

# ProQuad<sup>®</sup>

*Measles, Mumps, Rubella and Varicella Virus Vaccine Live*  
Single dose vial

## What is in this leaflet

This leaflet answers some common questions about ProQuad. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the risks of you or your child being given ProQuad against the benefits they expect it will have for you.

If you have any concerns about being given this vaccine, ask your doctor.

Keep this leaflet with the medicine. You may need to read it again.

## What ProQuad is used for

ProQuad is a vaccine used to help protect people from getting measles, mumps, rubella (German measles) and varicella (chickenpox). It should be given to children 12 months through 12 years of age.

Protection against these infections is important as they can cause serious problems in some people.

Measles is a serious disease that is very easily passed from one person to another. It causes a high fever (temperature), 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 school children and teenagers who catch measles.

Mumps is easily passed from one person to another and causes fever, headache, and swollen, painful glands under the jaw (salivary glands). Mumps 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 one person in every 10 who catch it. About one 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.

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's 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.

ProQuad contains weakened strains of living measles, mumps, rubella and varicella viruses. These strains of live viruses cause either mild or no symptoms of infection. When injected the vaccine causes the body to produce its own protection by making disease-fighting substances (antibodies) against these infections. If a vaccinated child comes into contact with measles, mumps, rubella or varicella virus, the body is usually ready, and produces antibodies to destroy the virus. However, as with all vaccines, 100% protection against measles, mumps, rubella and varicella cannot be guaranteed. Also it may take up to 4-6 weeks for maximum protection to develop, so occasionally infections may occur during this time.

The chance of a severe reaction from ProQuad is very small, but the risks from **not** being vaccinated are very serious.

## **Before you or your child are given ProQuad**

### **When you or your child must not be given it**

Do not have the vaccine if you have an allergy to ProQuad or any of the ingredients listed at the end of this leaflet.

Do not have ProQuad if you have a serious allergy to:

- the antibiotic neomycin

### **Do not have ProQuad if:**

- you have an infection with fever (high temperature)
- you have active untreated tuberculosis (TB)
- you are taking medicines which decrease the body's immune defence system (eg, corticosteroids, cyclosporin, cancer medicines).  
This does not include taking corticosteroids (eg, cortisone, prednisone) as replacement therapy for Addison's disease.
- you have diseases which decrease the body's immune defence system, such as cancers of the blood cells (eg, leukaemia, lymphoma) and AIDS.

Do not have ProQuad if you are pregnant. Also, do not become pregnant for 3 months after being given the vaccine.

Do not have ProQuad if the expiry date on the pack has passed. If the vaccine is used after the expiry date has passed, it may not work.

If you are not sure whether you or your child should have ProQuad, talk to your doctor.

### **Before you or your child are given it**

Tell the doctor if you:

1. have the following medical conditions or a family history of them:
  - febrile convulsions (fits or seizures due to a high temperature)

- brain damage
  - epilepsy
2. have recently had a blood transfusion.  
Your doctor may need to delay giving the vaccine for 3 months.
  3. have been given human serum globulin within the last 3 months
  4. are breast-feeding.  
Your doctor will discuss the possible risks and benefits of you being given ProQuad while breast-feeding.
  5. have any allergies to any other medicines or vaccines, or any other substances, such as foods, preservatives or dyes.

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.

If you have not told your doctor about any of the above, tell them before you or your child are given ProQuad.

### **Taking other medicines**

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

ProQuad may not work as well as it should if you or your child are taking medicines that decrease the immune system, such as corticosteroids (eg. prednisone) or cyclosporin.

Your doctor will advise you if you are taking any of these or other medicines that decrease the immune system. Your doctor will decide whether or not to give the vaccine.

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's syndrome (see What ProQuad is Used For).

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.

## **How ProQuad is given**

### **How much is given**

The entire contents of the vial.

### **How it is given**

ProQuad is injected just under the skin (subcutaneously) of the upper arm by a doctor or trained nurse.

The vaccine should **not** be injected directly into veins (intravenously).

### **Vaccination schedule**

ProQuad is given by 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.

### **If you or your child miss a dose**

If you or your child miss a scheduled dose, talk to your doctor and arrange another visit as soon as possible.

## **Adverse Effects**

Tell your doctor as soon as possible if you or your child does not feel well during or after having had an injection of ProQuad.

ProQuad helps protect most people from measles, mumps, rubella and varicella, but it may have unwanted adverse effects in a few people. All medicines and vaccines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor to answer any questions you may have.

### **Tell your doctor if the vaccine recipient has any of the following and they are troublesome or ongoing:**

- pain, tenderness or soreness at the injection site
- local reaction around the injection site such as soreness, redness, swelling or bruising
- fever
- diarrhoea
- vomiting
- rash including measles or varicella like rash, viral exanthema, and injection site rash
- irritability
- upper respiratory infection

These are the more common adverse effects of ProQuad. For the most part these have been mild. They usually improve or disappear within a few days.

**Other less common side effects have been reported with ProQuad, and some of these were serious. These included:**

- allergic reactions (see below)
- seizures with fever;
- cough and bronchiolitis;
- unsteadiness walking

Other adverse events have been reported with the use of at least one of the following: ProQuad, M-M-R<sup>®</sup> II, the monovalent components of M-M-R II, or VARIVAX<sup>®</sup>. 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, herpes zoster (shingles); inflammation of the brain (encephalitis); 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 varicella (chickenpox).

Tell your doctor immediately if you notice any of the above.

These are serious adverse effects. You may need urgent medical attention. Serious adverse effects are rare.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if the vaccine recipient gets any of the following:

- a seizure or convulsion, which may or may not be accompanied by a very high fever
- headache and fever, progressing to hallucinations, confusion, stiff neck and sensitivity to light
- pain, numbness, or tingling of the hands, arms, legs or feet

These are serious adverse effects. You may need urgent medical attention. Serious adverse effects are rare.

### **Allergic Reaction:**

As with all vaccines given by injection, there is a very small risk of a serious allergic reaction.

Tell your doctor immediately or go to accident and emergency if you notice any of the following:

- swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing
- pinkish, itchy swellings on the skin, also called hives or nettlerash
- skin rash, itchiness

If you have these you may have had a serious allergic reaction to ProQuad. You may need urgent medical attention or hospitalisation. Most of these adverse effects occur within 15-30 minutes of vaccination, before you or your child leave the doctor's surgery or clinic.

Other adverse effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You or your child may not experience any of them.

## **Storage**

ProQuad is usually stored in the doctor's surgery or clinic, or at the pharmacy. However if you need to store ProQuad:

- Keep it where children cannot reach it.
- Keep it in a refrigerator where the temperature is 2° to 8°C (36° to 46°F) or colder.
- Protect the injection from light by keeping it in the original pack until it is time for it to be given.

## **Product description**

### **What it looks like**

ProQuad comes as white to pale yellow powder in glass vials. It is reconstituted with a special diluent to make a solution suitable for injection.

### **Ingredients**

The active ingredients of ProQuad are weakened strains of measles, mumps, rubella (German measles) and varicella (chickenpox) viruses.

#### Inactive ingredients:

Sucrose, hydrolysed gelatin, urea, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate, human albumin, sodium bicarbonate, potassium phosphate, potassium chloride.

The product also contains residual components of MRC-5 cells, neomycin, bovine serum albumin, and other buffer and cell growth media ingredients.

ProQuad does not contain any preservatives.

## **Supplier**

ProQuad is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Ltd,  
P O Box 99851  
Newmarket  
Auckland  
NEW ZEALAND

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