

Summary of Key Characteristics of WHO Prequalified Rotavirus Vaccines*

Characteristics		<i>Rotarix</i> TM (GSK)	<i>Rotateq</i> TM (Merck)	<i>Rotavac</i> TM (Bharat)	<i>Rotasii</i> TM (Serum Institute)
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
Safety		<ul style="list-style-type: none"> WHO has concluded that the prequalified rotavirus vaccines (RVVs) are safe and should be among the vaccine options to prevent severe rotavirus gastroenteritis globally.^{1,2,3} Continued monitoring of the risk for intussusception is recommended.³ 			
Mixed schedules & interchangeability of products ⁴		<ul style="list-style-type: none"> 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. If any dose in the series was from a product that has a 3-dose schedule, or if the vaccine product is unknown for any dose, a total of 3 doses of rotavirus vaccine should be administered for a complete vaccination series. The published safety and efficacy data on mixed schedules or interchangeability that exist for <i>Rotarix</i>TM and <i>Rotateq</i>TM are reassuring;^{5,6} No published data yet exist on performance of any mixed vaccine courses that include <i>Rotavac</i>TM or <i>Rotasii</i>TM. 			

* 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.

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://www.who.int/immunization/sage/meetings/2020/october/SAGE_eYB_Oct2020final.pdf?ua=1; SAGE Meeting slide deck. Rotavirus Vaccines - Session 6. October 2020. https://www.who.int/immunization/sage/meetings/2020/october/SAGE_Slidedeck_Oct2020-Web.pdf?ua=1

² 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>

³ 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>

⁴ WHO Programmatic Guidance Note Use of more than one rotavirus vaccine product to complete the vaccination series. November 12, 2019. https://www.who.int/immunization/diseases/rotavirus/Rota_mixed_schedules_interchangeability.pdf?ua=1

⁵ Libster R, et al. Safety and Immunogenicity of Sequential Rotavirus Vaccine Schedules. *Pediatrics*. 2016 Feb;137(2).

⁶ 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.

* 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.

Appendices:

- For current information and additional details, please visit: <https://www.who.int/immunization/diseases/rotavirus/en/>
- Gavi's detailed product profiles for rotavirus vaccines: <https://www.gavi.org/about/market-shaping/detailed-product-profiles/>

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