

Case Series Drug Analysis Print

Name: FOI 22/405: H-B-VAX, H-B-VAX II Vaccine Analysis Print

Report Run Date: 24-Feb-2022
Data Lock Date: 20-Feb-2022 18:30:04
Earliest Reaction Date: 01-Jul-1982
MedDRA Version: MedDRA 24.1

FOI 22/405: H-B-VAX, H-B-VAX and H-B-VAX II Vaccine Analysis Print. All H-B-VAX II Vaccine UK, spontaneous suspected reports associated with the H-B-VAX, H-B-VAX II brand up to and including the 20th February 2022.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	13	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	7	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	2	0
Tachycardia	2	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
Cardiac disorders SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Congenital hand malformation	1	0
Limb malformation	1	0
<i>Ocular disorders congenital NEC</i>		
Congenital eye disorder	1	0
Congenital disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	3	0
<i>Hearing losses</i>		
Deafness transitory	2	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	1	0
Vertigo	6	0
Ear disorders SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	1	0
<i>Thyroid disorders NEC</i>		
Goitre	1	0
Endocrine disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye pain	2	0
Eye swelling	3	0
Periorbital oedema	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye pruritus	2	0
<i>Ocular sensation disorders</i>		
Photophobia	4	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Vision blurred	4	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness transient	1	0
Visual impairment	4	0
Eye disorders SOC TOTAL	25	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	31	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	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	24	0
Abdominal pain lower	1	0
Abdominal pain upper	3	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Dysphagia	3	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Irritable bowel syndrome	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	76	0
Vomiting	44	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	3	0
<i>Oral soft tissue infections</i>		
Angular cheilitis	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	3	0
Paraesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	4	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	4	0
<i>Tongue signs and symptoms</i>		
Tongue discolouration	1	0
Gastrointestinal disorders SOC TOTAL	205	0

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Reaction Name	Total	Fatal
General disorders		
<i>Application and instillation site reactions</i>		
Application site reaction	1	0
<i>Asthenic conditions</i>		
Asthenia	12	0
Fatigue	31	0
Malaise	71	0
<i>Febrile disorders</i>		
Pyrexia	69	0
<i>Feelings and sensations NEC</i>		
Chills	12	0
Feeling abnormal	3	0
Feeling hot	5	0
Feeling jittery	1	0
Thirst	1	0
<i>Gait disturbances</i>		
Gait disturbance	1	0
<i>General signs and symptoms NEC</i>		
Illness	1	0
Influenza like illness	69	0
Local reaction	7	0
Peripheral swelling	8	0
Swelling	12	0
Swelling face	2	0
<i>Inflammations</i>		
Granuloma	1	0
<i>Injection site reactions</i>		
Injection site inflammation	9	0
Injection site pain	16	0
Injection site reaction	37	0
<i>Interactions</i>		
Drug interaction	2	0
<i>Oedema NEC</i>		
Face oedema	1	0
Gravitational oedema	1	0
Oedema	7	0
Oedema peripheral	3	0
<i>Pain and discomfort NEC</i>		
Axillary pain	1	0
Chest discomfort	7	0
Chest pain	5	0
Discomfort	1	0
Facial pain	1	0
Pain	24	0
Tenderness	2	0
<i>Therapeutic and nontherapeutic responses</i>		
Therapy non-responder	1	0
<i>Vaccination site reactions</i>		
Vaccination site pain	1	0
General disorders SOC TOTAL	426	0

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	6	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	5	0
<i>Hepatobiliary signs and symptoms</i>		
Liver tenderness	1	0
Hepatic disorders SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	5	0
Anaphylactoid reaction	3	0
Immune system disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Folliculitis	1	0
<i>Central nervous system and spinal infections</i>		
Myelitis	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	3	0
<i>Herpes viral infections</i>		
Herpes simplex	1	0
Herpes zoster	2	0
Oral herpes	1	0
<i>Skin structures and soft tissue infections</i>		
Rash pustular	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	1	0
Pharyngitis	6	0
Rhinitis	3	0
Tonsillitis	1	0
Tracheitis	1	0
<i>Viral infections NEC</i>		
Post viral fatigue syndrome	1	0
Viral pericarditis	1	0
Infections SOC TOTAL	25	0

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Reaction Name	Total	Fatal
Injuries		
<i>Skin injuries NEC</i>		
Contusion	5	0
Injuries SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Investigations		
<i>Liver function analyses</i>		
Alanine aminotransferase increased	1	0
Liver function test increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature fluctuation	1	0
Weight decreased	2	0
<i>Urinary tract function analyses NEC</i>		
Urine output increased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	2	0
Investigations SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	6	0
Metabolic disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	5	0
Arthropathy	1	0
Seronegative arthritis	1	0
<i>Bone related signs and symptoms</i>		
Pain in jaw	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	73	0
Joint stiffness	1	0
Joint swelling	2	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	54	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	6	0
<i>Muscle weakness conditions</i>		
Muscular weakness	6	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	7	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	8	0
Limb discomfort	4	0
Neck pain	2	0
Pain in extremity	22	0
<i>Myopathies</i>		
Myopathy	1	0
<i>Osteoarthropathies</i>		
Osteoarthritis	1	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Soft tissue disorders NEC</i>		
Groin pain	1	0
Muscle & tissue disorders SOC TOTAL	200	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Neoplasm skin	1	0
Neoplasms SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Autonomic nervous system disorders</i>		
Autonomic neuropathy	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	1	0
Dysstasia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	19	0
Somnolence	10	0
Syncope	9	0
<i>Dyskinesias and movement disorders NEC</i>		
Extrapyramidal disorder	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Headache	99	0
<i>Memory loss (excl dementia)</i>		
Memory impairment	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	2	0
<i>Migraine headaches</i>		
Migraine	3	0
<i>Multiple sclerosis acute and progressive</i>		
Multiple sclerosis	1	0
<i>Muscle tone abnormal</i>		
Hypertonia	1	0
Hypotonia	1	0
<i>Neurologic visual problems NEC</i>		
Tunnel vision	2	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	49	0
Meningism	1	0
Presyncope	2	0
Unresponsive to stimuli	1	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	1	0
<i>Paraesthesias and dysaesthesias</i>		
Hyperaesthesia	1	0
Hypoaesthesia	6	0
Paraesthesia	19	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	1	0
<i>Peripheral neuropathies NEC</i>		
Neuralgic amyotrophy	1	0
Neuropathy peripheral	4	0
<i>Seizures and seizure disorders NEC</i>		
Seizure	4	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	2	0
Sensory disturbance	1	0
<i>Speech and language abnormalities</i>		

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Dysarthria	1	0
Speech disorder	1	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculopathy	1	0
<i>Tremor (excl congenital)</i>		
Tremor	5	0
Nervous system disorders SOC TOTAL	256	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
Pregnancy conditions SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Affect alterations NEC</i>		
Affect lability	1	0
<i>Anxiety symptoms</i>		
Agitation	1	0
Anxiety	1	0
Nervousness	2	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
Disorientation	1	0
<i>Deliria</i>		
Delirium	1	0
<i>Depressive disorders</i>		
Depression	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	4	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	1	0
Hallucination, auditory	1	0
Psychiatric disorders SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	2	0
Micturition urgency	1	0
Pollakiuria	1	0
<i>Urinary abnormalities</i>		
Haematuria	2	0
Renal & urinary disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Menstruation and uterine bleeding NEC</i>		
Intermenstrual bleeding	1	0
Premenstrual syndrome	1	0
<i>Menstruation with decreased bleeding</i>		
Oligomenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	2	0
Reproductive & breast disorders SOC TOTAL	5	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	6	0
<i>Bronchospasm and obstruction</i>		
Asthma	3	0
Bronchospasm	2	0
Wheezing	2	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	7	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	3	0
<i>Nasal disorders NEC</i>		
Epistaxis	3	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
<i>Respiratory signs and symptoms NEC</i>		
Painful respiration	2	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	1	0
Oropharyngeal pain	11	0
Sneezing	3	0
Throat tightness	4	0
Respiratory disorders SOC TOTAL	49	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Angioedemas</i>		
Angioedema	4	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	15	0
Sweat discolouration	1	0
<i>Bullous conditions</i>		
Blister	3	0
Erythema multiforme	3	0
<i>Dermal and epidermal conditions NEC</i>		
Pain of skin	1	0
Skin burning sensation	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	1	0
Eczema	9	0
Skin irritation	1	0
<i>Erythemas</i>		
Erythema	3	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Hyperkeratoses</i>		
Lichenoid keratosis	1	0
<i>Panniculitides</i>		
Erythema nodosum	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	29	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
Psoriasis	1	0
<i>Purpura and related conditions</i>		
Purpura	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	48	0
Rash erythematous	8	0
Rash macular	6	0
Rash maculo-papular	3	0
Rash papular	1	0
Rash pruritic	10	0
<i>Urticarias</i>		
Urticaria	37	0
Skin disorders SOC TOTAL	193	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	2	0
<i>Haemorrhages NEC</i>		
Haemorrhage	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	8	0
Hot flush	4	0
Peripheral vascular disorder	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	3	0
<i>Vascular hypotensive disorders</i>		
Hypotension	4	0
Vascular disorders SOC TOTAL	25	0
TOTAL REACTIONS FOR DRUG	1516	0
TOTAL REPORTS	579	