

Case Series Drug Analysis Print
Name: Rabipur Vaccine Analysis Print

Report Run Date: 03-May-2022
Data Lock Date: 02-May-2022 18:30:04
Earliest Reaction Date: 21-Jun-2005
MedDRA Version: MedDRA 25.0
Rabipur Vaccine Analysis Print: All UK spontaneous ADR Reports for Rabipur vaccine between 01/01/2008 and 01/04/2022.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	1	0
Lymphadenopathy	5	0
Blood disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	6	0
<i>Rate and rhythm disorders NEC</i>		
Tachycardia	2	0
Cardiac disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	2	0
<i>Hearing losses</i>		
Deafness	1	0
<i>Inner ear signs and symptoms</i>		
Vertigo	2	0
Ear disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Lid, lash and lacrimal structural disorders</i>		
Lagophthalmos	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye pain	2	0
Eye swelling	6	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye pruritus	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	1	0
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Exophthalmos	1	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Vision blurred	4	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	3	0
Eye disorders SOC TOTAL	22	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	11	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	4	0
Abdominal pain upper	1	0
Gastrointestinal pain	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Dysphagia	3	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
Irritable bowel syndrome	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival swelling	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	18	0
Vomiting	13	0
Vomiting projectile	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	3	0
<i>Oral soft tissue disorders NEC</i>		
Oral lichen planus	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral pain	1	0
Paraesthesia oral	4	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	4	0
Gastrointestinal disorders SOC TOTAL	72	0

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	9	0
Fatigue	12	0
Malaise	21	0
<i>Febrile disorders</i>		
Pyrexia	32	0
<i>Feelings and sensations NEC</i>		
Chills	9	0
Feeling abnormal	5	0
Feeling cold	2	0
Feeling drunk	1	0
Feeling hot	4	0
Feeling of body temperature change	4	0
Temperature intolerance	1	0
<i>Gait disturbances</i>		
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
General physical health deterioration	1	0
Illness	2	0
Induration	1	0
Influenza like illness	14	0
Peripheral swelling	6	0
Swelling	7	0
Swelling face	10	0
<i>Inflammations</i>		
Systemic inflammatory response syndrome	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	1	0
Injection site erythema	2	0
Injection site haemorrhage	1	0
Injection site inflammation	1	0
Injection site mass	1	0
Injection site pain	4	0
Injection site paraesthesia	1	0
Injection site reaction	2	0
Injection site swelling	2	0
Injection site vesicles	1	0
Injection site warmth	1	0
<i>Oedema NEC</i>		
Localised oedema	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	1	0
Chest discomfort	2	0
Chest pain	4	0
Discomfort	1	0
Facial pain	2	0
Pain	13	0
Tenderness	1	0
<i>Vaccination site reactions</i>		
Vaccination site discomfort	1	0
Vaccination site movement impairment	1	0
Vaccination site pain	2	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site reaction	1	0
Vaccination site swelling	1	0
General disorders SOC TOTAL	192	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>		
Allergic oedema	1	0
Hypersensitivity	11	0
Type III immune complex mediated reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	9	0
<i>Immune and associated conditions NEC</i>		
Decreased immune responsiveness	1	0
Immune system disorders SOC TOTAL	25	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Gastroenteritis	1	0
<i>Campylobacter infections</i>		
Campylobacter gastroenteritis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
Meningitis	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	1	0
<i>Skin structures and soft tissue infections</i>		
Pustule	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	1	0
<i>Viral infections NEC</i>		
Meningitis viral	1	0
Infections SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Drug exposure before pregnancy	1	0
Foetal exposure during pregnancy	1	0
<i>Eye injuries NEC</i>		
Eye contusion	1	0
<i>Non-site specific injuries NEC</i>		
Fall	2	0
Sports injury	1	0
<i>Product administration errors and issues</i>		
Inappropriate schedule of product administration	5	0
Incomplete course of vaccination	6	0
Wrong product administered	1	0
Injuries SOC TOTAL	18	0

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Reaction Name	Total	Fatal
Investigations		
<i>Auditory and vestibular diagnostic procedures</i>		
Acoustic stimulation tests abnormal	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate increased	3	0
Heart rate irregular	1	0
<i>Neurologic diagnostic procedures</i>		
Visual evoked potentials abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature increased	2	0
<i>Toxicology laboratory analyses</i>		
Blood ethanol increased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
Investigations SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	2	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
<i>Joint related disorders NEC</i>		
Periarthritis	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	15	0
Joint noise	1	0
Joint stiffness	2	0
Joint swelling	3	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	11	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	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	5	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	1	0
Posture abnormal	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	7	0
Limb discomfort	5	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	1	0
Neck pain	1	0
Pain in extremity	5	0
<i>Soft tissue disorders NEC</i>		
Groin pain	1	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	1	0
Muscle & tissue disorders SOC TOTAL	70	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Coordination and balance disturbances</i>		
Balance disorder	2	0
Nystagmus	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	4	0
Loss of consciousness	4	0
Somnolence	2	0
Syncope	7	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	1	0
Dyskinesia	2	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	2	0
Facial paralysis	2	0
Facial paresis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Headache	39	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
Memory impairment	2	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	2	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	1	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	29	0
Head discomfort	1	0
Presyncope	5	0
Unresponsive to stimuli	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	1	0
Formication	1	0
Hyperaesthesia	2	0
Hypoaesthesia	12	0
Paraesthesia	23	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Monoplegia	1	0
<i>Seizures and seizure disorders NEC</i>		
Febrile convulsion	1	0
Seizure	7	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	1	0
Electric shock sensation	1	0
Neuralgia	2	0
Sensory disturbance	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Speech disorder	1	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	1	0
<i>Tremor (excl congenital)</i>		
Tremor	3	0
Nervous system disorders SOC TOTAL	171	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>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
<i>Affect alterations NEC</i>		
Inappropriate affect	1	0
<i>Anxiety symptoms</i>		
Anxiety	4	0
Stress	1	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
<i>Deliria</i>		
Delirium	1	0
<i>Emotional and mood disturbances NEC</i>		
Irritability	1	0
Mood altered	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	2	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
<i>Mood disorders NEC</i>		
Listless	1	0
<i>Parasomnias</i>		
Abnormal sleep-related event	1	0
Nightmare	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	1	0
<i>Thinking disturbances</i>		
Intrusive thoughts	1	0
Psychiatric disorders SOC TOTAL	21	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Micturition urgency	1	0
Urinary incontinence	2	0
<i>Myoneurogenic bladder disorders</i>		
Atonic urinary bladder	1	0
Renal & urinary disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast infections and inflammations</i>		
Nipple inflammation	1	0
<i>Breast signs and symptoms</i>		
Nipple pain	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	1	0
Menstrual disorder	1	0
<i>Menstruation with decreased bleeding</i>		
Menstruation delayed	1	0
Reproductive & breast disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	16	0
Dyspnoea exertional	1	0
Grunting	2	0
Respiration abnormal	1	0
<i>Bronchospasm and obstruction</i>		
Bronchospasm	2	0
Wheezing	1	0
<i>Coughing and associated symptoms</i>		
Cough	4	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	3	0
Throat irritation	1	0
Throat tightness	5	0
Respiratory disorders SOC TOTAL	41	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Angioedemas</i>		
Angioedema	2	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	4	0
Hyperhidrosis	5	0
Night sweats	2	0
<i>Dermal and epidermal conditions NEC</i>		
Scar pain	1	0
Skin burning sensation	1	0
Skin discolouration	2	0
Skin reaction	2	0
Skin warm	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	2	0
<i>Erythemas</i>		
Erythema	12	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
<i>Pruritus NEC</i>		
Pruritus	10	0
<i>Purpura and related conditions</i>		
Petechiae	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	24	0
Rash erythematous	5	0
Rash macular	2	0
Rash papular	1	0
Rash pruritic	9	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	1	0
<i>Urticarias</i>		
Urticaria	18	0
Skin disorders SOC TOTAL	108	0

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

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Therapeutic procedures NEC</i>		
Interchange of vaccine products	1	0
Surgical & medical procedures SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	2	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	2	0
Flushing	1	0
Hot flush	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
Vascular disorders SOC TOTAL	11	0
TOTAL REACTIONS FOR DRUG	803	0
TOTAL REPORTS	228	