Alberta Health Services	***Haemophilus influenzae* Type B Conjugate Vaccine Biological Page**		
Section 7:	**Biological Product Information**		**Standard #: 07.220**
Created by:	Province-wide Immunization Program Standards and Quality		
Approved by:	Province-wide Immunization Program, Standards and Quality		
Approval Date:	March 1, 2013	**Revised:**	April 15, 2019

	Act-HIB®	**HIBERIX®**
Manufacturer	Sanofi Pasteur SA (distributed by Sanofi Pasteur Limited	GlaxoSmithKline Inc.
Biological Classification	Inactivated: Conjugate	
Indications for Provincially Funded Vaccine	**Children 2 months up to and including 59 months of age:** • Who require single antigen *Haemophilus influenzae* type b (Hib) vaccine for initiating or completing a primary series. **Note:** ○ Routinely given as a component in the combined DTaP-IPV-Hib- HB or DTaP-IPV-Hib vaccine at the 2, 4, 6 and 18 month immunization appointment. ○ For immunization schedules for solid organ transplant (SOT) candidates or recipients see *Standard for Immunization of Transplant Candidates and Recipients*. ○ Refer to the appropriate combined vaccine biological page for further detail. **Individuals 5 years of age and older regardless of prior history of *Haemophilus influenzae* type b (Hib) immunization, with specified chronic conditions who do not require antigens contained in the combined vaccines:** • Asplenia - anatomic or functional (including sickle cell disease). • Acquired complement deficiency (e.g., due to receipt of the terminal complement inhibitor eculizumab [Soliris®]). • Cochlear implant candidates and recipients. • 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).Includes B cell deficiency, T cell and mixed defects, complement deficiency, phagocytic and neutrophil disorders. • Hematopoietic stem cell transplant (HSCT) recipients. See *Standard for Immunization of Transplant Candidates and Recipients.* • HIV infection. • Malignant hematologic disorders (e.g., leukemia, lymphomas, or other malignant neoplasms affecting the bone marrow or lymphatic systems. • SOT candidates or recipients. See *Standard for Immunization of Transplant Candidates and Recipients.*	

<table>
<tr><th></th><th>Act-HIB®</th><th>HIBERIX®</th></tr>
<tr><td>Schedule</td><td colspan="2">These schedules should only be used for individuals receiving single antigen Hib vaccine.
2 months up to and including 59 months of age:
<table>
<tr><th colspan="3">Recommended Immunization Schedule for Single Antigen Hib Vaccine</th></tr>
<tr><th>Age of Child at time of immunization</th><th>Primary Series
(separate doses by 4 to 8 weeks)</th><th>Reinforcing Dose
(minimum 8 weeks from previous dose)</th></tr>
<tr><td>2 months up to and including 6 months</td><td>3 doses</td><td>15 months of age or older</td></tr>
<tr><td>7 months up to and including 11 months</td><td>2 doses</td><td>15 months of age or older</td></tr>
<tr><td>12 months up to and including 14 months</td><td>1 dose</td><td>15 months of age or older</td></tr>
<tr><td>15 months up to and including 59 months</td><td>1 dose</td><td>None</td></tr>
</table>
Notes:
• Hib vaccine is routinely given as a component in the combined DTaP-IPV-Hib-HB or DTaP-IPV-Hib vaccine at the 2, 4, 6 and 18 month immunization appointment. For children who require diphtheria, tetanus, acellular pertussis and polio vaccine refer to the appropriate combined vaccine biological page for further details.
• To provide complete protection, 1 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.
• Interrupted series require special consideration. Children will require fewer doses of Hib vaccine as they grow older. Refer to the table above.
• See Standard for Immunization of Transplant Candidates and Recipients for the recommended schedule for HSCT and SOT clients.
Individuals 5 years of age and older with specified chronic conditions regardless of prior history of Haemophilus influenzae type b (Hib) immunization:
• 1 dose
Notes:
• See Standard for Immunization of Transplant Candidates and Recipients for the recommended schedule for HSCT and SOT clients.
• Individuals prescribed eculizumab (Soliris®) should receive Haemophilus influenzae type b (Hib) vaccine at least two weeks before receiving the first dose if possible. If this is not possible the individual may still receive the vaccine but the immune response may be diminished.</td></tr>
<tr><td>Preferred Use</td><td colspan="2">• There is no preference indicated for the use of either vaccine in specific age or risk groups.
• Both vaccines are safe and immunogenic in individuals 2 months of age and older
• Persons with medical contraindications to one product should be offered the alternate product if supply is available.</td></tr>
<tr><td>Dose</td><td colspan="2">0.5 mL
Withdraw the entire contents of the diluent and inject into the vial containing the powder. Once reconstituted withdraw the entire contents of the vial and inject the entire volume.</td></tr>
<tr><td>Route</td><td colspan="2">IM</td></tr>
</table>

	Act-HIB®	HIBERIX®
Contraindications/ Precautions	**Contraindications:** • Known severe hypersensitivity to any component of Hib vaccine • Anaphylactic or other severe allergic reaction to a previous dose of Hib-containing vaccine **Precautions:** • Capsular polysaccharide antigen can be detected in the urine of vaccines for up to 2 weeks following immunization with conjugate vaccines. This phenomenon should not be confused with invasive Hib infections. • Hib infection does not always confer immunity. Individuals who have recovered from Hib should be immunized as appropriate for age and risk factors. At the time of administering vaccine, there should be a 1 month interval from invasive Hib disease.[4] • Hib vaccines should never be given to a child younger than 6 weeks of age. Data suggest that Hib conjugate vaccines given before 6 weeks of age may induce immunologic tolerance (reduced response to subsequent doses).	
Possible Reactions	**Common:** • Pain, redness, swelling or induration. • Fever, irritability, drowsiness, restlessness, prolonged or abnormal crying, anorexia, diarrhea and vomiting. **Rare:** • Convulsions • Anaphylaxis, allergic reaction • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.	
Pregnancy	Adequate data is not available for the use of Hib vaccine during pregnancy and therefore will not routinely be recommended in Alberta for pregnant women. However, use of this vaccine during pregnancy may be considered in consultation with your MOH if the individual is at high risk of disease.	
Lactation	Can be administered to eligible breastfeeding women.	
Composition	Each 0.5 mL of reconstituted vaccine contains: • 10 mcg purified polyribosylribitol phosphate capsular polysaccharide (PRP) of *Haemophilus influenzae* type b • 18-30 mcg tetanus protein • 0.6 mg tris (hydroxymethyl) aminomethane • 42.5 mg sucrose • 2.0 mg sodium chloride • Diluent: 0.4% saline solution	Each 0.5 mL of reconstituted vaccine contains: • 10 mcg purified polyribosyl-ribitol-phosphate capsular polysaccharide (PRP) of *Haemophilus influenzae* type b • 25 mcg tetanus toxoid • Lactose • Sodium chloride • Water • Diluent: sterile saline
Blood/Blood Products	Contains no human blood/blood products	
Bovine/Porcine Products	Contains no bovine/porcine products	Contains no bovine/porcine products
Latex	The stoppers of the vials containing the diluent for reconstitution of Act-HIB® contain latex.	Does not contain latex.
Interchangeability	Hib vaccines may be used interchangeably provided the appropriate dose and schedule recommended by the manufacturer are used.	

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Administration with Other Products	• May be given at the same time as other inactivated vaccine using a separate needle and syringe for each vaccine. • The same limb may be used if necessary, but different sites on the limb must be chosen.	
Appearance	Clear colourless solution when reconstituted with supplied diluent	
Storage	• Store at +2^{0}C to +8^{0}C • Do not freeze • Do not use beyond the labeled expiry date • Store in original packaging when possible to protect form light.	
Vaccine Code	Hib	
Antigen Code	Hib	
Licensed for	• Act-HIB® is licensed for persons 2 months of age and older.	• HIBERIX® is licensed for infants and children 2 months up to 5 years of age. HIBERIX® may be used off license for children 5 years of age and older and adults with specific chronic diseases.

Notes:

- July 1987 - Hib (PRP) introduced into routine immunization schedule for 2 to 3 year olds (single antigen).
- 1988 - Hib (PRPD) introduced into routine immunization schedule for 18 month olds.
- August 1994 - Hib (PRPT) introduced into routine immunization schedule for 2 month olds in diphtheria, tetanus, pertussis, polio and Hib combination vaccine.
- 2015 February - Act-Hib®/Hiberix® indicated for individual 5 years and older regardless of previous Hib immunization with specific chronic conditions.

Related Resources:

- *Haemophilus influenzae* type b Conjugate Vaccine Information Sheet

References:

1. Alberta Health and Wellness, Communicable Disease Control and Prevention. (2018, December). *Haemophilus influenzae* serotype b, Invasive. In *Public health notifiable disease management guidelines.*
2. Alberta Health, Health System Accountability and Performance Division, Alberta Immunization Policy2018, October 16). *Haemophilus influenzae type b Conjugate Vaccine*
3. Alexion Pharma International Sàrl. (2018, August 20). ^{Pr}Soliris® (eculizumab). *Product Monograph.*
4. Centers for Disease Control and Prevention. (2015, May). Haemophilus influenza type b. In *Epidemiology and Prevention of Vaccine-preventable Diseases 13th ed. (*chap. 8). Retrieved September 13, 2018 from, www.cdc.gov/vaccines/pubs/pinkbook/downloads/hib.pdf.
5. Alberta Health. (2016, December). *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers. https://open.alberta.ca/publications/aefi-policy-for-alberta-immunization-providers*
6. GlaxoSmithKline Inc. (2018, March5). HIBERIX®: *Haemophilus influenzae* type b (Hib) conjugate vaccine (Tetanus Protein – Conjugate). *Product monograph*.
7. Grabenstein, J. D. (2012). *ImmunoFacts: Vaccines and Immunologic Drugs 2013*. St. Louis, MO: Wolters Kluwer Health.
8. National Advisory Committee on Immunization. (2018). *Canadian immunization guide (Evergreen Edition).* Ottawa, ON: Public Health Agency of Canada. https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html
9. Sanofi Pasteur Limited. (2016, August 18). Act-HIB®: Haemophilus b Conjugate Vaccine (Tetanus Protein – Conjugate). *Product monograph*.