

**הנדון: פרקוואד ProQuad®**  
Measles, Mumps, Rubella and Varicella Virus Vaccine (Live).

**Dosage Form:** Powder and Solvent for Suspension for Injection

**Composition:**

Measles virus Enders' Edmonston strain (live, attenuated) (not less than 3.00 log<sub>10</sub> TCID<sub>50</sub>)  
Varicella virus Oka/Merck strain (live, attenuated) (not less than 3.99 LOG<sub>10</sub> PFU)  
Rubella virus Wistar RA 27/3 strain (live, attenuated) (not less than 3.00 log<sub>10</sub> TCID<sub>50</sub>)  
Mumps virus Jeryl Lynn™ (Level B) strain (live, attenuated) (not less than 4.30 log<sub>10</sub> TCID<sub>50</sub>)

חברת מרק שארפ ודוהם ישראל (MSD) מבקשת ליידע על עדכון העלון לרופא של פרקוואד.  
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 חוצה.

**4.4 Special warnings and precautions for use**

**Traceability**

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

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**Transmission**

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Post-marketing experience with ~~Varicella Vaccine live (Oka/Merck)~~ suggests that transmission of varicella vaccine virus (Oka/Merck strain) resulting in varicella infection including disseminated disease may rarely occur between ~~healthy~~-vaccine recipients (who develop or do not develop a varicella-like rash) and contacts susceptible to varicella including healthy, as well as high-risk individuals ~~susceptible to varicella~~-(see section 4.8).

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**Sodium**

This medicinal product contains less than 1 mmol (23 mg) sodium per dose and is considered to be essentially sodium-free.

**Potassium**

This medicinal product contains less than 1 mmol (39 mg) potassium per dose and is considered to be essentially potassium-free.

**Sorbitol**

The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.

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## 4.8 Undesirable effects

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### Transmission

Based on ~~isolated case reports from post-marketing surveillance for Varicella Vaccine live (Oka/Merck)~~, the possibility exists that varicella vaccine virus (Oka/Merck strain) may rarely be transmitted to contacts of recipients of ProQuad who develop or do not develop a varicella-like rash (see section 4.4).

## 6.6 Special precautions for disposal and other handling

Before mixing with the solvent, the powder vaccine is a white to pale yellow compact crystalline cake. The solvent is a clear colourless liquid. When completely reconstituted, the vaccine is a clear pale yellow to light pink liquid.

To reconstitute the vaccine, use only the solvent supplied, because it is free of preservatives or other antiviral substances, which might inactivate the vaccine. ~~ProQuad, when reconstituted, is clear pale yellow to light pink liquid.~~

It is important to use a separate sterile syringe and needle for each individual to prevent transmission of infectious agents from one individual to another.

One needle should be used for reconstitution and a separate, new needle for injection.

ProQuad must not be mixed in a syringe with other vaccines.

### Reconstitution instructions

To attach the needle, it should be firmly placed on the tip of the syringe and secured by rotating a quarter of a turn (90°).

Inject the entire content of the syringe into the vial containing the powder. Gently agitate to dissolve completely. ~~Withdraw the entire content of the reconstituted vaccine from the vial into the same syringe and inject the entire volume.~~

The reconstituted vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance prior to administration. In the event of either being observed, discard the vaccine.

**It is recommended that the vaccine be administered immediately after reconstitution, to minimize loss of potency. Discard if reconstituted vaccine is not used within 30 minutes.**

### Do not freeze the reconstituted vaccine.

Withdraw the entire content of the reconstituted vaccine from the vial into a syringe, change the needle, and inject the entire volume by subcutaneous or intramuscular route.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

בעלון לרופא היו עדכונים נוספים שאינם מהותיים ואינם נכללים בהודעה זו. העלון נשלח לרופא 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,  
אורית בילין  
רוקחת ממונה  
MSD ישראל

### References:

Proquad Israeli SPC revised in August 2020