Patient Information ProQuad® (pronounced "pro kwod") Measles, Mumps, Rubella, Varicella Virus Vaccine Live Frozen Formulation

This is a summary of information about ProQuad®. You should read it before your child receives each dose of the vaccine. If you have any questions about the vaccine after reading this leaflet, you should ask your healthcare provider. This information does not take the place of talking about ProQuad with your healthcare provider.

What is ProQuad?

- ProQuad is a vaccine that helps prevent measles (rubeola), mumps, rubella (German measles), and chickenpox (varicella).
- It is for children 12 months to 12 years of age.
- ProQuad contains weakened live forms of measles virus, mumps virus, rubella virus, and chickenpox virus.
- ProQuad works by helping the immune system protect your child from getting measles, mumps, rubella, or chickenpox.
- ProQuad may not protect everyone who gets the vaccine.
- ProQuad does not treat measles, mumps, rubella, or chickenpox once your child has them.

What are measles, mumps, rubella, and chickenpox?

Measles is also known as rubeola. It is a serious illness. Measles virus can be passed to others if you have it. Measles can give you a high fever, cough, and a rash. The illness can last for 1 to 2 weeks. In rare cases, it can also cause an infection of the brain. This could lead to seizures, hearing loss, intellectual disability, and even death.

Mumps can also be passed to others. This virus can cause fever and headache. It can also make the glands under your jaw swell and be painful. The illness often lasts for several days. Sometimes, mumps can make the testicles swell and be painful. In some cases, it can cause meningitis, which is a swelling of the coverings of the brain and spinal cord.

Rubella is also known as German measles. It is often a mild illness. Rubella virus can cause a mild fever, swollen glands in the neck, pain and swelling in the joints, and a rash that lasts for a short time. It can be very dangerous if a pregnant woman catches it. Women who catch German measles when they are pregnant can have babies who are stillborn. Also, the babies may be blind or deaf, or have heart disease or intellectual disability.

Chickenpox is an illness that occurs most often in children who are 5 to 9 years old. It can be passed to others. The illness can include headache, fever, and general discomfort. Then an itchy rash occurs, which can turn into blisters. The most common complication is that the blisters can get infected. Less common but very serious complications can occur. These include pneumonia, inflammation of the brain, Reye syndrome (which affects the liver and the brain), and death. Severe disease and serious complications are more likely to occur in adolescents and adults.

Who should not get ProQuad?

Your child should not get ProQuad if he or she:

- is allergic to ProQuad or any of its ingredients. This includes gelatin or neomycin. (See the ingredient list at the end of this leaflet.)
- has a weakened immune system (which includes taking high doses of steroids by mouth or in a shot).

- has a fever.
- has active tuberculosis that is not treated.
- is pregnant or plans to get pregnant within the next 3 months.

What should I tell my child's healthcare provider before my child gets ProQuad?

Tell your healthcare provider if your child:

- has or had any medical problems.
- has a history of seizures or someone in your family has a history of seizures.
- has received blood or plasma transfusions or human serum globulin.
- takes any medicines. (This includes non-prescription medicines and dietary supplements.)
- has any allergies. (This includes allergies to neomycin or gelatin.)
- had an allergic reaction to any other vaccine.
- has or had a low blood platelet count.
- is allergic to eggs.
- has a family member with a weakened immune system.

How is ProQuad given?

ProQuad is a shot given in the arm or thigh.

Your child will get 2 doses on two different dates:

- The first shot is given at 12 to 15 months old but may be given anytime through 12 years old.
- The second shot is given at 4 to 6 years old.

There should be at least 1 month between a dose of a measles-containing vaccine and a dose of ProQuad. There should be at least 3 months between a dose of a varicella-containing vaccine and a dose of ProQuad.

Your healthcare provider will decide the best time and number of shots by using official recommendations.

If a dose is missed, your healthcare provider will let you know when your child should get it.

What should my child avoid when getting ProQuad?

Do not take aspirin or aspirin-containing products for 6 weeks after getting ProQuad.

It is possible to catch chickenpox from a person who has been vaccinated with ProQuad. For 6 weeks after getting ProQuad, your child should avoid close contact with the following:

- people who are not vaccinated or who didn't have chickenpox.
- people who have a weakened immune system.
- pregnant women who have never had chickenpox.
- newborn babies whose mothers have never had chickenpox.
- newborn babies born at less than 28 weeks of pregnancy.

What are the possible side effects of ProQuad?

The most common side effects reported after getting ProQuad are:

- pain, tenderness, soreness, redness, or swelling at the site of the shot
- fever
- irritability
- rash (including measles-like rash and chickenpox-like rash)

If your child has any of the following problems, tell your healthcare provider right away because these may be signs of an allergic reaction:

- trouble breathing
- wheezing
- hives
- rash

If your child has any side effects that worry you or seem to get worse, tell your healthcare provider right away.

These are not all the possible side effects of ProQuad. For more information, ask your healthcare provider. Contact your healthcare provider if your child has any new or unusual symptoms after receiving ProQuad.

Report the following to your healthcare provider.

- any side effects following vaccination
- exposure to ProQuad during pregnancy
- exposure to ProQuad during the 3 months before getting pregnant

You may also report any side effects directly to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or <u>www.vaers.hhs.gov</u>, or to Merck Sharp and Dohme LLC at 1-877-888-4231.

What are the ingredients of ProQuad?

Active Ingredients: weakened forms of the measles, mumps, rubella, and varicella viruses.

Inactive Ingredients: sucrose, hydrolyzed gelatin, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, recombinant human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride, potassium phosphate dibasic, and residual components from the manufacturing process: MRC-5 cells including DNA and protein, neomycin, bovine calf serum, and other buffer and media ingredients.

ProQuad does not contain any preservatives.

What else should I know about ProQuad?

If you would like more information, talk to your healthcare provider or call 1-800-622-4477.

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For patent information: www.msd.com/research/patent

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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