

COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 01-Jul-2022
Data Lock Date: 29-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

COVID-19 mRNA Pfizer/BioNTech Vaccine Analysis Print: FOI 22/761 - All suspected spontaneous reports from Guernsey received up to and including 29/06/2022 for the COVID-19 mRNA Pfizer/BioNTech vaccine.

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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Reaction Name	Total	Fatal
Blood disorders		
<i>Leukocytoses NEC</i>		
Neutrophilia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	3	0
Lymphadenopathy	10	0
Blood disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Intracardiac thrombus	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	1	0
Palpitations	9	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	1	0
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Heart failures NEC</i>		
Cardiac failure	1	0
<i>Myocardial disorders NEC</i>		
Ventricular hypokinesia	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	6	0
<i>Noninfectious pericarditis</i>		
Pericarditis	2	0
<i>Pericardial disorders NEC</i>		
Pericardial rub	1	0
<i>Rate and rhythm disorders NEC</i>		
Tachycardia	3	0
<i>Supraventricular arrhythmias</i>		
Atrial flutter	1	0
Cardiac disorders SOC TOTAL	28	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
<i>Hearing losses</i>		
Deafness	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	3	0
Vertigo	2	0
Ear disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid oedema	1	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Ocular vascular disorder	1	0
<i>Ocular disorders NEC</i>		
Eye pain	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	2	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Photopsia	1	0
Vision blurred	2	0
Eye disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	2	0
<i>Flatulence, bloating and distension</i>		
Flatulence	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	1	0
Abdominal pain upper	4	0
Gastrointestinal pain	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	21	0
Vomiting	7	0
<i>Oral dryness and saliva altered</i>		
Salivary hypersecretion	1	0
<i>Oral soft tissue signs and symptoms</i>		
Paraesthesia oral	3	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	1	0
Gastrointestinal disorders SOC TOTAL	46	0

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	3	0
Fatigue	32	0
Malaise	7	0
<i>Body temperature altered</i>		
Temperature regulation disorder	1	0
<i>Death and sudden death</i>		
Death	1	1
<i>Febrile disorders</i>		
Pyrexia	22	0
<i>Feelings and sensations NEC</i>		
Chills	15	0
Feeling abnormal	1	0
Feeling cold	5	0
Feeling hot	1	0
Feeling of body temperature change	1	0
<i>General signs and symptoms NEC</i>		
Illness	1	0
Influenza like illness	3	0
Peripheral swelling	5	0
Swelling	2	0
Swelling face	3	0
<i>Inflammations</i>		
Inflammation	1	0
<i>Injection site reactions</i>		
Injection site pain	4	0
<i>Oedema NEC</i>		
Oedema	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	7	0
Chest discomfort	3	0
Chest pain	10	0
Pain	10	0
<i>Vaccination site reactions</i>		
Vaccination site bruising	1	0
Vaccination site mass	1	0
Vaccination site pain	2	0
<i>Withdrawal and rebound effects</i>		
Withdrawal syndrome	1	0
General disorders SOC TOTAL	144	1

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Reaction Name	Total	Fatal
Infections		
<i>Coronavirus infections</i>		
COVID-19	2	0
<i>Herpes viral infections</i>		
Herpes zoster	5	0
Ophthalmic herpes zoster	1	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	3	0
Pharyngitis	1	0
Tonsillitis	1	0
Infections SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Injuries		
<i>Cerebral injuries NEC</i>		
Brain contusion	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	1	0
Maternal exposure during breast feeding	1	0
Maternal exposure during pregnancy	2	0
<i>Skin injuries NEC</i>		
Contusion	3	0
Scar	1	0
Injuries SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Investigations		
<i>Coagulation and bleeding analyses</i>		
Fibrin D dimer increased	1	0
<i>ECG investigations</i>		
Electrocardiogram ST segment elevation	1	0
Electrocardiogram T wave inversion	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	1	0
Heart rate increased	3	0
Heart rate irregular	1	0
<i>Metabolism tests NEC</i>		
N-terminal prohormone brain natriuretic peptide increased	1	0
<i>Mineral and electrolyte analyses</i>		
Serum ferritin decreased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	1	0
Respiratory rate increased	1	0
Temperature difference of extremities	1	0
Weight decreased	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Troponin increased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure increased	1	0
Investigations SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Type 2 diabetes mellitus	1	0
<i>Disorders of purine metabolism</i>		
Gout	1	0
Metabolic disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Joint related disorders NEC</i>		
Periarthritis	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	7	0
<i>Muscle pains</i>		
Myalgia	13	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	1	0
Muscle spasms	3	0
Muscle twitching	1	0
<i>Muscle tone abnormalities</i>		
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	1	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	1	0
Musculoskeletal stiffness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	2	0
Limb discomfort	4	0
Musculoskeletal chest pain	1	0
Neck pain	1	0
Pain in extremity	15	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
Muscle & tissue disorders SOC TOTAL	54	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified</i>		
NEC		
Lung neoplasm malignant	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	2	0
Ischaemic stroke	1	0
Lacunar infarction	1	0
<i>Coma states</i>		
Coma	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	3	0
Loss of consciousness	1	0
<i>Headaches NEC</i>		
Headache	37	0
Tension headache	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
Memory impairment	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	1	0
<i>Migraine headaches</i>		
Migraine	3	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	8	0
Presyncope	2	0
<i>Neuromuscular disorders NEC</i>		
Muscle spasticity	1	0
<i>Paraesthesias and dysaesthesias</i>		
Hypoaesthesia	6	0
Paraesthesia	4	0
Vibration syndrome	1	0
<i>Parkinson's disease and parkinsonism</i>		
Parkinsonian rest tremor	1	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	3	0
Restless legs syndrome	1	0
Sensory disturbance	1	0
Sensory loss	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	1	0
<i>Tremor (excl congenital)</i>		
Tremor	1	0
Nervous system disorders SOC TOTAL	85	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Normal pregnancy, labour and delivery</i>		
Live birth	1	0
Pregnancy conditions SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Anxiety	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Mental fatigue	1	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	2	0
<i>Emotional and mood disturbances NEC</i>		
Emotional disorder	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	1	0
<i>Stereotypies and automatisms</i>		
Head banging	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	2	0
Breast tenderness	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	6	0
Intermenstrual bleeding	2	0
Menstruation irregular	2	0
Premenstrual headache	1	0
Premenstrual pain	1	0
Premenstrual syndrome	1	0
<i>Menstruation with decreased bleeding</i>		
Menstruation delayed	3	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	4	0
Polymenorrhoea	1	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation pain	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	2	0
Reproductive & breast disorders SOC TOTAL	27	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	11	0
Dyspnoea exertional	1	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	2	1
<i>Coughing and associated symptoms</i>		
Cough	2	0
Haemoptysis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Pulmonary pain	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	3	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal hypoaesthesia	1	0
Tonsillar hypertrophy	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	1	1
<i>Respiratory signs and symptoms NEC</i>		
Pleural rub	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Dysphonia	1	0
Oropharyngeal pain	2	0
Paranasal sinus discomfort	1	0
Throat tightness	1	0
Respiratory disorders SOC TOTAL	31	2

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Reaction Name	Total	Fatal
Skin disorders		
<i>Apocrine and eccrine gland disorders</i>		
Hyperhidrosis	2	0
<i>Bullous conditions</i>		
Blister	1	0
<i>Dermal and epidermal conditions NEC</i>		
Skin sensitisation	1	0
<i>Erythemas</i>		
Erythema	3	0
<i>Papulosquamous conditions</i>		
Pityriasis rosea	1	0
<i>Pruritus NEC</i>		
Pruritus	5	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	4	0
<i>Urticarias</i>		
Urticaria	1	0
Skin disorders SOC TOTAL	18	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Therapeutic procedures NEC</i>		
Injection	1	0
Therapeutic procedure	1	0
Surgical & medical procedures SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Haemorrhages NEC</i>		
Haemorrhage	2	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	2	0
Pelvic venous thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Raynaud's phenomenon	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
Vascular disorders SOC TOTAL	10	0
TOTAL REACTIONS FOR DRUG	531	4
TOTAL REPORTS	176	
TOTAL FATAL OUTCOME REPORTS		4