**M-M-R II**

(MEASLES, MUMPS, and RUBELLA VIRUS VACCINE LIVE)

M-M-R® II (Measles, Mumps, and Rubella Virus Vaccine Live) is a live virus vaccine for vaccination against measles (rubeola), mumps and rubella (German measles).

M-M-R II is a sterile lyophilized preparation of (1) ATTENUVAX® (Measles Virus Vaccine Live, MSD), a more attenuated line of measles virus, derived from Enders' attenuated Edmonston strain and propagated in chick embryo cell culture; (2) MUMPSVAX® (Mumps Virus Vaccine Live, MSD), the Jeryl Lynn™ (B level) strain of mumps virus propagated in chick embryo cell culture; and (3) MERUVAX® II (Rubella Virus Vaccine Live, MSD), the Wistar RA 27/3 strain of live attenuated rubella virus propagated in WI-38 human diploid lung fibroblasts.

The reconstituted vaccine is for subcutaneous administration. When reconstituted as directed, the dose for injection is 0.5 mL and contains not less than 1,000 CCID50 (50% cell culture infectious dose) of measles virus; 12,500 CCID50 of mumps virus; and 1,000 CCID50 of rubella virus. Each dose of the vaccine is calculated to contain sorbitol (14.5 mg), sodium phosphate, sucrose (1.9 mg), hydrolyzed gelatin (14.5 mg), recombinant human albumin (≤ 0.3 mg), fetal bovine serum (<1 ppm), other buffer and media ingredients and approximately 25 mcg of neomycin. The product contains no preservative.

## CLINICAL PHARMACOLOGY

Measles, mumps, and rubella are three common childhood diseases, caused by measles virus, mumps virus (paramyxoviruses), and rubella virus (togavirus), respectively, that may be associated with serious complications and/or death. For example, pneumonia and encephalitis are caused by measles. Mumps is associated with aseptic meningitis, deafness and orchitis; and rubella during pregnancy may cause congenital rubella syndrome in the infants of infected mothers.

Clinical studies of 284 triple seronegative children, 11 months to 7 years of age, demonstrated that M-M-R II is highly immunogenic and generally well tolerated. In these

studies, a single injection of the vaccine induced measles hemagglutination-inhibition (HI) antibodies in 95%, mumps neutralizing antibodies in 96%, and rubella HI antibodies in 99% of susceptible persons. However, a small percentage (1-5%) of vaccinees may fail to seroconvert after the primary dose.

A study of 6 month old and 15 month old infants born to vaccine immunized mothers demonstrated that, following vaccination with ATTENUVAX, 74% of the 6 month old infants developed detectable neutralizing antibody (NT) titers while 100% of the 15 month old infants developed NT. This rate of seroconversion is higher than that previously reported for 6 month old infants born to naturally immune mothers tested by HI assay. When the 6 month old infants of immunized mothers were revaccinated at 15 months, they developed antibody titers equivalent to the 15 month old vaccinees. The lower seroconversion rate in 6 month olds has two possible explanations: 1) Due to the limit of the detection level of the assays (NT and enzyme immunoassay [EIA]), the presence of trace amounts of undetectable maternal antibody might interfere with the seroconversion of infants; or 2) the immune system of 6 month olds is not always capable of mounting a response to measles vaccine as measured by the two antibody assays.

Efficacy of measles, mumps, and rubella vaccines was established in a series of double blind controlled field trials which demonstrated a high degree of protective efficacy afforded by the individual vaccine components. These studies also established that seroconversion in response to vaccination against measles, mumps, and rubella paralleled protection from these diseases.

Following vaccination, antibodies associated with protection can be measured by neutralization assays, HI, or ELISA (enzyme linked immunosorbent assay) tests. Neutralizing and ELISA antibodies to measles, mumps, and rubella viruses are still detectable in most individuals 11 to 13 years after primary vaccination.

## INDICATIONS

M-M-R II is indicated for simultaneous vaccination against measles, mumps, and rubella in individuals 12 months of age or older (see DOSAGE AND ADMINISTRATION).

There is some evidence to suggest that infants who are born to mothers who had wild type measles and who are vaccinated at less than one year of age may not develop sustained antibody levels when later revaccinated. The advantage of early protection must be weighed against the chance for failure to respond adequately on reimmunization.

Infants who are less than 12 months of age may fail to respond to the measles component of the vaccine due to presence in the circulation of residual measles antibody of maternal origin; the younger the infant, the lower the likelihood of seroconversion. In geographically isolated or other relatively inaccessible populations for whom immunization programs are logistically difficult, and in population groups in which wild-type measles infection may occur in a significant proportion of infants before 15 months of age, it may be desirable to give the vaccine to infants at an earlier age. Infants vaccinated under these conditions at less than 12 months of age should be revaccinated after reaching 12 to 15 months of age.

## REVACCINATION

Children first vaccinated when younger than 12 months of age should be revaccinated at 15 months of age.

A number of national, governmental vaccine authorities, the American Academy of Pediatrics (AAP), and the Immunization Practices Advisory Committee (ACIP), have recommended guidelines for routine measles revaccination and to help control measles outbreaks.

If the prevention of sporadic measles outbreaks is the sole objective, revaccination with a measles-containing vaccine should be considered (see appropriate product circular). If concern also exists about immune status regarding mumps or rubella, revaccination with appropriate mumps- or rubella containing vaccine should be considered after consulting the appropriate product circulars. Unnecessary doses of a vaccine are best avoided by ensuring that

written documentation of vaccination is preserved and a copy given to each vaccine's parent or guardian.

## CONTRAINDICATIONS

- Hypersensitivity to any component of the vaccine, including gelatin.
- Do not give M-M-R II to pregnant females; the possible effects of the vaccine on fetal development are unknown at this time. If vaccination of postpubertal females is undertaken, pregnancy should be avoided for one month following vaccination (see PRECAUTIONS, PREGNANCY).
- Anaphylactic or anaphylactoid reactions to neomycin (each dose of reconstituted vaccine contains approximately 25 mcg of neomycin).
- Any febrile respiratory illness or other active febrile infection.
- Active untreated tuberculosis.
- Patients receiving immunosuppressive therapy. This contraindication does not apply to patients who are receiving corticosteroids as replacement therapy, e.g., for Addison's disease.
- Individuals with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems.
- Primary and acquired immunodeficiency states, including patients who are immunosuppressed in association with AIDS or other clinical manifestations of infection with human immunodeficiency viruses; cellular immune deficiencies; and hypogammaglobulinemic and dysgammaglobulinemic states. Measles inclusion body encephalitis (MIBE), pneumonitis and death as a direct consequence of disseminated measles vaccine virus infection have been reported in severely immunocompromised individuals inadvertently vaccinated with measles-containing vaccine.
- Individuals with a family history of congenital or hereditary immunodeficiency, until the immune competence of the potential vaccine recipient is demonstrated.

## PRECAUTIONS

### GENERAL

Adequate treatment provisions including epinephrine injection (1:1000) should be available for immediate use should an anaphylactic or anaphylactoid reaction occur.

Due caution should be employed in administration of M-M-R II to persons with individual or family histories of convulsions, a history of cerebral injury or any other condition in which

stress due to fever should be avoided. The physician should be alert to the temperature elevation which may occur following vaccination (see ADVERSE REACTIONS).

**HYPERSENSITIVITY TO EGGS**

Live measles vaccine and live mumps vaccine are produced in chick embryo cell culture. Persons with a history of anaphylactic, anaphylactoid, or other immediate reactions (e.g., hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) subsequent to egg ingestion may be at an enhanced risk of immediate type hypersensitivity reactions after receiving vaccines containing traces of chick embryo antigen. The potential risk to benefit ratio should be carefully evaluated before considering vaccination in such cases. Such individuals may be vaccinated with extreme caution, having adequate treatment on hand should a reaction occur.

**THROMBOCYTOPENIA**

Individuals with current thrombocytopenia may develop more severe thrombocytopenia following vaccination. In addition, individuals who experienced thrombocytopenia with the first dose of M M R II (or its component vaccines) may develop thrombocytopenia with repeat doses. Serologic status may be evaluated to determine whether or not additional doses of vaccine are needed. The potential risk to benefit ratio should be carefully evaluated before considering vaccination in such cases (see ADVERSE REACTIONS).

**PREGNANCY**

It is not known whether M-M-R II can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, the vaccine should not be administered to pregnant females; furthermore, pregnancy should be avoided for one month following vaccination (see CONTRAINDICATIONS).

In an 18-year survey involving over 1200 pregnant women who received rubella vaccine within 3 months before or after conception (of whom 683 received the Wistar RA 27/3 strain), none of the newborns had abnormalities compatible with congenital rubella syndrome. Additional data from post-marketing reports and published observational studies have not identified abnormalities compatible with congenital rubella syndrome in patients who

received M-M-R II. Mumps infection during the first trimester of pregnancy may increase the rate of spontaneous abortion. Although mumps vaccine virus has been shown to infect the placenta and fetus, there is no evidence that it causes congenital malformations in humans. Reports have indicated that contracting of wild-type measles during pregnancy enhances fetal risk. Increased rates of spontaneous abortion, stillbirth, congenital defects and prematurity have been observed subsequent to infection with wild-type measles during pregnancy. There are no adequate studies of the attenuated (vaccine) strain of measles virus in pregnancy. However, it would be prudent to assume that the vaccine strain of virus is also capable of inducing adverse fetal effects.

**NURSING MOTHERS**

It is not known whether measles or mumps vaccine virus is secreted in human milk. Recent studies have shown that lactating postpartum women immunized with live attenuated rubella vaccine may secrete the virus in breast milk and transmit it to breast-fed infants. In the infants with serological evidence of rubella infection, none exhibited severe disease; however, one exhibited mild clinical illness typical of acquired rubella. Caution should be exercised when M-M-R II is administered to a nursing woman.

**PEDIATRIC USE**

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

**OTHER**

Children and young adults who are known to be infected with human immunodeficiency viruses and are not immunosuppressed may be vaccinated. However, the vaccinees who are infected with HIV should be monitored closely for vaccine preventable diseases because immunization may be less effective than for uninfected persons (see CONTRAINDICATIONS).

Excretion of small amounts of the live attenuated rubella virus from the nose or throat has occurred in the majority of susceptible individuals 7 to 28 days after vaccination. There is no confirmed evidence to indicate that such virus is transmitted to susceptible persons who are

in contact with the vaccinated individuals. Consequently, transmission through close personal contact, while accepted as a theoretical possibility, is not regarded as a significant risk. However, transmission of the rubella vaccine virus to infants via breast milk has been documented (see NURSING MOTHERS).

There are no reports of transmission of live attenuated measles or mumps viruses from vaccinees to susceptible contacts.

It has been reported that live attenuated measles, mumps, and rubella virus vaccines given individually may result in a temporary depression of tuberculin skin sensitivity. Therefore, if a tuberculin test is to be done, it should be administered either any time before, simultaneously with, or at least 4 to 6 weeks after M-M-R II.

Children under treatment for tuberculosis have not experienced exacerbation of the disease when immunized with live measles virus vaccine; no studies have been reported to date of the effect of measles virus vaccines on untreated tuberculous children.

As for any vaccine, vaccination with M-M-R II may not result in protection in 100% of vaccinees.

## DRUG INTERACTIONS

Administration of immune globulins concurrently with M-M-R II may interfere with the expected immune response. Vaccination should be deferred for 3 months or longer following administration of immune globulin (human) and blood or plasma transfusions.

## ADVERSE REACTIONS

The adverse reactions associated with the use of M-M-R II are those which have been reported following administration of the monovalent or combination vaccines.

COMMON

Burning and/or stinging of short duration at the injection site.

OCCASIONAL

*Body as a whole:* Fever (101°F [38.3°C] or higher)

*Skin:* Rash, or measles-like rash, usually minimal but may be generalized.

Generally, fever, rash, or both appear between the 5th and the 12th days.

RARE

*Body as a whole:* Mild local reactions such as erythema, induration and tenderness; sore throat, malaise, atypical measles, syncope, irritability.

*Cardiovascular:* Vasculitis.

*Digestive:* Parotitis, nausea, vomiting, diarrhea.

*Hematologic/Lymphatic:* Regional lymphadenopathy, thrombocytopenia, purpura.

*Hypersensitivity:* Allergic reactions such as wheal and flare at injection site, anaphylaxis and anaphylactoid reactions, as well as related phenomena such as angioneurotic edema (including peripheral or facial edema) and bronchial spasm, urticaria in individuals with or without an allergic history.

*Musculoskeletal:* Arthralgia and/or arthritis (usually transient and rarely chronic [see below]), myalgia.

*Nervous/Psychiatric:* Febrile convulsions in children, afebrile convulsions or seizures, headache, dizziness, paresthesia, polyneuritis, polyneuropathy, Guillain-Barre syndrome, ataxia, acute disseminated encephalomyelitis (ADEM), transverse myelitis aseptic meningitis (see below), measles inclusion body encephalitis (MIBE) (see CONTRAINDICATIONS), encephalitis/encephalopathy (see below).

*Respiratory System:* Pneumonia, pneumonitis (see CONTRAINDICATIONS), cough, rhinitis

*Skin:* Erythema multiforme, Stevens-Johnson syndrome, Henoch-Schönlein purpura, Acute Hemorrhagic Edema of Infancy, vesiculation at injection site, swelling, pruritus

*Special senses:* Forms of optic neuritis, including retrobulbar neuritis, papillitis, and retinitis; ocular palsies, otitis media, nerve deafness, conjunctivitis.

*Urogenital:* Epididymitis, orchitis

*Other*: Death from various, and in some cases unknown, causes has been reported rarely following vaccination with measles, mumps, and rubella vaccines; however, a causal relationship has not been established in healthy individuals (see

CONTRAINDICATIONS). No deaths or permanent sequelae were reported in a published post-marketing surveillance study in Finland involving 1.5 million children and adults who were vaccinated with M-M-R II

during 1982 to 1993.

Arthralgia and/or arthritis

Arthralgia and/or arthritis (usually transient and rarely chronic), and polyneuritis are features of wild-type rubella and vary in frequency and severity with age and sex, being greatest in adult females and least in prepubertal children.

Chronic arthritis has been associated with wild-type rubella infection and has been related to persistent virus and/or viral antigen isolated from body tissues. Only rarely have vaccine recipients developed chronic joint symptoms.

Following vaccination in children, reactions in joints are uncommon and generally of brief duration. In women, incidence rates for arthritis and arthralgia are generally higher than those seen in children (children: 0-3%; women: 12-20%), and the reactions tend to be more marked and of longer duration. Symptoms may persist for a matter of months or on rare occasions for years. In adolescent girls, the reactions appear to be intermediate in incidence between those seen in children and adult women. Even in older women (35 to 45 years), these reactions are generally well tolerated and rarely interfere with normal activities.

Subacute Sclerosing Panencephalitis (SSPE)

There have been reports of SSPE in children who did not have a history of infection with wild type measles but did receive measles vaccine. Some of these cases may have resulted from unrecognized measles in the first year of life or possibly from the measles vaccination. Based on estimated nationwide measles vaccine distribution, the association of SSPE cases to measles vaccination is about one case per million vaccine doses distributed. This is far less than the association with infection with wild type measles, 6-22 cases of SSPE per million cases of measles. The results of a retrospective case-controlled study conducted by the Centers for Disease Control and Prevention suggest that the overall effect of measles vaccine has been to protect against SSPE by preventing measles with its inherent higher risk of SSPE.

Aseptic meningitis

Cases of aseptic meningitis have been reported following measles, mumps, and rubella

vaccination. Although a causal relationship between the Urabe strain of mumps vaccine and aseptic meningitis has been shown, there is no evidence to link Jeryl Lynn™ mumps vaccine to aseptic meningitis.

Encephalitis/encephalopathy

Encephalitis/encephalopathy have been reported approximately once for every 3 million doses of the measles, mumps, and rubella vaccine manufactured by Merck & Co., Inc. Since 1978, post-marketing surveillance indicates that serious adverse events such as encephalitis and encephalopathy continue to be rarely reported. The risk of such serious neurological disorders following live measles virus vaccine administration remains far less than that for encephalitis and encephalopathy with wild type measles (one per one thousand reported cases).

In severely immunocompromised individuals inadvertently vaccinated with measles-containing vaccine, measles inclusion body encephalitis, pneumonitis, and fatal outcome as a direct consequence of disseminated measles vaccine virus infection have been reported (see Contraindications); disseminated mumps and rubella vaccine virus infection have also been reported.

Panniculitis

Panniculitis has been reported rarely following administration of measles vaccine.

## ANIMAL TOXICITY

Animal reproduction studies have not been conducted with M-M-R II. M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility.

## DOSAGE AND ADMINISTRATION

**FOR SUBCUTANEOUS ADMINISTRATION**

**Do not inject intravascularly**

Do not give immune globulin (IG) concurrently with M-M-R II. (See DRUG INTERACTIONS.)

The dose for any age is 0.5 mL administered subcutaneously, preferably into the outer aspect of the upper arm.

CAUTION: A sterile syringe free of preservatives, antiseptics, and detergents should be used for each injection and/or reconstitution of the vaccine because these substances may inactivate the live virus vaccine. A 25 gauge, 5/8" needle is recommended.

To reconstitute, use only the diluent supplied, since it is free of preservatives or other antiviral substances which might inactivate the vaccine.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Before reconstitution, the lyophilized vaccine is a light yellow compact crystalline plug. M-M-R II, when reconstituted, is clear yellow.

## OTHER VACCINATION CONSIDERATIONS

Non-Pregnant Adolescent and Adult Females

Immunization of susceptible non-pregnant adolescent and adult females of childbearing age with live attenuated rubella virus vaccine is indicated if certain precautions are observed (see PRECAUTIONS). Vaccinating susceptible postpubertal females confers individual protection against subsequently acquiring rubella infection during pregnancy, which in turn prevents infection of the fetus and consequent congenital rubella injury.

Women of childbearing age should be advised not to become pregnant for one month after vaccination and should be informed of the reasons for this precaution (see PRECAUTIONS, PREGNANCY).

If it is practical and if reliable laboratory services are available, women of childbearing age who are potential candidates for vaccination can have serologic tests to determine

susceptibility to rubella. However, with the exception of premarital and prenatal screening, routinely performing serologic tests for all women of childbearing age to determine susceptibility (so that vaccine is given only to proven susceptible women) can be effective but is expensive. Also, 2 visits to the health-care provider would be necessary - one for screening and one for vaccination. Accordingly, rubella vaccination of a woman who is not known to be pregnant and has no history of vaccination is justifiable without serologic testing and may be preferable, particularly when costs of serology are high and follow-up of identified susceptible women for vaccination is not assured.

Postpubertal females should be informed of the frequent occurrence of generally self-limited arthralgia and/or arthritis beginning 2 to 4 weeks after vaccination (see ADVERSE REACTIONS).

Postpartum Women

It has been found convenient in many instances to vaccinate rubella-susceptible women in the immediate postpartum period (see PRECAUTIONS, NURSING MOTHERS).

**OTHER POPULATIONS**

Previously unvaccinated children older than 12 months who are in contact with susceptible pregnant women should receive live attenuated rubella vaccine (such as that contained in monovalent rubella vaccine or in M-M-R II) to reduce the risk of exposure of the pregnant woman.

Individuals planning travel abroad, if not immune, can acquire measles, mumps, or rubella and import these diseases to their country. Therefore, prior to international travel, individuals known to be susceptible to one or more of these diseases can receive either a monovalent vaccine (measles, mumps, or rubella), or a combination vaccine as appropriate. However, M-M-R II is preferred for persons likely to be susceptible to mumps and rubella; and if monovalent measles vaccine is not readily available, travelers should receive M-M-R II regardless of their immune status to mumps or rubella.

Vaccination has been recommended for susceptible individuals in high-risk groups such as

college students, health-care workers, and military personnel.

## POST-EXPOSURE VACCINATION

Vaccination of individuals exposed to wild-type measles may provide some protection if the vaccine can be administered within 72 hours of exposure. If, however, vaccine is given a few days before exposure, substantial protection may be afforded. There is no conclusive evidence that vaccination of individuals recently exposed to wild-type mumps or wild-type rubella will provide protection.

## USE WITH OTHER VACCINES

M-M-R II should be given one month before or after administration of other live viral vaccines.

M-M-R II has been administered concurrently with live attenuated varicella and inactivated *Haemophilus influenzae* type b (Hib) conjugate vaccines using separate injection sites and syringes. No impairment of immune response to individually tested vaccine antigens was demonstrated. The type, frequency, and severity of adverse experiences observed with M-M-R II were similar to those seen when each vaccine was given alone.

Routine administration of DTP (diphtheria, tetanus, pertussis) and/or OPV (oral poliovirus vaccine) concurrently with measles, mumps, and rubella vaccines is not recommended because there are limited data relating to the simultaneous administration of these antigens.

However, other schedules have been used. Data from published studies concerning the simultaneous administration of the entire recommended vaccine series (i.e., DTaP [or DTwP], IPV [or OPV], Hib with or without Hepatitis B vaccine, and varicella vaccine), indicate no interference between routinely recommended childhood vaccines (either live, attenuated, or killed).

## SINGLE DOSE VIAL

If the prevention of sporadic measles outbreaks is the sole objective, revaccination with a measles-containing vaccine should be considered (see appropriate product circular). If

concern also exists about immune status regarding mumps or rubella, revaccination with appropriate mumps- or rubella-containing vaccine should be considered after consulting the appropriate product circulars.

First withdraw the entire volume of diluent into the syringe to be used for reconstitution. Inject all the diluent in the syringe into the vial of lyophilized vaccine, and agitate to mix thoroughly. If the lyophilized vaccine cannot be dissolved, discard. Withdraw the entire contents into a syringe and inject the total volume of reconstituted vaccine subcutaneously.

It is important to use a separate sterile syringe and needle for each individual patient to prevent transmission of Hepatitis B and other infectious agents from one person to another.

## HOW SUPPLIED

M-M-R II is supplied as a single-dose vial of lyophilized vaccine and a vial of diluent.

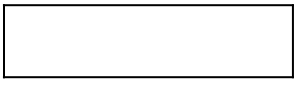
## STORAGE

Shelf life: 24 months.

Before reconstitution, store M-M-R II at 2-8°C (35.6-46.4°F). **Do not freeze. Protect from light.**

M-M-R II retains at least 8 times the minimum immunizing dose even after 6 weeks at 22℃ or 1 week at 37℃. Storage at temperature above 2 to 8℃ cannot be recommended due to the difficulty in monitoring the exact temperature and monitoring repeated exposures to time out of refrigeration.

It is recommended that the vaccine be used as soon as possible after reconstitution. Protect vaccine from light at all times, since such exposure may inactivate the virus. Store reconstituted vaccine in the vaccine vial in a dark place at 2-8°C (35.6-46.4°F) and discard if not used within 8 hours.



Mengandung Babi

HARUS DENGAN RESEP DOKTER

No. Reg: DKI1863501144A1

Manufactured by:
Merck Sharp & Dohme LLC
5325 Old Oxford Road
Durham, North Carolina, 27712 USA

Released by:
Merck Sharp & Dohme B.V
Waarderweg 39, Haarlem, 2031 BN
Netherlands

Registered by:
PT Organon Pharma Indonesia Tbk
Pasuruan, Jawa Timur

Distributed by:
PT Merck Sharp & Dohme Indonesia
Jakarta, Indonesia

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# Informasi Untuk Pasien Tentang M-M-R II (Refrigerated)

*(measles, mumps, and rubella virus vaccine live)* [Serbuk Injeksi]

## Apakah itu M-M-R II?

M-M-R II (*measles, mumps, and rubella virus vaccine live*) adalah vaksin hidup yang diinjeksi untuk membantu mencegah campak (*measles*), gondongan (*mumps*), dan rubella (Campak Jerman/*German Measles*).

M-M-R II sebelum dilarutkan berbentuk serbuk injeksi kristal padat berwarna kuning muda dan ketika dilarutkan berwarna kuning jernih.

M-M-R II mengandung beberapa zat tambahan sebagai berikut:

*Porcine Hydrolyzed Gelatin*
*Medium 199 with Hank's Salts*
*Minimum Essential Medium, Eagle*
*Monosodium L-Glutamate Monohydrate*
*Neomycin*
*Phenol Red*
*Potassium Phosphate Dibasic (Anhydrous)*
*Potassium Phosphate Monobasic*
*Sodium Bicarbonate*
*Sodium Phosphate Dibasic (Anhydrous)*
*Sodium Phosphate Monobasic*
*Sorbitol*
*Sucrose*

M-M-R II tersedia:
Dus, 1 vial @ 0.5 mL + 1 vial pelarut @ 0.7 mL No. Reg: DKI1863501144A1

Didaftarkan oleh:
PT Organon Pharma Indonesia Tbk
Pasuruan, Jawa Timur

Didistribusikan oleh:

PT Merck Sharp & Dohme Indonesia
Jakarta, Indonesia

Diproduksi oleh:
Merck Sharp & Dohme LLC
5325 Old Oxford Road
Durham, North Carolina, 27712 USA

Dirilis oleh:
Merck Sharp & Dohme B.V.
Waarderweg 39, Haarlem, 2031 BN
Netherlands

## Mengapa dokter saya meresepkan M-M-R II?

Dokter Anda merekomendasikan atau memberikan M-M-R II untuk membantu melindungi Anda atau anak Anda dari campak, gondongan, dan rubella. Vaksin ini dapat diberikan pada seseorang usia 12 bulan ke atas.

**Campak** adalah penyakit serius yang sangat mudah berpindah dari satu orang ke orang lain. Penyakit tersebut mengakibatkan demam tinggi, batuk, dan ruam dan dapat terjadi selama 1 sampai 2 minggu. Satu dari 10 anak yang menderita campak dapat juga menderita infeksi telinga atau pneumonia. Pada kasus yang jarang, campak dapat juga menyebabkan infeksi pada otak yang dapat mengarah kepada kejang, hilang pendengaran, retardasi mental, dan kematian. Bayi dan orang dewasa yang terkena campak biasanya lebih menderita dan mengalami penyakit tersebut lebih lama atau lebih mungkin mengalami kematian dibanding penderita anak-anak dan remaja.

**Gondongan** sangat mudah berpindah dari satu orang ke orang lain dan menyebabkan demam, sakit kepala, serta bengkak dan rasa sakit pada kelenjar di bawah rahang (kelenjar ludah). Penyakit tersebut kadang dapat menjadi serius dan berlangsung selama beberapa hari. Gondongan dapat menyebabkan radang ringan pada penutup otak dan saraf tulang belakang (meningitis) pada tiap 1 dari 10 orang penderita. Pada tiap 1 dari 4 orang laki-laki remaja atau dewasa, penyakit ini dapat menyebabkan rasa sakit pada kemaluan yang berlangsung dalam beberapa hari (biasanya tidak berakibat pada kemampuan bereproduksi). Remaja dan dewasa,

khususnya laki-laki, yang terkena gondongan biasanya lebih menderita dan mengalami penyakit tersebut lebih lama dari pada penderita anak-anak.

**Rubella** biasanya merupakan penyakit ringan yang menyebabkan demam ringan, bengkak pada kelenjar di leher, rasa sakit dan bengkak pada sendi-sendi, serta ruam yang berlangsung dalam waktu singkat **akan tetapi berbahaya pada ibu hamil yang menderita penyakit tersebut**. Wanita yang terkena rubella pada saat hamil dapat menyebabkan kematian janin dalam kandungan, atau janin mengalami penyakit jantung, kebutaan, tuli, atau masalah pada kemampuan belajar.

## Apa yang harus saya ketahui sebelum vaksinasi dengan M-M-R II?

### *Siapa yang tidak boleh divaksinasi dengan M-M-R II?*

Setiap orang yang:

- Alergi terhadap salah satu komponen (termasuk neomisin)
- Sedang hamil (sebagai tambahan, kehamilan harus dihindari dalam rentang waktu 1 bulan setelah vaksinasi)
- Sedang demam
- Memiliki tuberculosis aktif yang tidak diobati
- Sedang dalam pengobatan untuk menekan sistem imun (selain pengganti kortikosteroid)
- Memiliki kelainan darah atau beberapa jenis kanker yang mempengaruhi sistem imun
- Memiliki kekurangan imun sebagai akibat dari penyakit atau pengobatan

### *Apa yang harus Saya katakan ke Dokter Saya sebelum vaksinasi dengan M-M-R II?*

Katakan pada dokter Anda mengenai segala masalah medis yang Anda atau anak Anda miliki, dan segala alergi (terutama neomisin).

Katakan pada dokter Anda jika Anda atau anak Anda memiliki riwayat kejang atau cedera pada otak, jumlah trombosit yang rendah, atau telah menerima donor darah atau plasma atau pemberian globulin serum manusia dalam waktu 3 bulan terakhir.

### *Penggunaan pada anak-anak.*

M-M-R II digunakan pada anak-anak usia 12 bulan ke atas.

*Pengunaan pada kehamilan.*

M-M-R II tidak boleh diberikan pada wanita hamil. Wanita pada masa reproduksi harus mengambil tindakan pencegahan untuk menghindari kehamilan 1 bulan paska vaksinasi.

*Penggunaan pada masa menyusui.*

Katakan pada dokter Anda jika Anda sedang menyusui atau berniat untuk menyusui. Dokter Anda akan memutuskan apakah Anda dapat menerima M-M-R II.

*Dapatkah Saya atau Anak saya divaksinasi M-M-R II dan vaksin lain secara bersamaan?*

M-M-R II harus diberikan satu bulan sebelum atau sesudah pemberian vaksin lain. Namun, jadwal lain dapat diberikan. Dokter Anda akan memutuskan jadwal pemberian tersebut.

*Dapatkah Saya mengemudi atau mengoperasikan mesin setelah vaksinasi M-M-R II?*

Penggunaan M-M-R II secara umum tidak berpengaruh pada kemampuan untuk mengemudi atau mengoperasikan mesin.

*Apa yang harus Saya ketahui mengenai bahan tambahan pada M-M-R II?*

M-M-R II mengandung neomisin sebagai bahan tambahan. Katakan pada dokter Anda jika Anda atau anak Anda memiliki riwayat alergi terhadap bahan ini.

## Bagaimana jadwal vaksinasi M-M-R II?

M-M-R II diberikan secara injeksi dengan jadwal sebagai berikut:

- M-M-R II diberikan pada seseorang dengan usia 12 bulan ke atas. Dosis vaksin adalah sama untuk semua orang.
- Anak-anak yang menerima vaksinasi pertama kurang dari 12 bulan harus mendapatkan dosis kedua pada umur 15 bulan.
- Orang dewasa yang tidak hamil dan wanita dewasa masa produktif yang rentan terhadap rubella dapat divaksinasi dengan M-M-R II (atau vaksin virus rubella *live attenuated*) jika beberapa tindakan pencegahan tertentu telah diketahui (lihat pada "Penggunaan pada Kehamilan"). Telah ditemukan pada beberapa kasus kenyamanan untuk memvaksinasi wanita yang rentan terhadap rubella pada masa setelah melahirkan (lihat pada "Penggunaan pada Masa Menyusui").

Konsultasikan pada dokter Anda untuk lebih jelasnya.

## Apa yang harus saya lakukan jika saya melewatkan dosis?

Dokter Anda akan memutuskan kapan untuk memberikan dosis yang terlewat.

## Apa efek yang tidak diinginkan mungkin M-M-R II miliki?

Setiap vaksin mungkin memiliki efek yang tidak diinginkan atau tidak diinginkan , yang disebut efek samping. Yang paling umum adalah rasa terbakar atau menyengat pada area suntikan dalam waktu singkat. Nyeri sendi sementara dan/atau bengkak telah terjadi lebih sering pada wanita dewasa; kadang gelaja-gejala ini dapat menjadi kronik. Ada kalanya, demam dan ruam dapat terjadi. Pada kasus yang jarang, pendarahan yang tidak biasa atau memar di bawah kulit, dan bengkak pada kemaluan pria dapat terjadi.

Beberapa efek samping lain dapat pula terjadi dalam frekuensi jarang dan beberapa dapat menjadi serius. Efek ini termasuk reaksi alergi, kejang, dan radang pada sistem saraf (otak dan/atau tulang belakang).

Dokter Anda memiliki list yang lebih lengkap mengenaii efek samping.

Beritahu dokter Anda secepatnya mengenai gejala-gejala ini atau gejala lain yang tidak biasa. Jika kondisinya berlanjut atau memburuk, carilah bantuan medis.

## Bagaimana saya bisa belajar lebih banyak tentang M-M-R II (dan dalam kondisi apa tidak diresepkan)?

Tidak semua informasi tentang vaksin ini dicetak di sini. Jika Anda memiliki pertanyaan tambahan, tanyakan pada dokter anda yang memiliki informasi resep detail.

HARUS DENGAN RESEP DOKTER

Mengandung Babi

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