

Approval Date: [December 19, 2018](#)

Product: ENGERIX-B

Proper Name: Hepatitis B Vaccine (Recombinant)

Manufacturer: GlaxoSmithKline Biologicals

Indication: ENGERIX-B is a vaccine indicated for immunization against infection caused by all known subtypes of hepatitis B virus.

Description: ENGERIX-B [Hepatitis B Vaccine (Recombinant)] is a sterile suspension of noninfectious HBsAg for intramuscular administration. It contains purified surface antigen of the virus obtained by culturing genetically engineered *Saccharomyces cerevisiae* cells, which carry the surface antigen gene of the hepatitis B virus.

BLA: 103239

Regulatory Milestone:

In September 2011, GSK submitted a Type C Meeting Request to discuss GSK's plan to conduct an open-label clinical study to assess the immunogenicity and safety of Engerix-B in adults with type 2 diabetes mellitus and to submit the results of that study in a supplement to the Engerix BLA.

PDUFA Goal Date: September 20, 2015

Package Insert: [Package Insert - Engerix-B](#)

Summary Basis for Regulatory Approval: [September 11, 2015 Summary Basis for Regulatory Action - Engerix - B](#)

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

Advisory Committee:

The review team and CBER management determined that the discussion of the review of Engerix-B by the Vaccines and Related Biological Products Advisory Committee was not necessary because of CBER’s experience with the currently licensed Engerix-B. Our review of the supplement did not raise concerns or controversial issues which would have benefited from an advisory committee discussion.

NCT Numbers:

- NCT02901951
- NCT02798952
- NCT01847430
- NCT00435812
- NCT03393754
- NCT00984139
- NCT02434848
- NCT01627340
- NCT00831311
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- NCT00393523
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- NCT00440297
- NCT00534638
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- NCT00619502
- NCT00440531
- NCT00343915
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- NCT03083158
- NCT04326803
- NCT00426712
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- NCT01311674
- NCT00697125
- NCT01437475
- NCT00873652
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- NCT00289731
- NCT03567382
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- NCT00142753
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- NCT01457495
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- NCT02096263
- NCT01049035
- NCT00839254
- NCT00861380

EudraCT Numbers:

- 2007-002221-76
- 2004-005262-20
- 2014-002112-16
- 2015-004099-31
- 2017-001819-36
- 2010-022372-31
- 2010-019633-10
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- 2017-001820-22
- 2006-006743-31
- 2011-001508-37
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- 2006-000556-41
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- 2014-003756-32
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- 2006-000553-22
- 2010-023947-14

- 2008-005149-48
- 2011-002076-16
- 2008-006551-51
- 2006-006204-11
- 2014-005568-14
- 2013-004194-27
- 2006-003762-33
- 2007-001731-55

Publications:

- Martins, R. M., Bensabath, G., Arraes, L. C., Oliveira, M., Miguel, J. C., Barbosa, G. G., & Camacho, L. A. (2004). Multicenter study on the immunogenicity and safety of two recombinant vaccines against hepatitis B. *Memorias do Instituto Oswaldo Cruz*, 99(8), 865–871. <https://doi.org/10.1590/s0074-02762004000800014>
- Raz, R., Koren, R., & Bass, D. (2001). Safety and immunogenicity of a new mammalian cell-derived recombinant hepatitis B vaccine containing Pre-S1 and Pre-S2 antigens in adults. *The Israel Medical Association journal : IMAJ*, 3(5), 328–332
- Bienzle, U., Günther, M., Neuhaus, R., & Neuhaus, P. (2002). Successful hepatitis B vaccination in patients who underwent transplantation for hepatitis B virus-related cirrhosis: preliminary results. *Liver transplantation : official publication of the American Association for the Study of Liver Diseases and the International Liver Transplantation Society*, 8(6), 562–564. <https://doi.org/10.1053/jlts.2002.33699>
- Martins, R. M., Bensabath, G., Arraes, L. C., Oliveira, M., Miguel, J. C., Barbosa, G. G., & Camacho, L. A. (2004). Multicenter study on the immunogenicity and safety of two recombinant vaccines against hepatitis B. *Memorias do Instituto Oswaldo Cruz*, 99(8), 865–871. <https://doi.org/10.1590/s0074-02762004000800014>
- Connor, B. A., Blatter, M. M., Beran, J., Zou, B., & Trofa, A. F. (2007). Rapid and sustained immune response against hepatitis A and B achieved with combined vaccine using an accelerated administration schedule. *Journal of travel medicine*, 14(1), 9–15. <https://doi.org/10.1111/j.1708-8305.2006.00106.x>
- Sharma, R., Ahlm, C., Ostergaard, L., Dowell, A., Tran, C., Thomas, S., & Eymin, C. (2015). Persistence of immunity in healthy adults aged ≥ 50 years primed with a hepatitis B vaccine 3 years previously. *Human vaccines & immunotherapeutics*, 11(7), 1709–1716. <https://doi.org/10.1080/21645515.2015.1019187>
- Van Der Meeren, O., Peterson, J. T., Dionne, M., Beasley, R., Ebeling, P. R., Ferguson, M., Nissen, M. D., Rheault, P., Simpson, R. W., De Ridder, M., Crasta, P. D., Miller, J. M., & Trofa, A. F. (2016). Prospective clinical trial of hepatitis B vaccination in adults with and

without type-2 diabetes mellitus. *Human vaccines & immunotherapeutics*, 12(8), 2197–2203. <https://doi.org/10.1080/21645515.2016.1164362>

- Van Damme, P., Dionne, M., Leroux-Roels, G., Van Der Meeren, O., Di Paolo, E., Salaun, B., Surya Kiran, P., & Folschweiller, N. (2019). Persistence of HBsAg-specific antibodies and immune memory two to three decades after hepatitis B vaccination in adults. *Journal of viral hepatitis*, 26(9), 1066–1075. <https://doi.org/10.1111/jvh.13125>