

# Hib Vaccine

## Haemophilus influenzae type b Conjugate Vaccine

Revision Date: October 16, 2018

### Rationale for Update:

- Incorporated catch-up schedule for Hib.
- Updated referencing.

Please consult the Product Monograph <sup>1,2</sup> for further information about the vaccine.		
	<b>Act-HIB®</b>	<b>HIBERIX®</b>
<b>Manufacturer</b>	Sanofi Pasteur SA distributed by Sanofi Pasteur Limited	GlaxoSmithKline Inc.
<b>Licensed use</b>	Individuals 2 months of age and older	Infants and children two months to five years of age.
<b>Off-license use</b>	None	Children five years of age and older and adults with specific chronic diseases.
<b>Indications for use of provincially funded vaccine</b>	<p><b>Children two months up to and including 59 months of age</b></p> <p><b>Individuals five years of age and older including adults regardless of prior history of <i>Haemophilus influenzae</i> type b (Hib) immunization and with specified chronic conditions as below:</b></p> <ul style="list-style-type: none"><li>• Asplenia or hyposplenism (including sickle cell disease).<sup>1,2,3</sup></li><li>• Acquired complement deficiency e.g., due to receipt of the terminal complement inhibitor eculizumab (Soliris®).<sup>1,3</sup></li></ul> <p><b>Note:</b> Individuals prescribed eculizumab (Soliris®) are at increased risk of serious infections, especially with encapsulated bacteria, such as <i>Haemophilus influenzae</i> type b,<sup>4</sup> therefore, they should receive Hib vaccine at least two weeks before receiving the first dose of Soliris® if possible.</p> <ul style="list-style-type: none"><li>• Cochlear implant candidates and recipients.<sup>1,2,3</sup></li><li>• Congenital (primary) immunodeficiency involving any part of the immune system including persons with partial T-lymphocyte defects (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome, ataxia-telangiectasia, hyper IgM syndrome, hyper IgE syndrome, X-linked lymphoproliferative disease, familial predisposition to hemophagocytic lymphohistiocytosis).<sup>3</sup> Includes B cell deficiency, T cell and combined deficiency, complement deficiency, phagocytic and neutrophil disorders.<sup>3</sup></li><li>• Hematopoietic stem cell transplant (HSCT) recipients. See <a href="#">Immunization for Child Hematopoietic Stem Cell Transplant Recipients</a> and <a href="#">Immunization for Adult Hematopoietic Stem Cell Transplant Recipients</a>.<sup>1,2,3</sup></li><li>• HIV infection.<sup>1,2,3</sup></li><li>• Malignant hematologic disorders (e.g., leukemia, lymphomas, blood dyscrasias, or other malignant neoplasms affecting the bone marrow or lymphatic systems).<sup>3</sup></li></ul>	

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	<ul style="list-style-type: none"> <li>• Solid organ transplant (SOT) candidates and recipients.<sup>1,2,3</sup> See <a href="#">Immunization for Children Expecting Solid Organ Transplant at 18 Months of Age or Older (Catch-up and Ongoing Schedule)</a> and <a href="#">Immunization for Adult Solid Organ Transplant Recipients</a>.</li> </ul> <p><b>Note:</b> When both Hib and diphtheria, tetanus, acellular pertussis and polio combined vaccine are indicated in children younger than seven years of age, provincially provided combined vaccine (DTaP-IPV-Hib or DTaP-IPV-Hib-HB) may be used.</p>															
<b>Dose</b>	0.5 mL															
<b>Route</b>	Intramuscular injection															
<b>Schedule</b>	<p><b>Children two months up to and including 59 months of age:</b></p> <table border="1"> <thead> <tr> <th>Age of Child at time of immunization</th> <th>Primary Series (4 to 8 weeks apart)</th> <th>Reinforcing Dose (at least 8 weeks after last dose)</th> </tr> </thead> <tbody> <tr> <td>2 months up to and including 6 months</td> <td>3 doses</td> <td>15 months of age or older <sup>a</sup></td> </tr> <tr> <td>7 up to and including 11 months</td> <td>2 doses</td> <td>15 months of age or older <sup>a</sup></td> </tr> <tr> <td>12 up to and including 14 months</td> <td>1 dose</td> <td>15 months of age or older <sup>a</sup></td> </tr> <tr> <td>15 up to and including 59 months</td> <td>1 dose</td> <td>None</td> </tr> </tbody> </table> <ul style="list-style-type: none"> <li>❖ <b>Note:</b> To provide complete protection, one dose of Hib-containing vaccine is required at 15 months of age or older regardless of the number of doses received prior to 15 months of age. Children require fewer doses of Hib as they grow older therefore, an interrupted series requires special consideration.</li> <li>❖ Hib is routinely given as a component in the combined vaccine at 2, 4, 6 and 18 months of age. Refer to <a href="#">DTaP-IPV-Hib</a> or <a href="#">DTaP-IPV-Hib-HB</a> for further information.</li> </ul> <p><b>Individuals five years of age and older with specified chronic conditions</b> (see Indications regardless of prior history of Hib immunization.)</p> <ul style="list-style-type: none"> <li>❖ 1 dose</li> </ul>	Age of Child at time of immunization	Primary Series (4 to 8 weeks apart)	Reinforcing Dose (at least 8 weeks after last dose)	2 months up to and including 6 months	3 doses	15 months of age or older <sup>a</sup>	7 up to and including 11 months	2 doses	15 months of age or older <sup>a</sup>	12 up to and including 14 months	1 dose	15 months of age or older <sup>a</sup>	15 up to and including 59 months	1 dose	None
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<b>Contraindications</b>	<ul style="list-style-type: none"> <li>• Anaphylactic or other severe allergic reaction to a previous dose of Hib-containing vaccine.</li> <li>• Known severe hypersensitivity to any component of Haemophilus influenzae type b vaccine.</li> </ul> <p><u>For Act-HIB® only:</u></p> <ul style="list-style-type: none"> <li>• Diluent vial stoppers in Act-HIB® contain latex.<sup>1</sup></li> </ul>															
<b>Precautions</b>	<ul style="list-style-type: none"> <li>• Capsular polysaccharide antigen can be detected in the urine of vaccinees for up to two weeks following immunization with conjugate vaccines. This phenomenon should not be confused with invasive Hib infections.<sup>1,2</sup></li> <li>• Hib infection does not always confer immunity. Individuals who have recovered from Hib should be immunized as appropriate for age and risk factors.<sup>3</sup></li> </ul>															

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	<ul style="list-style-type: none"> <li>Hib vaccines should never be administered to a child younger than six weeks of age.<sup>5</sup> Data suggest that Hib conjugate vaccines administered before six weeks of age may induce immunologic tolerance (reduced response to subsequent doses).<sup>5</sup></li> </ul>
<b>Possible reactions</b>	<p><b>Common:</b></p> <ul style="list-style-type: none"> <li>Pain, redness, swelling or induration.<sup>1,2,3</sup></li> <li>Reactions generally occur early and are transient and of mild intensity.<sup>3</sup></li> <li>Fever, irritability, drowsiness, prolonged or abnormal crying, anorexia, vomiting and diarrhea.<sup>1,2</sup></li> </ul> <p><b>Rare:</b></p> <ul style="list-style-type: none"> <li>Convulsions (including febrile convulsions)<sup>1,2</sup></li> <li>Anaphylactic reaction<sup>1,2</sup></li> </ul> <p><u>For Act-HIB<sup>®</sup> only:</u></p> <ul style="list-style-type: none"> <li>The following additional adverse events have been reported from post-marketing surveillance: edema of the lower limbs, extensive swelling of the limb injected (from injection site beyond one or both joints), hypersensitivity reactions, convulsions, urticaria and pruritus.<sup>1</sup></li> </ul> <p><u>For Hiberix<sup>®</sup> only:</u></p> <ul style="list-style-type: none"> <li>The following additional adverse events have been reported from post-marketing surveillance: allergic reactions (including anaphylactic and anaphylactoid reactions), angioedema, hypotonic-hypo-responsive episodes, apnea, urticaria, rash and extensive swelling of the injected limb.<sup>2</sup></li> </ul> <p>Refer to: <i>Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers.</i><sup>6</sup></p>
<b>Pregnancy</b>	Generally not recommended but is not contraindicated. <sup>7</sup> If indicated, should be administered following an assessment of the risks and benefits. It is not known if Hib vaccine or corresponding antibodies cross the placenta. <sup>7</sup>
<b>Lactation</b>	It is not known if Hib vaccine or corresponding antibodies are excreted in breast milk. <sup>7</sup> If indicated, should be administered to breastfeeding women.
<b>Program Notes</b>	<ul style="list-style-type: none"> <li>1987 July - Hib (PRP) introduced into routine immunization schedule for 2 to 3 year olds (single antigen).</li> <li>1988 - Hib (PRPD) introduced into routine immunization schedule for 18 month olds.</li> <li>1994 August - Hib (PRPT) introduced into routine immunization schedule for 2 month olds in diphtheria, tetanus, pertussis, polio and Hib combination vaccine.</li> <li>2015 February – Act-Hib<sup>®</sup>/Hiberix<sup>®</sup> indicated for individuals 5 years and older regardless of previous Hib immunization with specified chronic conditions.</li> </ul>

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## References

- <sup>1</sup> Sanofi Pasteur Limited. (2016, August 18). Act-HIB®: Haemophilus b conjugate vaccine (tetanus protein – conjugate). *Product Monograph*.
- <sup>2</sup> GlaxoSmithKline Inc. (2018, March 5). Hiberix®: Haemophilus b conjugate vaccine (tetanus protein – conjugate). *Product Monograph*.
- <sup>3</sup> National Advisory Committee on Immunization. (2018). *Canadian Immunization Guide* (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. [www.canada.ca/en/public-health/services/canadian-immunization-guide.html](http://www.canada.ca/en/public-health/services/canadian-immunization-guide.html)
- <sup>4</sup> Alexion Pharma International Sàrl. (2018, August 20). Soliris® (eculizumab). *Product Monograph*.
- <sup>5</sup> Centers for Disease Control and Prevention. (2015, May). Haemophilus influenza type b. In *Epidemiology and Prevention of Vaccine-preventable Diseases 13<sup>th</sup> ed.* (chap. 8 ). Retrieved September 13, 2018 from, [www.cdc.gov/vaccines/pubs/pinkbook/downloads/hib.pdf](http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hib.pdf).
- <sup>6</sup> Alberta Health. (2018, December). *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers* <https://open.alberta.ca/dataset/d86b52a9-45f4-4948-8a06-53b2c045135e/resource/f2da2a7a-e350-4bab-b2c2-77677beeb22b/download/aip-adverse-events-following-immunization-policy.pdf>.
- <sup>7</sup> Grabenstein, J. D. (2012). *ImmunoFacts: Vaccines and Immunologic Drugs 2013*. St. Louis, MO: Wolters Kluwer Health.