

Case Series Drug Analysis Print
Name: COVID-19 Vaccine Moderna

Report Run Date: 13-Dec-2021

Data Lock Date: 12-Dec-2021 18:30:04

Earliest Reaction Date: 14-Jun-2021

MedDRA Version: MedDRA 24.1

COVID-19 Vaccine Moderna: FOI 21/1280 - Spontaneous ADR reports for COVID-19 Vaccine Moderna received from Isle of Man up to and including 12/12/2021

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Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	5	0
Blood disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Cardiac disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	1	0
<i>Hearing losses</i>		
Deafness	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	1	0
Ear disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Ocular disorders NEC</i>		
Eye pain	2	0
Eye disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain upper	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	6	0
Vomiting	7	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
Gastrointestinal disorders SOC TOTAL	17	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	6	0
Malaise	1	0
<i>Febrile disorders</i>		
Pyrexia	8	0
<i>Feelings and sensations NEC</i>		
Chills	9	0
Feeling cold	1	0
Feeling of body temperature change	1	0
<i>General signs and symptoms NEC</i>		
Illness	1	0
Influenza like illness	1	0
Peripheral swelling	2	0
Swelling	1	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	3	0
Chest pain	1	0
Pain	4	0
<i>Vaccination site reactions</i>		
Vaccination site swelling	1	0
General disorders SOC TOTAL	45	0

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Reaction Name	Total	Fatal
Infections		
<i>Influenza viral infections</i>		
Influenza	2	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	2	0
Infections SOC TOTAL	4	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	1	0
Injuries SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Investigations		
<i>Physical examination procedures and organ system status</i>		
Body temperature	1	0
Investigations SOC TOTAL	1	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	3	0
<i>Muscle pains</i>		
Myalgia	4	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	2	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	2	0
Limb discomfort	1	0
Neck pain	2	0
Pain in extremity	3	0
Muscle & tissue disorders SOC TOTAL	17	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Disturbances in consciousness NEC</i>		
Lethargy	1	0
Somnolence	1	0
Syncope	1	0
<i>Facial cranial nerve disorders</i>		
Facial spasm	1	0
<i>Headaches NEC</i>		
Headache	10	0
Sinus headache	2	0
<i>Migraine headaches</i>		
Migraine	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	2	0
Dizziness postural	1	0
Head discomfort	1	0
Presyncope	1	0
<i>Paraesthesias and dysaesthesias</i>		
Hypoaesthesia	3	0
Paraesthesia	2	0
<i>Seizures and seizure disorders NEC</i>		
Seizure	1	0
<i>Tremor (excl congenital)</i>		
Tremor	2	0
Nervous system disorders SOC TOTAL	30	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<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	5	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	2	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Polycystic ovaries	1	0
Reproductive & breast disorders SOC TOTAL	6	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	3	0
<i>Coughing and associated symptoms</i>		
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	7	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	1	0
<i>Dermal and epidermal conditions NEC</i>		
Papule	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	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	2	0
Rash erythematous	1	0
Skin disorders SOC TOTAL	12	0
TOTAL REACTIONS FOR DRUG	160	0
TOTAL REPORTS	46	