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# U.S. Child and Adolescent Immunization Schedule

Merck affirms that every child deserves to grow up safe, healthy and able to thrive, and that nothing is more important than the safety of our medicines and vaccines. Childhood vaccination has been remarkably successful, and it is critical that changes to the immunization schedule are informed by comprehensive data, guided by experts and evaluated in the proper context. Merck stands firmly behind an immunization framework grounded in rigorous science, strong regulatory processes and ongoing safety monitoring.

## Our Position

At Merck, we share the same fundamental belief with health care providers and parents alike: every child deserves to grow up safe, healthy and able to thrive. Nothing is more important to us than the safety of our medicines and vaccines and the wellbeing of the people who rely on them.

For families today, many infectious diseases may feel like distant history. That progress exists because childhood vaccination has been remarkably successful. Decades of science-based immunization policy, supported by continuous safety monitoring and real-life evidence across millions of children, have helped protect communities.

The U.S. child and adolescent immunization schedule has long reflected this rigorous approach. Vaccines are studied extensively in clinical trials using specific dosing regimens, and vaccinations are timed based on multiple scientific considerations, including when maternal antibodies wane, when children are most likely to be exposed to or susceptible to certain diseases, how immune systems respond at different ages and how healthcare providers can most effectively deliver protection.

As the Department of Health and Human Services (HHS) makes changes to the immunization schedule, it is critical that changes are informed by comprehensive data and guided by experts in vaccinology, pediatrics, infectious diseases and epidemiology. International comparisons should also be evaluated in the proper context, recognizing differences in disease burden, healthcare infrastructure and population needs.

Shared clinical decision-making plays an important role in healthcare, helping clinicians and families consider individual circumstances and risks. However, clear, evidence-based recommendations remain essential to support informed decisions and ensure that children and adolescents receive reliable protection against preventable diseases.

As recent outbreaks in the U.S. have shown, sustained confidence in vaccination programs is critical to protecting individuals and communities. When vaccination rates decline, the consequences can be serious.

Merck stands firmly behind an immunization framework grounded in rigorous science, strong regulatory processes and ongoing safety monitoring. We remain committed to working with public health partners to support policies that help protect children and adolescents, strengthen communities and preserve the progress achieved through immunization.

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**Indication for M-M-R®II**

M-M-R®II is a vaccine indicated for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age or older.

The first dose of M-M-R®II is administered at 12 to 15 months of age and the second dose of M-M-R®II is administered at 4 to 6 years of age.

**Select Safety Information for M-M-R®II**

M-M-R®II is contraindicated in certain individuals, including those with: a history of hypersensitivity to any component of the vaccine, including gelatin; a history of anaphylactic reaction to neomycin; individuals who are immunodeficient or immunosuppressed due to disease or medical therapy; an active febrile illness; active untreated tuberculosis; or those who are pregnant or are planning to become pregnant within the next month.

Due caution should be employed in administration of M-M-R®II to persons with: a history of febrile seizure or family history of febrile seizures; immediate-type hypersensitivity reactions to eggs; thrombocytopenia.

Vaccination should be deferred in individuals with a family history of congenital or hereditary immunodeficiency until the individual's immune status has been evaluated and the individual has been found to be immunocompetent.

Immune globulins (IG) and other blood products should not be given concurrently with M-M-R®II. The ACIP has specific recommendations for intervals between administration of antibody-containing products and live virus vaccines.

The following adverse reactions have been identified during both the subcutaneous and intramuscular use of M-M-R®II or its components in clinical trials or reported during post-approval use: fever, rash, and injection-site reactions.

The following adverse reactions have been identified during the subcutaneous use of M-M-R®II or its components in clinical trials or reported during post-approval use: headache, dizziness,

febrile convulsions, anaphylaxis and anaphylactoid reactions, arthritis, thrombocytopenia, encephalitis and encephalopathy.

**Dosage and Administration for M-M-R®II**

FOR INTRAMUSCULAR OR SUBCUTANEOUS USE ONLY.

M-M-R®II vaccine can be administered concurrently with other live viral vaccines. If not given concurrently, M-M-R®II vaccine should be given one month before or one month after administration of other live viral vaccines to avoid potential for immune interference.

Before administering M-M-R®II, please read the accompanying **Prescribing Information**. The **Patient Information** also is available.

**Indication for ProQuad®**

ProQuad is a vaccine indicated for active immunization for the prevention of measles, mumps, rubella, and varicella in children 12 months through 12 years of age.

VARIVAX is a vaccine indicated for active immunization for the prevention of varicella in individuals 12 months of age or older.

M-M-R®II is indicated for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age or older.

**Select Safety Information for ProQuad**

**Hypersensitivity:** ProQuad, M-M-R®II (Measles, Mumps, and Rubella Virus Vaccine Live), and VARIVAX® (Varicella Virus Vaccine Live)are contraindicated in patients with a history of anaphylactic reaction or hypersensitivity to any component of the vaccine (including gelatin or neomycin) or to a prior dose of measles, mumps, rubella, or varicella-containing vaccine. Use caution when administering ProQuad and M-M-R®II to individuals with anaphylaxis or immediate hypersensitivity to eggs.

ProQuad, M-M-R®II, and VARIVAXare contraindicated in certain individuals, including those with: immunodeficiency or who are immunosuppressed; an active febrile illness; untreated tuberculosis.

**Pregnancy:** ProQuad, M-M-R®II, and VARIVAX are contraindicated for use in pregnant women. Do not administer ProQuad or VARIVAX to individuals who are planning to become pregnant in the next 3 months. Do not administer M-M-R®II to individuals who are planning to become pregnant in the next month.

**Febrile Seizures:** Administration of ProQuad (dose 1) to children 12 to 23 months old who have not been previously vaccinated against measles, mumps, rubella, or varicella, nor had a history of the wild-type infections, is associated with higher rates of fever and febrile seizures at 5 to

12 days after vaccination when compared to children vaccinated with a first dose of both M-M-R®II and VARIVAX administered concomitantly.

**Febrile Seizures:** Use caution when administering ProQuad and M-M-R®II to individuals with a history of febrile seizures.

**Family History of Immunodeficiency:** Vaccination with ProQuad, M-M-R®II, and VARIVAX should be deferred in individuals with a family history of congenital or hereditary immunodeficiency until the individual's immune status has been evaluated and the individual has been found to be immunocompetent.

**Thrombocytopenia:** Transient thrombocytopenia has been reported within 4-6 weeks following vaccination with measles, mumps, and rubella vaccine. Carefully evaluate the potential risk and benefit of vaccination in children with thrombocytopenia or in those who experienced thrombocytopenia after vaccination with a previous dose of a measles, mumps, and rubella-containing vaccine.

**Varicella Transmission and Precautions:** Advise vaccinees administered ProQuad or VARIVAX to avoid: close contact with high-risk individuals susceptible to varicella for up to 6 weeks following vaccination since transmission of varicella vaccine virus to susceptible contacts has been reported. Varicella vaccine virus transmission may occur between vaccine recipients and contacts susceptible to varicella including healthy individuals.

**Immune Globulins and Other Blood Products**: Immune Globulins and other blood products should not be given concomitantly with ProQuad, M-M-R®II, or VARIVAX.

**Use of Salicylates:** Avoid use of salicylates in children and adolescents administered ProQuad or VARIVAX for 6 weeks following vaccination due to the association of Reye Syndrome with salicylate therapy and wild-type varicella infection.

**Adverse Events:** The following adverse events have been reported for both subcutaneous and intramuscular injections of ProQuad, M-M-R®II, and VARIVAX: fever, injection-site reactions (pain/tenderness/soreness, erythema, and swelling); and rash on the body or at the injection site. Additionally, irritability has been reported for the subcutaneous injections of ProQuad, M-M-R®II, and VARIVAX.

**ProQuad Systemic Vaccine-Related Adverse Events:** Systemic vaccine-related adverse events that were reported at a significantly greater rate in recipients of subcutaneous ProQuad than in recipients of the component vaccines administered concomitantly were fever and measles-like rash.

**VARIVAX Dose-related Adverse Events:** In a clinical trial involving children who received 2 doses of VARIVAX 3 months apart, the incidence of injection-site clinical complaints observed

in the first 4 days following vaccination was slightly higher post-dose 2 (overall incidence 25.4%) than post-dose 1 (overall incidence 21.7%), whereas the incidence of systemic clinical complaints in the 42-day follow-up period was lower post-dose 2 (66.3%) than post-dose 1 (85.8%).

**Concomitant Vaccines With ProQuad:** ProQuad may be administered concomitantly with diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed (DTaP), *Haemophilus influenzae* type b conjugate (meningococcal protein conjugate) and hepatitis B (recombinant) vaccine. It may also be administered concomitantly with pneumococcal 7-valent conjugate vaccine and/or hepatitis A vaccine (inactivated) at separate injection sites.

**Concomitant Vaccines With VARIVAX:** VARIVAX can be administered with other live viral vaccines. If not given concurrently, at least 1 month should elapse between a dose of a live attenuated measles virus-containing vaccine and a dose of VARIVAX. In children, at least 3 months should elapse between administration of 2 doses of a live attenuated varicella virus-containing vaccine.

**Tuberculin Testing:** If a tuberculin test is to be done with M-M-R®II and ProQuad, it should be administered either any time before, simultaneously with, or at least 4 to 6 weeks after vaccination. With VARIVAX, tuberculin testing may be performed before the vaccine is administered or at least 4 weeks following vaccination.

**Additional M-M-R®II Precautions:** Additional adverse reactions, which have been reported without regard to causality, include febrile convulsions, arthritis, thrombocytopenia, anaphylaxis, anaphylactoid reactions, arthritis, encephalitis and encephalopathy in their diverse clinical presentations.

**Additional VARIVAX Precautions:** It is not known if varicella vaccine virus is excreted in human milk. A boost in antibody levels has been observed in vaccinees following exposure to wild-type varicella, which could account for the apparent long-term persistence of antibody levels in studies. The duration of protection from varicella infection after vaccination is unknown.

**ProQuad/VARIVAX and Herpes Zoster:** The long-term effect of VARIVAX on the incidence of herpes zoster, particularly in those vaccinees exposed to wild-type varicella, is unknown at present.

**Efficacy:** Vaccination with ProQuad, VARIVAX, or M-M-R®II may not result in protection in 100% of vaccinees.

**Dosage and Administration for ProQuad**

**ProQuad:**

- Each dose of ProQuad is approximately 0.5 mL and is administered intramuscularly or subcutaneously.
- At least 1 month should elapse between a dose of a measles-containing vaccine such as M-M-R®II and a dose of ProQuad. At least 3 months should elapse between a dose of varicella-containing vaccine and ProQuad.

**VARIVAX:**

- Each dose is approximately 0.5 mL and is administered intramuscularly or subcutaneously.
    - The first dose is administered at 12 to 15 months of age.
    - The second dose is administered at 4 to 6 years of age.
    - There should be a minimum interval of 3 months between doses.
    - 12 months to 12 years of age: If a second dose is administered, there should be a minimum interval of 3 months between doses.
    - Adolescents (≥13 years of age) and Adults: 2 doses, to be administered with aminimum interval of 4 weeks between doses.

**M-M-R®II:**

- The dose for any age is approximately 0.5 mL administered intramuscularly or subcutaneously.
    - The recommended age for primary vaccination is 12 to 15 months and the second dose should be given at 4 to 6 years of age.

Before administering **VARIVAX** (Varicella Virus Vaccine Live), **M-M-R®II** (Measles, Mumps, and Rubella Virus Vaccine Live), or **ProQuad** (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), please read the accompanying Prescribing Information. The Patient Information also is available for **VARIVAX**, **M-M-R®II**, and **ProQuad**.

**Indication for RECOMBIVAX HB®**

RECOMBIVAX HB is indicated for prevention of infection caused by all known subtypes of hepatitis B virus. RECOMBIVAX HB is approved for use in individuals of all ages. RECOMBIVAX HB Dialysis Formulation is approved for use in adult predialysis and dialysis patients 18 years of age and older.

**Select Safety Imformation for RECOMBIVAX HB**

Do not administer RECOMBIVAX HB to individuals with a history of severe allergic or hypersensitivity reactions (eg, anaphylaxis) after a previous dose of any hepatitis B-containing vaccine or to any component of RECOMBIVAX HB, including yeast.

The vial stopper and the syringe plunger stopper and tip cap contain dry natural latex rubber, which may cause allergic reactions in latex-sensitive individuals.

Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including RECOMBIVAX HB, to infants born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination. For RECOMBIVAX HB, this assessment should include consideration of the mother's hepatitis B antigen status and high probability of maternal transmission of hepatitis B virus to infants born to mothers who are HBsAg positive if vaccination is delayed.

Hepatitis B vaccination should be delayed until 1 month of age or hospital discharge in infants weighing <2000 g if the mother is documented to be HBsAg negative at the time of the infant's birth. Infants weighing <2000 g born to HBsAg positive or HBsAg unknown mothers should receive vaccine and hepatitis B immune globulin (HBIG) in accordance with ACIP recommendations if HBsAg status cannot be determined.

Hepatitis B virus has a long incubation period. RECOMBIVAX HB may not prevent hepatitis B infection in individuals who have an unrecognized hepatitis B infection at the time of vaccination.

Vaccination with RECOMBIVAX HB may not protect all individuals.

In healthy infants and children (up to 10 years of age), injection site reactions and systemic adverse reactions were reported following 0.2% and 10.4% of the injections, respectively. The most frequently reported systemic adverse reactions (>1% injections), in decreasing order of frequency, were irritability, fever, diarrhea, fatigue/weakness, diminished appetite, and rhinitis. In a study that compared the 3-dose regimen (5 mcg) with the 2-dose regimen (10 mcg) of RECOMBIVAX HB in adolescents, the overall frequency of adverse reactions was generally similar.

In a group of studies involving healthy adults, injection site reactions and systemic adverse reactions were reported following 17% and 15% of the injections, respectively. The following adverse reactions were reported (≥1% of injections) injection site reactions, fatigue/weakness, headache, fever, malaise, nausea, diarrhea, pharyngitis, and upper respiratory infection.

Additional adverse reactions have been reported with the use of the marketed vaccine. Because these reactions are reported voluntarily from a population of uncertain size, it is not

possible to reliably estimate their frequency or establish a causal relationship to a vaccine exposure.

**Use in Special Populations**

*Pregnancy*

There are no adequate and well-controlled studies designed to evaluate RECOMBIVAX HB in pregnant women. Available post-approval data do not suggest an increased risk of miscarriage or major birth defects in women who received RECOMBIVAX HB during pregnancy.

*Nursing Mothers*

Data are not available to assess the effects of RECOMBIVAX HB on the breastfed infant or on milk productions/excretion. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for RECOMBIVAX HB and any potential adverse effects on the breastfed child from RECOMBIVAX HB or from the underlying maternal condition.

*Pediatric Use*

The safety and effectiveness of RECOMBIVAX HB Dialysis Formulation in children have not been established.

*Geriatric Use*

Clinical studies of RECOMBIVAX HB did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. However, in later studies it has been shown that a diminished antibody response can be expected in persons older than 60 years of age. In addition, the responses to these vaccines may be lower if the vaccine is administered as a buttock injection.

*Predialysis and Dialysis Patients*

Predialysis and dialysis adult patients respond less well to hepatitis B vaccines than do healthy individuals; however, vaccination of adult patients early in the course of their renal disease produces higher seroconversion rates than vaccination after dialysis has been initiated.

*Known or Presumed Exposure to HBsAg*

Refer to recommendations of the Advisory Committee on Immunization Practices (ACIP) and to the package insert for hepatitis B immune globulin (HBIG) for management of persons with known or presumed exposure to the hepatitis B virus (eg, neonates born of infected mothers or persons who experienced percutaneous or permucosal exposure to the virus). When recommended, administer RECOMBIVAX HB and HBIG intramuscularly at separate sites (eg, opposite anterolateral thighs for exposed neonates) as soon as possible after exposure.

**Dosage and Administration for RECOMBIVAX HB**

The vaccination regimen for RECOMBIVAX HB for persons from birth through 19 years of age consists of a series of 3 doses (0.5 mL each) given on a 0-, 1-, and 6-month schedule.

The vaccination regimen for RECOMBIVAX HB for adolescents 11 through 15 years of age consists of a series of 3 doses (0.5 mL each) given on a 0-, 1-, and 6-month schedule, or a series of 2 doses (1.0 mL each) on a 0- and 4- to 6-month schedule.

The vaccination regimen for RECOMBIVAX HB for persons 20 years of age and older consists of a series of 3 doses (1.0 mL each) given on a 0-, 1-, and 6-month schedule.

The deltoid muscle is the preferred site for intramuscular injection for adults, adolescents, and children 1 year of age and older whose deltoid is large enough for intramuscular injection. The anterolateral aspect of the thigh is the preferred site for intramuscular injection for infants younger than 1 year of age. RECOMBIVAX HB should not be administered in the gluteal region, as injections given in the buttocks have resulted in lower seroconversion rates than expected. Consider subcutaneous administration only in persons who are at risk of hemorrhage following intramuscular injections.

Predialysis and Dialysis Adult Patients: The vaccination regimen for RECOMBIVAX HB Dialysis Formulation for adults on predialysis and dialysis consists of a series of 3 doses (1.0 mL each) given on a 0-, 1-, and 6-month schedule.

Consider a booster dose or revaccination with RECOMBIVAX HB Dialysis Formulation (blue color code) in predialysis/dialysis patients if the anti-HBs level is less than 10 mIU/mL at 1 to 2 months after the third dose.

The duration of the protective effect on RECOMBIVAX HB in healthy vaccinees is unknown at present and the need for booster doses is not yet defined.

RECOMBIVAX HB should be administered as soon as possible after being removed from refrigeration.

Before administering RECOMBIVAX HB, please read the accompanying **Prescribing Information**.

**Indication for VAXELIS®**

VAXELIS is a vaccine indicated for active immunization to prevent diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, and invasive disease due to Haemophilus influenzaetype b. VAXELIS is approved for use as a 3-dose series in children 6 weeks through 4 years of age (prior to the 5th birthday).

**Select Safety Information for VAXELIS**

VAXELIS is contraindicated in children with a history of severe allergic reaction (eg, anaphylaxis) to a previous dose of VAXELIS, any ingredient of VAXELIS, or any other diphtheria toxoid, tetanus toxoid, pertussis-containing vaccine, inactivated poliovirus vaccine, hepatitis B vaccine, or H. influenzaetype b vaccine.

Do not administer VAXELIS to anyone with a history of encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures), within 7 days of a pertussis-containing vaccine that is not attributable to another identifiable cause.

Do not administer VAXELIS to anyone with a history of progressive neurologic disorder until a treatment regimen has been established and the condition has stabilized.

Vaccination with VAXELIS may not protect all individuals.

Carefully consider benefits and risks before administering VAXELIS to persons with a history of:

- fever of ≥40.5°C (≥105°F), hypotonic-hyporesponsive episode (HHE) or persistent, inconsolable crying lasting ≥3 hours within 48 hours after a previous pertussis-containing vaccine.
- seizures within 3 days after a previous pertussis-containing vaccine.

If Guillain-Barré syndrome occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following VAXELIS.

Apnea following intramuscular vaccination has been observed in some infants born prematurely. The decision about when to administer an intramuscular vaccine, including VAXELIS, to an infant born prematurely should be based on considerations of the individual infant's medical status and the potential benefits and possible risks of vaccination.

Urine antigen detection may not have definitive diagnostic value in suspected H. influenzatype b disease following vaccination with VAXELIS.

The solicited adverse reactions following any dose were irritability (≥55%), crying (≥45%), injection site pain (≥44%), somnolence (≥40%), injection site erythema (≥25%), decreased appetite (≥23%), fever ≥38.0°C (≥19%), injection site swelling (≥18%), and vomiting (≥9%).

**Dosage and Administration for VAXELIS**

The 3-dose immunization series consists of a 0.5 mL intramuscular injection, administered at 2, 4, and 6 months of age.

A 3-dose series of VAXELIS does not constitute a primary immunization series against pertussis; an additional dose of pertussis-containing vaccine is needed to complete the primary series.

Before administering VAXELIS, please read the accompanying **Prescribing Information**. The **Patient Information** also is available.