World Health Organization

Summary of Key Characteristics of WHO Prequalified Rotavirus Vaccines*

Characteristics		***Rotarix*** *(GlaxoSmithKline)*	***Rotateq*** *(Merck)***	***Rotavac*** *(Bharat Biotech International)*	***ROTASIIL*** *(Serum Institute of India Pvt Ltd)*
Efficacy for severe rotavirus gastroenteritis, at 2 years follow-up,*** by child mortality rate stratum of country of study site [1]	**Low Mortality**	**90%** (95% CI, 86-93%)	**94%** (95% CI, 61-99%)	No data available	No data available
	Medium Mortality	**78%** (95% CI, 70-83%)	**81%** (95% CI, 66-89%)	No data available	No data available
	High Mortality	**54%** (95% CI, 9-77%)	**44%** (95% CI, 23-59%)	**54%** (95% CI, 40-65%)	**44%** (95% CI, 26-58%)
	Study sites	Multiple countries at different income and mortality levels.		3 sites in India	6 sites in India; 1 center, multiple sites in Niger
Date of WHO prequalification		March 2009	October 2008	January 2018	September 2018
WHO recommended schedules and catch-up policy[2,3,4,5]		• WHO recommends that the first dose of rotavirus vaccine be administered as soon as possible after 6 weeks of age. A minimum interval of 4 weeks should be maintained between doses. RotaTeq, Rotavac, and ROTASIIL should be administered in a 3-dose schedule, while a 2-dose schedule should be used for Rotarix. • If a child misses a rotavirus dose or series for any reason, late vaccination for that child can take place at any time before 24 months of age.			
Safety		• WHO has concluded that the prequalified rotavirus vaccines are safe and should be among the vaccine options to prevent severe rotavirus gastroenteritis globally.[1,2,6,7] Continued monitoring of the risk for intussusception is recommended.[2,6] However, lack of such surveillance should not be an impediment to rotavirus vaccine introduction.			
Mixed schedules & interchangeability of products[4]		• If the product used for a prior dose is unavailable or unknown, the series should be completed with any available licensed product. Restarting the vaccine series is not recommended. • For a mixed series or a series with any unknown vaccine products, a total of 3 doses of rotavirus vaccine should be administered for a complete vaccination series. • The published immunogenicity, effectiveness, and safety data on mixed schedules or interchangeability are reassuring for all products;[8, 9, 10]			

** For the rotavirus vaccines discussed in this document, the following disclaimer applies: WHO does not approve or endorse the use of specific branded products over others; this publication may not be used for any commercial or promotional purposes.*

*** Rotateq™* is not available to countries receiving Gavi support for vaccine implementation.

*** One year follow-up efficacy estimates for severe rotavirus gastroenteritis diarrhea were reported in the 2020 Cochrane review and are similar to those for 2 year follow-up.

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Appendices:

- For current information and additional details, please visit: https://www.who.int/teams/immunization-vaccines-and-biologicals/diseases/rotavirus and the WHO List of Prequalified Vaccines https://extranet.who.int/pqweb/vaccines/prequalified-vaccines.
- Gavi's detailed product profiles for rotavirus vaccines: https://www.gavi.org/about/market-shaping/detailed-product-profiles/

References:

[1] Systematic review and meta-analysis of the safety, effectiveness and efficacy of childhood schedules using Rotavirus Vaccines – Cochrane Response. October 2020 SAGE Meeting, Rotavirus Vaccines – Session 6. Background documents (https://terrance.who.int/mediacentre/data/sage/SAGE_eYB_October_2020.pdf?ua=1); SAGE Meeting slide deck. Rotavirus Vaccines - Session 6. October 2020 (https://terrance.who.int/mediacentre/data/sage/SAGE_Slidedeck_Oct2020-Web.pdf?ua=1).

[2] Rotavirus vaccines: WHO position paper, July 2021 (https://www.who.int/publications/i/item/weekly-epidemiological-record-vol.-28-2021-96-301-320).

[3]. WHO recommendations for routine immunization (Summary Table 3). https://www.who.int/publications/m/item/table-3-who-recommendations-for-routine-immunization

[4]. Leave no one behind: guidance for planning and implementing catch-up vaccination. https://www.who.int/publications/i/item/9789240016514

[5]. Rotavirus vaccine catch-up vaccination training materials.https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/training/vaccine-specific-training-materials/training-materials-rotavirus

[6] Report of the WHO Global Advisory Committee on Vaccine Safety, 6-7 December 2017. (http://apps.who.int/iris/bitstream/handle/10665/259874/WER9303.pdf?sequence=1).

[7] Report of the WHO Global Advisory Committee on Vaccine Safety, 4–5 December 2019. (https://apps.who.int/iris/bitstream/handle/10665/330607/WER9504-eng-fre.pdf?ua=1).

[8] Libster R, McNeal M, Walter EB, Shane AL, Winokur P, Cress G, et al. Safety and Immunogenicity of Sequential Rotavirus Vaccine Schedules. Pediatrics. 2016 Feb;137(2). (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4732359/).

[9] Payne DC, Sulemana I, Parashar UD, for the New Vaccine Surveillance Network. Evaluation of Effectiveness of Mixed Rotavirus Vaccine Course for Rotavirus Gastroenteritis. *JAMA Pediatrics.* 2016;170(7):708–710 (https://jamanetwork.com/journals/jamapediatrics/fullarticle/2526062)

[10] Kanungo S, Chatterjee P, Bavdekar A, Murhekar M, Babji S, Garg R, et al. Safety and immunogenicity of the Rotavac and Rotasiil rotavirus vaccines administered in an interchangeable dosing schedule among healthy Indian infants: a multicentre, open-label, randomised, controlled, phase 4, non-inferiority trial. Lancet Infect Dis. 2022 May 16:S1473-3099(22)00161-X (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9464301/).

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