

Case Series Drug Analysis Print

Name: Td IPV Vaccine

Report Run Date: 27-Oct-2022
Data Lock Date: 26-Oct-2022 18:30:05
Earliest Reaction Date: 01-May-1983
MedDRA Version: MedDRA 25.0
Td IPV Vaccine: UK spontaneous ADRs received up to 26/10/2022

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Bleeding tendencies</i>		
Haemorrhagic disorder	1	0
<i>Coagulopathies</i>		
Coagulopathy	2	0
Disseminated intravascular coagulation	1	0
<i>Leukocytoses NEC</i>		
Leukocytosis	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenitis	2	0
Lymphadenopathy	38	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	2	1
Pancytopenia	1	0
<i>Neutropenias</i>		
Neutropenia	4	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	2	0
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	56	1

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	7	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	0
<i>Left ventricular failures</i>		
Left ventricular failure	1	1
<i>Myocardial disorders NEC</i>		
Cardiomegaly	1	0
Left ventricular dysfunction	1	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	2	0
Bradycardia	3	0
Tachycardia	23	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Supraventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	42	1

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Autosomal chromosomal abnormalities</i>		
Trisomy 21	1	0
<i>Congenital disorders NEC</i>		
Congenital cyst	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Syndactyly	1	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		
Plagiocephaly	1	0
<i>Neurological disorders congenital NEC</i>		
Tourette's disorder	1	0
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Congenital skin dimples	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	3	0
Ear pain	4	0
Ear swelling	1	0
<i>Hearing losses</i>		
Deafness	2	0
Deafness neurosensory	1	0
Deafness unilateral	1	0
Hypoacusis	7	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear disorders NEC</i>		
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	6	0
Vertigo	12	0
Vertigo positional	1	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	1	0
Ear disorders SOC TOTAL	41	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Adrenal gland disorders NEC</i>		
Adrenal disorder	1	0
Endocrine disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctivitis allergic	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Erythema of eyelid	1	0
Eyelid oedema	2	0
Swelling of eyelid	6	0
<i>Ocular disorders NEC</i>		
Eye pain	13	0
Eye swelling	19	0
Periorbital swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye irritation	5	0
Eye pruritus	5	0
Ocular hyperaemia	8	0
<i>Ocular nerve and muscle disorders</i>		
Binocular eye movement disorder	1	0
Eye movement disorder	31	0
Gaze palsy	2	0
Strabismus	1	0
<i>Ocular sensation disorders</i>		
Asthenopia	3	0
Photophobia	29	0
<i>Orbital infections, inflammations and irritations</i>		
Parophthalmia	1	0
<i>Pupil disorders</i>		
Mydriasis	11	0
Pupil fixed	2	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Retinal vasculitis	1	0
<i>Visual colour distortions</i>		
Xanthopsia	1	0
<i>Visual disorders NEC</i>		
Diplopia	3	0
Photopsia	3	0
Vision blurred	35	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Amaurosis fugax	1	0
Blindness	3	0
Blindness transient	2	0
Visual impairment	12	0
Eye disorders SOC TOTAL	205	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Colitis (excl infective)</i>		
Colitis ulcerative	2	0
<i>Dental pain and sensation disorders</i>		
Hyperaesthesia teeth	1	0
<i>Dental surface disorders</i>		
Tooth discolouration	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	74	0
Diarrhoea haemorrhagic	1	0
<i>Faecal abnormalities NEC</i>		
Faeces pale	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	38	0
Abdominal pain lower	1	0
Abdominal pain upper	50	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	3	0
Gastrooesophageal reflux disease	4	0
Impaired gastric emptying	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	12	0
Anal incontinence	1	0
Dysphagia	13	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	2	0
Irritable bowel syndrome	2	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	353	0
Retching	2	0
Vomiting	227	0
Vomiting projectile	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	2	0
Salivary hypersecretion	1	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	1	0
Oral disorder	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	4	0
Oral discomfort	1	0
Oral pain	3	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oral pruritus	2	0
Paraesthesia oral	16	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	23	0
Mouth swelling	3	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	1	0
Stomatitis	1	0
<i>Tongue disorders</i>		
Glossitis	1	0
Tongue disorder	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	11	0
Tongue discolouration	1	0
Tongue movement disturbance	1	0
<i>Umbilical hernias</i>		
Umbilical hernia	2	0
Gastrointestinal disorders SOC TOTAL	876	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	1	0
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
<i>Asthenic conditions</i>		
Asthenia	49	0
Chronic fatigue syndrome	1	0
Fatigue	143	0
Malaise	365	0
<i>Febrile disorders</i>		
Hyperpyrexia	2	0
Pyrexia	507	0
<i>Feelings and sensations NEC</i>		
Chills	95	0
Feeling abnormal	22	0
Feeling cold	22	0
Feeling hot	85	0
Feeling of body temperature change	21	0
Sensation of foreign body	2	0
Thirst	3	0
Thirst decreased	1	0
<i>Gait disturbances</i>		
Gait disturbance	8	0
Gait inability	4	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	7	0
Crepitations	2	0
Crying	7	0
Developmental delay	1	0
Effusion	1	0
Exercise tolerance decreased	1	0
Illness	48	0
Induration	3	0
Influenza like illness	88	0
Irritability postvaccinal	1	0
Local reaction	24	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	74	0
Screaming	1	0
Swelling	39	0
Swelling face	26	0
<i>Inflammations</i>		
Inflammation	17	0
Systemic inflammatory response syndrome	2	0
<i>Infusion site reactions</i>		
Infusion site discomfort	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	3	0
Injection site bruising	3	0
Injection site coldness	1	0
Injection site discolouration	2	0
Injection site discomfort	1	0
Injection site erythema	33	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site haemorrhage	3	0
Injection site hypersensitivity	1	0
Injection site induration	4	0
Injection site inflammation	8	0
Injection site irritation	1	0
Injection site mass	7	0
Injection site movement impairment	3	0
Injection site necrosis	1	0
Injection site nodule	1	0
Injection site pain	27	0
Injection site paraesthesia	1	0
Injection site pruritus	8	0
Injection site rash	12	0
Injection site reaction	18	0
Injection site swelling	24	0
Injection site urticaria	1	0
Injection site vesicles	1	0
Injection site warmth	5	0
Mass conditions NEC		
Cyst	1	0
Mass	4	0
Oedema NEC		
Face oedema	5	0
Pain and discomfort NEC		
Axillary pain	9	0
Chest discomfort	20	0
Chest pain	25	0
Discomfort	9	0
Facial pain	1	0
Pain	112	0
Tenderness	11	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	6	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	2	0
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	3	0
Vaccination site discomfort	1	0
Vaccination site eczema	1	0
Vaccination site erythema	24	0
Vaccination site induration	2	0
Vaccination site inflammation	5	0
Vaccination site joint pain	2	0
Vaccination site mass	2	0
Vaccination site movement impairment	3	0
Vaccination site nodule	1	0
Vaccination site pain	38	0
Vaccination site papule	1	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	2	0
Vaccination site rash	3	0
Vaccination site reaction	4	0
Vaccination site scab	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site swelling	28	0
Vaccination site vesicles	1	0
Vaccination site warmth	6	0
General disorders SOC TOTAL	2180	0

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Cholangitis sclerosing	1	0
<i>Cholestasis and jaundice</i>		
Jaundice	11	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	2	0
Hypertransaminasaemia	1	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatomegaly	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	1	0
Hepatitis acute	2	0
Liver injury	1	0
Hepatic disorders SOC TOTAL	21	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergy to animal	1	0
Hypersensitivity	32	0
Mite allergy	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	1	0
Allergy to vaccine	2	0
Food allergy	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	54	0
Anaphylactic shock	2	0
Anaphylactoid reaction	1	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	2	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
Haemophagocytic lymphohistiocytosis	1	1
Immune system disorder	1	0
Immune-mediated adverse reaction	1	0
Immunisation reaction	4	0
Multisystem inflammatory syndrome in children	1	0
Immune system disorders SOC TOTAL	107	1

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis perforated	1	0
<i>Bacterial infections NEC</i>		
Arthritis bacterial	1	0
Cellulitis	10	0
Injection site cellulitis	3	0
Meningitis bacterial	1	0
Tonsillitis bacterial	1	0
<i>Bordetella infections</i>		
Pertussis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
Meningitis	1	0
Meningitis aseptic	1	0
Myelitis	1	0
<i>Corynebacteria infections</i>		
Corynebacterium infection	2	0
Diphtheria	1	0
<i>Ear infections</i>		
Ear infection	1	0
Labyrinthitis	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	3	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
<i>Flaviviral infections</i>		
Yellow fever vaccine-associated viscerotropic disease	1	0
<i>Hepatitis virus infections</i>		
Hepatitis A	1	0
<i>Herpes viral infections</i>		
Herpes simplex	1	0
Herpes zoster	1	0
<i>Infections NEC</i>		
Infection	3	0
Injection site abscess	1	0
Respiratory tract infection	1	0
Vestibulitis	1	0
<i>Influenza viral infections</i>		
Influenza	8	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	1	0
Lower respiratory tract infection	4	0
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Muscle and soft tissue infections</i>		
Soft tissue infection	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Neutropenic sepsis	1	0
Sepsis	4	0
<i>Skin structures and soft tissue infections</i>		
Skin infection	3	0
<i>Staphylococcal infections</i>		
Staphylococcal abscess	1	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
<i>Streptococcal infections</i>		
Pneumococcal sepsis	1	1
Streptococcal infection	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	21	0
Pharyngitis	3	0
Rhinitis	2	0
Sinusitis	1	0
Tonsillitis	3	0
<i>Urinary tract infections</i>		
Urinary tract infection	1	0
<i>Vascular infections</i>		
Lymphangitis	1	0
<i>Viral infections NEC</i>		
Encephalitis viral	1	0
Meningitis viral	1	0
Post viral fatigue syndrome	2	0
Viral diarrhoea	1	0
Viral infection	3	0
Viral pericarditis	1	0
Infections SOC TOTAL	108	1

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	10	0
Foetal exposure during pregnancy	7	0
Foetal exposure timing unspecified	1	0
Maternal exposure before pregnancy	2	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	2	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	1	0
Muscle injury	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	1	0
<i>Non-site specific injuries NEC</i>		
Fall	5	0
Traumatic haematoma	1	0
<i>Non-site specific procedural complications</i>		
Shunt malfunction	1	0
<i>Off label uses</i>		
Off label use	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Poisoning and toxicity</i>		
Toxicity to various agents	1	0
<i>Product administration errors and issues</i>		
Expired product administered	3	0
Extra dose administered	4	0
Product administered at inappropriate site	1	0
Product administered to patient of inappropriate age	1	0
Wrong product administered	5	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	1	0
<i>Site specific injuries NEC</i>		
Head injury	1	0
<i>Skin injuries NEC</i>		
Contusion	9	0
Scratch	1	0
Injuries SOC TOTAL	62	0

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Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen consumption increased	1	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	5	0
Blood glucose increased	1	0
<i>Cell marker analyses</i>		
Carbohydrate antigen 19-9 increased	1	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	1	0
<i>Coagulation and bleeding analyses</i>		
International normalised ratio increased	1	0
<i>ECG investigations</i>		
Electrocardiogram abnormal	1	0
<i>Foetal and neonatal diagnostic procedures</i>		
Foetal heart rate abnormal	1	0
Foetal monitoring abnormal	1	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	2	0
Heart rate increased	11	0
Heart rate irregular	3	0
Pulse abnormal	18	0
Pulse absent	1	0
<i>Hepatobiliary function diagnostic procedures</i>		
Alanine aminotransferase increased	4	0
Aspartate aminotransferase increased	1	0
Blood bilirubin increased	3	0
Liver function test abnormal	4	0
Liver function test increased	1	0
Transaminases increased	1	0
<i>Investigations NEC</i>		
Quality of life decreased	1	0
<i>Mineral and electrolyte analyses</i>		
Blood iron decreased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature abnormal	1	0
Body temperature decreased	1	0
Body temperature fluctuation	1	0
Body temperature increased	80	0
General physical condition abnormal	1	0
Respiratory rate increased	5	0
Weight decreased	3	0
Weight increased	1	0
<i>Platelet analyses</i>		
Platelet count increased	1	0
Platelet morphology abnormal	1	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	3	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Vital capacity decreased	1	0
<i>Urinalysis NEC</i>		
Blood urine present	3	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	1	0
Blood pressure decreased	5	0
Blood pressure diastolic increased	1	0
Blood pressure increased	5	0
<i>Vitamin analyses</i>		
Vitamin D decreased	1	0
<i>White blood cell analyses</i>		
Lymphocyte count increased	1	0
Lymphocyte morphology abnormal	2	0
Neutrophil count abnormal	2	0
Neutrophil toxic granulation present	1	0
Investigations SOC TOTAL	186	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	1	0
Decreased appetite	59	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Dairy intolerance	1	0
Food intolerance	1	0
Milk soy protein intolerance	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	2	0
Feeding disorder	2	0
<i>Hyperglycaemic conditions NEC</i>		
Glucose tolerance impaired	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	1	0
<i>Mixed acid-base disorders</i>		
Acidosis	1	0
Metabolic disorders SOC TOTAL	70	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	3	0
Arthropathy	2	0
<i>Bone disorders NEC</i>		
Jaw disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
Pain in jaw	2	0
Spinal pain	2	0
<i>Bursal disorders</i>		
Bursitis	1	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	1	0
Morphoea	1	0
Myofascitis	1	0
Polymyalgia rheumatica	1	0
<i>Joint related disorders NEC</i>		
Periarthritis	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	82	0
Joint effusion	1	0
Joint stiffness	7	0
Joint swelling	6	0
<i>Metabolic bone disorders</i>		
Osteoporosis	1	0
<i>Muscle infections and inflammations</i>		
Myositis	1	0
<i>Muscle pains</i>		
Myalgia	95	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	2	0
Muscle fatigue	4	0
Muscle spasms	16	0
Muscle swelling	3	0
Muscle twitching	18	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	15	0
Trismus	5	0
<i>Muscle weakness conditions</i>		
Muscular weakness	29	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Growth retardation	1	0
Limb mass	1	0
Mastication disorder	1	0
Mobility decreased	3	0
Musculoskeletal stiffness	47	0
Posture abnormal	2	0
Weight bearing difficulty	1	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Dactylitis	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	63	0
Limb discomfort	21	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Musculoskeletal chest pain	1	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	4	0
Neck pain	33	0
Pain in extremity	186	0
Rheumatic disorder	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	3	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	4	0
Groin pain	1	0
Neck mass	1	0
<i>Tendon disorders</i>		
Tendonitis	1	0
Tenosynovitis	1	0
Muscle & tissue disorders SOC TOTAL	681	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Adenocarcinoma pancreas	1	0
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	1	0
Neoplasms SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Acute polyneuropathies		
Guillain-Barre syndrome	5	0
Central nervous system haemorrhages and cerebrovascular accidents		
Cerebral haemorrhage	1	1
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	1	0
Chronic polyneuropathies		
Chronic inflammatory demyelinating polyradiculoneuropathy	1	0
Demyelinating polyneuropathy	1	0
Coma states		
Coma	1	0
Coordination and balance disturbances		
Ataxia	3	0
Balance disorder	5	0
Cerebellar ataxia	1	0
Cerebellar syndrome	1	0
Coordination abnormal	2	0
Dysstasia	2	0
Cortical dysfunction NEC		
Aphasia	2	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	4	0
Disturbances in consciousness NEC		
Altered state of consciousness	1	0
Consciousness fluctuating	1	0
Depressed level of consciousness	3	0
Lethargy	67	0
Loss of consciousness	37	0
Somnolence	54	0
Syncope	225	0
Dyskinesias and movement disorders NEC		
Dyskinesia	34	0
Hypokinesia	7	0
Movement disorder	1	0
Psychomotor hyperactivity	2	0
Dystonias		
Opisthotonus	2	0
Encephalopathies NEC		
Encephalopathy	1	0
Facial cranial nerve disorders		
Bell's palsy	4	0
Facial paralysis	2	0
Facial paresis	1	0
Facial spasm	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	3	0
Headaches NEC		
Cluster headache	1	0
Headache	532	0
Tension headache	3	0
Intellectual disabilities		
Intellectual disability	1	0
Memory loss (excl dementia)		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Amnesia	4	0
Memory impairment	2	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	3	0
Disturbance in attention	9	0
Judgement impaired	1	0
Migraine headaches		
Migraine	10	0
Migraine with aura	1	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	1	0
Muscle tone abnormal		
Hypertonia	1	0
Hypotonia	6	0
Myelitis (incl infective)		
Myelitis transverse	1	0
Narcolepsy and hypersomnia		
Hypersomnia	7	0
Nervous system disorders NEC		
Brain stem syndrome	1	0
Neurologic visual problems NEC		
Tunnel vision	2	0
Neurological signs and symptoms NEC		
Dizziness	437	0
Dizziness postural	4	0
Drooling	1	0
Head discomfort	6	0
Hyporesponsive to stimuli	1	0
Myoclonus	4	0
Neurological symptom	1	0
Presyncope	34	0
Unresponsive to stimuli	20	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	1	0
Muscle spasticity	1	0
Paraesthesias and dysaesthesias		
Burning sensation	5	0
Dysaesthesia	1	0
Formication	1	0
Hyperaesthesia	8	0
Hypoaesthesia	53	0
Paraesthesia	80	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	2	0
Hemiparesis	2	0
Monoparesis	1	0
Monoplegia	1	0
Paralysis	3	0
Quadriparesis	1	0
Peripheral neuropathies NEC		
Neuropathy peripheral	3	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	5	0
Febrile convulsion	3	0
Seizure	31	0
Seizure like phenomena	4	0
Tonic clonic movements	3	0
Tonic convulsion	1	0
<i>Sensory abnormalities NEC</i>		
Ageusia	1	0
Dysgeusia	3	0
Electric shock sensation	1	0
Neuralgia	3	0
Sensory disturbance	3	0
Sensory loss	6	0
Taste disorder	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	10	0
Incoherent	1	0
Speech disorder	4	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	4	0
<i>Tremor (excl congenital)</i>		
Intention tremor	1	0
Tremor	69	0
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	2	0
Nervous system disorders SOC TOTAL	1891	1

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortion related conditions and complications</i>		
Anembryonic gestation	1	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	13	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Meconium in amniotic fluid	1	0
<i>Foetal complications NEC</i>		
Foetal cardiac disorder	1	0
Foetal distress syndrome	4	0
Foetal hypokinesia	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	1	0
<i>Labour onset and length abnormalities</i>		
Prolonged labour	1	0
<i>Maternal complications of delivery NEC</i>		
Complication of delivery	1	0
<i>Maternal complications of pregnancy NEC</i>		
Complication of pregnancy	1	0
Ectopic pregnancy	1	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	1	0
<i>Normal newborn status</i>		
Normal newborn	1	0
Pregnancy conditions SOC TOTAL	29	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	3	0
<i>Adjustment disorders</i>		
Adjustment disorder	7	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
<i>Anxiety symptoms</i>		
Agitation	7	0
Anxiety	16	0
Nervousness	3	0
Stress	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	3	0
Indifference	1	0
Paranoia	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Mental fatigue	1	0
<i>Communications disorders</i>		
Communication disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	16	0
Disorientation	19	0
<i>Deliria</i>		
Delirium	7	0
<i>Depressive disorders</i>		
Depression	1	0
<i>Dissociative states</i>		
Dissociation	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	13	0
<i>Dyssomnias</i>		
Poor quality sleep	2	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Emotional disorder	4	0
Emotional distress	3	0
Irritability	3	0
Mood altered	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	11	0
Hallucination, visual	1	0
<i>Increased physical activity levels</i>		
Restlessness	1	0
<i>Learning disorders</i>		
Learning disability	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	2	0
Tearfulness	2	0
<i>Mood disorders NEC</i>		
Affective disorder	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Listless	3	0
<i>Panic attacks and disorders</i>		
Panic attack	2	0
Panic reaction	3	0
<i>Parasomnias</i>		
Nightmare	1	0
<i>Personality disorders with dramatic behaviour (Cluster B)</i>		
Borderline personality disorder	1	0
<i>Psychiatric elimination disorders</i>		
Enuresis	2	0
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
Psychotic disorder	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	12	0
<i>Somatic symptom disorders</i>		
Conversion disorder	1	0
Somatic symptom disorder	1	0
<i>Speech articulation and rhythm disturbances</i>		
Lack of spontaneous speech	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	2	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	169	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	2	0
Incontinence	5	0
Mixed incontinence	1	0
Pollakiuria	1	0
Urinary incontinence	5	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis acute	1	0
Goodpasture's syndrome	1	0
<i>Nephritis NEC</i>		
Nephritis	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	2	0
Renal failure	1	0
<i>Renal failure complications</i>		
Azotaemia	1	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	1	0
<i>Urinary abnormalities</i>		
Chromaturia	4	0
Haematuria	1	0
Renal & urinary disorders SOC TOTAL	27	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast tenderness	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Menstrual disorder	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	2	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular swelling	1	0
Reproductive & breast disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	58	0
Grunting	2	0
Hyperventilation	8	0
Hypopnoea	3	0
Respiration abnormal	1	0
Respiratory arrest	2	0
Tachypnoea	1	0
<i>Bronchial conditions NEC</i>		
Fibrinous bronchitis	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	8	0
Bronchospasm	1	0
Obstructive airways disorder	1	0
Wheezing	11	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	19	0
Haemoptysis	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	5	0
<i>Nasal disorders NEC</i>		
Epistaxis	7	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	1	0
<i>Parenchymal lung disorders NEC</i>		
Lung consolidation	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal hypoaesthesia	2	0
Pharyngeal inflammation	1	0
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	11	0
<i>Pleural infections and inflammations</i>		
Pleurisy	1	0
<i>Respiratory signs and symptoms NEC</i>		
Painful respiration	2	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	2	0
Choking	1	0
Dry throat	1	0
Dysphonia	4	0
Oropharyngeal discomfort	2	0
Oropharyngeal pain	59	0
Rhinorrhoea	4	0
Throat irritation	8	0
Throat tightness	13	0
Respiratory disorders SOC TOTAL	245	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	1	0
<i>Angioedemas</i>		
Angioedema	7	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	39	0
Hyperhidrosis	49	0
Night sweats	3	0
<i>Bullous conditions</i>		
Blister	1	0
Erythema multiforme	3	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	5	0
Macule	1	0
Pain of skin	3	0
Papule	1	0
Sensitive skin	1	0
Skin burning sensation	1	0
Skin discolouration	15	0
Skin discomfort	1	0
Skin induration	1	0
Skin lesion	1	0
Skin reaction	2	0
Skin swelling	1	0
Skin warm	16	0
<i>Dermatitis and eczema</i>		
Dermatitis	2	0
Dermatitis allergic	6	0
Eczema	2	0
Skin irritation	2	0
<i>Erythemas</i>		
Erythema	98	0
<i>Exfoliative conditions</i>		
Exfoliative rash	1	0
Skin exfoliation	2	0
<i>Papulosquamous conditions</i>		
Pityriasis rosea	2	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	3	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pruritus NEC</i>		
Pruritus	54	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
Henoch-Schonlein purpura	3	0
Petechiae	3	0
Purpura	3	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	134	0
Rash erythematous	9	0
Rash macular	23	0
Rash maculo-papular	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash papular	8	0
Rash pruritic	12	0
Rash rubelliform	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Subcutaneous emphysema	2	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	1	0
<i>Skin vasculitides</i>		
Cutaneous vasculitis	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	6	0
<i>Urticarias</i>		
Urticaria	59	0
Urticaria chronic	2	0
Skin disorders SOC TOTAL	595	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Impaired work ability	2	0
Loss of personal independence in daily activities	1	0
Social circumstances SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Induced abortions</i>		
Abortion induced	4	0
<i>Obstetric therapeutic procedures</i>		
Caesarean section	3	0
Vacuum extractor delivery	1	0
Surgical & medical procedures SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	1	0
<i>Blood pressure disorders NEC</i>		
Labile blood pressure	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	6	0
Shock	3	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	1	0
<i>Peripheral embolism and thrombosis</i>		
Thrombophlebitis	2	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	6	0
Flushing	22	0
Hot flush	4	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	15	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	111	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	3	0
<i>Vascular hypotensive disorders</i>		
Hypotension	22	0
Orthostatic hypotension	1	0
Vascular disorders SOC TOTAL	203	0
TOTAL REACTIONS FOR DRUG	7822	5
TOTAL REPORTS	2322	
TOTAL FATAL OUTCOME REPORTS		5