

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this vaccine, speak to your doctor, nurse or pharmacist.

1. Why am I or my child being given M-M-R II?

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

For more information, see Section [1. Why am I or my child being given M-M-R II?](#) in the full CMI.

2. What should I know before my child or I are given M-M-R II?

Do not get M-M-R II if you or your child have ever had an allergic reaction to M-M-R II, to the antibiotic neomycin, to eggs or to any of the ingredients listed at the end of the CMI.

Talk to your doctor if you or your child have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before my child or I are given M-M-R II?](#) in the full CMI.

3. What if my child or I are taking other medicines?

Some medicines may interfere with M-M-R II and affect how it works. Tell your doctor, nurse or pharmacist if you or your child is taking, has recently taken or might take any other vaccines or medicines, including medicines obtained without a prescription.

A list of these medicines is in Section [3. What if my child or I are taking other medicines?](#) in the full CMI.

4. How is M-M-R II given?

A doctor or nurse will give you or your child this vaccine as an injection, just under the skin or into the muscle (subcutaneously or intramuscularly) of the upper arm or in the area of the outer thigh.

More instructions can be found in Section [4. How is M-M-R II given?](#) in the full CMI.

5. What should I know after my child or I are given M-M-R II?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or nurse that you or your child have been given M-M-R IIKeep 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.
Looking after your medicine	It is unlikely that you will be asked to store M-M-R II. If you are, keep it in the refrigerator at a temperature between 2°C and 8°C, but not in the door compartment. Do not freeze it. Keep it where children cannot reach it.

For more information, see Section [5. What should I know after my child or I are given M-M-R II?](#) in the full CMI.

6. Are there any side effects?

Common side effects include: 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

Serious side effects can include signs of allergic reaction such as: 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; and skin rash, itchiness.

For a complete list of side effects and more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

M-M-R II

Active ingredient: Measles, Mumps and Rubella Virus Vaccine Live

Consumer Medicine Information (CMI)

This leaflet provides important information about using M-M-R II. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using M-M-R II.

Where to find information in this leaflet:

1. Why am I or my child being given M-M-R II?
2. What should I know before my child or I are given M-M-R II?
3. What if my child or I are taking other medicines?
4. How is M-M-R II given?
5. What should I know after my child or I are given M-M-R II?
6. Are there any side effects?
7. Product details

1. Why am I or my child being given M-M-R II?

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

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

What is measles?

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.

What is mumps?

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.

What is rubella?

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.

How it works

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.

2. What should I know before my child or I are given M-M-R II?

Warnings

Do not get M-M-R II if you or your child:

- have an allergy to M-M-R II or any of the ingredients listed at the end of this leaflet, including gelatin.
- have a serious allergy to:
 - neomycin (an antibiotic)
 - 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.

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

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

- **have diseases which decrease the body's immune defence system**, such as cancers of the blood cells (e.g., leukaemia, lymphoma) and AIDS
- **are pregnant.**

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

Check with your doctor if you or your child:

- **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
- **have recently had a blood transfusion or been given immune serum globulins**

Your doctor may need to delay giving the vaccine for 3 months.

- **have allergies to any other medicines or vaccines, or any other substances, such as foods, preservatives or dyes.**
- **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).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you or your child are pregnant or intend to become pregnant.

Do not get M-M-R II if you are pregnant. Also, do not become pregnant for 1 month after being given the vaccine.

Talk to your doctor if you or your child are breastfeeding or intend to breastfeed. Your doctor will discuss the possible risks and benefits of you being given M-M-R II while breastfeeding.

Use in children under 12 months of age

The safety and effectiveness of measles vaccine in infants below the age of 6 months have not been established. The safety and effectiveness of mumps and rubella vaccine in infants below the age of 12 months have not been established.

3. What if my child or I are taking other medicines?

Tell your doctor, nurse or pharmacist if you or your child are taking any other medicines, including any medicines, vitamins or supplements 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 (e.g. prednisone) or cyclosporin.

Your doctor will advise you if you or your child 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.

Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vitamins or supplements you or your child are taking and if these affect M-M-R II.

4. How is M-M-R II 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).

When is it given

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.

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.

5. What should I know after my child or I are given M-M-R II?

Things you should do

- 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.
- 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.

Looking after your vaccine

It is unlikely that you will be asked to store M-M-R II.

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.

6. Are there any side effects?

All medicines, including vaccines, can have side effects. If you or your child experiences any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
<ul style="list-style-type: none">• 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• 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 <p>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</p>	<p>Speak to your doctor if you or your child have any of these less serious side effects and they are troublesome or ongoing .</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• 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• 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 <p>As with all vaccines given by injection, there is a very small risk of a serious allergic reaction.</p> <ul style="list-style-type: none">• 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• Skin rash, itchiness <p>If you or your child have these symptoms, 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.</p> <p>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).</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>These are serious side effects. You or your child may need urgent medical attention. Serious side effects are rare.</p>

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this vaccine.

7. Product details

This vaccine is only available with a doctor's prescription.

What M-M-R II contains

Active ingredient (main ingredient)	Weakened strains of measles, mumps and rubella viruses
Other ingredients (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 *contains sulfites The diluent contains water for injections
Potential allergens	Egg Neomycin

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.

Do not take this medicine if you are allergic to any of these ingredients.

What M-M-R II looks like

M-M-R II comes as light-yellow powder in glass vials. It is reconstituted with a special diluent (water for injections) to make a solution suitable for injection.

M-M-R II powder for injection vial with diluent vial (AUST R 118449)

M-M-R II powder for injection vial (AUST R 118451)

M-M-R II powder for injection vial with pre-filled diluent syringe (AUST R 201877)

Who distributes M-M-R II

Merck Sharp & Dohme (Australia) Pty Limited
Level 1, Building A, 26 Talavera Road
Macquarie Park NSW 2113

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