

## Case Series Drug Analysis Print

### Name: DTPa IPV Vaccine

Report Run Date: 11-Feb-2021

Data Lock Date: 03-Feb-2021 19:00:04

Earliest Reaction Date: 05-Jan-2004

MedDRA Version: MedDRA 23.1

DTPa IPV Vaccine: UK Spontaneous ADR reports for DTPa IPV until 31/01/2021.

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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>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>9</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear discomfort	1	0
Ear pain	1	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Vertigo	2	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane hyperaemia	1	0
<b>Ear disorders SOC TOTAL</b>	<b>6</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	2	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye pain	2	0
Eye swelling	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye pruritus	2	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	7	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	1	0
<b>Eye disorders SOC TOTAL</b>	<b>26</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	38	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	16	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	3	0
Gastrooesophageal reflux disease	2	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
<i>Nausea and vomiting symptoms</i>		
Nausea	25	0
Retching	2	0
Vomiting	90	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>		
Odynophagia	1	0
Oral discomfort	1	0
Oral mucosal blistering	1	0
Oral pain	2	0
Paraesthesia oral	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	4	0
<i>Tongue disorders</i>		
Tongue ulceration	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>216</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	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	5	0
Fatigue	38	0
Malaise	40	0
<b><i>Complications associated with device NEC</i></b>		
Injury associated with device	1	0
<b><i>Febrile disorders</i></b>		
Pyrexia	189	0
<b><i>Feelings and sensations NEC</i></b>		
Chills	11	0
Feeling abnormal	1	0
Feeling cold	1	0
Feeling drunk	1	0
Feeling hot	80	0
Feeling jittery	1	0
Feeling of body temperature change	1	0
Thirst	1	0
<b><i>Gait disturbances</i></b>		
Gait disturbance	1	0
<b><i>General signs and symptoms NEC</i></b>		
Condition aggravated	1	0
Crepitations	1	0
Crying	8	0
Discharge	1	0
Illness	9	0
Induration	15	0
Influenza like illness	9	0
Local reaction	166	0
Peripheral swelling	356	0
Screaming	5	0
Secretion discharge	1	0
Swelling	151	0
Swelling face	10	0
<b><i>Inflammations</i></b>		
Inflammation	110	0
<b><i>Infusion site reactions</i></b>		
Infusion site erythema	1	0
<b><i>Injection site reactions</i></b>		
Injection site bruising	3	0
Injection site dermatitis	1	0
Injection site discolouration	6	0
Injection site discomfort	3	0
Injection site erythema	175	0
Injection site hypersensitivity	3	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site hypoaesthesia	1	0
Injection site induration	23	0
Injection site inflammation	72	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	51	0
Injection site pruritus	16	0
Injection site rash	16	0
Injection site reaction	65	0
Injection site swelling	137	0
Injection site urticaria	1	0
Injection site vesicles	20	0
Injection site warmth	43	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	4	0
Oedema	4	0
Oedema peripheral	8	0
<b>Pain and discomfort NEC</b>		
Chest discomfort	1	0
Chest pain	4	0
Discomfort	7	0
Facial pain	1	0
Pain	60	0
Tenderness	22	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse event	1	0
Adverse reaction	1	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	12	0
Vaccination site bruising	10	0
Vaccination site discharge	1	0
Vaccination site discolouration	2	0
Vaccination site discomfort	4	0
Vaccination site erythema	137	0
Vaccination site granuloma	2	0
Vaccination site haemorrhage	1	0
Vaccination site hypersensitivity	1	0
Vaccination site induration	15	0
Vaccination site inflammation	18	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

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Vaccination site mass	12	0
Vaccination site movement impairment	1	0
Vaccination site pain	39	0
Vaccination site pruritus	8	0
Vaccination site rash	16	0
Vaccination site reaction	9	0
Vaccination site scab	1	0
Vaccination site scar	1	0
Vaccination site swelling	107	0
Vaccination site urticaria	1	0
Vaccination site vesicles	6	0
Vaccination site warmth	58	0
<b>General disorders SOC TOTAL</b>	<b>2468</b>	<b>0</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	27	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
Food allergy	2	0
Reaction to excipient	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	10	0
Anaphylactic shock	1	0
Anaphylactoid reaction	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>46</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
Cellulitis	137	0
Injection site cellulitis	19	0
Vaccination site cellulitis	23	0
<b><i>Bordetella infections</i></b>		
Pertussis	3	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>Infections NEC</i></b>		
Abscess	1	0
Infection	11	0
Injection site abscess	2	0
Injection site infection	5	0
Localised infection	3	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	2	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>		
Nasopharyngitis	7	0
Rhinitis	1	0
Tonsillitis	3	0
Upper respiratory tract infection	1	0
<b><i>Vascular infections</i></b>		

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Lymphangitis	1	0
<b><i>Viral infections NEC</i></b>		
Viral infection	1	0
<b>Infections SOC TOTAL</b>	<b>270</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	24	0
Foetal exposure during pregnancy	16	0
Maternal exposure during pregnancy	33	0
Maternal exposure timing unspecified	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	3	0
Wrong technique in product usage process	3	0
<i><b>Non-site specific injuries NEC</b></i>		
Fall	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	4	0
Inappropriate schedule of product administration	5	0
Product administered at inappropriate site	1	0
Product administered to patient of inappropriate age	3	0
Wrong product administered	7	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>Skin injuries NEC</b></i>		
Contusion	18	0
Scar	1	0
Skin abrasion	1	0
<i><b>Underdoses NEC</b></i>		
Underdose	1	0
<i><b>Vaccination related complications</b></i>		
Vaccination failure	1	0
<b>Injuries SOC TOTAL</b>	<b>131</b>	<b>0</b>

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Reaction Name	Total	Fatal
<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>Imaging procedures NEC</b></i>		
Magnetic resonance imaging abnormal	1	0
<i><b>Liver function analyses</b></i>		
Alanine aminotransferase increased	1	0
Blood bilirubin increased	1	0
Liver function test abnormal	2	0
Total bile acids increased	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	1	0
Body temperature increased	14	0
Respiratory rate decreased	1	0
Respiratory rate increased	2	0
Temperature difference of extremities	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>56</b>	<b>0</b>

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<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	31	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>46</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Arthropathies NEC</i>		
Arthritis	2	0
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
<i>Bursal disorders</i>		
Bursitis	1	0
<i>Joint related disorders NEC</i>		
Hypermobility syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	16	0
Joint effusion	2	0
Joint stiffness	2	0
Joint swelling	3	0
<i>Muscle infections and inflammations</i>		
Myositis	4	0
<i>Muscle pains</i>		
Myalgia	10	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	4	0
Muscle swelling	2	0
Muscle twitching	5	0
<i>Muscle tone abnormalities</i>		
Floppy infant	1	0
Muscle rigidity	3	0
<i>Muscle weakness conditions</i>		
Muscular weakness	5	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	1	0
Musculoskeletal stiffness	5	0
Weight bearing difficulty	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	3	0
Limb discomfort	10	0
Neck pain	2	0
Pain in extremity	77	0
<i>Rheumatoid arthropathies</i>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	1	0
<i>Synovial disorders</i>		
Synovitis	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>164</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>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<b>Absence seizures</b>		
Petit mal epilepsy	1	0
<b>Acute polyneuropathies</b>		
Guillain-Barre syndrome	2	0
<b>Coordination and balance disturbances</b>		
Coordination abnormal	2	0
Dysstasia	1	0
Hand-eye coordination impaired	1	0
<b>Cortical dysfunction NEC</b>		
Dyspraxia	1	0
<b>Disturbances in consciousness NEC</b>		
Depressed level of consciousness	1	0
Lethargy	15	0
Loss of consciousness	8	0
Somnolence	20	0
Syncope	31	0
<b>Dyskinesias and movement disorders NEC</b>		
Dyskinesia	6	0
Movement disorder	1	0
Psychomotor hyperactivity	3	0
<b>Dystonias</b>		
Opisthotonus	1	0
<b>Encephalitis NEC</b>		
Encephalitis post immunisation	1	0
<b>Facial cranial nerve disorders</b>		
Facial paralysis	2	0
Facial spasm	1	0
<b>Generalised tonic-clonic seizures</b>		
Generalised tonic-clonic seizure	4	0
<b>Headaches NEC</b>		
Headache	46	0
Sinus headache	2	0
Tension headache	2	0
<b>Migraine headaches</b>		
Migraine	3	0
<b>Muscle tone abnormal</b>		
Hypotonia	14	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	3	0
<b>Narcolepsy and hypersomnia</b>		
Hypersomnia	1	0
<b>Nervous system disorders NEC</b>		
Central nervous system lesion	1	0
Nervous system disorder	1	0
<b>Neurological signs and symptoms NEC</b>		
Dizziness	19	0
Head discomfort	1	0
Presyncope	6	0
Unresponsive to stimuli	11	0
<b>Neuromuscular disorders NEC</b>		
Hypotonic-hyporesponsive episode	4	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	1	0

# Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Hyperaesthesia	1	0
Hypoaesthesia	1	0
Paraesthesia	6	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	3	0
Myoclonic epilepsy	1	0
Neonatal seizure	1	0
Partial seizures	1	0
Seizure	11	0
Seizure like phenomena	1	0
<b>Sensory abnormalities NEC</b>		
Neuralgia	1	0
Sensory disturbance	3	0
<b>Speech and language abnormalities</b>		
Speech disorder	1	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	5	0
<b>Nervous system disorders SOC TOTAL</b>	<b>261</b>	<b>0</b>

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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	14	0
<b><i>Foetal growth complications</i></b>		
Foetal growth restriction	3	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	1	0
<b><i>Haemorrhagic complications of pregnancy</i></b>		
Premature separation of placenta	1	0
<b><i>Labour onset and length abnormalities</i></b>		
Premature delivery	2	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	1	0
Pregnancy	1	0
Uterine contractions during pregnancy	1	0
<b><i>Placental abnormalities (excl neoplasms)</i></b>		
Foetal placental thrombosis	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	4	3
Stillbirth	11	11
<b><i>Umbilical cord complications</i></b>		
Umbilical cord thrombosis	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>66</b>	<b>14</b>

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MedDRA Version: MedDRA 23.1

<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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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	1	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	5	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	17	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	2	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>Pervasive developmental disorders NEC</i></b>		
Autism spectrum disorder	6	0
<b><i>Psychiatric elimination disorders</i></b>		
Enuresis	1	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	1	0
<b><i>Speech and language usage disturbances</i></b>		
Disorganised speech	1	0
<b><i>Thinking disturbances</i></b>		
Thinking abnormal	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>76</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<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
<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>11</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<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>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
Testicular swelling	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	8	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>13</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i>Breathing abnormalities</i>		
Dyspnoea	9	0
Respiratory depression	1	0
Respiratory distress	1	0
<i>Bronchospasm and obstruction</i>		
Obstructive airways disorder	1	0
Wheezing	2	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	26	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Lower respiratory tract inflammation	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	4	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
Nasal pruritus	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Tonsillar hypertrophy	1	0
Tonsillar inflammation	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory tract congestion	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Dry throat	1	0
Nasal discharge discolouration	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	13	0
Rhinorrhoea	5	0
Snoring	1	0
Upper respiratory tract congestion	1	0
Yawning	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>76</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
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	6	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	3	0
Papule	3	0
Skin burning sensation	3	0
Skin discolouration	8	0
Skin disorder	1	0
Skin induration	6	0
Skin lesion	4	0
Skin reaction	19	0
Skin texture abnormal	2	0
Skin tightness	4	0
Skin warm	58	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	2	0
Dermatitis allergic	8	0
Eczema	8	0
Skin irritation	6	0
<b><i>Erythemas</i></b>		
Erythema	430	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 photodermatitis conditions</i></b>		
Photosensitivity reaction	2	0
<b><i>Pruritus NEC</i></b>		
Pruritus	85	0
<b><i>Purpura and related conditions</i></b>		
Petechiae	2	0
Purpura	1	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	68	0
Rash erythematous	14	0
Rash macular	10	0
Rash maculo-papular	2	0
Rash morbilliform	2	0
Rash papular	9	0
Rash pruritic	11	0
Rash vesicular	2	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Skin mass	2	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<i>Skin vascular conditions NEC</i>		
Skin oedema	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	1	0
<i>Urticarias</i>		
Urticaria	39	0
<b>Skin disorders SOC TOTAL</b>	<b>891</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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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Surgical &amp; medical procedures</b>		
<i>Obstetric therapeutic procedures</i>		
Caesarean section	5	0
Vacuum extractor delivery	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>6</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
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Peripheral coldness	2	0
Poor peripheral circulation	1	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	43	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	3	0
<i><b>Vascular hypotensive disorders</b></i>		
Hypotension	2	0
<b>Vascular disorders SOC TOTAL</b>	<b>78</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>4950</b>	<b>15</b>
<b>TOTAL REPORTS</b>	<b>2014</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>15</b>