

Case Series Drug Analysis Print

Name: FOI 21/177- DTPA IPV Vaccine in Pregnancy DAP

Report Run Date: 11-Mar-2021
Data Lock Date: 22-Feb-2021 19:00:03
Earliest Reaction Date: 05-Oct-2012
MedDRA Version: MedDRA 23.1

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

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	2	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	1	0
Blood disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	2	0
<i>Rate and rhythm disorders NEC</i>		
Tachycardia	2	0
Cardiac disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac septal defects congenital</i>		
Ventricular septal defect	1	0
<i>Lens disorders congenital</i>		
Cataract congenital	3	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Polydactyly	1	0
Syndactyly	1	0
<i>Neurological disorders congenital NEC</i>		
Congenital neurological disorder	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	2	0
Congenital disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Hyperacusia</i>		
Hyperacusis	1	0
Ear disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Ocular nerve and muscle disorders</i>		
Strabismus	1	0
<i>Ocular sensation disorders</i>		
Photophobia	1	0
Eye disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	1	0
Abdominal pain upper	2	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
Gastroesophageal reflux disease	2	0
<i>Nausea and vomiting symptoms</i>		
Nausea	4	0
Retching	1	0
Vomiting	5	0
<i>Non-mechanical ileus</i>		
Ileus paralytic	1	0
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Reaction Name	Total	Fatal
General disorders		
<i>Application and instillation site reactions</i>		
Application site pruritus	1	0
Application site swelling	1	0
<i>Asthenic conditions</i>		
Asthenia	2	0
Fatigue	9	0
Malaise	4	0
<i>Death and sudden death</i>		
Death	2	2
Death neonatal	1	1
<i>Febrile disorders</i>		
Pyrexia	8	0
<i>Feelings and sensations NEC</i>		
Chills	2	0
Feeling abnormal	1	0
<i>General signs and symptoms NEC</i>		
Crying	1	0
Illness	1	0
Influenza like illness	1	0
Peripheral swelling	3	0
Swelling	2	0
<i>Injection site reactions</i>		
Injection site erythema	2	0
Injection site pain	3	0
Injection site warmth	1	0
<i>Interactions</i>		
Food interaction	1	0
<i>Pain and discomfort NEC</i>		
Facial pain	1	0
Pain	6	0
<i>Vaccination site reactions</i>		
Vaccination site discomfort	1	0
Vaccination site erythema	2	0
Vaccination site mass	1	0
Vaccination site movement impairment	1	0
Vaccination site pain	5	0
Vaccination site pruritus	1	0
Vaccination site rash	1	0
Vaccination site reaction	1	0
Vaccination site swelling	1	0
Vaccination site warmth	2	0
General disorders SOC TOTAL	69	3

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
Hepatic disorders SOC TOTAL	1	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	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic shock	1	0
Immune system disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Cellulitis	1	0
<i>Bordetella infections</i>		
Pertussis	4	0
<i>Ear infections</i>		
Otitis media	1	0
<i>Female reproductive tract infections</i>		
Amniotic cavity infection	1	0
<i>Infections NEC</i>		
Infection	1	0
Injection site infection	1	0
Purulent discharge	1	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	2	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	1
Sepsis neonatal	1	0
Infections SOC TOTAL	14	1

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	26	0
Foetal exposure during pregnancy	18	0
Maternal exposure during pregnancy	36	0
Maternal exposure timing unspecified	3	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	2	0
Wrong technique in product usage process	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	3	0
Inappropriate schedule of product administration	3	0
Product administered at inappropriate site	1	0
Product administered to patient of inappropriate age	1	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	2	0
<i>Skin injuries NEC</i>		
Scar	1	0
<i>Underdoses NEC</i>		
Underdose	1	0
Injuries SOC TOTAL	106	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>Foetal and neonatal diagnostic procedures</i>		
Amniotic fluid volume decreased	1	0
Foetal monitoring abnormal	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate increased	1	0
<i>Liver function analyses</i>		
Blood bilirubin increased	1	0
Liver function test abnormal	1	0
Total bile acids increased	1	0
<i>Neurologic diagnostic procedures</i>		
Lumbar puncture	1	0
<i>Urinalysis NEC</i>		
Protein urine present	1	0
<i>White blood cell analyses</i>		
White blood cell count increased	1	0
Investigations SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	2	0
Hypophagia	2	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus inadequate control	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Dairy intolerance	1	0
<i>General nutritional disorders NEC</i>		
Poor feeding infant	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia neonatal	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Ketoacidosis	3	0
Metabolic acidosis	2	0
Metabolic disorders SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Bursal disorders</i>		
Bursitis	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	4	0
<i>Muscle pains</i>		
Myalgia	3	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	2	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Limb discomfort	1	0
Neck pain	1	0
Pain in extremity	3	0
Muscle & tissue disorders SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Disturbances in consciousness NEC</i>		
Lethargy	2	0
Somnolence	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	1	0
<i>Headaches NEC</i>		
Headache	10	0
Sinus headache	1	0
Tension headache	2	0
<i>Migraine headaches</i>		
Migraine	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	3	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	1	0
Paraesthesia	2	0
<i>Seizures and seizure disorders NEC</i>		
Neonatal seizure	1	0
<i>Sensory abnormalities NEC</i>		
Neuralgia	1	0
<i>Structural brain disorders NEC</i>		
Brain injury	1	0
Nervous system disorders SOC TOTAL	27	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	1	0
Meconium in amniotic fluid	1	0
<i>Foetal complications NEC</i>		
Foetal distress syndrome	3	0
Foetal hypokinesia	14	0
<i>Foetal growth complications</i>		
Foetal growth restriction	4	0
<i>Foetal position and presentation abnormalities</i>		
Breech presentation	2	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Haemorrhagic complications of pregnancy</i>		
Premature separation of placenta	1	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	2	0
Premature labour	4	0
Premature rupture of membranes	1	0
Prolonged labour	5	0
<i>Maternal complications of delivery NEC</i>		
Retained placenta or membranes	1	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	3	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	2	0
Normal labour	1	0
Pregnancy	1	0
Uterine contractions during pregnancy	1	0
<i>Placental abnormalities (excl neoplasms)</i>		
Foetal placental thrombosis	1	0
Placental disorder	1	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	3	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	4	3
Stillbirth	11	11
<i>Umbilical cord complications</i>		
Umbilical cord thrombosis	1	0
Pregnancy conditions SOC TOTAL	71	14

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	2	0
Psychiatric disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Renal failure and impairment</i>		
Renal impairment	1	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	1	0
<i>Renal structural abnormalities and trauma</i>		
Pyelocaliectasis	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	7	0
Reproductive & breast disorders SOC TOTAL	7	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	1	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	2	0
Upper respiratory tract congestion	1	0
Respiratory disorders SOC TOTAL	7	0

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Skin disorders		
<i>Acnes</i>		
Acne infantile	1	0
<i>Dermal and epidermal conditions NEC</i>		
Papule	1	0
Skin disorder	1	0
Skin warm	1	0
<i>Erythemas</i>		
Erythema	7	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	2	0
<i>Pruritus NEC</i>		
Pruritus	4	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	3	0
Rash pruritic	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
Skin disorders SOC TOTAL	22	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Obstetric therapeutic procedures</i>		
Caesarean section	5	0
Vacuum extractor delivery	1	0
Surgical & medical procedures SOC TOTAL	6	0

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Vascular disorders		
<i>Haemorrhages NEC</i>		
Haemorrhage	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Poor peripheral circulation	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	2	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
Vascular disorders SOC TOTAL	5	0
TOTAL REACTIONS FOR DRUG	425	18
TOTAL REPORTS	120	
TOTAL FATAL OUTCOME REPORTS		18