

ROTAVIRUS VACCINE LIVE ORAL

Rotavirus Vaccine Live Oral

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Introduction

Rotavirus vaccine is commercially available in the US as a monovalent live, attenuated virus vaccine derived from a human rotavirus strain (Rotarix[®]; RV1)²², and a pentavalent live virus vaccine containing 5 live, reassortant rotaviruses derived from human and bovine hosts (RotaTeq[®]; RV5).¹

Uses

■ Prevention of Rotavirus Gastroenteritis

Rotavirus vaccine live oral (Rotarix[®]; RV1) is used to prevent gastroenteritis caused by rotavirus type G1 and non-G1 types (G3, G4, G9) in infants 6–24 weeks of age.²²

Rotavirus vaccine live oral pentavalent (RotaTeq[®]; RV5) is used to prevent gastroenteritis caused by rotavirus types G1, G2, G3, G4, and G9 in infants 6–32 weeks of age.¹

Prior to widespread use of rotavirus vaccines, rotavirus was the most common cause of severe gastroenteritis in infants and young children,^{11,29,105,166} and an important cause of acute gastroenteritis in children attending child-care centers.¹⁰⁵ Worldwide, rotavirus gastroenteritis was the cause of approximately 500,000 deaths each year in children younger than 5 years of age.¹⁶⁶ In the US, rotavirus gastroenteritis was estimated to cause up to 70,000 hospitalizations^{11,29} and 20–60 deaths each year in children younger than 5 years of age.^{11,29,166}

After rotavirus vaccine (RotaTeq[®]) was licensed in the US in 2006, there was a marked decrease in the incidence of rotavirus disease and substantial changes in the epidemiology of the disease.^{29,105,166} A second rotavirus vaccine (Rotarix[®]) was licensed in the US in 2008.¹⁶⁶ After vaccine introduction, in children younger than 5 years of age, there was an estimated decrease of 62,000 emergency department visits and 45,000 hospitalizations due to rotavirus disease.^{105,166} A biennial pattern of rotavirus activity emerged with small, short seasons starting in late winter or early spring in odd-numbered years, and extremely low circulation without a defined season in even-numbered years.^{105,166}

Transmission of rotavirus occurs through the fecal-oral route, both person-to-person and via fomites such as toys.^{105,166} There are high concentrations of rotaviruses shed in the stool of infected persons beginning 2 days before the onset of diarrhea, which can continue for at least 10 days after the onset of symptoms.^{105,166} On contaminated surfaces, the virus can be viable for weeks to months.¹⁰⁵

The clinical manifestations of rotavirus can vary and depend on whether it is the first infection or a reinfection.^{105,166} Usually, the first infection is the most severe in infants and young children after 3 months of age.^{105,166} Infections can be asymptomatic or result in severe dehydrating diarrhea with fever and vomiting.^{105,166} High fever (i.e., temperature >39°C) occurs in up to one-third of infected children.^{105,166} Generally, symptoms improve over time and resolve in 3–7 days.^{105,166}

Clinical Experience

Rotavirus Vaccine Live Oral (Rotarix[®])

Efficacy of Rotarix[®] (both its reconstituted lyophilized formulation and liquid formulation) is based on data from using the reconstituted lyophilized formulation; both formulations contain the same live, attenuated rotavirus strain and are manufactured using a similar process.²²

Safety and efficacy of Rotarix® for prevention of rotavirus gastroenteritis have been evaluated in several randomized, placebo-controlled, multinational studies that included healthy infants from Europe and Latin America.^{22,23,24,25} These infants received a 2-dose series of Rotarix® (initial dose given at 6–14 weeks of age, second dose given at least 4 weeks after the first dose) that was generally completed by 24 weeks of age.^{22,23,24,25}

In a European study that involved 3994 infants, efficacy of Rotarix® in preventing rotavirus gastroenteritis (any grade of severity) from 2 weeks following vaccination through the first rotavirus season was 87%, and efficacy in preventing severe rotavirus gastroenteritis through the first rotavirus season was 96%.^{22,23} In a Latin American study that involved more than 15,000 infants, efficacy of Rotarix® in preventing severe rotavirus gastroenteritis from 2 weeks following vaccination up to 1 year of age was 83%.²⁵ There was a 100% reduction in hospitalizations for rotavirus gastroenteritis in the European infants through the first rotavirus season, and an 85% reduction in hospitalizations for this infection in infants in Latin America or Finland up to 1 year of age.^{22,23,24}

In the European study, Rotarix® was 79% effective in preventing rotavirus gastroenteritis (any grade of severity) from 2 weeks following vaccination through the second rotavirus season.^{22,23} In the Latin American study, vaccine efficacy was 80.5% in preventing severe rotavirus gastroenteritis from the time of the first dose up to 2 years of age.^{22,25} Efficacy of Rotarix® beyond the second rotavirus season following vaccination has not been evaluated to date.²²

Efficacy of Rotarix® in preventing any grade of severity and severe rotavirus gastroenteritis based on the specific type (i.e., G1, G3, G4, G9, and combined non-G1) was substantially better compared with placebo through 1 year following vaccination.²² In addition, efficacy against any grade of severity and severe rotavirus gastroenteritis caused by G1, G2, G3, G4, G9, and combined non-G1 types was substantially better compared with placebo through 2 years following vaccination.²²

A relationship between antibody responses to rotavirus vaccination and protection against rotavirus gastroenteritis has not been established; seroconversion was defined in clinical studies as the appearance of anti-rotavirus IgA antibodies at a concentration ≥ 20 Units/mL post-vaccination in infants' serum previously negative for rotavirus.²²

The immunogenicity of the Rotarix® reconstituted lyophilized formulation was assessed in 2 studies, 1–2 months after a 2-dose series.²² The seroconversion rate was 86.5% in vaccine recipients and 6.7% in placebo recipients in the first study, and 76.8% and 9.7% of vaccine and placebo recipients, respectively, in the second study.²²

The immunogenicity of the Rotarix® liquid formulation was assessed in infants 6–17 weeks of age.^{22,26} The Rotarix® liquid formulation was found to be non-inferior to the reconstituted lyophilized formulation based on seroconversion rates and geometric mean concentrations at 1–2 months following the second immunization of a 2-dose series.²² In another study, the number of patients with anti-rotavirus IgA antibodies ≥ 20 Units/mL 3 months after a 2-dose series of the Rotarix® liquid formulation was comparable to that of patients who received the reconstituted lyophilized formulation.²²

Rotavirus Vaccine Live Oral Pentavalent (RotaTeq®)

RotaTeq® has been evaluated in 4 placebo-controlled, phase 3 studies that included 73,086 infants.¹ Efficacy of the vaccine for preventing rotavirus gastroenteritis was demonstrated in 7,744 infants who were enrolled in 3 of these studies (Rotavirus Efficacy and Safety Trial [REST; study 006]; study 007; study 029).¹ An additional placebo-controlled, phase 3 trial (study 009) contributed data to the overall safety evaluation of RotaTeq®.¹

Study 006 and study 007 included 6983 healthy infants in the US and Finland who received a 3-dose series of RotaTeq® (initial dose given at 6–12 weeks of age, second and third doses given at 4- to 10-week intervals with the third dose given by 32 weeks of age).^{1,2,19} Efficacy of the vaccine in preventing rotavirus gastroenteritis caused by naturally occurring types G1, G2, G3, or G4 (any grade of severity occurring at least 14 days after the third vaccine dose through the first rotavirus season following vaccination) was 74% in study 006 and 72.5% in study 007.^{1,2,19} Vaccine efficacy in preventing severe rotavirus gastroenteritis caused by these types (occurring through the first rotavirus season following vaccination) in study 006 and study 007 was 98 and 100%, respectively.^{1,2,19} In study 006, vaccine efficacy was 62.6% against any grade of severity of rotavirus gastroenteritis caused by these types during the second rotavirus season after vaccination and there was a 95.8% reduction in hospitalizations for severe rotavirus gastroenteritis caused by types G1, G2, G3, and G4 during the first 2 years following the final dose of RotaTeq®.^{1,2} Vaccine efficacy beyond the second rotavirus season after vaccination has not been fully evaluated to date.¹

The efficacy of RotaTeq® against any grade of severity of naturally occurring rotavirus gastroenteritis, regardless of type, was 71.8% and 72.7% in study 006 and study 007, respectively.¹

A relationship between antibody responses to RotaTeq[®] and protection against rotavirus gastroenteritis has not been established.¹ In clinical studies, most patients who received a 3-dose series of RotaTeq[®] (92.9–100%) achieved a 3-fold or higher rise (i.e., seroconversion) in serum anti-rotavirus IgA.^{1,11}

Clinical Perspective

The Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) and American Academy of Pediatrics (AAP) recommend that all infants be vaccinated against rotavirus gastroenteritis beginning as early as 6 weeks of age, unless contraindicated.^{11,105,199,304} For patients receiving Rotarix[®], vaccination is recommended as a 2-dose series at 2 and 4 months of age.^{11,105,199,304} For patients receiving RotaTeq[®], a 3-dose vaccination series is recommended at 2, 4, and 6 months of age.^{11,105,199,304} If any dose in the series is RotaTeq[®] or is unknown, a 3-dose series at 2, 4, and 6 months of age should be administered.^{105,199,304} Previously unvaccinated infants should receive catch-up vaccination depending on the infant's age.^{199,304} The maximum age for the first dose of rotavirus vaccine (either RotaTeq[®] or Rotarix[®]) is 14 weeks, 6 days.^{11,105,199,304} The minimum interval between doses is 4 weeks.^{11,105,199,304} The maximum age recommended for the final dose is 8 months, 0 days.^{11,105,199,304} ACIP and AAP do not state a preference for Rotarix[®] or RotaTeq[®] vaccine for primary immunization in infants.^{11,105} The vaccine series should be completed with the same product whenever possible; however, vaccination should not be deferred if the product used for a previous dose is unavailable or unknown.^{11,105}

Dosage and Administration

■ General

Dispensing and Administration Precautions

- Ensure that appropriate medical treatment and supervision are available to manage possible anaphylactic reactions following administration.¹

Other General Considerations

- To minimize potential virus transmission from the vaccine recipient, all household contacts should be advised to use hygienic measures (e.g., good hand washing) following contact with the feces of a recently vaccinated infant (e.g., diaper changing).¹¹

■ Administration

Rotavirus vaccine live oral (Rotarix[®]; RV1) and rotavirus vaccine live oral pentavalent (RotaTeq[®]; RV5) are administered orally.^{1,22}

The vaccines are for oral use only and should not be given by IM, IV, or via subcutaneous injection.^{1,22}

Rotavirus vaccine should not be mixed with any other vaccine or solution.¹

There is no need to restrict food or liquid intake, including breast milk, either before or after administration of rotavirus vaccine.^{1,22}

Rotavirus vaccine may be given simultaneously with other age-appropriate vaccines during the same health-care visit.¹⁶⁶

Rotavirus Vaccine Live Oral (Rotarix[®]; RV1)

Rotarix[®] lyophilized vaccine is supplied in 2 presentations; one is a vial with oral dosing applicator that should be reconstituted using the diluent and transfer adapter provided by the manufacturer, and the other is an oral dosing only applicator that does not require reconstitution or dilution before use.²² The presentation that requires reconstitution delivers a total dose volume of 1 mL, while the oral dosing applicator only presentation delivers a total dose volume of 1.5 mL.²²

Consult the manufacturer's information for complete reconstitution instructions.²² Once the dose is ready for administration, Rotarix[®] is administered orally directly into the infant's mouth from the oral applicator supplied by the manufacturer.²² Administer the entire contents of the oral applicator into the infant's mouth on the inside of the cheek.²²

If an incomplete dose is given (e.g., infant spits or regurgitates during or after vaccine dose), the manufacturer states that a single replacement dose may be considered at the same vaccination visit.²² However, the US Public Health Service Advisory Committee on Immunization Practices (ACIP) does not recommend a replacement dose if an incomplete dose is given, since data are not available on the benefits or risks associated with readministration.^{11,105} The infant should receive the remaining dose in the recommended 2-dose series at the usually recommended interval (minimum interval: 4 weeks between doses).¹¹

Rotarix[®] vial and oral dosing applicator presentation: Single-dose vials of lyophilized Rotarix[®] for oral suspension should be stored at 2–8°C and protected from light.²² The diluent supplied by the manufacturer should be stored at 2–8°C or at room temperature (up to 25°C); the diluent should be protected from freezing and should be discarded if frozen.²² Reconstituted Rotarix[®] may be stored for up to 24 hours at 2–8°C or at room temperature (up to 25°C).²² The reconstituted vaccine should be discarded if exposed to freezing temperatures or if not used within 24 hours.²²

Rotarix[®] oral dosing applicator only presentation: Single-dose prefilled oral dosing applicator Rotarix[®] should be stored at 2–8°C and protected from light.²² The vaccine should not be frozen and should be discarded if frozen.²²

Rotarix[®] does not contain thimerosal or any other preservatives.²²

Rotavirus Vaccine Live Oral Pentavalent (RotaTeq[®]; RV5)

RotaTeq[®] is administered orally directly from the single-dose ampule or tube supplied by the manufacturer.¹ The 2 mL dose should be administered by gently squeezing the entire contents of the ampule or tube into the infant's mouth toward the inner cheek.¹ A residual drop may remain in the tip of the dosing tube.¹

If an incomplete dose is administered (e.g., infant spits or regurgitates during or after vaccine dose), a replacement dose is not recommended since data are not available on the benefits or risks associated with readministration.^{1,11,105} The infant should continue to receive any remaining doses in the recommended 3-dose series at usually recommended intervals (minimum interval: 4 weeks between doses).^{1,11,105}

RotaTeq[®] oral solution is a pale yellow, clear liquid that may have a pink tint.¹ The vaccine should be stored at 2–8°C and protected from light.¹ The vaccine should be administered as soon as possible following removal from refrigeration.¹

RotaTeq[®] does not contain thimerosal or any other preservatives.¹

■ Dosage

Prevention of Rotavirus Gastroenteritis

Dosage and dosing schedule (i.e., number and timing of doses) differ depending on the specific vaccine (Rotarix[®] or RotaTeq[®]) administered.^{1,22} Dosage recommendations for the specific vaccine used should be followed.^{1,22} Rotarix[®] is a 2-dose series that consists of one strain of live-attenuated virus, while RotaTeq[®] is a 3-dose series that consists of five reassortant strains.^{1,22,166}

The specific rotavirus vaccine (Rotarix[®] or RotaTeq[®]) used for the initial dose should be used to complete the vaccination series, whenever possible.¹⁶⁶ If the specific rotavirus vaccine used for previous doses is unknown or unavailable, the vaccination series should be continued or completed with the currently available rotavirus vaccine.¹⁶⁶

If RotaTeq[®] or an unknown rotavirus vaccine was administered for any dose in the vaccination series, a total of 3 primary doses should be administered to complete the series.¹⁶⁶

ACIP and AAP state that the first dose of rotavirus vaccine should be given at 6 through 14 weeks of age (up to 14 weeks 6 days of age).^{11,199,304} Because of insufficient data, ACIP and the American Academy of Pediatrics (AAP) state that the vaccination series should not be initiated in infants who are 15 weeks of age or older.^{11,199,304} If the first dose of rotavirus vaccine is inadvertently administered to an infant 15 weeks of age or older, the remainder of the series should be completed according to the usually recommended vaccination schedule since timing of the first vaccine dose should not affect the safety and efficacy of subsequent doses.¹¹

Preterm infants who are medically stable should receive rotavirus vaccine at the usual chronologic age using the usual dosage, provided the vaccine is administered to the age-eligible infant after or at the time of discharge from the neonatal intensive care unit (NICU) or hospital nursery.^{11,105,166} Because of possible transmission of vaccine virus from vaccine strains of rotavirus shed in the stool of vaccinated infants, ACIP states that, in usual circumstances, the possible risk of transmission of rotavirus vaccine virus to other hospitalized infants outweighs the benefits of vaccination in age-eligible infants who will remain in the NICU or hospital nursery after the dose.¹¹

Because natural rotavirus infection frequently provides only partial immunity, ACIP and AAP recommend that the rotavirus vaccination series be initiated or completed in infants who had rotavirus gastroenteritis before receiving the complete series.^{11,105,166}

Infants 6–24 Weeks of Age (Rotarix[®]; RV1)

Rotarix[®] is given in a series of 2 doses.^{11,22,166,199} Each dose consists of the entire contents of the reconstituted single-dose vial or prefilled oral dosing applicator.²²

The manufacturer recommends that the initial dose of Rotarix[®] be given beginning at 6 weeks of age and the second dose given at least 4 weeks after the first dose.²² In addition, the manufacturer recommends that the 2-dose vaccination series be completed by 6 months (24 weeks) of age.²²

ACIP and AAP recommend that infants receive a dose of Rotarix[®] at 2 and 4 months of age with a minimum interval of 4 weeks between doses.^{11,199,304} These experts state that the maximum age for the final dose in the 2-dose vaccination series is 8 months 0 days of age.^{11,199,304}

Infants 6–32 Weeks of Age (RotaTeq[®]; RV5)

RotaTeq[®] is given orally in a series of 3 doses.^{1,11,199,304} Each dose consists of the entire contents of the commercially available single-dose tube or ampule containing the vaccine.¹

The manufacturer recommends that the initial dose of RotaTeq[®] be given starting at 6–12 weeks of age and the remaining 2 doses given at 4- to 10-week intervals.¹ In addition, the manufacturer states that the third dose should not be given after 32 weeks of age.¹

ACIP and AAP recommend that infants receive a dose of RotaTeq[®] at 2, 4, and 6 months of age with a minimum interval of 4 weeks between doses.^{11,199,304} These experts state that the maximum age for the final dose in the 3-dose vaccination series is 8 months 0 days of age.^{11,199,304}

Special Populations

Hepatic Impairment

No specific dosage recommendations.^{1,22}

Renal Impairment

No specific dosage recommendations.^{1,22}

Geriatric Patients

Not indicated in adults, including geriatric adults.^{1,22}

Cautions

■ Contraindications

- Known hypersensitivity to the vaccine or any vaccine component (e.g., latex for Rotarix®).^{1,22}
- History of intussusception.^{1,22}
- History of uncorrected congenital malformation of the GI tract (e.g., Meckel's diverticulum) that would predispose an infant to intussusception (Rotarix®).²²
- Severe combined immunodeficiency disease (SCID).^{1,22}

■ Warnings/Precautions

Hypersensitivity

Infants who develop symptoms suggestive of hypersensitivity after receiving a dose of rotavirus vaccine should not receive any further doses of the vaccine.^{1,22}

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of rotavirus vaccine.¹

Latex Sensitivity

A packaging component of Rotarix® (i.e., tip cap of the prefilled oral dosing applicator) contains natural rubber latex, which may cause hypersensitivity reactions in susceptible individuals.²² Rotarix® vial stoppers are not made with natural rubber latex.²²

The US Public Health Service Advisory Committee on Immunization Practices (ACIP) states that vaccines supplied in vials or syringes containing dry natural rubber or natural rubber latex may be administered to individuals with latex allergies other than anaphylactic allergies (e.g., history of contact allergy to latex gloves), but should not be used in those with a history of severe (anaphylactic) allergy to latex, unless the benefits of vaccination outweigh the risks of a potential allergic reaction.¹¹

Use of RotaTeq® (which is latex-free) should be considered as an alternative to Rotarix® in infants with a severe allergy to latex.¹¹ Some experts prefer that infants with spina bifida or bladder exstrophy, who are at high risk for acquiring latex allergy, receive RotaTeq® as an alternative to Rotarix® to minimize latex exposure.¹¹ However, ACIP states that Rotarix® should be administered if it is the only rotavirus vaccine available since the benefits of rotavirus vaccination are considered to be greater than the risk for latex sensitization.¹¹

Individuals with Altered Immunocompetence

Safety and efficacy of Rotarix® or RotaTeq® have not been established in immunocompromised or potentially immunocompromised infants.^{1,11,22} Examples of such infants include those with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic system; those with primary and acquired immunodeficiency states such as human immunodeficiency virus (HIV) infection, cellular immune deficiencies, or hypogammaglobulinemic and dysgammaglobulinemic states; those of indeterminate HIV status born to HIV-infected mothers (HIV-exposed); those receiving a blood transfusion or blood products within 42 days; or those receiving immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, or greater than physiologic doses of corticosteroids.¹

There have been postmarketing reports of vaccine-acquired rotavirus gastroenteritis, including severe diarrhea and prolonged shedding of vaccine virus, in infants who received Rotarix® or RotaTeq® and were subsequently diagnosed with SCID.^{1,22} Rotarix® and RotaTeq® are contraindicated in infants with SCID.^{1,22}

The potential risks and benefits of administering rotavirus vaccine to infants with known or suspected altered immunocompetence should be considered.¹¹ Consultation with an immunologist or infectious diseases specialist is advised.¹¹

ACIP states that use of rotavirus vaccine in HIV-infected or HIV-exposed infants is supported since HIV diagnosis in infants born to HIV-infected mothers may not be established before the recommended age for the first dose of the vaccine, only 1.5–3% of HIV-exposed infants in the US will eventually be determined to be HIV-infected, and the rotavirus strains used in the vaccines are considerably attenuated.¹¹

Intussusception

Cases of intussusception, including some fatalities, have been reported rarely in infants who received Rotarix[®] or RotaTeq[®].^{1,22} Although data from initial clinical trials of these 2 vaccines did not suggest an increased risk of intussusception relative to placebo,^{1,22} there is postmarketing evidence that rotavirus vaccines are associated with an increased risk of intussusception, particularly during the first week after the first vaccine dose.¹

In a postmarketing observational study in Mexico, cases of intussusception were observed in temporal association (within 31 days) following the first dose of Rotarix[®], with a clustering of cases in the first 7 days.²² Other postmarketing observational studies in Brazil and Australia also suggest an increased risk of intussusception within the first 7 days following the second dose of Rotarix[®].²²

In a postmarketing observational study in the US, cases of intussusception were observed in temporal association (within 21 days) following the first dose of RotaTeq[®], with a clustering of cases in the first 7 days.¹ Cases of intussusception in temporal association with RotaTeq[®] also were reported in worldwide passive postmarketing experience.¹

Rotarix[®] and RotaTeq[®] are contraindicated in infants with a history of intussusception.^{1,22} During postmarketing experience, intussusception resulting in death was reported when a second dose of Rotarix[®] was given to an infant with a history of intussusception after the first dose.²²

The temporal association between vaccination with RotaTeq[®] and intussusception was evaluated in the Post-licensure Rapid Immunization Safety Monitoring (PRISM) program, an electronic active surveillance program comprised of 3 US health insurance plans.¹ PRISM evaluated more than 1.2 million RotaTeq vaccinations (507,000 first doses) administered to infants 5 through 36 weeks of age.¹ From 2004 through 2011, potential cases of intussusception in either inpatient or emergency department settings and vaccine exposures were identified through electronic procedure and diagnosis codes.¹ Medical records were reviewed to confirm intussusception and rotavirus vaccination status.¹ Intussusception was observed in temporal association within 21 days following the first dose of RotaTeq[®], with a clustering of cases in the first 7 days.¹ Based on these results, approximately 1–1.5 excess cases of intussusception occur per 100,000 vaccinated US infants within 21 days following the first dose of RotaTeq[®].¹ In the first year of life, the background rate of hospitalizations in the US related to intussusception is estimated to be approximately 34 per 100,000 infants.¹

Other GI Disorders or Illnesses

Safety and efficacy of Rotarix[®] have not been evaluated in infants with chronic GI disorders, and administration of the vaccine should be delayed in infants with acute diarrhea or vomiting.²²

RotaTeq[®] should be used with caution in infants with a history of GI disorders (e.g., active acute GI illness, chronic diarrhea and failure to thrive, history of congenital abdominal disorders, abdominal surgery) since safety and efficacy data are not available regarding use of the vaccine in such infants.¹ The manufacturer states that clinical study data are available that support use of RotaTeq[®] in infants with controlled gastroesophageal reflux disease (GERD).¹

Although safety and efficacy of rotavirus vaccine have not been evaluated in infants with preexisting chronic GI disorders, ACIP states that benefits outweigh theoretical risks in those with certain preexisting GI tract conditions (e.g., congenital malabsorption syndrome, Hirschsprung disease, short-gut syndrome) if they are not receiving immunosuppressive therapy.¹¹

Use of rotavirus vaccine has not been studied in infants with concurrent acute gastroenteritis,¹¹ and ACIP states that immunogenicity and efficacy of rotavirus vaccine may be compromised in these infants.¹¹ These experts state that the vaccine should not be administered to infants with acute, moderate-to-severe gastroenteritis until improvement of the condition is noted.¹¹ However, infants with mild acute gastroenteritis can be vaccinated, particularly if the delay in vaccination is substantial and may result in the child becoming ineligible to receive the vaccine based on age at first dose.¹¹

Transmission of Vaccine Virus

Rotarix[®] contains live, attenuated rotavirus²² and RotaTeq[®] contains live, reassortant rotaviruses.¹ Viral shedding can occur in vaccine recipients and the vaccine virus has been transmitted between vaccinees and susceptible contacts.^{1,11,22}

After a dose of Rotarix[®], peak shedding occurs approximately 7 days after the dose.²² In a prospective, randomized, double-blind, placebo-controlled study, healthy twins 6–14 weeks of age were randomized so that 1 twin in each household received Rotarix[®] and the other twin received placebo.²² Transmission of vaccine virus from the vaccinated twin to the twin who received placebo was reported in 19% of the pairs; GI symptoms related to transmitted virus were not reported.²² The median duration of vaccine virus shedding was 10 days in twins who received Rotarix[®] compared with 4 days in the twin sibling who received placebo, but acquired the vaccine virus.²²

In a clinical study evaluating safety and efficacy of RotaTeq[®] (REST; study 006), shedding of vaccine virus was assessed among a subset of infants 4–6 days after each vaccine dose and among all study participants who submitted a stool sample that was positive for rotavirus antigen at any time.¹ The RotaTeq[®] vaccine virus was shed in the stools of 9% of vaccine recipients tested after dose 1 and in 0 or 0.3% of vaccine recipients tested after dose 2 or 3, respectively.¹ In phase 3 studies evaluating RotaTeq[®], viral shedding was observed as early as 1 day and as late as 15 days after a dose.¹ Transmission of the vaccine virus to susceptible contacts was not evaluated in phase 3 studies, but there have been postmarketing reports of such transmission.¹

Caution is advised when considering whether to administer rotavirus vaccine to infants with close contacts who are immunocompromised (e.g., individuals who have malignancies or are otherwise immunocompromised, individuals with primary immunodeficiencies, or individuals receiving immunosuppressive therapy).^{1,22} The manufacturers state that the risk of possible transmission of the vaccine virus should be weighed against the risk of the infant developing natural rotavirus infection that could be transmitted to susceptible contacts.^{1,22}

ACIP states that infants living in households with individuals who are immunocompromised should receive rotavirus vaccine when indicated.¹¹ Protection of immunocompromised household contacts afforded by rotavirus vaccination of infants in the household and prevention of wild-type rotavirus disease outweighs the small risk of transmitting vaccine virus to the immunocompromised individual and any subsequent theoretical risk of vaccine virus-associated disease.¹¹

To minimize potential virus transmission from the vaccinee, all household contacts should be advised to use hygienic measures (e.g., good hand washing) following contact with the feces of a vaccinated infant (e.g., diaper changing).¹¹

If an infant recently vaccinated with rotavirus vaccine is hospitalized for any reason, no special cautionary measures (other than standard precautions) are necessary to prevent the spread of vaccine virus in the hospital setting.¹¹

Febrile Illness

Recent febrile illness may be the reason for delaying administration of RotaTeq[®], except when the provider decides that withholding the vaccine entails greater risk.¹ The manufacturer of RotaTeq[®] states that the presence of low-grade fever (temperature <38.1°C) or mild upper respiratory infection does not preclude vaccination.¹

ACIP states that rotavirus vaccine may be administered to infants with transient, mild illnesses (with or without low-grade fever).¹¹ However, vaccination of individuals with moderate or severe acute illness generally should be deferred until they have recovered from the acute phase of the illness.¹¹

Limitations of Vaccine Efficacy

Rotavirus vaccine may not protect all vaccine recipients against rotavirus infection.¹

Data are not available to determine the level of protection provided against rotavirus infection in infants who have not received the complete vaccination series (i.e., have received only a single dose of Rotarix[®] or only 1 or 2 doses of RotaTeq[®]).^{1,22}

No data are available for rotavirus vaccines administered as post-exposure prophylaxis.^{1,22}

Specific Populations

Pregnancy

Rotavirus vaccine is not indicated for use in adults, including pregnant women.^{1,22}

*ACIP states that infants living in households with pregnant women may receive rotavirus vaccine.*¹¹ *Most women of childbearing age would be expected to have preexisting immunity to rotavirus.*¹¹ *Most experts agree that the risk of acquiring rotavirus infection from potential exposure to the vaccine virus is very low.*¹¹ *In addition, there is no evidence that infection with rotavirus during pregnancy poses any risk to the fetus.*¹¹ *Furthermore, vaccination of infants against rotavirus avoids potential exposure of pregnant women to natural rotavirus from unvaccinated infants with rotavirus gastroenteritis.*¹¹

Lactation

Rotavirus vaccine is not indicated for use in adults, including nursing women.^{1,22}

*ACIP states that nursing infants may receive rotavirus vaccine, since efficacy of the vaccine in breast-feeding infants is similar to that in infants not breast-feeding.*¹¹

Pediatric Use

*Rotarix[®]: Safety and efficacy have not been established in infants younger than 6 weeks or older than 24 weeks of age.*²² *The manufacturer states that efficacy in preterm infants has not been established.*²² *Safety data to date in preterm infants indicate serious adverse events in 5.2% of vaccine recipients compared with 5% in placebo recipients; deaths or cases of intussusception have not been reported in this patient population to date.*²²

*RotaTeq[®]: Safety and efficacy have not been established in infants younger than 6 weeks or older than 32 weeks of age.*¹ *The manufacturer states that RotaTeq[®] has been studied in preterm infants (i.e., gestational age 25–36 weeks), and clinical study data support use of the vaccine in such infants according to their age in weeks since birth.*¹ *Safety data in preterm infants indicate serious adverse events in 5.5% of vaccine recipients compared with 5.8% of placebo recipients; there were 2 deaths among vaccine recipients and no cases of intussusception.*¹

*Pending additional data, ACIP states that the benefits of routine vaccination with rotavirus vaccine outweigh the theoretical risks in medically stable preterm infants.*¹¹ *These experts state that clinically stable preterm infants who meet the age requirements (at least 6 weeks and not greater than 14 weeks 6 days of age) may receive the first dose of rotavirus vaccine after or at the time of discharge from the NICU or hospital nursery.*¹¹

*ACIP states that a replacement dose of rotavirus vaccine is not recommended if an infant receives an incomplete vaccine dose (e.g., infant spits or regurgitates the dose).*¹¹ *No data are available on the risks and benefits of administering another dose.*¹¹

Geriatric Use

Rotavirus vaccine is not recommended for use in adults, including geriatric adults.^{1,22}

■ Common Adverse Effects

Rotarix[®]: Adverse events reported within 8 days following the first dose of vaccine include fussiness/irritability (52%), cough/runny nose (28%), fever (25%), loss of appetite (25%), vomiting (13%), and diarrhea (4%).²² Frequency of adverse events within 8 days following the second dose of vaccine is similar and includes fussiness/irritability (42%), cough/runny nose (31%), fever (28%), loss of appetite (21%), vomiting (8%), and diarrhea (3%).²² The incidence of adverse events in the week following the first and second doses of vaccine was similar to that occurring with placebo.²²

RotaTeq[®]: Fever has occurred in 42.6% of infants within 42 days of any dose of the vaccine; this was similar to the incidence reported with placebo.¹ Adverse events reported within 42 days following any dose of the vaccine and reported more frequently than with placebo include diarrhea (24.1%), vomiting (15.2%), otitis media (14.5%), nasopharyngitis (6.9%), and bronchospasm (1.1%).¹

Drug Interactions

■ Immune Globulins and Blood Products

Safety and efficacy data are not available regarding use of Rotarix[®] (RV1) or RotaTeq[®] (RV5) in infants who have received blood transfusions or blood products (including immunoglobulins).^{1,11} The US Public Health Service Advisory Committee on Immunization Practices (ACIP) states that immune globulin preparations are not expected to affect the immune response to rotavirus vaccine; therefore, rotavirus vaccine may be administered simultaneously with or at any time before or after administration of blood or antibody-containing products.¹¹

■ Immunosuppressive Agents

Individuals receiving immunosuppressive therapy (e.g., alkylating agents, antimetabolites, corticosteroids, cytotoxic agents, radiation) may have a diminished antibody response to vaccines, including rotavirus vaccine.^{1,22}

Rotarix[®]: Safety and efficacy of the vaccine in infants receiving immunosuppressive therapy have not been established.²²

RotaTeq[®]: Safety and efficacy data are not available regarding use of the vaccine in infants receiving immunosuppressive therapy (e.g., systemic corticosteroid therapy at greater than physiologic dosages);^{1,11} however, the manufacturer states that the vaccine may be administered to infants receiving topical or inhaled corticosteroids.¹

■ Vaccines

Although specific studies may not be available evaluating concurrent administration of rotavirus vaccine with each antigen, simultaneous administration with other age-appropriate vaccines, including live virus vaccines, toxoids, or inactivated or recombinant vaccines, during the same health-care visit is not expected to affect immunologic responses or adverse reactions to any of the preparations.^{1,11,22}

Immunization with rotavirus vaccine can be integrated with immunization against diphtheria, tetanus, pertussis, haemophilus influenza type b (Hib), hepatitis B, influenza, poliovirus, measles, mumps, rubella, pneumococcal disease, and varicella.¹¹

Inactivated Vaccines or Toxoids

Rotavirus vaccine may be administered concomitantly with or at any interval before or after inactivated vaccines (e.g., Hib vaccine, poliovirus vaccine inactivated [IPV], hepatitis B vaccine, influenza virus vaccines, pneumococcal vaccine) indicated in infants.^{1,22}

Studies using RotaTeq[®] indicate that concomitant administration with Hib vaccine, IPV, hepatitis B vaccine, and pneumococcal conjugate vaccine does not affect the immune response to the vaccines.¹ Studies using Rotarix[®] indicate that concomitant administration with the Hib vaccine and pneumococcal conjugate vaccine does not affect the immune response to the vaccines.²²

Although the immune response resulting from concomitant administration of rotavirus vaccine and inactivated influenza virus vaccines in infants 6 months of age has not been studied, ACIP states that inactivated vaccines (e.g., influenza virus vaccines) may be administered simultaneously with or at any time before or after a live vaccine (e.g., rotavirus vaccine).¹¹

Rotavirus vaccine may be administered concomitantly with or at any interval before or after toxoids (e.g., diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed [DTaP]) routinely recommended in infants.^{1,22} Studies using RotaTeq[®] indicate that concomitant administration with DTaP does not reduce the antibody response to the diphtheria or tetanus antigens, but data are insufficient to date to determine whether there is any interference with the immune response to the pertussis antigens.^{1,11} Studies using Rotarix[®] indicate that concomitant administration with DTaP does not affect the immune response to the vaccines.²²

Live Vaccines

RotaTeq[®] may be administered concomitantly with or at any interval before or after other live vaccines recommended in infants.¹¹

Concomitant administration of poliovirus vaccine live oral (OPV; not commercially available in the US) was not permitted during clinical studies of rotavirus vaccine.^{1,22}

Description

Rotavirus vaccine live oral (Rotarix[®]; RV1) is a lyophilized vaccine containing live, attenuated rotavirus derived from a human strain (89-12) belonging to type G1P[8] type.^{11,22}

Rotavirus vaccine live oral pentavalent (RotaTeq[®]; RV5) is a solution containing 5 live, reassortant rotaviruses that represent the G types responsible for most cases of rotavirus gastroenteritis worldwide (G1, G2, G3, G4, and G9) and the most common P type associated with these strains (P1A; genotype P[8]).^{1,11}

Porcine-derived materials are used during the manufacture of Rotarix[®]; DNA from porcine circovirus type 1 (PCV1) has been detected in Rotarix[®].²²

Following vaccination, the live, attenuated virus in Rotarix[®] or the live, reassortant rotaviruses in RotaTeq[®] replicate in the small intestine and induce active immunity to rotavirus types represented in the vaccine.^{1,22}

RotaTeq[®] contains reassortant rotaviruses produced using human parent strains and a parent bovine strain (Wistar calf 3 [WC3]).¹

The exact immunologic mechanism by which rotavirus vaccine protects against rotavirus gastroenteritis has not been determined.^{1,22} A correlation between antibody response to rotavirus vaccine and protection against rotavirus gastroenteritis has not been established to date.²² Studies using Rotarix[®] indicate that 76.8–86.5% of vaccine recipients seroconvert after 2 doses.²² Seroconversion in these studies was defined as appearance of anti-rotavirus IgA antibody in infants previously negative for rotavirus.²² Studies using RotaTeq[®] indicate that a 3-fold or greater increase in serum anti-rotavirus IgA concentrations occurred in 93–100% of those who received a 3-dose vaccination series compared with 12–20% of those who received placebo.^{1,11}

Because Rotarix[®] contains live, attenuated rotavirus and RotaTeq[®] contains live, reassortant rotaviruses, vaccine virus can be shed in the stools of vaccinees and transmitted between vaccinees and susceptible contacts.^{1,11,22}

Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from [MedlinePlus](#) (in English and Spanish; written at a 6th- to 8th-grade reading level).

- Prior to administration of each vaccine dose, provide a copy of the manufacturer's patient information to the patient's parent or guardian.^{1,22} Also provide a copy of the appropriate CDC Vaccine Information Statement (VIS) to the patient's parent or legal representative (VISs are available at [\[Web\]](#)).^{1,22}
- Advise the patient's parent or legal guardian of the risks and benefits of vaccination with rotavirus vaccine.^{1,22}
- Advise the patient's parent or legal guardian that porcine circoviruses (or fragments of the viruses) have been found in rotavirus vaccines, and that there is no evidence to date that these viruses cause infection or disease in humans or pose a safety risk.^{1,22}
- Advise the patient's parent or legal guardian that rotavirus vaccine may not provide complete protection in all vaccinees.^{1,22} In addition, the vaccine will not protect against disease due to rotavirus strains not represented in the vaccine.^{1,22}
- Advise the patient's parent or legal guardian of the possible risk of transmitting the vaccine virus to rotavirus-susceptible individuals, including household or other close contacts with a weakened immune system (e.g., individual with cancer or one who is receiving immunosuppressive therapy) or pregnant women who have not had rotavirus infection.^{1,22}
- Advise the patient's parent or legal guardian to inform clinicians if a child has any illness with fever, diarrhea, or vomiting; has failure to gain weight or is not growing as expected; has a blood disorder, any type of cancer, a weakened immune system (e.g., human immunodeficiency virus [HIV] infection, severe combined immunodeficiency disease [SCID]), or a history of GI problems (e.g., intussusception, blockage, abdominal surgery); or receives treatment that may weaken the immune system (e.g., high-dose corticosteroids).^{1,22}
- For infants receiving Rotarix[®] (2-dose vaccination series) or RotaTeq[®] (3-dose vaccination series), advise the patient's parent or legal guardian of the importance of completing the vaccination series by the time the infant is 8 months 0 days of age, unless contraindicated.¹¹
- Advise the patient's parent or legal guardian to inform clinicians if any adverse reactions (including allergic reactions) occur.^{1,22} Clinicians or individuals can report any adverse reactions that occur following vaccination to VAERS at 800-822-7967 or [\[Web\]](#) .^{1,22}
- Advise the patient's parent or legal guardian that rotavirus vaccine should not be administered to children who have an allergic reaction following a dose of the vaccine or in those who are allergic to any components of the vaccine.^{1,22}
- Advise the patient's parent or legal guardian to inform clinicians immediately if a child has any signs and/or symptoms of intussusception, including vomiting, diarrhea, severe stomach pain, blood in their stools, or high fever.^{1,22}
- Advise the patient's parent or legal guardian to inform clinicians of existing or contemplated concomitant therapy, including prescription and OTC drugs, and dietary and herbal supplements, as well as any concomitant illnesses.^{1,22}
- Inform patients of other important precautionary information.^{1,22}

Additional Information

The American Society of Health-System Pharmacists, Inc. represents that the information provided in the accompanying monograph was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are advised that decisions regarding use of drugs are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and that the information contained in the monograph is provided for informational purposes only. The manufacturer's labeling should be consulted for more detailed information. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. The information contained in the monograph is not a substitute for medical care.

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

Rotavirus Vaccine Live Oral

ROUTES	FORMS	STRENGTHS	BRAND NAMES	MANUFACTURER
Oral	For Suspension	Live attenuated rotavirus content: $\geq 1 \times 10^6$ median cell culture infective dose of G1P[8] per 1 mL	Rotarix [®]	GlaxoSmithKline
		Live attenuated rotavirus content: $\geq 1 \times 10^6$ median cell culture infective dose of G1P[8] per 1.5 mL	Rotarix [®]	GlaxoSmithKline

Rotavirus Vaccine Live Oral Pentavalent

ROUTES	FORMS	STRENGTHS	BRAND NAMES	MANUFACTURER
Oral	Solution	Live human-bovine reassortant rotavirus content: $\geq 2.2 \times 10^6$ infectious units of G1, 2.8×10^6 infectious units of G2, 2.2×10^6 infectious units of G3, 2×10^6 infectious units of G4, and 2.3×10^6 infectious units of P1A (P[8]) per 2 mL	RotaTeq [®]	Merck

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

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