

Case Series Drug Analysis Print

Name: FOI 22/875 - Pfizer/BioNTech Vaccine - Jersey

Report Run Date: 15-Aug-2022

FOI 22/875 - Pfizer/BioNTech Vaccine - Jersey: All UK Spontaneously received Adverse Drug Reaction (ADR) reports received upto 04/08/2022 associated with the Pfizer/BioNTech COVID-19 Vaccine reported from within Jersey

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.

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Leukytoses NEC</i>		
Neutrophilia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	3	0
Lymphadenopathy	16	0
<i>Neutropenias</i>		
Neutropenia	1	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	22	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiovascular disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	7	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	1	0
Tachycardia	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Sinus tachycardia	1	0
Supraventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	1	0
<i>Hearing losses</i>		
Deafness	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	5	0
Vertigo	4	0
Ear disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Female gonadal function disorders</i>		
Anovulatory cycle	1	0
Ovulation delayed	1	0
Endocrine disorders SOC TOTAL	2	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>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Ocular disorders NEC</i>		
Eye swelling	2	0
<i>Ocular sensation disorders</i>		
Photophobia	3	0
<i>Visual disorders NEC</i>		
Vision blurred	3	0
Eye disorders SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	9	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	2	0
Abdominal pain upper	2	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	26	0
Vomiting	8	0
<i>Oral soft tissue signs and symptoms</i>		
Oral pain	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
Gastrointestinal disorders SOC TOTAL	55	0

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Reaction Name	Total	Fatal
General disorders		
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
<i>Asthenic conditions</i>		
Asthenia	2	0
Fatigue	28	0
Malaise	8	0
<i>Febrile disorders</i>		
Pyrexia	22	0
<i>Feelings and sensations NEC</i>		
Chills	12	0
Feeling abnormal	1	0
Feeling hot	1	0
Sense of oppression	1	0
<i>General signs and symptoms NEC</i>		
Influenza like illness	2	0
Peripheral swelling	3	0
Swelling	4	0
Swelling face	1	0
<i>Inflammations</i>		
Inflammation	2	0
<i>Injection site reactions</i>		
Injection site pain	4	0
<i>Mass conditions NEC</i>		
Nodule	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	2	0
Chest discomfort	4	0
Chest pain	6	0
Discomfort	1	0
Facial pain	1	0
Pain	8	0
Tenderness	1	0
<i>Therapeutic and nontherapeutic responses</i>		
Therapeutic response unexpected	1	0
<i>Vaccination site reactions</i>		
Vaccination site erythema	1	0
Vaccination site pain	1	0
Vaccination site swelling	1	0
Vaccination site warmth	1	0
General disorders SOC TOTAL	121	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	4	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
Immune system disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Infections		
<i>Coronavirus infections</i>		
COVID-19	3	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
<i>Herpes viral infections</i>		
Herpes zoster	4	0
Oral herpes	1	0
<i>Infections NEC</i>		
Infection	1	0
<i>Influenza viral infections</i>		
Influenza	1	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	1	0
Pneumonia	1	1
<i>Skin structures and soft tissue infections</i>		
Rash pustular	1	0
<i>Staphylococcal infections</i>		
Furuncle	1	0
<i>Upper respiratory tract infections</i>		
Sinusitis	1	0
Infections SOC TOTAL	16	1

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Foetal exposure during pregnancy	1	0
Maternal exposure during breast feeding	2	0
Maternal exposure during pregnancy	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	1	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	1	0
<i>Skin injuries NEC</i>		
Contusion	1	0
Injuries SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Investigations		
<i>Physical examination procedures and organ system status</i>		
Body temperature increased	1	0
<i>Platelet analyses</i>		
Platelet count	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure increased	1	0
Investigations SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	1	0
Metabolic disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	2	0
Rheumatic fever	1	0
<i>Cartilage disorders</i>		
Costochondritis	1	0
<i>Joint related disorders NEC</i>		
Periarthritis	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	6	0
Joint swelling	2	0
Joint vibration	1	0
<i>Muscle pains</i>		
Myalgia	18	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	3	0
Muscle twitching	2	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	2	0
Limb discomfort	1	0
Neck pain	4	0
Pain in extremity	15	0
Muscle & tissue disorders SOC TOTAL	60	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Hepatic neoplasms malignant</i>		
Hepatocellular carcinoma	1	0
Neoplasms SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	1	0
Lacunar stroke	1	0
<i>Coordination and balance disturbances</i>		
Dysstasia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	2	0
Somnolence	1	0
<i>Facial cranial nerve disorders</i>		
Facial spasm	1	0
<i>Headaches NEC</i>		
Headache	28	0
Sinus headache	1	0
<i>Memory loss (excl dementia)</i>		
Memory impairment	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	1	0
<i>Migraine headaches</i>		
Migraine	7	0
Migraine with aura	1	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	1	0
<i>Neurological signs and symptoms NEC</i>		
Clonus	1	0
Dizziness	9	0
Presyncope	1	0
<i>Olfactory nerve disorders</i>		
Anosmia	2	0
Parosmia	1	0
<i>Paraesthesias and dysaesthesias</i>		
Hypoaesthesia	1	0
Paraesthesia	4	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	1	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	1	0
Febrile convulsion	1	0
Seizure	2	0
<i>Sensory abnormalities NEC</i>		
Ageusia	1	0
Dysgeusia	2	0
Neuralgia	1	0
Restless legs syndrome	1	0
Sensory disturbance	1	0
Taste disorder	1	0
Nervous system disorders SOC TOTAL	79	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
<i>Maternal complications of pregnancy NEC</i>		
Biochemical pregnancy	1	0
<i>Stillbirth and foetal death</i>		
Stillbirth	1	1
Pregnancy conditions SOC TOTAL	3	1

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Anxiety	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	2	0
<i>Increased physical activity levels</i>		
Restlessness	1	0
<i>Mood disorders NEC</i>		
Listless	1	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
<i>Sexual desire disorders</i>		
Loss of libido	1	0
<i>Stereotypies and automatisms</i>		
Automatism	1	0
Psychiatric disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	1	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	3	0
Menstrual disorder	3	0
Menstruation irregular	3	0
<i>Menstruation with decreased bleeding</i>		
Hypomenorrhoea	1	0
Menstruation delayed	8	0
Oligomenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	11	0
Polymenorrhoea	2	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	1	0
<i>Uterine disorders NEC</i>		
Endometriosis	1	0
Uterine pain	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1	0
Reproductive & breast disorders SOC TOTAL	39	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	8	0
<i>Bronchospasm and obstruction</i>		
Wheezing	1	0
<i>Coughing and associated symptoms</i>		
Cough	9	0
Productive cough	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	3	0
<i>Nasal disorders NEC</i>		
Epistaxis	2	0
<i>Upper respiratory tract signs and symptoms</i>		
Increased viscosity of upper respiratory secretion	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	6	0
Rhinorrhoea	3	0
Sneezing	1	0
Throat tightness	2	0
Respiratory disorders SOC TOTAL	39	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Alopecias</i>		
Alopecia	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	1	0
Night sweats	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	1	0
Skin burning sensation	1	0
Skin warm	2	0
<i>Dermatitis and eczema</i>		
Seborrhoeic dermatitis	1	0
<i>Erythemas</i>		
Erythema	1	0
<i>Pruritus NEC</i>		
Pruritus	3	0
<i>Purpura and related conditions</i>		
Petechiae	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	8	0
Rash erythematous	2	0
Rash macular	1	0
Rash pruritic	1	0
<i>Urticarias</i>		
Urticaria	1	0
Skin disorders SOC TOTAL	28	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Immunisations</i>		
COVID-19 immunisation	1	0
Surgical & medical procedures SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Haemorrhages NEC</i>		
Arterial haemorrhage	1	0
Haemorrhage	2	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Peripheral vascular disorders NEC</i>		
Hot flush	2	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	2	0
<i>Vascular hypotensive disorders</i>		
Hypotension	3	0
Vascular disorders SOC TOTAL	11	0
TOTAL REACTIONS FOR DRUG	538	2
TOTAL REPORTS	179	
TOTAL FATAL OUTCOME REPORTS		2