

Case Series Drug Analysis Print

Name: FOI 22/405: HBPVAXPRO Vaccine Analysis

Report Run Date: 24-Feb-2022
Data Lock Date: 20-Feb-2022 18:30:04
Earliest Reaction Date: 25-Sep-2000
MedDRA Version: MedDRA 24.1

FOI 22/405: HBPVAXPRO Vaccine Analysis Print. All UK,
HBPVAXPRO Vaccine spontaneous suspected reports associated with the
Analysis: HBPVAXPRO brand up to and including the 20h
February 2022.

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	1	0
Lymphadenopathy	8	0
<i>Platelet disorders NEC</i>		
Platelet disorder	1	0
Blood disorders SOC TOTAL	11	0

Case Series Drug Analysis Print

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Report Run Date: 24-Feb-2022

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Earliest Reaction Date: 25-Sep-2000

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	9	0
<i>Coronary artery disorders NEC</i>		
Coronary artery disease	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	1	0
Extrasystoles	1	0
Tachycardia	7	0
Cardiac disorders SOC TOTAL	19	0

Case Series Drug Analysis Print

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Report Run Date: 24-Feb-2022
Earliest Reaction Date: 25-Sep-2000

Data Lock Date: 20-Feb-2022 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	2	0
Ear pain	1	0
<i>Hearing losses</i>		
Hypoacusis	3	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	2	0
Vertigo	7	0
Ear disorders SOC TOTAL	15	0

Case Series Drug Analysis Print

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Report Run Date: 24-Feb-2022
 Earliest Reaction Date: 25-Sep-2000

Data Lock Date: 20-Feb-2022 18:30:04
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Eye disorders		
<i>Conjunctival structural change, deposit and degeneration</i>		
Conjunctival disorder	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iritis	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	2	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	1	0
<i>Ocular disorders NEC</i>		
Eye pain	4	0
Eye swelling	3	0
Periorbital swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Eye irritation	2	0
Ocular hyperaemia	2	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	1	0
<i>Ocular sensation disorders</i>		
Photophobia	2	0
<i>Pupil disorders</i>		
Mydriasis	3	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Vision blurred	6	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
Blindness transient	1	0
Visual impairment	3	0
Eye disorders SOC TOTAL	36	0

Case Series Drug Analysis Print

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Report Run Date: 24-Feb-2022

Data Lock Date: 20-Feb-2022 18:30:04

Earliest Reaction Date: 25-Sep-2000

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	26	0
Diarrhoea haemorrhagic	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	8	0
Abdominal pain lower	1	0
Abdominal pain upper	7	0
Gastrointestinal pain	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1	0
Dysphagia	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	50	0
Retching	1	0
Vomiting	37	0
Vomiting projectile	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	2	0
Salivary hypersecretion	1	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	1	0
Oral disorder	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	4	0
Paraesthesia oral	10	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	3	0
Mouth swelling	2	0
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	1	0
Swollen tongue	7	0
Tongue discolouration	1	0
<i>Tooth missing</i>		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	176	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders		
<i>Adverse effect absent</i>		
No adverse event	2	0
<i>Asthenic conditions</i>		
Asthenia	10	0
Chronic fatigue syndrome	1	0
Fatigue	44	0
Malaise	50	0
<i>Febrile disorders</i>		
Pyrexia	35	0
<i>Feelings and sensations NEC</i>		
Chills	11	0
Feeling abnormal	10	0
Feeling cold	4	0
Feeling hot	19	0
Feeling of body temperature change	1	0
Hunger	1	0
Sensation of foreign body	1	0
Thirst	1	0
<i>Gait disturbances</i>		
Gait disturbance	2	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Influenza like illness	47	0
Local reaction	3	0
Peripheral swelling	22	0
Swelling	11	0
Swelling face	12	0
<i>Inflammations</i>		
Inflammation	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	2	0
Injection site bruising	1	0
Injection site discolouration	2	0
Injection site discomfort	1	0
Injection site dryness	1	0
Injection site erythema	8	0
Injection site hypoaesthesia	1	0
Injection site inflammation	6	0
Injection site irritation	1	0
Injection site mass	2	0
Injection site pain	10	0
Injection site pruritus	1	0
Injection site rash	2	0
Injection site reaction	6	0
Injection site swelling	7	0
Injection site warmth	2	0
<i>Mass conditions NEC</i>		
Mass	2	0
<i>Oedema NEC</i>		
Localised oedema	2	0
Oedema	1	0
Oedema peripheral	1	0

Case Series Drug Analysis Print

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 Earliest Reaction Date: 25-Sep-2000

Data Lock Date: 20-Feb-2022 18:30:04
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Pain and discomfort NEC</i>		
Chest discomfort	15	0
Chest pain	12	0
Discomfort	2	0
Pain	16	0
Tenderness	2	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse event	1	0
Drug ineffective	2	0
Therapeutic product effect delayed	1	0
Therapeutic response decreased	1	0
Therapy non-responder	56	0
Vaccination failure	8	0
<i>Vaccination site reactions</i>		
Vaccination site discomfort	1	0
Vaccination site erythema	1	0
Vaccination site pain	1	0
General disorders SOC TOTAL	468	0

Case Series Drug Analysis Print

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Report Run Date: 24-Feb-2022
Earliest Reaction Date: 25-Sep-2000

Data Lock Date: 20-Feb-2022 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	2	0
Hepatic disorders SOC TOTAL	3	0

Case Series Drug Analysis Print

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Report Run Date: 24-Feb-2022
Earliest Reaction Date: 25-Sep-2000

Data Lock Date: 20-Feb-2022 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	8	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	6	0
<i>Immunodeficiency disorders NEC</i>		
Immunosuppression	1	0
Immune system disorders SOC TOTAL	15	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 25-Sep-2000

Data Lock Date: 20-Feb-2022 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Cellulitis	1	0
Injection site cellulitis	1	0
<i>Candida infections</i>		
Candida infection	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	1	0
<i>Hepatitis virus infections</i>		
Chronic hepatitis B	2	0
<i>Herpes viral infections</i>		
Herpes zoster	1	0
<i>Influenza viral infections</i>		
Influenza	1	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	4	0
<i>Skin structures and soft tissue infections</i>		
Rash pustular	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	1	0
Sinusitis	1	0
Tracheitis	1	0
Upper respiratory tract infection	1	0
<i>Urinary tract infections</i>		
Cystitis	1	0
Urinary tract infection	2	0
<i>Viral infections NEC</i>		
Viral infection	1	0
Infections SOC TOTAL	23	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 25-Sep-2000

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	1	0
Maternal exposure before pregnancy	1	0
Maternal exposure timing unspecified	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
Product use issue	1	0
<i>Non-site specific injuries NEC</i>		
Fall	2	0
Wound secretion	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Product administration errors and issues</i>		
Expired product administered	1	0
Inappropriate schedule of product administration	24	0
Incorrect dose administered	1	0
Incorrect route of product administration	1	0
Product dose omission issue	1	0
<i>Product prescribing errors and issues</i>		
Product prescribing error	1	0
<i>Reproductive system and breast injuries</i>		
Perineal injury	1	0
<i>Skin injuries NEC</i>		
Contusion	3	0
Scar	1	0
<i>Underdoses NEC</i>		
Underdose	2	0
Injuries SOC TOTAL	45	0

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Reaction Name	Total	Fatal
Investigations		
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose increased	1	0
<i>Coagulation and bleeding analyses</i>		
International normalised ratio increased	1	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	1	0
<i>Heart rate and pulse investigations</i>		
Pulse abnormal	2	0
<i>Imaging procedures NEC</i>		
Ultrasound scan abnormal	1	0
<i>Immunology analyses NEC</i>		
Antibody test abnormal	1	0
<i>Liver function analyses</i>		
Blood bilirubin increased	1	0
Hepatic enzyme abnormal	1	0
Liver function test abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature fluctuation	1	0
Body temperature increased	1	0
Weight decreased	5	0
Weight increased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
<i>Toxicology laboratory analyses</i>		
Blood aluminium increased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	2	0
Blood pressure increased	2	0
<i>Virus identification and serology</i>		
Hepatitis B antibody abnormal	45	0
Hepatitis B antibody negative	2	0
Hepatitis B surface antibody negative	1	0
Investigations SOC TOTAL	72	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	4	0
Increased appetite	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	1	0
Type 1 diabetes mellitus	1	0
<i>Hyperlipidaemias NEC</i>		
Hyperlipidaemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	9	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthropathy	1	0
SLE arthritis	1	0
<i>Bone disorders NEC</i>		
Jaw disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	3	0
Pain in jaw	3	0
<i>Connective tissue disorders NEC</i>		
Myofascitis	1	0
Polymyalgia rheumatica	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	42	0
Joint stiffness	4	0
Joint swelling	11	0
<i>Muscle pains</i>		
Myalgia	36	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	2	0
Muscle swelling	1	0
Muscle tightness	1	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	2	0
Trismus	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	5	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Extremity contracture	1	0
Musculoskeletal stiffness	9	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	4	0
Limb discomfort	3	0
Musculoskeletal pain	1	0
Neck pain	8	0
Pain in extremity	40	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
<i>Soft tissue disorders NEC</i>		
Groin pain	1	0
Muscle & tissue disorders SOC TOTAL	185	0

Case Series Drug Analysis Print

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Data Lock Date: 20-Feb-2022 18:30:04

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Absence seizures</i>		
Petit mal epilepsy	2	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	2	0
Coordination abnormal	1	0
<i>Cortical dysfunction NEC</i>		
Dysgraphia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	17	0
Loss of consciousness	4	0
Somnolence	9	0
Syncope	12	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	2	0
Dyskinesia	2	0
Hypokinesia	1	0
Movement disorder	2	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	2	0
Facial paralysis	2	0
<i>Headaches NEC</i>		
Headache	69	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
Memory impairment	3	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	3	0
Mental impairment	1	0
<i>Migraine headaches</i>		
Migraine	2	0
Ophthalmic migraine	1	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	1	0
Nerve compression	1	0
<i>Motor neurone diseases</i>		
Motor neurone disease	1	0
<i>Multiple sclerosis acute and progressive</i>		
Multiple sclerosis	1	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	1	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	2	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	55	0
Head discomfort	2	0
Neurological symptom	1	0
Presyncope	1	0
Unresponsive to stimuli	1	0

Case Series Drug Analysis Print

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Report Run Date: 24-Feb-2022
 Earliest Reaction Date: 25-Sep-2000

Data Lock Date: 20-Feb-2022 18:30:04
 MedDRA Version: MedDRA 24.1

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Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	4	0
Hypoaesthesia	16	0
Paraesthesia	28	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	1	0
Paralysis	1	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	1	0
<i>Seizures and seizure disorders NEC</i>		
Seizure	5	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	3	0
Sensory disturbance	1	0
Sensory loss	4	0
Taste disorder	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	5	0
Speech disorder	5	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	1	0
<i>Tremor (excl congenital)</i>		
Tremor	8	0
Nervous system disorders SOC TOTAL	293	0

Case Series Drug Analysis Print

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Report Run Date: 24-Feb-2022
Earliest Reaction Date: 25-Sep-2000

Data Lock Date: 20-Feb-2022 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	2	0
<i>Labour onset and length abnormalities</i>		
Prolonged labour	1	0
<i>Maternal complications of pregnancy NEC</i>		
Ectopic pregnancy	1	0
<i>Normal newborn status</i>		
Normal newborn	1	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	1	0
Pregnancy conditions SOC TOTAL	6	0

Case Series Drug Analysis Print

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Report Run Date: 24-Feb-2022
Earliest Reaction Date: 25-Sep-2000

Data Lock Date: 20-Feb-2022 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<i>Product supply and availability issues</i>		
Product availability issue	1	0
null SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: FOI 22/405: HBPVAXPRO Vaccine Analysis

Report Run Date: 24-Feb-2022
 Earliest Reaction Date: 25-Sep-2000

Data Lock Date: 20-Feb-2022 18:30:04
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Agitation	1	0
Anxiety	4	0
Nervousness	1	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
Disorientation	2	0
<i>Deliria</i>		
Delirium	1	0
<i>Depressive disorders</i>		
Depression	2	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	2	0
<i>Emotional and mood disturbances NEC</i>		
Irritability	2	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	2	0
<i>Learning disorders</i>		
Reading disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
<i>Panic attacks and disorders</i>		
Panic attack	2	0
<i>Sexual desire disorders</i>		
Loss of libido	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	2	0
Psychiatric disorders SOC TOTAL	26	0

Case Series Drug Analysis Print

Name: FOI 22/405: HBPVAXPRO Vaccine Analysis

Report Run Date: 24-Feb-2022
 Earliest Reaction Date: 25-Sep-2000

Data Lock Date: 20-Feb-2022 18:30:04
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Pollakiuria	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	1	0
<i>Urinary abnormalities</i>		
Ketonuria	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	1	0
Renal & urinary disorders SOC TOTAL	5	0

Case Series Drug Analysis Print

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Data Lock Date: 20-Feb-2022 18:30:04

Earliest Reaction Date: 25-Sep-2000

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Menstruation and uterine bleeding NEC</i>		
Premenstrual syndrome	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1	0
Reproductive & breast disorders SOC TOTAL	2	0

Case Series Drug Analysis Print

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Data Lock Date: 20-Feb-2022 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	24	0
Hypopnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	3	0
Bronchospasm	1	0
Wheezing	2	0
<i>Coughing and associated symptoms</i>		
Cough	6	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Laryngospasm	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Rales	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal hypoaesthesia	1	0
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	4	0
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	2	0
Choking sensation	1	0
Dry throat	1	0
Dysphonia	4	0
Oropharyngeal blistering	1	0
Oropharyngeal pain	12	0
Rhinorrhoea	1	0
Sneezing	2	0
Throat irritation	4	0
Throat tightness	10	0
Respiratory disorders SOC TOTAL	86	0

Case Series Drug Analysis Print

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 Earliest Reaction Date: 25-Sep-2000

Data Lock Date: 20-Feb-2022 18:30:04
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	1	0
Dermatitis acneiform	1	0
<i>Alopecias</i>		
Alopecia	4	0
Alopecia areata	2	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	2	0
Hyperhidrosis	8	0
Night sweats	1	0
<i>Bullous conditions</i>		
Blister	4	0
Pemphigoid	1	0
<i>Dermal and epidermal conditions NEC</i>		
Pain of skin	1	0
Papule	2	0
Skin disorder	1	0
Skin warm	2	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	1	0
Eczema	2	0
Skin irritation	1	0
<i>Erythemas</i>		
Erythema	13	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	21	0
<i>Purpura and related conditions</i>		
Petechiae	1	0
Purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	51	0
Rash erythematous	2	0
Rash macular	4	0
Rash papular	4	0
Rash pruritic	5	0
<i>Skin and subcutaneous conditions NEC</i>		
Eosinophilic cellulitis	1	0
<i>Urticarias</i>		
Urticaria	15	0
Skin disorders SOC TOTAL	155	0

Case Series Drug Analysis Print

Name: FOI 22/405: HBPVAXPRO Vaccine Analysis

Report Run Date: 24-Feb-2022
Earliest Reaction Date: 25-Sep-2000

Data Lock Date: 20-Feb-2022 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	1	0
Social circumstances SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: FOI 22/405: HBPVAXPRO Vaccine Analysis

Report Run Date: 24-Feb-2022

Data Lock Date: 20-Feb-2022 18:30:04

Earliest Reaction Date: 25-Sep-2000

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Nervous system therapeutic procedures NEC</i>		
Central nervous system stimulation	1	0
<i>Obstetric therapeutic procedures</i>		
Caesarean section	1	0
<i>Renal therapeutic procedures</i>		
Dialysis	1	0
Surgical & medical procedures SOC TOTAL	3	0

Case Series Drug Analysis Print

Name: FOI 22/405: HBPVAXPRO Vaccine Analysis

Report Run Date: 24-Feb-2022
 Earliest Reaction Date: 25-Sep-2000

Data Lock Date: 20-Feb-2022 18:30:04
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Haemorrhages NEC</i>		
Haemorrhage	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	2	0
Flushing	5	0
Hot flush	7	0
<i>Site specific vascular disorders NEC</i>		
Pallor	4	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	2	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	23	0
TOTAL REACTIONS FOR DRUG	1678	0
TOTAL REPORTS	492	