

A Quick Look at Using Rotavirus (RV) Vaccines

Available Rotavirus Vaccines

- Rotarix® (RV1), GlaxoSmithKline
- RotaTeq® (RV5), Merck
- Both RV vaccines are live, attenuated vaccines

Indications for Use and Schedule

- Number of doses in series depends on RV vaccine used
 - RV1: 2-dose series at 2 months and 4 months
 - RV5: 3-dose series at 2, 4, and 6 months
- Minimum age to start RV vaccine series is 6 weeks
- Maximum age for 1st dose of RV vaccine series is 14 weeks, 6 days
- Maximum age for last dose of RV vaccine series is 8 months, 0 days
- Minimum interval between RV vaccine doses is 4 weeks
- If both RV vaccines are available, continue series with the same product (RV1 or RV5); if not, use the product in stock
- If any dose in RV vaccine series is RV5 or the brand is unknown, give the 3-dose series

Vaccine Administration

- Administer both RV vaccines **orally (PO)**
- RV1 dosage is 1.0 mL; needs to be reconstituted, see Further Points below
- RV5 dosage is 2.0 mL; is premixed
- Can be given with other vaccines at the same visit
- May give before or after injectable vaccines
- Do not add to other liquids or food; may give food/fluids before or after RV vaccine
- Do not repeat doses that are regurgitated or spit up; count the dose and give the next dose as scheduled
- Dispose vaccine vial, syringe, tube, and cap in biologic waste container

Storage and Handling

- Store vaccine in the refrigerator at **36°F to 46°F (2°C to 8°C)**
- Do **not** freeze
- Pharmaceutical-grade (purpose-built) units are preferred for vaccine storage
- Keep in the original boxes and **protect from light**

CONTRAINDICATIONS

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of vaccine or to a vaccine component
 - Note: Latex rubber is contained in the **RV1** oral applicator. Infants with a severe allergy to latex should not receive RV1. The RV5 dosing tube is latex free.
- History of severe combined immunodeficiency (SCID)
- History of intussusception
- History of uncorrected congenital malformation of the gastrointestinal tract (such as Meckel's diverticulum) that predisposes the infant to intussusception (**RV1 only**)

PRECAUTIONS

- Moderate or severe illness with or without fever
- Altered immunocompetence other than SCID (e.g., blood dyscrasias, leukemia, HIV, on immunosuppressive therapy including high-dose systemic corticosteroids, primary and acquired)
- Chronic gastrointestinal disease
- Spina bifida or bladder exstrophy (**RV1 only**)
 - Infants with spina bifida or bladder exstrophy are at high risk for acquiring latex allergy; providers may want to consider administering RV5 to these infants if it's available
 - Refer to the 2009 MMWR (see footnote on page 2) for more information
- Moms who are HIV/AIDS positive and the infant's HIV status is unknown (**RV5 only**)

- History of receiving a blood transfusion or blood product, including immunoglobulins, within previous 42 days (**RV5 only**)
 - Note: The Advisory Committee on Immunization Practices (ACIP) recommendation is that RV vaccine may be administered at any time before, concurrent with, or after administration of any blood product, including antibody-containing products, following the routine schedule for infants who are eligible for vaccination

FURTHER POINTS

- Do **not** start the RV series **on or after** age 15 weeks, 0 days
- If using RV1, reconstitute just before administering using only the applicator and diluent supplied with the vaccine; discard vaccine if not used by the end of the clinic day
 - Before reconstitution the diluent may be stored separately at room temperature; if storing after reconstitution store the vaccine in the refrigerator at **36°F to 46°F (2°C to 8°C)** and reagituate prior to administration
- Both RV vaccines are associated with a small risk of intussusception; CDC continues to recommend that all U.S. infants receive RV vaccine (following age and contraindication/precaution criteria) because the vaccine benefits outweigh the small excess risk of intussusception
 - Make parents aware of the small risk of intussusception, signs and symptoms of intussusception, and the need for prompt care if signs and symptoms develop
 - For more information, see www.cdc.gov/vaccinesafety/vaccines/rotavirus-vaccine.html
- ACIP supports vaccination of preterm (i.e., <37 weeks' gestation) infants according to the same schedule and precautions as full-term infants and under the following conditions:
 - The infant's chronological age meets the age requirements for RV vaccine (i.e., age 6 weeks through 14 weeks, 6 days for dose 1)
 - The infant is clinically stable
 - The vaccine is administered at the time of discharge from the neonatal intensive care unit (NICU) or nursery, or after discharge from the NICU or nursery
- Infants living in households with immunocompromised persons can be vaccinated; ACIP considers the risk to be greater for contracting wild-type RV disease from an unvaccinated infant than the risk of vaccine virus-associated disease; handwashing after diaper changing is always recommended
- Infants living in households with pregnant women should be vaccinated following routine recommendations
- ACIP considerations that support vaccination of HIV-exposed or infected infants: the HIV diagnosis might not be established in infants born to HIV-infected mothers before the age of the first RV vaccine dose, and vaccine strains or RV are considerably attenuated
- The Rotavirus Vaccine Information Statement (VIS), including information about MCIR, can be found at www.michigan.gov/immunize or your local health department
- Document as "RV1 (Rotarix)" or "RV5 (Rotateq)" in MCIR, on the vaccine administration record, and on the immunization record card

Publicly purchased RV vaccine can be administered to eligible children 6 weeks through 8 months of age through the Vaccines for Children (VFC) Program. Eligible children include those who are uninsured, underinsured, Medicaid eligible, Native American, or Alaskan Natives. Contact your local health department for more information.

For additional information: MMWRs: "Prevention of Rotavirus Gastroenteritis Among Infants and Children: Recommendations of the ACIP" (February 6, 2009); "Addition of Severe Combined Immunodeficiency as a Contraindication for Administration of Rotavirus Vaccine" (June 11, 2010); and "Addition of History of Intussusception as a Contraindication for Rotavirus Vaccination" (October 21, 2011) at www.cdc.gov/vaccines.