

MERUVAX® II **(RUBELLA VIRUS VACCINE LIVE)** **Wistar RA 27/3 Strain**

DESCRIPTION

MERUVAX^{*} II (Rubella Virus Vaccine Live) is a live virus vaccine for vaccination against rubella (German measles).

MERUVAX II is a sterile lyophilized preparation of the Wistar Institute RA 27/3 strain of live attenuated rubella virus. The virus was adapted to and propagated in WI-38 human diploid lung fibroblasts.^{1,2}

The growth medium is Minimum Essential Medium (MEM) [a buffered salt solution containing vitamins and amino acids and supplemented with fetal bovine serum] containing human serum albumin and neomycin. Sorbitol and hydrolyzed gelatin stabilizer are added to the individual virus harvests.

The cells, virus pools, fetal bovine serum, and human albumin are all screened for the absence of adventitious agents. Human albumin is processed using the Cohn cold ethanol fractionation procedure.

The reconstituted vaccine is for subcutaneous administration. Each 0.5 mL dose contains not less than 1,000 TCID₅₀ (tissue culture infectious doses) of rubella virus. Each dose of the vaccine is calculated to contain sorbitol (14.5 mg), sodium phosphate, sucrose (1.9 mg), sodium chloride, hydrolyzed gelatin (14.5 mg), 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.

Before reconstitution, the lyophilized vaccine is a light yellow compact crystalline plug. MERUVAX II, when reconstituted as directed, is clear yellow.

CLINICAL PHARMACOLOGY

Rubella is a common childhood disease, caused by rubella virus (togavirus), that may be associated with serious complications and/or death. For example, rubella during pregnancy may cause congenital rubella syndrome in the infants of infected mothers.

The impact of measles, mumps, and rubella vaccination on the natural history of each disease in the United States can be quantified by comparing the maximum number of rubella cases reported in a given year prior to vaccine use to the number of cases of each disease reported in 1995. For rubella, 57,686 cases reported in 1969 compared to 200 cases reported in 1995 resulted in a 99.65% decrease.³

Extensive clinical trials of rubella virus vaccines, prepared using RA 27/3 strain rubella virus, have been carried out in more than 28,000 human subjects (approximately 11,000 with MERUVAX II) in the U.S.A. and more than 20 additional countries. A single injection of the vaccine has been shown to induce rubella hemagglutination-inhibition (HI) antibodies in 97% or more of susceptible persons. However, a small percentage (1-5%) of vaccinees may fail to seroconvert after the primary dose (see also INDICATIONS AND USAGE, *Recommended Vaccination Schedule*).

Efficacy of rubella vaccine was established in a series of double-blind controlled field trials which demonstrated a high degree of protective efficacy.⁴ These studies also established that seroconversion in response to rubella vaccination paralleled protection from this disease.⁵

Following vaccination, antibodies associated with protection can be measured by neutralization assays, HI, or ELISA (enzyme linked immunosorbent assay) tests. Neutralizing and ELISA

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antibodies to rubella virus are still detectable in most individuals 11-13 years after primary vaccination.^{6,7} See INDICATIONS AND USAGE, *Non-Pregnant Adolescents and Adult Females*, for Rubella Susceptibility Testing.

The RA 27/3 rubella strain elicits higher immediate post-vaccination HI, complement-fixing and neutralizing antibody levels than other strains of rubella vaccine⁸⁻¹⁴ and has been shown to induce a broader profile of circulating antibodies including anti-theta and anti-iota precipitating antibodies.^{15,16} The RA 27/3 rubella strain immunologically simulates natural infection more closely than other rubella vaccine viruses.¹⁶⁻¹⁸ The increased levels and broader profile of antibodies produced by RA 27/3 strain rubella virus vaccine appear to correlate with greater resistance to subclinical reinfection with the wild virus,^{16,18-20} and provide greater confidence for lasting immunity.

INDICATIONS AND USAGE

Recommended Vaccination Schedule

MERUVAX II is indicated for vaccination against rubella in persons 12 months of age or older.

It is not recommended for infants younger than 12 months because they may retain maternal rubella neutralizing antibodies that may interfere with the immune response.

Children in kindergarten and the first grades of elementary school deserve priority for vaccination because often they are epidemiologically the major source of virus dissemination in the community. A history of rubella illness is usually not reliable enough to exclude children from immunization.

Previously unimmunized children of susceptible pregnant women should receive live attenuated rubella vaccine, because an immunized child will be less likely to acquire natural rubella and introduce the virus into the household.

Individuals first vaccinated with MERUVAX II at 12 months of age or older should be revaccinated with M-M-R* II (Measles, Mumps, and Rubella Virus Vaccine Live) prior to elementary school entry. Revaccination is intended to seroconvert those who do not respond to the first dose. The Advisory Committee on Immunization Practices (ACIP) recommends administration of the first dose of M-M-R II at 12-15 months of age and administration of the second dose of M-M-R II at 4-6 years of age.³⁹ In addition, some public health jurisdictions mandate the age for revaccination. Consult the complete text of applicable guidelines regarding routine revaccination including that of high-risk adult populations.

Unnecessary doses of a vaccine are best avoided by ensuring that written documentation of vaccination is preserved and a copy given to each vaccinee's parent or guardian.

Other Vaccination Considerations

Adolescent and Adult Males

Vaccination of adolescent or adult males may be a useful procedure in preventing or controlling outbreaks of rubella in circumscribed population groups (e.g., military bases and schools).

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 below and 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.²²

Women of childbearing age should be advised not to become pregnant for 3 months after vaccination and should be informed of the reason for this precaution.

The ACIP has stated "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

** NOTE: The ACIP has recommended "In view of the importance of protecting this age group against rubella, reasonable practices in a rubella immunization program include a) asking women if they are pregnant, b) excluding those who say they are, c) explaining the concern about risk for the fetus to the others..."²²

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."²²

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).

Other Populations

Previously unvaccinated children in contact with susceptible pregnant women should receive live attenuated rubella vaccine (such as that contained in MERUVAX II) to reduce the risk of exposure of the pregnant woman.

Individuals planning travel outside the United States, if not immune, can acquire measles, mumps or rubella and import these diseases into the United States. 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.²³⁻²⁵

Vaccination is recommended for susceptible individuals in high-risk groups such as college students, health-care workers, and military personnel.^{22,26}

Postpartum Women

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

Post-Exposure Vaccination

There is no conclusive evidence that vaccination of individuals recently exposed to natural rubella will provide protection.^{22,26} There is, however, no contraindication to vaccinating children already exposed to natural rubella.

Use With Other Vaccines

See DOSAGE AND ADMINISTRATION, *Use With Other Vaccines*.

CONTRAINDICATIONS

Hypersensitivity to any component of the vaccine, including gelatin.²⁷

Do not give MERUVAX 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 three months following vaccination (see INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females* and PRECAUTIONS, *Pregnancy*).

Anaphylactic or anaphylactoid reactions to neomycin (each dose of reconstituted vaccine contains approximately 25 mcg of neomycin).

Febrile respiratory illness or other active febrile infection. However, the ACIP has recommended that all vaccines can be administered to persons with minor illnesses such as diarrhea, mild upper respiratory infection with or without low-grade fever, or other low-grade febrile illness.²⁶

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;^{26,28,29} cellular immune deficiencies; and hypogammaglobulinemic and dysgammaglobulinemic states.

Individuals with a family history of congenital or hereditary immunodeficiency, until the immune competence of the potential vaccine recipient is demonstrated.

WARNINGS

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

This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. Although there is a theoretical risk for transmission of Creutzfeldt-Jacob disease (CJD), no cases of transmission of CJD or viral disease have ever been identified that were associated with the use of albumin.

Hypersensitivity to Neomycin

The AAP states, "Persons who have experienced anaphylactic reactions to topically or systemically administered neomycin should not receive measles vaccine. Most often, however, neomycin allergy manifests as a contact dermatitis, which is a delayed-type (cell-mediated) immune response rather than anaphylaxis. In such persons, an adverse reaction to neomycin in the vaccine would be an erythematous, pruritic nodule or papule, 48 to 96 hours after vaccination. A history of contact dermatitis to neomycin is not a contraindication to receiving measles vaccine."³⁰

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).

PRECAUTIONS

General

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

Special care should be taken to ensure that the injection does not enter a blood vessel.

Excretion of small amounts of the live attenuated rubella virus from the nose or throat has occurred in the majority of susceptible individuals 7-28 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.²² However, transmission of the vaccine virus to infants via breast milk has been documented (see *Nursing Mothers*).

Children and young adults who are known to be infected with human immunodeficiency viruses and are not immunosuppressed may be vaccinated. However, 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).^{28,29}

Vaccination should be deferred for 3 months or longer following blood or plasma transfusions, or administration of immune globulin (human).³⁰ However, susceptible postpartum patients who received blood products may receive MERUVAX II prior to discharge provided that a repeat HI titer is drawn 6-8 weeks after vaccination to ensure seroconversion. Similarly, although studies with other live rubella virus vaccines suggest that MERUVAX II may be given in the immediate postpartum period to those non-immune women who have received anti-Rho (D) globulin (human)

without interfering with vaccine effectiveness, a follow-up post-vaccination HI titer should also be determined.

It has been reported that attenuated rubella virus vaccine live, may result in a temporary depression of tuberculin skin sensitivity. Therefore, if a tuberculin test is to be done, it should be administered either before or simultaneously with MERUVAX II.

Individuals with active untreated tuberculosis should not be vaccinated.

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

The health-care provider should determine the current health status and previous vaccination history of the vaccinee.

The health-care provider should question the patient, parent or guardian about reactions to a previous dose of MERUVAX II or other measles-, mumps-, or rubella-containing vaccines.

Information For Patients

The health-care provider should provide the vaccine information required to be given with each vaccination to the patient, parent or guardian.

The health-care provider should inform the patient, parent or guardian of the benefits and risks associated with vaccination. For risks associated with vaccination see WARNINGS, PRECAUTIONS, ADVERSE REACTIONS.

Patients, parents or guardians should be instructed to report any serious adverse reactions to their health-care provider who in turn should report such events to the U.S. Department of Health and Human Services through the Vaccine Adverse Event Reporting System (VAERS), 1-800-822-7967.³¹

Pregnancy should be avoided for three months following vaccination, and patients should be informed of the reasons for this precaution (see INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females*, CONTRAINDICATIONS, and PRECAUTIONS, *Pregnancy*).

Laboratory Tests

See INDICATIONS AND USAGE, *Non-Pregnant Adolescents and Adult Females*, for Rubella Susceptibility Testing, and CLINICAL PHARMACOLOGY.

Immunosuppressive Therapy

The immune status of patients about to undergo immunosuppressive therapy should be evaluated so that the physician can consider whether vaccination prior to the initiation of treatment is indicated (see CONTRAINDICATIONS and PRECAUTIONS).

The ACIP has stated that "patients with leukemia in remission who have not received chemotherapy for at least 3 months may receive live-virus vaccines. Short-term (<2 weeks), low- to moderate-dose systemic corticosteroid therapy, topical steroid therapy (e.g., nasal, skin), long-term alternate-day treatment with low to moderate doses of short-acting systemic steroid, and intra-articular, bursal, or tendon injection of corticosteroids are not immunosuppressive in their usual doses and do not contraindicate the administration of rubella vaccine."²²

Immune Globulin

Administration of immune globulins concurrently with MERUVAX II may interfere with the expected immune response.^{22,30}

See also PRECAUTIONS, *General*.

Carcinogenesis, Mutagenesis, Impairment of Fertility

MERUVAX II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility.

Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with MERUVAX II. It is also not known whether MERUVAX II can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. There is evidence suggesting transmission of rubella vaccine viruses to products of conception.³² Therefore, rubella vaccine should not be administered to pregnant females (see INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females* and CONTRAINDICATIONS).

In counseling women who are inadvertently vaccinated when pregnant or who become pregnant within 3 months of vaccination, the physician should be aware of the following: In a 10 year survey involving over 700 pregnant women who received rubella vaccine within 3 months before or after conception, (of whom 189 received the Wistar RA 27/3 strain) none of the newborns had abnormalities compatible with congenital rubella syndrome.³²

Nursing Mothers

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.³³ In the infants with serological evidence of rubella infection, none exhibited severe disease; however, one exhibited mild clinical illness typical of acquired rubella.^{34,35} Caution should be exercised when MERUVAX II is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in infants below the age of 12 months have not been established (see INDICATIONS AND USAGE, *Recommended Vaccination Schedule*).

Geriatric Use

Clinical studies of MERUVAX II did not include sufficient numbers of seronegative subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger subjects.

ADVERSE REACTIONS

The following adverse reactions are listed in decreasing order of severity, without regard to causality, within each body system category and have been reported during clinical trials, with use of the marketed vaccine, or with use of polyvalent vaccine containing rubella:

Body as a Whole

Fever; syncope; headache; dizziness; malaise; irritability.

Cardiovascular System

Vasculitis.

Digestive System

Diarrhea; vomiting; nausea.

Hemic and Lymphatic System

Thrombocytopenia (see WARNINGS, *Thrombocytopenia*); purpura; regional lymphadenopathy; leukocytosis.

Immune System

Anaphylaxis and anaphylactoid reactions have been reported as well as related phenomena such as angioneurotic edema (including peripheral or facial edema) and bronchial spasm in individuals with or without an allergic history.

Musculoskeletal System

Arthritis; arthralgia; myalgia.

Chronic arthritis has been associated with natural 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: 12-26%)^{7,36,37} 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 in adult women. Even in women older than 35 years, these reactions are generally well tolerated and rarely interfere with normal activities. Myalgia and paresthesia have been reported rarely after administration of MERUVAX II.

Nervous System

Encephalitis; Guillain-Barré Syndrome (GBS); polyneuritis; polyneuropathy; paresthesia.

Respiratory System

Sore throat; cough; rhinitis.

Skin

Stevens-Johnson Syndrome; erythema multiforme; urticaria; rash.

Local reactions including burning/stinging at injection site; wheal and flare; redness (erythema); pain; induration.

Special Senses — Ear

Nerve deafness; otitis media.

Special Senses — Eye

Optic neuritis; papillitis; retrobulbar neuritis; conjunctivitis.

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. 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 1982-1993.³⁸

Under the National Childhood Vaccine Injury Act of 1986, health-care providers and manufacturers are required to record and report certain suspected adverse events occurring within specific time periods after vaccination. However, the U.S. Department of Health and Human Services (DHHS) has established a Vaccine Adverse Event Reporting System (VAERS) which will accept all reports of suspected events.³¹ A VAERS report form as well as information regarding reporting requirements can be obtained by calling VAERS 1-800-822-7967.

DOSAGE AND ADMINISTRATION*FOR SUBCUTANEOUS ADMINISTRATION**Do not inject intravenously*

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

The recommended age for primary vaccination is 12 to 15 months.

Revaccination with M-M-R II is recommended prior to elementary school entry. See also INDICATIONS AND USAGE, *Recommended Vaccination Schedule*.

Immune Globulin (IG) is not to be given concurrently with MERUVAX II.

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.

Single Dose Vial— 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 restored 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.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. MERUVAX II, when reconstituted, is clear yellow.

Use With Other Vaccines

MERUVAX II should not be given less than one month before or after administration of other live viral vaccines.

M-M-R II has been administered concurrently with VARIVAX* [Varicella Virus Vaccine Live (Oka/Merck)], and PedvaxHIB* [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)] using separate sites and syringes. No impairment of immune response to individual

tested vaccine antigens was demonstrated. The type, frequency, and severity of adverse experiences observed in these studies 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. The ACIP has stated "Although data are limited concerning the simultaneous administration of the entire recommended vaccine series (i.e., DTP, OPV, MMR, and Hib vaccines, with or without hepatitis B vaccine), data from numerous studies have indicated no interference between routinely recommended childhood vaccines (either live, attenuated, or killed). These findings support the simultaneous use of all vaccines as recommended."²¹

HOW SUPPLIED

No. 4747 — MERUVAX II is supplied as a single-dose vial of lyophilized vaccine **NDC** 0006-4747-00, and a vial of diluent.

No. 4673/4309 — MERUVAX II is supplied as follows: (1) a box of 10 single-dose vials of lyophilized vaccine (package A) **NDC** 0006-4673-00; and (2) a box of 10 vials of diluent (package B). To conserve refrigerator space, the diluent may be stored separately at room temperature.

Storage

During shipment, to ensure that there is no loss of potency, the vaccine must be maintained at a temperature of 10°C (50°F) or colder. Freezing during shipment will not affect potency.

Protect the vaccine from light at all times, since such exposure may inactivate the virus.

Before reconstitution, store the vial of lyophilized vaccine at 2-8°C (36-46°F) or colder. The diluent may be stored in the refrigerator with the lyophilized vaccine or separately at room temperature.

It is recommended that the vaccine be used as soon as possible after reconstitution. Store reconstituted vaccine in the vaccine vial in a dark place at 2-8°C (36-46°F) and discard if not used within 8 hours.

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