

Case Series Drug Analysis Print

Name: FOI 24/307 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch FM3092)

Report Run Date: 23-Apr-2024
Data Lock Date: 22-Apr-2024 18:30:03
Earliest Reaction Date: 26-Jan-2021
MedDRA Version: MedDRA 26.1

FOI 24/307 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch FM3092): FOI 24/307 All UK spontaneous Yellow card reports for COVID-19 Pfizer-BioNTech vaccine (batch FM3092) received up until 15/04/2024

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	4	0
Lymphadenopathy	27	0
Blood disorders SOC TOTAL	32	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	18	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	2	0
Myocardial infarction	2	0
<i>Myocardial disorders NEC</i>		
Myocardial injury	1	0
<i>Noninfectious pericarditis</i>		
Pericarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Extrasystoles	1	0
Tachycardia	6	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	4	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
Cardiac disorders SOC TOTAL	37	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	3	0
<i>Hearing losses</i>		
Deafness	1	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	6	0
Vertigo	4	0
Ear disorders SOC TOTAL	15	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Thyroid disorders NEC</i>		
Thyroid pain	1	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	1	0
Endocrine disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	2	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye pain	3	0
Eye swelling	5	0
Periorbital oedema	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	1	0
<i>Visual disorders NEC</i>		
Vision blurred	2	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	1	0
Eye disorders SOC TOTAL	19	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	10	0
<i>Diverticula</i>		
Diverticulum	1	0
<i>Dyspeptic signs and symptoms</i>		
Eructation	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain upper	4	0
Abdominal rigidity	1	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	2	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	3	0
Anal incontinence	1	0
Dysphagia	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	28	0
Vomiting	13	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	1	0
Paraesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
Mouth swelling	1	0
Palatal swelling	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	1	0
Gastrointestinal disorders SOC TOTAL	76	0

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	11	0
Fatigue	48	0
Malaise	16	0
<i>Febrile disorders</i>		
Pyrexia	34	0
<i>Feelings and sensations NEC</i>		
Chills	24	0
Feeling abnormal	5	0
Feeling cold	5	0
Feeling hot	5	0
Feeling of body temperature change	2	0
Thirst	1	0
<i>Gait disturbances</i>		
Gait disturbance	1	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	2	0
Illness	6	0
Influenza like illness	6	0
Local reaction	1	0
Peripheral swelling	13	0
Swelling	4	0
Swelling face	3	0
<i>Implant and catheter site reactions</i>		
Implant site reaction	1	0
<i>Inflamations</i>		
Inflammation	2	0
<i>Injection site reactions</i>		
Injection site erythema	3	0
Injection site mass	1	0
Injection site pain	10	0
Injection site pruritus	3	0
Injection site swelling	1	0
Injection site warmth	1	0
<i>Interactions</i>		
Drug interaction	1	0
<i>Mass conditions NEC</i>		
Cyst	1	0
Mass	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	12	0
Chest discomfort	2	0
Chest pain	16	0
Discomfort	1	0
Pain	13	0
Tenderness	3	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	1	0
Drug ineffective	2	0
Vaccination failure	1	0
<i>Vaccination site reactions</i>		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Shoulder injury related to vaccine administration	1	0
Vaccination site pain	2	0
General disorders SOC TOTAL	267	0

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
Hepatic disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	1	0
<i>Transplant rejections</i>		
Kidney transplant rejection	1	0
Immune system disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Cellulitis	1	0
<i>Coronavirus infections</i>		
COVID-19	5	0
<i>Herpes viral infections</i>		
Herpes simplex	1	0
Herpes zoster	4	0
<i>Infections NEC</i>		
Infection	1	0
<i>Influenza viral infections</i>		
Influenza	9	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	2	0
Pneumonia	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
<i>Staphylococcal infections</i>		
Furuncle	1	0
<i>Urinary tract infections</i>		
Urinary tract infection	1	0
<i>Viral infections NEC</i>		
Viral infection	1	0
Infections SOC TOTAL	28	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	3	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	2	0
<i>Nerve injuries NEC</i>		
Nerve injury	1	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
<i>Off label uses</i>		
Off label use	7	0
<i>Product administration errors and issues</i>		
Expired product administered	1	0
Inappropriate schedule of product administration	1	0
Incorrect dose administered	3	0
<i>Skin injuries NEC</i>		
Contusion	1	0
<i>Thermal burns</i>		
Thermal burn	1	0
<i>Vaccination related complications</i>		
Immunisation reaction	1	0
Injuries SOC TOTAL	22	0

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Reaction Name	Total	Fatal
Investigations		
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose increased	1	0
<i>Central nervous system imaging procedures</i>		
Magnetic resonance imaging head	1	0
<i>Fertility analyses and other reproductive function procedures</i>		
Sperm concentration decreased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	3	0
Heart rate decreased	2	0
Heart rate increased	3	0
Heart rate irregular	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature increased	4	0
Weight decreased	2	0
<i>White blood cell analyses</i>		
Neutrophil count decreased	1	0
Investigations SOC TOTAL	19	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	8	0
<i>Total fluid volume increased</i>		
Fluid retention	1	0
Metabolic disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	3	0
Pain in jaw	2	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	16	0
Joint stiffness	2	0
Joint swelling	3	0
<i>Muscle pains</i>		
Myalgia	17	0
<i>Muscle weakness conditions</i>		
Muscular weakness	2	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	2	0
Musculoskeletal stiffness	3	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	4	0
Limb discomfort	1	0
Pain in extremity	23	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
<i>Soft tissue disorders NEC</i>		
Neck mass	1	0
Muscle & tissue disorders SOC TOTAL	83	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	2	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebrovascular disorder	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	2	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	6	0
Loss of consciousness	1	0
Somnolence	4	0
Syncope	13	0
<i>Dyskinesias and movement disorders NEC</i>		
Movement disorder	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	1	0
Facial paralysis	3	0
<i>Headaches NEC</i>		
Exertional headache	1	0
Headache	48	0
Sinus headache	1	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	2	0
Mental impairment	1	0
<i>Migraine headaches</i>		
Migraine	9	0
Migraine with aura	1	0
<i>Neurologic visual problems NEC</i>		
Hemianopia homonymous	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	16	0
Dizziness postural	1	0
Neurological symptom	1	0
Presyncope	1	0
Unresponsive to stimuli	1	0
<i>Olfactory nerve disorders</i>		
Anosmia	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	2	0
Hypoaesthesia	4	0
Paraesthesia	6	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	1	0
Hemiplegia	1	0
<i>Seizures and seizure disorders NEC</i>		
Partial seizures	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Seizure	2	0
Sensory abnormalities NEC		
Aura	1	0
Dysgeusia	3	0
Sensory disturbance	2	0
Sensory loss	2	0
Transient cerebrovascular events		
Transient ischaemic attack	1	0
Tremor (excl congenital)		
Tremor	9	0
Nervous system disorders SOC TOTAL	158	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Anxiety	1	0
<i>Confusion and disorientation</i>		
Confusional state	2	0
Disorientation	1	0
<i>Deliria</i>		
Delirium	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	4	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	2	0
Psychiatric disorders SOC TOTAL	15	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Pollakiuria	1	0
<i>Renal failure and impairment</i>		
Renal impairment	2	0
<i>Urinary abnormalities</i>		
Haematuria	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	1	0
Renal & urinary disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
Breast tenderness	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Menstrual disorder	3	0
Menstruation irregular	1	0
<i>Menstruation with decreased bleeding</i>		
Menstruation delayed	7	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	2	0
Polymenorrhoea	2	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovarian hyperstimulation syndrome	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular swelling	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	3	0
Reproductive & breast disorders SOC TOTAL	23	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	17	0
Orthopnoea	1	0
<i>Bronchospasm and obstruction</i>		
Chronic obstructive pulmonary disease	1	0
Wheezing	1	0
<i>Coughing and associated symptoms</i>		
Cough	4	0
<i>Nasal disorders NEC</i>		
Epistaxis	4	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	5	0
Rhinorrhoea	3	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	3	0
Alopecia areata	2	0
<i>Angioedemas</i>		
Angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	2	0
Hyperhidrosis	6	0
Miliaria	1	0
Night sweats	2	0
<i>Bullous conditions</i>		
Blister	1	0
Blood blister	1	0
<i>Dermal and epidermal conditions NEC</i>		
Pain of skin	1	0
Scab	1	0
Sensitive skin	2	0
Skin warm	1	0
<i>Erythemas</i>		
Erythema	6	0
<i>Pruritus NEC</i>		
Pruritus	10	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	12	0
Rash erythematous	1	0
Rash macular	1	0
Rash pruritic	2	0
Rash vesicular	2	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin erosion	1	0
Skin ulcer	1	0
<i>Skin cysts and polyps</i>		
Dermal cyst	1	0
<i>Urticarias</i>		
Urticaria	9	0
Skin disorders SOC TOTAL	70	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Loss of personal independence in daily activities	1	0
Social circumstances SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Immunisations</i>		
Immunisation	6	0
<i>Mastectomies</i>		
Breast conserving surgery	1	0
<i>Therapeutic procedures NEC</i>		
Interchange of vaccine products	5	0
Surgical & medical procedures SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Aneurysms and dissections non-site specific</i>		
Artery dissection	1	0
<i>Haemorrhages NEC</i>		
Haemorrhage	3	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	2	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	2	0
<i>Peripheral vascular disorders NEC</i>		
Hot flush	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	1	0
<i>Varicose veins NEC</i>		
Varicose vein	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
Vascular disorders SOC TOTAL	12	0
TOTAL REACTIONS FOR DRUG	953	0
TOTAL REPORTS	292	