

## Case Series Drug Analysis Print

**Name: FOI 21/877- Live Attenuated Influenza Virus Vaccine DAP  
2020**

Report Run Date: 09-Aug-2021

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

Earliest Reaction Date: 15-Jul-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 2020: Virus Vaccine in 2020

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	1	0
<b>Blood disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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

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

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Lacrimation disorders</i>		
Lacrimation increased	5	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 swelling	2	0
Periorbital swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	2	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
<b>Eye disorders SOC TOTAL</b>	<b>19</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Colitis (excl infective)</i>		
Colitis	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	8	0
<i>Faecal abnormalities NEC</i>		
Faecaloma	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	4	0
Abdominal pain lower	1	0
Abdominal pain upper	6	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	1	0
Gingival swelling	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	8	0
Retching	1	0
Vomiting	18	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	1	0
<i>Tongue disorders</i>		
Tongue geographic	2	0
<i>Tongue signs and symptoms</i>		
Strawberry tongue	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>60</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Administration site reactions NEC</i>		
Administration site rash	1	0
<i>Asthenic conditions</i>		
Asthenia	2	0
Fatigue	9	0
Malaise	10	0
<i>Death and sudden death</i>		
Death	2	2
<i>Febrile disorders</i>		
Pyrexia	53	0
<i>Feelings and sensations NEC</i>		
Chills	6	0
Feeling abnormal	1	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	1	0
Illness	3	0
Induration	1	0
Influenza like illness	6	0
Peripheral swelling	3	0
Swelling	1	0
Swelling face	6	0
<i>Oedema NEC</i>		
Face oedema	1	0
Oedema	1	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	1	0
Pain	7	0
<i>Vaccination site reactions</i>		
Vaccination site pain	1	0
<b>General disorders SOC TOTAL</b>	<b>119</b>	<b>2</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	3	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	3	0
Anaphylactic shock	1	0
Anaphylactoid reaction	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>11</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Bacterial infections NEC</b></i>		
Bacterial infection	1	0
Tonsillitis bacterial	1	0
<i><b>Ear infections</b></i>		
Labyrinthitis	1	0
<i><b>Infectious transmissions</b></i>		
Infection via vaccinee	1	0
<i><b>Influenza viral infections</b></i>		
Influenza	3	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Lower respiratory tract infection	1	0
<i><b>Upper respiratory tract infections</b></i>		
Nasopharyngitis	2	0
Tonsillitis	1	0
Upper respiratory tract infection	2	0
<i><b>Viral infections NEC</b></i>		
Metapneumovirus infection	1	0
Viral rash	1	0
<b>Infections SOC TOTAL</b>	<b>15</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<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
Product administered to patient of inappropriate age	2	0
Product administration error	1	0
<b>Injuries SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<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 decreased	1	0
Body temperature increased	3	0
<b>Investigations SOC TOTAL</b>	<b>6</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	13	0
<i>Diabetes mellitus (incl subtypes)</i>		
Type 1 diabetes mellitus	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>14</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Joint related signs and symptoms</i>		
Arthralgia	2	0
Joint swelling	2	0
<i>Muscle infections and inflammations</i>		
Myositis	1	0
<i>Muscle pains</i>		
Myalgia	4	0
<i>Muscle weakness conditions</i>		
Muscular weakness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Neck pain	1	0
Pain in extremity	3	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>14</b>	<b>0</b>

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

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	3	0
<i><b>Choreiform movements</b></i>		
Chorea	1	0
<i><b>Coordination and balance disturbances</b></i>		
Balance disorder	1	0
<i><b>Disturbances in consciousness NEC</b></i>		
Lethargy	10	0
Loss of consciousness	1	0
Somnolence	1	0
Syncope	5	0
<i><b>Dyskinesias and movement disorders NEC</b></i>		
Movement disorder	1	0
<i><b>Facial cranial nerve disorders</b></i>		
Bell's palsy	1	0
Facial paresis	1	0
<i><b>Headaches NEC</b></i>		
Headache	25	0
<i><b>Increased intracranial pressure disorders</b></i>		
Brain oedema	1	0
<i><b>Muscle tone abnormal</b></i>		
Hypotonia	2	0
<i><b>Narcolepsy and hypersomnia</b></i>		
Cataplexy	3	0
Hypersomnia	1	0
Narcolepsy	3	0
<i><b>Neurological signs and symptoms NEC</b></i>		
Dizziness	3	0
Unresponsive to stimuli	1	0
<i><b>Paraesthesias and dysaesthesias</b></i>		
Paraesthesia	1	0
<i><b>Seizures and seizure disorders NEC</b></i>		
Epilepsy	1	0
Febrile convulsion	1	0
Seizure	1	0
Status epilepticus	1	0
<i><b>Tremor (excl congenital)</b></i>		
Head titubation	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>70</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i><b>Abnormal behaviour NEC</b></i>		
Abnormal behaviour	2	0
Staring	1	0
<i><b>Disturbances in initiating and maintaining sleep</b></i>		
Insomnia	1	0
<i><b>Emotional and mood disturbances NEC</b></i>		
Irritability	2	0
<i><b>Hallucinations (excl sleep-related)</b></i>		
Hallucination	2	0
<i><b>Mental disorders NEC</b></i>		
Mental disorder	2	0
<i><b>Mood alterations with depressive symptoms</b></i>		
Decreased interest	1	0
<i><b>Obsessive-compulsive disorders and symptoms</b></i>		
Obsessive-compulsive disorder	1	0
<i><b>Parasomnias</b></i>		
Somnambulism	1	0
<i><b>Pervasive developmental disorders NEC</b></i>		
Autism spectrum disorder	1	0
<i><b>Sleep disorders NEC</b></i>		
Sleep disorder	2	0
<i><b>Tic disorders</b></i>		
Tic	4	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>20</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	2	0
Dyspnoea	4	0
Respiratory distress	2	0
Tachypnoea	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	4	0
Bronchospasm	1	0
Wheezing	4	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Hypoxia	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	9	0
Productive cough	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Stridor	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	13	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	18	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	2	0
<i><b>Respiratory tract disorders NEC</b></i>		
Respiratory tract congestion	1	0
Respiratory tract irritation	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Dry throat	1	0
Dysphonia	1	0
Nasal discomfort	4	0
Oropharyngeal pain	10	0
Rhinorrhoea	24	0
Sneezing	8	0
Snoring	1	0
Throat clearing	1	0
Throat irritation	1	0
Throat tightness	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>117</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i><b>Apocrine and eccrine gland disorders</b></i>		
Cold sweat	3	0
Hyperhidrosis	1	0
<i><b>Bullous conditions</b></i>		
Blister	1	0
<i><b>Dermal and epidermal conditions NEC</b></i>		
Dry skin	1	0
Pain of skin	1	0
Papule	2	0
Skin discolouration	2	0
Skin lesion	1	0
Skin reaction	1	0
Skin warm	3	0
<i><b>Dermatitis and eczema</b></i>		
Dermatitis allergic	1	0
Dermatitis contact	1	0
Eczema	1	0
<i><b>Erythemas</b></i>		
Erythema	4	0
<i><b>Exfoliative conditions</b></i>		
Skin exfoliation	1	0
<i><b>Photosensitivity and photodermatosis conditions</b></i>		
Photosensitivity reaction	1	0
<i><b>Pruritus NEC</b></i>		
Pruritus	10	0
<i><b>Psoriatic conditions</b></i>		
Psoriasis	1	0
<i><b>Purpura and related conditions</b></i>		
Henoch-Schonlein purpura	2	0
Petechiae	1	0
<i><b>Rashes, eruptions and exanthems NEC</b></i>		
Rash	18	0
Rash erythematous	3	0
Rash macular	3	0
Rash papular	1	0
Rash pruritic	3	0
<i><b>Urticarias</b></i>		
Mechanical urticaria	1	0
Urticaria	18	0
<b>Skin disorders SOC TOTAL</b>	<b>86</b>	<b>0</b>

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

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<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>Site specific vascular disorders NEC</i>		
Pallor	5	0
<b>Vascular disorders SOC TOTAL</b>	<b>10</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>578</b>	<b>2</b>
<b>TOTAL REPORTS</b>	<b>197</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>2</b>