

Case Series Drug Analysis Print

Name: MFR (minus studies)

Report Run Date: 25-Feb-2015

Data Lock Date: 23-Feb-2015 19:00:10

Earliest Reaction Date: 01-Oct-2005

MedDRA Version: MedDRA 17.1

MFR (minus studies): M-M-RVAXPRO, MMR, MÆSLINGER OG
FÅRESYGE OG RØDE HUNDE, PRIORIX

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Reaction Name	Total	Fatal
Blood disorders		
<i>Leukopenias NEC</i>		
Leukopenia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	5	0
<i>Neutropenias</i>		
Neutropenia	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenic purpura	4	0
Thrombocytopenia	1	0
<i>Thrombocytoses</i>		
Thrombocytosis	1	0
Blood disorders SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	1	0
Bradycardia	1	0
Cardiac disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Central nervous system disorders congenital NEC</i>		
Syringomyelia	1	0
Congenital disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	1	0
Ear pruritus	1	0
<i>Hearing losses</i>		
Deafness	1	0
Hearing impaired	2	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	2	0
Ear disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
Endocrine disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Ocular disorders NEC</i>		
Eye swelling	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	2	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Photopsia	1	0
Vision blurred	3	0
Visual impairment	3	0
Eye disorders SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain upper	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Dysphagia	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	5	0
Vomiting	5	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	1	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	1	0
Gastrointestinal disorders SOC TOTAL	20	0

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	3	0
Fatigue	11	0
Malaise	4	0
<i>Febrile disorders</i>		
Pyrexia	62	0
<i>Feelings and sensations NEC</i>		
Chills	1	0
<i>Gait disturbances</i>		
Gait disturbance	8	0
<i>General signs and symptoms NEC</i>		
Crying	1	0
General physical health deterioration	2	0
Influenza like illness	4	0
Local reaction	1	0
Swelling	2	0
<i>Healing abnormal NEC</i>		
Impaired healing	1	0
<i>Injection site reactions</i>		
Injection site eczema	4	0
Injection site erosion	1	0
Injection site erythema	4	0
Injection site extravasation	2	0
Injection site granuloma	4	0
Injection site nodule	1	0
Injection site pain	8	0
Injection site papule	1	0
Injection site pruritus	8	0
Injection site rash	3	0
Injection site swelling	4	0
<i>Mass conditions NEC</i>		
Nodule	2	0
<i>Pain and discomfort NEC</i>		
Chest pain	1	0
Discomfort	1	0
Pain	4	0
<i>Vaccination site reactions</i>		
Vaccination site discolouration	2	0
Vaccination site granuloma	9	0
Vaccination site irritation	1	0
Vaccination site nodule	1	0
Vaccination site pain	2	0
Vaccination site pruritus	4	0
Vaccination site rash	1	0
General disorders SOC TOTAL	168	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergy to metals	5	0
Hypersensitivity	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Reaction to drug excipients	8	0
<i>Anaphylactic responses</i>		
Anaphylactic reaction	1	0
Immune system disorders SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Tonsillitis bacterial	1	0
<i>Candida infections</i>		
Oral candidiasis	1	0
<i>Dental and oral soft tissue infections</i>		
Parotitis	3	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	2	0
<i>Herpes viral infections</i>		
Herpes zoster	1	0
<i>Male reproductive tract infections</i>		
Orchitis	1	0
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Mycoplasma infections</i>		
Mycoplasma infection	1	0
<i>Rubella viral infections</i>		
Rubella	2	0
<i>Rubeola viral infections</i>		
Measles	3	0
Measles post vaccine	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	4	0
Rhinitis	2	0
Tonsillitis	1	0
<i>Viral infections NEC</i>		
Viral rash	1	0
Infections SOC TOTAL	25	0

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Reaction Name	Total	Fatal
Injuries		
<i>Cerebral injuries NEC</i>		
Concussion	1	0
<i>Maladministrations</i>		
Incorrect route of drug administration	1	0
<i>Non-site specific injuries NEC</i>		
Fall	3	0
<i>Skin injuries NEC</i>		
Contusion	2	0
<i>Vaccination related complications</i>		
Vaccination failure	1	0
Injuries SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Investigations		
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF cell count abnormal	1	0
<i>Coagulation and bleeding analyses</i>		
Coagulation factor increased	1	0
<i>Investigations NEC</i>		
Quality of life decreased	1	0
<i>Physical examination procedures and organ system status</i>		
Weight decreased	1	0
Weight increased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	2	0
<i>Urinalysis NEC</i>		
Protein urine	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
<i>Virus identification and serology</i>		
Morbillivirus test positive	1	0
Investigations SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	5	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Food intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis reactive	3	0
Arthropathy	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	5	0
Joint swelling	1	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Muscle pains</i>		
Myalgia	3	0
<i>Muscle weakness conditions</i>		
Muscular weakness	2	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Musculoskeletal pain	2	0
Neck pain	5	0
Pain in extremity	4	0
<i>Musculoskeletal and connective tissue signs and symptoms NEC</i>		
Growth retardation	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
<i>Spine and neck deformities</i>		
Scoliosis	1	0
<i>Synovial disorders</i>		
Synovitis	1	0
Muscle & tissue disorders SOC TOTAL	34	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	3	0
Polyneuropathy	1	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	4	0
Coordination abnormal	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	1	0
Demyelination	1	0
<i>Developmental disorders cognitive</i>		
Autism	3	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Syncope	4	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	1	0
Hypokinesia	1	0
<i>Dystonias</i>		
Opisthotonus	1	0
<i>Encephalitis NEC</i>		
Encephalitis post immunisation	1	0
<i>Facial cranial nerve disorders</i>		
Facial paresis	3	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Headache	10	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	1	0
<i>Motor neurone diseases</i>		
Motor neurone disease	1	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	1	0
<i>Nervous system disorders NEC</i>		
Motor dysfunction	2	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	5	0
Drooling	1	0
Presyncope	3	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	1	0
Hypoaesthesia	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Paraesthesia	1	0
Paralysis and paresis (excl cranial nerve)		
Paralysis	1	0
Paresis	1	0
Seizures and seizure disorders NEC		
Convulsion	4	0
Epilepsy	2	0
Febrile convulsion	6	0
Status epilepticus	2	0
Speech and language abnormalities		
Dyslalia	1	0
Speech disorder	1	0
Speech disorder developmental	1	0
Nervous system disorders SOC TOTAL	79	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Behaviour and socialisation disturbances</i>		
Social avoidant behaviour	1	0
<i>Confusion and disorientation</i>		
Confusional state	2	0
<i>Dissociative states</i>		
Dissociation	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	2	0
<i>Emotional and mood disturbances NEC</i>		
Irritability	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Personality disorders NEC</i>		
Personality disorder	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	1	0
<i>Psychotic disorder NEC</i>		
Psychotic disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	1	0
Psychiatric disorders SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Urinary retention	1	0
Renal & urinary disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
Testicular swelling	1	0
Reproductive & breast disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	1	0
<i>Coughing and associated symptoms</i>		
Cough	2	0
Productive cough	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	2	0
Tonsillar hypertrophy	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Catarrh	3	0
Increased viscosity of nasal secretion	1	0
Oropharyngeal pain	2	0
Respiratory disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Alopecias</i>		
Alopecia	1	0
<i>Apocrine and eccrine gland disorders</i>		
Hyperhidrosis	1	0
<i>Bullous conditions</i>		
Blister	1	0
<i>Dermal and epidermal conditions NEC</i>		
Skin induration	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis atopic	1	0
Eczema	3	0
Eczema asteatotic	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
<i>Erythemas</i>		
Erythema	5	0
Rash erythematous	5	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail disorder	1	0
<i>Papulosquamous conditions</i>		
Rash papular	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pilar disorders NEC</i>		
Hair growth abnormal	4	0
<i>Pruritus NEC</i>		
Pruritus	12	0
Rash pruritic	5	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	1	0
Petechiae	3	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	14	0
Rash generalised	3	0
Rash macular	2	0
Rash maculo-papular	2	0
Rash morbilliform	14	0
<i>Skin and subcutaneous conditions NEC</i>		
Excessive granulation tissue	2	0
Skin mass	3	0
<i>Skin cysts and polyps</i>		
Dermal cyst	1	0
<i>Urticarias</i>		
Cold urticaria	1	0
Urticaria	9	0
Skin disorders SOC TOTAL	100	0

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

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Inner ear therapeutic procedures</i>		
Cochlea implant	1	0
Surgical & medical procedures SOC TOTAL	1	0

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Vascular disorders		
<i>Peripheral vascular disorders NEC</i>		
Hot flush	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
Raynaud's phenomenon	1	0
Vascular disorders SOC TOTAL	3	0
TOTAL REACTIONS FOR DRUG	540	0
TOTAL REPORTS	173	