

## Vaccines for Children (VFC) Program Rotavirus Vaccine Use in Children Vaccine Summary March 1, 2023

### **Purpose of Vaccine Summary**

- Effective March 1, 2023, a new oral-dosing applicator-only presentation of Rotarix rotavirus vaccine, manufactured by GSK is available to order through the Iowa VFC Program. The new liquid formulation does not require reconstitution. The existing lyophilized vaccine formulation will no longer be available to order effective March 1, 2023, however VFC Providers are required to use existing lyophilized stock to avoid wastage.
- RotaTeq rotavirus vaccine (Merck) will continue to be an available option for Iowa VFC Providers.

### **Rotavirus Recommendations in Children**

#### **Food and Drug Administration (FDA)**

- November 4, 2022 the FDA approved a supplement to the Biologics License of oral Rotarix vaccine (GSK) to include an oral dosing applicator only presentation.

#### **Advisory Committee on Immunization Practices (ACIP)**

There are no changes to the ACIP recommendations for the use of rotavirus vaccines. Additionally, there is no preferential recommendation among the currently available presentations.

- [Prevention of Rotavirus Gastroenteritis Among Infants and Children](#) (February 6, 2009)
- [Addition of Severe Combined Immunodeficiency as a Contraindication for Administration of Rotavirus Vaccine](#) (June 11, 2010)
- [Addition of History of Intussusception as a Contraindication for Rotavirus Vaccination](#) (October 21, 2011)

#### **VFC Resolution**

The Federal VFC Program follows the ACIP recommendations for the use of rotavirus vaccine as an option for vaccinating eligible children ages 6 weeks through 8 months 0 days.

#### **ACIP Recommended Schedule for Rotavirus Vaccines in Children**

[Child and Adolescent Immunization Schedule Recommendations for Ages 18 Years or Younger, United States, 2023](#)

### **Recommended Dosage and Administration**

Two different rotavirus vaccines are licensed: RotaTeq (Merck & Co) (RV5) and ROTARIX (GSK) (RV1). These vaccines are considered equally safe and effective. These vaccines differ in composition and schedule. The following is a harmonized schedule approved by the ACIP.

	<b>RotaTeq (RV5 - Merck)</b>	<b>Rotarix (RV1 - GSK)</b>
Number of doses in series *	3	2
Recommended ages for doses	2, 4, and 6 months	2 and 4 months
Minimum age for first dose	6 weeks	
Maximum age for first dose	14 weeks 6 days	
Interval between doses	4 weeks or more	
Maximum age for last dose	8 months 0 days	

\*If any dose in the series was RV5 vaccine or the vaccine brand used for any prior dose in the series is not known, a total of three doses of rotavirus vaccine should be administered.

### **Vaccine Administration and Route**

Oral, not for injection.

### **Presentations**

#### **Rotarix (GSK):**

The number of doses and the intervals are the same for the new liquid formulation as they are for the lyophilized formulation.

#### **Vial and oral dosing applicator presentation:**

- A carton of 10 single-dose vials of lyophilized vaccine, accompanied by a prefilled oral dosing applicator of liquid diluent.
- The vial contains the lyophilized vaccine component and the oral dosing applicator contains the diluent. The contents of the vial must be reconstituted with the diluent to form Rotarix prior to use.
  - Vial and oral dosing applicator presentation: a single dose is 1.0 mL

#### **Oral-dosing applicator-only presentation:**

- A carton of 10 single-dose prefilled oral dosing only applicators with a plunger stopper.
- The oral dosing applicator contains Rotarix and does not require reconstitution or dilution before use.
  - Oral-dosing applicator-only presentation: a single dose is 1.5 mL

#### **RotaTeq (Merck):**

- A carton of 10 individually pouched single-dose tubes.
- The dosing tube contains RotaTeq and does not require reconstitution or dilution before use.
  - Oral dosing: a single dose is 2 mL

### **Vaccine Storage and Handling**

- Store refrigerated at 2 - 8°C (36 - 46°F).
- Do not freeze.
- Store in original packaging. Protect from light.
- Do not use products if exposed to out of range temperatures.
- Do not use after expiration date shown on the label.

### **Precautions**

- Moderate or severe acute illness with or without fever, including acute gastroenteritis (defer until symptoms improve)
- Altered immunocompetence (Severe combined immunodeficiency [SCID] is a contraindication)
- Chronic gastrointestinal disease

### **Contraindications**

- Severe allergic reaction (e.g. anaphylaxis) to any vaccine component or following a prior dose
- Latex rubber is contained in the Rotarix oral applicator, so infants with a severe allergy to latex should not receive Rotarix. The RotaTeq dosing tube is latex free.
- History of intussusception
- Severe combined immunodeficiency (SCID)

### **Additional Resources**

- CDC: Potential Questions and Answers for the New Liquid Formulation ROTARIX Licensure ([www.cdc.gov/vaccines/vpd/rotavirus/hcp/rotarix-licensure-faq.html](http://www.cdc.gov/vaccines/vpd/rotavirus/hcp/rotarix-licensure-faq.html) )
- FDA: ROTARIX Package Insert and Patient Information (Vial with Oral Dosing Applicator Presentation and Oral Dosing Applicator Only Presentation) ([www.fda.gov/media/163009/download](http://www.fda.gov/media/163009/download)).
- GSK: ROTARIX (Rotavirus Vaccine, Live, Oral) for HCPs ([www.rotarixhcp.com/](http://www.rotarixhcp.com/)).
- FDA: RotaTeq Package Insert (<https://www.fda.gov/media/75718/download>)
- CDC Rotavirus Vaccination: Information for Healthcare Professionals (<https://www.cdc.gov/vaccines/vpd/rotavirus/hcp/index.html>)
- Ask the Experts Rotavirus Vaccine ([https://www.immunize.org/askexperts/experts\\_rota.asp](https://www.immunize.org/askexperts/experts_rota.asp))
- Pink Book Rotavirus (<https://www.cdc.gov/vaccines/pubs/pinkbook/rota.html#vaccination-schedule-use>)
- CDC Rotavirus VIS (<https://www.cdc.gov/vaccines/hcp/vis/vis-statements/rotavirus.html>)

### **Reporting of Adverse Events**

Adverse events following administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reports can be submitted to VAERS online, by fax, or by mail. Additional information about VAERS is available by telephone (1-800-822-7967) or online (<https://vaers.hhs.gov>).

### **Iowa Department of Health and Human Services (Iowa HHS) /Immunization Program Recommendations**

The Iowa HHS Immunization Program routinely follows and promotes the ACIP Recommended Immunization Schedule. The Immunization Program is implementing rotavirus vaccine in accordance with the ACIP recommendations and the federal VFC resolution.

### **CPT Codes**

Rotarix - 90681

RotaTeq - 90680