

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ProQuad®

Measles, Mumps, Rubella and Varicella Virus Vaccine Live

Read this carefully before you are vaccinated with **ProQuad®**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ProQuad®**.

What is ProQuad® used for?

ProQuad® is an injectable live, attenuated virus vaccine to help prevent measles, mumps, rubella, and chickenpox (varicella).

How does ProQuad® work?

The doctor has recommended or administered ProQuad® to help protect your child against measles, mumps, rubella, and chickenpox. The vaccine can be administered to persons 12 months through 12 years of age.

Measles is a serious infectious illness that is very easily passed from one person to another. It causes a high fever, cough, and a rash and lasts for 1 to 2 weeks. One out of every 10 children who catch measles will also have an ear infection or pneumonia. On rare occasions, measles can also cause an infection of the brain that could lead to seizures, hearing loss, mental retardation, and even death. Babies and adults who catch measles are often much sicker for a longer time or are more likely to die than elementary school children and teenagers who catch measles.

Mumps is an infectious illness that is easily passed from one person to another and causes fever, headache, and swollen, painful glands under the jaw (salivary glands). It can sometimes be a very serious disease and usually lasts for several days. Mumps can cause a mild inflammation of the coverings of the brain and spinal cord (meningitis) in about 1 person in every 10 who catch it. About 1 out of every 4 teenage or adult males with mumps will have a painful swelling of the testicles for several days (this does not usually affect their ability to father children). Teenagers and adults, especially males, who catch mumps are often much sicker and more likely to suffer longer than children do.

Rubella is usually a mild disease that causes a mild fever, swollen glands in the neck, pain and swelling in the joints, and a rash that lasts for a short time but is very dangerous if a pregnant woman catches it. Women who catch rubella when they are pregnant can have babies who are stillborn, or have heart disease, blindness, deafness, or problems with learning.

Chickenpox (varicella) is an infectious illness that is easily passed from one person to another and occurs most often in children 5 to 9 years of age. It is primarily spread from person to person through the air by sneezing or coughing. Symptoms of chickenpox include mild headache, moderate fever, and general discomfort. These are followed by a rash of itchy, little red spots which usually start on the chest, stomach or back, but can appear anywhere on the body. There may be only a few spots or clusters of spots, or even hundreds of spots that develop over the next 3 to 5 days. The spots will change into clear blisters filled with fluid which then become cloudy, break open, dry, scab, and heal, usually within 5 to 20 days. The most common complications are bacterial skin infections. Less

frequent but very serious complications include pneumonia, inflammation of the brain (encephalitis), Reye Syndrome (inflammation of the liver associated with disturbances of consciousness), and death. Severe disease and serious complications are more likely to occur in adolescents and adults. Disease and accompanying complications of chickenpox have significantly fallen since the introduction of a varicella vaccine in 1995.

What are the ingredients in ProQuad®?

Medicinal ingredient:

The medicinal ingredient is an injectable live attenuated virus vaccine to help prevent measles, mumps, rubella, and varicella (chickenpox).

Non-medicinal ingredients:

ProQuad® contains gelatin, human albumin and a trace amount of neomycin as inactive ingredients. Tell the doctor if your child has ever had an allergic reaction to these ingredients.

For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

ProQuad® comes in the following dosage forms:

- ProQuad® is a lyophilized powder for injection
- ProQuad® is available in a pack of 10 single dose vials (lyophilized vaccine and a separate package of vial of diluent)

Do not use ProQuad® if:

ProQuad® should not be used if the vaccine recipient:

- is allergic to any of its components (including neomycin and gelatin)
- has a blood disorder or any type of cancer that affects the immune system (other than corticosteroid replacement)
- is taking medications to suppress the immune system (other than corticosteroid replacement)
- has an immune deficiency as a result of a disease (such as AIDS) or a treatment
- has active untreated tuberculosis
- has a fever higher than 38.5 °C; however, low-grade fever itself is not a reason to delay vaccination
- is pregnant (in addition, pregnancy should be avoided for 3 months after vaccination)

To help avoid side effects and ensure proper use, talk to your healthcare professional before your child gets ProQuad®. Talk about any health conditions or problems your child may have, including if your child:

- has any allergies (especially to neomycin).
- has a history of seizures or a brain injury
- has a low blood platelet count
- has received blood or plasma transfusions or administration of human serum globulin within the last 5 months.
- has a family member with a weakened immune system

In rare circumstances, it is possible to catch chickenpox, including severe chickenpox, from a person who has been vaccinated with ProQuad®. This may occur in persons who have not previously been vaccinated against chickenpox or had chickenpox, as well as persons who fall into one of the following categories:

- individuals with a weakened immune system
- pregnant women who never had chickenpox
- newborn babies whose mothers never had chickenpox

Whenever possible, individuals who have been vaccinated with ProQuad® should attempt to avoid close contact, for up to 6 weeks following the vaccination, with anyone who falls into one of the categories above. Tell the doctor if there is anyone who falls into one of the categories above and is expected to be in close contact with the person being vaccinated.

Use in pregnancy

- ProQuad® should not be administered to pregnant women. Women of child-bearing age should take the necessary precautions to avoid pregnancy for 3 months following vaccination.

Use in breast-feeding

- Tell the doctor if the vaccine recipient is breast-feeding or intends to breast-feed. Your doctor will decide if ProQuad® should be given.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ProQuad®:

- Tell the doctor if your child has recently received a vaccine or if one is scheduled to be given in the near future. The doctor will determine when ProQuad® may be given. At least 1 month should elapse between a dose of measles, mumps, and rubella vaccine and ProQuad®. If for any reason a second dose of a varicella-containing vaccine is required, at least 1 month should elapse between administration of the doses.
- The doctor may delay vaccination for 3 or more months following blood or plasma transfusions, or administration of normal human immune globulin (IG), or varicella zoster immune globulin (VZIG).
- If a tuberculin test is to be performed, it should be done either any time before, simultaneously with, or 4 to 6 weeks after vaccination with ProQuad®.
- The use of salicylates (for example, acetylsalicylic acid or aspirin) should be avoided for 6 weeks following vaccination with ProQuad® because the use of salicylates during natural chickenpox infection has been associated with Reye Syndrome (see How does ProQuad® work?)

How to take ProQuad®:

ProQuad® will be given to you by a healthcare professional in a healthcare setting.

Usual dose:

ProQuad® is given by subcutaneous injection to persons 12 months through 12 years of age. If a second dose of a measles- containing vaccine is needed, then ProQuad® can be used for this dose. The appropriate time and number of injections will be determined by your doctor using appropriate official recommendations.

Talk to the doctor for more details.

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®.

If you think you, or a person you are caring for, have received too much ProQuad®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using ProQuad®?

These are not all the possible side effects you may have when taking ProQuad®. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects reported with the use of ProQuad® were: injection-site complaints including pain/tenderness/soreness, redness, swelling or bruising; fever (38.9°C or higher); irritability; rash (including measles-like rash, varicella-like rash, viral exanthema, and injection-site rash); upper respiratory infection; vomiting and diarrhea.

Other less common side effects have been reported following administration of ProQuad®, and some of these were serious. These included: allergic reactions (hives); seizures with a fever; cough and unsteadiness with walking.

Other adverse events have been reported with the use of at least one of the following: ProQuad®, M-M-R® II (measles, mumps and rubella virus vaccine, live, attenuated, Merck Std.), the monovalent components of M-M-R® II, or VARIVAX® (varicella virus vaccine, live, attenuated, [Oka/Merck]). These adverse events include bruising more easily than normal; red or purple, flat, pinhead spots under the skin; severe paleness; unusual bleeding or bruising under the skin; swelling of the testicles; tingling of the skin; shingles (herpes zoster)†; inflammation of the brain and spinal cord (encephalitis)†; inflammation of the coverings of the brain and spinal cord (meningitis)†, severe skin disorders; skin infection; stroke; seizures without a fever; joint pain and/or swelling (which could be transient or chronic); inflammation of the lung (pneumonia/pneumonitis); and chickenpox (varicella).

† Can be from naturally occurring chickenpox or the vaccine in healthy individuals or individuals with lowered immunity in those given VARIVAX®.

The doctor has a more complete list of side effects for ProQuad® and for the vaccine components for ProQuad® (M-M-R® II and VARIVAX®).

Tell the doctor promptly about any of these or any other unusual symptoms. If the condition persists or worsens, seek medical attention.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Merck Canada Inc. cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>) and send it to your local Health Unit.

Storage:

Keep out of reach and sight of children.

If you want more information about ProQuad®:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.merck.ca, or by calling 1-800-567-2594.

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