Approval Date: August 14, 2020

Product: RotaTeq®

Proper Name: Rotavirus Vaccine, Live, Oral, Pentavalent

Manufacturer: Merck Sharp & Dohme Corp

Indication: For the prevention of rotavirus gastroenteritis caused by the types G1, G2, G3, G4, and G9 for use in infants 6 weeks to 32 weeks of age.

Description: RotaTeq is a live, oral pentavalent vaccine that contains 5 live reassortant rotaviruses. The rotavirus parent strains of the reassortants were isolated from human and bovine hosts. Four reassortant rotaviruses express one of the outer capsid proteins (G1, G2, G3, or G4) from the human rotavirus parent strain and the attachment protein (type P7) from the bovine rotavirus parent strain. The fifth reassortant virus expresses the attachment protein, P1A (genotype P), herein referred to as type P1A, from the human rotavirus parent strain and the outer capsid protein of type G6 from the bovine rotavirus parent strain.

BLA: BL 125122

Regulatory Milestone:

PDUFA Goal Date: February 23, 2017

Package Insert: Package Insert - RotaTeq

Summary Basis for Regulatory Approval: February 22, 2017 Summary Basis for Regulatory Action - RotaTeq

European Public Assessment Report: Human medicine European public assessment report (EPAR): RotaTeq

Advisory Committee:

A Vaccines and Related Biologics Products Advisory Committee meeting was not held for this supplement as there were no issues or concerns that presented during the course of review of the supplement that required consult from the advisory committee.

Safety: no new safety concerns.

NCT Numbers:

- NCT04481191
- NCT00767364
- NCT01600092
- NCT00836498
- NCT01960725
- NCT01926015
- NCT00496054
- NCT00362648
- NCT01357174
- NCT00443846
- NCT01074242
- NCT01003431
- NCT00880698
- NCT00718237
- NCT01340937
- NCT01266850
- NCT00090233
- NCT01337167
- NCT02193061
- NCT00092443
- NCT00740935
- NCT00092456
- NCT00953056
- NCT02728869
- NCT01236066
- NCT00130832
- NCT02542462
- NCT02286895
- NCT01341639
- NCT01026779
- NCT00258154
- NCT02847026
- NCT01839188
- NCT02062385
- NCT03893448
- NCT01682005
- NCT01480258
- NCT00166517
- NCT01273077

- NCT01199874
- NCT02028910
- NCT03620162
- NCT00875641
- NCT01839175
- NCT01435967
- NCT01049035
- NCT00474526
- NCT01177826

EudraCT Numbers:

- 2014-004252-60
- 2005-003508-12
- 2006-005445-11
- 2012-001611-23
- 2006-007067-85
- 2017-000263-32
- 2017-000264-15
- 2016-005159-25
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Publications:

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- Vesikari, T., Karvonen, A., Ferrante, S. A., & Ciarlet, M. (2010). Efficacy of the pentavalent rotavirus vaccine, RotaTeq®, in Finnish infants up to 3 years of age: the Finnish Extension Study. European journal of pediatrics, 169(11), 1379–1386. https://doi.org/10.1007/s00431-010-1242-3
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Pentavalent rotavirus vaccine, and NeisVac-C, a meningococcal serogroup C conjugate vaccine. Clinical and vaccine immunology: CVI, 18(5), 878–884. https://doi.org/10.1128/CVI.00437-10

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- McGrath, E. J., Thomas, R., Duggan, C., & Asmar, B. I. (2014). Pentavalent rotavirus vaccine in infants with surgical gastrointestinal disease. Journal of pediatric gastroenterology and nutrition, 59(1), 44–48. https://doi.org/10.1097/MPG.0000000000000361
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