

Case Series Drug Analysis Print

Name: FOI 23/857 - COVID-19 Vaccine Moderna Isle of Man DAP

Report Run Date: 29-Nov-2023
Data Lock Date: 15-Nov-2023 18:30:06
Earliest Reaction Date: 14-Jun-2021
MedDRA Version: MedDRA 26.1

FOI 23/857 - COVID-19 Vaccine Moderna Isle of Man DAP: All spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the COVID-19 Vaccine Moderna from the Isle of Man received up to and including 15/11/2023.

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Name: FOI 23/857 - COVID-19 Vaccine Moderna Isle of Man DAP

Report Run Date: 29-Nov-2023

Data Lock Date: 22-Nov-2023 18:30:06

Earliest Reaction Date: 14-Jun-2021

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	7	0
Blood disorders SOC TOTAL	7	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	2	0
Cardiac disorders SOC TOTAL	12	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
Endocrine disorders		
<i>Female gonadal function disorders</i>		
Polycystic ovarian syndrome	1	0
Endocrine disorders SOC TOTAL	1	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>		
Blindness	1	0
Visual impairment	1	0
Eye disorders SOC TOTAL	7	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	9	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	26	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	3	0
<i>Febrile disorders</i>		
Pyrexia	12	0
<i>Feelings and sensations NEC</i>		
Chills	12	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	5	0
<i>Vaccination site reactions</i>		
Vaccination site pain	1	0
Vaccination site swelling	1	0
General disorders SOC TOTAL	79	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	1	0
Immune system disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Infections		
<i>Coronavirus infections</i>		
COVID-19	1	0
<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	9	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>Nerve injuries NEC</i>		
Nerve injury	2	0
Injuries SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Investigations		
<i>Heart rate and pulse investigations</i>		
Heart rate	1	0
<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	3	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	7	0
<i>Muscle pains</i>		
Myalgia	6	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	1	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	1	0
Pain in extremity	5	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	1	0
Muscle & tissue disorders SOC TOTAL	28	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	17	0
Sinus headache	3	0
Tension headache	1	0
<i>Migraine headaches</i>		
Migraine	5	0
<i>Neurological signs and symptoms NEC</i>		
Brain fog	1	0
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	53	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>Cognitive and attention disorders and disturbances NEC</i>		
Mental fatigue	1	0
<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	7	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>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1	0
Reproductive & breast disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
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
Night sweats	1	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	2	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	4	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	20	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Haemorrhages NEC</i>		
Haemorrhage	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
Vascular disorders SOC TOTAL	2	0
TOTAL REACTIONS FOR DRUG	288	0
TOTAL REPORTS	96	