

Case Series Drug Analysis Print

Name: Flublok Vaccine Analysis Print

Report Run Date: 07-Nov-2023
Data Lock Date: 27-Oct-2023 18:30:03
Earliest Reaction Date: 29-Nov-2020
MedDRA Version: MedDRA 26.0

Flublok Vaccine
Analysis Print: FOI 23/779 - All UK spontaneous suspected Adverse
Drug Reaction (ADR) reports associated with Flublok
up to and including 27/10/2023

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Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	7	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	1	0
Blood disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	4	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
Cardiac disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	2	0
<i>Hearing losses</i>		
Hypoacusis	1	0
<i>Inner ear signs and symptoms</i>		
Vertigo	2	0
Ear disorders SOC TOTAL	5	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>Ocular disorders NEC</i>		
Eye pain	1	0
Periorbital swelling	1	0
<i>Visual disorders NEC</i>		
Photopsia	1	0
Vision blurred	1	0
Eye disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Dental pain and sensation disorders</i>		
Toothache	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	6	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	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	7	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	19	0
Vomiting	4	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	2	0
Oral pain	1	0
Paraesthesia oral	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
Gastrointestinal disorders SOC TOTAL	54	0

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General disorders		
<i>Asthenic conditions</i>		
Asthenia	2	0
Fatigue	36	0
Malaise	4	0
<i>Febrile disorders</i>		
Pyrexia	13	0
<i>Feelings and sensations NEC</i>		
Chills	10	0
Feeling abnormal	4	0
Feeling cold	4	0
Feeling hot	3	0
Feeling of body temperature change	1	0
Thirst	1	0
<i>Gait disturbances</i>		
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Illness	1	0
Influenza like illness	7	0
Peripheral swelling	5	0
Swelling	8	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	1	0
Injection site discomfort	1	0
Injection site erythema	3	0
Injection site induration	1	0
Injection site mass	3	0
Injection site pain	5	0
Injection site pruritus	4	0
Injection site reaction	1	0
Injection site swelling	2	0
<i>Pain and discomfort NEC</i>		
Axillary pain	9	0
Chest discomfort	4	0
Chest pain	3	0
Discomfort	1	0
Facial pain	1	0
Pain	10	0
Tenderness	1	0
<i>Vaccination site reactions</i>		
Vaccination site bruising	1	0
Vaccination site discolouration	1	0
Vaccination site erythema	11	0
Vaccination site induration	3	0
Vaccination site joint pain	1	0
Vaccination site mass	4	0
Vaccination site movement impairment	1	0
Vaccination site pain	18	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	6	0
Vaccination site rash	2	0
Vaccination site reaction	2	0
Vaccination site swelling	13	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site warmth	7	0
General disorders SOC TOTAL	222	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	1	0
Immune system disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Infections		
<i>Central nervous system and spinal infections</i>		
Myelitis	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
<i>Herpes viral infections</i>		
Herpes zoster	1	0
<i>Influenza viral infections</i>		
Influenza	2	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	1	0
Infections SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Injuries		
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	2	0
<i>Off label uses</i>		
Off label use	1	0
Injuries SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Investigations		
<i>Heart rate and pulse investigations</i>		
Heart rate increased	3	0
<i>Physical examination procedures and organ system status</i>		
Body temperature increased	2	0
<i>Red blood cell analyses</i>		
Haemoglobin decreased	1	0
Investigations SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	4	0
Metabolic disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Bone related signs and symptoms</i>		
Pain in jaw	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	16	0
Joint stiffness	1	0
<i>Muscle pains</i>		
Myalgia	30	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle discomfort	1	0
Muscle fatigue	1	0
Muscle tightness	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	2	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Limb mass	1	0
Musculoskeletal stiffness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	3	0
Limb discomfort	2	0
Musculoskeletal chest pain	2	0
Musculoskeletal discomfort	1	0
Neck pain	4	0
Pain in extremity	18	0
Muscle & tissue disorders SOC TOTAL	85	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Coordination and balance disturbances</i>		
Dysstasia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	4	0
Somnolence	2	0
Syncope	2	0
<i>Dyskinesias and movement disorders NEC</i>		
Movement disorder	1	0
<i>Headaches NEC</i>		
Headache	29	0
Sinus headache	1	0
Tension headache	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	8	0
Dizziness postural	1	0
Head discomfort	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	3	0
Formication	1	0
Hypoaesthesia	6	0
Paraesthesia	7	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Paresis	1	0
<i>Seizures and seizure disorders NEC</i>		
Seizure	1	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	2	0
Neuralgia	1	0
<i>Tremor (excl congenital)</i>		
Tremor	2	0
Nervous system disorders SOC TOTAL	75	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Stress	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	1	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	1	0
Psychiatric disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	3	0
Respiratory arrest	1	0
<i>Coughing and associated symptoms</i>		
Cough	7	0
Productive cough	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Catarrh	1	0
Dry throat	1	0
Oropharyngeal pain	11	0
Rhinalgia	1	0
Sinus pain	2	0
Respiratory disorders SOC TOTAL	30	0

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Reaction Name	Total	Fatal
Skin disorders		
Angioedemas		
Angioedema	2	0
Apocrine and eccrine gland disorders		
Cold sweat	1	0
Hyperhidrosis	2	0
Bullous conditions		
Blister	1	0
Dermal and epidermal conditions NEC		
Sensitive skin	1	0
Skin disorder	1	0
Skin induration	2	0
Skin warm	6	0
Dermatitis and eczema		
Dermatitis allergic	4	0
Erythemas		
Erythema	8	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	1	0
Pruritus NEC		
Pruritus	18	0
Purpura and related conditions		
Petechiae	1	0
Rashes, eruptions and exanthems NEC		
Rash	7	0
Rash erythematous	1	0
Rash macular	1	0
Rash papular	3	0
Rash pruritic	1	0
Skin and subcutaneous conditions NEC		
Skin mass	1	0
Skin haemorrhages		
Skin haemorrhage	1	0
Urticarias		
Urticaria	5	0
Skin disorders SOC TOTAL	68	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Impaired work ability	1	0
Loss of personal independence in daily activities	1	0
Social circumstances SOC TOTAL	2	0

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Vascular disorders		
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	1	0
<i>Vascular hypotensive disorders</i>		
Orthostatic hypotension	1	0
Vascular disorders SOC TOTAL	2	0
TOTAL REACTIONS FOR DRUG	586	0
TOTAL REPORTS	177	