

Approval Date: [November 12, 2019](#)

Product: Rotarix

Proper Name: Rotavirus Vaccine, Live, Oral

Manufacturer: GlaxoSmithKline Biologicals

Indication: For the prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (G3, G4, and G9), for use in infants 6 weeks to 24 weeks of age.

Description: ROTARIX (Rotavirus Vaccine, Live, Oral), for oral administration, is a live, attenuated rotavirus vaccine derived from the human 89-12 strain which belongs to G1P[8] type. The rotavirus strain is propagated on Vero cells. After reconstitution, the final formulation (1 mL) contains at least 106.0 median Cell Culture Infective Dose (CCID50) of live, attenuated rotavirus.

BLA: BL 125265

Regulatory Milestone:

The Biologics License Application (BLA) for Rotavirus Vaccine, Live, Oral (ROTARIX®) from GlaxoSmithKline Biologicals (GSK) was received by CBER on June 4, 2007. GSK had filed an Investigational New Drug Application (IND) under which an initial Phase 2 study had been conducted in the U.S. in June 2000. A Pre-BLA meeting was held in September of 2006.

PDUFA Goal Date: April 3, 2008

Package Insert: [Package Insert - Rotarix](#)

Summary Basis for Regulatory Approval: [June 04, 2007 Summary Basis for Regulatory Action - Rotarix](#)

European Public Assessment Report: [Human medicine European public assessment report \(EPAR\): Rotarix](#)

Advisory Committee:

The Vaccines and Related Biological Products Advisory Committee meeting took place on February 20, 2008. The committee voted unanimously regarding the adequacy of the efficacy of the vaccine and all except one member voted in favor of the adequacy of the safety data to support the licensure of ROTARIX.

Safety:

The reviewer recommends that Rotarix be approved for use in infants 6 to 24 weeks of age. As part of the pre-BLA agreement, the applicant will conduct a prospective US post-licensure observational safety study that will be adequately powered to evaluate the risk of intussusception. Other measured outcomes will include deaths from all causes, hospitalizations due to acute lower respiratory tract infections (including pneumonia), convulsions, and Kawasaki disease.

NCT Numbers:

- NCT00737503
- NCT01636193
- NCT01435967
- NCT01636739
- NCT00938327
- NCT02907216
- NCT01871038
- NCT00750893
- NCT01915888
- NCT01198769
- NCT00480324
- NCT01177657
- NCT01162590
- NCT01177826
- NCT00875641

- NCT00969228
- NCT01003431
- NCT02141204
- NCT00655187
- NCT01086436
- NCT02220439
- NCT00595205
- NCT01177722
- NCT02153333
- NCT01339221
- NCT00653198
- NCT01511133

EudraCT Numbers:

- 2017-000451-14
- 2012-001481-16
- 2012-005200-18
- 2015-001546-28
- 2006-006552-36
- 2012-004137-16
- 2013-003459-39
- 2018-003787-31
- 2015-001484-39
- 2012-004039-21
- 2011-004428-36
- 2015-001485-26
- 2011-004451-39
- 2015-001542-29
- 2006-003239-61
- 2015-001510-10
- 2013-003428-34
- 2011-001508-37
- 2015-001547-37
- 2015-001543-36
- 2016-003210-27
- 2006-000559-16
- 2011-003731-63
- 2006-003762-33
- 2014-005282-78
- 2015-001544-11
- 2016-003268-37
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- 2015-001545-81
- 2012-003026-25
- 2008-006551-51
- 2018-001986-18
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- 2013-004495-34
- 2016-000598-19
- 2011-002077-35
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- 2010-021491-28
- 2013-004304-19
- 2014-000101-12
- 2011-004449-42
- 2015-001540-10
- 2009-012460-14
- 2015-001511-12
- 2015-001541-92

Publications:

- Ruiz-Palacios, G. M., Pérez-Schael, I., Velázquez, F. R., Abate, H., Breuer, T., Clemens, S. C., Chevart, B., Espinoza, F., Gillard, P., Innis, B. L., Cervantes, Y., Linhares, A. C., López, P., Macías-Parra, M., Ortega-Barría, E., Richardson, V., Rivera-Medina, D. M., Rivera, L., Salinas, B., Pavía-Ruz, N., ... Human Rotavirus Vaccine Study Group (2006). Safety and efficacy of an attenuated vaccine against severe rotavirus gastroenteritis. *The New England journal of medicine*, 354(1), 11–22. <https://doi.org/10.1056/NEJMoa052434>
- Araujo, E. C., Clemens, S. A., Oliveira, C. S., Justino, M. C., Rubio, P., Gabbay, Y. B., da Silva, V. B., Mascarenhas, J. D., Noronha, V. L., Clemens, R., Gusmão, R. H., Sanchez, N., Monteiro, T. A., & Linhares, A. C. (2007). Safety, immunogenicity, and protective efficacy of two doses of RIX4414 live attenuated human rotavirus vaccine in healthy infants. *Jornal de pediatria*, 83(3), 217–224. <https://doi.org/10.2223/JPED.1600>
- Buyse, H., Vinals, C., Karkada, N., & Han, H. H. (2014). The human rotavirus vaccine Rotarix™ in infants: an integrated analysis of safety and reactogenicity. *Human vaccines & immunotherapeutics*, 10(1), 19–24. <https://doi.org/10.4161/hv.26476>
- Chevart, B., Neuzil, K. M., Steele, A. D., Cunliffe, N., Madhi, S. A., Karkada, N., Han, H. H., & Vinals, C. (2014). Association of serum anti-rotavirus immunoglobulin A antibody seropositivity and protection against severe rotavirus gastroenteritis: analysis of clinical trials of human rotavirus vaccine. *Human vaccines & immunotherapeutics*, 10(2), 505–511. <https://doi.org/10.4161/hv.27097>
- Ali, A., Kazi, A. M., Cortese, M. M., Fleming, J. A., Moon, S., Parashar, U. D., Jiang, B., McNeal, M. M., Steele, D., Bhutta, Z., & Zaidi, A. K. (2015). Impact of withholding breastfeeding at the time of vaccination on the immunogenicity of oral rotavirus vaccine--a randomized trial. *PloS one*, 10(6), e0127622. <https://doi.org/10.1371/journal.pone.0127622>
- Harris, V. C., Haak, B. W., Handley, S. A., Jiang, B., Velasquez, D. E., Hykes, B. L., Jr, Droit, L., Berbers, G., Kemper, E. M., van Leeuwen, E., Boele van Hensbroek, M., & Wiersinga, W. J. (2018). Effect of Antibiotic-Mediated Microbiome Modulation on Rotavirus Vaccine Immunogenicity: A Human, Randomized-Control Proof-of-Concept Trial. *Cell host & microbe*, 24(2), 197–207.e4. <https://doi.org/10.1016/j.chom.2018.07.005>