

הנדון: פרוקוואד ProQuad®

Dosage Form: Powder and Solvent for Suspension for Injection

Composition:

Measles virus Enders' Edmonston strain (live, attenuated) (not less than 3.00 log₁₀ TCID₅₀)
 Varicella virus Oka/Merck strain (live, attenuated) (not less than 3.99 LOG₁₀ PFU)
 Rubella virus Wistar RA 27/3 strain (live, attenuated) (not less than 3.00 log₁₀ TCID₅₀)
 Mumps virus Jeryl Lynn™ (Level B) strain (live, attenuated) (not less than 4.30 log₁₀ TCID₅₀)

חברת מרק שארפ ודוהם (ישראל-1996) בע"מ, (MSD ישראל) מבקשת ליידע על עדכון העלון לרופא של פרוקוואד.
 להלן לשון ההתוויה המאושרת לתכשיר:

ProQuad is indicated for simultaneous vaccination against measles, mumps, rubella, and varicella in individuals from 12 months of age to 12 years of age.

ProQuad can be administered to individuals from 9 months of age under special circumstances: outbreak situations, or travel to a region with high prevalence of measles.

למידע מלא ולהוראות מתן מפורטות יש לעיין בעלון לרופא המאושר על ידי משרד הבריאות.

עדכונים מהותיים בעלון לרופא:

טקסט מהותי שהוסף מודגש בקו תחתון. טקסט שנמחק מסומן בקו

4.8 Undesirable effects

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 Very common (≥1/10); Common (≥1/100, <1/10); Uncommon (≥1/1,000, <1/100); Rare (≥1/10,000, <1/1,000); Not known (cannot be estimated from the available data)

Adverse reactions	Frequency
Infections and infestations	
Upper respiratory infection	Common
Ear infection, Gastroenteritis, Nasopharyngitis , Otitis media, Pharyngitis, Roseola , Viral infection, Viral rash	Uncommon
Bronchiolitis, Candida nappy rash, Candidiasis, Cellulitis, Infectious croup, Viral gastroenteritis, Hand-foot-mouth disease, Influenza, Pseudocroup, Respiratory tract infection, Skin infection, Tonsillitis, Varicella*†, Viral conjunctivitis	Rare
Aseptic meningitis*, Atypical measles , Encephalitis*, Epididymitis, Herpes zoster*, Infection, Measles, Orchitis, Parotitis	Not known
Blood and the lymphatic system disorders	
Leukocytosis, Lymphadenopathy	Rare
Lymphadenitis, Regional lymphadenopathy , Thrombocytopenia	Not known
Immune system disorders	
Hypersensitivity	Rare
Anaphylactoid reaction, Anaphylactic reaction, Angioedema, Anaphylaxis and related phenomenon such as Angioneurotic oedema, Facial oedema, and Peripheral oedema, Anaphylaxis in individuals with or without an allergic history	Not known
Metabolism and nutrition disorders	
Anorexia , Decreased appetite	Uncommon
Dehydration	Rare
Psychiatric disorders	
Irritability	Common
Crying, Insomnia , Sleep disorder	Uncommon

Adverse reactions	Frequency
Agitation, Apathy, Clinging, Emotional changes, Nervousness, Restlessness	Rare
Nervous system disorders	
Febrile seizure*, Somnolence	Uncommon
Ataxia, Seizure Convulsion , Headache, High-pitched crying , Hyperkinesia, Hypersomnia, Lethargy, Tremor	Rare
Afebrile convulsions or seizures , Bell's palsy, Cerebrovascular accident, Dizziness, Dream abnormality , Encephalopathy*, Guillain-Barré syndrome, Measles inclusion body encephalitis (see section 4.3), Ocular palsies, Paraesthesia, Polyn neuritis , Polyneuropathy, Subacute sclerosing panencephalitis*, Syncope, Transverse myelitis, Tremor	Not known
Eye disorders	
Conjunctivitis, Eye discharge, Blepharitis , Eyelid inflammation , Eye irritation, Eye swelling, Ocular hyperaemia, Increased lacrimation , Tearing , Visual Ocular discomfort	Rare
Eyelid oedema Oedema of the eyelid , Irritation, Optic neuritis, Retinitis, Retrobulbar neuritis	Not known
Ear and labyrinth disorders	
Ear pain	Rare
Neurosensory Nerve deafness	Not known
Vascular disorders	
Flushing, Pallor	Rare
Extravasation	Not known
Respiratory, thoracic, and mediastinal disorders	
Cough, Nasal congestion , Respiratory tract congestion, Rhinorrhoea	Uncommon
Asthma, Pulmonary congestion , Sinus disorder, Sneezing, Wheezing	Rare
Bronchial Bronchospasm, Bronchitis, Epistaxis , Pneumonitis (see section 4.3), Pneumonia, Pulmonary congestion , Rhinitis, Sinusitis, Oropharyngeal pain Sore throat	Not known
Gastrointestinal disorders	
Diarrhoea, Vomiting	Common
Abdominal pain upper, Abnormal faeces , Constipation, Flatulence, Nausea, Salivation increase , Stomatitis, Teething	Rare
Abdominal pain, Haematochezia, Mouth ulcer	Not known
Skin and subcutaneous tissue disorders	
Measles-like rash [‡] , Rash, Varicella-like rash [‡]	Common
Dermatitis (including contact, and atopic, and diaper rash), Heat rash, Rubella-like rash [‡] , Urticaria, Viral exanthema , Eczema, Erythema	Uncommon
Acne, Clammy skin Cold sweat, Exfoliative dermatitis, Drug eruption, Exanthema , Henoch-Schönlein purpura, Livedo reticularis , Papular rash, Pruritus, Skin discolouration, Skin lesion, Zosteriform rash	Rare
Erythema multiforme, Herpes simplex , Impetigo, Panniculitis, Purpura, Skin induration, Stevens-Johnson syndrome, Sunburn	Not known
Musculoskeletal and, connective tissue and bone disorders	
Arm pain, Musculoskeletal stiffness	Rare
Arthritis, and/or a Arthralgia (usually transient and rarely chronic)*, Musculoskeletal pain, Myalgia, Pain of the hip, leg, or neck, Swelling	Not known
General disorders and administration site conditions	
Fever [‡] , Erythema [‡] or Pain/Tenderness/Soreness [‡] at the injection site	Very common
Ecchymosis or Swelling [‡] at the injection site, Injection site rash [‡]	Common
Asthenia, # Fatigue, Injection site haemorrhage, Injection site induration or warmth , Injection site mass, Malaise	Uncommon
Influenza like illness, Injection site exfoliation desquamation, Injection site discolouration, Injection site pruritus, Injection site rash non-specific , Injection site reaction, Injection site scar, Hyperthermia, Pain	Rare
Injection site complaints (Burning and/or Stinging of short duration Pain, Eczema, Oedema/Swelling, Hive-like rash Urticaria, Haematoma, Induration, Lump/Mass, Vesicles, Wheal and Flare), Inflammation, Lip abnormality, Papillitis, Roughness/Dryness , Stiffness, Trauma, Varicella-like rash, Venipuncture site haemorrhage, Warm sensation, Warm to touch	Not known
Investigations	
Weight loss	Rare
Injury, and poisoning, and procedural complications	
Contusion, Non-venomous bite/sting	Rare



Adverse reactions	Frequency
Social circumstances	
Activities of daily living impaired	Rare

* Varicella caused by vaccine strain was observed in post-marketing use with Varicella Vaccine live (Oka/Merck).

* See section c

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4.9 Overdose

Administration of a higher than recommended dose of ProQuad was reported rarely and the adverse reaction profile was comparable to that observed with the recommended dose of ProQuad.~~No case of overdose has been reported.~~

בעלון לרופא היו עדכונים נוספים שאינם מהותיים ואינם נכללים בהודעה זו. העלון נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום, חברת MSD, בטלפון 09-9533333.

ProQuad® מופץ ע"י חברת נובולוג בע"מ.

בברכה,
מיכל סרפר
רוקחת ממונה
MSD ישראל

References:

Proquad Israeli SPC revised in January 2022