Approval Date: April 30, 2018

Product: HIBERIX

Proper Name: Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)

Manufacturer: GlaxoSmithKline Biologicals

Indication: For active immunization for the prevention of invasive disease caused by *Haemophilus influenzae* type b. HIBERIX is approved for use in children 6 weeks through 4 years of age (prior to fifth birthday).

Description: HIBERIX [Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)] is a solution for intramuscular injection, supplied as a sterile, lyophilized powder which is reconstituted at the time of use with the accompanying saline diluent.

BLA: 125347

Regulatory Milestone:

Hiberix was licensed in the US on August 19, 2009. GSK submitted the first efficacy supplement (STN 125347/231, Primary series/PREA) on March 16, 2015, which was approved January 14, 2016.

PDUFA Goal Date: April 30, 2018

Package Insert: Package Insert - Hiberix

Summary Basis for Regulatory Approval: April 27, 2018 Summary Basis for Regulatory Action - Hiberix

European Public Assessment Report: No data

Advisory Committee:

The application was not referred to the Vaccines and Related Biological Products Advisory Committee because the review of information submitted in this supplement did not raise concerns or controversial issues which would have benefited from an advisory committee discussion.

NCT Numbers:

- NCT01000974
- NCT03207750
- NCT00228917
- NCT01214889
- NCT00680914
- NCT00317187
- NCT00317135
- NCT01062477
- NCT00359983
- NCT01251133
- NCT01019772
- NCT01061541
- NCT01732198
- NCT02139228
- NCT01578070
- NCT01025544
- NCT02817451
- NCT01105559
- NCT01177722
- NCT00911144
- NCT00317122
- NCT00290303
- NCT00326118
- NCT00197275
- NCT03891758
- NCT01977170
- NCT00255047
- NCT00291343
- NCT01379846
- NCT00342628
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- NCT00348881
- NCT00197236
- NCT02428491
- NCT02697474
- NCT00412854
- NCT00317161
- NCT00134719
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- NCT00534833
- NCT01777308
- NCT00771849
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- NCT00362336
- NCT04071379
- NCT02095314
- NCT01098474
- NCT00551629
- NCT00474526
- NCT00551915
- NCT01986322
- NCT03673462
- NCT02643472
- NCT00657709
- NCT00667602

EudraCT Numbers:

- 2014-005013-23
- 2014-005136-33
- 2014-005135-13
- 2014-005159-24
- 2014-005246-22
- 2013-004194-27
- 2016-003210-27
- 2011-005032-26
- 2013-004304-19
- 2015-001506-34
- 2015-001453-32
- 2006-005891-41
- 2015-001505-14
- 2012-000254-64
- 2015-001507-31
- 2012-004137-16
- 2012-002575-34
- 2013-002537-37
- 2014-000750-11
- 2012-005695-34
- 2016-003268-37
- 2012-005716-26
- 2011-004644-22
- 2006-000557-21
- 2012-002727-15

Publications:

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- Briere E. C. (2016). Food and Drug Administration Approval for Use of Hiberix as a 3-Dose Primary Haemophilus influenzae Type b (Hib) Vaccination Series. *MMWR. Morbidity and mortality weekly report*, *65*(16), 418–419. https://doi.org/10.15585/mmwr.mm6516a3
- Centers for Disease Control and Prevention (CDC) (2009). Licensure of a Haemophilus influenzae type b (Hib) vaccine (Hiberix) and updated recommendations for use of Hib vaccine. *MMWR. Morbidity and mortality weekly report*, *58*(36), 1008–1009

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- Moro, P. L., Jankosky, C., Menschik, D., Lewis, P., Duffy, J., Stewart, B., & Shimabukuro, T. T. (2015). Adverse events following Haemophilus influenzae type b vaccines in the Vaccine Adverse Event Reporting System, 1990-2013. *The Journal of pediatrics*, *166*(4), 992–997. https://doi.org/10.1016/j.jpeds.2014.12.014
- Sikora, J. P., Chlebna-Sokół, D., Ligenza, I., & Sikora, A. (2006). Haemophilus influenzae type b and pertussis vaccinations in preterm infants. *Archivum immunologiae et therapiae experimentalis*, *54*(3), 193–199. https://doi.org/10.1007/s00005-006-0020-4