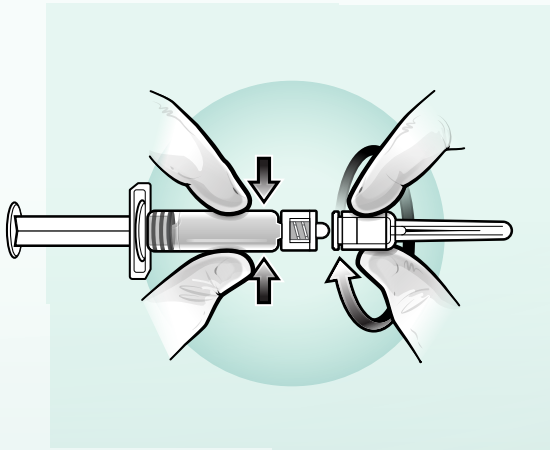


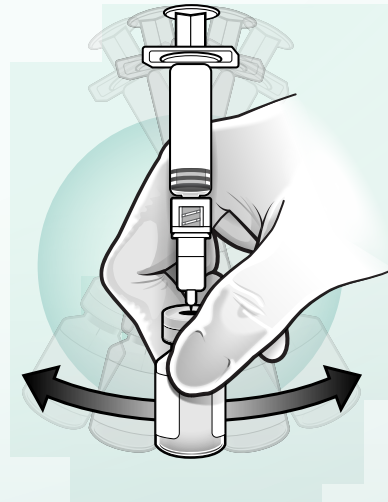
M-M-R® IIMeasles, Mumps,
& Rubella Virus
Vaccine Live**VARIVAX®**VARICELLA VIRUS
VACCINE LIVE**ProQuad®**Measles, Mumps,
Rubella and
Varicella Virus
Vaccine Live

One less step for prep: **M-M-R® II**, **VARIVAX**, and **ProQuad** come with a prefilled diluent syringe

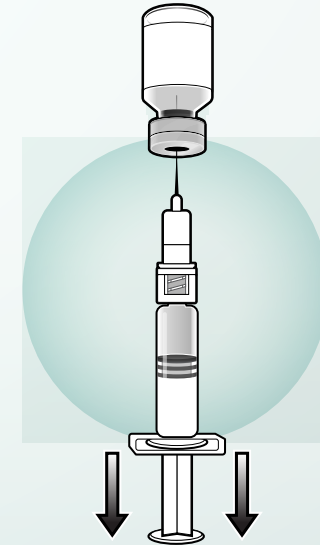
Preparation for Administration Using a Prefilled Diluent Syringe



Hold the syringe barrel in one hand and **unscrew the syringe tip cap** by twisting it **counterclockwise**. Attach a needle by **twisting clockwise** until the needle fits securely on the syringe.



Visually inspect the vaccine for discoloration. **Slowly inject the entire volume of sterile diluent prefilled syringe** into the lyophilized vaccine vial. **Gently agitate to dissolve completely**. Discard if the lyophilized vaccine cannot be dissolved. Do not use the product if particulates are present or if it appears discolored.



Visually inspect the vaccine again for discoloration. **Withdraw and administer the entire volume of the reconstituted vaccine.**

Preparation for Administration Using a Pre-Filled Diluent Syringe continues on next page.

Indications and Usage

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.

VARIVAX is a vaccine indicated for active immunization for the prevention of varicella in individuals 12 months of age or older.

M-M-R® II is indicated for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age or older.

Selected Safety Information

• **Hypersensitivity:** **ProQuad**, **M-M-R® II**, and **VARIVAX** are contraindicated in patients with a history of anaphylactic reaction or hypersensitivity to any component of the vaccine (including gelatin or neomycin) or to a prior dose of measles, mumps, rubella, or varicella-containing vaccine. Use caution

when administering **ProQuad** and **M-M-R® II** to individuals with anaphylaxis or immediate hypersensitivity to eggs.

- **ProQuad**, **M-M-R® II**, and **VARIVAX** are contraindicated in certain individuals, including those with: immunodeficiency or who are immunosuppressed; an active febrile illness; untreated tuberculosis.
- **Pregnancy:** **ProQuad**, **M-M-R® II**, and **VARIVAX** are contraindicated for use in pregnant women. Do not administer **ProQuad** or **VARIVAX** to individuals who are planning to become pregnant in the next 3 months. Do not administer **M-M-R® II** to individuals who are planning to become pregnant in the next month.
- **Febrile Seizures:** 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 a first dose of both **M-M-R® II** and **VARIVAX** administered concomitantly.

- **Febrile Seizures:** Use caution when administering **ProQuad** and **M-M-R® II** to individuals with a history of febrile seizures.
- **Family History of Immunodeficiency:** Vaccination with **ProQuad**, **M-M-R® II**, and **VARIVAX** should be deferred in individuals with a family history of congenital or hereditary immunodeficiency until the individual's immune status has been evaluated and the individual has been found to be immunocompetent.
- **Thrombocytopenia:** Transient thrombocytopenia has been reported within 4-6 weeks following vaccination with measles, mumps, and rubella vaccine. Carefully evaluate the potential risk and benefit of vaccination in children with thrombocytopenia

Selected Safety Information continues on next page.

Preparation for Administration Using a Prefilled Diluent Syringe (continued)

- **M-M-R[®]_{II}**: If not used immediately, the reconstituted vaccine may be stored between 36°F to 46°F (2°C to 8°C), protected from light, for up to 8 hours. Discard reconstituted vaccine if it is not used within 8 hours.
- **VARIVAX**: Discard if reconstituted vaccine is not used within 30 minutes. Do not freeze reconstituted vaccine. Do not combine VARIVAX with any other vaccine through reconstitution or mixing.
- **ProQuad**: If not used immediately, the reconstituted vaccine may be stored at room temperature, protected from light, for up to 30 minutes. Discard reconstituted vaccine if it is not used within 30 minutes.

Selected Safety Information (continued)

- or in those who experienced thrombocytopenia after vaccination with a previous dose of a measles, mumps, and rubella-containing vaccine.
- **Varicella Transmission and Precautions:** Advise vaccinees administered **ProQuad** or **VARIVAX** to avoid close contact with high-risk individuals susceptible to varicella for up to 6 weeks following vaccination since transmission of varicella vaccine virus to susceptible contacts has been reported. Varicella vaccine virus transmission may occur between vaccine recipients and contacts susceptible to varicella including healthy individuals.
 - **Immune Globulins and Transfusions:** Immune Globulins and other blood products should not be given concomitantly with **ProQuad**, **M-M-R[®]_{II}**, or **VARIVAX**.
 - **Use of Salicylates:** Avoid use of salicylates in children and adolescents administered **ProQuad** or **VARIVAX** for 6 weeks following vaccination due to the association of Reye Syndrome with salicylate therapy and wild-type varicella infection.
 - **Adverse Events:** The following adverse events have been reported for both subcutaneous and intramuscular injections of **ProQuad**, **M-M-R[®]_{II}**, and **VARIVAX**: fever, injection-site reactions (pain/tenderness/soreness, erythema, and swelling); and rash on the body or at the injection site. Additionally, irritability has been reported for the subcutaneous injections of **ProQuad**, **M-M-R[®]_{II}**, and **VARIVAX**.
 - **ProQuad Systemic Vaccine-Related Adverse Events:** Systemic vaccine-related adverse events that were reported at a significantly greater rate in recipients of subcutaneous **ProQuad** than in recipients of the component vaccines administered concomitantly were fever and measles-like rash.
 - **VARIVAX Dose-related Adverse Events:** In a clinical trial involving children who received 2 doses of **VARIVAX** 3 months apart, the incidence of injection-site clinical complaints observed in the first 4 days following vaccination was slightly higher post-dose 2 (overall incidence 25.4%) than post-dose 1 (overall incidence 21.7%), whereas the incidence of systemic clinical complaints in the 42-day follow-up period was lower post-dose 2 (66.3%) than post-dose 1 (85.8%).
 - **Concomitant Vaccines With ProQuad:** **ProQuad** may be administered concomitantly with diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed (DTaP), *Haemophilus influenzae* type b conjugate (meningococcal protein conjugate) and hepatitis B (recombinant) vaccine. It may also be administered concomitantly with pneumococcal 7-valent conjugate vaccine and/or hepatitis A vaccine (inactivated) at separate injection sites.
 - **Concomitant Vaccines With VARIVAX:** **VARIVAX** can be administered with other live viral vaccines. If not given concurrently, at least 1 month should elapse between a dose of a live attenuated measles virus-containing vaccine and a dose of **VARIVAX**. In children, at least 3 months should elapse between administration of 2 doses of a live attenuated varicella virus-containing vaccine.
 - **Tuberculin Testing:** If a tuberculin test is to be done with **M-M-R[®]_{II}** and **ProQuad**, it should be administered either any time before, simultaneously with, or at least 4 to 6 weeks after vaccination. With **VARIVAX**, tuberculin testing may be performed before the vaccine is administered or at least 4 weeks following vaccination.
 - **Additional M-M-R[®]_{II} Precautions:** Additional adverse reactions, which have been reported without regard to causality, include febrile convulsions, arthritis, thrombocytopenia, anaphylaxis, anaphylactoid reactions, arthritis, encephalitis and encephalopathy in their diverse clinical presentations.
 - **Additional VARIVAX Precautions:** It is not known if varicella vaccine virus is excreted in human milk. A boost in antibody levels has been observed in vaccinees following exposure to wild-type varicella, which could account for the apparent long-term persistence of antibody levels in studies. The duration of protection from varicella infection after vaccination is unknown.
 - **ProQuad/VARIVAX and Herpes Zoster:** The long-term effect of **VARIVAX** on the incidence of herpes zoster, particularly in those vaccinees exposed to wild-type varicella, is unknown at present.
 - **Efficacy:** Vaccination with **ProQuad**, **VARIVAX**, or **M-M-R[®]_{II}** may not result in protection in 100% of vaccinees.

Dosage and Administration

ProQuad:

- Each dose of **ProQuad** is approximately 0.5 mL and is administered intramuscularly or subcutaneously.
- At least 1 month should elapse between a dose of a measles-containing vaccine such as **M-M-R[®]_{II}** and a dose of **ProQuad**. At least 3 months should elapse between a dose of varicella-containing vaccine and **ProQuad**.

VARIVAX:

- Each dose is approximately 0.5 mL and is administered intramuscularly or subcutaneously.
 - The first dose is administered at 12 to 15 months of age.
 - The second dose is administered at 4 to 6 years of age.
 - There should be a minimum interval of 3 months between doses.
 - 12 months to 12 years of age: If a second dose is administered, there should be a minimum interval of 3 months between doses.
 - Adolescents (≥13 years of age) and Adults: 2 doses, to be administered with a minimum interval of 4 weeks between doses.

M-M-R[®]_{II}:

- The dose for any age is approximately 0.5 mL administered intramuscularly or subcutaneously.
- The recommended age for primary vaccination is 12 to 15 months and the second dose should be given at 4 to 6 years of age.

Before administering **VARIVAX**[®] (Varicella Virus Vaccine Live), **M-M-R[®]_{II}** (Measles, Mumps, and Rubella Virus Vaccine Live), or **ProQuad**[®] (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), please read the accompanying Prescribing Information. The Patient Information also is available for **VARIVAX**, **M-M-R[®]_{II}** and **ProQuad**.

