

Package leaflet: information for the user

M-M-RvaxPro®

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

Measles, mumps and rubella 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.
- 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 M-M-RVAXPRO is and what it is used for
2. What you need to know before you receive M-M-RVAXPRO
3. How to use M-M-RVAXPRO
4. Possible side effects
5. How to store M-M-RVAXPRO
6. Content of the pack and other information

1. What M-M-RVAXPRO is and what it is used for

M-M-RVAXPRO is a vaccine containing measles, mumps, and rubella 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, and rubella viruses. The antibodies help protect against infections caused by these viruses.

M-M-RVAXPRO is given to help protect you or your child against measles, mumps, and rubella. The vaccine may be administered to persons 12 months of age or older.

M-M-RVAXPRO can be administered to infants from 9 to 12 months of age under special circumstances.

M-M-RVAXPRO can also be used in measles outbreaks, or for post-exposure vaccination, or for use in previously unvaccinated persons older than 9 months who are in contact with susceptible pregnant women, and persons likely to be susceptible to mumps and rubella.

Although M-M-RVAXPRO contains live viruses, they are too weak to cause measles, mumps, or rubella in healthy people.

2. What you need to know before you receive M-M-RVAXPRO

Do not use M-M-RVAXPRO:

- If you or your child are allergic to any of the components of this vaccine (including neomycin or any of the other ingredients listed in section 6)
- If you or your child are pregnant (in addition, pregnancy should be avoided for 1 month after vaccination, see Pregnancy)
- If you or your child have any illness with fever higher than 38.5°C; however, low-grade fever itself is not a reason to delay vaccination
- If you or your child have active untreated tuberculosis
- If you or your child have a blood disorder or any type of cancer that affects the immune system
- If you or your child are receiving treatment or taking medicines that may weaken the immune system (except low-dose corticosteroid therapy for asthma or replacement therapy)
- If you or your child have a weakened immune system because of a disease (including AIDS)

- If you or your child have a family history of congenital or hereditary immunodeficiency, unless the immune competence of you or your child is demonstrated.

Warnings and precautions

Talk to the doctor or pharmacist before you or your child receive M-M-RVAXPRO if you have experienced any of the following:

- If you or your child have an allergic reaction to eggs or anything that contained egg
- If you or your child have a history or family history of allergies or of convulsions (fits)
- If you or your child have a side effect after vaccination with measles, mumps, or rubella vaccine (in a single component vaccine or a combined vaccine, such as the measles, mumps, and rubella vaccine manufactured by Merck & Co., Inc., or M-M-RVAXPRO) that involved easy bruising or bleeding for longer than usual
- If you or your child have infection with Human Immunodeficiency Virus (HIV) but do not show symptoms of HIV disease. You or your child should be monitored closely for measles, mumps, and rubella because vaccination may be less effective than for uninfected persons (see section **Do not use M-M-RVAXPRO**).

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

M-M-RVAXPRO can be given to persons who have been in recent (within 3 days) contact with a case of measles and may be incubating the disease. However, M-M-RVAXPRO may not always be able to prevent measles developing in these cases.

Other medicines and M-M-RVAXPRO

Tell your doctor or pharmacist if you or your child are taking or have recently taken any other medicines (or other vaccines).

The doctor may delay vaccination for at least 3 months following blood or plasma transfusions, or immune globulin (known as IG). After vaccination with M-M-RVAXPRO, IG 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 M-M-RVAXPRO.

M-M-RVAXPRO may be given with Prevenar and/or hepatitis A vaccine at the same visit at a separate injection site (e.g. the other arm or leg).

M-M-RVAXPRO may be given with some routine childhood vaccines that may be due to be given at the same time. For vaccines that cannot be given at the same time, M-M-RVAXPRO should be given 1 month before or after administration of those vaccines.

Pregnancy and breast-feeding

M-M-RVAXPRO should not be given to pregnant females. Females of child-bearing age should take the necessary precautions to avoid pregnancy for 1 month, or according to doctor's recommendation, after they have been given the vaccine.

Persons who are breast-feeding or intend to breast-feed should tell the doctor. The doctor will decide if M-M-RVAXPRO 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.

Driving and using machines

There is no information to suggest that M-M-RVAXPRO affects the ability to drive or operate machinery.

M-M-RVAXPRO contains sorbitol.

If you have been told by your doctor that you or your child have an intolerance to some sugars, inform your doctor before you or your child receive this vaccine.

3. How to use M-M-RVAXPRO

M-M-RVAXPRO 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. M-M-RVAXPRO is not to be injected directly into any blood vessel.

M-M-RVAXPRO is given as follows:

One dose is given at an elected date usually from 12 months of age. Under special circumstances, it can be given from 9 months of age. Further doses should be administered according to your doctor's recommendation. The interval between 2 doses should be at least 4 weeks.

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

4. Possible side effects

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

The following side effects were reported with the use of M-M-RVAXPRO:

| Frequency | Side effect |
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| Very common (may affect more than 1 in 10 vaccinees) | <ul style="list-style-type: none">• Fever (38.5°C or higher).• Injection-site redness; injection-site pain; injection-site swelling. |
| Common (may affect 1 to 10 in 100 vaccinees) | <ul style="list-style-type: none">• Rash (including measles-like rash).• Injection-site bruising. |
| Uncommon (may affect 1 to 10 in 1,000 vaccinees) | <ul style="list-style-type: none">• Nasal congestion and sore throat; upper respiratory tract infection or viral infection; runny nose.• Diarrhoea, vomiting.• Hives.• Injection-site rash. |
| Not known (Frequency cannot be estimated from the available data)* | <ul style="list-style-type: none">• Aseptic meningitis (fever, feeling sick, vomiting, headache, stiff neck, and sensitivity to light); swollen testicles; infection of the middle ear; inflamed salivary glands; atypical measles (described in patients who received a killed measles virus vaccine, usually given before 1975).• Swollen lymph nodes.• Bruising or bleeding more easily than normal.• Severe allergic reaction that may include difficulty in breathing, facial swelling, localised swelling, and swelling of the limbs.• Irritability.• Seizures (fits) without fever; seizures (fits) with fever in children; walking unsteadily; dizziness; illnesses involving inflammation of the nervous system (brain and/or spinal cord). |

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|--|---|
| | <ul style="list-style-type: none"> • An illness consisting of muscle weakness, abnormal sensations, tingling in the arms, legs, and upper body (Guillain-Barré syndrome). • Headache; fainting; nerve disorders which can cause weakness, tingling, or numbness; eye nerve disturbances. • Discharge and itching of the eyes with crusting of eyelids (conjunctivitis). • Inflammation of the retina (in the eye) with changes in sight. • Deafness. • Cough; lung infection with or without fever. • Feeling sick (nausea). • Itching; inflammation of the fatty tissue under the skin; red or purple, flat, pinhead spots under the skin; hardened, raised area of the skin; serious illness with ulcers or blistering of the skin, mouth, eyes, and/or genitals (Stevens-Johnson syndrome). • Joint pain and/or swelling (usually transient and rarely chronic); muscle pain. • Burning and/or stinging of short duration at the injection site; blisters and/or hives at the injection site. • Generally feeling unwell (malaise); swelling; soreness. • Inflammation of blood vessels. |
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*These side effects were reported with the use of M-M-RVAXPRO or with the measles, mumps, and rubella vaccine manufactured by Merck & Co., Inc., or with its monovalent (single) components, during post-marketing use and/or during clinical studies.

Reporting of side effects

If you get 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 M-M-RVAXPRO

Keep 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).

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

Do not freeze the vaccine.

Once the vaccine has been mixed with the solvent supplied, it should be either used immediately or stored in the refrigerator and used within 8 hours.

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

6. Contents of the pack and other information

What M-M-RVAXPRO contains

The active substances are:

After reconstitution, one dose (0.5 ml) contains:

| | |
|--|---|
| Measles virus ¹ Enders' Edmonston strain (live, attenuated)..... | not less than 1×10^3 CCID ₅₀ * |
| Mumps virus ¹ Jeryl Lynn™ [Level B] strain (live, attenuated) | not less than 12.5×10^3 CCID ₅₀ * |
| Rubella virus ² Wistar RA 27/3 strain (live, attenuated) | not less than 1×10^3 CCID ₅₀ * |

* 50% cell culture infectious dose

¹ produced in chick embryo cells.

² produced in WI-38 human diploid lung fibroblasts.

The other ingredients are:

Powder:

sorbitol, sodium phosphate, potassium phosphate, sucrose, hydrolysed gelatin, medium 199 with Hanks' salts, MEM, monosodium L-glutamate, neomycin, phenol red, sodium bicarbonate, hydrochloric acid (to adjust pH), and sodium hydroxide (to adjust pH)

Solvent:

water for injections

What M-M-RVAXPRO 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.

The solvent is a clear and colourless liquid. The powder is a light yellow compact crystalline cake.

M-M-RVAXPRO is available in packs of 1, 10 and 20, with or without needles. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: MSD VACCINS, 162 avenue Jean Jaurès, 69007 Lyon, France

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 local representative of the Marketing Authorisation Holder.

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This leaflet was last revised in January 2017.

Other sources of information

Detailed information on this vaccine is available on the European Agency website:
<http://www.ema.europa.eu>.

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The following information is intended for healthcare professionals only:

Reconstitution instructions

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

Do not use the reconstituted vaccine if you notice any particulate matter or if the appearance of the solvent or powder or of the reconstituted vaccine differs from that described above.

Inject the entire content of the pre-filled syringe into the vial containing the powder. Gently agitate to dissolve completely. Withdraw the entire content of the reconstituted vaccine vial into the same syringe and inject the entire volume.

If two needles are provided: use one needle to reconstitute the vaccine and the other for its administration to the person to be vaccinated.

It is recommended that the vaccine be administered immediately after reconstitution or stored in the refrigerator and used within 8 hours to minimize loss of potency. Discard if reconstituted vaccine is not used within 8 hours.

Do not freeze the reconstituted vaccine.

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

See also section 3 **How to use M-M-RVAXPRO.**

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