

## Case Series Drug Analysis Print

### Name: FOI 21/1164 Bacillus Calmette-Guerin (BCG) Vaccine Drug Analysis Print

Report Run Date: 23-Nov-2021

Data Lock Date: 17-Oct-2021 10:57:05

Earliest Reaction Date: 12-Nov-1965

MedDRA Version: MedDRA 24.0

FOI 21/1164 Bacillus Calmette-Guerin (BCG) Vaccine Drug Analysis Print: All spontaneous suspected UK Adverse Drug Reaction (ADR) reports associated with the Bacillus Calmette-Guerin (BCG) vaccine.

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Bleeding tendencies</b></i>		
Increased tendency to bruise	1	0
<i><b>Leukopenias NEC</b></i>		
Leukopenia	1	0
<i><b>Lymphatic system disorders NEC</b></i>		
Lymph node calcification	1	0
Lymphadenitis	55	0
Lymphadenopathy	57	0
Lymphadenopathy mediastinal	1	0
<i><b>Marrow depression and hypoplastic anaemias</b></i>		
Pancytopenia	3	0
<i><b>Neutropenias</b></i>		
Neutropenia	2	0
<i><b>Spleen disorders</b></i>		
Splenic lesion	1	0
Splenomegaly	2	0
<i><b>Thrombocytopenias</b></i>		
Thrombocytopenia	1	0
Thrombocytopenic purpura	1	0
<b>Blood disorders SOC TOTAL</b>	<b>126</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	3	0
<i>Heart failures NEC</i>		
Cardiac failure congestive	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	4	0
Tachycardia	8	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>17</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Gastrointestinal tract disorders congenital NEC</i>		
Diverticulitis Meckel's	1	0
<i>Immune system abnormalities congenital</i>		
Immunodeficiency congenital	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Ear disorders</b>		
<i>Hearing losses</i>		
Deafness	2	0
Deafness transitory	1	0
Hypoacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	5	0
Vertigo	25	0
<b>Ear disorders SOC TOTAL</b>	<b>34</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Conjunctival structural change, deposit and degeneration</i>		
Conjunctival disorder	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	1	0
Uveitis	3	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis allergic	1	0
Swelling of eyelid	9	0
<i>Ocular disorders NEC</i>		
Eye disorder	4	0
Eye pain	4	0
Eye swelling	7	0
Periorbital oedema	6	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye irritation	1	0
Ocular hyperaemia	2	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	12	0
<i>Ocular sensation disorders</i>		
Photophobia	5	0
<i>Pupil disorders</i>		
Miosis	1	0
Mydriasis	5	0
Pupil fixed	1	0
<i>Visual disorders NEC</i>		
Photopsia	1	0
Vision blurred	17	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	5	0
<b>Eye disorders SOC TOTAL</b>	<b>86</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	9	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	35	0
Abdominal pain lower	1	0
Abdominal pain upper	5	0
Abdominal rigidity	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1	0
Dysphagia	6	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	103	0
Retching	2	0
Vomiting	78	0
Vomiting projectile	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	4	0
Salivary hypersecretion	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	4	0
Oral mucosal blistering	1	0
Oral pain	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	9	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	1	0
<i>Tongue disorders</i>		
Tongue disorder	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	3	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>269</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Administration site reactions NEC</i>		
Administration site granuloma	1	0
<i>Application and instillation site reactions</i>		
Application site reaction	3	0
Application site vesicles	1	0
<i>Asthenic conditions</i>		
Asthenia	26	0
Chronic fatigue syndrome	1	0
Fatigue	41	0
Malaise	98	0
<i>Complications associated with device NEC</i>		
Complication associated with device	1	0
<i>Death and sudden death</i>		
Death	1	1
Sudden death	1	1
Sudden infant death syndrome	1	1
<i>Febrile disorders</i>		
Pyrexia	54	0
<i>Feelings and sensations NEC</i>		
Chills	20	0
Feeling abnormal	6	0
Feeling cold	9	0
Feeling drunk	1	0
Feeling hot	27	0
Feeling of body temperature change	3	0
Thirst	2	0
<i>Gait disturbances</i>		
Gait disturbance	3	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Crepitations	1	0
Crying	6	0
Disease recurrence	1	0
Illness	15	0
Induration	1	0
Influenza like illness	8	0
Local reaction	63	0
Peripheral swelling	21	0
Secretion discharge	2	0
Swelling	39	0
Swelling face	15	0
<i>Healing abnormal NEC</i>		
Impaired healing	13	0
<i>Implant and catheter site reactions</i>		
Catheter site haemorrhage	1	0
<i>Inflammations</i>		
Granuloma	8	0
Inflammation	21	0
<i>Injection site reactions</i>		
Injection site abscess sterile	2	0
Injection site atrophy	1	0
Injection site bruising	1	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site discharge	10	0
Injection site discolouration	3	0
Injection site dryness	1	0
Injection site eczema	1	0
Injection site erythema	124	0
Injection site fibrosis	1	0
Injection site granuloma	6	0
Injection site haemorrhage	4	0
Injection site induration	5	0
Injection site inflammation	42	0
Injection site irritation	2	0
Injection site lymphadenopathy	2	0
Injection site mass	16	0
Injection site necrosis	2	0
Injection site nodule	2	0
Injection site pain	38	0
Injection site pruritus	1	0
Injection site rash	8	0
Injection site reaction	231	0
Injection site scab	2	0
Injection site scar	10	0
Injection site swelling	30	0
Injection site ulcer	46	0
Injection site urticaria	3	0
Injection site warmth	3	0
<b>Mass conditions NEC</b>		
Mass	6	0
<b>Necrosis NEC</b>		
Necrosis	1	0
<b>Oedema NEC</b>		
Face oedema	10	0
Oedema	2	0
Oedema peripheral	5	0
<b>Pain and discomfort NEC</b>		
Axillary pain	3	0
Chest discomfort	14	0
Chest pain	7	0
Pain	18	0
Suprapubic pain	1	0
Tenderness	3	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	2	0
Drug ineffective	34	0
Drug intolerance	1	0
Drug tolerance decreased	1	0
Vaccination failure	1	0
<b>Ulcers NEC</b>		
Ulcer	6	0
Ulcer haemorrhage	1	0
<b>Vaccination site reactions</b>		
Vaccination site cyst	2	0
Vaccination site discharge	9	0

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<b>General disorders</b> General disorders cont'd		
Vaccination site erythema	10	0
Vaccination site haemorrhage	4	0
Vaccination site induration	3	0
Vaccination site inflammation	4	0
Vaccination site irritation	1	0
Vaccination site laceration	1	0
Vaccination site lymphadenopathy	1	0
Vaccination site mass	8	0
Vaccination site pain	5	0
Vaccination site pruritus	1	0
Vaccination site reaction	5	0
Vaccination site scab	2	0
Vaccination site scar	6	0
Vaccination site swelling	10	0
Vaccination site ulcer	3	0
Vaccination site vesicles	3	0
<b>General disorders SOC TOTAL</b>	<b>1307</b>	<b>3</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Hepatic disorders</b>		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Hepatic fibrosis and cirrhosis</i>		
Biliary cirrhosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatomegaly	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Hypersensitivity	19	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	42	0
Anaphylactic shock	3	0
Anaphylactoid reaction	14	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	20	0
Haemophagocytic lymphohistiocytosis	2	0
Immune system disorder	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>103</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Atypical mycobacterial infections</i></b>		
Atypical mycobacterial infection	1	0
Mycobacterial infection	3	0
<b><i>Bacterial infections NEC</i></b>		
Acid fast bacilli infection	1	0
Arthritis bacterial	1	0
Bacterial infection	1	0
Cellulitis	1	0
Lymphadenitis bacterial	5	0
Pyomyositis	1	0
<b><i>Bone and joint infections</i></b>		
Intervertebral discitis	2	0
Osteomyelitis	6	0
<b><i>Ear infections</i></b>		
Otitis externa	1	0
<b><i>Epstein-Barr viral infections</i></b>		
Epstein-Barr virus infection	1	0
<b><i>Escherichia infections</i></b>		
Escherichia bacteraemia	1	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	3	0
<b><i>Herpes viral infections</i></b>		
Herpes zoster	1	0
Varicella	1	0
<b><i>Infections NEC</i></b>		
Abscess	211	1
Abscess limb	2	0
Abscess rupture	1	0
Abscess soft tissue	1	0
Infection	7	0
Injection site abscess	554	0
Injection site infection	5	0
Localised infection	3	0
Lymph node abscess	13	0
Purulent discharge	7	0
Vaccination site abscess	26	0
Vaccination site infection	6	1
Wound abscess	1	0
<b><i>Influenza viral infections</i></b>		
Influenza	2	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Lower respiratory tract infection	1	0
Pneumonia	1	0
<b><i>Male reproductive tract infections</i></b>		
Orchitis	5	0
<b><i>Prion-associated disorders</i></b>		
Creutzfeldt-Jakob disease	1	1
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Neutropenic sepsis	1	0
Sepsis	5	0
Urosepsis	2	0
<b><i>Skin structures and soft tissue infections</i></b>		

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<b>Infections</b>		
Infections cont'd		
Blister infected	2	0
Infected skin ulcer	1	0
Injection site pustule	9	0
Pustule	12	0
Rash pustular	1	0
Subcutaneous abscess	12	0
Vaccination site pustule	3	0
<b><i>Staphylococcal infections</i></b>		
Furuncle	2	0
Staphylococcal infection	1	0
<b><i>Tuberculous infections</i></b>		
Bone tuberculosis	1	0
Bovine tuberculosis	2	0
Cutaneous tuberculosis	1	0
Disseminated Bacillus Calmette-Guerin infection	52	2
Disseminated tuberculosis	3	2
Epididymitis tuberculous	2	0
Erythema induratum	19	0
Lupus vulgaris	1	0
Lymph node tuberculosis	6	0
Meningitis tuberculous	2	0
Peritoneal tuberculosis	1	0
Pulmonary tuberculosis	8	0
Renal tuberculosis	2	0
Tuberculosis	23	0
Tuberculosis of eye	13	0
<b><i>Upper respiratory tract infections</i></b>		
Nasopharyngitis	5	0
Pharyngitis	2	0
Rhinitis	2	0
<b><i>Urinary tract infections</i></b>		
Cystitis	1	0
Urinary tract infection	2	0
<b><i>Vascular infections</i></b>		
Infective aneurysm	3	1
<b><i>Viral infections NEC</i></b>		
Post viral fatigue syndrome	2	0
<b>Infections SOC TOTAL</b>	<b>1081</b>	<b>8</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Cerebral injuries NEC</b></i>		
Concussion	1	0
<i><b>Chemical injuries</b></i>		
Chemical cystitis	1	0
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Foetal exposure during pregnancy	3	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Medication error	2	0
Wrong technique in product usage process	5	0
<i><b>Non-site specific injuries NEC</b></i>		
Fall	10	0
Wound	1	0
Wound secretion	7	0
<i><b>Non-site specific procedural complications</b></i>		
Post procedural discharge	1	0
<i><b>Off label uses</b></i>		
Off label use	1	0
<i><b>Poisoning and toxicity</b></i>		
Toxicity to various agents	1	0
<i><b>Product administration errors and issues</b></i>		
Accidental overdose	2	0
Inappropriate schedule of product administration	2	0
Incorrect dose administered	1	0
Incorrect route of product administration	5	0
Product administered at inappropriate site	1	0
Product administration error	2	0
Wrong product administered	3	0
<i><b>Site specific injuries NEC</b></i>		
Head injury	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	3	0
Scar	17	0
Scratch	1	0
Skin abrasion	2	0
<b>Injuries SOC TOTAL</b>	<b>73</b>	<b>0</b>



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<b>Investigations</b>		
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose decreased	2	0
<i><b>ECG investigations</b></i>		
Electrocardiogram abnormal	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate decreased	11	0
Heart rate increased	12	0
Heart rate irregular	1	0
Pulse abnormal	16	0
Pulse absent	2	0
<i><b>Immunoglobulin analyses</b></i>		
Immunoglobulins abnormal	1	1
<i><b>Immunology skin tests NEC</b></i>		
Skin test positive	5	0
<i><b>Liver function analyses</b></i>		
Liver function test abnormal	1	0
Transaminases increased	1	0
<i><b>Neurologic diagnostic procedures</b></i>		
Electroencephalogram abnormal	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature	2	0
Body temperature decreased	1	0
Body temperature increased	5	0
Respiratory rate decreased	1	0
Respiratory rate increased	3	0
Weight decreased	4	0
Weight increased	2	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	2	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Blood pressure decreased	2	0
Blood pressure increased	1	0
<i><b>White blood cell analyses</b></i>		
White blood cell count decreased	1	0
<b>Investigations SOC TOTAL</b>	<b>78</b>	<b>1</b>

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<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	9	0
<i>Calcium metabolism disorders</i>		
Tetany	2	0
<i>Diabetes mellitus (incl subtypes)</i>		
Type 1 diabetes mellitus	1	0
<i>General nutritional disorders NEC</i>		
Poor feeding infant	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>14</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
Polyarthritits	1	0
<i><b>Bone disorders NEC</b></i>		
Osteitis	1	0
<i><b>Bone related signs and symptoms</b></i>		
Pain in jaw	2	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	14	0
Joint stiffness	3	0
Joint swelling	5	0
<i><b>Muscle pains</b></i>		
Myalgia	4	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle atrophy	1	0
Muscle disorder	1	0
Muscle spasms	6	0
Muscle tightness	3	0
Muscle twitching	28	0
<i><b>Muscle tone abnormalities</b></i>		
Muscle rigidity	17	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	3	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Mobility decreased	1	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	10	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	1	0
Limb discomfort	2	0
Musculoskeletal chest pain	1	0
Neck pain	5	0
Pain in extremity	25	0
<i><b>Rheumatoid arthropathies</b></i>		
Rheumatoid arthritis	2	0
<i><b>Soft tissue disorders NEC</b></i>		
Axillary mass	2	0
<i><b>Spondyloarthropathies</b></i>		
Arthritis reactive	6	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>150</b>	<b>0</b>

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Earliest Reaction Date: 12-Nov-1965

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Bladder neoplasms malignant</i>		
Bladder cancer recurrent	1	0
<i>Fibrosarcomas malignant</i>		
Dermatofibrosarcoma protuberans	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Neoplasm skin	1	0
<b>Neoplasms SOC TOTAL</b>	<b>3</b>	<b>0</b>

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Abnormal reflexes</i>		
Areflexia	1	0
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	3	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	3	0
Dysstasia	1	0
Nystagmus	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Depressed level of consciousness	1	0
Lethargy	8	0
Loss of consciousness	31	0
Somnolence	34	0
Syncope	202	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	21	0
Movement disorder	2	0
<i>Dystonias</i>		
Opisthotonus	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	4	0
<i>Headaches NEC</i>		
Headache	147	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	1	0
<i>Migraine headaches</i>		
Migraine	1	0
<i>Muscle tone abnormal</i>		
Hypertonia	1	0
Hypotonia	3	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	1	0
<i>Nervous system disorders NEC</i>		
Cerebral disorder	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	271	0
Meningism	2	0
Presyncope	15	0
Unresponsive to stimuli	4	0
<i>Neuromuscular disorders NEC</i>		
Hypotonic-hypo-responsive episode	1	0
<i>Olfactory nerve disorders</i>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Anosmia	1	0
<b><i>Optic nerve disorders NEC</i></b>		
Optic neuritis	1	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Hyperaesthesia	1	0
Hypoaesthesia	11	0
Paraesthesia	40	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Paraplegia	1	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Epilepsy	1	0
Seizure	34	0
<b><i>Sensory abnormalities NEC</i></b>		
Ageusia	1	0
Dysgeusia	2	0
Loss of proprioception	1	0
Neuralgia	2	0
Sensory loss	1	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	1	0
Incoherent	1	0
Speech disorder	2	0
Speech disorder developmental	1	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	20	0
<b>Nervous system disorders SOC TOTAL</b>	<b>889</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Pregnancy conditions</b>		
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Normal newborn status</i>		
Normal newborn	1	0
<b>Pregnancy conditions 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	1	0
Staring	2	0
<b><i>Anxiety symptoms</i></b>		
Agitation	2	0
Anxiety	1	0
Nervousness	3	0
Tension	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	8	0
Disorientation	3	0
<b><i>Deliria</i></b>		
Delirium	2	0
<b><i>Dissociative states</i></b>		
Dissociation	1	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Emotional distress	4	0
Irritability	1	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Tearfulness	3	0
<b><i>Panic attacks and disorders</i></b>		
Panic attack	3	0
<b><i>Parasomnias</i></b>		
Nightmare	1	0
<b><i>Pervasive developmental disorders NEC</i></b>		
Autism spectrum disorder	3	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	1	0
<b><i>Stereotypies and automatisms</i></b>		
Bruxism	2	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>44</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Dysuria	2	0
Micturition urgency	2	0
Pollakiuria	2	0
Urinary incontinence	9	0
Urinary retention	1	0
<i><b>Bladder disorders NEC</b></i>		
Bladder disorder	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	1	0
Renal failure	1	0
<i><b>Renal failure complications</b></i>		
Azotaemia	1	0
<i><b>Urethral disorders NEC</b></i>		
Urethral discharge	1	0
<i><b>Urinary abnormalities</b></i>		
Haematuria	3	0
<i><b>Urinary tract lithiasis (excl renal)</b></i>		
Calculus bladder	1	0
Ureterolithiasis	1	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Renal colic	2	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>28</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	22	0
<i>Reproductive tract signs and symptoms NEC</i>		
Oedema genital	1	0
<i>Sexual function and fertility disorders NEC</i>		
Infertility	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular mass	1	0
Testicular necrosis	1	0
<i>Testicular and epididymal infections and inflammations</i>		
Orchitis noninfective	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>28</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	3	0
Dyspnoea	34	0
Hyperventilation	10	0
Hypopnoea	2	0
Respiration abnormal	1	0
Respiratory arrest	1	0
Respiratory distress	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	8	0
Bronchospasm	4	0
Wheezing	6	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	10	0
Haemoptysis	1	0
Productive cough	1	0
Sputum increased	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Stridor	1	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Granulomatous pneumonitis	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	1	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	3	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Paranasal sinus hypersecretion	1	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Interstitial lung disease	2	0
Lung consolidation	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal swelling	1	0
<i><b>Pneumothorax and pleural effusions NEC</b></i>		
Pleural effusion	1	0
<i><b>Respiratory signs and symptoms NEC</b></i>		
Painful respiration	1	0
<i><b>Respiratory tract disorders NEC</b></i>		
Pulmonary mass	1	0
Respiratory tract congestion	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Dry throat	2	0
Dysphonia	1	0
Oropharyngeal pain	11	0
Rhinorrhoea	2	0
Sinus pain	2	0
Sneezing	1	0
Throat irritation	3	0
Throat tightness	8	0
<b>Respiratory disorders SOC TOTAL</b>	<b>128</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	2	0
<b><i>Angioedemas</i></b>		
Angioedema	3	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	48	0
Hyperhidrosis	55	0
Night sweats	1	0
<b><i>Bullous conditions</i></b>		
Blister	11	0
Erythema multiforme	4	0
Stevens-Johnson syndrome	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	4	0
Scab	10	0
Scar pain	1	0
Skin burning sensation	1	0
Skin discolouration	4	0
Skin disorder	2	0
Skin induration	18	0
Skin lesion	9	0
Skin plaque	1	0
Skin reaction	12	0
Skin swelling	1	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	2	0
Dermatitis allergic	6	0
Eczema	15	0
Skin irritation	4	0
<b><i>Erythemas</i></b>		
Erythema	128	0
<b><i>Exfoliative conditions</i></b>		
Skin exfoliation	4	0
<b><i>Granulomatous and deep cutaneous inflammatory conditions</i></b>		
Granuloma skin	2	0
Granulomatous dermatitis	1	0
<b><i>Hypertrichoses</i></b>		
Hypertrichosis	1	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	4	0
<b><i>Papulosquamous conditions</i></b>		
Pityriasis rosea	3	0
<b><i>Photosensitivity and photodermatitis conditions</i></b>		
Photosensitivity reaction	1	0
<b><i>Pigmentation changes NEC</i></b>		
Pigmentation disorder	1	0
<b><i>Pruritus NEC</i></b>		
Itching scar	1	0
Pruritus	32	0
<b><i>Psoriatic conditions</i></b>		
Psoriasis	2	0
<b><i>Purpura and related conditions</i></b>		

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Petechiae	2	0
Purpura	6	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	63	0
Rash erythematous	20	0
Rash macular	12	0
Rash maculo-papular	10	0
Rash morbilliform	2	0
Rash papular	4	0
Rash pruritic	16	0
Rash vesicular	2	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Skin mass	1	0
<b><i>Skin and subcutaneous tissue ulcerations</i></b>		
Skin ulcer	28	0
<b><i>Skin cysts and polyps</i></b>		
Dermal cyst	1	0
<b><i>Skin dystrophies</i></b>		
Hypertrophic scar	1	0
Keloid scar	14	0
<b><i>Skin haemorrhages</i></b>		
Skin haemorrhage	1	0
<b><i>Skin hyperplasias and hypertrophies</i></b>		
Skin hypertrophy	2	0
<b><i>Skin hypoplasias and atrophies</i></b>		
Skin atrophy	1	0
<b><i>Skin vasculitides</i></b>		
Vasculitic rash	1	0
<b><i>Skin vasomotor conditions</i></b>		
Livedo reticularis	1	0
<b><i>Urticarias</i></b>		
Urticaria	72	0
<b>Skin disorders SOC TOTAL</b>	<b>655</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Social issues NEC</i>		
Contraindication to vaccination	11	0
<b>Social circumstances SOC TOTAL</b>	<b>11</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Testicular and scrotal therapeutic procedures</i>		
Orchidectomy	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><b>Aortic aneurysms and dissections</b></i>		
Aortic aneurysm	1	0
<i><b>Arterial infections and inflammations</b></i>		
Kawasaki's disease	4	0
<i><b>Circulatory collapse and shock</b></i>		
Circulatory collapse	19	0
Peripheral circulatory failure	1	0
Shock	3	0
<i><b>Haemorrhages NEC</b></i>		
Bloody discharge	1	0
Haemorrhage	5	0
<i><b>Lymphangiopathies</b></i>		
Lymphorrhoea	1	0
<i><b>Non-site specific vascular disorders NEC</b></i>		
Hyperaemia	2	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Cyanosis	6	0
Flushing	29	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Peripheral coldness	2	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	139	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	1	0
<i><b>Vascular hypotensive disorders</b></i>		
Hypotension	6	0
Orthostatic hypotension	1	0
<i><b>Vasculitides NEC</b></i>		
Vasculitis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>222</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>5356</b>	<b>12</b>
<b>TOTAL REPORTS</b>	<b>2970</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>12</b>