

Case Series Drug Analysis Print

Name: FOI 22/668 - BCG Vaccine Drug Analysis Print

Report Run Date: 23-May-2022
Data Lock Date: 17-May-2022 18:30:04
Earliest Reaction Date: 12-Nov-1965
MedDRA Version: MedDRA 25.0

FOI 22/668 - BCG Vaccine Drug Analysis Print: FOI 22/668 - BCG Vaccine Drug Analysis Print (DAP). All spontaneous suspected Adverse Drug Reaction (ADR) reports associated with BCG vaccines within the UK up to and including 17/05/2022.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Bleeding tendencies</i>		
Increased tendency to bruise	1	0
<i>Coagulopathies</i>		
Thrombotic microangiopathy	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node calcification	1	0
Lymphadenitis	55	0
Lymphadenopathy	58	0
Lymphadenopathy mediastinal	1	0
<i>Neutropenias</i>		
Neutropenia	1	0
<i>Spleen disorders</i>		
Splenic lesion	1	0
Splenomegaly	2	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	1	0
Thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	123	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	3	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	4	0
Tachycardia	8	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Cardiac disorders SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Immune system abnormalities congenital</i>		
Immunodeficiency congenital	1	0
Congenital disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Hearing losses</i>		
Deafness	2	0
Deafness transitory	1	0
Hypoacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	6	0
Vertigo	25	0
Ear disorders SOC TOTAL	35	0

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

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Reaction Name	Total	Fatal
Eye disorders		
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Uveitis	2	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	1	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	16	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	5	0
Eye disorders SOC TOTAL	81	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	5	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	34	0
Abdominal pain upper	3	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>Nausea and vomiting symptoms</i>		
Nausea	101	0
Retching	2	0
Vomiting	75	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
Gastrointestinal disorders SOC TOTAL	255	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site granuloma	1	0
<i>Application and instillation site reactions</i>		
Application site reaction	3	0
<i>Asthenic conditions</i>		
Asthenia	26	0
Chronic fatigue syndrome	1	0
Fatigue	37	0
Malaise	90	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	43	0
<i>Feelings and sensations NEC</i>		
Chills	15	0
Feeling abnormal	7	0
Feeling cold	10	0
Feeling drunk	1	0
Feeling hot	27	0
Feeling of body temperature change	2	0
Thirst	2	0
<i>Gait disturbances</i>		
Gait disturbance	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Crying	6	0
Illness	14	0
Induration	1	0
Influenza like illness	6	0
Local reaction	63	0
Peripheral swelling	20	0
Secretion discharge	2	0
Swelling	37	0
Swelling face	15	0
<i>Healing abnormal NEC</i>		
Impaired healing	13	0
<i>Inflammations</i>		
Granuloma	6	0
Inflammation	16	0
<i>Injection site reactions</i>		
Injection site abscess sterile	2	0
Injection site atrophy	1	0
Injection site bruising	1	0
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

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
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	37	0
Injection site pruritus	1	0
Injection site rash	7	0
Injection site reaction	231	0
Injection site scab	2	0
Injection site scar	9	0
Injection site swelling	30	0
Injection site ulcer	46	0
Injection site urticaria	3	0
Injection site warmth	3	0
Mass conditions NEC		
Mass	6	0
Mucosal findings abnormal		
Mucosal inflammation	1	0
Necrosis NEC		
Necrosis	1	0
Oedema NEC		
Face oedema	10	0
Oedema	2	0
Oedema peripheral	3	0
Pain and discomfort NEC		
Axillary pain	3	0
Chest discomfort	15	0
Chest pain	7	0
Pain	14	0
Suprapubic pain	1	0
Tenderness	3	0
Therapeutic and nontherapeutic responses		
Drug ineffective	33	0
Drug tolerance decreased	1	0
Vaccination failure	1	0
Ulcers NEC		
Ulcer	6	0
Ulcer haemorrhage	1	0
Vaccination site reactions		
Vaccination site cyst	2	0
Vaccination site discharge	10	0
Vaccination site erythema	10	0
Vaccination site haemorrhage	4	0
Vaccination site induration	4	0
Vaccination site inflammation	4	0
Vaccination site laceration	1	0
Vaccination site lymphadenopathy	1	0
Vaccination site mass	9	0
Vaccination site pain	7	0
Vaccination site pruritus	1	0

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General disorders General disorders cont'd		
Vaccination site reaction	5	0
Vaccination site scab	2	0
Vaccination site scar	6	0
Vaccination site swelling	12	0
Vaccination site ulcer	3	0
Vaccination site vesicles	5	0
Vaccination site warmth	1	0
General disorders SOC TOTAL	1259	3

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Hepatic fibrosis and cirrhosis</i>		
Biliary cirrhosis	1	0
Hepatic disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Hypersensitivity	17	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	4	0
Haemophagocytic lymphohistiocytosis	1	0
Immune reconstitution inflammatory syndrome	1	0
Immune system disorder	1	0
Immune system disorders SOC TOTAL	85	0

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Reaction Name	Total	Fatal
Infections		
<i>Adenoviral infections</i>		
Adenovirus infection	1	0
<i>Atypical mycobacterial infections</i>		
Atypical mycobacterial infection	1	0
<i>Bacterial infections NEC</i>		
Acid fast bacilli infection	1	0
Arthritis bacterial	1	0
Bacterial infection	1	0
Cellulitis	1	0
Lymphadenitis bacterial	5	0
<i>Bone and joint infections</i>		
Osteomyelitis	5	0
<i>Caliciviral infections</i>		
Gastroenteritis norovirus	1	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	1	0
<i>Ear infections</i>		
Otitis externa	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
<i>Herpes viral infections</i>		
Herpes zoster	1	0
Varicella	1	0
<i>Infections NEC</i>		
Abscess	214	1
Abscess limb	2	0
Abscess rupture	1	0
Abscess soft tissue	1	0
Infection	7	0
Injection site abscess	553	0
Injection site infection	5	0
Localised infection	3	0
Lymph node abscess	13	0
Purulent discharge	7	0
Vaccination site abscess	27	0
Vaccination site infection	6	1
Wound abscess	1	0
<i>Influenza viral infections</i>		
Influenza	1	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	1	0
<i>Male reproductive tract infections</i>		
Orchitis	1	0
<i>Prion-associated disorders</i>		
Creutzfeldt-Jakob disease	1	1
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	4	0
<i>Skin structures and soft tissue infections</i>		
Blister infected	2	0
Infected skin ulcer	1	0
Injection site pustule	9	0

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Infections		
Infections cont'd		
Pustule	12	0
Rash pustular	1	0
Subcutaneous abscess	12	0
Vaccination site pustule	4	0
<i>Staphylococcal infections</i>		
Furuncle	2	0
Staphylococcal infection	1	0
<i>Tuberculous infections</i>		
Bone tuberculosis	1	0
Cutaneous tuberculosis	1	0
Disseminated Bacillus Calmette-Guerin infection	13	2
Disseminated tuberculosis	2	2
Erythema induratum	19	0
Lupus vulgaris	1	0
Lymph node tuberculosis	5	0
Meningitis tuberculous	2	0
Pulmonary tuberculosis	8	0
Tuberculosis	21	0
Tuberculosis of eye	13	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	5	0
Pharyngitis	2	0
Rhinitis	2	0
<i>Viral infections NEC</i>		
Post viral fatigue syndrome	2	0
Infections SOC TOTAL	1012	7

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Reaction Name	Total	Fatal
Injuries		
<i>Cerebral injuries NEC</i>		
Concussion	1	0
<i>Chemical injuries</i>		
Chemical cystitis	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Foetal exposure during pregnancy	3	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
Product use in unapproved indication	1	0
Product use issue	1	0
Wrong technique in product usage process	5	0
<i>Non-site specific injuries NEC</i>		
Fall	10	0
Wound	1	0
Wound secretion	7	0
<i>Non-site specific procedural complications</i>		
Post procedural discharge	1	0
<i>Off label uses</i>		
Off label use	2	0
<i>Poisoning and toxicity</i>		
Toxicity to various agents	1	0
<i>Product administration errors and issues</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>Product preparation errors and issues</i>		
Product preparation issue	1	0
<i>Site specific injuries NEC</i>		
Head injury	1	0
<i>Skin injuries NEC</i>		
Contusion	2	0
Scar	15	0
Scratch	1	0
Skin abrasion	2	0
Injuries SOC TOTAL	73	0

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Reaction Name	Total	Fatal
Investigations		
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	2	0
<i>ECG investigations</i>		
Electrocardiogram abnormal	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	11	0
Heart rate increased	13	0
Heart rate irregular	1	0
Pulse abnormal	16	0
Pulse absent	2	0
<i>Immunoglobulin analyses</i>		
Immunoglobulins abnormal	1	1
<i>Immunology skin tests NEC</i>		
Skin test positive	5	0
<i>Neurologic diagnostic procedures</i>		
Electroencephalogram abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	1	0
Body temperature decreased	1	0
Body temperature increased	4	0
Respiratory rate decreased	1	0
Respiratory rate increased	3	0
Weight decreased	1	0
Weight increased	2	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	2	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	2	0
Blood pressure increased	1	0
Investigations SOC TOTAL	71	1

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Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	5	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
Metabolic disorders SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	2	0
Arthropathy	1	0
Polyarthritis	1	0
<i>Bone disorders NEC</i>		
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Pain in jaw	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	8	0
Joint stiffness	2	0
Joint swelling	1	0
<i>Muscle pains</i>		
Myalgia	1	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	1	0
Muscle disorder	1	0
Muscle spasms	6	0
Muscle tightness	2	0
Muscle twitching	28	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	17	0
<i>Muscle weakness conditions</i>		
Muscular weakness	3	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	10	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Limb discomfort	2	0
Musculoskeletal chest pain	1	0
Neck pain	4	0
Pain in extremity	22	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	2	0
Muscle & tissue disorders SOC TOTAL	121	0

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Neoplasms		
<i>Fibrosarcomas malignant</i>		
Dermatofibrosarcoma protuberans	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Neoplasm skin	1	0
Neoplasms SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	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	7	0
Loss of consciousness	31	0
Somnolence	34	0
Syncope	201	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	144	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	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
Head discomfort	1	0
Meningism	2	0
Presyncope	15	0
Unresponsive to stimuli	4	0
<i>Neuromuscular disorders NEC</i>		
Hypotonic-hyporesponsive episode	1	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	1	0
<i>Paraesthesias and dysaesthesias</i>		
Hyperaesthesia	1	0
Hypoaesthesia	10	0
Paraesthesia	40	0
<i>Paralysis and paresis (excl cranial nerve)</i>		

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Nervous system disorders		
Nervous system disorders cont'd		
Paraplegia	1	0
Seizures and seizure disorders NEC		
Epilepsy	1	0
Seizure	34	0
Sensory abnormalities NEC		
Dysgeusia	2	0
Neuralgia	1	0
Speech and language abnormalities		
Dysarthria	1	0
Incoherent	1	0
Speech disorder	2	0
Speech disorder developmental	1	0
Tremor (excl congenital)		
Tremor	20	0
Nervous system disorders SOC TOTAL	874	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Normal newborn status</i>		
Normal newborn	1	0
Pregnancy conditions SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
Staring	2	0
<i>Anxiety symptoms</i>		
Agitation	2	0
Anxiety	1	0
Nervousness	3	0
Tension	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	1	0
<i>Confusion and disorientation</i>		
Confusional state	8	0
Disorientation	3	0
<i>Dissociative states</i>		
Dissociation	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	1	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	4	0
Irritability	1	0
<i>Mood alterations with depressive symptoms</i>		
Tearfulness	3	0
<i>Panic attacks and disorders</i>		
Panic attack	3	0
<i>Parasomnias</i>		
Nightmare	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	3	0
<i>Sleep disorders NEC</i>		
Sleep disorder	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	2	0
Psychiatric disorders SOC TOTAL	42	0

Case Series Drug Analysis Print

Name: FOI 22/668 - BCG Vaccine Drug Analysis Print

Report Run Date: 23-May-2022
 Earliest Reaction Date: 12-Nov-1965

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 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Micturition urgency	2	0
Pollakiuria	1	0
Urinary incontinence	9	0
<i>Renal failure and impairment</i>		
Renal failure	1	0
<i>Renal failure complications</i>		
Azotaemia	1	0
<i>Urinary abnormalities</i>		
Haematuria	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal colic	2	0
Renal & urinary disorders SOC TOTAL	17	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Oedema genital	1	0
Reproductive & breast disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	3	0
Dyspnoea	31	0
Hyperventilation	10	0
Hypopnoea	2	0
Respiration abnormal	1	0
Respiratory arrest	1	0
Respiratory distress	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	8	0
Bronchospasm	4	0
Wheezing	6	0
<i>Coughing and associated symptoms</i>		
Cough	9	0
Haemoptysis	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonitis	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Paranasal sinus hypersecretion	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
<i>Respiratory signs and symptoms NEC</i>		
Painful respiration	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory tract congestion	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Dry throat	2	0
Dysphonia	1	0
Oropharyngeal pain	12	0
Rhinorrhoea	2	0
Sinus pain	1	0
Sneezing	1	0
Throat irritation	3	0
Throat tightness	7	0
Respiratory disorders SOC TOTAL	114	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	2	0
<i>Angioedemas</i>		
Angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	48	0
Hyperhidrosis	50	0
<i>Bullous conditions</i>		
Blister	11	0
Erythema multiforme	4	0
Stevens-Johnson syndrome	1	0
<i>Dermal and epidermal conditions NEC</i>		
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	11	0
Skin swelling	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	6	0
Eczema	15	0
Skin irritation	3	0
<i>Erythemas</i>		
Erythema	125	0
<i>Exfoliative conditions</i>		
Skin exfoliation	4	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Granuloma skin	2	0
Granulomatous dermatitis	1	0
<i>Hypertrichoses</i>		
Hypertrichosis	1	0
<i>Panniculitides</i>		
Erythema nodosum	4	0
<i>Papulosquamous conditions</i>		
Pityriasis rosea	3	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	1	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pruritus NEC</i>		
Itching scar	1	0
Pruritus	27	0
<i>Psoriatic conditions</i>		
Psoriasis	2	0
<i>Purpura and related conditions</i>		
Petechiae	2	0
Purpura	6	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	59	0
Rash erythematous	19	0
Rash macular	11	0
Rash maculo-papular	10	0
Rash morbilliform	2	0
Rash papular	4	0
Rash pruritic	15	0
Rash vesicular	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin ulcer	29	0
<i>Skin cysts and polyps</i>		
Dermal cyst	1	0
<i>Skin dystrophies</i>		
Hypertrophic scar	1	0
Keloid scar	14	0
<i>Skin haemorrhages</i>		
Skin haemorrhage	1	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	2	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	1	0
<i>Skin vasculitides</i>		
Vasculitic rash	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	1	0
<i>Urticarias</i>		
Urticaria	71	0
Skin disorders SOC TOTAL	630	0

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

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Arterial infections and inflammations</i>		
Kawasaki's disease	4	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	19	0
Peripheral circulatory failure	1	0
Shock	3	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haemorrhage	4	0
<i>Lymphangiopathies</i>		
Lymphorrhoea	1	0
<i>Non-site specific vascular disorders NEC</i>		
Hyperaemia	2	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	6	0
Flushing	29	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	139	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	2	0
<i>Vascular hypotensive disorders</i>		
Hypotension	6	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	220	0
TOTAL REACTIONS FOR DRUG	5059	11
TOTAL REPORTS	2859	
TOTAL FATAL OUTCOME REPORTS		11