

## Case Series Drug Analysis Print

### Name: DTPA IPV Vaccine Analysis Print

Report Run Date: 31-May-2023

Data Lock Date: 30-May-2023 18:30:04

Earliest Reaction Date: 05-Jan-2004

MedDRA Version: MedDRA 26.0

DTPA IPV Vaccine Analysis Print: FOI 23/323 - All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the DTPA IPV vaccine up to and including 30/05/2023.

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	9	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>11</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	2	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	4	0
Tachycardia	5	0
<b>Cardiac disorders SOC TOTAL</b>	<b>12</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Cardiac septal defects congenital</i>		
Ventricular septal defect	1	0
<i>Connective tissue disorders congenital</i>		
Hypermobility syndrome	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
<b>Congenital disorders SOC TOTAL</b>	<b>10</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear discomfort	1	0
Ear pain	2	0
Ear swelling	1	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	2	0
Vertigo	2	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane hyperaemia	1	0
<b>Ear disorders SOC TOTAL</b>	<b>10</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctivitis allergic	1	0
<i>Conjunctival structural change, deposit and degeneration</i>		
Conjunctival discolouration	1	0
<i>Eyelid movement disorders</i>		
Excessive eye blinking	2	0
<i>Lacrimation disorders</i>		
Lacrimation increased	4	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid rash	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye pain	3	0
Eye swelling	5	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Eye pruritus	2	0
Ocular hyperaemia	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	8	0
Strabismus	1	0
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<i>Orbital structural change, deposit and degeneration</i>		
Lid sulcus deepened	1	0
<i>Pupil disorders</i>		
Mydriasis	1	0
Pupil fixed	1	0
<i>Visual disorders NEC</i>		
Vision blurred	2	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
<b>Eye disorders SOC TOTAL</b>	<b>38</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Dental disorders NEC</i>		
Tooth disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	46	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Faecal abnormalities NEC</i>		
Faecaloma	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	10	0
Abdominal pain upper	25	0
Gastrointestinal pain	2	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	3	0
Gastrooesophageal reflux disease	3	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	5	0
Dysphagia	1	0
Odynophagia	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	35	0
Retching	2	0
Vomiting	106	0
Vomiting projectile	2	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 disorders NEC</i>		
Cheilitis	1	0
Oral disorder	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral discomfort	1	0
Oral mucosal blistering	1	0
Oral pain	4	0
Paraesthesia oral	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	5	0
<i>Stomatitis and ulceration</i>		
Stomatitis	1	0
<i>Tongue disorders</i>		
Tongue ulceration	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>265</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
Administration site erythema	1	0
Administration site joint pain	1	0
Administration site rash	2	0
Administration site reaction	1	0
Administration site swelling	1	0
<b><i>Application and instillation site reactions</i></b>		
Application site exfoliation	1	0
Application site pruritus	1	0
Application site swelling	2	0
<b><i>Asthenic conditions</i></b>		
Asthenia	7	0
Fatigue	53	0
Malaise	44	0
<b><i>Complications associated with device NEC</i></b>		
Injury associated with device	1	0
<b><i>Death and sudden death</i></b>		
Death	1	1
<b><i>Febrile disorders</i></b>		
Pyrexia	220	0
<b><i>Feelings and sensations NEC</i></b>		
Chills	16	0
Feeling abnormal	2	0
Feeling cold	2	0
Feeling drunk	1	0
Feeling hot	89	0
Feeling jittery	1	0
Feeling of body temperature change	1	0
Sensation of foreign body	1	0
Thirst	1	0
<b><i>Gait disturbances</i></b>		
Gait disturbance	1	0
Gait inability	1	0
<b><i>General signs and symptoms NEC</i></b>		
Condition aggravated	1	0
Crepitations	1	0
Crying	12	0
Developmental regression	1	0
Discharge	1	0
Disease progression	1	1
Energy increased	1	0
General physical health deterioration	1	0
Illness	15	0
Induration	15	0
Influenza like illness	9	0
Local reaction	166	0
Peripheral swelling	377	0
Prolapse	1	0
Screaming	6	0
Secretion discharge	1	0
Swelling	158	0
Swelling face	11	0
<b><i>Inflammations</i></b>		



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<b>General disorders</b> General disorders cont'd		
Inflammation	113	0
<b>Infusion site reactions</b>		
Infusion site erythema	1	0
<b>Injection site reactions</b>		
Injection site bruising	4	0
Injection site dermatitis	1	0
Injection site discolouration	6	0
Injection site discomfort	3	0
Injection site erythema	180	0
Injection site hypersensitivity	3	0
Injection site hypoaesthesia	1	0
Injection site induration	23	0
Injection site inflammation	73	0
Injection site irritation	4	0
Injection site joint erythema	1	0
Injection site joint warmth	1	0
Injection site mass	13	0
Injection site oedema	5	0
Injection site pain	54	0
Injection site pruritus	17	0
Injection site rash	17	0
Injection site reaction	66	0
Injection site swelling	142	0
Injection site urticaria	1	0
Injection site vesicles	20	0
Injection site warmth	44	0
<b>Interactions</b>		
Food interaction	1	0
<b>Mass conditions NEC</b>		
Nodule	1	0
<b>Mucosal findings abnormal</b>		
Mucosal disorder	1	0
<b>Oedema NEC</b>		
Localised oedema	5	0
Oedema	4	0
Oedema peripheral	8	0
<b>Pain and discomfort NEC</b>		
Chest discomfort	1	0
Chest pain	6	0
Discomfort	8	0
Facial pain	1	0
Pain	65	0
Tenderness	23	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	8	0
Adverse event	1	0
Adverse reaction	1	0
Therapeutic product ineffective	1	0
Vaccination failure	1	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	13	0
Vaccination site bruising	10	0
Vaccination site discharge	1	0

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<b>General disorders</b> General disorders cont'd		
Vaccination site discolouration	2	0
Vaccination site discomfort	4	0
Vaccination site erythema	147	0
Vaccination site granuloma	2	0
Vaccination site haemorrhage	1	0
Vaccination site hypersensitivity	1	0
Vaccination site induration	18	0
Vaccination site inflammation	22	0
Vaccination site irritation	2	0
Vaccination site joint erythema	2	0
Vaccination site joint inflammation	1	0
Vaccination site joint swelling	1	0
Vaccination site macule	1	0
Vaccination site mass	14	0
Vaccination site movement impairment	1	0
Vaccination site pain	42	0
Vaccination site pruritus	9	0
Vaccination site rash	20	0
Vaccination site reaction	9	0
Vaccination site scab	1	0
Vaccination site scar	1	0
Vaccination site swelling	116	0
Vaccination site urticaria	1	0
Vaccination site vesicles	6	0
Vaccination site warmth	67	0
<b>General disorders SOC TOTAL</b>	<b>2674</b>	<b>2</b>

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

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Hypersensitivity	30	0
Type III immune complex mediated reaction	1	0
Type IV hypersensitivity reaction	1	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergy to vaccine	2	0
Drug hypersensitivity	1	0
Food allergy	2	0
Reaction to excipient	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	13	0
Anaphylactic shock	1	0
Anaphylactoid reaction	1	0
<i><b>Immune and associated conditions NEC</b></i>		
Bacille Calmette-Guerin scar reactivation	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>54</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Bacterial infections NEC</i></b>		
Administration site cellulitis	6	0
Application site cellulitis	2	0
Bacterial infection	1	0
Cellulitis	139	0
Injection site cellulitis	19	0
Vaccination site cellulitis	23	0
<b><i>Bordetella infections</i></b>		
Pertussis	3	0
<b><i>Coronavirus infections</i></b>		
COVID-19	1	0
<b><i>Corynebacteria infections</i></b>		
Diphtheria	1	0
<b><i>Ear infections</i></b>		
Ear infection	3	0
Otitis media	1	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	2	0
Eye infection	1	0
<b><i>Herpes viral infections</i></b>		
Herpes zoster	1	0
<b><i>Infections NEC</i></b>		
Abscess	1	0
Infection	13	0
Injection site abscess	2	0
Injection site infection	5	0
Localised infection	4	0
Purulent discharge	1	0
Vaccination site abscess	1	0
Vaccination site infection	11	0
<b><i>Infectious transmissions</i></b>		
Infection via vaccinee	1	0
<b><i>Influenza viral infections</i></b>		
Influenza	3	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	1	0
Lower respiratory tract infection	3	0
<b><i>Molluscum contagiosum viral infections</i></b>		
Molluscum contagiosum	1	0
<b><i>Muscle and soft tissue infections</i></b>		
Muscle abscess	1	0
Soft tissue infection	1	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	2	1
<b><i>Skin structures and soft tissue infections</i></b>		
Dermatitis infected	1	0
Rash pustular	1	0
Skin infection	3	0
<b><i>Streptococcal infections</i></b>		
Scarlet fever	1	0
<b><i>Tuberculous infections</i></b>		
Erythema induratum	5	0
<b><i>Upper respiratory tract infections</i></b>		

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Nasopharyngitis	8	0
Rhinitis	1	0
Tonsillitis	3	0
Upper respiratory tract infection	1	0
<b>Urinary tract infections</b>		
Urinary tract infection	1	0
<b>Vascular infections</b>		
Lymphangitis	1	0
<b>Viral infections NEC</b>		
Viral infection	1	0
<b>Infections SOC TOTAL</b>	<b>281</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Exposure during pregnancy	29	0
Foetal exposure during pregnancy	17	0
Maternal exposure during pregnancy	72	0
Maternal exposure timing unspecified	2	0
<i><b>Eye injuries NEC</b></i>		
Eye injury	1	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Inadequate aseptic technique in use of product	1	0
Medication error	4	0
Product use in unapproved indication	4	0
Vaccination error	1	0
Wrong technique in product usage process	3	0
<i><b>Non-site specific injuries NEC</b></i>		
Fall	1	0
Injury	1	0
<i><b>Non-site specific procedural complications</b></i>		
Administration related reaction	1	0
Incision site inflammation	1	0
Wound dehiscence	1	0
<i><b>Overdoses NEC</b></i>		
Overdose	1	0
<i><b>Product administration errors and issues</b></i>		
Expired product administered	5	0
Extra dose administered	2	0
Inappropriate schedule of product administration	9	0
Product administered at inappropriate site	2	0
Product administered to patient of inappropriate age	5	0
Wrong product administered	8	0
<i><b>Product storage errors and issues in the product use system</b></i>		
Product storage error	1	0
<i><b>Reproductive system and breast injuries</b></i>		
Perineal injury	2	0
<i><b>Site specific injuries NEC</b></i>		
Limb injury	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	20	0
Scar	1	0
Skin abrasion	1	0
<i><b>Underdoses NEC</b></i>		
Underdose	1	0
<b>Injuries SOC TOTAL</b>	<b>198</b>	<b>0</b>

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<b>Investigations</b>		
<i><b>Blood gas and acid base analyses</b></i>		
Blood lactic acid decreased	1	0
Oxygen saturation decreased	3	0
<i><b>Cardiac auscultatory investigations</b></i>		
Cardiac murmur	1	0
<i><b>Cerebrospinal fluid tests (excl microbiology)</b></i>		
CSF white blood cell count increased	1	0
<i><b>Foetal and neonatal diagnostic procedures</b></i>		
Amniotic fluid volume decreased	1	0
Foetal monitoring abnormal	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate decreased	6	0
Heart rate increased	3	0
Heart rate irregular	2	0
Pulse abnormal	2	0
Radial pulse abnormal	1	0
<i><b>Hepatobiliary function diagnostic procedures</b></i>		
Alanine aminotransferase increased	1	0
Bile acids increased	1	0
Blood bilirubin increased	1	0
Hepatic enzyme abnormal	1	0
Liver function test abnormal	2	0
<i><b>Imaging procedures NEC</b></i>		
Magnetic resonance imaging abnormal	1	0
<i><b>Metabolism tests NEC</b></i>		
Urine ketone body present	1	0
<i><b>Neurologic diagnostic procedures</b></i>		
Lumbar puncture	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature decreased	2	0
Body temperature increased	17	0
Respiratory rate decreased	1	0
Respiratory rate increased	2	0
Temperature difference of extremities	1	0
<i><b>Platelet analyses</b></i>		
Platelet count decreased	1	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	1	0
<i><b>Renal function analyses</b></i>		
Blood creatinine increased	1	0
<i><b>Urinalysis NEC</b></i>		
Protein urine present	1	0
<i><b>Urinary tract function analyses NEC</b></i>		
Urine output decreased	1	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Blood pressure decreased	1	0
<i><b>White blood cell analyses</b></i>		
White blood cell count increased	2	0
<b>Investigations SOC TOTAL</b>	<b>62</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	38	0
Hypophagia	2	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus inadequate control	1	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Dairy intolerance	2	0
Food intolerance	1	0
<i><b>General nutritional disorders NEC</b></i>		
Feeding disorder	1	0
Poor feeding infant	1	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia neonatal	1	0
<i><b>Metabolic acidoses (excl diabetic acidoses)</b></i>		
Ketoacidosis	3	0
Metabolic acidosis	2	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>53</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	3	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	2	0
<i><b>Bursal disorders</b></i>		
Bursitis	2	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	18	0
Joint effusion	2	0
Joint stiffness	2	0
Joint swelling	3	0
<i><b>Muscle infections and inflammations</b></i>		
Myositis	4	0
<i><b>Muscle pains</b></i>		
Myalgia	13	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle fatigue	1	0
Muscle spasms	6	0
Muscle swelling	3	0
Muscle twitching	5	0
<i><b>Muscle tone abnormalities</b></i>		
Floppy infant	1	0
Muscle rigidity	3	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	8	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Limb mass	2	0
Mobility decreased	1	0
Musculoskeletal stiffness	6	0
Weight bearing difficulty	1	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	5	0
Limb discomfort	10	0
Musculoskeletal pain	1	0
Neck pain	4	0
Pain in extremity	87	0
<i><b>Rheumatoid arthropathies</b></i>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	1	0
<i><b>Synovial disorders</b></i>		
Synovitis	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>196</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Neoplasms unspecified malignancy and site unspecified NEC</i>		
Neoplasm	1	0
<b>Neoplasms SOC TOTAL</b>	<b>1</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: DTPA IPV Vaccine Analysis Print

Report Run Date: 31-May-2023  
Earliest Reaction Date: 05-Jan-2004

Data Lock Date: 30-May-2023 18:30:04  
MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<b><i>Absence seizures</i></b>		
Petit mal epilepsy	1	0
<b><i>Acute polyneuropathies</i></b>		
Guillain-Barre syndrome	3	0
<b><i>Coordination and balance disturbances</i></b>		
Coordination abnormal	2	0
Dysstasia	1	0
Hand-eye coordination impaired	1	0
<b><i>Cortical dysfunction NEC</i></b>		
Dyspraxia	1	0
<b><i>Disturbances in consciousness NEC</i></b>		
Depressed level of consciousness	1	0
Lethargy	16	0
Loss of consciousness	8	0
Somnolence	23	0
Syncope	33	0
<b><i>Dyskinesias and movement disorders NEC</i></b>		
Dyskinesia	6	0
Hypokinesia	2	0
Movement disorder	1	0
Psychomotor hyperactivity	3	0
<b><i>Dystonias</i></b>		
Opisthotonus	1	0
<b><i>Encephalitis NEC</i></b>		
Encephalitis post immunisation	1	0
<b><i>Facial cranial nerve disorders</i></b>		
Bell's palsy	2	0
Facial paralysis	1	0
Facial paresis	1	0
Facial spasm	1	0
<b><i>Generalised tonic-clonic seizures</i></b>		
Generalised tonic-clonic seizure	4	0
<b><i>Headaches NEC</i></b>		
Headache	58	0
Sinus headache	2	0
Tension headache	2	0
<b><i>Migraine headaches</i></b>		
Migraine	5	0
<b><i>Muscle tone abnormal</i></b>		
Hypotonia	14	0
<b><i>Myelitis (incl infective)</i></b>		
Myelitis transverse	2	0
<b><i>Narcolepsy and hypersomnia</i></b>		
Hypersomnia	1	0
<b><i>Nervous system disorders NEC</i></b>		
Central nervous system lesion	1	0
Nervous system disorder	1	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Brain fog	1	0
Dizziness	24	0
Head discomfort	1	0
Presyncope	6	0
Unresponsive to stimuli	11	0

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MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b>Neuromuscular disorders NEC</b>		
Hypotonic-hyporesponsive episode	4	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	1	0
Hyperaesthesia	1	0
Hypoaesthesia	1	0
Paraesthesia	7	0
<b>Partial complex seizures</b>		
Focal dyscognitive seizures	1	0
<b>Partial simple seizures NEC</b>		
Simple partial seizures	1	0
<b>Seizures and seizure disorders NEC</b>		
Epilepsy	2	0
Febrile convulsion	5	0
Myoclonic epilepsy	1	0
Neonatal seizure	1	0
Partial seizures	1	0
Seizure	12	0
Seizure like phenomena	1	0
<b>Sensory abnormalities NEC</b>		
Allodynia	1	0
Dysgeusia	1	0
Neuralgia	1	0
Sensory disturbance	3	0
<b>Speech and language abnormalities</b>		
Speech disorder	2	0
<b>Spinal cord and nerve root disorders NEC</b>		
Brown-Sequard syndrome	1	0
Spinal cord disorder	1	0
<b>Structural brain disorders NEC</b>		
Brain injury	2	0
<b>Tremor (excl congenital)</b>		
Tremor	6	0
<b>Nervous system disorders SOC TOTAL</b>	<b>299</b>	<b>0</b>

# Case Series Drug Analysis Print

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Report Run Date: 31-May-2023  
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Data Lock Date: 30-May-2023 18:30:04  
MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<b><i>Abortions spontaneous</i></b>		
Abortion spontaneous	1	0
<b><i>Amniotic fluid and cavity disorders of pregnancy NEC</i></b>		
Amniorrhoea	1	0
<b><i>Foetal complications NEC</i></b>		
Foetal distress syndrome	3	0
Foetal hypokinesia	13	0
<b><i>Foetal growth complications</i></b>		
Foetal growth restriction	4	0
<b><i>Foetal position and presentation abnormalities</i></b>		
Breech presentation	2	0
<b><i>Gestational age and weight conditions</i></b>		
Premature baby	2	0
<b><i>Haemorrhagic complications of pregnancy</i></b>		
Premature separation of placenta	1	0
<b><i>Hypertension associated disorders of pregnancy</i></b>		
Pre-eclampsia	1	0
<b><i>Labour onset and length abnormalities</i></b>		
Premature delivery	3	0
Premature labour	4	0
Premature rupture of membranes	1	0
Prolonged labour	5	0
<b><i>Maternal complications of delivery NEC</i></b>		
Retained placenta or membranes	1	0
<b><i>Neonatal hepatobiliary disorders</i></b>		
Jaundice neonatal	2	0
<b><i>Normal pregnancy, labour and delivery</i></b>		
Live birth	2	0
Pregnancy	1	0
Uterine contractions during pregnancy	1	0
<b><i>Placental abnormalities (excl neoplasms)</i></b>		
Foetal vascular malperfusion	1	0
Placental disorder	1	0
<b><i>Postpartum complications NEC</i></b>		
Postpartum haemorrhage	3	0
<b><i>Pregnancy complicated by maternal disorders</i></b>		
Gestational diabetes	1	0
<b><i>Stillbirth and foetal death</i></b>		
Foetal death	3	3
Stillbirth	11	11
<b><i>Umbilical cord complications</i></b>		
Umbilical cord thrombosis	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>69</b>	<b>14</b>

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## Name: DTPA IPV Vaccine Analysis Print

Report Run Date: 31-May-2023  
Earliest Reaction Date: 05-Jan-2004

Data Lock Date: 30-May-2023 18:30:04  
MedDRA Version: MedDRA 26.0

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b><i>Device physical property and chemical issues</i></b>		
Needle issue	1	0
<b><i>Product label issues</i></b>		
Product lot number issue	1	0
<b><i>Product quality issues NEC</i></b>		
Product complaint	2	0
Product quality issue	3	0
<b>null SOC TOTAL</b>	<b>7</b>	<b>0</b>

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Report Run Date: 31-May-2023  
Earliest Reaction Date: 05-Jan-2004

Data Lock Date: 30-May-2023 18:30:04  
MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	8	0
Staring	3	0
<b><i>Anxiety symptoms</i></b>		
Agitation	1	0
Anxiety	2	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	3	0
Social avoidant behaviour	2	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	2	0
Disorientation	1	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	6	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	1	0
<b><i>Eating disorders NEC</i></b>		
Eating disorder	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	1	0
Emotional disorder	1	0
Emotional distress	2	0
Irritability	20	0
Mood altered	1	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	1	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	1	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	3	0
Hallucination, visual	2	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	1	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	1	0
Tearfulness	4	0
<b><i>Mood disorders NEC</i></b>		
Apathy	1	0
Listless	3	0
<b><i>Obsessive-compulsive disorders and symptoms</i></b>		
Obsessive-compulsive symptom	1	0
<b><i>Parasomnias</i></b>		
Sleep terror	1	0
<b><i>Pervasive developmental disorders NEC</i></b>		
Autism spectrum disorder	10	0
<b><i>Psychiatric elimination disorders</i></b>		
Enuresis	1	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	2	0
<b><i>Speech and language usage disturbances</i></b>		
Disorganised speech	1	0
<b><i>Suicidal and self-injurious behaviour</i></b>		
Suicidal ideation	1	0



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MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
<i>Thinking disturbances</i>		
Thinking abnormal	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>90</b>	<b>0</b>

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Report Run Date: 31-May-2023  
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Data Lock Date: 30-May-2023 18:30:04  
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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Micturition frequency decreased	1	0
Urinary incontinence	3	0
Urinary retention	1	0
<i>Renal disorders NEC</i>		
Renal disorder	1	0
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
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>12</b>	<b>0</b>

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 MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile swelling	2	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital rash	1	0
Genital swelling	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
Testicular swelling	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	8	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>16</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	12	0
Respiration abnormal	1	0
Respiratory depression	1	0
Respiratory distress	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Obstructive airways disorder	1	0
Wheezing	2	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Hypoxia	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	34	0
Productive cough	1	0
Sputum discoloured	1	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Lower respiratory tract inflammation	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	1	0
Pulmonary pain	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	4	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	2	0
Nasal pruritus	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Tonsillar hypertrophy	1	0
Tonsillar inflammation	1	0
<i><b>Respiratory signs and symptoms NEC</b></i>		
Nasal flaring	1	0
<i><b>Respiratory tract disorders NEC</b></i>		
Respiratory tract congestion	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Dry throat	1	0
Nasal discharge discolouration	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	14	0
Rhinorrhoea	10	0
Sneezing	1	0
Snoring	2	0
Upper respiratory tract congestion	1	0
Yawning	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>101</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	1	0
Acne infantile	1	0
<b><i>Angioedemas</i></b>		
Angioedema	2	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	15	0
Hyperhidrosis	7	0
<b><i>Bullous conditions</i></b>		
Blister	44	0
Dermatitis bullous	1	0
Erythema multiforme	2	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	2	0
Pain of skin	4	0
Papule	3	0
Skin burning sensation	3	0
Skin discolouration	8	0
Skin disorder	1	0
Skin induration	7	0
Skin lesion	4	0
Skin reaction	20	0
Skin texture abnormal	3	0
Skin tightness	4	0
Skin warm	60	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	3	0
Dermatitis allergic	8	0
Eczema	9	0
Skin irritation	6	0
<b><i>Erythemas</i></b>		
Erythema	450	0
<b><i>Exfoliative conditions</i></b>		
Skin exfoliation	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Nail discolouration	1	0
<b><i>Papulosquamous conditions</i></b>		
Lichen sclerosus	1	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	2	0
<b><i>Pruritus NEC</i></b>		
Pruritus	90	0
<b><i>Purpura and related conditions</i></b>		
Petechiae	3	0
Purpura	1	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	80	0
Rash erythematous	21	0
Rash macular	11	0
Rash maculo-papular	2	0
Rash morbilliform	2	0
Rash papular	10	0
Rash pruritic	12	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash vesicular	2	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	2	0
<i>Skin vascular conditions NEC</i>		
Skin oedema	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	1	0
<i>Urticarias</i>		
Urticaria	45	0
<b>Skin disorders SOC TOTAL</b>	<b>956</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Immobile	1	0
<b>Social circumstances SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Obstetric therapeutic procedures</i>		
Caesarean section	5	0
Vacuum extractor delivery	1	0
<i>Therapeutic procedures NEC</i>		
Hospitalisation	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>7</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Arterial infections and inflammations</b></i>		
Kawasaki's disease	1	0
<i><b>Circulatory collapse and shock</b></i>		
Circulatory collapse	2	0
Shock	2	0
<i><b>Haemorrhages NEC</b></i>		
Haematoma	1	0
Haemorrhage	3	0
<i><b>Non-site specific vascular disorders NEC</b></i>		
Hyperaemia	1	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Cyanosis	12	0
Flushing	5	0
Hot flush	1	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Peripheral coldness	3	0
Poor peripheral circulation	1	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	44	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	3	0
<i><b>Vascular hypotensive disorders</b></i>		
Hypotension	3	0
<b>Vascular disorders SOC TOTAL</b>	<b>82</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>5507</b>	<b>17</b>
<b>TOTAL REPORTS</b>	<b>2208</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>17</b>