

Case Series Drug Analysis Print

Name: FOI 22/1193 - Influvac Sub-Unit Tetra DAP

Report Run Date: 10-Jan-2023
Data Lock Date: 09-Jan-2023 18:30:04
Earliest Reaction Date: 24-Aug-2018
MedDRA Version: MedDRA 25.1

FOI 22/1193 - Influvac Sub-Unit Tetra DAP: FOI 22/1193 - All spontaneous suspected UK Adverse Drug Reaction (ADR) reports associated with the Influvac Sub-Unit Tetra vaccine received up to and including 13/12/2022

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Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	1	0
Lymphadenopathy	5	0
<i>Marrow depression and hypoplastic anaemias</i>		
Pure white cell aplasia	2	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	1	0
<i>Rate and rhythm disorders NEC</i>		
Tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	1
Cardiac disorders SOC TOTAL	3	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	1	0
Ear inflammation	1	0
<i>Hearing losses</i>		
Hypoacusis	1	0
<i>Inner ear disorders NEC</i>		
Meniere's disease	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	3	0
Vertigo	2	0
Ear disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	1	0
<i>Ocular disorders NEC</i>		
Eye pain	1	0
Eye swelling	1	0
Eyelid pain	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye inflammation	2	0
Eye irritation	2	0
Eye pruritus	1	0
Eye disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Anal and rectal signs and symptoms</i>		
Rectal tenesmus	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	4	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain upper	2	0
<i>Nausea and vomiting symptoms</i>		
Nausea	9	0
Vomiting	5	0
<i>Oral soft tissue signs and symptoms</i>		
Paraesthesia oral	2	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	1	0
Gastrointestinal disorders SOC TOTAL	25	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	1	0
Administration site joint erythema	1	0
<i>Asthenic conditions</i>		
Asthenia	3	0
Fatigue	16	0
Malaise	14	0
<i>Death and sudden death</i>		
Brain death	1	1
<i>Febrile disorders</i>		
Pyrexia	5	0
<i>Feelings and sensations NEC</i>		
Chills	1	0
Feeling abnormal	3	0
<i>General signs and symptoms NEC</i>		
Influenza like illness	2	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	6	0
Secretion discharge	1	0
Swelling	5	0
Swelling face	1	0
<i>Injection site reactions</i>		
Injection site erythema	2	0
Injection site inflammation	1	0
Injection site mass	1	0
Injection site pain	1	0
Injection site swelling	1	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	2	0
Facial pain	1	0
Pain	7	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	1	0
<i>Vaccination site reactions</i>		
Shoulder injury related to vaccine administration	1	0
Vaccination site erythema	3	0
Vaccination site inflammation	1	0
Vaccination site irritation	1	0
Vaccination site pain	9	0
Vaccination site pruritus	2	0
Vaccination site reaction	1	0
Vaccination site swelling	6	0
Vaccination site urticaria	1	0
Vaccination site warmth	1	0
General disorders SOC TOTAL	104	1

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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	2	0
Anaphylactic shock	3	0
Immune system disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Infections		
<i>Ear infections</i>		
Labyrinthitis	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Septic shock	1	0
Infections SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Injuries		
<i>Cerebral injuries NEC</i>		
Brain herniation	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 administration error	1	0
<i>Skin injuries NEC</i>		
Contusion	4	0
Injuries SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Investigations		
<i>Physical examination procedures and organ system status</i>		
Body temperature increased	1	0
Investigations SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	1	0
Metabolic disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	3	0
Joint swelling	1	0
<i>Muscle pains</i>		
Myalgia	6	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Limb discomfort	1	0
Musculoskeletal discomfort	1	0
Neck pain	2	0
Pain in extremity	3	0
Muscle & tissue disorders SOC TOTAL	19	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Ischaemic stroke	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	3	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	1	0
Syncope	1	0
<i>Headaches NEC</i>		
Headache	15	0
<i>Migraine headaches</i>		
Migraine	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	8	0
Head discomfort	2	0
Presyncope	2	0
<i>Paraesthesias and dysaesthesias</i>		
Hypoaesthesia	1	0
Paraesthesia	3	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Paralysis	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	1	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	1	0
Neuralgia	1	0
Taste disorder	1	0
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	44	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	1	0
Psychiatric disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	1	0
Renal & urinary disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast swelling	1	0
Reproductive & breast disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	2	0
<i>Bronchospasm and obstruction</i>		
Wheezing	3	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal hypoaesthesia	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	2	0
Respiratory disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	1	0
<i>Dermal and epidermal conditions NEC</i>		
Skin reaction	2	0
Skin warm	2	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	1	0
<i>Erythemas</i>		
Erythema	5	0
<i>Pruritus NEC</i>		
Pruritus	7	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	8	0
Rash erythematous	1	0
Rash papular	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
<i>Urticarias</i>		
Urticaria	1	0
Skin disorders SOC TOTAL	31	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Peripheral vascular disorders NEC</i>		
Flushing	1	0
Hot flush	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	2	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
Vascular disorders SOC TOTAL	7	0
TOTAL REACTIONS FOR DRUG	289	2
TOTAL REPORTS	105	
TOTAL FATAL OUTCOME REPORTS		2