

MUMPSVAX®
(MUMPS VIRUS VACCINE LIVE)
JERYL LYNN™ STRAIN

DESCRIPTION

MUMPSVAX* (Mumps Virus Vaccine Live) is a live virus vaccine for vaccination against mumps.

MUMPSVAX is a sterile lyophilized preparation of the Jeryl Lynn** (B level) strain of mumps virus. The virus was adapted to and propagated in chick embryo cell culture.

The growth medium for mumps is Medium 199 (a buffered salt solution containing vitamins and amino acids and supplemented with fetal bovine serum) containing SPGA (sucrose, phosphate, glutamate, and human albumin) as stabilizer and neomycin.

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 20,000 TCID₅₀ (tissue culture infectious doses) of mumps 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. MUMPSVAX, when reconstituted as directed, is clear yellow.

CLINICAL PHARMACOLOGY

Mumps is a common childhood disease, caused by mumps virus (paramyxovirus), that may be associated with serious complications and/or death. For example, mumps is associated with aseptic meningitis, deafness and orchitis.

The impact of mumps vaccination on the natural history of each disease in the United States can be quantified by comparing the maximum number of mumps cases reported in a given year prior to vaccine use to the number of cases of each disease reported in 1995. For mumps, 152,209 cases reported in 1968 compared to 840 cases reported in 1995 resulted in a 99.45% decrease in reported cases.¹

Extensive clinical trials have demonstrated that MUMPSVAX is highly immunogenic and well tolerated.²⁻¹⁵ A single injection of the vaccine has been shown to induce mumps neutralizing antibodies in approximately 97% of susceptible children and approximately 93% of susceptible adults.⁶ The pattern of antibody response closely resembles that observed for natural mumps. Although the antibody level is significantly lower than that following natural infection; it is protective and long lasting.¹⁶ 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 mumps vaccine was established in a series of double-blind controlled field trials which demonstrated a high degree of protective efficacy.^{15,17,18} These studies also established that seroconversion in response to mumps vaccination paralleled protection from these diseases.¹⁹

Following vaccination, antibodies associated with protection can be measured by neutralization assays, hemagglutination-inhibition (HI), or ELISA (enzyme linked immunosorbent assay) tests. Neutralizing and ELISA antibodies to mumps virus are still detectable in most individuals 11-13 years after primary vaccination.²⁰

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INDICATIONS AND USAGE

Recommended Vaccination Schedule

MUMPSVAX is indicated for vaccination against mumps in persons 12 months of age or older.

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

Individuals first vaccinated with MUMPSVAX 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 may seroconvert primary failures or boost antibody titers of those individuals whose titers have declined. 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.³⁴ 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

Other Populations

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.²²⁻²⁴

Vaccination is recommended for susceptible individuals in high-risk groups such as college students, health-care workers, and military personnel.¹⁶

Post Exposure Vaccination

There is no conclusive evidence that vaccination of individuals recently exposed to natural mumps will provide protection.¹⁶

Use With Other Vaccines

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

CONTRAINDICATIONS

Hypersensitivity to any component of the vaccine, including gelatin.²⁵

Do not give MUMPSVAX 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 3 months 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. 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 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 Eggs

Live mumps vaccine is 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 (see PRECAUTIONS).³⁰

However, the American Academy of Pediatrics (AAP) has stated, "Most children with a history of anaphylactic reactions to eggs have no untoward reactions to measles or MMR vaccine. Persons are not at increased risk if they have egg allergies that are not anaphylactic, and they should be vaccinated in the usual manner. In addition, skin testing of egg-allergic children with vaccine has not been predictive of which children will have an immediate hypersensitivity reaction. Persons with allergies to chickens or chicken feathers are not at increased risk of reaction to the vaccine."²⁹

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."²⁹

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.

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.

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).^{27,28}

Vaccination should be deferred for 3 months or longer following blood or plasma transfusions, or administration of immune globulin (human).²⁹

There are no reports of transmission of live mumps virus from vaccinees to susceptible contacts.

It has been reported that mumps 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 MUMPSVAX.^{7,31}

Individuals with active untreated tuberculosis should not be vaccinated.

As for any vaccine, vaccination with MUMPSVAX 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 MUMPSVAX or other mumps-containing vaccines.

Drug Interactions

See DOSAGE AND ADMINISTRATION, *Use With Other 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), 1-800-822-7967.³²

Pregnancy should be avoided for 3 months following vaccination.

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 indicated 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 mumps vaccine.¹⁶

Immune Globulin

Administration of immune globulins concurrently with MUMPSVAX may interfere with the expected immune response.^{16,29}

See also PRECAUTIONS, *General*.

Carcinogenesis, Mutagenesis, Impairment of Fertility

MUMPSVAX 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 MUMPSVAX. It is also not known whether MUMPSVAX can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, mumps virus vaccine should not be given to persons known to be pregnant; furthermore, pregnancy should be avoided for 3 months following vaccination (see CONTRAINDICATIONS).

In counseling women who are inadvertently vaccinated when pregnant or who become pregnant within 3 months of vaccination, the physician should be aware that 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.¹⁶

Nursing Mothers

It is not known whether mumps vaccine virus is secreted in human milk. Therefore, because many drugs are excreted in human milk, caution should be exercised when MUMPSVAX 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 MUMPSVAX 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 mumps:

Body as a Whole

Fever; syncope; irritability.

Cardiovascular System

Vasculitis.

Digestive System

Pancreatitis; diarrhea; parotitis.

Endocrine System

Diabetes mellitus.

Hemic and Lymphatic System

Thrombocytopenia; purpura; 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.

Nervous System

Encephalitis; Guillain-Barré Syndrome (GBS); febrile seizures; ocular palsies.

Cases of aseptic meningitis have been reported to VAERS following measles, mumps, and rubella vaccination. Although a causal relationship between the Urabe strain of mumps vaccine and aseptic meningitis has been shown, there are no data to link Jeryl Lynn mumps vaccine to aseptic meningitis.

Respiratory System

Cough; rhinitis.

Skin

Stevens-Johnson Syndrome; erythema multiforme; urticaria.

Local reactions including burning/stinging at injection site; wheal and flare.

Special Senses — Ear

Nerve deafness; otitis media.

Special Senses — Eye

Optic neuritis; papillitis; retrobulbar neuritis; conjunctivitis.

Urogenital System

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. 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 1982-1993.³³

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.³² 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 MUMPSVAX.

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. MUMPSVAX, when reconstituted, is clear yellow.

Use With Other Vaccines

MUMPSVAX 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 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. 4753 — MUMPSVAX is supplied as a single-dose vial of lyophilized vaccine, **NDC** 0006-4753-00, and a vial of diluent.

No. 4584X/4309 — MUMPSVAX is supplied as follows: (1) a box of 10 single-dose vials of lyophilized vaccine (package A), **NDC** 0006-4584-00; 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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