

PART III: CONSUMER INFORMATION

M-M-R® II

(measles, mumps and rubella virus vaccine, live, attenuated, Merck Std.)

This leaflet is part III of a three-part "Product Monograph" and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about M-M-R® II. Contact your doctor or pharmacist if you have any questions about the vaccine.

ABOUT THIS VACCINE

What the vaccine is used for:

M-M-R® II is an injectable live virus vaccine to help prevent measles (rubeola), mumps, and rubella (German Measles).

Why has my doctor prescribed M-M-R® II?

Your doctor has recommended or administered M-M-R® II to help protect you or your child against measles, mumps, and rubella. The vaccine can be administered to persons 12 months of age or older.

Measles is a serious disease that is very easily passed from one person to another. It causes a high fever, 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 elementary 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). It 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 1 person in every 10 who catch it. About 1 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.

What the medicinal ingredient is:

measles, mumps and rubella virus vaccine, live

What the important non-medicinal ingredients are:

M-M-R® II contains neomycin, gelatin and recombinant human albumin as inactive ingredients. Tell your doctor if you or your child has ever had an allergic reaction to these ingredients.

For a full listing of non-medicinal ingredients see Part I of the product monograph.

What dosage forms it comes in:

M-M-R® II is supplied as follows:

- a box of 10 single-dose vials of lyophilized vaccine, and
- a box of 10 vials (0.7 mL) of diluent.

WARNINGS AND PRECAUTIONS

What should I tell my doctor before vaccination with M-M-R® II?

Tell your doctor about any medical problems you or your child has or has had, and about any allergies (especially to neomycin).

Tell your doctor if you or your child has a history of convulsions or a brain injury, or a low blood platelet count.

Who should not be vaccinated with M-M-R® II?

Anyone who:

- is allergic to any of its components (including neomycin)
- is pregnant (in addition, pregnancy should be avoided for 3 months after vaccination)
- has a fever
- has active untreated tuberculosis
- is taking medications to suppress their immune system (other than corticosteroid replacement)
- has a blood disorder or any type of cancer that affects their immune system
- has an immune deficiency as a result of a disease or a treatment

Use in children

M-M-R[®] II should be used in children 12 months of age or older. However, your doctor may recommend that M-M-R[®] II be given to infants who are less than 12 months of age in special situations.

Use in pregnancy

M-M-R[®] II should not be administered to pregnant women. Women of child-bearing age should take the necessary precautions to avoid pregnancy for 3 months following vaccination.

Use in breast-feeding

Tell your doctor if you are breast-feeding or intend to breast-feed. Your doctor will decide if you should receive M-M-R[®] II.

INTERACTIONS WITH THIS VACCINE

Administration of immunoglobulins with M-M-R[®] II may interfere with immune response.

Tell your doctor if your child has received blood or plasma transfusions or administration of human serum globulin within the last 3 months.

PROPER USE OF THIS VACCINE

Usual Dose:

M-M-R[®] II is given by injection as follows:

- M-M-R[®] II is given to persons 12 months of age or older. The dose of the vaccine is the same for everyone.
- For persons vaccinated at 12 months of age or older, a second dose of the vaccine is recommended at a later date which will be decided by your doctor.
- Children first vaccinated at less than 12 months of age should receive two additional doses after reaching 12 months of age.
- Non-pregnant adolescent and adult females of childbearing age who are susceptible to rubella can be vaccinated with M-M-R[®] II (or live attenuated rubella virus vaccine) if certain precautions are observed (see Use in Pregnancy). It has been found convenient in many instances to vaccinate women who are susceptible to rubella in the immediate post-partum period.

See your doctor for more details.

Overdose:

In case of overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose

Your doctor will decide when to give the missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

What undesirable effects may M-M-R[®] II have?

Any vaccine may have unintended or undesirable effects, so-called side effects. The most common is burning and/or stinging at the injection site for a short time. Transient joint pain and/or swelling have occurred more frequently in adult females; sometimes these symptoms may be chronic. Occasionally, fever and rash may occur. Rarely, unusual bleeding or bruising under the skin, and swelling of the testicles may occur.

Other side effects may also occur rarely and some of these may be serious. These include allergic reactions, seizures, and inflammation of the brain (encephalitis).

Your doctor has a more complete list of side effects.

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

HOW TO STORE IT

Vial of powder: Store at 2°C to 8°C. The vaccine may also be stored in a freezer at temperatures above -50°C; if subsequently transferred to a refrigerator, the vaccine may be placed back in the freezer. Keep the vial in the outer carton in order to protect from light.

Diluent: Store separately from the vaccine vial at room temperature (20°C to 25°C) or in the refrigerator at 2°C to 8°C.

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects information on serious and unexpected adverse events following vaccination. If you suspect you have had a serious or unexpected event following receipt of a vaccine you may notify the Public Health Agency of Canada:

By toll-free telephone: 1-866-844-0018

By toll-free fax: 1-866-844-5931

By e-mail: CAEFI@phac-aspc.gc.ca

By regular mail:

The Public Health Agency of Canada
Vaccine Safety Section
130 Colonnade Road
Ottawa, ON K1A 0K9
A/L 6502A

or Merck Canada Inc. by one of the following 2 ways:

- Call toll-free telephone: 1-800-567-2594
- Complete a Canada Vigilance Reporting Form and
 - Fax toll-free to 1-866-496-9092
 - Mail to: Merck Canada Inc.
Pharmacovigilance
P.O. Box 1005
Pointe-Claire - Dorval, QC H9R 4P8

NOTE: Should you require information related to the management of the side effects, contact your health professional. The Public Health Agency of Canada or Merck do not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.merck.ca> or by contacting the sponsor, Merck Canada Inc., at: 1-800-567-2594

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