

DTaP IPV Vaccine Pregnancy Cases Vaccine Analysis Print

Report Run Date: 21-Nov-2022
Data Lock Date: 18-Nov-2022 18:30:05

All Spontaneous UK cases received up to 11/11/2022 involving administration of the DTaP IPV vaccine to pregnant women.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of different vaccines. All reports are kept under continual review in order to identify possible new risks.

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Earliest Reaction Date: 17-Sep-2012

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	2	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	4	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	3	0
Cardiac disorders SOC TOTAL	5	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>Ear disorders NEC</i>		
Ear swelling	1	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Vertigo	2	0
Ear disorders SOC TOTAL	4	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>		
Eyelid rash	1	0
<i>Ocular disorders NEC</i>		
Eye swelling	3	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye pruritus	1	0
<i>Ocular nerve and muscle disorders</i>		
Strabismus	1	0
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
Eye disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	13	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	2	0
Abdominal pain upper	10	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	2	0
Gastrooesophageal reflux disease	2	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	3	0
Dysphagia	1	0
Odynophagia	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	22	0
Retching	1	0
Vomiting	19	0
<i>Non-mechanical ileus</i>		
Ileus paralytic	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral discomfort	1	0
Paraesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
Gastrointestinal disorders SOC TOTAL	83	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site rash	1	0
Administration site reaction	1	0
<i>Application and instillation site reactions</i>		
Application site pruritus	1	0
Application site swelling	1	0
<i>Asthenic conditions</i>		
Asthenia	4	0
Fatigue	25	0
Malaise	18	0
<i>Febrile disorders</i>		
Pyrexia	23	0
<i>Feelings and sensations NEC</i>		
Chills	5	0
Feeling abnormal	1	0
Feeling hot	4	0
Thirst	1	0
<i>General signs and symptoms NEC</i>		
Crying	2	0
Illness	3	0
Induration	1	0
Influenza like illness	6	0
Local reaction	5	0
Peripheral swelling	15	0
Prolapse	1	0
Swelling	5	0
Swelling face	1	0
<i>Inflammations</i>		
Inflammation	1	0
<i>Injection site reactions</i>		
Injection site erythema	12	0
Injection site hypoaesthesia	1	0
Injection site inflammation	4	0
Injection site mass	2	0
Injection site pain	14	0
Injection site pruritus	3	0
Injection site reaction	2	0
Injection site swelling	4	0
Injection site warmth	4	0
<i>Interactions</i>		
Food interaction	1	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	1	0
Chest pain	2	0
Discomfort	1	0
Facial pain	1	0
Pain	15	0
Tenderness	1	0
<i>Vaccination site reactions</i>		
Vaccination site discomfort	1	0
Vaccination site erythema	7	0
Vaccination site mass	2	0
Vaccination site pain	10	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site pruritus	1	0
Vaccination site rash	2	0
Vaccination site reaction	1	0
Vaccination site swelling	2	0
Vaccination site warmth	4	0
General disorders SOC TOTAL	223	0

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Cholestasis	1	0
Jaundice	1	0
Hepatic disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Drug hypersensitivity	1	0
Food allergy	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	2	0
Anaphylactic shock	1	0
Anaphylactoid reaction	1	0
Immune system disorders SOC TOTAL	7	0

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Infections		
<i>Bacterial infections NEC</i>		
Cellulitis	1	0
<i>Ear infections</i>		
Otitis media	1	0
<i>Infections NEC</i>		
Infection	1	0
Injection site infection	2	0
Purulent discharge	1	0
<i>Influenza viral infections</i>		
Influenza	2	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
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	2	0
<i>Urinary tract infections</i>		
Urinary tract infection	1	0
Infections SOC TOTAL	14	1

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Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	28	0
Foetal exposure during pregnancy	17	0
Maternal exposure during pregnancy	62	0
Maternal exposure timing unspecified	2	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	3	0
Wrong technique in product usage process	2	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	4	0
Extra dose administered	1	0
Inappropriate schedule of product administration	3	0
Product administered at inappropriate site	2	0
Product administered to patient of inappropriate age	1	0
Wrong product administered	5	0
<i>Reproductive system and breast injuries</i>		
Perineal injury	2	0
<i>Site specific injuries NEC</i>		
Limb injury	1	0
<i>Skin injuries NEC</i>		
Contusion	3	0
Scar	1	0
<i>Underdoses NEC</i>		
Underdose	1	0
Injuries SOC TOTAL	140	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	2	0
<i>Hepatobiliary function diagnostic procedures</i>		
Alanine aminotransferase increased	1	0
Blood bilirubin increased	1	0
Hepatic enzyme abnormal	1	0
Liver function test abnormal	2	0
Total bile acids increased	1	0
<i>Metabolism tests NEC</i>		
Urine ketone body present	1	0
<i>Neurologic diagnostic procedures</i>		
Lumbar puncture	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature increased	2	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
<i>Urinalysis NEC</i>		
Protein urine present	1	0
<i>White blood cell analyses</i>		
White blood cell count increased	2	0
Investigations SOC TOTAL	20	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	4	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>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	14	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
<i>Bursal disorders</i>		
Bursitis	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	8	0
<i>Muscle pains</i>		
Myalgia	11	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	1	0
Muscle spasms	5	0
<i>Muscle weakness conditions</i>		
Muscular weakness	5	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Limb mass	2	0
Mobility decreased	1	0
Musculoskeletal stiffness	2	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	3	0
Limb discomfort	3	0
Musculoskeletal pain	1	0
Neck pain	2	0
Pain in extremity	20	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
Muscle & tissue disorders SOC TOTAL	68	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	4	0
Somnolence	3	0
Syncope	2	0
<i>Dyskinesias and movement disorders NEC</i>		
Hypokinesia	2	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	2	0
Facial paralysis	1	0
<i>Headaches NEC</i>		
Headache	30	0
Sinus headache	1	0
Tension headache	2	0
<i>Migraine headaches</i>		
Migraine	2	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	12	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	1	0
Hypoaesthesia	1	0
Paraesthesia	6	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	1	0
Neonatal seizure	1	0
<i>Sensory abnormalities NEC</i>		
Allodynia	1	0
Neuralgia	1	0
Sensory disturbance	1	0
<i>Speech and language abnormalities</i>		
Speech disorder	1	0
<i>Structural brain disorders NEC</i>		
Brain injury	1	0
<i>Tremor (excl congenital)</i>		
Tremor	2	0
Nervous system disorders SOC TOTAL	81	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
<i>Foetal complications NEC</i>		
Foetal distress syndrome	3	0
Foetal hypokinesia	13	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	2	0
<i>Haemorrhagic complications of pregnancy</i>		
Premature separation of placenta	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	3	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	2	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	2	0
Pregnancy	1	0
Uterine contractions during pregnancy	1	0
<i>Placental abnormalities (excl neoplasms)</i>		
Foetal vascular malperfusion	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	3	3
Stillbirth	11	11
<i>Umbilical cord complications</i>		
Umbilical cord thrombosis	1	0
Pregnancy conditions SOC TOTAL	69	14

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Psychiatric disorders		
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	3	0
<i>Mood alterations with depressive symptoms</i>		
Tearfulness	1	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	1	0
Psychiatric disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Urinary retention	1	0
<i>Renal disorders NEC</i>		
Single functional kidney	1	0
<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	7	0

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Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital rash	1	0
Genital swelling	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	7	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	1	0
Reproductive & breast disorders SOC TOTAL	11	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	4	0
<i>Bronchospasm and obstruction</i>		
Wheezing	1	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	7	0
Productive cough	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	2	0
<i>Upper respiratory tract signs and symptoms</i>		
Dry throat	1	0
Oropharyngeal pain	9	0
Rhinorrhoea	3	0
Sneezing	1	0
Upper respiratory tract congestion	1	0
Respiratory disorders SOC TOTAL	32	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne infantile	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	2	0
Hyperhidrosis	2	0
<i>Bullous conditions</i>		
Blister	1	0
<i>Dermal and epidermal conditions NEC</i>		
Papule	1	0
Skin burning sensation	1	0
Skin discolouration	1	0
Skin disorder	1	0
Skin lesion	1	0
Skin reaction	1	0
Skin warm	3	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	1	0
<i>Erythemas</i>		
Erythema	18	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	2	0
<i>Pruritus NEC</i>		
Pruritus	14	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	9	0
Rash pruritic	4	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
<i>Urticarias</i>		
Urticaria	6	0
Skin disorders SOC TOTAL	71	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
<i>Therapeutic procedures NEC</i>		
Hospitalisation	1	0
Surgical & medical procedures SOC TOTAL	7	0

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Vascular disorders		
<i>Haemorrhages NEC</i>		
Haemorrhage	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	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	7	0
TOTAL REACTIONS FOR DRUG	894	15
TOTAL REPORTS	259	
TOTAL FATAL OUTCOME REPORTS		15