

ProQuad®

Measles, Mumps, Rubella and Varicella [Oka/Merck] Virus Vaccine Live, Refrigerator-stable formulation

Consumer Medicine Information

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 your child being given ProQuad against the benefits they expect it will have for your child.

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

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 chicken pox. It can be given to children aged 12 months to 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 causes a high fever (temperature), runny nose, cough, conjunctivitis and a rash. It usually lasts for about 1 to 2 weeks. It is very easily passed from one person to another in the tiny droplets of moisture which are expelled during coughing or sneezing. 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 causes fever, headache, and swollen, painful glands under the jaw (salivary glands) and usually lasts several days. It is easily passed from one person to another by the tiny droplets of moisture expelled during coughing or sneezing. Mumps can sometimes be a very serious disease, causing 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, but can cause sterility in rare cases. 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 2 or 3 days. Rubella is very dangerous if a pregnant woman catches it. Pregnant women who catch rubella can have babies who are stillborn, or have heart disease, blindness, deafness, or problems with learning. Rubella is also spread to others in the tiny

droplets of moisture expelled during coughing or sneezing.

Chickenpox (Varicella) is an infectious disease caused by the varicella-zoster virus, or otherwise known as varicella virus. It occurs in millions of people around the world each year, most often in children 5 to 9 years of age. Chickenpox is easily passed from one person to another. It is commonly spread from person to person through the air by sneezing or coughing. Once a person is infected, it usually takes about 2 to 3 weeks before symptoms of the infection start.

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 groups 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.

Although chickenpox is generally a fairly harmless infection, it may be associated with serious complications and/or rarely death. In children, the most common complications are bacterial skin infections. Less frequent but very serious complications include pneumonia, inflammation of the brain (encephalitis), Reye Syndrome (which causes brain and liver damage), and death. Severe disease and serious complications

are more likely to occur in teenagers and adults.

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 chickenpox 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.

It is not known whether ProQuad will prevent measles, mumps, rubella or chickenpox if it is given after you have been exposed to the natural measles, mumps, rubella or varicella virus. Therefore, vaccination before exposure is the best way to help protect against infection and possible serious complications.

Only one injection of ProQuad is needed to help protect against chickenpox in children aged 12 months through 12 years.

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

Before ProQuad is given

When your child must not be given it

Do not let your child have the vaccine if your child had an

allergy to ProQuad or any of the ingredients listed at the end of this leaflet, including gelatin.

Do not let your child have ProQuad if your child has a serious allergy to:

- the antibiotic neomycin.

Symptoms of a serious allergic reaction include swelling of the face, lips, tongue, throat, difficulty in breathing, or hives.

Do not let your child have ProQuad if:

- **your child has an infection with fever (high temperature)**
- **your child has active untreated tuberculosis (TB)**
- **your child is 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.

- **your child has diseases which decrease the body's immune defence system, such as blood disorders, cancers of the blood cells or lymph system (eg, leukaemia, lymphoma) and HIV/AIDS**
- **your child has a family history of immune deficiency**
- **your child is pregnant**
Pregnancy should be avoided for 3 months following vaccination.
- **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 your child should have ProQuad, talk to your doctor.

Do not give ProQuad to children under 12 months of age.

The safety and effectiveness of ProQuad in children below the age of 12 months have not been established.

Before your child is given it

Tell your doctor if:

1. your child has the following medical conditions or a family history of them:

- febrile convulsions (fits or seizures due to a high temperature)
- brain damage
- epilepsy
- low blood platelet count
- seizures

2. your child has a history of serious allergy to eggs

The strains of measles and mumps viruses used to make ProQuad are grown in egg-derived cultures.

3. your child has received blood or plasma transfusions or immune globulins within the past three months

Your doctor may decide to delay the injection of ProQuad.

4. your child is about to have a tuberculin test

This should be given either before or at the same time as the injection of ProQuad.

5. your child is breast-feeding

The vaccine should not be given if the recipient is breast-feeding or intends to breast-feed.

6. your child has any allergies to any other medicines especially to neomycin or vaccines, or any other substances, such as foods, preservatives or dyes.

7. your child has a blood-clotting disorder or bleeds or bruises more easily. In this case, your doctor will give your child the vaccine under the skin (subcutaneously).

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

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.

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

Taking other medicines

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

ProQuad should not be given to children who are using the following:

- medicines that decrease the immune system, such as corticosteroids (eg. prednisone), cyclosporine, or cancer medicines
- aspirin or other salicylate medicines

Your doctor will advise you whether your child is receiving any of these medicines.

Some medicines should not be used for 6 to 8 weeks after

receiving ProQuad. These include:

- aspirin or other salicylates. A serious condition called Reye Syndrome has been reported following the use of aspirin or other salicylate medicines during a natural chickenpox infection. Therefore, aspirin or other salicylates should be avoided for 6 weeks following vaccination with ProQuad.
- Immune globulins. Your doctor will discuss with you the possible risks and benefits of having immune globulin injections in the 2 months following vaccination with ProQuad.

Use with other vaccines

ProQuad can be given at the same time as Haemophilus b conjugate, hepatitis B, pneumococcal 7-valent conjugate, and hepatitis A (inactivated) vaccines. The injections should be given at different places on the body and using separate syringes. At least one month should elapse between a dose of ProQuad and all other vaccines. If a second dose of a varicella-containing vaccine is given, there should be a minimum of 1 month between doses. Your doctor will decide if ProQuad should be given with other vaccines.

How ProQuad is given

How much is given

The entire contents of the vial.

How it is given

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

If your child has a blood-clotting disorder or bleeds or bruises more easily, the vaccine should be given

under the skin because bleeding may occur following administration into the muscle.

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

Vaccination schedule

ProQuad is given by injection to persons aged 12 months through 12 years of age. The appropriate time and number of injections will be determined by your doctor.

If your child misses a dose

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

After your child has been given ProQuad

Things you must do

Keep a record of your child's vaccinations and update this after each injection.

Keep your child's follow-up appointment with your doctor or clinic.

If your child is about to be injected with any immune globulin (including varicella zoster) and your child has been injected with ProQuad within the past 2 months, tell your doctor.

If your child has been given ProQuad, avoid them coming into contact, for 6 weeks, with a person who falls into one of the following categories:

- People with a weakened immune system
- Pregnant women who have never had chickenpox
- Newborn babies whose mothers have never had chickenpox

These people may be at risk of catching chickenpox from your child.

Things you must not do

Do not give aspirin or other salicylate medicines to your child for 6 weeks after being given ProQuad.

A serious condition called Reye Syndrome has been reported following the use of aspirin or other salicylate medicines during a natural chickenpox infection.

Side Effects

Tell your doctor or pharmacist as soon as possible if 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 side effects in a few children. All medicines and vaccines can have side effects. Sometimes they are serious, most of the time they are not. Your child may need medical treatment if they get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if your child 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
- Vomiting and diarrhoea
- Rash including measles or varicella like rash, viral skin rash and injection site rash
- Irritability
- Upper respiratory tract infection (URTI)
- Swelling of the epididymis, a part of the male reproductive system
- viral exanthema
- vomiting and diarrhea

These are the more common side 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 at least one of the following: ProQuad, M-M-R II, the monovalent components of M-M-R II or VARIVAX. 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 swelling or infection of the brain (encephalitis)†
- Inflammation of the coverings of the brain and spinal cord (meningitis)†
- Severe skin disorders
- Skin infection
- Chickenpox (varicella)
- Stroke
- Seizures without a fever
- Joint pain and/or swelling (which could be transient or chronic)
- Inflammation of the lung (pneumonia/pneumonitis)

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

Tell your doctor immediately if you notice any of the above or any other

unusual symptoms. If the condition persists or worsens, seek medical attention.

These are serious side effects. Your child may need urgent medical attention. Serious side effects are rare.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if you or your child get 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
- fainting
- severe blisters with bleeding in the lips, eyes, mouth, nose or genitals

These are serious side effects. You may need urgent medical attention. Serious side 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:

- wheezing or shortness of breath
- swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing
- swelling of the hands, feet, or ankles
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- skin rash, itchiness

If your child has these, your child may have had a serious allergic reaction to ProQuad. Your child may need urgent medical attention or hospitalisation. Most of these side effects occur within 15-30 minutes of vaccination, before your

child leave the doctor's surgery or clinic.

Other side 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 side effects. 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 the refrigerator where the temperature is between 2°C and 8°C, but not in the door compartment, until ready to use. ProQuad is stable for up to 18 months when stored in the refrigerator. THE VACCINE SHOULD NOT BE FROZEN.**
- **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 viruses.

Inactive ingredients:

- sucrose
- hydrolysed gelatin (porcine)

- urea
- sodium chloride
- sorbitol
- monosodium glutamate monohydrate
- monobasic sodium phosphate
- dibasic sodium phosphate
- sodium bicarbonate
- monobasic potassium phosphate
- potassium chloride
- dibasic potassium phosphate
- neomycin
- phenolsulfonphthalein

This product also contains residual components of recombinant human albumin, bovine serum albumin and other buffer and media ingredients.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

Supplier

ProQuad is supplied in Australia by:
Seqirus (Australia) Pty Ltd
63 Poplar Road
PARKVILLE VIC 3052

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Australian Register Numbers:

ProQuad vial AUST R 126153

ProQuad vial and sterile diluent syringe AUST R 126157

ProQuad vial and sterile diluent vial AUST R 337388

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