

Case Series Drug Analysis Print
Name: FOI 21/636 Repevax vaccine

Report Run Date: 25-Jun-2021
Data Lock Date: 24-Jun-2021 18:30:03
Earliest Reaction Date: 30-Sep-2004
MedDRA Version: MedDRA 24.0
FOI 21/636 Repevax vaccine: All UK spontaneous suspected ADR reports associated with Repevax received up to and including 24 June 2021

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	3	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	3	0
Tachycardia	1	0
Cardiac disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Lens disorders congenital</i>		
Cataract congenital	3	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Polydactyly	1	0
Syndactyly	1	0
Congenital disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Vertigo	1	0
Ear disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye pruritus	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	5	0
Strabismus	1	0
<i>Pupil disorders</i>		
Mydriasis	1	0
Pupil fixed	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
Eye disorders SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	10	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	2	0
Abdominal pain upper	4	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Odynophagia	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	13	0
Vomiting	34	0
<i>Oral soft tissue disorders NEC</i>		
Oral disorder	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral discomfort	1	0
Paraesthesia oral	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
<i>Tongue disorders</i>		
Tongue ulceration	1	0
Gastrointestinal disorders SOC TOTAL	73	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site erythema	1	0
Administration site rash	1	0
Administration site swelling	1	0
<i>Application and instillation site reactions</i>		
Application site exfoliation	1	0
Application site swelling	1	0
<i>Asthenic conditions</i>		
Asthenia	1	0
Fatigue	8	0
Malaise	18	0
<i>Febrile disorders</i>		
Pyrexia	64	0
<i>Feelings and sensations NEC</i>		
Chills	3	0
Feeling cold	1	0
Feeling drunk	1	0
Feeling hot	38	0
Thirst	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Crepitations	1	0
Crying	4	0
Discharge	1	0
Illness	2	0
Induration	10	0
Influenza like illness	1	0
Local reaction	98	0
Peripheral swelling	170	0
Screaming	2	0
Swelling	83	0
Swelling face	4	0
<i>Inflammations</i>		
Inflammation	61	0
<i>Injection site reactions</i>		
Injection site bruising	3	0
Injection site dermatitis	1	0
Injection site discolouration	5	0
Injection site discomfort	2	0
Injection site erythema	80	0
Injection site induration	15	0
Injection site inflammation	45	0
Injection site irritation	3	0
Injection site joint warmth	1	0
Injection site mass	9	0
Injection site oedema	1	0
Injection site pain	28	0
Injection site pruritus	11	0
Injection site rash	6	0
Injection site reaction	45	0
Injection site swelling	72	0
Injection site urticaria	1	0
Injection site vesicles	10	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site warmth	20	0
<i>Mucosal findings abnormal</i>		
Mucosal disorder	1	0
<i>Oedema NEC</i>		
Localised oedema	1	0
Oedema	2	0
Oedema peripheral	5	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	1	0
Chest pain	2	0
Discomfort	3	0
Pain	22	0
Tenderness	9	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	2	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	4	0
Vaccination site bruising	2	0
Vaccination site discharge	1	0
Vaccination site discolouration	1	0
Vaccination site discomfort	2	0
Vaccination site erythema	63	0
Vaccination site induration	2	0
Vaccination site inflammation	7	0
Vaccination site irritation	1	0
Vaccination site joint erythema	2	0
Vaccination site joint inflammation	1	0
Vaccination site joint swelling	1	0
Vaccination site mass	6	0
Vaccination site pain	17	0
Vaccination site pruritus	1	0
Vaccination site rash	6	0
Vaccination site reaction	8	0
Vaccination site swelling	52	0
Vaccination site vesicles	3	0
Vaccination site warmth	29	0
General disorders SOC TOTAL	1193	0

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Cholestasis	1	0
Jaundice	1	0
Hepatic disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	17	0
Type IV hypersensitivity reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	6	0
Immune system disorders SOC TOTAL	25	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Administration site cellulitis	5	0
Application site cellulitis	1	0
Cellulitis	52	0
Injection site cellulitis	8	0
Vaccination site cellulitis	14	0
<i>Bordetella infections</i>		
Pertussis	1	0
<i>Corynebacteria infections</i>		
Diphtheria	1	0
<i>Ear infections</i>		
Ear infection	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
<i>Infections NEC</i>		
Infection	4	0
Injection site infection	2	0
Vaccination site infection	3	0
<i>Influenza viral infections</i>		
Influenza	2	0
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	1	0
<i>Muscle and soft tissue infections</i>		
Muscle abscess	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	2	1
<i>Skin structures and soft tissue infections</i>		
Rash pustular	1	0
Skin infection	1	0
<i>Tuberculous infections</i>		
Erythema induratum	4	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	3	0
Rhinitis	1	0
Tonsillitis	2	0
Upper respiratory tract infection	1	0
Infections SOC TOTAL	113	1

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	15	0
Foetal exposure during pregnancy	10	0
Maternal exposure during pregnancy	6	0
<i>Medication errors, product use errors and issues NEC</i>		
Inadequate aseptic technique in use of product	1	0
Medication error	3	0
Wrong technique in product usage process	3	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
<i>Non-site specific procedural complications</i>		
Administration related reaction	1	0
Wound dehiscence	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Product administration errors and issues</i>		
Expired product administered	4	0
Inappropriate schedule of product administration	5	0
Product administered to patient of inappropriate age	1	0
Wrong product administered	6	0
<i>Product storage errors and issues in the product use system</i>		
Product storage error	1	0
<i>Reproductive system and breast injuries</i>		
Perineal injury	2	0
<i>Skin injuries NEC</i>		
Contusion	9	0
Scar	1	0
Skin abrasion	1	0
<i>Underdoses NEC</i>		
Underdose	1	0
Injuries SOC TOTAL	73	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	1	0
<i>Foetal and neonatal diagnostic procedures</i>		
Foetal monitoring abnormal	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	3	0
Heart rate irregular	2	0
Radial pulse abnormal	1	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	1	0
Liver function test abnormal	1	0
<i>Metabolism tests NEC</i>		
Urine ketone body present	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature increased	6	0
Respiratory rate decreased	1	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	1	0
<i>Renal function analyses</i>		
Blood creatinine increased	1	0
<i>Urinalysis NEC</i>		
Protein urine present	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
<i>White blood cell analyses</i>		
White blood cell count increased	1	0
Investigations SOC TOTAL	23	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	10	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus inadequate control	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Dairy intolerance	1	0
Food intolerance	1	0
<i>General nutritional disorders NEC</i>		
Feeding disorder	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia neonatal	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Metabolic acidosis	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	17	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
<i>Joint related disorders NEC</i>		
Hypermobility syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	6	0
Joint effusion	1	0
Joint stiffness	2	0
Joint swelling	1	0
<i>Muscle infections and inflammations</i>		
Myositis	3	0
<i>Muscle pains</i>		
Myalgia	5	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	1	0
Muscle spasms	3	0
Muscle swelling	1	0
Muscle twitching	3	0
<i>Muscle tone abnormalities</i>		
Floppy infant	1	0
Muscle rigidity	3	0
<i>Muscle weakness conditions</i>		
Muscular weakness	3	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	1	0
Musculoskeletal stiffness	4	0
Weight bearing difficulty	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	2	0
Limb discomfort	2	0
Pain in extremity	33	0
<i>Rheumatoid arthropathies</i>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	1	0
Muscle & tissue disorders SOC TOTAL	80	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Absence seizures		
Petit mal epilepsy	1	0
Acute polyneuropathies		
Guillain-Barre syndrome	2	0
Coordination and balance disturbances		
Coordination abnormal	1	0
Hand-eye coordination impaired	1	0
Cortical dysfunction NEC		
Dyspraxia	1	0
Disturbances in consciousness NEC		
Depressed level of consciousness	1	0
Lethargy	2	0
Loss of consciousness	5	0
Somnolence	9	0
Syncope	20	0
Dyskinesias and movement disorders NEC		
Dyskinesia	3	0
Hypokinesia	1	0
Movement disorder	1	0
Psychomotor hyperactivity	1	0
Dystonias		
Opisthotonus	1	0
Encephalitis NEC		
Encephalitis post immunisation	1	0
Facial cranial nerve disorders		
Bell's palsy	1	0
Facial paralysis	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	2	0
Headaches NEC		
Headache	13	0
Tension headache	1	0
Migraine headaches		
Migraine	1	0
Muscle tone abnormal		
Hypotonia	12	0
Myelitis (incl infective)		
Myelitis transverse	1	0
Narcolepsy and hypersomnia		
Hypersomnia	1	0
Neurological signs and symptoms NEC		
Dizziness	10	0
Head discomfort	1	0
Presyncope	3	0
Unresponsive to stimuli	7	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	2	0
Paraesthesias and dysaesthesias		
Hypoaesthesia	1	0
Paraesthesia	2	0
Seizures and seizure disorders NEC		
Epilepsy	1	0
Febrile convulsion	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Myoclonic epilepsy	1	0
Neonatal seizure	1	0
Partial seizures	1	0
Seizure	4	0
Seizure like phenomena	1	0
Sensory abnormalities NEC		
Allodynia	1	0
Sensory disturbance	1	0
Speech and language abnormalities		
Speech disorder	1	0
Structural brain disorders NEC		
Brain injury	1	0
Tremor (excl congenital)		
Tremor	4	0
Nervous system disorders SOC TOTAL	128	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	1	0
<i>Foetal complications NEC</i>		
Foetal distress syndrome	1	0
Foetal hypokinesia	8	0
<i>Foetal position and presentation abnormalities</i>		
Breech presentation	2	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	2	0
Premature labour	2	0
Premature rupture of membranes	1	0
Prolonged labour	5	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	1	0
<i>Placental abnormalities (excl neoplasms)</i>		
Foetal placental thrombosis	1	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	3	0
<i>Stillbirth and foetal death</i>		
Foetal death	3	2
Stillbirth	7	7
<i>Umbilical cord complications</i>		
Umbilical cord thrombosis	1	0
Pregnancy conditions SOC TOTAL	39	9

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	3	0
Staring	3	0
<i>Anxiety symptoms</i>		
Anxiety	2	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	1	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	1	0
Emotional distress	1	0
Irritability	4	0
Mood altered	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	1	0
Hallucination, visual	1	0
<i>Mood disorders NEC</i>		
Apathy	1	0
Listless	2	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive symptom	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	4	0
<i>Sleep disorders NEC</i>		
Sleep disorder	1	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	1	0
Psychiatric disorders SOC TOTAL	31	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Urinary incontinence	3	0
Urinary retention	1	0
<i>Renal disorders NEC</i>		
Renal disorder	1	0
<i>Renal failure and impairment</i>		
Renal impairment	1	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	1	0
<i>Renal structural abnormalities and trauma</i>		
Pyelocaliectasis	1	0
Renal & urinary disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile swelling	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	5	0
Reproductive & breast disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	6	0
Respiration abnormal	1	0
Respiratory depression	1	0
Respiratory distress	1	0
<i>Bronchospasm and obstruction</i>		
Wheezing	2	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	14	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	2	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
Nasal pruritus	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	4	0
Rhinorrhoea	1	0
Snoring	1	0
Respiratory disorders SOC TOTAL	36	0

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Reaction Name	Total	Fatal
Skin disorders		
Angioedemas		
Angioedema	1	0
Apocrine and eccrine gland disorders		
Cold sweat	7	0
Hyperhidrosis	2	0
Bullous conditions		
Blister	26	0
Dermatitis bullous	1	0
Erythema multiforme	2	0
Dermal and epidermal conditions NEC		
Dry skin	1	0
Papule	1	0
Skin discolouration	3	0
Skin induration	2	0
Skin lesion	3	0
Skin reaction	10	0
Skin texture abnormal	1	0
Skin warm	15	0
Dermatitis and eczema		
Dermatitis	2	0
Dermatitis allergic	3	0
Eczema	4	0
Skin irritation	3	0
Erythemas		
Erythema	217	0
Nail and nail bed conditions (excl infections and infestations)		
Nail discolouration	1	0
Photosensitivity and photodermatitis conditions		
Photosensitivity reaction	1	0
Pruritus NEC		
Pruritus	39	0
Rashes, eruptions and exanthems NEC		
Rash	19	0
Rash erythematous	6	0
Rash macular	2	0
Rash maculo-papular	1	0
Rash morbilliform	1	0
Rash pruritic	6	0
Skin vascular conditions NEC		
Skin oedema	1	0
Urticarias		
Urticaria	22	0
Skin disorders SOC TOTAL	403	0

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

Case Series Drug Analysis Print

Name: FOI 21/636 Repevax vaccine

Report Run Date: 25-Jun-2021
Earliest Reaction Date: 30-Sep-2004

Data Lock Date: 24-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Obstetric therapeutic procedures</i>		
Caesarean section	5	0
Vacuum extractor delivery	1	0
Surgical & medical procedures SOC TOTAL	6	0

Case Series Drug Analysis Print

Name: FOI 21/636 Repevax vaccine

Report Run Date: 25-Jun-2021
 Earliest Reaction Date: 30-Sep-2004

Data Lock Date: 24-Jun-2021 18:30:03
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders		
<i>Arterial infections and inflammations</i>		
Kawasaki's disease	1	0
<i>Circulatory collapse and shock</i>		
Shock	1	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
<i>Non-site specific vascular disorders NEC</i>		
Hyperaemia	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	9	0
Flushing	3	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	2	0
Poor peripheral circulation	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	24	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	2	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
Vascular disorders SOC TOTAL	46	0
TOTAL REACTIONS FOR DRUG	2332	10
TOTAL REPORTS	1007	
TOTAL FATAL OUTCOME REPORTS		10