**Rotavirus (RV5) Vaccine, RotaTeq®**

**Precautions and Contraindications**

Screen all patients for precautions and contraindications to immunization.

**Recommended Schedule**

* The vaccination series consists of three ready-to-use liquid doses of **RotaTeq**® administered orally at 6 to 12 weeks of age, with the subsequent doses administered at 4 to 10-week intervals. The third dose should not be given after 32 weeks of age.

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

To administer the vaccine:

* Tear open the pouch and remove the dosing tube
* Clear the fluid from the dispensing tip by holding tube vertically and tapping the cap
* Puncture the dispensing tip by screwing cap ***clockwise*** until it becomes tight
* Remove cap by turning it ***counterclockwise***
* Administer dose by gently squeezing liquid into infant’s mouth toward the inner cheek until dosing tube is empty

**Anatomical Site**

* Mouth/inner cheek

**Precautions**

* **Immunocompromised populations.** No safety or efficacy data are available from clinical trials regarding the administration of **RotaTeq**® to infants who are potentially immunocompromised including:
  + Infants with blood dyscrasias, leukemia, lymphomas of any type or other malignant neoplasms affecting the bone marrow or lymphatic system.
  + Infants on immunosuppressive therapy (including high-dose systemic corticosteroids). **RotaTeq**® may be administered to infants who are being treated with topical corticosteroids or inhaled steroids.
  + Infants with primary and acquired immunodeficiency states, including HIV/AIDS or other clinical manifestations of infection with human immunodeficiency viruses; cellular immune deficiencies; and hypogammaglobulinemic and dysgammaglobulinemic states. There are insufficient data from clinical trials to support administration of **RotaTeq**® to infants with indeterminate HIV status who are born to mothers with HIV/AIDS.
  + Infants who have received a blood transfusion or blood products, including immunoglobulins within 42 days.
* **Gastrointestinal Illness.** No safety or efficacy data are available for administration of **RotaTeq**® to infants with a history of gastrointestinal disorders including infants with active acute gastrointestinal illness, infants with chronic diarrhea and failure to thrive, and infants with a history of congenital abdominal disorders, and abdominal surgery. Caution is advised when considering administration of **RotaTeq**® to these infants.
* **Intussusception.** An increased risk of intussusception following administration of **RotaTeq**® was observed in some, but not all, postmarketing studies, particularly during the first week following the first dose of vaccine.
* **Febrile illness**. Low-grade fever (<100.5 F) itself and mild upper respiratory infection do not preclude vaccination.

**Precautions (continued)**

* **Immunodeficient close contacts**. Caution is advised when considering whether to administer RotaTeq® to individuals with immunodeficient close contacts such as:
  + Individuals with malignancies or who are otherwise immunocompromised
  + Individuals with primary immunodeficiency; or
  + Individuals receiving immunosuppressive therapy.

**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 Severe Combined Immunodeficiency Disease (SCID).
* With a history of intussusception.

**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)
* Administer as soon as possible after being removed from refrigerator
* Protect from light

**Other Important Notes**

* The ACIP recommends that **RotaTeq**® be given during the current routine well-baby visits at 2, 4, and 6 months of age.
* There are no restrictions on the infant’s consumption of food or liquid, including breast milk, either before or after vaccination with **RotaTeq**®.
* Re-administration of a dose of **RotaTeq**® to an infant who regurgitates, spits out or vomits during or after administration of vaccines **is not recommended**. The infant should receive the remaining recommended doses of **RotaTeq**® at appropriate intervals.

**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 (RV5)**

* Apply TST at same visit as RV5 (preferred strategy)
* Apply TST first and administer RV5 when TST is read (least favored option because receipt of RV5 is delayed) (least preferred strategy)
* Delay TST at least 4 weeks if RV5 is given first.

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