

## Rotavirus Vaccine (Human rotavirus, live attenuated, oral vaccine) ROTARIX®

Supplier: GlaxoSmithKline Inc.

### INDICATIONS:

For routine immunization of infants beginning at 2 months of age.

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### DOSES AND SCHEDULE:

Routine infant series: 2 doses given as 1.5 mL by mouth at 2 and 4 months of age. <sup>A, B</sup>

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### ADMINISTRATION:

- Give entire contents of applicator.
- If an infant spits out or regurgitates any of the vaccine dose, no replacement dose should be administered.

NOTE: It is recommended that rotavirus vaccine be given prior to injectable vaccines for the added benefit of pain relief. <sup>C, D</sup>

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### BOOSTER DOSES:

No booster doses are recommended at this time.

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### SEROLOGICAL TESTING:

Serological testing is not recommended before or after immunization.

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### CONTRAINDICATIONS:

1. History of anaphylactic reaction to a previous dose of rotavirus vaccine, or to any component of ROTARIX®.
2. History of intussusception or an uncorrected congenital gastrointestinal malformation (e.g., Meckel's diverticulum) that predisposes to intussusception.
3. Infants diagnosed with Severe Combined Immunodeficiency (SCID).
4. Infants with a suspected or known immunocompromising condition or family history of congenital or hereditary immunodeficiency should receive this vaccine only upon the recommendation from their primary care physician, nurse practitioner or medical specialist. [Referral Form for Rotavirus Vaccination](#) may be used. <sup>E</sup>

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<sup>A</sup> The maximum age for the 1<sup>st</sup> dose of ROTARIX® vaccine is 20 weeks less 1 day of age. There should be an interval of at least 4 weeks between doses. Administer last dose by 8 months plus 0 days of age.

<sup>B</sup> For infants in whom the 1<sup>st</sup> dose of ROTARIX® vaccine is inadvertently administered at age ≥ 20 weeks, the rest of the ROTARIX® vaccination series should be completed with a minimum of 4 weeks between doses.

<sup>C</sup> Taddio A, Flanders D, Weinberg E, et al. A randomized trial of rotavirus vaccine versus sucrose solution for vaccine injection pain. *Vaccine*. 2015;33:2939-2943.

<sup>D</sup> Yin H-C, Shih W-M, Lee H-L et al. Comparison of iatrogenic pain between rotavirus vaccination before and after vaccine injection in 2-month-old infants. *Human Vaccines & Immunotherapeutics*. 2017;13(5):1136-1140.

<sup>E</sup> Infants exposed to or infected with HIV should be immunized with rotavirus vaccine according to the routine schedule. A referral is not required.

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### PRODUCT COMPONENTS:

Potential allergens: none.

Other components: sucrose, Dulbecco's Modified Eagle Medium (DMEM), di-sodium adipate, porcine circovirus type 1. <sup>A</sup>

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### PRECAUTIONS:

- Acute gastroenteritis: in infants with moderate to severe gastroenteritis, rotavirus vaccine should be deferred until the condition improves unless deferral will result in scheduling of the 1<sup>st</sup> dose at more than 20 weeks less 1 day of age. Infants with mild gastroenteritis can be vaccinated.
- Pre-existing chronic gastrointestinal disease: the safety and efficacy of rotavirus vaccines has not been established in children with pre-existing chronic gastrointestinal disease. However, infants with chronic gastrointestinal disease who are not receiving immunosuppressive therapy are likely to benefit from rotavirus vaccination and therefore can be vaccinated.

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### SPECIAL CONSIDERATIONS:

- There are no restrictions on the infant's consumption of food or liquid, including breast milk, either before or after vaccination.
- Rotavirus vaccine may be administered at any time before, concurrently with, or after administration of any blood product, including antibody-containing products.
- Infants who have had rotavirus gastroenteritis before receiving the full course of vaccinations should still initiate or complete the rotavirus vaccine schedule because the initial infection frequently provides only partial immunity.
- There are limited data on the interchangeability of ROTARIX® and RotaTeq® vaccines. Whenever possible, the series should be completed with the same product. However, if the product used for a previous dose(s) is not known or unavailable, complete the series with the available product. **If any dose in the series was RotaTeq® or the product is unknown, a total of 3 doses of vaccine should be administered.**
- Preterm infants who are healthy and not hospitalized can receive rotavirus vaccine.
- Hospitalization in the NICU is not a contraindication to receipt of rotavirus vaccine. Refer to the hospital NICU policies and recommendations for rotavirus immunization of hospitalized infants.
- There are no restrictions on the timing of administration of oral polio virus (OPV) and rotavirus vaccines; this situation may arise for infants who have received OPV overseas.

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<sup>A</sup> There is no evidence that porcine circovirus types 1 and 2 pose a safety risk in humans and neither virus causes infection or illness in humans. These viruses are commonly found in pigs and pork products, but are not pork products.

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**ADVERSE EVENTS:**

**Local:** diarrhea, abdominal pain (<1%), flatulence (<1%).

**Systemic:** dermatitis (<1%), irritability.

A small increased risk of intussusception, about 1-2 cases per 100,000 infants following the first or second dose of rotavirus vaccine, has been reported in some countries. Most of this risk is following the first dose and within 7 days of dose receipt. This is considerably lower than the background rate of intussusception of 25 in 100,000 BC infants.