

Case Series Drug Analysis Print

**Name: FOI 21/877- Live Attenuated Influenza Virus Vaccine DAP
2018**

Report Run Date: 09-Aug-2021

Data Lock Date: 08-Aug-2021 18:30:04

Earliest Reaction Date: 01-May-2015

MedDRA Version: MedDRA 24.0

FOI 21/877- Influenza All spontaneous suspected UK Adverse Drug Reaction
Live Virus Vaccine (ADR) reports associated with the Live Attenuated Influenza
DAP 2018: Virus Vaccine in 2018

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Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	6	0
Blood disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	1	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	1	0
Cardiac disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	1	0
Ear pain	11	0
<i>Hearing losses</i>		
Hypoacusis	1	0
Ear disorders SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Lacrimation disorders</i>		
Lacrimation increased	3	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 disorder	1	0
Eye pain	4	0
Eye swelling	5	0
Periorbital swelling	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Eye inflammation	1	0
Eye pruritus	4	0
Ocular hyperaemia	4	0
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<i>Optic disc abnormalities NEC</i>		
Papilloedema	1	0
<i>Pupil disorders</i>		
Mydriasis	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	1	0
Eye disorders SOC TOTAL	33	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	23	0
<i>Faecal abnormalities NEC</i>		
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	4	0
Abdominal pain upper	26	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Infrequent bowel movements	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastric disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
<i>Nausea and vomiting symptoms</i>		
Cyclic vomiting syndrome	1	0
Nausea	11	0
Vomiting	47	0
Vomiting projectile	4	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	2	0
<i>Oral soft tissue signs and symptoms</i>		
Lip pain	1	0
Oral pain	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	4	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	2	0
Stomatitis	1	0
<i>Tongue disorders</i>		
Tongue disorder	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	1	0
Swollen tongue	2	0
Tongue discomfort	1	0
Gastrointestinal disorders SOC TOTAL	138	0

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Reaction Name	Total	Fatal
General disorders		
<i>Application and instillation site reactions</i>		
Application site rash	1	0
<i>Asthenic conditions</i>		
Asthenia	9	0
Fatigue	32	0
Malaise	18	0
<i>Body temperature altered</i>		
Temperature regulation disorder	1	0
<i>Febrile disorders</i>		
Pyrexia	114	0
<i>Feelings and sensations NEC</i>		
Chills	12	0
Feeling cold	6	0
Feeling hot	6	0
Thirst decreased	1	0
<i>Gait disturbances</i>		
Gait inability	2	0
<i>General signs and symptoms NEC</i>		
Crying	3	0
Illness	8	0
Influenza like illness	19	0
Irritability postvaccinal	1	0
Moaning	1	0
Peripheral swelling	2	0
Swelling	1	0
Swelling face	5	0
<i>Oedema NEC</i>		
Face oedema	1	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	1	0
Chest pain	4	0
Pain	14	0
<i>Vaccination site reactions</i>		
Vaccination site erythema	1	0
Vaccination site inflammation	1	0
Vaccination site pain	1	0
Vaccination site scab	1	0
General disorders SOC TOTAL	266	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	7	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	2	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	1	0
Immune system disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Cellulitis	1	0
<i>Ear infections</i>		
Ear infection	3	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
<i>Herpes viral infections</i>		
Herpes zoster	1	0
<i>Infectious transmissions</i>		
Infection via vaccinee	20	0
Vaccine virus shedding	3	0
<i>Influenza viral infections</i>		
Influenza	6	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	4	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Blister infected	1	0
Impetigo	2	0
<i>Upper respiratory tract infections</i>		
Croup infectious	3	0
Laryngitis	1	0
Nasopharyngitis	14	0
Peritonsillar abscess	1	0
Rhinitis	2	0
Tonsillitis	4	0
<i>Viral infections NEC</i>		
Bronchiolitis	1	0
Viral infection	1	0
Infections SOC TOTAL	70	0

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Reaction Name	Total	Fatal
Injuries		
<i>Accidental exposures to product</i>		
Accidental exposure to product	4	0
<i>Occupational exposures</i>		
Occupational exposure to product	5	0
<i>Product administration errors and issues</i>		
Extra dose administered	1	0
Inappropriate schedule of product administration	1	0
Product administered to patient of inappropriate age	1	0
<i>Skin injuries NEC</i>		
Contusion	1	0
<i>Vaccination related complications</i>		
Vaccination complication	1	0
Injuries SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Investigations		
<i>Physical examination procedures and organ system status</i>		
Body temperature abnormal	1	0
Body temperature increased	2	0
Respiratory rate increased	1	0
<i>Protein analyses NEC</i>		
C-reactive protein abnormal	1	0
Investigations SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	29	0
Hypophagia	3	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	1	0
<i>General nutritional disorders NEC</i>		
Feeding disorder	1	0
Metabolic disorders SOC TOTAL	34	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
<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	9	0
<i>Muscle weakness conditions</i>		
Muscular weakness	2	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	2	0
Weight bearing difficulty	2	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	2	0
Neck pain	3	0
Pain in extremity	8	0
<i>Synovial disorders</i>		
Synovitis	1	0
Muscle & tissue disorders SOC TOTAL	36	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Coordination and balance disturbances</i>		
Balance disorder	2	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	20	0
Loss of consciousness	3	0
Somnolence	5	0
Syncope	11	0
<i>Dyskinesias and movement disorders NEC</i>		
Motor dysfunction	1	0
<i>Encephalitis NEC</i>		
Noninfective encephalitis	1	0
<i>Headaches NEC</i>		
Headache	57	0
<i>Mononeuropathies</i>		
Ulnar nerve palsy	1	0
<i>Narcolepsy and hypersomnia</i>		
Cataplexy	2	0
Hypersomnia	2	0
Narcolepsy	4	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	7	0
Head discomfort	1	0
Hyporesponsive to stimuli	1	0
Unresponsive to stimuli	2	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	2	0
Seizure	3	0
Tonic clonic movements	1	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	1	0
Sensory disturbance	1	0
<i>Speech and language abnormalities</i>		
Speech disorder	1	0
<i>Tremor (excl congenital)</i>		
Tremor	4	0
Nervous system disorders SOC TOTAL	134	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	2	0
Behaviour disorder	1	0
<i>Anxiety symptoms</i>		
Anxiety	3	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	1	0
Personality change	1	0
<i>Confusion and disorientation</i>		
Disorientation	1	0
<i>Deliria</i>		
Delirium	2	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	1	0
Irritability	2	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	2	0
<i>Increased physical activity levels</i>		
Restlessness	2	0
<i>Infancy, childhood and adolescence psychiatric disorders NEC</i>		
School refusal	1	0
<i>Mental disorders due to a general medical condition NEC</i>		
Neuropsychiatric syndrome	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
<i>Mood disorders NEC</i>		
Listless	1	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive disorder	2	0
<i>Parasomnias</i>		
Sleep terror	1	0
<i>Psychiatric elimination disorders</i>		
Enuresis	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	1	0
<i>Thinking disturbances</i>		
Thinking abnormal	1	0
<i>Tic disorders</i>		
Tic	2	0
Psychiatric disorders SOC TOTAL	33	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	12	0
Hyperventilation	1	0
Mouth breathing	1	0
Respiration abnormal	2	0
Respiratory arrest	1	0
Respiratory distress	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	6	0
Wheezing	16	0
<i>Coughing and associated symptoms</i>		
Cough	54	0
Productive cough	5	0
Sputum increased	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	11	0
<i>Nasal disorders NEC</i>		
Epistaxis	31	0
Nasal disorder	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
Tonsillar hypertrophy	1	0
Tonsillar inflammation	1	0
<i>Respiratory signs and symptoms NEC</i>		
Use of accessory respiratory muscles	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory tract congestion	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Dysphonia	1	0
Oropharyngeal pain	26	0
Rhinorrhoea	46	0
Sneezing	3	0
Throat clearing	1	0
Throat irritation	1	0
Respiratory disorders SOC TOTAL	226	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Alopecias</i>		
Alopecia	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	3	0
<i>Bullous conditions</i>		
Blister	2	0
Erythema multiforme	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	1	0
Papule	3	0
Scab	1	0
Skin reaction	1	0
Skin swelling	1	0
Skin tightness	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	7	0
Eczema	1	0
Skin irritation	1	0
<i>Erythemas</i>		
Erythema	8	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	1	0
<i>Pruritus NEC</i>		
Pruritus	10	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	2	0
Petechiae	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	26	0
Rash erythematous	3	0
Rash macular	6	0
Rash papular	5	0
Rash pruritic	5	0
<i>Urticarias</i>		
Urticaria	24	0
Skin disorders SOC TOTAL	117	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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Reaction Name	Total	Fatal
Vascular disorders		
<i>Arterial infections and inflammations</i>		
Kawasaki's disease	1	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	6	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	9	0
Vascular disorders SOC TOTAL	20	0
TOTAL REACTIONS FOR DRUG	1159	0
TOTAL REPORTS	358	