



Dear Pharmacy Colleague:

I am writing to let you know that the Prescribing Information (PI) for ProQuad® (Measles, Mumps, Rubella and Varicella Virus Vaccine Live) has been updated. Major changes were made to many sections of the PI, including:

- Indications and Usage
- Contraindications
- Warning and Precautions
- Adverse Reactions
- Clinical Studies

Overview of the major changes:

Indications and Usage:

The Indications and Usage section now states:

"ProQuad is a vaccine indicated for active immunization for the prevention of measles, mumps, rubella, and varicella in children 12 months through 12 years of age."

Contraindications:

Section 4.2, Immunosuppression, was revised. Changes include the addition of the following language (which was previously in the Precautions section):

"Vaccination with a live, attenuated vaccine, such as varicella, can result in a more extensive vaccine-associated rash or disseminated disease in individuals on immunosuppressive drugs."

Warnings and Precautions:

The Warnings and Precautions sections have now been combined. Section 5.1, "Fever and Febrile Seizures," was revised and added to the Warnings and Precautions section of the PI. The Prescribing Information now states:

"Administration of ProQuad (dose 1) to children 12 to 23 months old who have not been previously vaccinated against measles, mumps, rubella, or varicella, nor had a history of the wild-type infections, is associated with higher rates of fever and febrile seizures at 5 to 12 days after vaccination when compared to children vaccinated with dose 1 of both M-M-R®_{II} (Measles, Mumps, and Rubella Virus Vaccine Live) and VARIVAX® (Varicella Virus Vaccine Live) administered separately."

Adverse Reactions:

This section has been extensively revised to include additional safety data from clinical trials.

Clinical Studies:

This section has been extensively revised to include additional clinical trial data, including data from concomitant use trials.

Additional Changes to the PI:

Drug Interactions and Use in Specific Populations:

These sub-sections have been moved from the Precautions sections and now are separate sections. The following language was added regarding concomitant use:

"ProQuad may be administered concomitantly with pneumococcal 7-valent conjugate vaccine, and/or hepatitis A (inactivated)vaccines."

The updated PI is enclosed and also may be accessed from the following link:

http://www.merck.com/product/usa/pi_circulars/p/proquad/proquad_pi.pdf

We feel it is important to provide you with the most current information in the event you receive questions from your members.

About ProQuad® (Measles, Mumps, Rubella and Varicella Virus Vaccine Live)

ProQuad is a vaccine indicated for active immunization for the prevention of measles, mumps, rubella, and varicella in children 12 months through 12 years of age. Each 0.5-mL dose of ProQuad is administered subcutaneously.

—The first dose is usually administered at 12 to 15 months of age.

—A second dose, if needed, is usually administered at 4 to 6 years of age.

Select Safety Information for ProQuad

ProQuad is contraindicated in individuals with any of the following: history of anaphylactic reaction to neomycin or hypersensitivity to gelatin or any other component of the vaccine; primary or acquired immunodeficiency states; family history of congenital or hereditary immunodeficiency; immunosuppressive therapy; active untreated tuberculosis or febrile illness (>101.3°F or >38.5°C); or those who are pregnant.

Administration of ProQuad (dose 1) to children 12 to 23 months old who have not been previously vaccinated against measles, mumps, rubella, or varicella, nor had a history of the wild-type infections, is associated with higher rates of fever and febrile seizures at 5 to 12 days after vaccination when compared to children vaccinated with dose 1 of both M-M-R®_{II} (Measles, Mumps, and Rubella Virus Vaccine Live) and VARIVAX® (Varicella Virus Vaccine Live) administered separately.

Use caution when administering ProQuad® (Measles, Mumps, Rubella and Varicella Virus Vaccine Live) to children with: a history of cerebral injury or seizures or any other condition in which stress due to fever should be avoided; anaphylaxis or immediate hypersensitivity to eggs; contact hypersensitivity to neomycin; thrombocytopenia.

Advise vaccinees to avoid: close contact with high-risk individuals susceptible to varicella; pregnancy for 3 months after vaccination; using salicylates for 6 weeks after vaccination. Defer vaccination for at least 3 months following blood or plasma transfusions, or administration of immune globulins (IG).

The most frequent vaccine-related adverse events reported in ≥5% of subjects vaccinated with ProQuad were: injection-site reactions (pain/tenderness/soreness, erythema, and swelling); fever; and irritability. Systemic vaccine-related adverse events that were reported at a significantly greater rate in recipients of ProQuad than in recipients of the component vaccines administered concomitantly were fever and measles-like rash.

Before administering ProQuad please read the accompanying Prescribing Information.

For additional copies of the Prescribing Information, call 1-800-672-6372, visit MerckVaccines.com®, or contact your Merck representative.

Sincerely,



Julie M. Gerhart
Manager, Pharmacy Affairs
Merck & Co., Inc.

Enclosure: Prescribing Information for ProQuad