

M-M-R® II

Measles, mumps and rubella virus vaccine live

Single dose vial

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.

Keep this leaflet with the medicine. 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 should be given to children 12 months of age or older. However, your doctor may recommend that M-M-R II be given to infants between 6-12 months of age in special situations.

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

Measles is a serious disease that is very easily passed from one person to another. It causes a high fever (temperature), cough and a rash and lasts for 1 to 2 weeks. 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 is easily passed from one person to another and causes fever, headache, and swollen, painful glands under the jaw (salivary glands). Mumps can sometimes be a very serious disease and usually lasts for several days. Mumps can cause 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). 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 a short time **but is very dangerous if a pregnant woman catches it**. Women who catch rubella when they are pregnant can have babies who are stillborn, or have heart disease, blindness, deafness, or problems with learning.

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.

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

- the antibiotic neomycin

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 1 month 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
2. you have recently had a blood transfusion
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 any allergies to any other medicines or vaccines, or any other substances, such as foods, preservatives or dyes.

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.

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 (subcutaneously) of the upper arm by a doctor or trained nurse.

The vaccine should **not** be injected directly into veins (intravenously).

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 followed by revaccination at the time of primary school entry (4-6 years of age).

For children vaccinated at 12 to 15 months of age or older, a second dose is recommended at the time of primary school entry (4-6 years 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. The NZ Ministry of Health recommends the booster dose currently at 11 years of age. ⁽¹⁾.

If you miss a dose

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

Adverse Effects

Tell your doctor 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 adverse effects in a few people. All medicines and vaccines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor 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, itching
- fever, feeling unwell, sore throat
- dizziness, headache
- feeling sick (nausea), vomiting, diarrhoea
- unsteadiness when walking
- 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)

These are the more common adverse 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
- unusual bleeding under the skin
- swelling of the testicles

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

These are serious adverse effects. You may need urgent medical attention. Serious adverse 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:

- swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing
- pinkish, itchy swellings on the skin, also called hives or nettlerash
- 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 adverse effects occur within 15-30 minutes of vaccination, before you or your child leave the doctor's surgery or clinic.

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

Do not be alarmed by this list of possible adverse 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, but not in the door compartment (at 2°C to 8°C).
- 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 light-yellow 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 gelatin

Supplier

M-M-R II is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited
P O Box 99 851
Newmarket
Auckland
NEW ZEALAND
Tel: 0800 500 673

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(1) Ministry of Health Immunisation Handbook 2006

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