

Case Series Drug Analysis Print

Name: FOI 24/307 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch GD6797)

Report Run Date: 23-Apr-2024
Data Lock Date: 22-Apr-2024 18:30:03
Earliest Reaction Date: 05-Nov-2021
MedDRA Version: MedDRA 26.1

FOI 24/307 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch GD6797): FOI 24/307 All UK spontaneous Yellow card reports for COVID-19 Pfizer-BioNTech vaccine (batch GD6797) received up until 15/04/2024

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Reaction Name	Total	Fatal
Blood disorders		
<i>Bleeding tendencies</i>		
Increased tendency to bruise	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	2	0
Lymphadenitis	1	0
Lymphadenopathy	9	0
Blood disorders SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	6	0
<i>Ischaemic coronary artery disorders</i>		
Angina unstable	1	0
<i>Rate and rhythm disorders NEC</i>		
Cardiac flutter	1	0
Tachycardia	3	0
Cardiac disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Inner ear signs and symptoms</i>		
Vertigo positional	1	0
Ear disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid margin crusting	1	0
Swelling of eyelid	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
Eye disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	6	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain upper	1	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Irritable bowel syndrome	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	8	0
Vomiting	3	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
Gastrointestinal disorders SOC TOTAL	28	0

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Fatigue	17	0
Malaise	6	0
<i>Febrile disorders</i>		
Pyrexia	8	0
<i>Feelings and sensations NEC</i>		
Chills	1	0
Feeling abnormal	2	0
Feeling of body temperature change	1	0
<i>Gait disturbances</i>		
Gait disturbance	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Illness	2	0
Peripheral swelling	2	0
Swelling	4	0
Swelling face	2	0
<i>Injection site reactions</i>		
Injection site mass	1	0
Injection site pain	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	4	0
Chest discomfort	3	0
Chest pain	8	0
Discomfort	1	0
Pain	6	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	9	0
Therapeutic response unexpected	2	0
<i>Vaccination site reactions</i>		
Vaccination site pain	1	0
General disorders SOC TOTAL	84	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	1	0
Immune system disorders SOC TOTAL	1	0

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Infections		
<i>Coronavirus infections</i>		
COVID-19	1	0
<i>Herpes viral infections</i>		
Herpes zoster	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	1	0
<i>Urinary tract infections</i>		
Cystitis	1	0
<i>Viral infections NEC</i>		
Vestibular neuronitis	1	0
Infections SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Injuries		
<i>Cerebral injuries NEC</i>		
Craniocerebral injury	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
Product use issue	1	0
<i>Product administration errors and issues</i>		
Product administered at inappropriate site	1	0
Injuries SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation abnormal	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	2	0
Heart rate increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	1	0
Investigations SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	3	0
<i>General nutritional disorders NEC</i>		
Feeding disorder	1	0
<i>Lipid metabolism and deposit disorders NEC</i>		
Lipoedema	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
<i>Extremity deformities</i>		
Foot deformity	1	0
Knee deformity	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	12	0
Joint stiffness	2	0
Joint swelling	1	0
<i>Muscle pains</i>		
Myalgia	2	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	1	0
Muscle tightness	1	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	2	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	4	0
Limb discomfort	3	0
Pain in extremity	8	0
Muscle & tissue disorders SOC TOTAL	39	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Skin neoplasms benign</i>		
Skin papilloma	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>		
Middle cerebral artery stroke	1	1
<i>Disturbances in consciousness NEC</i>		
Loss of consciousness	2	0
Syncope	3	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	1	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	13	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	2	0
<i>Migraine headaches</i>		
Migraine	4	0
<i>Multiple sclerosis acute and progressive</i>		
Multiple sclerosis pseudo relapse	1	0
Multiple sclerosis relapse	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	5	0
Dizziness postural	1	0
Head discomfort	1	0
<i>Paraesthesias and dysaesthesias</i>		
Hypoaesthesia	2	0
Paraesthesia	4	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	1	0
Seizure	2	0
<i>Sensory abnormalities NEC</i>		
Sensory loss	2	0
<i>Tremor (excl congenital)</i>		
Tremor	2	0
Nervous system disorders SOC TOTAL	52	1

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Anxiety	1	0
<i>Depressive disorders</i>		
Depression	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	1	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	1	0
<i>Parasomnias</i>		
Nightmare	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	2	0
Psychiatric disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Pollakiuria	1	0
<i>Urinary abnormalities</i>		
Chromaturia	1	0
Renal & urinary disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Menstruation and uterine bleeding NEC</i>		
Menstruation irregular	1	0
<i>Menstruation with decreased bleeding</i>		
Menstruation delayed	1	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vulva cyst	1	0
Reproductive & breast disorders SOC TOTAL	3	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	8	0
Hypopnoea	1	0
<i>Bronchospasm and obstruction</i>		
Wheezing	1	0
<i>Coughing and associated symptoms</i>		
Cough	3	0
Productive cough	2	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	2	0
Rhinalgia	1	0
Respiratory disorders SOC TOTAL	21	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Apocrine and eccrine gland disorders</i>		
Hyperhidrosis	2	0
Night sweats	2	0
<i>Dermal and epidermal conditions NEC</i>		
Pain of skin	1	0
Skin lesion	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	1	0
Eczema asteatotic	1	0
<i>Erythemas</i>		
Erythema	2	0
<i>Pruritus NEC</i>		
Pruritus	3	0
<i>Psoriatic conditions</i>		
Psoriasis	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	5	0
Rash erythematous	2	0
Rash pruritic	1	0
<i>Urticarias</i>		
Urticaria	2	0
Skin disorders SOC TOTAL	24	0

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

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Vascular disorders		
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	1	0
<i>Peripheral embolism and thrombosis</i>		
Superficial vein thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Hot flush	1	0
<i>Varicose veins NEC</i>		
Varicophlebitis	1	0
Vascular disorders SOC TOTAL	4	0
TOTAL REACTIONS FOR DRUG	317	1
TOTAL REPORTS	135	
TOTAL FATAL OUTCOME REPORTS		1