



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/433362/2020  
EMA/H/C/000622

## ProQuad (*measles, mumps, rubella and varicella vaccine (live)*)

An overview of ProQuad and why it is authorised in the EU

### What is ProQuad and what is it used for?

ProQuad is a vaccine against measles, mumps, rubella, and varicella (chickenpox).

ProQuad is given to children from 12 months of age to help protect them against measles, mumps, rubella, and chickenpox. ProQuad may also be given to children from 9 months of age in certain situations, for example as part of a national vaccination programme, during an outbreak or for travel to a region where measles is common.

### ProQuad contains attenuated (weakened) viruses for the diseases. How is ProQuad used?

ProQuad is injected into a muscle or under the skin, preferably in the thigh in younger children and in the upper arm in older children and adults. Rarely, in a child with a bleeding disorder, the vaccine is injected under the skin to prevent excessive bleeding.

For children above 12 months of age, one ProQuad injection is sufficient for protection against measles, mumps and rubella. To protect against chickenpox, a second injection needs to be given 1 to 3 months after the first one; this can be done either by giving a second dose of ProQuad or by giving a vaccine that only protects against chickenpox.

Children between 9 and 12 months of age should receive a second dose at least 3 months after the first dose for adequate protection against measles and chickenpox.

ProQuad can only be obtained with a prescription. It is used according to official recommendations, including recommendations about the number of doses and the interval between them.

### How does ProQuad work?

ProQuad contains weakened forms of the viruses that cause measles, mumps, rubella and chickenpox. When a person receives the vaccine, it triggers an immune response against the weakened viruses. Later, when the person comes into contact with the actual viruses, the immune system recognises them and is already prepared to attack the viruses and so protects the person from the disease.

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands  
**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)  
**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European  
Union



## **What benefits of ProQuad have been shown in studies??**

Because ProQuad contains well known weakened viruses, which are used in other vaccines, the company presented data from vaccines that are already on the market. Five main studies were carried out in 6,987 healthy children (aged 12 to 23 months). In these studies, after one dose, the response rates in children (measuring how well the immune system had responded to the viruses) were: 98% for measles, 96 to 99% for mumps, 99% for rubella and 91% for chickenpox. After the second dose, the rates were around 99% for measles, 100% for mumps, 98% for rubella, and 99% for chickenpox.

Another study in 1,620 children from 9 to 12 months of age showed that, after two doses of ProQuad given 3 months apart, the immune response against mumps, rubella and chickenpox in children who received the first dose at 9 months of age was comparable with those who received the first dose at 12 months of age. However, children who received the first dose at 9 months of age had a lower immune response against measles.

## **What are the risks associated with ProQuad?**

The most common side effects with ProQuad (which may affect more than 1 in 10 people) are fever, and pain and erythema (redness) at the site of injection. For the full list of side effects of ProQuad, see the package leaflet.

ProQuad must not be used in children who are hypersensitive (allergic) to any chickenpox vaccine or measles, mumps or rubella vaccine, or to any of the other ingredients including neomycin. It must not be used in children who have severely weakened immune systems. It must also not be used in a pregnant woman. For the full list of restrictions, see the package leaflet.

## **Why has ProQuad been approved?**

The European Medicines Agency decided that ProQuad's benefits are greater than its risks and it can be authorised for use in the EU in children above 12 months of age and in certain situations from 9 months of age, noting that a second vaccination against chickenpox should be given for full protection against the disease.

The Agency also recommended that the vaccine be authorised in children from 9 to 12 months of age only in certain situations, for example as part of a national vaccination programme, during an outbreak or for travel to a region where measles is common.

## **Other information about ProQuad**

ProQuad received a marketing authorisation valid throughout the EU on 6 April 2006.

Further information on ProQuad can be found on the Agency's website:  
[ema.europa.eu/medicines/human/EPAR/proquad](http://ema.europa.eu/medicines/human/EPAR/proquad).

This overview was last updated in 08-2020.