

M-M-R[®] II

Measles, Mumps and Rubella Virus Vaccine Live

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about M-M-R II. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the risks of you being given M-M-R II against the benefits they expect it will have for you.

If you have any concerns about being given this vaccine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What M-M-R II is used for

M-M-R II is a vaccine used to help protect people from getting measles, mumps and rubella (German measles). It can be given to people 12 months of age and older.

Protection against these infections is important as they can cause serious problems in some people.

Measles is a serious disease that causes a high fever (temperature), runny nose, cough, conjunctivitis and a rash. It usually lasts for about 1 to 2 weeks. It is very easily passed from one person to another in the tiny droplets of moisture which are expelled during coughing or sneezing. One out of every 10 children who catch measles will also have an ear infection or pneumonia. On rare occasions, measles can also

cause an infection of the brain that could lead to seizures, hearing loss, mental retardation, and even death. Babies and adults who catch measles are often much sicker for a longer time or are more likely to die than school children and teenagers who catch measles.

Mumps causes fever, headache, and swollen, painful glands under the jaw (salivary glands) and usually lasts several days. It is easily passed from one person to another by the tiny droplets of moisture expelled during coughing or sneezing. Mumps can sometimes be a very serious disease, causing a mild inflammation of the coverings of the brain and spinal cord (meningitis) in about one person in every 10 who catch it. About one out of every 4 teenage or adult males with mumps will have a painful swelling of the testicles for several days. This does not usually affect their ability to father children, but can cause sterility in rare cases. Teenagers and adults, especially males, who catch mumps are often much sicker and more likely to suffer longer than children do.

Rubella is usually a mild disease that causes a mild fever, swollen glands in the neck, pain and swelling in the joints, and a rash that lasts for 2 or 3 days. Rubella is very dangerous if a pregnant woman catches it. Pregnant women who catch rubella can have babies who are stillborn, or have heart disease, blindness, deafness, or problems with learning. Rubella is also spread to others in the tiny droplets of moisture expelled during coughing or sneezing.

M-M-R II contains weakened strains of living measles, mumps and rubella viruses. These strains of live viruses

cause either mild or no symptoms of infection. When injected the vaccine causes the body to produce its own protection by making disease-fighting substances (antibodies) against these infections. If a vaccinated child comes into contact with measles, mumps or rubella virus, the body is usually ready, and produces antibodies to destroy the virus. However, as with all vaccines, 100% protection against measles, mumps and rubella cannot be guaranteed. Also it may take up to 4-6 weeks for maximum protection to develop, so occasionally infections may occur during this time.

The chance of a severe reaction from M-M-R II is very small, but the risks from not being vaccinated are very serious.

Before you are given M-M-R II

When you or your child must not be given it

Do not have the vaccine if you have an allergy to M-M-R II or any of the ingredients listed at the end of this leaflet, including gelatin.

Do not have M-M-R II if you have a serious allergy to:

- the antibiotic neomycin
- eggs - this is because the strains of measles and mumps viruses used to make M-M-R II are grown in eggs.

Symptoms of a serious allergic reaction include swelling of the face, lips, tongue, throat, difficulty in breathing, or hives.

Do not have M-M-R II if:

- **you have an infection with fever (high temperature)**
- **you have active untreated tuberculosis (TB)**
- **you are taking medicines which decrease the body's immune defence system (eg, corticosteroids, cyclosporin, cancer medicines).**

This does not include taking corticosteroids (eg, cortisone, prednisone) as replacement therapy for Addison's disease.

- **you have diseases which decrease the body's immune defence system, such as cancers of the blood cells (eg, leukaemia, lymphoma) and AIDS**

Do not have M-M-R II if you are pregnant. Also, do not become pregnant for 3 months after being given the vaccine.

Do not have M-M-R II if the expiry date on the pack has passed.

If the vaccine is used after the expiry date has passed, it may not work.

If you are not sure whether you or your child should have M-M-R II, talk to your doctor.

Before you or your child are given it

Tell your doctor if:

1. **you have the following medical conditions or a family history of them:**
 - febrile convulsions (fits or seizures due to a high temperature)
 - brain damage
 - epilepsy
 - low blood platelet count
 - HIV
2. **you have recently had a blood transfusion or been given immune serum globulins**

Your doctor may need to delay giving the vaccine for 3 months.
3. **you are breast feeding**

Your doctor will discuss the possible risks and benefits of you being given M-M-R II while breast-feeding.

4. **you have allergies to any other medicines or vaccines, or any other substances, such as foods, preservatives or dyes.**
5. **you have a blood clotting disorder or bleed or bruise more easily. In this case your doctor will give you the vaccine under the skin (subcutaneously).**

If you have not told your doctor about any of the above, tell them before you or your child are given M-M-R II.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

M-M-R II may not work as well as it should if you or your child are taking medicines that decrease the immune system, such as corticosteroids (eg, prednisone) or cyclosporin.

Your doctor will advise you if you are taking any of these or other medicines that decrease the immune system. Your doctor will decide whether or not to give the vaccine.

M-M-R II should be given one month before or after administration of other vaccines. However, other schedules have been used. Your doctor will decide the vaccination schedule.

How M-M-R II is given

How much is given

The dose for children, teenagers and adults is 0.5 mL.

How it is given

M-M-R II is usually injected just under the skin or into the muscle

(subcutaneously or intramuscularly) of the upper arm or in the area of the outer thigh by a doctor or trained nurse.

If your child has a blood-clotting disorder or bleeds or bruises more easily, the vaccine should be given under the skin because bleeding may occur following administration into the muscle.

The vaccine should not be injected directly into blood vessels (intravascularly).

Vaccination schedule

M-M-R II is usually given once to people 12 months of age or older. If the vaccine is given to children younger than 12 months old, a second injection should be given on or after 15 months of age.

Keep a record of your child's vaccinations and update this after each injection.

Keep your child's follow-up appointment with your doctor or clinic.

It is important for your child to have the follow-up dose of M-M-R II, if indicated, at the appropriate time to make sure the vaccine has the best chance of providing protection against measles, mumps and rubella.

If you miss a dose

If you miss a scheduled dose, talk to your doctor and arrange another visit as soon as possible.

Side Effects

Tell your doctor or pharmacist as soon as possible if you or your child does not feel well during or after having had an injection of M-M-R II.

M-M-R II helps protect most people from measles, mumps and rubella, but it may have unwanted side effects in a few people. All medicines and vaccines can have side effects. Sometimes they are serious, most of

the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you or your child have any of the following and they are troublesome or ongoing:

- mild burning and/or stinging at the injection site
- local reaction around the injection site such as soreness, redness, swelling, or a hard lump
- fever, feeling unwell, sore throat, cough, runny or blocked nose
- dizziness, headache
- feeling sick (nausea), vomiting, diarrhoea
- unsteadiness when walking
- irritability
- limited rash
- swelling of the glands in the neck
- swelling of the salivary glands (in front of the ear and/or under the back of the jaw)
- unusual bleeding or bruising under the skin, and swelling of the testicles
- swelling of the epididymis, a part of the male reproductive system
- itchiness of the skin
- Transient joint pain and/or swelling have occurred more frequently in adult females; sometimes these symptoms may be chronic

These are the more common side effects of M-M-R II. For the most part these have been mild. They usually improve or disappear within a few days.

Tell your doctor immediately if you notice any of the following:

- rash all over the body
- aches or pains in joints, arthritis
- bruising or purple spots on the skin
- swelling of the lungs causing coughing, difficulty breathing and

wheezing with or without fever, chills, shortness of breath, cough, phlegm and occasionally blood

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if you or your child get any of the following:

- a seizure or convulsion, which may or may not be accompanied by a very high fever
- headache and fever, progressing to hallucinations, confusion, stiff neck and sensitivity to light
- pain, numbness, or tingling of the hands, arms, legs or feet
- fainting
- severe blisters with bleeding in the lips, eyes, mouth, nose or genitals

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

Other side effects may also occur rarely and some of these may be serious. These include allergic reactions, seizures, and inflammation of the nervous system (brain and/or spinal cord).

Allergic Reaction:

As with all vaccines given by injection, there is a very small risk of a serious allergic reaction.

Tell your doctor immediately or go to accident and emergency if you notice any of the following:

- wheezing or shortness of breath
- swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing
- swelling of the hands, feet, or ankles
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- skin rash, itchiness

If you have these, you may have had a serious allergic reaction to M-M-R II. You may need urgent medical attention or hospitalisation. Most of these side effects occur within 15-30 minutes of vaccination, before you or your child leave the doctor's surgery or clinic.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Tell your doctor promptly about any of these or any other unusual symptoms. If the condition persists or worsens, seek medical attention.

Do not be alarmed by this list of possible side effects. You or your child may not experience any of them.

Storage

M-M-R II is usually stored in the doctor's surgery or clinic, or at the pharmacy. However if you need to store M-M-R II:

- **Keep it where children cannot reach it.**
- **Keep it in the refrigerator at a temperature between 2°C and 8°C, but not in the door compartment. Do not freeze it.**
- **Protect the injection from light by keeping it in the original pack until it is time for it to be given.**

Product description

What it looks like

M-M-R II comes as white powder in glass vials. It is reconstituted with a special diluent to make a solution suitable for injection.

Ingredients

The active ingredients of M-M-R II are weakened strains of measles,

mumps and rubella (German measles) viruses.

Inactive ingredients:

- neomycin
- sorbitol
- hydrolysed porcine gelatin
- dibasic sodium phosphate
- sucrose
- monobasic sodium phosphate
- dibasic potassium phosphate
- monobasic potassium phosphate
- phenolsulfonphthalein
- sodium bicarbonate
- monosodium glutamate monohydrate

This product may also contain residual recombinant human albumin, foetal bovine serum and other buffer and media ingredients.

The product contains no preservative.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

Supplier

M-M-R II is supplied in Australia by:

Seqirus (Australia) Pty Ltd
63 Poplar Road
PARKVILLE VIC 3052

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