



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

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Division of Public Health

March 14th

MEMORANDUM

TO: North Carolina Immunization Vaccines for Children (VFC) Providers

FROM: Carrie Blanchard, PharmD, MPH *CB*
Interim Immunization Director

SUBJECT: New Liquid Formulation of ROTARIX

On November 4, 2022, the FDA approved a [new liquid formulation of ROTARIX](#). This new presentation (NDC 58160-0740-21) is fully liquid and **does not require reconstitution or dilution**. This will replace the current lyophilized formulation (NDC 58160-0854-52), which requires reconstitution with the diluent before administration. The old formulation has been removed, and the new formulation is now available for ordering in NCIR.

A single dose of the new liquid formulation is 1.5 mL (the old, lyophilized formulation dose is 1 mL). Both formulations contain the same live, attenuated rotavirus strain and are manufactured using a similar process. Clinical trials comparing the two formulations showed safety profiles that were generally similar. Compared to the old formulation, the new formulation contains disodium adipate, and no longer contains sorbitol or phenol red. Since the new formulation does not require reconstitution or dilution, please review the "[Oral Dosing Applicator Only Presentation](#)" section in the [Full Prescribing Information](#) for details on how to prepare and administer the vaccine. See Sections 2, 3, 6.1, 11, and 14 of the Full Prescribing Information for further details.

Please continue to maintain best practices by rotating your inventory and using your current inventory of ROTARIX® before ordering and administering the new formulation of ROTARIX®. **Inventory should be kept separate, and diluent must only be used with the old, lyophilized formulation.**

New ROTARIX liquid formulation dose, route, and storage

Formulation	Fully liquid formulation; no reconstitution necessary
Number of doses to complete the series	2 doses
Dose volume	1.5 mL
Storage	Store refrigerated at 2° to 8°C (36° to 46°F)

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF PUBLIC HEALTH • IMMUNIZATION BRANCH

LOCATION: 5601 Six Forks Road, Raleigh, NC 27609
MAILING ADDRESS: 1917 Mail Service Center, Raleigh, NC 27699-1917
www.ncdhhs.gov • TEL: 919-707-5550 • FAX: 919-870-4824

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	Do not freeze. Discard if the vaccine has been frozen
Administration	Oral dose applicator
Dosing schedule	Dosing can begin at 6 weeks of age and should be completed by 24 weeks

Resources

- [Dosing schedule for ROTARIX](#)
- [FDA: ROTARIX Package Insert and Patient Information](#)
- [GSK: ROTARIX \(Rotavirus Vaccine, Live, Oral\) for HCPs](#)
- [GSK: ROTARIX \(Liquid formulation\) Digital Demonstration](#)

If you have any questions or need assistance, please contact the Immunization Branch Help Desk at 1-877-873-6247.

Sincerely,

Carrie Blanchard, PharmD, MPH
Interim Immunization Director