

Case Series Drug Analysis Print

Name: FOI 21/177- Influenza Virus Vaccine in Preganacy DAP

Report Run Date: 11-Mar-2021
Data Lock Date: 22-Feb-2021 19:00:03
Earliest Reaction Date: 25-Nov-1971
MedDRA Version: MedDRA 23.1

FOI 21/177- Influenza Virus Vaccine in Preganacy DAP: All spontaneous suspected UK Adverse Drug Reaction (ADR) reports associated in Pregnancy with the Influenza virus vaccine.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	1	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	2	0
Blood disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Rate and rhythm disorders NEC</i>		
Bradycardia foetal	1	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	1	0
Tachycardia foetal	1	0
Cardiac disorders SOC TOTAL	4	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac septal defects congenital</i>		
Ventricular septal defect	1	0
<i>Cerebral disorders congenital</i>		
Cerebral atrophy congenital	1	1
Dandy-Walker syndrome	1	0
<i>Congenital disorders NEC</i>		
Congenital anomaly	1	0
Multiple congenital abnormalities	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	1	0
<i>Endocrine disorders congenital NEC</i>		
Cystic fibrosis related diabetes	1	0
<i>External ear disorders congenital</i>		
Accessory auricle	1	0
Low set ears	1	0
Microtia	1	0
<i>Musculoskeletal and connective tissue disorders of face, neck and jaw congenital</i>		
Branchial cyst	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Polydactyly	1	0
Talipes	1	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		
Plagiocephaly	1	0
<i>Musculoskeletal and connective tissue disorders of spine congenital</i>		
Hemivertebra	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital musculoskeletal anomaly	1	0
Dysmorphism	1	0
<i>Neurological disorders congenital NEC</i>		
Congenital neurological disorder	1	0
Spinal muscular atrophy	2	0
<i>Ocular disorders congenital NEC</i>		
Amblyopia congenital	1	0
Colour blindness	1	0
<i>Renal and urinary tract disorders congenital NEC</i>		
Urinary tract malformation	1	0
<i>Retinal disorders congenital</i>		
Retinal anomaly congenital	1	0
<i>Sex chromosomal abnormalities</i>		
Turner's syndrome	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	26	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Hearing losses</i>		
Deafness neurosensory	1	0
Ear disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	1	0
Eye disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	4	0
Vomiting	6	0
Gastrointestinal disorders SOC TOTAL	12	0

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	1	0
Fatigue	3	0
Malaise	5	0
<i>Death and sudden death</i>		
Death	1	1
Death neonatal	1	1
<i>Febrile disorders</i>		
Pyrexia	5	0
<i>Feelings and sensations NEC</i>		
Chills	1	0
Feeling abnormal	2	0
Feeling hot	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	3	0
Crying	1	0
Exercise tolerance decreased	2	0
Influenza like illness	3	0
Swelling	1	0
Swelling face	1	0
<i>Injection site reactions</i>		
Injection site reaction	1	0
<i>Pain and discomfort NEC</i>		
Facial pain	1	0
Pain	5	0
<i>Vaccination site reactions</i>		
Vaccination site erythema	5	0
Vaccination site inflammation	1	0
Vaccination site mass	1	0
Vaccination site movement impairment	1	0
Vaccination site pruritus	1	0
Vaccination site swelling	3	0
Vaccination site warmth	1	0
General disorders SOC TOTAL	51	2

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Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Hyperbilirubinaemia neonatal	1	0
Jaundice	1	0
Jaundice cholestatic	1	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
Hepatic disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	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>Bacterial infections NEC</i>		
Cellulitis	1	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	2	0
<i>Female reproductive tract infections</i>		
Amniotic cavity infection	3	0
<i>Influenza viral infections</i>		
Influenza	4	0
<i>Lower respiratory tract and lung infections</i>		
Infective pulmonary exacerbation of cystic fibrosis	1	0
Lower respiratory tract infection	3	0
Pneumonia	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	2	1
<i>Skin structures and soft tissue infections</i>		
Eczema infected	1	0
<i>Streptococcal infections</i>		
Streptococcal infection	1	0
<i>Upper respiratory tract infections</i>		
Rhinitis	2	0
<i>Urinary tract infections</i>		
Kidney infection	1	0
Urinary tract infection	1	0
<i>Viral infections NEC</i>		
Viral infection	1	0
Infections SOC TOTAL	24	1

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	29	0
Foetal exposure during pregnancy	17	0
Maternal exposure before pregnancy	1	0
Maternal exposure during pregnancy	26	0
Maternal exposure timing unspecified	3	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
<i>Non-site specific procedural complications</i>		
Wound dehiscence	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Product administration errors and issues</i>		
Expired product administered	2	0
Extra dose administered	1	0
Incorrect dose administered	3	0
Wrong product administered	5	0
<i>Product monitoring errors and issues</i>		
Labelled drug-disease interaction medication error	1	0
<i>Reproductive system and breast injuries</i>		
Perineal injury	1	0
<i>Skin injuries NEC</i>		
Contusion	1	0
Skin abrasion	1	0
Skin laceration	1	0
<i>Vaccination related complications</i>		
Vaccination failure	2	0
Injuries SOC TOTAL	97	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Blood lactic acid decreased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	1	0
<i>Investigations NEC</i>		
Blood test abnormal	1	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	1	0
Aspartate aminotransferase increased	1	0
Liver function test abnormal	2	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Vital capacity decreased	1	0
<i>Virus identification and serology</i>		
Cytomegalovirus test positive	1	0
Epstein-Barr virus antibody positive	2	0
<i>White blood cell analyses</i>		
Neutrophil count increased	1	0
White blood cell count increased	2	0
Investigations SOC TOTAL	15	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Hypophagia	3	0
<i>General nutritional disorders NEC</i>		
Starvation	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia neonatal	3	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Ketoacidosis	4	0
Metabolic acidosis	3	0
Metabolic disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	1	0
<i>Muscle pains</i>		
Myalgia	1	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	2	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Pain in extremity	1	0
Muscle & tissue disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Reproductive neoplasms female benign NEC</i>		
Placental chorioangioma	1	0
Neoplasms SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	2	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	2	0
Loss of consciousness	1	0
Syncope	2	0
<i>Dyskinesias and movement disorders NEC</i>		
Motor dysfunction	1	0
<i>Headaches NEC</i>		
Headache	5	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	1	0
<i>Migraine headaches</i>		
Migraine	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	4	0
<i>Paraesthesias and dysaesthesias</i>		
Paraesthesia	3	0
<i>Seizures and seizure disorders NEC</i>		
Neonatal seizure	1	0
<i>Structural brain disorders NEC</i>		
Brain injury	1	0
Cerebral ventricle dilatation	1	0
<i>Tremor (excl congenital)</i>		
Tremor	1	0
Nervous system disorders SOC TOTAL	26	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	43	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Meconium in amniotic fluid	1	0
<i>Foetal complications NEC</i>		
Foetal distress syndrome	5	0
Foetal hypokinesia	3	0
<i>Foetal growth complications</i>		
Foetal growth restriction	3	0
<i>Gestational age and weight conditions</i>		
Premature baby	8	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	2	0
Premature separation of placenta	2	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	3	0
Premature labour	3	0
Premature rupture of membranes	1	0
Prolonged labour	3	0
<i>Maternal complications of delivery NEC</i>		
Breech delivery	1	0
<i>Maternal complications of pregnancy NEC</i>		
Hyperemesis gravidarum	1	0
Preterm premature rupture of membranes	1	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	2	0
<i>Normal newborn status</i>		
Normal newborn	3	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	4	0
Normal labour	1	0
Uterine contractions during pregnancy	2	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	2	2
Stillbirth	9	9
Pregnancy conditions SOC TOTAL	104	11

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Depressive disorders</i>		
Depression	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	2	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Mood disorders NEC</i>		
Listless	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	1	0
Psychiatric disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
<i>Renal disorders NEC</i>		
Single functional kidney	1	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	1	0
<i>Urinary abnormalities</i>		
Ketonuria	2	0
Renal & urinary disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	8	0
Reproductive & breast disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	2	0
Tachypnoea	1	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	5	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	1	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	1	0
Respiratory disorders SOC TOTAL	13	0

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Skin disorders		
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	1	0
Papule	1	0
Skin disorder	1	0
<i>Dermatitis and eczema</i>		
Eczema	1	0
<i>Erythemas</i>		
Erythema	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Ingrowing nail	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	3	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	2	0
Rash pruritic	1	0
<i>Urticarias</i>		
Urticaria	2	0
Skin disorders SOC TOTAL	15	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Obstetric therapeutic procedures</i>		
Caesarean section	2	0
Episiotomy	1	0
Forceps delivery	1	0
Vacuum extractor delivery	1	0
Surgical & medical procedures SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Haemorrhages NEC</i>		
Haemorrhage	1	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Ischaemia	1	0
<i>Peripheral vascular disorders NEC</i>		
Hot flush	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Poor peripheral circulation	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	1	0
Vascular disorders SOC TOTAL	5	0
TOTAL REACTIONS FOR DRUG	454	15
TOTAL REPORTS	150	
TOTAL FATAL OUTCOME REPORTS		15