

## Case Series Drug Analysis Print

### Name: M-M-RVAXPRO Product Analysis Print

Report Run Date: 27-Sep-2021

Data Lock Date: 26-Sep-2021 18:30:04

Earliest Reaction Date: 22-Nov-2013

MedDRA Version: MedDRA 24.0

M-M-RVAXPRO M-M-RVAXPRO product analysis print. All UK

Product Analysis Print: spontaneous reports between 01/01/2019-31/12/2020

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Leukopenias NEC</i>		
Lymphopenia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	4	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>7</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Pericardial disorders NEC</i>		
Pericardial effusion	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>2</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Immune system abnormalities congenital</i>		
Primary immunodeficiency syndrome	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Inner ear signs and symptoms</i>		
Tinnitus	1	0
<b>Ear disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	1	0
<b>Eye disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	5	0
<i>Nausea and vomiting symptoms</i>		
Nausea	2	0
Vomiting	3	0
<i>Oral soft tissue signs and symptoms</i>		
Paraesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	1	0
Submaxillary gland enlargement	1	0
<i>Tongue signs and symptoms</i>		
Strawberry tongue	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>16</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Fatigue	1	0
Malaise	2	0
<i><b>Febrile disorders</b></i>		
Pyrexia	16	0
<i><b>Gait disturbances</b></i>		
Gait disturbance	1	0
<i><b>General signs and symptoms NEC</b></i>		
Influenza like illness	1	0
Peripheral swelling	1	0
Screaming	1	0
Swelling	1	0
<i><b>Injection site reactions</b></i>		
Injection site erythema	5	0
Injection site mass	1	0
Injection site pruritus	1	0
Injection site swelling	4	0
<i><b>Pain and discomfort NEC</b></i>		
Chest pain	1	0
Pain	2	0
<i><b>Therapeutic and nontherapeutic responses</b></i>		
Adverse event	1	0
<i><b>Vaccination site reactions</b></i>		
Extensive swelling of vaccinated limb	1	0
Vaccination site bruising	2	0
Vaccination site discomfort	1	0
Vaccination site erythema	6	0
Vaccination site haematoma	1	0
Vaccination site mass	2	0
Vaccination site pain	1	0
Vaccination site rash	1	0
Vaccination site reaction	1	0
Vaccination site swelling	5	0
<b>General disorders SOC TOTAL</b>	<b>60</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	1	0
<i>Immune and associated conditions NEC</i>		
Haemophagocytic lymphohistiocytosis	1	1
<b>Immune system disorders SOC TOTAL</b>	<b>3</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Bacterial infections NEC</b></i>		
Cellulitis	1	0
Injection site cellulitis	1	0
Vaccination site cellulitis	1	0
<i><b>Central nervous system and spinal infections</b></i>		
Encephalitis	3	0
<i><b>Eye and eyelid infections</b></i>		
Conjunctivitis	1	0
<i><b>Herpes viral infections</b></i>		
Human herpesvirus 6 infection	1	0
<i><b>Infections NEC</b></i>		
Vaccination site infection	1	0
<i><b>Male reproductive tract infections</b></i>		
Orchitis	1	0
<i><b>Mumps viral infections</b></i>		
Encephalitis mumps	1	0
<i><b>Rubella viral infections</b></i>		
Encephalomyelitis rubella	1	0
<i><b>Rubeola viral infections</b></i>		
Measles	2	0
Measles post vaccine	1	0
<i><b>Upper respiratory tract infections</b></i>		
Nasopharyngitis	1	0
Tonsillitis	1	0
Upper respiratory tract infection	1	0
<i><b>Viral infections NEC</b></i>		
Encephalitis viral	1	0
Viral infection	1	0
<b>Infections SOC TOTAL</b>	<b>20</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Occupational exposures</i>		
Occupational exposure to product	1	0
<i>Pathways and sources of exposure</i>		
Exposure via skin contact	1	0
<i>Product administration errors and issues</i>		
Booster dose missed	2	0
Inappropriate schedule of product administration	1	0
<b>Injuries SOC TOTAL</b>	<b>6</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Investigations</b>		
<i>Heart rate and pulse investigations</i>		
Heart rate increased	1	0
<i>Liver function analyses</i>		
Transaminases increased	1	0
<i>Virus identification and serology</i>		
Mumps antibody test negative	2	0
<b>Investigations SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	3	0
Hypophagia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Joint related signs and symptoms</i>		
Arthralgia	1	0
Joint swelling	1	0
<i>Muscle pains</i>		
Myalgia	2	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	2	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Weight bearing difficulty	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Pain in extremity	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral infarction	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	1	0
Lethargy	1	0
Loss of consciousness	1	0
<i>Headaches NEC</i>		
Headache	2	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	3	0
<i>Paraesthesias and dysaesthesias</i>		
Hypoaesthesia	2	0
Paraesthesia	3	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Paralysis	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	2	0
Partial seizures	1	0
Seizure	2	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>21</b>	<b>0</b>



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Reaction Name	Total	Fatal
<i>Device physical property and chemical issues</i>		
Syringe issue	1	0
<b>null SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i>Confusion and disorientation</i>		
Disorientation	1	0
<i>Emotional and mood disturbances NEC</i>		
Irritability	3	0
<i>Increased physical activity levels</i>		
Restlessness	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	1	0
<i>Stereotypies and automatisms</i>		
Head banging	1	0
Posturing	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	1	0
Respiratory arrest	1	0
Tachypnoea	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	5	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Alveolitis	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	1	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Interstitial lung disease	1	0
Lung consolidation	1	0
Organising pneumonia	1	0
Pulmonary alveolar haemorrhage	1	0
<i><b>Pleural conditions NEC</b></i>		
Pleural adhesion	1	0
<i><b>Pneumothorax and pleural effusions NEC</b></i>		
Pleural effusion	1	0
<i><b>Pulmonary oedemas</b></i>		
Acute lung injury	1	0
Acute respiratory distress syndrome	1	0
Pulmonary congestion	1	0
Pulmonary oedema	1	0
<i><b>Pulmonary thrombotic and embolic conditions</b></i>		
Pulmonary embolism	1	0
<i><b>Respiratory failures (excl neonatal)</b></i>		
Respiratory failure	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Catarrh	1	0
Oropharyngeal pain	3	0
Snoring	1	0
Throat irritation	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>28</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Angioedemas</i>		
Angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	1	0
<i>Dermal and epidermal conditions NEC</i>		
Skin reaction	1	0
<i>Dermatitis and eczema</i>		
Skin irritation	1	0
<i>Erythemas</i>		
Erythema	2	0
<i>Pruritus NEC</i>		
Pruritus	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	16	0
Rash erythematous	2	0
Rash maculo-papular	1	0
Rash morbilliform	6	0
<i>Urticarias</i>		
Urticaria	3	0
<b>Skin disorders SOC TOTAL</b>	<b>37</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Vascular disorders</b>		
<i>Peripheral vascular disorders NEC</i>		
Flushing	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	2	0
<b>Vascular disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>236</b>	<b>2</b>
<b>TOTAL REPORTS</b>	<b>71</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>2</b>