusia	82	0
Electric shock sensation	2	0
Hypogeusia	1	0
Neuralgia	22	0
Post herpetic neuralgia	2	0
Restless legs syndrome	13	0
Sensory disturbance	5	0
Sensory loss	4	0
Taste disorder	14	0
Vibratory sense increased	1	0
Sleep disturbances NEC		
Sleep deficit	1	0
Speech and language abnormalities		
Dysarthria	13	0
Incoherent	3	0
Slow speech	1	0
Speech disorder	4	0
Spinal cord and nerve root disorders NEC		
Radiculopathy	1	0
Transient cerebrovascular events		
Transient ischaemic attack	5	0
Tremor (excl congenital)		
Tremor	120	0
Trigeminal disorders		
Facial neuralgia	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	5384	1

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	18	0
<i>Foetal complications NEC</i>		
Foetal disorder	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	2	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
Morning sickness	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	6	0
<i>Stillbirth and foetal death</i>		
Foetal death	1	1
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	1	0
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	37	1

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device expulsion	1	0
Device leakage	1	0
<i>Product contamination and sterility issues</i>		
Product contamination physical	7	0
<i>Product quality issues NEC</i>		
Product quality issue	1	0
null SOC TOTAL	10	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	7	0
Anxiety	103	0
Nervousness	18	0
Stress	7	0
Tension	5	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	2	0
<i>Behaviour and socialisation disturbances</i>		
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	20	0
<i>Confusion and disorientation</i>		
Confusional state	52	0
Disorientation	22	0
<i>Deliria</i>		
Delirium	10	0
<i>Delusional disorders</i>		
Alice in wonderland syndrome	1	0
<i>Depressive disorders</i>		
Depression	30	0
Depression suicidal	2	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Dissociation	5	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	90	0
Middle insomnia	5	0
Terminal insomnia	6	0
<i>Dyssomnias</i>		
Poor quality sleep	22	0
<i>Eating disorders NEC</i>		
Binge eating	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	6	0
Emotional disorder	8	0
Emotional distress	6	0
Euphoric mood	6	0
Irritability	16	0
Mood altered	4	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
Fear of death	1	0
Fear of injection	5	0
<i>Fluctuating mood symptoms</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Mood swings	8	0
Hallucinations (excl sleep-related)		
Hallucination	28	0
Hallucination, auditory	2	0
Hallucination, visual	1	0
Increased physical activity levels		
Restlessness	19	0
Mental disorders NEC		
Mental disorder	2	0
Mood alterations with depressive symptoms		
Depressed mood	23	0
Feeling of despair	2	0
Tearfulness	2	0
Mood alterations with manic symptoms		
Mania	3	0
Mood disorders NEC		
Apathy	4	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	24	0
Panic reaction	5	0
Parasomnias		
Abnormal dreams	15	0
Nightmare	14	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	3	0
Libido increased	1	0
Loss of libido	1	0
Sleep disorders NEC		
Sleep disorder	11	0
Somatic symptom disorders		
Conversion disorder	1	0
Habit cough	2	0
Speech and language usage disturbances		
Disorganised speech	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	2	0
Lack of spontaneous speech	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>		
Suicidal behaviour	2	0
Suicidal ideation	4	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	681	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	2	0
Micturition urgency	2	0
Pollakiuria	11	0
Urinary incontinence	3	0
Urinary retention	1	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Urinary bladder haemorrhage	2	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
IgA nephropathy	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	2	0
Oliguria	1	0
Renal impairment	2	0
<i>Urinary abnormalities</i>		
Chromaturia	7	0
Haematuria	1	0
Urine abnormality	2	0
Urine odour abnormal	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	4	0
Renal pain	20	0
Renal & urinary disorders SOC TOTAL	71	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	5	0
Fibrocystic breast disease	1	0
<i>Breast signs and symptoms</i>		
Breast discomfort	1	0
Breast pain	35	0
Breast swelling	4	0
Breast tenderness	1	0
Nipple swelling	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Ejaculation failure	2	0
Erectile dysfunction	4	0
Organic erectile dysfunction	1	0
Painful ejaculation	1	0
<i>Gender disorders</i>		
Feminisation acquired	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	5	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	156	0
Intermenstrual bleeding	90	0
Menstrual discomfort	1	0
Menstrual disorder	156	0
Menstruation irregular	253	0
Premenstrual headache	1	0
Premenstrual pain	3	0
Premenstrual syndrome	5	0
Withdrawal bleed	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	37	0
Hypomenorrhoea	54	0
Menstruation delayed	317	0
Oligomenorrhoea	11	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	421	0
Menometrorrhagia	3	0
Polymenorrhoea	53	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	1	0
Polycystic ovaries	2	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation pain	7	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Premature ovulation	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	3	0
Pelvic haemorrhage	1	0
<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
Genital paraesthesia	1	0
Genital ulceration	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	6	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	1	0
Testicular mass	1	0
Testicular pain	5	0
Testicular swelling	1	0
<i>Uterine disorders NEC</i>		
Endometriosis	6	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	115	0
Vulval haemorrhage	5	0
<i>Vulvovaginal signs and symptoms</i>		
Labia enlarged	1	0
Vaginal discharge	6	0
Vulvovaginal discomfort	1	0
Vulvovaginal pain	2	0
Reproductive & breast disorders SOC TOTAL	1829	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	224	0
Dyspnoea exertional	3	0
Hyperventilation	2	0
Hypopnoea	5	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	28	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	123	0
Haemoptysis	1	0
Productive cough	12	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 inflammatory and immunologic conditions</i>		
Pneumonitis	1	0
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	12	0
Pulmonary haemorrhage	1	0
Pulmonary pain	7	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	17	0
<i>Nasal disorders NEC</i>		
Epistaxis	58	0
Nasal oedema	1	0
Nasal pruritus	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	3	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	28	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	5	0
<i>Pleural infections and inflammations</i>		
Pleurisy	2	0
<i>Pneumothorax and pleural effusions NEC</i>		

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Pleural effusion	1	0
Pulmonary hypertension		
Pulmonary hypertension	1	0
Pulmonary oedemas		
Pulmonary congestion	1	0
Pulmonary oedema	1	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	10	0
Respiratory signs and symptoms NEC		
Diaphragmalgia	1	0
Respiratory tract disorders NEC		
Respiratory disorder	1	0
Upper respiratory tract signs and symptoms		
Aphonia	5	0
Catarrh	1	0
Choking	1	0
Dry throat	10	0
Dysphonia	3	0
Increased viscosity of upper respiratory secretion	1	0
Nasal discomfort	3	0
Oropharyngeal discomfort	3	0
Oropharyngeal pain	169	0
Paranasal sinus discomfort	5	0
Rhinalgia	1	0
Rhinorrhoea	40	0
Sinus pain	16	0
Sneezing	8	0
Throat irritation	16	0
Throat tightness	21	0
Upper-airway cough syndrome	1	0
Yawning	1	0
Respiratory disorders SOC TOTAL	893	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	11	0
<i>Alopecias</i>		
Alopecia	13	0
Alopecia areata	1	0
<i>Angioedemas</i>		
Angioedema	16	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	83	0
Hyperhidrosis	241	0
Miliaria	41	0
Night sweats	43	0
<i>Bullous conditions</i>		
Blister	28	0
Blister rupture	1	0
Dermatitis bullous	1	0
Erythema multiforme	9	0
Stevens-Johnson syndrome	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	35	0
Pain of skin	24	0
Papule	10	0
Scab	2	0
Scar pain	1	0
Sensitive skin	39	0
Skin burning sensation	22	0
Skin discolouration	11	0
Skin induration	5	0
Skin lesion	18	0
Skin reaction	64	0
Skin sensitisation	5	0
Skin swelling	11	0
Skin tightness	4	0
Skin warm	113	0
Yellow skin	2	0
<i>Dermatitis and eczema</i>		
Dermatitis	15	0
Dermatitis allergic	60	0
Dermatitis atopic	4	0
Dermatitis contact	2	0
Dyshidrotic eczema	8	0
Eczema	21	0
Eczema nummular	1	0
Skin irritation	12	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	589	0
<i>Exfoliative conditions</i>		
Exfoliative rash	1	0
Skin exfoliation	4	0
<i>Hyperpigmentation disorders</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin hyperpigmentation	1	0
Solar lentigo	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Onychoclasia	1	0
<i>Panniculitides</i>		
Erythema nodosum	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
Pityriasis rosea	2	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	11	0
<i>Pilar disorders NEC</i>		
Piloerection	4	0
<i>Pruritus NEC</i>		
Itching scar	2	0
Pruritus	1312	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
Psoriasis	8	0
<i>Purpura and related conditions</i>		
Petechiae	11	0
Purpura	6	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	1	0
Rash	1488	0
Rash erythematous	603	0
Rash macular	89	0
Rash maculo-papular	1	0
Rash morbilliform	4	0
Rash papular	106	0
Rash pruritic	357	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
Skin mass	4	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin ulcer	1	0
<i>Skin cysts and polyps</i>		
Dermal cyst	3	0
<i>Skin haemorrhages</i>		
Skin haemorrhage	1	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	2	0
<i>Skin injuries and mechanical dermatoses</i>		
Needle track marks	1	0
<i>Skin vasculitides</i>		
Cutaneous vasculitis	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Skin vasomotor conditions</i>		
Livedo reticularis	2	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	1	0
Urticaria	197	0
Urticaria cholinergic	1	0
Urticaria chronic	1	0
Skin disorders SOC TOTAL	5814	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	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	4	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	9	0
Immunisation	8	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	4	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	30	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>Circulatory collapse and shock</i>		
Neurogenic shock	1	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	3	0
Haemorrhage	99	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	4	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	2	0
Thrombosis	40	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	10	0
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	3	0
Flushing	17	0
Hot flush	100	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	22	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	44	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	40	0
Prehypertension	1	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	44	0
Orthostatic hypotension	3	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	454	0
TOTAL REACTIONS FOR DRUG	35207	8
TOTAL REPORTS	11783	

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
TOTAL FATAL OUTCOME REPORTS		8