

**Approval Date:** [December 21, 2018](#)

**Product:** RECOMBIVAX HB

**Proper Name:** Hepatitis B Vaccine (Recombinant)

**Manufacturer:** Merck & Co, Inc

**Indication:** For prevention of infection caused by all known subtypes of hepatitis B virus.

**Description:** RECOMBIVAX HB Hepatitis B Vaccine (Recombinant) is a sterile suspension of non-infectious subunit viral vaccine derived from HBsAg produced in yeast cells.

**BLA:** BL 101066

**Regulatory Milestone:** No data

**PDUFA Goal Date:** No data

**Package Insert:** [Package Insert - Recombivax HB](#)

**Summary Basis for Regulatory Approval:** [Summary Basis for Regulatory Action - Recombivax HB](#)

**European Public Assessment Report:** No data

**Advisory Committee:** No data

**Safety:** No data

**NCT Numbers:**

- NCT04162223
- NCT00414050
- NCT00440531
- NCT00393523
- NCT02055365
- NCT00322361
- NCT02429583
- NCT00107042
- NCT01463683
- NCT00551915
- NCT03893448
- NCT02040636
- NCT01340937
- NCT01337167
- NCT00142753
- NCT03620162
- NCT02057263
- NCT04456504
- NCT00489099
- NCT00643097
- NCT01049035

**EudraCT Numbers:**

- 2009-016721-33
- 2006-001638-42
- 2016-003981-15
- 2006-003648-46
- 2018-001151-12
- 2015-005196-24
- 2011-004108-39
- 2011-004095-10

**Publications:**

- Pielak, K. L., McIntyre, C. C., Remple, V. P., Buxton, J. A., & Skowronski, D. M. (2008). One arm or two? Concurrent administration of meningococcal C conjugate and hepatitis B vaccines in pre-teens. *Canadian journal of public health = Revue canadienne de sante publique*, 99(1), 52–56. <https://doi.org/10.1007/BF03403741>
- Cunningham, C. K., Rudy, B. J., Xu, J., Bethel, J., Kapogiannis, B. G., Ahmad, S., Wilson, C. M., Flynn, P. M., & Adolescent Medicine Trials Network for HIV/AIDS Interventions (2010). Randomized trial to determine safety and immunogenicity of two strategies for hepatitis B vaccination in healthy urban adolescents in the United States. *The Pediatric infectious disease journal*, 29(6), 530–534. <https://doi.org/10.1097/INF.0b013e3181d285c7>
- Gilca, V., De Serres, G., Boulianne, N., Murphy, D., Ouakki, M., De Wals, P., Trudeau, G., Massé, R., & Dionne, M. (2013). Long-term persistence of immunity after vaccination of pre-adolescents with low doses of a recombinant hepatitis B vaccine. *Human vaccines & immunotherapeutics*, 9(8), 1685–1690. <https://doi.org/10.4161/hv.25015>