**Rotavirus (RV1) Vaccine, Live, Oral, ROTARIX®**

**Precautions and Contraindications**

Screen all patients for precautions and contraindications to immunization.

**Indications and Usage:** **ROTARIX**® is a vaccine indicated for the prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (G3, G4, and G9) in infants and children.

**Recommended Schedule**

* The vaccination series consists of two 1-mL doses administered orally at 6 to 24 weeks of age. There should be an interval of at least 4 weeks between the first and second doses.
* Maximum age for the first dose is 14 weeks 6 days.

**Dosage and Route FOR ORAL USE ONLY. DO NOT INJECT.**

To administer the vaccine:

* Remove plastic cover from vial of lyophilized vaccine.
* Connect transfer adapter onto vial by pushing it downwards until the transfer adapter is properly and securely in place.
* Shake the oral applicator containing the liquid diluent vigorously. The shaken suspension will appear as a turbid liquid with a slow settling white deposit.
* Remove the protective tip cap from the oral applicator.
* Connect the oral applicator into the transfer adapter by pushing it firmly on the device.
* Transfer the entire content of the oral applicator into the vial of lyophilized vaccine.
* With the oral applicator still attached, shake the vial and examine for complete suspension. The reconstituted vaccine will appear more turbid than the diluent alone. This appearance is normal.
* Withdraw the entire mixture back into the oral applicator.
* The infant should be seated in a reclining position. Administer orally the entire content of the oral applicator (on the inside of the cheek). Dispose of applicator and vaccine vial in biohazard waste container.

**Anatomical Site**

* Mouth/inner cheek

**Precautions**

* Prior to administering the vaccine, review infant immunization history for hypersensitivity and other reactions to any component of **ROTARIX**®, including latex rubber contained in the oral applicator.
* Administration of **ROTARIX**® should be delayed in infants suffering from acute diarrhea or vomiting.
* An increased risk of intussusception following administration of **ROTARIX**®was observed in some, but not all, postmarketing studies, particularly during the first week following the first dose of vaccine.
* Since **ROTARIX**® is a live virus, safety and effectiveness in infants with known primary or secondary immunodeficiencies have not been evaluated.

**Contraindications**

**DO NOT** administer to infants:

* With a history of severe allergic reaction (e.g. anaphylaxis) after a previous dose of rotavirus vaccine or exposure to a vaccine component.
* With a history of uncorrected congenital malformation of the gastrointestinal tract (such as Meckel’s diverticulum) that would predispose the infant for intussusception.
* With a history of intussusception.
* With Severe Combined Immunodeficiency Disease (SCID).

**Adverse Events**

* See the product’s package insert
* See Adverse Events Following Vaccinations page of this section

**Storage and Handling**

* Store in refrigerator at 36oF – 46oF (2oC – 8oC) **(DO NOT FREEZE)**.
* Administer within 24 hours of reconstitution.
* May be stored at room temperature up to 25°C (77°F) after reconstitution.
* Discard reconstituted vaccine if not used within 24 hours.
* Discard if the vaccine has been frozen.
* Protect from light.

**Other Important Notes**

* The ACIP recommends that **ROTARIX**® be given during the current routine well-baby visits at 2 and 4 months of age.
* Breast-feeding is not a contraindication for vaccination. No restrictions were placed on infants’ liquid consumption, including breast-milk, either before or after vaccination.
* In the event that the infants spits out or regurgitates most of the vaccine dose, a single replacement dose of **ROTARIX**® may be considered at the same vaccination visit.
* Rotavirus shedding in stool occurs after vaccination with peak excretion occurring around day 7 after dose 1 of **ROTARIX**®.
* CPT 90680

**Tuberculin Testing and Live Vaccines**

Recommendations for use of the tuberculin skin test are independent of those for immunization. Tuberculin testing at any age is not required before administration of live-virus vaccines. A tuberculin skin test (TST) can be applied at the same visit during which these vaccines are administered. Measles vaccine temporarily can suppress tuberculin reactivity for at least 4 to 6 weeks. The effect of live-virus varicella, yellow fever, and live-attenuated influenza vaccines on tuberculin skin test reactivity is not known. In the absence of data, the same TST spacing recommendation should be applied to these vaccines as described for MMR. There is no evidence that inactivated vaccines, polysaccharide vaccines or recombinant or subunit vaccines or toxoids interfere with immune response to TST.

**Tuberculin Skin Testing (TST) and Rotavirus Vaccine (RV1)**

* Apply TST at same visit as RV1 (preferred strategy)
* Apply TST first and administer RV1 when TST is read (least favored option because receipt of RV1 is delayed) (least preferred strategy)
* Delay TST at least 4 weeks if RV1 is given first.

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