

MnVFC Announcement

Date: Feb. 25, 2023

To: MnVFC Providers

From: MnVFC Program

Re: **New ROTARIX Liquid Formulation**

Please route to:

- Clinical supervisor
- Medical director
- Clinic manager
- Clinic staff
- Pharmacy
- Vaccine staff

On Nov. 4, 2022, the FDA approved an oral-dosing applicator-only presentation (liquid formulation) of ROTARIX. This new formulation does not require reconstitution and will be available for ordering in March 2023. There will be two ROTARIX presentations available until early 2025 when the lyophilized formulation (that requires reconstitution) will retire.

New ROTARIX liquid formulation dose, route, and storage

- Single 1.5 mL dose, oral route, **no reconstitution**.
- Prefilled oral dosing applicator with a plunge stopper.
- Store at 2° to 8°C (36° to 46°F).
- **Do not freeze. Discard if the vaccine has been frozen.**
- **Keep in original package to protect from light.**

ROTARIX lyophilized formulation dose, route, and storage

- Single 1 mL dose, oral route, **must be reconstituted**.
- Single dose vial of lyophilized vaccine component, prefilled oral dosing applicator with 1 mL liquid diluent with a plunger stopper, and transfer adapter for reconstitution.
- Store vials at 2° to 8°C (36° to 46°F) and **protect from light**.
- Store diluent in oral dosing applicator at 2° to 8°C (36° to 46°F) or at room temperature up to 25°C (77°F).
- **Do not freeze. Discard if the diluent has been frozen.**
- Refer to the package insert for storage after reconstitution.

To avoid vaccine errors

- Use up current ROTARIX lyophilized formulation (that requires reconstitution) first before using the new liquid formulation.
- Educate staff on how to prepare and administer the ROTARIX formulation(s) in stock.
- Refer to [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) for more information.

Resources

- [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/).