

Case Series Drug Analysis Print

Name: FLUENZ TETRA

Report Run Date: 29-Nov-2023

Data Lock Date: 28-Nov-2023 18:30:03

Earliest Reaction Date: 01-Sep-2013

MedDRA Version: MedDRA 26.1

FLUENZ TETRA: FOI 23/925 - Spontaneous suspected ADR reports for
Fluenz Tetra received up to and including 28/11/2023

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias haemolytic mechanical factor</i>		
Haemolytic uraemic syndrome	2	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	3	0
Lymphadenopathy	25	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	3	0
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	34	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	1	0
Palpitations	1	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	3	0
<i>Noninfectious myocarditis</i>		
Myocarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Tachycardia	4	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
Cardiac disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Neurological disorders congenital NEC</i>		
Tourette's disorder	2	0
Congenital disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	3	0
Ear discomfort	1	0
Ear pain	60	0
Ear pruritus	1	0
Ear swelling	3	0
Otorrhoea	2	0
<i>Hearing losses</i>		
Hypoacusis	2	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	1	0
Vertigo	1	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	1	0
Ear disorders SOC TOTAL	76	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	1	0
<i>Thyroid disorders NEC</i>		
Thyroid mass	1	0
Endocrine disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	1	0
Excessive eye blinking	2	0
<i>Lacrimation disorders</i>		
Lacrimation increased	31	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	1	0
Erythema of eyelid	5	0
Eyelid oedema	2	0
Swelling of eyelid	11	0
<i>Lid, lash and lacrimal structural disorders</i>		
Lagophthalmos	1	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	2	0
Eye disorder	2	0
Eye pain	27	0
Eye swelling	37	0
Ocular discomfort	1	0
Periorbital oedema	1	0
Periorbital swelling	11	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	7	0
Eye inflammation	1	0
Eye irritation	2	0
Eye pruritus	19	0
Ocular hyperaemia	24	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	2	0
Ophthalmoplegia	1	0
Strabismus	2	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Asthenopia	1	0
Photophobia	12	0
<i>Optic disc abnormalities NEC</i>		
Papilloedema	1	0
<i>Pupil disorders</i>		
Mydriasis	3	0
Pupil fixed	1	0
Pupillary disorder	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	1	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Exophthalmos	1	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Photopsia	2	0
Vision blurred	8	0
<i>Visual impairment and blindness (excl colour blindness)</i>		

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Blindness	1	0
Blindness unilateral	1	0
Visual impairment	7	0
Eye disorders SOC TOTAL	237	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Colitis (excl infective)</i>		
Colitis	2	0
<i>Dental pain and sensation disorders</i>		
Toothache	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	181	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
Eructation	1	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	3	0
Faecaloma	1	0
Faeces soft	1	0
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
Flatulence	4	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	48	0
Abdominal pain lower	3	0
Abdominal pain upper	129	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	2	0
Gastrooesophageal reflux disease	1	0
Infrequent bowel movements	1	0
<i>Gastrointestinal disorders NEC</i>		
Appendix disorder	1	0
Gastrointestinal disorder	3	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	21	0
Anal incontinence	1	0
Dysphagia	4	0
Odynophagia	3	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
Irritable bowel syndrome	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	1	0
Gingival pain	1	0
Gingival swelling	1	0
<i>Nausea and vomiting symptoms</i>		
Cyclic vomiting syndrome	1	0
Discoloured vomit	1	0
Nausea	140	0
Regurgitation	2	0
Retching	3	0
Vomiting	415	0
Vomiting projectile	24	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	2	0
Haematochezia	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Lip dry	4	0
Oral soft tissue disorders NEC		
Chapped lips	5	0
Cheilitis	3	0
Lip blister	2	0
Oral soft tissue infections		
Angular cheilitis	1	0
Oral soft tissue signs and symptoms		
Lip discolouration	1	0
Lip erythema	3	0
Lip exfoliation	1	0
Lip pain	6	0
Oral discomfort	2	0
Oral mucosal blistering	4	0
Oral mucosal eruption	1	0
Oral mucosal erythema	2	0
Oral pain	7	0
Paraesthesia oral	1	0
Oral soft tissue swelling and oedema		
Lip swelling	26	0
Mouth swelling	2	0
Salivary gland enlargements		
Parotid gland enlargement	1	0
Stomatitis and ulceration		
Lip ulceration	1	0
Mouth ulceration	14	0
Stomatitis	1	0
Tongue disorders		
Tongue disorder	1	0
Tongue geographic	2	0
Tongue ulceration	1	0
Tongue signs and symptoms		
Glossodynia	1	0
Protrusion tongue	1	0
Strawberry tongue	1	0
Swollen tongue	6	0
Tongue blistering	1	0
Tongue discolouration	1	0
Tongue discomfort	1	0
Tongue dry	1	0
Tongue pruritus	1	0
Gastrointestinal disorders SOC TOTAL	1117	0

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Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site rash	1	0
Application and instillation site reactions		
Application site rash	1	0
Application site vesicles	2	0
Asthenic conditions		
Asthenia	80	0
Chronic fatigue syndrome	3	0
Decreased activity	1	0
Fatigue	227	0
Malaise	274	0
Sluggishness	1	0
Body temperature altered		
Temperature regulation disorder	1	0
Death and sudden death		
Death	6	6
Febrile disorders		
Hyperpyrexia	1	0
Pyrexia	936	0
Feelings and sensations NEC		
Chills	95	0
Feeling abnormal	20	0
Feeling cold	25	0
Feeling hot	27	0
Feeling of body temperature change	7	0
Hunger	1	0
Sensation of foreign body	2	0
Thirst	4	0
Thirst decreased	1	0
Gait disturbances		
Gait disturbance	2	0
Gait inability	6	0
Loss of control of legs	2	0
General signs and symptoms NEC		
Condition aggravated	5	0
Crying	12	0
General physical health deterioration	1	0
Glassy eyes	2	0
Illness	94	0
Induration	2	0
Influenza like illness	141	0
Irritability postvaccinal	1	0
Local reaction	1	0
Moaning	1	0
Peripheral swelling	17	0
Secretion discharge	3	0
Swelling	18	0
Swelling face	53	0
Inflammations		
Inflammation	6	0
Interactions		
Drug interaction	1	0
Mass conditions NEC		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Mass	1	0
Oedema NEC		
Face oedema	5	0
Oedema	1	0
Pain and discomfort NEC		
Axillary pain	1	0
Chest discomfort	12	0
Chest pain	18	0
Discomfort	4	0
Facial pain	2	0
Non-cardiac chest pain	1	0
Pain	101	0
Tenderness	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	30	0
Drug ineffective	3	0
No reaction on previous exposure to drug	1	0
Vaccination failure	3	0
Vaccination site reactions		
Vaccination site erythema	2	0
Vaccination site haemorrhage	1	0
Vaccination site hypersensitivity	1	0
Vaccination site inflammation	2	0
Vaccination site mass	1	0
Vaccination site pain	3	0
Vaccination site scab	1	0
Vaccination site swelling	1	0
General disorders SOC TOTAL	2280	6

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Ocular icterus	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	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	47	0
Type I hypersensitivity	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	1	0
Food allergy	7	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	18	0
Anaphylactic shock	2	0
Anaphylactoid reaction	1	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	1	0
Multisystem inflammatory syndrome in children	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	82	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	1	0
Gastric infection	1	0
Gastroenteritis	1	0
<i>Adenoviral infections</i>		
Adenoviral upper respiratory infection	1	0
<i>Bacterial infections NEC</i>		
Bacterial infection	1	0
Cellulitis	4	0
Ear infection bacterial	2	0
Tonsillitis bacterial	1	0
<i>Bordetella infections</i>		
Pertussis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
Myelitis	1	0
<i>Coronavirus infections</i>		
COVID-19	2	0
<i>Coxiella infections</i>		
Q fever	1	0
<i>Ear infections</i>		
Ear infection	13	0
Labyrinthitis	1	0
Otitis media	2	0
Otitis media chronic	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	13	0
Dacryocystitis	1	0
<i>Female reproductive tract infections</i>		
Pelvic inflammatory disease	1	0
<i>Herpes viral infections</i>		
Herpes zoster	1	0
Oral herpes	1	0
Varicella	2	0
<i>Infections NEC</i>		
Abscess limb	1	0
Infection	5	0
Localised infection	1	0
Purulence	1	0
Respiratory tract infection	1	0
Vaccination site infection	1	0
<i>Infectious transmissions</i>		
Infection via vaccinee	125	0
Secondary transmission	1	0
Vaccine virus shedding	19	0
<i>Influenza viral infections</i>		
H1N1 influenza	1	0
Influenza	77	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	2	0
Lower respiratory tract infection	20	0
Pneumonia aspiration	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Bacteraemia	2	0
Sepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Blister infected	2	0
Impetigo	4	0
Rash pustular	1	0
<i>Staphylococcal infections</i>		
Furuncle	1	0
Staphylococcal sepsis	1	0
<i>Streptococcal infections</i>		
Pneumococcal sepsis	2	1
Pneumonia pneumococcal	2	0
Scarlet fever	5	0
Streptococcal infection	1	0
<i>Upper respiratory tract infections</i>		
Croup infectious	21	0
Laryngitis	2	0
Nasopharyngitis	96	0
Peritonsillar abscess	1	0
Rhinitis	11	0
Sinusitis	4	0
Tonsillitis	16	0
Upper respiratory tract infection	9	0
<i>Urinary tract infections</i>		
Urinary tract infection	1	0
<i>Viral infections NEC</i>		
Bronchiolitis	1	0
Conjunctivitis viral	1	0
Meningitis viral	1	0
Metapneumovirus infection	1	0
Viral infection	12	0
Viral myositis	1	0
Viral rash	5	0
Viral upper respiratory tract infection	2	0
Infections SOC TOTAL	517	1

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Reaction Name	Total	Fatal
Injuries		
<i>Accidental exposures to product</i>		
Accidental exposure to product	9	0
Accidental exposure to product by child	2	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	1	0
Foetal exposure during pregnancy	1	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to vaccinated person	2	0
<i>Eye injuries NEC</i>		
Eye contusion	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	4	0
Product use in unapproved indication	1	0
Vaccination error	1	0
<i>Non-site specific injuries NEC</i>		
Fall	4	0
Wound	1	0
Wound secretion	1	0
<i>Occupational exposures</i>		
Occupational exposure to product	18	0
<i>Off label uses</i>		
Off label use	4	0
<i>Poisoning and toxicity</i>		
Metal poisoning	2	0
<i>Product administration errors and issues</i>		
Accidental overdose	2	0
Contraindicated product administered	1	0
Expired product administered	2	0
Extra dose administered	1	0
Inappropriate schedule of product administration	2	0
Incorrect route of product administration	1	0
Product administered to patient of inappropriate age	5	0
Product administration error	2	0
Wrong product administered	1	0
<i>Site specific injuries NEC</i>		
Head injury	1	0
Nasal injury	2	0
<i>Skin injuries NEC</i>		
Contusion	6	0
Scratch	1	0
<i>Vaccination related complications</i>		
Immunisation reaction	2	0
Injuries SOC TOTAL	81	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	6	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	1	0
Heart rate increased	7	0
Heart rate irregular	1	0
Pulse abnormal	3	0
<i>Imaging procedures NEC</i>		
Magnetic resonance imaging abnormal	1	0
<i>Mineral and electrolyte analyses</i>		
Blood sodium increased	1	0
<i>Neurologic diagnostic procedures</i>		
Sensory level abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	3	0
Body temperature abnormal	10	0
Body temperature decreased	2	0
Body temperature fluctuation	7	0
Body temperature increased	69	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
Respiratory rate increased	1	0
Temperature difference of extremities	1	0
<i>Platelet analyses</i>		
Platelet count decreased	2	0
<i>Protein analyses NEC</i>		
C-reactive protein abnormal	1	0
<i>Urinalysis NEC</i>		
Blood urine present	1	0
Urinary sediment present	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
<i>Virus identification and serology</i>		
SARS-CoV-2 test positive	1	0
Investigations SOC TOTAL	124	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	273	0
Hypophagia	5	0
Increased appetite	2	0
<i>Diabetes mellitus (incl subtypes)</i>		
Type 1 diabetes mellitus	3	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	3	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Feeding disorder	7	0
Food aversion	4	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	4	0
Metabolic disorders SOC TOTAL	303	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	4	0
<i>Joint related signs and symptoms</i>		
Arthralgia	27	0
Joint swelling	10	0
<i>Muscle infections and inflammations</i>		
Myositis	3	0
<i>Muscle pains</i>		
Myalgia	92	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle discomfort	2	0
Muscle fatigue	1	0
Muscle spasms	4	0
Muscle tightness	1	0
Muscle twitching	4	0
<i>Muscle tone abnormalities</i>		
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	12	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	1	0
Musculoskeletal stiffness	16	0
Weight bearing difficulty	3	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	9	0
Limb discomfort	1	0
Musculoskeletal chest pain	1	0
Musculoskeletal pain	1	0
Neck pain	20	0
Pain in extremity	56	0
<i>Synovial disorders</i>		
Synovitis	2	0
Muscle & tissue disorders SOC TOTAL	272	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Bone sarcomas</i>		
Ewing's sarcoma	1	0
<i>Leukaemias acute lymphocytic</i>		
Acute lymphocytic leukaemia	1	0
Neoplasms SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	1	0
Hyporeflexia	1	0
<i>Absence seizures</i>		
Petit mal epilepsy	6	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	3	0
<i>Choreiform movements</i>		
Chorea	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	8	0
Cerebellar ataxia	1	0
Dysstasia	3	0
<i>Cortical dysfunction NEC</i>		
Aphasia	2	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve palsies multiple	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	2	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	2	0
Lethargy	145	0
Loss of consciousness	12	0
Somnolence	52	0
Syncope	67	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	1	0
Hypokinesia	1	0
Motor dysfunction	2	0
Movement disorder	3	0
Psychomotor hyperactivity	2	0
<i>Dystonias</i>		
Dystonia	1	0
Opisthotonus	1	0
<i>Encephalitis NEC</i>		
Encephalitis autoimmune	1	0
Noninfective encephalitis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	3	0
Facial paralysis	1	0
Facial paresis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Cold-stimulus headache	1	0
Headache	549	0
Tension headache	2	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	2	0
Mental impairment	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Migraine headaches		
Migraine	6	0
Migraine with aura	1	0
Mixed cranial nerve disorders		
Palatal palsy	1	0
Mononeuropathies		
Ulnar nerve palsy	1	0
Muscle tone abnormal		
Hypotonia	9	0
Narcolepsy and hypersomnia		
Cataplexy	17	0
Hypersomnia	12	0
Narcolepsy	21	0
Nervous system disorders NEC		
Nervous system disorder	1	0
Neurological signs and symptoms NEC		
Brain fog	4	0
Dizziness	104	0
Dizziness postural	1	0
Head discomfort	5	0
Hyporesponsive to stimuli	1	0
Presyncope	10	0
Unresponsive to stimuli	13	0
Olfactory nerve disorders		
Parosmia	2	0
Optic nerve disorders NEC		
Optic neuritis	1	0
Paraesthesias and dysaesthesias		
Hyperaesthesia	2	0
Hypoaesthesia	3	0
Paraesthesia	12	0
Paraesthesia mucosal	1	0
Paralysis and paresis (excl cranial nerve)		
Paralysis	1	0
Partial simple seizures NEC		
Simple partial seizures	1	0
Seizures and seizure disorders NEC		
Epilepsy	7	0
Febrile convulsion	11	0
Partial seizures	3	0
Seizure	25	0
Seizure like phenomena	2	0
Status epilepticus	3	0
Tonic clonic movements	1	0
Sensory abnormalities NEC		
Aura	1	0
Dysgeusia	2	0
Loss of proprioception	1	0
Neuralgia	1	0
Sensory disturbance	3	0
Sensory loss	1	0
Taste disorder	1	0
Sleep disturbances NEC		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Sudden onset of sleep	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	2	0
Incoherent	1	0
Speech disorder	4	0
<i>Tremor (excl congenital)</i>		
Head titubation	1	0
Tremor	15	0
Nervous system disorders SOC TOTAL	1200	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	1	0
Pregnancy conditions SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	10	0
Behaviour disorder	1	0
Staring	2	0
<i>Affect alterations NEC</i>		
Inappropriate affect	1	0
<i>Anxiety symptoms</i>		
Agitation	4	0
Anxiety	7	0
Nervousness	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	3	0
Personality change	1	0
Social avoidant behaviour	2	0
<i>Communications disorders</i>		
Communication disorder	1	0
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	8	0
Disorientation	8	0
<i>Deliria</i>		
Delirium	6	0
Delirium febrile	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	13	0
<i>Dyssomnias</i>		
Poor quality sleep	5	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	2	0
Emotional disorder	1	0
Emotional distress	8	0
Irritability	19	0
Mood altered	2	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	17	0
Hallucination, auditory	1	0
Hallucination, visual	3	0
Hallucinations, mixed	1	0
<i>Impulse control disorders</i>		
Impulsive behaviour	1	0
<i>Increased physical activity levels</i>		
Restlessness	3	0
<i>Infancy, childhood and adolescence psychiatric disorders NEC</i>		
School refusal	1	0
<i>Mental disorders NEC</i>		
Mental disorder	2	0
<i>Mental disorders due to a general medical condition NEC</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Neuropsychiatric syndrome	1	0
Mood alterations with depressive symptoms		
Decreased interest	1	0
Depressed mood	7	0
Mood disorders NEC		
Apathy	1	0
Listless	8	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	1	0
Obsessive-compulsive disorders and symptoms		
Obsessive thoughts	1	0
Obsessive-compulsive disorder	3	0
Panic attacks and disorders		
Panic attack	1	0
Panic reaction	2	0
Parasomnias		
Abnormal dreams	1	0
Nightmare	5	0
Sleep talking	2	0
Sleep terror	7	0
Somnambulism	2	0
Personality disorders NEC		
Personality disorder	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	2	0
Psychiatric elimination disorders		
Enuresis	3	0
Sleep disorders NEC		
Sleep disorder	11	0
Speech articulation and rhythm disturbances		
Dysphemia	4	0
Thinking disturbances		
Thinking abnormal	1	0
Tic disorders		
Tic	8	0
Psychiatric disorders SOC TOTAL	212	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Incontinence	1	0
Stress urinary incontinence	1	0
Urinary incontinence	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	2	0
<i>Renal failure and impairment</i>		
Acute kidney injury	1	0
<i>Urinary abnormalities</i>		
Chromaturia	1	0
Haematuria	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	1	0
Renal & urinary disorders SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive tract infections and inflammations NEC</i>		
Genital tract inflammation	1	0
Reproductive & breast disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	2	0
Dyspnoea	57	0
Grunting	1	0
Hyperventilation	1	0
Mouth breathing	1	0
Respiration abnormal	5	0
Respiratory arrest	2	0
Respiratory distress	3	0
Sleep apnoea syndrome	1	0
Tachypnoea	3	0
<i>Bronchospasm and obstruction</i>		
Asthma	45	0
Bronchospasm	4	0
Wheezing	93	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	386	0
Productive cough	25	0
Sputum discoloured	3	0
Sputum increased	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	3	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonitis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Increased bronchial secretion	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	148	0
Nasal inflammation	2	0
<i>Nasal disorders NEC</i>		
Epistaxis	291	0
Nasal crusting	2	0
Nasal disorder	1	0
Nasal dryness	1	0
Nasal mucosal discolouration	2	0
Nasal mucosal erosion	1	0
Nasal mucosal ulcer	2	0
Nasal odour	1	0
Nasal oedema	2	0
Nasal pruritus	6	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinonasal obstruction	5	0
Sinus congestion	4	0
Sinus disorder	6	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal swelling	5	0
Pharyngeal ulceration	1	0
Tonsillar disorder	1	0
Tonsillar hypertrophy	6	0
Tonsillar inflammation	1	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Velopharyngeal incompetence	1	0
Respiratory signs and symptoms NEC		
Painful respiration	1	0
Respiratory symptom	4	0
Use of accessory respiratory muscles	2	0
Respiratory tract disorders NEC		
Respiratory disorder	3	1
Respiratory tract congestion	3	0
Respiratory tract irritation	1	0
Upper respiratory tract signs and symptoms		
Aphonia	1	0
Catarrh	1	0
Dry throat	2	0
Dysphonia	10	0
Increased viscosity of upper respiratory secretion	2	0
Nasal discharge discolouration	1	0
Nasal discomfort	9	0
Nasal obstruction	1	0
Oropharyngeal blistering	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	229	0
Paranasal sinus discomfort	1	0
Rhinalgia	24	0
Rhinorrhoea	371	0
Sinus pain	7	0
Sneezing	53	0
Snoring	2	0
Throat clearing	2	0
Throat irritation	14	0
Throat tightness	8	0
Upper respiratory tract congestion	1	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	2	0
Respiratory disorders SOC TOTAL	1887	1

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Reaction Name	Total	Fatal
Skin disorders		
Acnes		
Dermatitis acneiform	2	0
Alopecias		
Alopecia	1	0
Angioedemas		
Angioedema	4	0
Apocrine and eccrine gland disorders		
Cold sweat	29	0
Hyperhidrosis	28	0
Night sweats	3	0
Bullous conditions		
Blister	11	0
Dermatitis bullous	1	0
Erythema multiforme	5	0
Stevens-Johnson syndrome	1	0
Dermal and epidermal conditions NEC		
Dry skin	6	0
Pain of skin	3	0
Papule	11	0
Scab	4	0
Skin discolouration	9	0
Skin fissures	1	0
Skin lesion	1	0
Skin reaction	6	0
Skin swelling	3	0
Skin tightness	1	0
Skin warm	11	0
Dermatitis and eczema		
Dermatitis	1	0
Dermatitis allergic	22	0
Eczema	9	0
Perioral dermatitis	1	0
Skin irritation	6	0
Erythemas		
Erythema	86	0
Exfoliative conditions		
Skin exfoliation	5	0
Hypopigmentation disorders		
Skin depigmentation	1	0
Nail and nail bed conditions (excl infections and infestations)		
Nail discolouration	1	0
Photosensitivity and photodermatitis conditions		
Photosensitivity reaction	1	0
Pilar disorders NEC		
Piloerection	1	0
Pruritus NEC		
Pruritus	93	0
Psoriatic conditions		
Psoriasis	2	0
Purpura and related conditions		
Henoch-Schonlein purpura	8	0
Petechiae	5	0
Purpura	5	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	239	0
Rash erythematous	43	0
Rash macular	37	0
Rash maculo-papular	7	0
Rash morbilliform	1	0
Rash papular	28	0
Rash pruritic	30	0
Rash vesicular	3	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin ulcer	1	0
<i>Skin dystrophies</i>		
Skin wrinkling	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	2	0
<i>Urticarias</i>		
Idiopathic urticaria	1	0
Mechanical urticaria	1	0
Urticaria	161	0
Skin disorders SOC TOTAL	943	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Dependents</i>		
Sick relative	1	0
<i>Disability issues</i>		
Bedridden	1	0
Disability	1	0
<i>Social issues NEC</i>		
Contraindication to vaccination	3	0
Social circumstances SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Therapeutic procedures NEC</i>		
Hospitalisation	2	0
Surgical & medical procedures SOC TOTAL	2	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>		
Peripheral circulatory failure	2	0
Shock	1	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	9	0
Flushing	36	0
Hot flush	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	4	0
<i>Site specific vascular disorders NEC</i>		
Pallor	82	0
<i>Vascular hypotensive disorders</i>		
Hypotension	4	0
Vascular disorders SOC TOTAL	142	0
TOTAL REACTIONS FOR DRUG	9548	8
TOTAL REPORTS	3201	
TOTAL FATAL OUTCOME REPORTS		8