

**Case Series Drug Analysis Print**  
**Name: FOI 21/590 Rabies Vaccine**

Report Run Date: 29-Jun-2021  
Data Lock Date: 08-Apr-2021 19:00:04  
Earliest Reaction Date: 12-Feb-1973  
MedDRA Version: MedDRA 23.1  
FOI 21/590 Rabies Vaccine: All UK suspected, spontaneous adverse drug reactions reports associated with the Rabies vaccine until 08/04/2021

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Bleeding tendencies</i>		
Increased tendency to bruise	1	0
<i>Leukocytoses NEC</i>		
Lymphocytosis	1	0
Neutrophilia	2	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	3	0
Lymphadenopathy	27	0
Lymphatic disorder	1	0
<i>Neutropenias</i>		
Neutropenia	4	0
<i>Spleen disorders</i>		
Splenomegaly	1	0
<b>Blood disorders SOC TOTAL</b>	<b>40</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	9	0
<i>Coronary artery disorders NEC</i>		
Coronary artery thrombosis	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	2	0
Tachycardia	9	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Atrial flutter	1	0
Supraventricular tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>24</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Congenital disorders</b>		
<i>Autosomal chromosomal abnormalities</i>		
Trisomy 21	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear discomfort	1	0
Ear disorder	1	0
Ear pain	2	0
<i>Hearing disorders NEC</i>		
Auditory disorder	1	0
<i>Hearing losses</i>		
Deafness	2	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	3	0
Vertigo	6	0
<b>Ear disorders SOC TOTAL</b>	<b>18</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Endocrine disorders</b>		
<i>Adrenal gland disorders NEC</i>		
Adrenal disorder	1	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	1	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Swelling of eyelid	3	0
<i><b>Lid, lash and lacrimal structural disorders</b></i>		
Lagophthalmos	1	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	1	0
Eye pain	5	0
Eye swelling	13	0
Periorbital oedema	1	0
Periorbital swelling	1	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye pruritus	4	0
Ocular hyperaemia	1	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	1	0
<i><b>Ocular sensation disorders</b></i>		
Photophobia	5	0
<i><b>Pupil disorders</b></i>		
Mydriasis	2	0
Pupillary reflex impaired	1	0
<i><b>Retinal structural change, deposit and degeneration</b></i>		
Retinal detachment	1	0
<i><b>Structural change, deposit and degeneration of eye NEC</b></i>		
Exophthalmos	1	0
<i><b>Visual disorders NEC</b></i>		
Diplopia	2	0
Vision blurred	7	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness transient	1	0
Visual impairment	7	0
<b>Eye disorders SOC TOTAL</b>	<b>59</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	29	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	4	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	2	0
Flatulence	1	0
<i>Gastritis (excl infective)</i>		
Reflux gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	14	0
Abdominal pain lower	1	0
Abdominal pain upper	4	0
Abdominal tenderness	1	0
Gastrointestinal pain	2	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	1	0
Gastrointestinal disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1	0
Dysphagia	6	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
Irritable bowel syndrome	3	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	1	0
Gingival swelling	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	64	0
Regurgitation	1	0
Retching	1	0
Vomiting	40	0
Vomiting projectile	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	5	0
Salivary hypersecretion	2	0
<i>Oral soft tissue disorders NEC</i>		
Oral lichen planus	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	2	0
Oral pain	2	0
Paraesthesia oral	10	0



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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	17	0
Mouth swelling	1	0
<b><i>Stomatitis and ulceration</i></b>		
Mouth ulceration	3	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	1	0
Swollen tongue	4	0
Tongue oedema	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>236</b>	<b>0</b>

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<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Asthenia	22	0
Chronic fatigue syndrome	1	0
Fatigue	35	0
Malaise	88	0
<i><b>Body temperature altered</b></i>		
Hypothermia	1	0
<i><b>Febrile disorders</b></i>		
Pyrexia	107	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	25	0
Feeling abnormal	9	0
Feeling cold	4	0
Feeling drunk	2	0
Feeling hot	12	0
Feeling of body temperature change	8	0
Hangover	1	0
Sensation of blood flow	1	0
Sensation of foreign body	1	0
Temperature intolerance	2	0
Thirst	3	0
<i><b>Gait disturbances</b></i>		
Gait disturbance	4	0
Gait inability	1	0
Loss of control of legs	1	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	3	0
General physical health deterioration	1	0
Illness	3	0
Induration	1	0
Influenza like illness	39	0
Local reaction	3	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	23	0
Swelling	17	0
Swelling face	21	0
<i><b>Inflammations</b></i>		
Inflammation	3	0
Systemic inflammatory response syndrome	1	0
<i><b>Injection site reactions</b></i>		
Injected limb mobility decreased	1	0
Injection site erythema	6	0
Injection site haemorrhage	1	0
Injection site inflammation	7	0
Injection site mass	2	0
Injection site pain	12	0
Injection site paraesthesia	1	0
Injection site pruritus	2	0
Injection site rash	4	0
Injection site reaction	16	0
Injection site swelling	4	0
Injection site vesicles	2	0
Injection site warmth	1	0

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<b>General disorders</b> General disorders cont'd		
<i><b>Oedema NEC</b></i>		
Face oedema	4	0
Localised oedema	1	0
Oedema peripheral	3	0
<i><b>Pain and discomfort NEC</b></i>		
Axillary pain	2	0
Chest discomfort	6	0
Chest pain	10	0
Discomfort	1	0
Facial pain	2	0
Pain	38	0
Tenderness	3	0
<i><b>Vaccination site reactions</b></i>		
Vaccination site discomfort	1	0
Vaccination site erythema	3	0
Vaccination site inflammation	1	0
Vaccination site movement impairment	1	0
Vaccination site pain	3	0
Vaccination site reaction	2	0
Vaccination site swelling	2	0
Vaccination site warmth	3	0
<b>General disorders SOC TOTAL</b>	<b>589</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Hepatic disorders</b>		
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	2	0
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	18	0
Mycotic allergy	1	0
Serum sickness	1	0
Type III immune complex mediated reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to chemicals	1	0
Drug hypersensitivity	1	0
Food allergy	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	22	0
Anaphylactic shock	2	0
Anaphylactoid reaction	5	0
<i>Immune and associated conditions NEC</i>		
Decreased immune responsiveness	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunosuppression	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>58</b>	<b>0</b>

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<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Appendicitis	1	0
Gastroenteritis	1	0
<b><i>Bacterial infections NEC</i></b>		
Cellulitis	1	0
<b><i>Campylobacter infections</i></b>		
Campylobacter gastroenteritis	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Encephalitis	6	0
Encephalomyelitis	1	0
Meningitis	1	0
<b><i>Epstein-Barr viral infections</i></b>		
Infectious mononucleosis	1	0
<b><i>Herpes viral infections</i></b>		
Herpes simplex	2	0
<b><i>Infections NEC</i></b>		
Abscess	1	0
Infection	1	0
Injection site abscess	1	0
<b><i>Influenza viral infections</i></b>		
Influenza	1	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Lower respiratory tract infection	3	0
Pneumonia	1	0
<b><i>Muscle and soft tissue infections</i></b>		
Soft tissue infection	1	0
<b><i>Rabies viral infections</i></b>		
Rabies	1	1
<b><i>Salmonella infections</i></b>		
Typhoid fever	2	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	1	0
<b><i>Skin structures and soft tissue infections</i></b>		
Pustule	2	0
Rash pustular	1	0
<b><i>Streptococcal infections</i></b>		
Scarlet fever	1	0
Streptococcal infection	1	0
<b><i>Upper respiratory tract infections</i></b>		
Nasopharyngitis	4	0
<b><i>Urinary tract infections</i></b>		
Cystitis	1	0
Urinary tract infection	1	0
<b>Infections SOC TOTAL</b>	<b>39</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Cerebral injuries NEC</b></i>		
Subdural haemorrhage	1	0
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Drug exposure before pregnancy	1	0
Foetal exposure during pregnancy	1	0
Maternal exposure timing unspecified	1	0
<i><b>Eye injuries NEC</b></i>		
Eye contusion	2	0
<i><b>Intentional product use issues</b></i>		
Intentional product use issue	1	0
<i><b>Neurological and psychiatric procedural complications</b></i>		
Procedural dizziness	1	0
<i><b>Non-site specific injuries NEC</b></i>		
Fall	3	0
Sports injury	1	0
<i><b>Off label uses</b></i>		
Off label use	1	0
<i><b>Product administration errors and issues</b></i>		
Expired product administered	1	0
Inappropriate schedule of product administration	6	0
Incomplete course of vaccination	6	0
Incorrect route of product administration	1	0
Product administration error	1	0
Wrong product administered	1	0
<i><b>Site specific injuries NEC</b></i>		
Head injury	1	0
<i><b>Vaccination related complications</b></i>		
Vaccination failure	1	0
<b>Injuries SOC TOTAL</b>	<b>31</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Auditory function diagnostic procedures</b></i>		
Acoustic stimulation tests abnormal	1	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose fluctuation	1	0
<i><b>Cardiac function diagnostic procedures</b></i>		
Cardiac output decreased	1	0
<i><b>Cerebrospinal fluid tests (excl microbiology)</b></i>		
CSF lymphocyte count abnormal	1	0
CSF test abnormal	1	0
<i><b>Gastrointestinal function diagnostic procedures</b></i>		
Gastric pH increased	1	0
<i><b>Haematological analyses NEC</b></i>		
Red blood cell sedimentation rate increased	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate decreased	1	0
Heart rate increased	4	0
Heart rate irregular	1	0
<i><b>Liver function analyses</b></i>		
Liver function test abnormal	1	0
<i><b>Microbiology and serology tests NEC</b></i>		
Seroconversion test negative	1	0
<i><b>Neurologic diagnostic procedures</b></i>		
Visual evoked potentials abnormal	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature increased	6	0
Weight decreased	2	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	1	0
<i><b>Toxicology laboratory analyses</b></i>		
Blood ethanol increased	1	0
Blood heavy metal increased	1	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Blood pressure decreased	2	0
Blood pressure increased	2	0
<i><b>Virus identification and serology</b></i>		
Lyssavirus test positive	1	0
<i><b>White blood cell analyses</b></i>		
White blood cell count increased	1	0
<b>Investigations SOC TOTAL</b>	<b>33</b>	<b>0</b>



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<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	5	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Food intolerance	1	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	1	0
<i><b>Metabolic acidoses (excl diabetic acidoses)</b></i>		
Lactic acidosis	1	0
<i><b>Mixed acid-base disorders</b></i>		
Acidosis	1	0
<i><b>Sodium imbalance</b></i>		
Hyponatraemia	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	2	0
<b>Metabolic disorders SOC TOTAL</b>	<b>12</b>	<b>0</b>

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<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	3	0
Arthropathy	2	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	1	0
<i><b>Joint related disorders NEC</b></i>		
Periarthritis	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	39	0
Joint noise	1	0
Joint range of motion decreased	1	0
Joint stiffness	4	0
Joint swelling	12	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	2	0
Myalgia	48	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle spasms	3	0
Muscle swelling	1	0
Muscle tightness	2	0
Muscle twitching	5	0
<i><b>Muscle tone abnormalities</b></i>		
Muscle rigidity	1	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	14	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Back disorder	1	0
Musculoskeletal stiffness	8	0
Posture abnormal	1	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	11	0
Limb discomfort	8	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	1	0
Neck pain	2	0
Pain in extremity	24	0
<i><b>Rheumatoid arthropathies</b></i>		
Rheumatoid arthritis	1	0
<i><b>Soft tissue disorders NEC</b></i>		
Groin pain	1	0
<i><b>Spondyloarthropathies</b></i>		
Arthritis reactive	2	0
<i><b>Synovial disorders</b></i>		
Synovitis	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>202</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Neoplasms</b>		
<i>Ovarian neoplasms malignant (excl germ cell)</i>		
Ovarian cancer	1	0
<b>Neoplasms SOC TOTAL</b>	<b>1</b>	<b>0</b>

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<b>Nervous system disorders</b>		
<i>Abnormal reflexes</i>		
Hyporeflexia	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	3	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	8	0
Coordination abnormal	1	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	2	0
Lethargy	16	0
Loss of consciousness	9	0
Somnolence	5	0
Syncope	20	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	1	0
Dyskinesia	2	0
Hypokinesia	1	0
Movement disorder	1	0
<i>Encephalopathies NEC</i>		
Encephalopathy	2	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	4	0
Facial paresis	1	0
Facial spasm	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	3	0
<i>Headaches NEC</i>		
Headache	123	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
Memory impairment	2	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	4	0
Mental impairment	1	0
<i>Migraine headaches</i>		
Migraine	3	0
<i>Muscle tone abnormal</i>		
Hypotonia	1	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	1	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	1	0

# Case Series Drug Analysis Print

## Name: FOI 21/590 Rabies Vaccine

Report Run Date: 29-Jun-2021  
Earliest Reaction Date: 12-Feb-1973

Data Lock Date: 08-Apr-2021 19:00:04  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b><i>Nervous system disorders NEC</i></b>		
Nervous system disorder	1	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Dizziness	69	0
Head discomfort	1	0
Meningism	1	0
Presyncope	8	0
Unresponsive to stimuli	1	0
<b><i>Neuromuscular junction dysfunction</i></b>		
Myasthenia gravis	1	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning sensation	3	0
Dysaesthesia	1	0
Formication	1	0
Hyperaesthesia	2	0
Hypoaesthesia	27	0
Paraesthesia	57	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Diplegia	1	0
Monoplegia	2	0
<b><i>Peripheral neuropathies NEC</i></b>		
Neuropathy peripheral	1	0
Polyneuropathy	2	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Febrile convulsion	1	0
Seizure	14	0
<b><i>Sensory abnormalities NEC</i></b>		
Dysgeusia	1	0
Neuralgia	3	0
Sensory disturbance	4	0
Sensory loss	2	0
Taste disorder	1	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	1	0
Speech disorder	3	0
<b><i>Spinal cord and nerve root disorders NEC</i></b>		
Myelopathy	1	0
Radiculitis brachial	1	0
<b><i>Transient cerebrovascular events</i></b>		
Transient ischaemic attack	1	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	11	0
<b>Nervous system disorders SOC TOTAL</b>	<b>448</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	2	0
<i>Foetal complications NEC</i>		
Foetal cardiac disorder	1	0
<i>Maternal complications of pregnancy NEC</i>		
Ectopic pregnancy	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>4</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<i>Device physical property and chemical issues</i>		
Needle issue	1	0
<i>Manufacturing laboratory controls issues</i>		
Out of specification test results	1	0
<b>null SOC TOTAL</b>	<b>2</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	2	0
<b><i>Affect alterations NEC</i></b>		
Inappropriate affect	1	0
<b><i>Amnesic symptoms</i></b>		
Paramnesia	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	3	0
Anxiety	8	0
Nervousness	1	0
Stress	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	3	0
Paranoia	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	7	0
Disorientation	6	0
<b><i>Deliria</i></b>		
Delirium	2	0
<b><i>Depressive disorders</i></b>		
Depression	1	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	2	0
<b><i>Eating disorders NEC</i></b>		
Eating disorder	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Irritability	3	0
Mood altered	1	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	1	0
Hydrophobia	1	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	1	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	6	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	2	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	1	0
<b><i>Mood disorders NEC</i></b>		
Listless	1	0
<b><i>Panic attacks and disorders</i></b>		
Panic attack	3	0
Panic reaction	1	0
<b><i>Parasomnias</i></b>		
Abnormal dreams	2	0
Abnormal sleep-related event	1	0
Nightmare	3	0
<b><i>Psychotic disorder NEC</i></b>		
Psychotic disorder	2	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	4	0
<b><i>Thinking disturbances</i></b>		



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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Bradyphrenia	1	0
Intrusive thoughts	1	0
Thinking abnormal	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>76</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Micturition urgency	1	0
Urinary incontinence	3	0
<i>Myoneurogenic bladder disorders</i>		
Atonic urinary bladder	1	0
<i>Urinary abnormalities</i>		
Proteinuria	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Polyuria	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>7</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Breast infections and inflammations</i>		
Nipple inflammation	1	0
<i>Breast signs and symptoms</i>		
Breast tenderness	1	0
Nipple pain	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	1	0
Menstrual disorder	1	0
<i>Menstruation with decreased bleeding</i>		
Menstruation delayed	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	1	0
Dyspnoea	24	0
Dyspnoea exertional	1	0
Dyspnoea paroxysmal nocturnal	1	0
Grunting	2	0
Respiration abnormal	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Bronchospasm	4	0
Wheezing	6	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Hypercapnia	1	0
Hypoxia	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	5	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Stridor	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Pleuritic pain	1	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	1	0
Nasal odour	1	0
Nasal oedema	1	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	1	0
Sinus disorder	1	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Lung consolidation	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal swelling	5	0
<i><b>Pulmonary oedemas</b></i>		
Pulmonary oedema	1	0
<i><b>Respiratory tract disorders NEC</b></i>		
Respiratory disorder	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Oropharyngeal pain	11	0
Rhinorrhoea	2	0
Sneezing	1	0
Throat irritation	1	0
Throat tightness	8	0
<b>Respiratory disorders SOC TOTAL</b>	<b>85</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b>Angioedemas</b>		
Angioedema	11	0
<b>Apocrine and eccrine gland disorders</b>		
Cold sweat	5	0
Hyperhidrosis	9	0
Night sweats	2	0
<b>Bullous conditions</b>		
Blister	5	0
Erythema multiforme	3	0
<b>Dermal and epidermal conditions NEC</b>		
Scar pain	1	0
Skin burning sensation	1	0
Skin discolouration	4	0
Skin disorder	1	0
Skin reaction	3	0
Skin warm	2	0
<b>Dermatitis and eczema</b>		
Dermatitis	1	0
Dermatitis allergic	8	0
Dyshidrotic eczema	1	0
Eczema	5	0
Skin irritation	1	0
<b>Erythemas</b>		
Erythema	26	0
<b>Exfoliative conditions</b>		
Dermatitis exfoliative generalised	1	0
Skin exfoliation	1	0
<b>Panniculitides</b>		
Erythema nodosum	2	0
<b>Papulosquamous conditions</b>		
Lichen planus	1	0
<b>Photosensitivity and photodermatosis conditions</b>		
Photosensitivity reaction	1	0
<b>Pruritus NEC</b>		
Pruritus	30	0
<b>Purpura and related conditions</b>		
Henoch-Schonlein purpura	1	0
Petechiae	1	0
Purpura	1	0
<b>Rashes, eruptions and exanthems NEC</b>		
Rash	77	0
Rash erythematous	10	0
Rash macular	13	0
Rash maculo-papular	3	0
Rash papular	3	0
Rash pruritic	17	0
Systemic lupus erythematosus rash	1	0
<b>Skin and subcutaneous conditions NEC</b>		
Skin mass	1	0
<b>Skin and subcutaneous tissue ulcerations</b>		
Skin ulcer	1	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	1	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<i>Urticarias</i>		
Urticaria	111	0
Urticarial vasculitis	1	0
<b>Skin disorders SOC TOTAL</b>	<b>367</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Impaired driving ability	1	0
Impaired work ability	1	0
Loss of personal independence in daily activities	2	0
<b>Social circumstances SOC TOTAL</b>	<b>4</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>Therapeutic procedures NEC</i>		
Interchange of vaccine products	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>1</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	6	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Peripheral venous disease	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	3	0
Flushing	9	0
Hot flush	1	0
Peripheral vascular disorder	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
Poor peripheral circulation	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	11	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
Orthostatic hypotension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>39</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>2387</b>	<b>1</b>
<b>TOTAL REPORTS</b>	<b>769</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>1</b>