

Case Series Drug Analysis Print
Name: FOI 21/1248 BCG Vaccine

Report Run Date: 14-Dec-2021
Data Lock Date: 13-Dec-2021 18:30:04
Earliest Reaction Date: 13-Nov-1991
MedDRA Version: MedDRA 24.1
FOI 21/1248 BCG Vaccine: All spontaneous UK Adverse Drug Reports (ADR) associated with the BCG vaccine between 1997 and 2003. Data ran 14.12.21

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Reaction Name	Total	Fatal
Blood disorders		
<i>Bleeding tendencies</i>		
Increased tendency to bruise	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenitis	3	0
Lymphadenopathy	6	0
<i>Spleen disorders</i>		
Splenomegaly	1	0
Blood disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	2	0
Tachycardia	3	0
Cardiac disorders SOC TOTAL	6	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	1	0
Vertigo	2	0
Ear disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	2	0
<i>Ocular disorders NEC</i>		
Eye disorder	4	0
Eye pain	2	0
Eye swelling	5	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	10	0
<i>Pupil disorders</i>		
Mydriasis	3	0
<i>Visual disorders NEC</i>		
Photopsia	1	0
Vision blurred	6	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	1	0
Eye disorders SOC TOTAL	35	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	5	0
Abdominal pain upper	3	0
Abdominal rigidity	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Dysphagia	2	0
<i>Nausea and vomiting symptoms</i>		
Nausea	41	0
Retching	2	0
Vomiting	26	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	2	0
Salivary hypersecretion	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	1	0
Oral pain	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	5	0
<i>Tongue disorders</i>		
Tongue disorder	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	2	0
Gastrointestinal disorders SOC TOTAL	95	0

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	4	0
Chronic fatigue syndrome	1	0
Fatigue	6	0
Malaise	44	0
<i>Death and sudden death</i>		
Sudden death	1	1
<i>Febrile disorders</i>		
Pyrexia	9	0
<i>Feelings and sensations NEC</i>		
Chills	3	0
Feeling abnormal	4	0
Feeling drunk	1	0
Feeling hot	15	0
Feeling of body temperature change	2	0
Thirst	1	0
<i>Gait disturbances</i>		
Gait disturbance	2	0
<i>General signs and symptoms NEC</i>		
Crying	2	0
Illness	3	0
Influenza like illness	3	0
Local reaction	24	0
Peripheral swelling	9	0
Swelling	13	0
Swelling face	3	0
<i>Healing abnormal NEC</i>		
Impaired healing	7	0
<i>Inflammations</i>		
Inflammation	7	0
<i>Injection site reactions</i>		
Injection site abscess sterile	1	0
Injection site granuloma	1	0
Injection site haemorrhage	4	0
Injection site induration	1	0
Injection site inflammation	18	0
Injection site mass	2	0
Injection site necrosis	1	0
Injection site pain	2	0
Injection site rash	2	0
Injection site reaction	100	0
Injection site swelling	1	0
Injection site ulcer	20	0
<i>Mass conditions NEC</i>		
Mass	1	0
<i>Oedema NEC</i>		
Face oedema	2	0
Oedema	1	0
Oedema peripheral	4	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	7	0
Chest pain	3	0
Pain	4	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Tenderness	1	0
General disorders SOC TOTAL	340	1

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	6	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	20	0
Anaphylactic shock	3	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Haemophagocytic lymphohistiocytosis	1	0
Immune system disorders SOC TOTAL	31	0

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Reaction Name	Total	Fatal
Infections		
<i>Atypical mycobacterial infections</i>		
Atypical mycobacterial infection	1	0
<i>Ear infections</i>		
Otitis externa	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	2	0
<i>Herpes viral infections</i>		
Herpes zoster	1	0
<i>Infections NEC</i>		
Abscess	60	0
Infection	3	0
Injection site abscess	54	0
Localised infection	2	0
Purulent discharge	1	0
<i>Skin structures and soft tissue infections</i>		
Pustule	6	0
Subcutaneous abscess	2	0
<i>Staphylococcal infections</i>		
Furuncle	2	0
Staphylococcal infection	1	0
<i>Tuberculous infections</i>		
Disseminated tuberculosis	1	1
Erythema induratum	19	0
Lymph node tuberculosis	1	0
Tuberculosis	6	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	4	0
Pharyngitis	1	0
<i>Viral infections NEC</i>		
Post viral fatigue syndrome	1	0
Infections SOC TOTAL	169	1

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Reaction Name	Total	Fatal
Injuries		
<i>Non-site specific injuries NEC</i>		
Fall	6	0
<i>Product administration errors and issues</i>		
Accidental overdose	1	0
<i>Site specific injuries NEC</i>		
Head injury	1	0
<i>Skin injuries NEC</i>		
Scar	4	0
Skin abrasion	2	0
Injuries SOC TOTAL	14	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	6	0
Heart rate increased	9	0
Heart rate irregular	1	0
Pulse abnormal	5	0
Pulse absent	2	0
<i>Immunology skin tests NEC</i>		
Skin test positive	4	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
Respiratory rate decreased	1	0
Respiratory rate increased	2	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	2	0
Investigations SOC TOTAL	38	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	1	0
<i>Calcium metabolism disorders</i>		
Tetany	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Type 1 diabetes mellitus	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	1	0
Metabolic disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Polyarthritis	1	0
<i>Bone related signs and symptoms</i>		
Pain in jaw	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	5	0
Joint stiffness	1	0
Joint swelling	3	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle disorder	1	0
Muscle spasms	2	0
Muscle tightness	1	0
Muscle twitching	18	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	16	0
<i>Muscle weakness conditions</i>		
Muscular weakness	1	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	1	0
Musculoskeletal stiffness	6	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Neck pain	3	0
Pain in extremity	12	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	3	0
Muscle & tissue disorders SOC TOTAL	77	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	3	0
Dysstasia	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Depressed level of consciousness	1	0
Lethargy	1	0
Loss of consciousness	18	0
Somnolence	3	0
Syncope	108	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	12	0
Movement disorder	1	0
<i>Dystonias</i>		
Opisthotonus	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	1	0
<i>Headaches NEC</i>		
Headache	54	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	2	0
<i>Nervous system disorders NEC</i>		
Cerebral disorder	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	110	0
Presyncope	5	0
Unresponsive to stimuli	3	0
<i>Paraesthesias and dysaesthesias</i>		
Hypoaesthesia	2	0
Paraesthesia	18	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	1	0
Seizure	18	0
<i>Sensory abnormalities NEC</i>		
Ageusia	1	0
Dysgeusia	2	0
<i>Speech and language abnormalities</i>		
Speech disorder	2	0
<i>Tremor (excl congenital)</i>		
Tremor	9	0
Nervous system disorders SOC TOTAL	381	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Staring	2	0
<i>Anxiety symptoms</i>		
Agitation	1	0
Nervousness	1	0
Tension	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	1	0
<i>Confusion and disorientation</i>		
Confusional state	4	0
Disorientation	1	0
<i>Dissociative states</i>		
Dissociation	1	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	1	0
<i>Mood alterations with depressive symptoms</i>		
Tearfulness	2	0
<i>Parasomnias</i>		
Nightmare	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	2	0
Psychiatric disorders SOC TOTAL	18	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Urinary incontinence	7	0
<i>Renal failure complications</i>		
Azotaemia	1	0
<i>Urinary abnormalities</i>		
Haematuria	1	0
<i>Urinary tract lithiasis (excl renal)</i>		
Calculus bladder	1	0
Ureterolithiasis	1	0
Renal & urinary disorders SOC TOTAL	11	0

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

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	13	0
Hyperventilation	8	0
Hypopnoea	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	4	0
Bronchospasm	1	0
Wheezing	1	0
<i>Coughing and associated symptoms</i>		
Cough	3	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	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>Upper respiratory tract signs and symptoms</i>		
Dry throat	1	0
Dysphonia	1	0
Oropharyngeal pain	3	0
Throat irritation	1	0
Throat tightness	3	0
Respiratory disorders SOC TOTAL	46	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	20	0
Hyperhidrosis	18	0
<i>Bullous conditions</i>		
Blister	8	0
Stevens-Johnson syndrome	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	2	0
Scab	4	0
Skin discolouration	2	0
Skin disorder	1	0
Skin induration	15	0
Skin lesion	5	0
Skin reaction	4	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	1	0
Eczema	2	0
<i>Erythemas</i>		
Erythema	18	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Papulosquamous conditions</i>		
Pityriasis rosea	2	0
<i>Pruritus NEC</i>		
Pruritus	9	0
<i>Purpura and related conditions</i>		
Purpura	4	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	24	0
Rash erythematous	5	0
Rash macular	6	0
Rash maculo-papular	2	0
Rash morbilliform	1	0
Rash pruritic	1	0
Rash vesicular	1	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin ulcer	15	0
<i>Skin dystrophies</i>		
Hypertrophic scar	1	0
Keloid scar	6	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	27	0
Skin disorders SOC TOTAL	209	0

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Vascular disorders		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	12	0
Peripheral circulatory failure	1	0
Shock	2	0
<i>Haemorrhages NEC</i>		
Haemorrhage	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	5	0
Flushing	14	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	61	0
Vascular disorders SOC TOTAL	98	0
TOTAL REACTIONS FOR DRUG	1591	2
TOTAL REPORTS	827	
TOTAL FATAL OUTCOME REPORTS		2