

Package leaflet: Information for the User

ProQuad®

Powder and solvent for suspension for injection in a pre-filled syringe

Measles, mumps, rubella and varicella vaccine (live)

Read all of this leaflet carefully before you or your child is vaccinated because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others.
- If you get any of the side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What ProQuad is and what it is used for
2. What you need to know before you receive ProQuad
3. How to use ProQuad
4. Possible side effects
5. How to store ProQuad
6. Contents of the pack and other information

1. What ProQuad is and what it is used for

ProQuad is a vaccine containing measles, mumps, rubella, and chickenpox (varicella) viruses that have been weakened. When a person is given the vaccine, the immune system (the body's natural defences) will make antibodies against the measles, mumps, rubella, and varicella viruses. The antibodies help protect against diseases caused by these viruses.

ProQuad is given to help protect your child against measles, mumps, rubella, and chickenpox (varicella). The vaccine may be administered to persons from 12 months of age.

ProQuad may also be administered to infants from 9 months of age under special circumstances (to conform with national vaccination schedules, outbreak situations, or travel to a region with high prevalence of measles).

Although ProQuad contains live viruses, they are too weak to cause measles, mumps, rubella, or chickenpox (varicella) in healthy people.

2. What you need to know before you receive ProQuad

Do not use ProQuad

- If the person to be vaccinated is allergic to any varicella vaccine or measles, mumps, or rubella vaccine or to any of the ingredients of this vaccine (listed in section 6) including neomycin.
- If the person to be vaccinated has a blood disorder or any type of cancer that affects the immune system.
- If the person to be vaccinated is receiving treatment or taking medications that may weaken the immune system (except low-dose corticosteroid therapy for asthma or replacement therapy).
- If the person to be vaccinated has a weakened immune system because of a disease (including AIDS).
- If the person to be vaccinated has a family history of congenital or hereditary immunodeficiency, unless the immune competence of this person is demonstrated.
- If the person to be vaccinated has active untreated tuberculosis.

- If the person to be vaccinated has any illness with fever higher than 38.5°C; however, low-grade fever itself is not a reason to delay vaccination.
- If the person to be vaccinated is pregnant (in addition, pregnancy should be avoided for 1 month after vaccination, see Pregnancy and breast-feeding).

Warnings and precaution

If the person to be vaccinated has experienced any of the following, talk to the doctor or pharmacist before ProQuad is given:

- An allergic reaction to eggs or anything that contained egg.
- A history or family history of allergies or of convulsions (fits).
- A side effect after vaccination with measles, mumps, and/or rubella-containing vaccines that involved easy bruising or bleeding for longer than usual.
- An infection with Human Immunodeficiency Virus (HIV) without showing symptoms of HIV disease. However, vaccination may be less effective than for uninfected persons (see **Do not use ProQuad**).

If you have a blood clotting disorder or low levels of platelets in your blood, the injection will be given under the skin.

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 lowered resistance to diseases.
- Pregnant women who have either not had chickenpox or have not been vaccinated against chickenpox.
- Newborn infants of mothers who have either not had chickenpox or have not been vaccinated against 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 your 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.

As with other vaccines, ProQuad may not completely protect all persons who are vaccinated. Also, if the person to be vaccinated has already been exposed to the measles, mumps, rubella, or varicella virus but is not yet ill, ProQuad may not be able to prevent the illness from appearing.

Other medicines and ProQuad

Tell your doctor or pharmacist if the person to be vaccinated is taking or has recently taken any other medicines (or other vaccines).

ProQuad can be given at the same time as other childhood vaccines such as Prevenar, and/or hepatitis A vaccine, or with vaccines containing diphtheria, tetanus, acellular pertussis, *Haemophilus influenzae* type b, inactivated poliomyelitis, or hepatitis B. A different place for the injection will be used for each vaccine.

The doctor may delay vaccination for at least 3 months following blood or plasma transfusions, or administration of immune globulin (Ig), or varicella-zoster immune globulin (VZIG). After vaccination with ProQuad, Ig or VZIG should not be given for 1 month, unless your doctor tells you otherwise.

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.

Tell the doctor if the person to be vaccinated 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.

The use of salicylates (for example, acetylsalicylic acid, a substance present in many medicines used to relieve pain and lower fever) should be avoided for 6 weeks following vaccination with ProQuad.

Pregnancy and breast-feeding

ProQuad should not be given to pregnant women. Women of child-bearing age should take the necessary precautions to avoid pregnancy for 1 month following vaccination.

Persons who are breast-feeding or who intend to breast-feed should tell the doctor. The doctor will decide if ProQuad should be given.

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this vaccine.

ProQuad contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

ProQuad contains potassium

This medicine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.

ProQuad contains sorbitol

This medicine contains 16 mg sorbitol per dose. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.

3. How to use ProQuad

ProQuad should be injected into the muscle or under the skin either in the area of the outer thigh or of the upper arm.

Usually for injections into the muscle the thigh area is preferred in young children, whereas for older individuals the upper arm area is the preferred injection site.

If the person to be vaccinated has a blood clotting disorder or low levels of platelets, the vaccine should be given under the skin because bleeding may occur following administration into the muscle.

ProQuad is not to be injected directly into any blood vessel.

ProQuad is given by injection as follows:

- Infants between 9 and 12 months of age:
ProQuad may be administered from 9 months of age. To ensure optimal protection against chickenpox and measles, two doses of ProQuad should be given at least three months apart.
- Individuals 12 months of age and older:
To ensure optimal protection against chickenpox, two doses of ProQuad should be given at least one month apart.

The appropriate time and number of injections will be determined by your doctor in accordance with official recommendations.

Reconstitution instructions intended for medical and healthcare professionals are included at the end of the leaflet

If you forget to take ProQuad

Your doctor will decide when to give the missed dose.

4. Possible side effects

Like all vaccines and medicines, this vaccine can cause side effects, although not everybody gets them.

Allergic reactions (hives) may occur. Some of these reactions may be serious and may include difficulty in breathing or swallowing. If the vaccinated person has an allergic reaction, call your doctor right away.

Other side effects have been reported following administration of ProQuad and some of these were serious. These included:

- Uncommon (may affect up to 1 in 100 people): seizures with a fever.
- Rare (may affect up to 1 in 1,000 people): unsteadiness with walking.

The following other side effects reported with the use of ProQuad were:

- Very common (may affect more than 1 in 10 people): injection site complaints including pain/tenderness/soreness, redness; fever (38.9°C or higher);
- Common (may affect up to 1 in 10 people): injection site complaints including swelling or bruising; irritability; rash (including measles-like rash, varicella-like rash, and injection-site rash); upper respiratory infection; vomiting and diarrhoea.

Other side effects have been reported with the use of at least one of the following: ProQuad, previous formulations of monovalent and of the combined measles, mumps, and rubella vaccines manufactured by Merck Sharp & Dohme LLC, Rahway, NJ 07065, USA (herein after MSD), or Varicella Vaccine live (Oka/Merck). These adverse events include:

- Uncommon (may affect up to 1 in 100 people): cough.
- Rare (may affect up to 1 in 1,000 people): skin infection; chickenpox (varicella).
- Not known (frequency cannot be estimated from the available data):
 - infection or inflammation of the brain (encephalitis) has been observed following vaccination with live attenuated measles, mumps, rubella and varicella vaccines. In a few cases, this condition has been fatal, especially in people with weakened immune systems (as noted in section 2, ProQuad must not be used in patients with weakened immune systems). Seek immediate medical attention if you or your child develop loss or reduced levels of consciousness, convulsions or loss of control of bodily movements, accompanied by fever and headache, as these might be a sign of infection or inflammation of the brain. Inform your doctor or pharmacist that you or your child received ProQuad.
 - unusual bleeding or bruising under the skin, swelling of the testicles; tingling of the skin, herpes zoster (shingles); inflammation of the coverings of the brain and spinal cord not caused by bacterial infection (aseptic meningitis), severe skin disorders; stroke; seizures without a fever; joint pain and/or swelling (which could be transient or chronic); and inflammation of the lung (pneumonia/pneumonitis).

The doctor has a more complete list of side effects for ProQuad and for the vaccine components for ProQuad (the measles, mumps, and rubella vaccine manufactured by MSD and Varicella Vaccine live (Oka/Merck)).

Reporting of side effects

If the vaccinated person gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play

or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ProQuad

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the outer carton after EXP. The expiry dates refers to the last day of that month.

Store and transport refrigerated (2°C-8°C).

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What ProQuad contains

After reconstitution, one dose (0.5 mL) contains:

The active substances are:

Measles virus¹ Enders' Edmonston strain (live, attenuated) not less than 3.00 log₁₀ TCID₅₀ *

Mumps virus¹ Jeryl Lynn™ (Level B) strain (live, attenuated) ... not less than 4.30 log₁₀ TCID₅₀ *

Rubella virus² Wistar RA 27/3 strain (live, attenuated) not less than 3.00 log₁₀ TCID₅₀ *

Varicella virus³ Oka/Merck strain (live, attenuated)..... not less than 3.99 log₁₀ PFU**

*50% tissue culture infectious dose

**plaque-forming units

(¹) Produced in chick embryo cells.

(²) Produced in human diploid lung (WI-38) fibroblasts.

(³) Produced in human diploid cells (MRC-5).

The other ingredients are:

Powder

Sucrose, hydrolysed gelatin, urea, sodium chloride, sorbitol (E 420), monosodium glutamate, sodium phosphate, sodium bicarbonate, potassium phosphate, potassium chloride, medium 199 with Hanks' Salts, MEM, neomycin, phenol red, hydrochloric acid and sodium hydroxide.

Solvent

Water for injections.

What ProQuad looks like and contents of the pack

The vaccine is a powder for suspension for injection contained in a single-dose vial, which should be mixed with solvent provided with the vial of powder.

The powder is a white to pale yellow compact crystalline cake and the solvent is a clear colourless liquid.

ProQuad is available in pack of 1, 10 and 20. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London EC2M 6UR, United Kingdom.

Manufacturer Responsible for Batch Release:

Merck Sharp and Dohme, B.V., Waarderweg, 39, 2031 BN Haarlem, The Netherlands

For any information about this medicinal product, please contact the Marketing Authorisation Holder:

Merck Sharp & Dohme (UK) Limited
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The following information is intended for healthcare professionals only:

Before mixing with the solvent, the powder vaccine is a white to pale yellow compact crystalline cake. The solvent is a clear colourless liquid. When completely reconstituted, the vaccine is a clear pale yellow to light pink liquid.

To reconstitute the vaccine, use only the solvent supplied, because it is free of preservatives or other antiviral substances, which might inactivate the vaccine.

It is important to use a separate sterile syringe and needle for each individual to prevent transmission of infectious agents from one individual to another.

One needle should be used for reconstitution and a separate, new needle for injection.

ProQuad must not be mixed in a syringe with other vaccines.

Reconstitution instructions

To attach the needle, it should be firmly placed on the tip of the syringe and secured by rotating.

Inject the entire content of the solvent syringe into the vial containing the powder. Gently agitate to dissolve completely.

The reconstituted vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance prior to administration. In the event of either being observed, discard the vaccine.

It is recommended that the vaccine be administered immediately after reconstitution to minimize loss of potency. Discard if reconstituted vaccine is not used within 30 minutes.

Do not freeze the reconstituted vaccine.

Withdraw the entire content of the reconstituted vaccine from the vial into a syringe, change the needle, and inject the entire volume by subcutaneous or intramuscular route.

Any unused product or waste material should be disposed of in accordance with local requirements.

See also section 3 How to use ProQuad.

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