

## FOI 21/1222 Pfizer/BioNTech Vaccine Analysis Print

All UK spontaneous reports with a Jersey postal code (JE1-5) received up to 01/12/21 for COVID-19 vaccine Pfizer BioNTech.

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

### Name: FOI 21/1222 Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 13-Dec-2021

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

Earliest Reaction Date: 15-Dec-2020

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Leukytoses NEC</i>		
Neutrophilia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	3	0
Lymphadenopathy	14	0
<i>Neutropenias</i>		
Neutropenia	1	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>20</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac disorders NEC</i>		
Cardiovascular disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	6	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
<b>Cardiac disorders SOC TOTAL</b>	<b>12</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Ear disorders</b>		
<i>Hearing losses</i>		
Deafness	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	3	0
Vertigo	4	0
<b>Ear disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Female gonadal function disorders</i>		
Anovulatory cycle	1	0
Ovulation delayed	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<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	2	0
<b>Eye disorders SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<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	1	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	20	0
Vomiting	8	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>47</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Application and instillation site reactions</b></i>		
Application site erythema	1	0
<i><b>Asthenic conditions</b></i>		
Asthenia	2	0
Fatigue	25	0
Malaise	8	0
<i><b>Febrile disorders</b></i>		
Pyrexia	20	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	12	0
Feeling abnormal	1	0
Feeling hot	1	0
<i><b>General signs and symptoms NEC</b></i>		
Influenza like illness	2	0
Peripheral swelling	2	0
Swelling face	1	0
<i><b>Inflammations</b></i>		
Inflammation	2	0
<i><b>Injection site reactions</b></i>		
Injection site pain	3	0
<i><b>Mass conditions NEC</b></i>		
Nodule	1	0
<i><b>Pain and discomfort NEC</b></i>		
Axillary pain	1	0
Chest discomfort	4	0
Chest pain	4	0
Discomfort	1	0
Facial pain	1	0
Pain	7	0
Tenderness	1	0
<i><b>Therapeutic and nontherapeutic responses</b></i>		
Therapeutic response unexpected	1	0
<i><b>Vaccination site reactions</b></i>		
Vaccination site erythema	1	0
Vaccination site pain	1	0
Vaccination site swelling	1	0
Vaccination site warmth	1	0
<b>General disorders SOC TOTAL</b>	<b>105</b>	<b>0</b>



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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Immune system disorders</b>		
<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	3	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>6</b>	<b>0</b>

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<b>Infections</b>		
<i>Coronavirus infections</i>		
COVID-19	2	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
<b>Infections SOC TOTAL</b>	<b>15</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	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
<b>Injuries SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<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
<b>Investigations SOC TOTAL</b>	<b>3</b>	<b>0</b>

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

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	1	0
Rheumatic fever	1	0
<i><b>Cartilage disorders</b></i>		
Costochondritis	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	6	0
Joint swelling	2	0
<i><b>Muscle pains</b></i>		
Myalgia	18	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle spasms	2	0
Muscle twitching	2	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Musculoskeletal stiffness	1	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	2	0
Limb discomfort	1	0
Neck pain	2	0
Pain in extremity	15	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>54</b>	<b>0</b>

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

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	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	24	0
Sinus headache	1	0
<i>Migraine headaches</i>		
Migraine	7	0
Migraine with aura	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
<i>Paraesthesias and dysaesthesias</i>		
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>		
Seizure	1	0
<i>Sensory abnormalities NEC</i>		
Ageusia	1	0
Dysgeusia	1	0
Neuralgia	1	0
Restless legs syndrome	1	0
Sensory disturbance	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>64</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<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>Stereotypies and automatisms</i>		
Automatism	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	2	0
Menstrual disorder	3	0
Menstruation irregular	2	0
<i>Menstruation with decreased bleeding</i>		
Hypomenorrhoea	1	0
Menstruation delayed	6	0
Oligomenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	11	0
Polymenorrhoea	2	0
<i>Uterine disorders NEC</i>		
Endometriosis	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>30</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i>Breathing abnormalities</i>		
Dyspnoea	6	0
<i>Coughing and associated symptoms</i>		
Cough	8	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 pain	6	0
Rhinorrhoea	3	0
Sneezing	1	0
Throat tightness	2	0
<b>Respiratory disorders SOC TOTAL</b>	<b>34</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i><b>Alopecias</b></i>		
Alopecia	1	0
<i><b>Apocrine and eccrine gland disorders</b></i>		
Cold sweat	1	0
Hyperhidrosis	1	0
Night sweats	1	0
<i><b>Dermal and epidermal conditions NEC</b></i>		
Dry skin	1	0
Skin burning sensation	1	0
Skin warm	2	0
<i><b>Erythemas</b></i>		
Erythema	1	0
<i><b>Pruritus NEC</b></i>		
Pruritus	3	0
<i><b>Purpura and related conditions</b></i>		
Petechiae	2	0
<i><b>Rashes, eruptions and exanthems NEC</b></i>		
Rash	6	0
Rash erythematous	2	0
Rash macular	1	0
Rash pruritic	1	0
<i><b>Urticarias</b></i>		
Urticaria	1	0
<b>Skin disorders SOC TOTAL</b>	<b>25</b>	<b>0</b>

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

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<b>Vascular disorders</b>		
<i><b>Haemorrhages NEC</b></i>		
Arterial haemorrhage	1	0
Haemorrhage	1	0
<i><b>Lymphoedemas</b></i>		
Lymphoedema	1	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Hot flush	2	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	2	0
<i><b>Vascular hypotensive disorders</b></i>		
Hypotension	3	0
<b>Vascular disorders SOC TOTAL</b>	<b>10</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>459</b>	<b>1</b>
<b>TOTAL REPORTS</b>	<b>147</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>1</b>