PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

M-M-R[®] II

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

Read this carefully before you are vaccinated with **M-M-R**[®] **II**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **M-M-R**[®] **II**.

What is M-M-R[®] II used for?

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

How does M-M-R[®] II work?

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 are the ingredients in M-M-R[®] II?

Medicinal ingredients: The medicinal ingredient is an injectable live attenuated virus vaccine to help

prevent measles, mumps and rubella virus.

<u>Non-medicinal ingredients</u>: 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 nonmedicinal ingredients see Part 1 of the product monograph.

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 sterile diluent.

Do not use M-M-R[®] II if the recipient:

- is allergic to any of its components (including neomycin)
- is pregnant (in addition, pregnancy should be avoided for 1 month 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

To help avoid side effects and ensure proper use, talk to your healthcare professional before your child gets M-M-R[®] II. Talk about any health conditions or problems you or your child may have, including if:

- you or your child has or has had any medical problems, and about any allergies (especially to neomycin).
- you or your child has a history of convulsions or a brain injury, or a low blood platelet count.

<u>Use in children</u>

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 1 month 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.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with M-M-R[®] II:

- 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.

How to take M-M-R[®] II:

M-M-R[®] II will be given to your child by a healthcare professional in a healthcare setting.

Usual dose:

- 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:

If you think you, or a person you are caring for, have received too much M-M-R[®] II, contact a healthcare professional, 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.

What are possible side effects from using M-M-R[®] II?

These are not all the possible side effects you may have when taking M-M-R[®] II. If you experience any side effects not listed here, tell your healthcare professional.

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 nervous system (brain and/or spinal cord).

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.

If you or your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Merck Canada Inc. cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<u>http://www.phac-aspc.gc.ca/im/aefi-essi-form-eng.php</u>) and send it to your local Health Unit.

Storage:

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: The diluent may be stored in the refrigerator with the lyophilized vaccine or separately at room temperature. Refrigeration of the diluent is not needed. Store at 2°C to 27°C.

All vaccines must be discarded after the expiration date.

Keep out of reach and sight of children.

If you want more information about M-M-R[®] II:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this
 Patient Medication Information by visiting the Health Canada website:
 <a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-produ

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