

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this vaccine, speak to your doctor, nurse or pharmacist.

1. Why is my child being given ProQuad?

ProQuad is a vaccine given to help prevent infection against measles, mumps, rubella and varicella in children aged 12 months to 12 years of age.

For more information, see Section [1. Why is my child being given ProQuad?](#) in the full CMI.

2. What should I know before my child is given ProQuad?

Do not give ProQuad to your child if they have ever had an allergic reaction to ProQuad, the antibiotic neomycin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if your child has any medical conditions, takes any other medicines, or is pregnant or is breastfeeding.

For more information, see Section [2. What should I know before my child is given ProQuad?](#) in the full CMI.

3. What if my child is taking other medicines?

Some medicines may interfere with ProQuad and affect how it works. Tell your doctor, nurse or pharmacist if your child is taking, has recently taken or might take any other vaccines or medicines, including medicines obtained without a prescription.

A list of these medicines is in Section [3. What if my child is taking other medicines?](#) in the full CMI.

4. How is my child given ProQuad?

- A doctor or nurse will give your child this vaccine as an injection just under the skin or into the muscle (subcutaneously or intramuscularly) of the upper arm or the upper thigh.

More instructions can be found in Section [4. How is my child given ProQuad?](#) in the full CMI.

5. What should I know after my child is given ProQuad?

Things you should do	<ul style="list-style-type: none">• 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.• Tell your doctor 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.
Things you should not do	<ul style="list-style-type: none">• 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.
Looking after your vaccine	<ul style="list-style-type: none">• It is unlikely that you would be asked to store ProQuad. If you are, 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.• The vaccine should not be frozen.

For more information, see Section [5. What should I know after my child is given ProQuad?](#) in the full CMI.

6. Are there any side effects?

Common side effects include: pain, tenderness or soreness at the injection site; local reaction around the injection site such as soreness, redness, swelling or bruising; fever, vomiting and diarrhea; rash including measles or varicella like rash, viral skin rash and injection site rash

Serious side effects can include signs of allergic reaction such as: cough, 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; and skin rash, itchiness

For a complete list of side effects and more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about using ProQuad. You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about using ProQuad.

Where to find information in this leaflet:

1. Why is my child being given ProQuad?
2. What should I know before my child is given ProQuad?
3. What if my child is taking other medicines?
4. How is my child given ProQuad?
5. What should I know after my child is given ProQuad?
6. Are there any side effects?
7. Product details

1. Why is my child being given ProQuad?

ProQuad is a vaccine used to help protect people from getting measles, mumps, rubella 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.

What is measles?

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.

What is mumps?

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.

What is rubella?

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.

What is chickenpox?

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.

How it works

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.

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

2. What should I know before my child is given ProQuad?

Warnings

Do not give your child ProQuad if:

- Your child is allergic to ProQuad, or any of the ingredients listed at the end of this leaflet including gelatin.
- 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.

- Always check the ingredients to make sure your child can get this vaccine.
- 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 (e.g., corticosteroids, cyclosporin, cancer medicines)

This does not include taking corticosteroids (e.g., 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 (e.g., leukaemia, lymphoma) and HIV/AIDS
- Your child has a family history of immune deficiency
- Your child is pregnant

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

Check with your doctor if 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
- has a history of serious allergy to eggs.
- has received blood or plasma transfusions or immune globulins within the past three months.

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

Your doctor may decide to delay the injection of ProQuad.

- is about to have a tuberculin test

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

- has any allergies to any other medicines especially to neomycin or vaccines, or any other substances, such as foods, preservatives or dyes.
- 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).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Pregnancy should be avoided for 3 months following vaccination.

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

In these situations, talk to your doctor.

Use in children under 12 months of age

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

3. What if my child is taking other medicines?

Tell your doctor, nurse or pharmacist if your child has been given any other vaccines or is taking any other medicines, including any medicines, vitamins or supplements 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 (e.g. 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.

Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vitamins or supplements your child is taking and if these affect ProQuad.

4. How is my child given ProQuad?

How much is given

- The entire contents of the vial.
- 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 (intravascularly).

When is it given

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.

5. What should I know after my child is given ProQuad?

Things you should 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 chickenpoxThese people may be at risk of catching chickenpox from your child.

Remind any doctor, nurse or pharmacist you visit that your child has been given ProQuad.

Things you should 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.

Looking after your vaccine

It is unlikely that you will be asked to store ProQuad. 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.

6. Are there any side effects?

All medicines, including vaccines, can have side effects. If your child experiences any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• 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	<p>Speak to your doctor if your child has any of these less serious side effects and they worry you.</p> <p>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.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> 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 Unsteadiness walking <p>As with all vaccines given by injection, there is a very small risk of a serious allergic reaction. Symptoms of an allergic reaction include:</p> <ul style="list-style-type: none"> Cough, 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 Skin rash, itchiness <p>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 leaves the doctor's surgery or clinic.</p> <p>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:</p> <ul style="list-style-type: none"> 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 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if your child gets any of these serious side effects.</p> <p>Your child may need urgent medical attention. Serious side effects are rare.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> Skin infection Chickenpox (varicella) Stroke Seizures with or without a fever Joint pain and/or swelling (which could be transient or chronic) Inflammation of the lung (pneumonia/pneumonitis) <p>†Can be from naturally occurring chickenpox or the vaccine in healthy individuals or individuals with lowered immunity in those given VARIVAX.</p>	

Tell your child's doctor, nurse or pharmacist if you notice anything else that may be making your child feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this vaccine.

7. Product details

This vaccine is only available with a doctor's prescription.

What ProQuad contains

Active ingredient (main ingredient)	Weakened strains of measles, mumps, rubella and varicella viruses.
Other ingredients (inactive ingredients)	<p>Sucrose</p> <p>Hydrolysed porcine gelatin*</p> <p>Urea</p> <p>Sodium chloride</p> <p>Sorbitol</p> <p>Monosodium glutamate monohydrate</p> <p>Monobasic sodium phosphate</p> <p>Dibasic sodium phosphate</p> <p>Sodium bicarbonate</p> <p>Monobasic potassium phosphate</p> <p>Potassium chloride</p> <p>Dibasic potassium phosphate</p> <p>Neomycin</p> <p>Phenolsulfonphthalein</p> <p>*contains sulfites</p>

	The diluent contains water for injections
Potential allergens	Neomycin

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.

Do not take this vaccine if you are allergic to any of these ingredients.

What ProQuad looks like

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

ProQuad vial (AUST R 126153)

ProQuad vial and sterile diluent syringe (AUST R 126157)

ProQuad vial and sterile diluent vial (AUST R 337388)

Not all presentations and pack sizes may be marketed.

Who distributes ProQuad

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road

Macquarie Park NSW 2113

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