

# Provider Information: Rotavirus VIS

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Many Vaccine Information Statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis).

Two rotavirus vaccines are approved for use in the United States:

- **Rotarix**<sup>®</sup> (RV1 - GlaxoSmithKline), a monovalent vaccine: **2-dose routine series** at 2 and 4 months
- **RotaTeq**<sup>®</sup> (RV5 - Merck), a pentavalent vaccine: **3-dose routine series** at 2, 4, and 6 months

## Additional ACIP recommendations for both vaccines:

- Minimum age: 6 weeks
- Maximum age for first dose: 14 weeks, 6 days  
(The series should not be initiated for infants 15 weeks, 0 days or older.)
- Maximum age for final dose: 8 months, 0 days
- Minimum intervals between doses: 4 weeks

For children who start late or fall behind, recommendations can be found on CDC's Pediatric Catch-Up Schedule: <http://www.cdc.gov/vaccines/schedules/downloads/child/catchup-schedule-pr.pdf>

## Contraindications and Precautions

### Contraindications:

- A history of a **severe allergic reaction** (e.g., anaphylaxis) after a previous dose of either rotavirus vaccine, or to any component of the vaccine being given. For a list of components for both Rotarix and RotaTeq, see the package inserts or <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf>.

### Latex Allergy:

- **Rotarix**: The tip cap and rubber plunger of the applicator contain latex.
- **RotaTeq**: Does not contain latex.

“Some experts prefer that infants with spina bifida or bladder exstrophy, who are at high risk for acquiring latex allergy, receive [RotaTeq] instead of [Rotarix] to minimize latex exposure in these children. However, if [Rotarix] is the only rotavirus vaccine available, it should be administered, because the benefit of vaccination is considered to be greater than the risk for sensitization.”<sup>3</sup>

- Severe combined immunodeficiency (“SCID”).  
([http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5922a3.htm?s\\_cid=mm5922a3\\_e%0d%0a](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5922a3.htm?s_cid=mm5922a3_e%0d%0a))
- A history of intussusception. (Children with a history of intussusception are at greater risk of intussusception than children who have never had it.)  
([http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6041a5.htm?s\\_cid=mm6041a5\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6041a5.htm?s_cid=mm6041a5_w))

## Precautions:

- **Altered immunocompetence.**

For children with known or suspected altered immunocompetence, ACIP advises consultation with an immunologist or Infectious diseases specialist before administration of rotavirus vaccine.

“Children and adults who are immunocompromised because of congenital immunodeficiency, hematopoietic transplantation, or solid organ transplantation sometimes experience severe or prolonged rotavirus gastroenteritis.”<sup>3</sup>

**HIV Infection:** Limited data from clinical trials do not indicate that rotavirus vaccines have a substantially different safety profile in HIV-infected infants who are clinically asymptomatic or mildly symptomatic, compared with infants who are not HIV infected. Two other considerations support vaccination of HIV-exposed or -infected infants in the United States. First, the HIV diagnosis might not be established in infants born to HIV-infected mothers by the time they reach the age of the first rotavirus vaccine dose. Only 3% or less of HIV-exposed infants in the United States will be determined to be HIV infected. Second, vaccine strains of rotavirus are considerably attenuated.

- “The presence of a **moderate or severe acute illness** with or without a fever is a precaution to administration of all vaccines.... Vaccination should not be delayed because of the presence of mild respiratory tract illness or other mild acute illness with or without fever.” (ACIP *General Recommendations on Immunization*, p. 11)  
*The definition of “moderate or severe acute illness” is left to the clinical judgment of the provider.*

## Intussusception

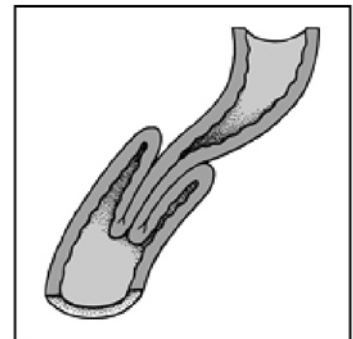
### Background Information

Intussusception is a disorder in which one segment of the intestine slides into another. The affected segments obstruct the bowel and block blood flow.

Intussusception is the most common cause of acute bowel obstruction in infants. In the great majority of cases, the cause of the intussusception is not known.

Before rotavirus vaccine introduction, each year in the United States:

- About 1,900 infants developed intussusception – about 44 cases per 100,000 (1 in 2,300) infants by age 1 year.
- About 37% of infants with intussusception required surgery.
- About 4 infants (0.2% of those with intussusception) died.



The baseline (background) rate of intussusception changes over the first year of life, with very low rates in the first month of life, rates increasing during the next 5 months to peak at age 6-7 months, and then decreasing.

With early detection and treatment, nearly all infants with intussusception recover fully.

Parents should be made aware of the signs of intussusception:

Early signs and symptoms include sudden onset of episodes of severe colicky abdominal pain (which may initially last just a few minutes and recur several times an hour). Infants might draw their legs up to their chest during these episodes. Infants with intussusception may also vomit several times, have blood in the stool, appear lethargic or very irritable.

## Risk of Intussusception Following Vaccination

Post-marketing studies indicate there is a small risk of intussusception from the currently licensed rotavirus vaccines. These studies on one or both of the vaccines were conducted in the United States, Australia, Mexico, and Brazil.

Two main studies in the U.S. have evaluated post-licensure risk following use of rotavirus vaccines.

- One study found an increased risk of intussusception during the first week following **dose 1 and dose 2 of Rotarix**. This study did not find a statistically significant increased risk of intussusception following **RotaTeq**.
- Another study found an increased risk of intussusception following the **dose 1 of RotaTeq**, primarily during the first week. No increased risk was detected following doses 2 or 3.

Studies in other countries have found increased risk of intussusception following both vaccines.

Though there are inconsistent findings across some studies and lack of precision in the risk estimates, the data indicate that **both currently licensed rotavirus vaccines are associated with a small risk of intussusception**. Monitoring is continuing in the U.S. and these risk estimates may change when additional data become available.

The rotavirus VIS describes the additional risk of intussusception from rotavirus vaccination overall, as an estimated range of 1 excess case in 20,000 to 100,000 vaccinated infants. Providers may use the above additional information as needed in discussions with parents.

More information about the risk of intussusception following rotavirus vaccination, and about the safety of rotavirus vaccines in general, can be found at <http://www.cdc.gov/vaccinesafety/vaccines/rotavsb.html>.

## Benefits of vaccination

Before the introduction of rotavirus vaccines in the U.S., rotavirus caused an estimated 20-60 deaths, 55,000-70,000 hospitalizations, more than 200,000 emergency department visits and more than 400,000 outpatient visits annually in children under 5. By age 5 years, almost all children had been infected by rotavirus and about 1 child in 70 was hospitalized for rotavirus disease.

Based on post-marketing evaluations in the U.S., the currently licensed vaccines have been found to be highly (85%-90%) protective in U.S. children against rotavirus disease requiring hospitalization, and also highly ( $\geq 80\%$ ) protective in preventing emergency department care for rotavirus disease. Approximately 40,000-50,000 hospitalizations for rotavirus disease have been prevented each year since 2008 in U.S. children aged <5 years.

### Risk/Benefit

CDC continues to recommend that all U.S. infants (following the age and precaution/contraindication criteria) receive rotavirus vaccine. The benefits of either vaccine outweigh the

small excess risk of intussusception. Parents should be made aware of the small risk of intussusception, the signs and symptoms of intussusception, and the need for prompt care if these develop.

## Other Information

- “ACIP supports vaccination of **preterm 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 rotavirus vaccine (e.g., age 6 weeks – 14 weeks and 6 days for dose 1),
  - the infant is clinically stable,
  - the vaccine is administered at the time of discharge from the NICU or nursery or after discharge from the NICU or nursery.”<sup>3</sup>
- Infants living in households with **pregnant women** should be vaccinated according to the same schedule as infants in households without pregnant women.

The majority of women of childbearing age have preexisting immunity to rotavirus.

- Infants living in households with **immunocompromised persons** can be vaccinated.

The risk of an immunocompromised person contracting wild-type rotavirus disease from an unvaccinated infant is considered greater than the risk of vaccine virus-associated disease.

- Post-marketing strain surveillance in the United States and other countries has occasionally detected RV5 vaccine-derived strains (reassortants, i.e., having genetic sequences from more than one RV5 strain) in stool samples of children with diarrhea. In some of these reports, the vaccine-derived strain seemed to be the likely cause of the diarrheal illness.
- A virus, or parts of a virus, called “porcine circovirus” have been detected in both rotavirus vaccines. There is no evidence that this virus is a safety risk or that it causes illness in humans. Questions & Answers about porcine circovirus in rotavirus vaccines from the World Health Organization’s website can be found at [http://www.who.int/immunization\\_standards/vaccine\\_quality/PCV1\\_Q\\_and\\_As\\_rotavirus\\_vaccines\\_3Jun10.pdf](http://www.who.int/immunization_standards/vaccine_quality/PCV1_Q_and_As_rotavirus_vaccines_3Jun10.pdf).

## References

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