

PART III: CONSUMER INFORMATION**ProQuad®****Measles, Mumps, Rubella and Varicella
Virus Vaccine Live**

This leaflet is part III of a three-part “Product Monograph” published when ProQuad® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ProQuad®. Contact your doctor or pharmacist if you have any questions about the vaccine.

ABOUT THIS VACCINE**What the vaccine is used for:**

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

What it does:

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

Measles (rubeola) 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 (German measles) 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.

Varicella (chickenpox) 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 varicella

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 from varicella have significantly fallen since the introduction of a varicella vaccine in 1995.

What the medicinal ingredient is:

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

What the important nonmedicinal ingredients are:

ProQuad® contains gelatine, 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.

WARNINGS AND PRECAUTIONS**When it should not be used:**

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)

What should the doctor be told before my child is vaccinated with ProQuad®?

Tell the doctor about any medical problems your child has or has had, and about any allergies (especially to neomycin).

Tell the doctor if your child has a history of seizures or a brain injury, a low blood platelet count, or has received blood or plasma transfusions or administration of human serum globulin within the last 5 months.

The Oka/Merck strain of varicella virus has been shown to be transmitted from recipients of varicella vaccine to people at risk

of catching varicella, although this has occurred rarely. This strain of varicella virus is in ProQuad[®]. Whenever possible, individuals who have been vaccinated with ProQuad[®] should attempt to avoid contact, for up to 6 weeks following the vaccination, with people for whom the disease may be particularly serious. These individuals include:

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

Tell the doctor if there is anyone who falls into one of the categories above and is expected to be in contact with the vaccine recipient.

ProQuad[®] may be used for vaccination against measles, mumps, rubella, and varicella. The appropriate time and number of injections will be determined by your doctor using appropriate official recommendations.

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.

INTERACTIONS WITH THIS VACCINE

Can my child be vaccinated with ProQuad[®] and other vaccines at the same time?

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).

Can my child have medical tests with ProQuad[®]?

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[®].

Can my child be vaccinated with ProQuad[®] and receive other medicines at the same time?

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 varicella infection has been associated with Reye Syndrome (see ABOUT THIS VACCINE, What it does)

PROPER USE OF THIS VACCINE

What is the vaccination schedule for ProQuad[®]?

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:

There are no data with regard to overdose.

In case of overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Your doctor will decide when to give the missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

What undesirable effects may ProQuad[®] have?

Like all vaccines, ProQuad[®] can have side effects.

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 bronchiolitis; 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[†] and acute disseminated encephalomyelitis); 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.

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Reporting Suspected Vaccine Adverse Events

For the general public:

If you suspect you have had a serious or unexpected event following receipt of a vaccine, please ask your healthcare professional to complete the Adverse Events Following Immunization (AEFI) Form and send it to your local [health unit](#) in your province/territory.

For healthcare professionals:

If a patient experiences an adverse event following immunization, please complete the Adverse Events Following Immunization (AEFI) Form and send it to your local [health unit](#) in your province/territory.

If you have any questions or have difficulty contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada:

Toll-free telephone: 1-866-844-0018

Toll-free fax: 1-866-844-5931

By email: caefi@phac-aspc.gc.ca

NOTE: Should you require information related to the management of the adverse events, please contact your health professional before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.

MORE INFORMATION

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 Consumer Information by visiting the Health Canada website or Merck Canada website www.merck.ca or by calling Merck Canada at 1 800-567-2594

To report an adverse event related to ProQuad[®], please contact 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

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