

Case Series Drug Analysis Print

Name: FOI 21/1164 Influenza (live) Vaccine DAP

Report Run Date: 24-Nov-2021
Data Lock Date: 17-Oct-2021 22:57:05
Earliest Reaction Date: 15-Jul-2015
MedDRA Version: MedDRA 24.0

FOI 21/1164 Influenza All spontaneous suspected UK Adverse Drug Reaction
(live) Vaccine DAP: (ADR) reports associated with influenza virus (live)
vaccine

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Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	1	0
Blood disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Neurological disorders congenital NEC</i>		
Tourette's disorder	2	0
Congenital disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	1	0
Ear pain	3	0
Ear swelling	2	0
Otorrhoea	1	0
Ear disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Lacrimation disorders</i>		
Lacrimation increased	7	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Erythema of eyelid	1	0
Swelling of eyelid	2	0
<i>Ocular disorders NEC</i>		
Eye pain	1	0
Eye swelling	3	0
Ocular discomfort	1	0
Periorbital swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	3	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	2	0
Ophthalmoplegia	1	0
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Vision blurred	1	0
Eye disorders SOC TOTAL	25	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Colitis (excl infective)</i>		
Colitis	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	13	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
Faecaloma	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	4	0
Abdominal pain lower	2	0
Abdominal pain upper	8	0
<i>Gastrointestinal disorders NEC</i>		
Appendix disorder	1	0
Gastrointestinal disorder	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	4	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	1	0
Gingival swelling	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	11	0
Retching	1	0
Vomiting	30	0
Vomiting projectile	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	1	0
<i>Oral soft tissue swelling and oedema</i>		
Mouth swelling	2	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	1	0
<i>Tongue disorders</i>		
Tongue geographic	2	0
<i>Tongue signs and symptoms</i>		
Strawberry tongue	1	0
Swollen tongue	1	0
Gastrointestinal disorders SOC TOTAL	90	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site rash	1	0
<i>Asthenic conditions</i>		
Asthenia	5	0
Fatigue	16	0
Malaise	11	0
<i>Death and sudden death</i>		
Death	3	3
<i>Febrile disorders</i>		
Pyrexia	71	0
<i>Feelings and sensations NEC</i>		
Chills	7	0
Feeling abnormal	2	0
Feeling cold	1	0
Feeling hot	1	0
<i>Gait disturbances</i>		
Gait disturbance	1	0
<i>General signs and symptoms NEC</i>		
Crying	2	0
Illness	7	0
Induration	1	0
Influenza like illness	7	0
Peripheral swelling	3	0
Swelling	1	0
Swelling face	7	0
<i>Oedema NEC</i>		
Face oedema	1	0
Oedema	1	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	3	0
Pain	8	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	6	0
Drug ineffective	1	0
No reaction on previous exposure to drug	1	0
<i>Vaccination site reactions</i>		
Vaccination site pain	1	0
General disorders SOC TOTAL	169	3

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	4	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	4	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	4	0
Anaphylactic shock	1	0
Anaphylactoid reaction	1	0
Immune system disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	1	0
<i>Bacterial infections NEC</i>		
Bacterial infection	1	0
Tonsillitis bacterial	1	0
<i>Ear infections</i>		
Ear infection	1	0
Labyrinthitis	1	0
Otitis media	1	0
<i>Infectious transmissions</i>		
Infection via vaccinee	2	0
<i>Influenza viral infections</i>		
Influenza	7	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	7	0
Tonsillitis	1	0
Upper respiratory tract infection	3	0
<i>Viral infections NEC</i>		
Metapneumovirus infection	1	0
Viral rash	1	0
Infections SOC TOTAL	29	0

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Reaction Name	Total	Fatal
Injuries		
<i>Accidental exposures to product</i>		
Accidental exposure to product	2	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to vaccinated person	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	2	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
<i>Off label uses</i>		
Off label use	1	0
<i>Poisoning and toxicity</i>		
Metal poisoning	1	0
<i>Product administration errors and issues</i>		
Accidental overdose	1	0
Contraindicated product administered	1	0
Expired product administered	1	0
Product administered to patient of inappropriate age	2	0
Product administration error	1	0
<i>Skin injuries NEC</i>		
Contusion	2	0
Injuries SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	1	0
<i>Neurologic diagnostic procedures</i>		
Sensory level abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature abnormal	1	0
Body temperature decreased	1	0
Body temperature increased	6	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
Investigations SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	26	0
<i>Diabetes mellitus (incl subtypes)</i>		
Type 1 diabetes mellitus	1	0
Metabolic disorders SOC TOTAL	27	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Joint related signs and symptoms</i>		
Arthralgia	3	0
Joint swelling	2	0
<i>Muscle infections and inflammations</i>		
Myositis	1	0
<i>Muscle pains</i>		
Myalgia	8	0
<i>Muscle weakness conditions</i>		
Muscular weakness	1	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Neck pain	2	0
Pain in extremity	4	0
Muscle & tissue disorders SOC TOTAL	22	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Bone sarcomas</i>		
Ewing's sarcoma	1	0
Neoplasms SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Absence seizures</i>		
Petit mal epilepsy	3	0
<i>Choreiform movements</i>		
Chorea	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	16	0
Loss of consciousness	1	0
Somnolence	1	0
Syncope	7	0
<i>Dyskinesias and movement disorders NEC</i>		
Movement disorder	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	1	0
Facial paresis	1	0
<i>Headaches NEC</i>		
Headache	37	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0
<i>Migraine headaches</i>		
Migraine with aura	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	2	0
<i>Narcolepsy and hypersomnia</i>		
Cataplexy	3	0
Hypersomnia	2	0
Narcolepsy	3	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	4	0
Head discomfort	1	0
Unresponsive to stimuli	1	0
<i>Paraesthesias and dysaesthesias</i>		
Paraesthesia	2	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Paralysis	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	1	0
Febrile convulsion	1	0
Seizure	1	0
Status epilepticus	1	0
<i>Sensory abnormalities NEC</i>		
Sensory disturbance	1	0
<i>Tremor (excl congenital)</i>		
Head titubation	1	0
Nervous system disorders SOC TOTAL	97	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	2	0
Staring	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	1	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	1	0
Irritability	4	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	3	0
<i>Mental disorders NEC</i>		
Mental disorder	2	0
<i>Mood alterations with depressive symptoms</i>		
Decreased interest	1	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive disorder	1	0
<i>Parasomnias</i>		
Somnambulism	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	4	0
<i>Tic disorders</i>		
Tic	4	0
Psychiatric disorders SOC TOTAL	27	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	1	0
<i>Urinary abnormalities</i>		
Chromaturia	1	0
Renal & urinary disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	2	0
Dyspnoea	5	0
Respiratory distress	2	0
Tachypnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	5	0
Bronchospasm	1	0
Wheezing	5	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	15	0
Productive cough	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	20	0
<i>Nasal disorders NEC</i>		
Epistaxis	30	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	3	0
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	1	0
Respiratory tract congestion	1	0
Respiratory tract irritation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Dry throat	1	0
Dysphonia	2	0
Nasal discomfort	5	0
Oropharyngeal pain	16	0
Rhinorrhoea	39	0
Sneezing	10	0
Snoring	1	0
Throat clearing	1	0
Throat irritation	1	0
Throat tightness	1	0
Upper-airway cough syndrome	1	0
Respiratory disorders SOC TOTAL	173	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	4	0
Hyperhidrosis	2	0
<i>Bullous conditions</i>		
Blister	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	1	0
Pain of skin	1	0
Papule	2	0
Skin discolouration	2	0
Skin lesion	1	0
Skin reaction	2	0
Skin warm	3	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	2	0
Dermatitis contact	1	0
Eczema	1	0
<i>Erythemas</i>		
Erythema	6	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	10	0
<i>Psoriatic conditions</i>		
Psoriasis	1	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	2	0
Petechiae	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	24	0
Rash erythematous	3	0
Rash macular	5	0
Rash maculo-papular	1	0
Rash papular	1	0
Rash pruritic	5	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	1	0
<i>Urticarias</i>		
Mechanical urticaria	1	0
Urticaria	20	0
Skin disorders SOC TOTAL	106	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Social issues NEC</i>		
Contraindication to vaccination	1	0
Social circumstances SOC TOTAL	1	0

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Vascular disorders		
<i>Circulatory collapse and shock</i>		
Peripheral circulatory failure	1	0
Shock	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	2	0
Flushing	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	7	0
Vascular disorders SOC TOTAL	13	0
TOTAL REACTIONS FOR DRUG	834	3
TOTAL REPORTS	306	
TOTAL FATAL OUTCOME REPORTS		3