

FOI 22-817 COVID-19 Vaccine Moderna Analysis Print

Report Run Date: 04-Aug-2022
Data Lock Date: 27-Jul-2022 18:30:04

All suspected spontaneous reports from Isle of Man received up to and including 27/07/2022 for the 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

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Report Run Date: 04-Aug-2022
Earliest Reaction Date: 14-Jun-2021

Data Lock Date: 27-Jul-2022 18:30:04
MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	6	0
Blood disorders SOC TOTAL	6	0

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

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

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

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1	0
<i>Flatulence, bloating and distension</i>		
Flatulence	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain upper	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	8	0
Vomiting	10	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
<i>Tongue signs and symptoms</i>		
Tongue eruption	1	0
Gastrointestinal disorders SOC TOTAL	27	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site extravasation	1	0
<i>Asthenic conditions</i>		
Asthenia	1	0
Fatigue	14	0
Malaise	4	0
<i>Febrile disorders</i>		
Pyrexia	12	0
<i>Feelings and sensations NEC</i>		
Chills	11	0
Feeling cold	3	0
Feeling hot	1	0
Feeling of body temperature change	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Illness	1	0
Influenza like illness	1	0
Peripheral swelling	4	0
Swelling	3	0
<i>Inflammations</i>		
Inflammation	1	0
<i>Injection site reactions</i>		
Injection site pain	1	0
<i>Mass conditions NEC</i>		
Nodule	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	5	0
Chest discomfort	2	0
Chest pain	4	0
Pain	4	0
<i>Vaccination site reactions</i>		
Vaccination site pain	1	0
Vaccination site swelling	1	0
General disorders SOC TOTAL	78	0

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Reaction Name	Total	Fatal
Infections		
<i>Ear infections</i>		
Labyrinthitis	2	0
<i>Infections NEC</i>		
Infection	1	0
<i>Influenza viral infections</i>		
Influenza	2	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	2	0
Infections SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during pregnancy	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat stroke	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	2	0
Injuries SOC TOTAL	4	0

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

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

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Joint related signs and symptoms</i>		
Arthralgia	5	0
<i>Muscle pains</i>		
Myalgia	7	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	2	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	4	0
Limb discomfort	1	0
Neck pain	2	0
Pain in extremity	7	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	1	0
Muscle & tissue disorders SOC TOTAL	29	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Coordination and balance disturbances</i>		
Balance disorder	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	2	0
Somnolence	1	0
Syncope	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	2	0
Facial spasm	1	0
<i>Headaches NEC</i>		
Headache	16	0
Sinus headache	3	0
Tension headache	1	0
<i>Migraine headaches</i>		
Migraine	6	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	3	0
Dizziness postural	1	0
Head discomfort	1	0
Presyncope	1	0
<i>Olfactory nerve disorders</i>		
Parosmia	1	0
<i>Paraesthesias and dysaesthesias</i>		
Hypoaesthesia	3	0
Paraesthesia	3	0
<i>Seizures and seizure disorders NEC</i>		
Seizure	1	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	2	0
<i>Tremor (excl congenital)</i>		
Tremor	2	0
Nervous system disorders SOC TOTAL	52	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
Pregnancy conditions SOC TOTAL	1	0

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

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Menstruation and uterine bleeding NEC</i>		
Intermenstrual bleeding	1	0
Menstruation irregular	1	0
<i>Menstruation with decreased bleeding</i>		
Menstruation delayed	1	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	4	0
Polymenorrhoea	1	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Polycystic ovaries	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1	0
Reproductive & breast disorders SOC TOTAL	10	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	8	0
<i>Coughing and associated symptoms</i>		
Cough	1	0
Productive cough	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary thrombosis	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	1	0
Rhinorrhoea	1	0
Respiratory disorders SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	2	0
<i>Bullous conditions</i>		
Erythema multiforme	1	0
<i>Dermal and epidermal conditions NEC</i>		
Pain of skin	1	0
Papule	1	0
Sensitive skin	1	0
Skin lesion	1	0
<i>Erythemas</i>		
Erythema	3	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	5	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	2	0
Rash erythematous	1	0
<i>Urticarias</i>		
Urticaria	1	0
Skin disorders SOC TOTAL	21	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Haemorrhages NEC</i>		
Haemorrhage	1	0
Vascular disorders SOC TOTAL	1	0
TOTAL REACTIONS FOR DRUG	282	0
TOTAL REPORTS	92	