

Case Series Drug Analysis Print

Name: Revaxis FOI 21/1063

Report Run Date: 07-Oct-2021
Data Lock Date: 30-Sep-2021 18:30:04
Earliest Reaction Date: 24-Feb-2004
MedDRA Version: MedDRA 24.0

Revaxis FOI 21/1063: All UK spontaneous reports received up until 30-Sep-2021 for the Revaxis Vaccine analysis print. A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

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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	34	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	52	1

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	6	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	21	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Supraventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	39	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	3	0
Ear swelling	1	0
<i>Hearing losses</i>		
Deafness	2	0
Deafness neurosensory	1	0
Deafness unilateral	1	0
Hypoacusis	7	0
<i>Inner ear disorders NEC</i>		
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	4	0
Vertigo	12	0
Vertigo positional	1	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	1	0
Ear disorders SOC TOTAL	37	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	12	0
Eye swelling	17	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	29	0
Gaze palsy	2	0
Strabismus	1	0
<i>Ocular sensation disorders</i>		
Asthenopia	3	0
Photophobia	25	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	31	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Amaurosis fugax	1	0
Blindness	3	0
Blindness transient	2	0
Visual impairment	11	0
Eye disorders SOC TOTAL	191	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	66	0
Diarrhoea haemorrhagic	1	0
<i>Faecal abnormalities NEC</i>		
Faeces pale	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	34	0
Abdominal pain lower	1	0
Abdominal pain upper	47	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	2	0
Gastrooesophageal reflux disease	3	0
Impaired gastric emptying	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	11	0
Anal incontinence	1	0
Dysphagia	11	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	2	0
Irritable bowel syndrome	1	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	331	0
Retching	2	0
Vomiting	214	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	2	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Oral pruritus	2	0
Paraesthesia oral	16	0
Oral soft tissue swelling and oedema		
Lip swelling	22	0
Mouth swelling	3	0
Salivary gland enlargements		
Parotid gland enlargement	1	0
Stomatitis and ulceration		
Mouth ulceration	1	0
Tongue disorders		
Glossitis	1	0
Tongue disorder	1	0
Tongue signs and symptoms		
Swollen tongue	10	0
Tongue discolouration	1	0
Tongue movement disturbance	1	0
Umbilical hernias		
Umbilical hernia	2	0
Gastrointestinal disorders SOC TOTAL	815	0

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Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site bruise	1	0
Application and instillation site reactions		
Application site erythema	1	0
Asthenic conditions		
Asthenia	43	0
Chronic fatigue syndrome	1	0
Fatigue	128	0
Malaise	355	0
Febrile disorders		
Hyperpyrexia	2	0
Pyrexia	486	0
Feelings and sensations NEC		
Chills	88	0
Feeling abnormal	21	0
Feeling cold	21	0
Feeling hot	84	0
Feeling of body temperature change	20	0
Sensation of foreign body	2	0
Thirst	3	0
Gait disturbances		
Gait disturbance	7	0
Gait inability	4	0
General signs and symptoms NEC		
Condition aggravated	7	0
Crepitations	2	0
Crying	7	0
Developmental delay	1	0
Effusion	1	0
Illness	48	0
Induration	3	0
Influenza like illness	86	0
Irritability postvaccinal	1	0
Local reaction	24	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	72	0
Screaming	1	0
Swelling	38	0
Swelling face	26	0
Inflammations		
Inflammation	16	0
Systemic inflammatory response syndrome	2	0
Infusion site reactions		
Infusion site discomfort	1	0
Injection site reactions		
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	32	0
Injection site haemorrhage	3	0
Injection site hypersensitivity	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
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	24	0
Injection site paraesthesia	1	0
Injection site pruritus	8	0
Injection site rash	12	0
Injection site reaction	17	0
Injection site swelling	25	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	4	0
Pain and discomfort NEC		
Axillary pain	9	0
Chest discomfort	20	0
Chest pain	24	0
Discomfort	9	0
Facial pain	1	0
Pain	102	0
Tenderness	10	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	8	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	23	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
Vaccination site swelling	26	0
Vaccination site vesicles	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site warmth	6	0
General disorders SOC TOTAL	2090	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
<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	20	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergy to animal	1	0
Hypersensitivity	31	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	52	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>		
Haemophagocytic lymphohistiocytosis	1	1
Immune system disorder	1	0
Immune-mediated adverse reaction	1	0
Immunisation reaction	1	0
Multisystem inflammatory syndrome in children	1	0
Immune system disorders SOC TOTAL	100	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	9	0
Injection site cellulitis	2	0
Meningitis bacterial	1	0
Tonsillitis bacterial	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	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
<i>Streptococcal infections</i>		
Pneumococcal sepsis	1	1
Streptococcal infection	1	0

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Infections		
Infections cont'd		
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	21	0
Pharyngitis	3	0
Rhinitis	2	0
Sinusitis	1	0
Tonsillitis	2	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	102	1

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	8	0
Foetal exposure during pregnancy	7	0
Maternal exposure before pregnancy	2	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	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	1	0
Extra dose administered	2	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	7	0
<i>Vaccination related complications</i>		
Vaccination complication	3	0
Injuries SOC TOTAL	54	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	2	0
Pulse abnormal	18	0
Pulse absent	1	0
<i>Investigations NEC</i>		
Quality of life decreased	1	0
<i>Liver function analyses</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	2	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	78	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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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	184	0

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Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	1	0
Decreased appetite	53	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	64	0

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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	1	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	75	0
Joint effusion	1	0
Joint stiffness	6	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	89	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	1	0
Muscle fatigue	4	0
Muscle spasms	14	0
Muscle swelling	3	0
Muscle twitching	17	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	13	0
Trismus	3	0
<i>Muscle weakness conditions</i>		
Muscular weakness	27	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Growth retardation	1	0
Limb mass	1	0
Mastication disorder	1	0
Mobility decreased	2	0
Musculoskeletal stiffness	42	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	59	0
Limb discomfort	20	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	31	0
Pain in extremity	180	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	637	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Adenocarcinoma pancreas	1	0
Neoplasms SOC TOTAL	1	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	66	0
Loss of consciousness	35	0
Somnolence	53	0
Syncope	221	0
Dyskinesias and movement disorders NEC		
Dyskinesia	32	0
Hypokinesia	7	0
Movement disorder	1	0
Psychomotor hyperactivity	2	0
Dystonias		
Opisthotonus	1	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	511	0
Tension headache	2	0
Intellectual disabilities		
Intellectual disability	1	0
Memory loss (excl dementia)		

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Amnesia	3	0
Memory impairment	1	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	2	0
Disturbance in attention	6	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	5	0
Myelitis (incl infective)		
Myelitis transverse	1	0
Narcolepsy and hypersomnia		
Hypersomnia	5	0
Nervous system disorders NEC		
Brain stem syndrome	1	0
Neurologic visual problems NEC		
Tunnel vision	2	0
Neurological signs and symptoms NEC		
Dizziness	422	0
Dizziness postural	4	0
Drooling	1	0
Head discomfort	5	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	7	0
Hypoaesthesia	51	0
Paraesthesia	75	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	2	0
Hemiparesis	2	0
Monoparesis	1	0
Monoplegia	1	0
Paralysis	2	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	3	0
Tonic clonic movements	2	0
Tonic convulsion	1	0
<i>Sensory abnormalities NEC</i>		
Ageusia	1	0
Dysgeusia	3	0
Neuralgia	2	0
Sensory disturbance	3	0
Sensory loss	6	0
Taste disorder	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	9	0
Incoherent	1	0
Speech disorder	3	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	3	0
<i>Tremor (excl congenital)</i>		
Intention tremor	1	0
Tremor	67	0
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	1814	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	12	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	28	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	15	0
Nervousness	3	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	3	0
Indifference	1	0
Paranoia	1	0
<i>Communications disorders</i>		
Communication disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	15	0
Disorientation	18	0
<i>Deliria</i>		
Delirium	7	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	1	0
Tearfulness	2	0
<i>Mood disorders NEC</i>		
Affective disorder	1	0
Listless	3	0
<i>Panic attacks and disorders</i>		
Panic attack	2	0
Panic reaction	3	0
<i>Parasomnias</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Nightmare	1	0
Personality disorders with dramatic behaviour (Cluster B)		
Borderline personality disorder	1	0
Psychiatric elimination disorders		
Enuresis	2	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic disorder	2	0
Sleep disorders NEC		
Sleep disorder	8	0
Somatic symptom disorders		
Somatic symptom disorder	1	0
Speech articulation and rhythm disturbances		
Lack of spontaneous speech	1	0
Stereotypies and automatisms		
Bruxism	2	0
Tic disorders		
Tic	1	0
Psychiatric disorders SOC TOTAL	157	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	2	0
Incontinence	4	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	1	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	25	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast tenderness	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	1	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	5	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	55	0
Grunting	1	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	18	0
Haemoptysis	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	3	0
<i>Nasal disorders NEC</i>		
Epistaxis	6	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 paraesthesia	1	0
Pharyngeal swelling	10	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	57	0
Rhinorrhoea	4	0
Throat irritation	8	0
Throat tightness	13	0
Respiratory disorders SOC TOTAL	233	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	38	0
Hyperhidrosis	47	0
Night sweats	3	0
<i>Bullous conditions</i>		
Erythema multiforme	3	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	5	0
Macule	1	0
Pain of skin	2	0
Papule	1	0
Sensitive skin	1	0
Skin burning sensation	1	0
Skin discolouration	14	0
Skin discomfort	1	0
Skin induration	1	0
Skin lesion	1	0
Skin reaction	2	0
Skin swelling	1	0
Skin warm	15	0
<i>Dermatitis and eczema</i>		
Dermatitis	2	0
Dermatitis allergic	6	0
Eczema	2	0
Skin irritation	2	0
<i>Erythemas</i>		
Erythema	93	0
<i>Exfoliative conditions</i>		
Exfoliative rash	1	0
Skin exfoliation	2	0
<i>Papulosquamous conditions</i>		
Pityriasis rosea	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	3	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pruritus NEC</i>		
Pruritus	52	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
Henoch-Schonlein purpura	2	0
Petechiae	1	0
Purpura	3	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	124	0
Rash erythematous	8	0
Rash macular	23	0
Rash maculo-papular	2	0
Rash papular	8	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
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	57	0
Urticaria chronic	2	0
Skin disorders SOC TOTAL	564	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	21	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	109	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	200	0
TOTAL REACTIONS FOR DRUG	7431	5
TOTAL REPORTS	2212	
TOTAL FATAL OUTCOME REPORTS		5