

Case Series Drug Analysis Print

Name: RABIES VACCINE CHIRON (Rabipur) FOI 21/1063

Report Run Date: 07-Oct-2021
Data Lock Date: 30-Sep-2021 18:30:04
Earliest Reaction Date: 22-May-2001
MedDRA Version: MedDRA 24.0

RABIES VACCINE
CHIRON (Rabipur)
FOI 21/1063:

All UK spontaneous reports received up until 30-Sep-2021 for the RABIES VACCINE CHIRON (Rabipur) Vaccine analysis print. A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	1	0
Lymphadenopathy	11	0
<i>Neutropenias</i>		
Neutropenia	1	0
Blood disorders SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	8	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	1	0
Tachycardia	2	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Atrial flutter	1	0
Supraventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear disorder	1	0
Ear pain	2	0
<i>Hearing losses</i>		
Deafness	1	0
<i>Inner ear signs and symptoms</i>		
Vertigo	4	0
Ear disorders SOC TOTAL	8	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	5	0
Eye swelling	7	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>Retinal structural change, deposit and degeneration</i>		
Retinal detachment	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	5	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	3	0
Eye disorders SOC TOTAL	28	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	12	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 pain	1	0
Gingival swelling	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	31	0
Vomiting	20	0
Vomiting projectile	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	4	0
<i>Oral soft tissue disorders NEC</i>		
Oral lichen planus	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral pain	2	0
Paraesthesia oral	4	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	6	0
Mouth swelling	1	0
Gastrointestinal disorders SOC TOTAL	99	0

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General disorders		
<i>Asthenic conditions</i>		
Asthenia	10	0
Fatigue	16	0
Malaise	37	0
<i>Febrile disorders</i>		
Pyrexia	50	0
<i>Feelings and sensations NEC</i>		
Chills	15	0
Feeling abnormal	6	0
Feeling cold	2	0
Feeling drunk	1	0
Feeling hot	8	0
Feeling of body temperature change	7	0
Temperature intolerance	1	0
Thirst	1	0
<i>Gait disturbances</i>		
Gait disturbance	3	0
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	21	0
Peripheral swelling	8	0
Swelling	10	0
Swelling face	10	0
<i>Inflammations</i>		
Inflammation	1	0
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	2	0
Injection site mass	2	0
Injection site pain	5	0
Injection site paraesthesia	1	0
Injection site reaction	5	0
Injection site swelling	3	0
Injection site vesicles	1	0
Injection site warmth	1	0
<i>Oedema NEC</i>		
Face oedema	1	0
Localised oedema	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	2	0
Chest discomfort	3	0
Chest pain	7	0
Discomfort	1	0
Facial pain	2	0
Pain	20	0
Tenderness	2	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Vaccination site reactions</i>		
Vaccination site discomfort	1	0
Vaccination site movement impairment	1	0
Vaccination site pain	2	0
Vaccination site reaction	1	0
Vaccination site swelling	1	0
General disorders SOC TOTAL	283	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	12	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	12	0
Anaphylactic shock	1	0
Anaphylactoid reaction	1	0
<i>Immune and associated conditions NEC</i>		
Decreased immune responsiveness	1	0
Immune system disorders SOC TOTAL	31	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	1	0
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>Muscle and soft tissue infections</i>		
Soft tissue infection	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Pustule	1	0
<i>Streptococcal infections</i>		
Scarlet fever	1	0
Streptococcal infection	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	2	0
<i>Urinary tract infections</i>		
Urinary tract infection	1	0
<i>Viral infections NEC</i>		
Meningitis viral	1	0
Infections SOC TOTAL	15	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	4	0
Incomplete course of vaccination	6	0
Product administration error	1	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	21	0
Joint noise	1	0
Joint stiffness	3	0
Joint swelling	4	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	20	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	2	0
Muscle swelling	1	0
Muscle tightness	1	0
Muscle twitching	3	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	7	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	3	0
Posture abnormal	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	9	0
Limb discomfort	7	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	1	0
Neck pain	2	0
Pain in extremity	8	0
<i>Soft tissue disorders NEC</i>		
Groin pain	1	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	1	0
Muscle & tissue disorders SOC TOTAL	102	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Hyporeflexia	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	2	0
<i>Coordination and balance disturbances</i>		
Balance disorder	4	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	7	0
Loss of consciousness	4	0
Somnolence	3	0
Syncope	11	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	1	0
Dyskinesia	2	0
Hypokinesia	1	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	55	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>Muscle tone abnormal</i>		
Hypotonia	1	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	41	0
Head discomfort	1	0
Presyncope	6	0
Unresponsive to stimuli	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	1	0
Formication	1	0
Hyperaesthesia	2	0
Hypoaesthesia	14	0
Paraesthesia	30	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	1	0
Monoplegia	2	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<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	3	0
Sensory disturbance	3	0
Sensory loss	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	1	0
Speech disorder	1	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	1	0
<i>Tremor (excl congenital)</i>		
Tremor	6	0
Nervous system disorders SOC TOTAL	234	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	2	0
Pregnancy conditions SOC TOTAL	2	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
Disorientation	2	0
<i>Deliria</i>		
Delirium	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	1	0
<i>Eating disorders NEC</i>		
Eating disorder	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>Increased physical activity levels</i>		
Restlessness	1	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	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	2	0
<i>Thinking disturbances</i>		
Intrusive thoughts	1	0
Psychiatric disorders SOC TOTAL	28	0

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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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Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	18	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	2	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	44	0

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Skin disorders		
<i>Angioedemas</i>		
Angioedema	2	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	4	0
Hyperhidrosis	7	0
Night sweats	2	0
<i>Bullous conditions</i>		
Blister	1	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	1	0
Dermatitis allergic	2	0
Eczema	1	0
<i>Erythemas</i>		
Erythema	12	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	0
Skin exfoliation	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
<i>Pruritus NEC</i>		
Pruritus	12	0
<i>Purpura and related conditions</i>		
Petechiae	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	33	0
Rash erythematous	5	0
Rash macular	3	0
Rash papular	1	0
Rash pruritic	10	0
Systemic lupus erythematosus rash	1	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	22	0
Skin disorders SOC TOTAL	132	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Loss of personal independence in daily activities	2	0
Social circumstances SOC TOTAL	2	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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Vascular disorders		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	3	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	2	0
Flushing	2	0
Hot flush	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
Poor peripheral circulation	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	5	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
Vascular disorders SOC TOTAL	17	0
TOTAL REACTIONS FOR DRUG	1093	0
TOTAL REPORTS	322	