

Case Series Drug Analysis Print

Name: FOI 22/405: Hepatitis B Vaccine Analysis Drug

Report Run Date: 24-Feb-2022

Data Lock Date: 22-Feb-2022 18:30:04

Earliest Reaction Date: 24-Apr-1983

MedDRA Version: MedDRA 24.1

FOI 22/405: Hepatitis B Vaccine Analysis Drug: Hepatitis B Vaccine (unbranded) Vaccine Analysis Print. All UK, spontaneous suspected reports associated with the Hepatitis B vaccine (unbranded) up to and including the 20th February 2022.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Coagulopathies</i>		
Disseminated intravascular coagulation	1	0
<i>Eosinophilic disorders</i>		
Eosinophilia	1	0
<i>Leukocytoses NEC</i>		
Leukocytosis	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	1	0
Lymphadenopathy	13	0
<i>Marrow depression and hypoplastic anaemias</i>		
Pancytopenia	2	0
<i>Neutropenias</i>		
Neutropenia	1	0
<i>Sickle cell trait and disorders</i>		
Sickle cell anaemia with crisis	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	1	0
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	24	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	8	0
<i>Noninfectious pericarditis</i>		
Pericarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	2	0
Extrasystoles	1	0
Tachycardia	2	0
Cardiac disorders SOC TOTAL	14	0

Case Series Drug Analysis Print

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 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac malpositions congenital</i>		
Ectopia cordis	1	0
<i>Cerebellar disorders congenital</i>		
Cerebellar hypoplasia	2	0
<i>Dental disorders congenital</i>		
Tooth hypoplasia	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Limb malformation	1	0
Limb reduction defect	1	0
<i>Palate disorders congenital</i>		
Cleft palate	2	0
<i>Viral infections congenital</i>		
Congenital herpes simplex infection	1	1
Congenital disorders SOC TOTAL	9	1

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	1	0
<i>Hearing losses</i>		
Deafness	1	0
Deafness unilateral	1	0
Sudden hearing loss	1	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	6	0
Vertigo	4	0
Ear disorders SOC TOTAL	15	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Thyroid disorders NEC</i>		
Goitre	2	0
Thyroid disorder	1	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
Endocrine disorders SOC TOTAL	4	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Eye disorders		
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Uveitis	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	1	0
<i>Ocular disorders NEC</i>		
Eye pain	3	0
Eye swelling	8	0
Periorbital oedema	2	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	4	0
Gaze palsy	1	0
Ophthalmoplegia	1	0
<i>Ocular sensation disorders</i>		
Foreign body sensation in eyes	1	0
Photophobia	4	0
<i>Visual disorders NEC</i>		
Diplopia	2	0
Photopsia	1	0
Vision blurred	11	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	10	0
Eye disorders SOC TOTAL	50	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal wall conditions NEC</i>		
Abdominal wall disorder	1	0
<i>Colitis (excl infective)</i>		
Crohn's disease	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	26	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	3	0
Eructation	1	0
<i>Faecal abnormalities NEC</i>		
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	2	0
Flatulence	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	25	0
Abdominal pain upper	5	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastric disorder	1	0
Gastrointestinal disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
Dysphagia	10	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Irritable bowel syndrome	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	60	0
Vomiting	46	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
<i>Oral soft tissue disorders NEC</i>		
Oral disorder	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	1	0
Paraesthesia oral	3	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	8	0
Mouth swelling	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland pain	1	0
<i>Salivary gland enlargements</i>		
Salivary gland enlargement	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	1	0
<i>Tongue signs and symptoms</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Swollen tongue	6	0
Gastrointestinal disorders SOC TOTAL	215	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	14	0
Chronic fatigue syndrome	8	0
Fatigue	48	0
Malaise	59	0
<i>Febrile disorders</i>		
Hyperpyrexia	1	0
Pyrexia	58	0
<i>Feelings and sensations NEC</i>		
Chills	14	0
Feeling abnormal	5	0
Feeling cold	3	0
Feeling hot	13	0
Feeling of body temperature change	1	0
Thirst	2	0
<i>Gait disturbances</i>		
Gait inability	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	2	0
General physical health deterioration	1	0
Illness	4	0
Influenza like illness	55	0
Local reaction	5	0
Peripheral swelling	11	0
Screaming	1	0
Swelling	10	0
Swelling face	11	0
<i>Healing abnormal NEC</i>		
Impaired healing	1	0
<i>Inflammations</i>		
Inflammation	2	0
<i>Injection site reactions</i>		
Injection site coldness	1	0
Injection site erythema	3	0
Injection site inflammation	3	0
Injection site joint pain	1	0
Injection site mass	1	0
Injection site movement impairment	1	0
Injection site pain	8	0
Injection site pruritus	1	0
Injection site rash	3	0
Injection site reaction	20	0
Injection site swelling	4	0
Injection site warmth	1	0
<i>Mass conditions NEC</i>		
Mass	1	0
Nodule	2	0
<i>Oedema NEC</i>		
Face oedema	2	0
Generalised oedema	1	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	8	0
Chest pain	7	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Discomfort	1	0
Non-cardiac chest pain	1	0
Pain	23	0
<i>Therapeutic and nontherapeutic responses</i>		
Therapy non-responder	11	0
Vaccination failure	6	0
<i>Vaccination site reactions</i>		
Vaccination site nerve damage	1	0
Vaccination site pain	3	0
Vaccination site swelling	2	0
Vaccination site warmth	3	0
General disorders SOC TOTAL	450	0

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholelithiasis	1	0
<i>Cholestasis and jaundice</i>		
Jaundice	8	0
<i>Gallbladder disorders NEC</i>		
Gallbladder enlargement	1	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	2	0
Hepatocellular injury	1	0
Hepatic disorders SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	11	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	1	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	14	0
Anaphylactic shock	1	0
Anaphylactoid reaction	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	2	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	4	0
<i>Immunodeficiency disorders NEC</i>		
Immunosuppression	1	0
Immune system disorders SOC TOTAL	36	0

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Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	1	0
Gastroenteritis	3	0
<i>Candida infections</i>		
Oral candidiasis	1	0
<i>Ear infections</i>		
Labyrinthitis	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	1	0
<i>Eye and eyelid infections</i>		
Hordeolum	1	0
<i>Hepatitis virus infections</i>		
Chronic hepatitis B	1	0
Hepatitis B	4	0
Hepatitis B reactivation	1	0
<i>Herpes viral infections</i>		
Herpes zoster	4	0
Oral herpes	2	0
<i>Infections NEC</i>		
Infection	1	0
<i>Infectious disorders carrier</i>		
Viral hepatitis carrier	1	0
<i>Infectious transmissions</i>		
Vertical infection transmission	1	0
<i>Influenza viral infections</i>		
Influenza	2	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	2	0
Pneumonia	1	0
<i>Salmonella infections</i>		
Typhoid fever	1	0
<i>Tuberculous infections</i>		
Erythema induratum	2	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	3	0
Pharyngitis	1	0
Rhinitis	1	0
<i>Urinary tract infections</i>		
Cystitis	1	0
Kidney infection	1	0
Urinary tract infection	1	0
<i>Viral infections NEC</i>		
Post viral fatigue syndrome	6	0
Viral infection	1	0
Infections SOC TOTAL	46	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	5	0
Exposure via breast milk	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural nausea	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
Vaccination error	1	0
<i>Product administration errors and issues</i>		
Inappropriate schedule of product administration	3	0
Incomplete course of vaccination	1	0
<i>Skin injuries NEC</i>		
Contusion	2	0
Skin wound	1	0
<i>Underdoses NEC</i>		
Underdose	1	0
Injuries SOC TOTAL	17	0

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Reaction Name	Total	Fatal
Investigations		
<i>Endocrine analyses and imaging NEC</i>		
Hormone level 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	1	0
Heart rate increased	2	0
<i>Immunology analyses NEC</i>		
Antibody test abnormal	1	0
<i>Liver function analyses</i>		
Gamma-glutamyltransferase increased	1	0
Liver function test abnormal	4	0
<i>Physical examination procedures and organ system status</i>		
Body temperature increased	1	0
Grip strength decreased	1	0
Respiratory rate increased	1	0
Weight decreased	1	0
Weight increased	2	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
Blood pressure increased	2	0
<i>Virus identification and serology</i>		
Hepatitis B antibody negative	1	0
<i>White blood cell analyses</i>		
Lymphocyte morphology abnormal	1	0
White blood cell count decreased	1	0
Investigations SOC TOTAL	24	0

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Data Lock Date: 22-Feb-2022 18:30:04
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	6	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	1	0
Type 1 diabetes mellitus	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	1	0
<i>Mixed acid-base disorders</i>		
Acidosis	1	0
Metabolic disorders SOC TOTAL	10	0

Case Series Drug Analysis Print

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Report Run Date: 24-Feb-2022
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Data Lock Date: 22-Feb-2022 18:30:04
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	11	0
Arthropathy	2	0
Polyarthritis	3	0
<i>Bone related signs and symptoms</i>		
Bone pain	3	0
<i>Connective tissue disorders NEC</i>		
Myofascitis	1	0
Polymyalgia rheumatica	2	0
<i>Joint related disorders NEC</i>		
Periarthritis	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	72	0
Joint stiffness	5	0
Joint swelling	7	0
<i>Muscle infections and inflammations</i>		
Polymyositis	1	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	36	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	2	0
Muscle disorder	1	0
Muscle fatigue	1	0
Muscle spasms	6	0
Muscle twitching	2	0
<i>Muscle tone abnormalities</i>		
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	10	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	7	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	15	0
Limb discomfort	1	0
Musculoskeletal chest pain	1	0
Neck pain	4	0
Pain in extremity	26	0
<i>Osteoarthropathies</i>		
Osteoarthritis	2	0
<i>Rheumatoid arthropathies</i>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	3	0
<i>Soft tissue disorders NEC</i>		
Groin pain	2	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	1	0
Muscle & tissue disorders SOC TOTAL	231	0

Case Series Drug Analysis Print

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Data Lock Date: 22-Feb-2022 18:30:04

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Reaction Name	Total	Fatal
Neoplasms		
<i>Myelodysplastic syndromes</i>		
Myelodysplastic syndrome	2	0
<i>Plasma cell myelomas</i>		
Plasmacytoma	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	1	0
Neoplasms SOC TOTAL	4	0

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Data Lock Date: 22-Feb-2022 18:30:04
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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	3	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	1	0
<i>Central nervous system vascular disorders NEC</i>		
Central nervous system vasculitis	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	3	0
Coordination abnormal	2	0
<i>Demyelinating disorders NEC</i>		
Demyelination	2	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	18	0
Loss of consciousness	7	0
Somnolence	6	0
Stupor	1	0
Syncope	16	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	1	0
Hypokinesia	1	0
Motor dysfunction	1	0
Movement disorder	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	1	0
Facial paralysis	2	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Headache	77	0
<i>Memory loss (excl dementia)</i>		
Amnesia	4	0
Memory impairment	3	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	2	0
Disturbance in attention	4	0
<i>Migraine headaches</i>		
Migraine	6	0
Migraine with aura	1	0
<i>Mononeuropathies</i>		
Mononeuropathy multiplex	1	0
<i>Motor neurone diseases</i>		
Lower motor neurone lesion	1	0
<i>Multiple sclerosis acute and progressive</i>		
Multiple sclerosis	3	0
<i>Muscle tone abnormal</i>		
Hypotonia	2	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	2	0
<i>Nervous system disorders NEC</i>		
Central nervous system lesion	1	0
Nervous system disorder	2	0
<i>Neurological signs and symptoms NEC</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Dizziness	58	0
Meningism	1	0
Neurological symptom	1	0
Presyncope	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	1	0
Optic nerve disorders NEC		
Optic neuritis	4	0
Paraesthesias and dysaesthesias		
Hyperaesthesia	1	0
Hypoaesthesia	15	0
Paraesthesia	28	0
Paraesthesia mucosal	1	0
Paralysis and paresis (excl cranial nerve)		
Paralysis	1	0
Paresis	1	0
Peripheral neuropathies NEC		
Neuralgic amyotrophy	1	0
Seizures and seizure disorders NEC		
Epilepsy	2	0
Seizure	4	0
Sensory abnormalities NEC		
Ageusia	1	0
Allodynia	1	0
Dysgeusia	4	0
Electric shock sensation	1	0
Sensory disturbance	2	0
Speech and language abnormalities		
Dysarthria	2	0
Speech disorder	1	0
Spinal cord and nerve root disorders NEC		
Radiculitis brachial	1	0
Tremor (excl congenital)		
Tremor	9	0
Nervous system disorders SOC TOTAL	320	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	4	0
<i>Foetal complications NEC</i>		
Hydrops foetalis	1	0
<i>Labour onset and length abnormalities</i>		
Prolonged labour	1	0
Pregnancy conditions SOC TOTAL	6	0

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Data Lock Date: 22-Feb-2022 18:30:04
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Agitation	2	0
Anxiety	3	0
<i>Confusion and disorientation</i>		
Confusional state	7	0
Disorientation	3	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	1	0
<i>Depressive disorders</i>		
Depression	5	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	2	0
<i>Dyssomnias</i>		
Poor quality sleep	1	0
<i>Emotional and mood disturbances NEC</i>		
Irritability	3	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	2	0
Hallucination, visual	1	0
<i>Mood disorders NEC</i>		
Listless	1	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
Panic reaction	1	0
<i>Psychiatric elimination disorders</i>		
Enuresis	1	0
<i>Psychotic disorder NEC</i>		
Psychotic behaviour	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	3	0
<i>Somatic symptom disorders</i>		
Conversion disorder	1	0
Psychiatric disorders SOC TOTAL	41	0

Case Series Drug Analysis Print

Name: FOI 22/405: Hepatitis B Vaccine Analysis Drug

Report Run Date: 24-Feb-2022

Data Lock Date: 22-Feb-2022 18:30:04

Earliest Reaction Date: 24-Apr-1983

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Micturition urgency	2	0
Urinary retention	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis	1	0
<i>Urinary abnormalities</i>		
Chromaturia	1	0
Haematuria	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	1	0
Renal & urinary disorders SOC TOTAL	8	0

Case Series Drug Analysis Print

Name: FOI 22/405: Hepatitis B Vaccine Analysis Drug

Report Run Date: 24-Feb-2022
 Earliest Reaction Date: 24-Apr-1983

Data Lock Date: 22-Feb-2022 18:30:04
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	2	0
<i>Menstruation and uterine bleeding NEC</i>		
Intermenstrual bleeding	1	0
Menstruation irregular	1	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatism	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	1	0
<i>Sexual function and fertility disorders NEC</i>		
Infertility	1	0
<i>Uterine disorders NEC</i>		
Endometriosis	1	0
Reproductive & breast disorders SOC TOTAL	8	0

Case Series Drug Analysis Print

Name: FOI 22/405: Hepatitis B Vaccine Analysis Drug

Report Run Date: 24-Feb-2022
 Earliest Reaction Date: 24-Apr-1983

Data Lock Date: 22-Feb-2022 18:30:04
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	22	0
Hypopnoea	2	0
Respiratory distress	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	3	0
Bronchospasm	3	0
Wheezing	2	0
<i>Conditions associated with abnormal gas exchange</i>		
Respiratory gas exchange disorder	1	0
<i>Coughing and associated symptoms</i>		
Cough	6	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Laryngeal disorder	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	2	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	9	0
Tonsillar hypertrophy	2	0
<i>Respiratory tract disorders NEC</i>		
Respiratory tract congestion	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Dry throat	1	0
Oropharyngeal pain	11	0
Rhinorrhoea	3	0
Sinus pain	1	0
Sneezing	2	0
Throat irritation	1	0
Throat tightness	2	0
Respiratory disorders SOC TOTAL	77	0

Case Series Drug Analysis Print

Name: FOI 22/405: Hepatitis B Vaccine Analysis Drug

Report Run Date: 24-Feb-2022
 Earliest Reaction Date: 24-Apr-1983

Data Lock Date: 22-Feb-2022 18:30:04
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders		
<i>Alopecias</i>		
Alopecia	3	0
Alopecia areata	1	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	6	0
<i>Apocrine and eccrine gland disorders</i>		
Hyperhidrosis	15	0
Night sweats	1	0
<i>Bullous conditions</i>		
Blister	2	0
Erythema multiforme	4	0
Stevens-Johnson syndrome	1	0
<i>Dermal and epidermal conditions NEC</i>		
Pain of skin	2	0
Papule	1	0
Scab	1	0
Skin discolouration	1	0
Skin disorder	2	0
Skin lesion	1	0
Skin swelling	1	0
Skin warm	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	2	0
Dermatitis allergic	2	0
Dermatitis diaper	1	0
Eczema	3	0
<i>Erythemas</i>		
Erythema	13	0
<i>Hyperkeratoses</i>		
Lichenoid keratosis	1	0
<i>Panniculitides</i>		
Erythema nodosum	5	0
<i>Papulosquamous conditions</i>		
Lichen planus	3	0
<i>Pruritus NEC</i>		
Pruritus	29	0
<i>Psoriatic conditions</i>		
Psoriasis	1	0
<i>Purpura and related conditions</i>		
Purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	58	0
Rash erythematous	7	0
Rash macular	5	0
Rash maculo-papular	8	0
Rash papular	4	0
Rash pruritic	6	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	1	0
<i>Urticarias</i>		
Mechanical urticaria	1	0
Urticaria	35	0

Case Series Drug Analysis Print

Name: FOI 22/405: Hepatitis B Vaccine Analysis Drug

Report Run Date: 24-Feb-2022

Data Lock Date: 22-Feb-2022 18:30:04

Earliest Reaction Date: 24-Apr-1983

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin disorders SOC TOTAL	230	0

Case Series Drug Analysis Print

Name: FOI 22/405: Hepatitis B Vaccine Analysis Drug

Report Run Date: 24-Feb-2022

Data Lock Date: 22-Feb-2022 18:30:04

Earliest Reaction Date: 24-Apr-1983

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Immobile	1	0
Loss of personal independence in daily activities	1	0
Social circumstances SOC TOTAL	2	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Joint therapeutic procedures</i>		
Joint stabilisation	1	0
<i>Obstetric therapeutic procedures</i>		
Caesarean section	3	0
Surgical & medical procedures SOC TOTAL	4	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	2	0
<i>Peripheral embolism and thrombosis</i>		
Superficial vein thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	2	0
Hot flush	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Raynaud's phenomenon	2	0
Vasoconstriction	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	2	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	4	0
Orthostatic hypotension	1	0
<i>Vasculitides NEC</i>		
Polyarteritis nodosa	1	0
Vasculitis	1	0
Vascular disorders SOC TOTAL	21	0
TOTAL REACTIONS FOR DRUG	1882	1
TOTAL REPORTS	642	
TOTAL FATAL OUTCOME REPORTS		1