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EPAR summary for the public

M-M-RVaxPro

measles, mumps and rubella vaccine (live)

This is a summary of the European public assessment report (EPAR) for M-M-RVaxPro. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use M-M-RVaxPro.

For practical information about using M-M-RVaxPro, patients should read the package leaflet or contact their doctor or pharmacist.

What is M-M-RVaxPro and what is it used for?

M-M-RVaxPro is a vaccine used to protect adults and children aged 12 months or older against measles, mumps, and rubella (German measles). Under some special circumstances, it can also be used in babies as young as nine months.

M-M-RVaxPro contains live attenuated (weakened) measles, mumps and rubella viruses.

How is M-M-RVaxPro used?

M-M-RVaxPro is available as a powder and solvent that are made up into a suspension for injection.

It is given as one dose injected into a muscle or under the skin, preferably in the thighs of younger children and the shoulder in older children and adults. For people with thrombocytopenia (low blood platelet counts) or any problems with blood clotting, the vaccine should only be injected under the skin to avoid bleeding. People who did not respond to the first dose can be given a second dose after at least four weeks.

Babies between nine and 12 months can be given the vaccine if they are considered to be at special risk, for example, if there is an outbreak in a day-care centre or the baby is travelling to an area where measles is common. They should be re-vaccinated at between 12 and 15 months. They may also be given an additional vaccination against measles.

The vaccine can only be obtained with a prescription. It is given according to official recommendations.

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How does M-M-RVaxPro work?

M-M-RVaxPro is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. M-M-RVaxPro contains small amounts of weakened forms of the viruses that cause measles, mumps, and rubella. When a person is given the vaccine, the immune system recognises the weakened viruses as 'foreign' and makes antibodies against them. In the future, the immune system will be able to produce antibodies more quickly when it is exposed to any of these viruses. This will help to protect against diseases caused by these viruses.

What benefits of M-M-RVaxPro have been shown in studies?

M-M-RVaxPro has been shown in studies to be effective at triggering the production of a sufficient amount of antibodies to protect against measles, mumps, and rubella.

In a study of 1,279 children, M-M-RVaxPro triggered the same level of immune response as a comparator vaccine, with more than 98% of vaccinated patients having sufficient levels of antibodies against the three viruses. A second study in 1,997 children looking specifically at mumps showed that M-M-RVaxPro led to sufficient amounts of antibodies against mumps, while a third study in 776 children showed that immune responses triggered by M-M-RVaxPro were the same regardless of whether it was injected into a muscle or under the skin.

A fourth study in 1,620 babies was carried out with ProQuad (a vaccine that contains similar weakened viruses to those of M-M-RVaxPro). This study showed that, after the second dose, the production of antibodies against mumps and rubella in babies who started vaccination as young as nine months was similar to those of babies who started vaccination at 12 months. However, the immune response for measles was lower in babies who started vaccination at nine months.

What are the risks associated with M-M-RVaxPro?

The most common side effects with M-M-RVaxPro (seen in more than 1 patient in 10) are fever (38.5°C or higher), and injection site redness, pain and swelling. Injection site reactions were less common when the vaccine was injected into a muscle. For the full list of all side effects reported with M-M-RVaxPro, see the package leaflet.

M-M-RVaxPro should not be used in people who may be hypersensitive (allergic) to any measles, mumps or rubella vaccine, or to any of the ingredients, including neomycin (an antibiotic). M-M-RVaxPro must not be given during pregnancy, any illness with fever (over 38.5°C) or active untreated tuberculosis (TB). It must also not be given to patients with certain blood or immune diseases. For the full list of restrictions, see the package leaflet.

Why is M-M-RVaxPro approved?

The CHMP decided that M-M-RVaxPro's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of M-M-RVaxPro?

The company that makes M-M-RVaxPro will continue to monitor the side effects to see if using recombinant albumin in the manufacturing process of M-M-RVaxPro leads to side effects such as allergic reactions.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of M-M-RVaxPro have also been included in the summary of product characteristics and the package leaflet.

Other information about M-M-RVaxPro

The European Commission granted a marketing authorisation valid throughout the European Union for M-M-RVaxPro on 5 May 2006.

The full EPAR for M-M-RVaxPro can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with M-M-Rvaxpro, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2017.