

Case Series Drug Analysis Print

Name: FOI 23/945 - DTaP/IPV Vaccine Analysis Print

Report Run Date: 20-Dec-2023

Data Lock Date: 07-Dec-2023 18:30:03

Earliest Reaction Date: 05-Jan-2004

MedDRA Version: MedDRA 26.1

FOI 23/945 - All UK spontaneous suspected Adverse Drug Reaction
DTaP/IPV Vaccine (ADR) reports associated with the DTaP/IPV vaccine
Analysis Print: up to and including 07/12/2023.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	10	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<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
Cardiac disorders SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Congenital disorders		
<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>Oral cavity disorders congenital NEC</i>		
Tethered oral tissue	2	0
Congenital disorders SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Ear disorders		
<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
Ear disorders SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Eye disorders		
<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	3	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>		
Asthenopia	1	0
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
Eye disorders SOC TOTAL	40	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<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	26	0
Gastrointestinal pain	2	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	4	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	107	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
Gastrointestinal disorders SOC TOTAL	268	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
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
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Application and instillation site reactions</i>		
Application site exfoliation	1	0
Application site pruritus	1	0
Application site swelling	2	0
<i>Asthenic conditions</i>		
Asthenia	7	0
Fatigue	55	0
Malaise	45	0
<i>Complications associated with device NEC</i>		
Injury associated with device	1	0
<i>Death and sudden death</i>		
Death	1	1
<i>Febrile disorders</i>		
Pyrexia	222	0
<i>Feelings and sensations NEC</i>		
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
<i>Gait disturbances</i>		
Gait disturbance	1	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
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

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General disorders General disorders cont'd		
Swelling face	11	0
Inflammations		
Inflammation	113	0
Infusion site reactions		
Infusion site erythema	1	0
Injection site reactions		
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	55	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
Interactions		
Food interaction	1	0
Mass conditions NEC		
Nodule	1	0
Mucosal findings abnormal		
Mucosal disorder	1	0
Oedema NEC		
Localised oedema	5	0
Oedema	4	0
Oedema peripheral	8	0
Pain and discomfort NEC		
Chest discomfort	1	0
Chest pain	6	0
Discomfort	8	0
Facial pain	1	0
Pain	65	0
Tenderness	23	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	7	0
Adverse event	1	0
Adverse reaction	1	0
Therapeutic product ineffective	1	0
Vaccination failure	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	13	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site bruising	10	0
Vaccination site discharge	1	0
Vaccination site discolouration	2	0
Vaccination site discomfort	4	0
Vaccination site erythema	148	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	3	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
General disorders SOC TOTAL	2682	2

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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>Allergic conditions NEC</i>		
Hypersensitivity	30	0
Type III immune complex mediated reaction	1	0
Type IV hypersensitivity reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	2	0
Drug hypersensitivity	1	0
Food allergy	2	0
Reaction to excipient	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	13	0
Anaphylactic shock	1	0
Anaphylactoid reaction	1	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
Immune system disorders SOC TOTAL	56	0

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Infections		
<i>Bacterial infections NEC</i>		
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
<i>Bordetella infections</i>		
Pertussis	3	0
<i>Coronavirus infections</i>		
COVID-19	1	0
<i>Corynebacteria infections</i>		
Diphtheria	1	0
<i>Ear infections</i>		
Ear infection	3	0
Otitis media	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	2	0
Eye infection	1	0
<i>Herpes viral infections</i>		
Herpes zoster	1	0
<i>Infections NEC</i>		
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
<i>Infectious transmissions</i>		
Infection via vaccinee	1	0
<i>Influenza viral infections</i>		
Influenza	3	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	1	0
Lower respiratory tract infection	3	0
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	1	0
<i>Muscle and soft tissue infections</i>		
Muscle abscess	1	0
Soft tissue infection	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	2	1
<i>Skin structures and soft tissue infections</i>		
Dermatitis infected	1	0
Rash pustular	1	0
Skin infection	3	0
<i>Streptococcal infections</i>		
Scarlet fever	1	0
<i>Tuberculous infections</i>		
Erythema induratum	5	0
<i>Upper respiratory tract infections</i>		

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

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	30	0
Foetal exposure during pregnancy	18	0
Maternal exposure during pregnancy	72	0
Maternal exposure timing unspecified	2	0
<i>Eye injuries NEC</i>		
Eye injury	1	0
<i>Medication errors, product use errors and issues NEC</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>Non-site specific injuries NEC</i>		
Fall	1	0
Injury	1	0
<i>Non-site specific procedural complications</i>		
Administration related reaction	1	0
Incision site inflammation	1	0
Wound dehiscence	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Product administration errors and issues</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>Product storage errors and issues in the product use system</i>		
Product storage error	1	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	20	0
Scar	1	0
Skin abrasion	1	0
<i>Underdoses NEC</i>		
Underdose	1	0
Injuries SOC TOTAL	200	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Blood lactic acid decreased	1	0
Oxygen saturation decreased	3	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF white blood cell count increased	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 decreased	6	0
Heart rate increased	3	0
Heart rate irregular	2	0
Pulse abnormal	2	0
Radial pulse abnormal	1	0
<i>Hepatobiliary function diagnostic procedures</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>Imaging procedures NEC</i>		
Magnetic resonance imaging abnormal	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 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>Platelet analyses</i>		
Platelet count decreased	1	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	1	0
<i>Renal function analyses</i>		
Blood creatinine increased	1	0
<i>Urinalysis NEC</i>		
Protein urine present	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output decreased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
<i>White blood cell analyses</i>		
White blood cell count increased	2	0
Investigations SOC TOTAL	62	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	39	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	2	0
Food intolerance	1	0
<i>General nutritional disorders NEC</i>		
Feeding disorder	1	0
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
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	54	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	3	0
<i>Bone related signs and symptoms</i>		
Bone pain	2	0
<i>Bursal disorders</i>		
Bursitis	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	18	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	13	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	1	0
Muscle spasms	6	0
Muscle swelling	3	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	8	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Limb mass	2	0
Mobility decreased	1	0
Musculoskeletal stiffness	6	0
Weight bearing difficulty	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	6	0
Limb discomfort	10	0
Musculoskeletal pain	1	0
Neck pain	4	0
Pain in extremity	87	0
<i>Rheumatoid arthropathies</i>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	1	0
<i>Synovial disorders</i>		
Synovitis	1	0
Muscle & tissue disorders SOC TOTAL	197	0

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

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

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Presyncope	6	0
Unresponsive to stimuli	11	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	4	0
Paraesthesias and dysaesthesias		
Burning sensation	1	0
Hyperaesthesia	1	0
Hypoaesthesia	1	0
Paraesthesia	8	0
Partial complex seizures		
Focal dyscognitive seizures	1	0
Partial simple seizures NEC		
Simple partial seizures	1	0
Seizures and seizure disorders NEC		
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
Sensory abnormalities NEC		
Allodynia	1	0
Dysgeusia	1	0
Neuralgia	1	0
Sensory disturbance	3	0
Speech and language abnormalities		
Speech disorder	2	0
Spinal cord and nerve root disorders NEC		
Brown-Sequard syndrome	1	0
Spinal cord disorder	1	0
Structural brain disorders NEC		
Brain injury	2	0
Tremor (excl congenital)		
Tremor	6	0
Nervous system disorders SOC TOTAL	302	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>		
Amniorrhea	1	0
<i>Foetal complications NEC</i>		
Foetal distress syndrome	3	0
Foetal hypokinesia	13	0
<i>Foetal growth complications</i>		
Foetal growth restriction	5	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	70	14

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

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	9	0
Regressive behaviour	1	0
Staring	3	0
<i>Anxiety symptoms</i>		
Agitation	1	0
Anxiety	2	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	3	0
Attention-seeking behaviour	1	0
Social avoidant behaviour	2	0
<i>Confusion and disorientation</i>		
Confusional state	2	0
Disorientation	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	6	0
<i>Dyssomnias</i>		
Poor quality sleep	1	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	1	0
Emotional disorder	1	0
Emotional distress	2	0
Irritability	20	0
Mood altered	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	3	0
Hallucination, visual	2	0
<i>Increased physical activity levels</i>		
Restlessness	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
Tearfulness	4	0
<i>Mood disorders NEC</i>		
Apathy	1	0
Listless	3	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive symptom	1	0
<i>Parasomnias</i>		
Sleep terror	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	11	0
<i>Psychiatric elimination disorders</i>		
Enuresis	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
<i>Speech and language usage disturbances</i>		
Disorganised speech	1	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	1	0
<i>Thinking disturbances</i>		
Thinking abnormal	1	0
Psychiatric disorders SOC TOTAL	95	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<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
Renal & urinary disorders SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<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
Reproductive & breast disorders SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	12	0
Respiration abnormal	1	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	34	0
Productive cough	1	0
Sputum discoloured	1	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
Pulmonary pain	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	4	0
<i>Nasal disorders NEC</i>		
Epistaxis	2	0
Nasal pruritus	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Tonsillar hypertrophy	1	0
Tonsillar inflammation	1	0
<i>Respiratory signs and symptoms NEC</i>		
Nasal flaring	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	15	0
Rhinorrhoea	10	0
Sneezing	1	0
Snoring	2	0
Upper respiratory tract congestion	1	0
Yawning	1	0
Respiratory disorders SOC TOTAL	102	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	1	0
Acne infantile	1	0
<i>Angioedemas</i>		
Angioedema	2	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	15	0
Hyperhidrosis	7	0
Hypohidrosis	1	0
<i>Bullous conditions</i>		
Blister	44	0
Dermatitis bullous	1	0
Erythema multiforme	2	0
<i>Dermal and epidermal conditions NEC</i>		
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
<i>Dermatitis and eczema</i>		
Dermatitis	3	0
Dermatitis allergic	8	0
Eczema	10	0
Skin irritation	6	0
<i>Erythemas</i>		
Erythema	450	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	1	0
<i>Papulosquamous conditions</i>		
Lichen sclerosus	1	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	2	0
<i>Pruritus NEC</i>		
Pruritus	90	0
<i>Purpura and related conditions</i>		
Petechiae	3	0
Purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	81	0
Rash erythematous	21	0
Rash macular	11	0
Rash maculo-papular	2	0
Rash morbilliform	2	0
Rash papular	10	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash pruritic	12	0
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
Skin disorders SOC TOTAL	959	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Immobile	1	0
Social circumstances SOC TOTAL	1	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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Reaction Name	Total	Fatal
Vascular disorders		
<i>Arterial infections and inflammations</i>		
Kawasaki's disease	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	2	0
Shock	2	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
Haemorrhage	3	0
<i>Non-site specific vascular disorders NEC</i>		
Hyperaemia	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	12	0
Flushing	5	0
Hot flush	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	3	0
Poor peripheral circulation	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	44	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	3	0
<i>Vascular hypotensive disorders</i>		
Hypotension	3	0
Vascular disorders SOC TOTAL	82	0
TOTAL REACTIONS FOR DRUG	5540	17
TOTAL REPORTS	2215	
TOTAL FATAL OUTCOME REPORTS		17