COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 04-May-2022

Data Lock Date: 20-Apr-2022 18:30:04

All UK spontaneous ADR reports for COVID-19 Vaccine Moderna received from Isle of Man up to and including 20/04/2022.

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.

Report Run Date: 04-May-2022 Data Lock Date: 20-Apr-2022 18:30:04
Earliest Reaction Date: 14-Jun-2021 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Blood disorders		
Lymphatic system disorders NEC		
Lymphadenopathy	6	0
Blood disorders SOC TOTAL	6	0

Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac disorders NEC		
Cardiac disorder	1	0
Cardiac signs and symptoms NEC		
Palpitations	5	0
Noninfectious myocarditis		
Myocarditis	1	0
Rate and rhythm disorders NEC		
Cardiac flutter	1	0
Tachyarrhythmia	1	0
Tachycardia	1	0
Supraventricular arrhythmias		
Atrial fibrillation	1	0
Cardiac disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear discomfort	•	1 0
Eustachian tube disorders		
Eustachian tube obstruction	•	1 0
Hearing losses		
Deafness	•	1 0
Inner ear disorders NEC		
Meniere's disease	•	1 0
Inner ear signs and symptoms		
Tinnitus	•	1 0
Ear disorders SOC TOTAL		5 0

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Reaction Name	Total	Fatal
Eye disorders		
Choroid and vitreous structural change, deposit and degeneration		
Vitreous floaters	1	0
Ocular disorders NEC		
Eye pain	3	0
Visual disorders NEC		
Vision blurred	1	0
Visual impairment and blindness (excl colour blindness)		
Visual impairment	1	0
Eye disorders SOC TOTAL	6	0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Diarrhoea (excl infective)		
Diarrhoea	1	0
Flatulence, bloating and distension		
Flatulence	1	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain upper	1	0
Nausea and vomiting symptoms		
Nausea	8	0
Vomiting	8	0
Oral dryness and saliva altered		
Dry mouth	1	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	2	0
Oral soft tissue swelling and oedema		
Lip swelling	2	0
Tongue signs and symptoms		
Tongue eruption	1	0
Gastrointestinal disorders SOC TOTAL	25	0

Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site extravasation	1	0
Asthenic conditions		
Asthenia	1	0
Fatigue	13	0
Malaise	3	0
Febrile disorders		
Pyrexia	12	0
Feelings and sensations NEC		
Chills	10	0
Feeling cold	3	0
Feeling hot	1	0
Feeling of body temperature change	1	0
General signs and symptoms NEC		
Condition aggravated	1	0
Illness	1	0
Influenza like illness	1	0
Peripheral swelling	4	0
Swelling	3	0
Inflammations		
Inflammation	1	0
Injection site reactions		
Injection site pain	1	0
Mass conditions NEC		
Nodule	1	0
Pain and discomfort NEC		
Axillary pain	5	0
Chest discomfort	1	0
Chest pain	4	0
Pain	4	0
Vaccination site reactions		
Vaccination site pain	1	0
Vaccination site swelling	1	0
General disorders SOC TOTAL	74	0

Reaction Name	Total	Fatal
Infections		
Ear infections		
Labyrinthitis	2	0
Infections NEC		
Infection	1	0
Influenza viral infections		
Influenza	2	0
Upper respiratory tract infections		
Nasopharyngitis	2	0
Infections SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Injuries		
Exposures associated with pregnancy, delivery and lactation		
Maternal exposure during pregnancy	1	0
Nerve injuries NEC		
Nerve injury	2	0
Injuries SOC TOTAL	3	0

Reaction Name	Total	Fatal
Investigations		
Immunology analyses NEC		
Immunology test	1	0
Physical examination procedures and organ system status		
Body temperature	1	0
Investigations SOC TOTAL	2	0

Reaction Name	Total	Fatal
Metabolic disorders		
Fluid intake decreased		
Fluid intake reduced	1	0
General nutritional disorders NEC		
Feeding disorder	1	0
Metabolic disorders SOC TOTAL	2	0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Joint related signs and symptoms		
Arthralgia	5	0
Muscle pains		
Myalgia	7	0
Musculoskeletal and connective tissue conditions NEC		
Musculoskeletal stiffness	2	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	3	0
Limb discomfort	1	0
Neck pain	2	0
Pain in extremity	7	0
Spondyloarthropathies		
Ankylosing spondylitis	1	0
Muscle & tissue disorders SOC TOTAL	28	0

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Reaction Name	Tot	tal_	Fatal
Nervous system disorders			
Coordination and balance disturbances			
Balance disorder		1	0
Disturbances in consciousness NEC			
Lethargy		2	0
Somnolence		1	0
Syncope		1	0
Facial cranial nerve disorders			
Bell's palsy		1	0
Facial spasm		1	0
Headaches NEC			
Headache		15	0
Sinus headache		3	0
Tension headache		1	0
Migraine headaches			
Migraine		6	0
Neurological signs and symptoms NEC			
Dizziness		3	0
Dizziness postural		1	0
Head discomfort		1	0
Presyncope		1	0
Olfactory nerve disorders			
Parosmia		1	0
Paraesthesias and dysaesthesias			
Hypoaesthesia		3	0
Paraesthesia		3	0
Seizures and seizure disorders NEC			
Seizure		1	0
Sensory abnormalities NEC			
Dysgeusia		2	0
Tremor (excl congenital)			
Tremor		2	0
Nervous system disorders SOC TOTAL		50	0

Reaction Name	Total	Fatal
Pregnancy conditions		
Abortions spontaneous		
Abortion spontaneous	1	0
Pregnancy conditions SOC TOTAL	1	0

Reaction Name	Total	Fatal
Psychiatric disorders		
Disturbances in initiating and maintaining sleep		
Insomnia	1	0
Dyssomnias		
Poor quality sleep	1	0
Emotional and mood disturbances NEC		
Anger	1	0
Mood altered	1	0
Mood alterations with depressive symptoms		
Depressed mood	1	0
Sleep disorders NEC		
Sleep disorder	1	0
Psychiatric disorders SOC TOTAL	6	0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Menstruation and uterine bleeding NEC		
Intermenstrual bleeding	1	0
Menstruation irregular	1	0
Menstruation with decreased bleeding		
Menstruation delayed	1	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	3	0
Polymenorrhoea	1	0
Ovarian and fallopian tube cysts and neoplasms		
Polycystic ovaries	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	1	0
Reproductive & breast disorders SOC TOTAL	9	0

Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	7	0
Coughing and associated symptoms		
Productive cough	1	0
Pulmonary thrombotic and embolic conditions		
Pulmonary thrombosis	1	0
Upper respiratory tract signs and symptoms		
Oropharyngeal pain	1	0
Rhinorrhoea	1	0
Respiratory disorders SOC TOTAL	11	0

Reaction Name	Total	Fatal
Skin disorders		
Apocrine and eccrine gland disorders		
Cold sweat	1	0
Hyperhidrosis	2	0
Dermal and epidermal conditions NEC		
Pain of skin	1	0
Papule	1	0
Sensitive skin	1	0
Skin lesion	1	0
Erythemas		
Erythema	2	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	1	0
Pruritus NEC		
Pruritus	4	0
Rashes, eruptions and exanthems NEC		
Rash	2	0
Rash erythematous	1	0
Urticarias		
Urticaria	1	0
Skin disorders SOC TOTAL	18	0

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Reaction Name	Total	Fatal
Vascular disorders		
Haemorrhages NEC		
Haemorrhage	1	0
Vascular disorders SOC TOTAL	1	0
TOTAL REACTIONS FOR DRUG	265	0
TOTAL REPORTS	86	