

Haemophilus influenzae Type B Conjugate Vaccine

BIOLOGICAL PAGE

Section 7	Biological Product Information	Standard # 07.220
Created and approved by	Provincial Immunization Program	
Approval date	March 1, 2013	Published January 30, 2026

	Act-HIB
Manufacturer	Sanofi Pasteur Ltd.
Classification	Inactivated: Conjugate
Indications for Provincially Funded Vaccine	Children 2 months up to and including 59 months of age: - Who require single antigen <i>Haemophilus influenzae</i> 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 appointments. - 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 including adults regardless of prior history of <i>Haemophilus influenzae</i> type b (Hib) immunization, with specified chronic conditions who do not require antigens contained in the combined vaccines: - Asplenia or hyposplenism (including sickle cell disease) - Acquired complement deficiency (for example, due to receipt of the terminal complement inhibitor eculizumab [Soliris]) Note: Individuals prescribed terminal complement inhibitors such as eculizumab (Soliris) are at increased risk of serious infections, especially with encapsulated bacteria, such as <i>Haemophilus influenzae</i> type b, therefore, they should receive Hib vaccine at least two weeks before receiving the first dose of if possible. - Cochlear implant candidates and recipients - Congenital (primary) immunodeficiency involving any part of the immune system including persons with partial T-lymphocyte defects (for example, DiGeorge syndrome, Wiskott-Aldrich syndrome, ataxia-telangiectasia, hyper IgM syndrome, hyper IgE syndrome, X-linked lymphoproliferative disease, familial predisposition to hemophagocytic lymphohistiocytosis). Includes B cell deficiency, T cell and combined deficiency, 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 (for example, leukemia, lymphomas, blood dyscrasias or other malignant neoplasms affecting the bone marrow or lymphatic systems). - SOT candidates or recipients. See Standard for Immunization of Transplant Candidates and Recipients.

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Schedule	Children 2 months up to and including 59 months of age:															
	Recommended Immunization Schedule for Single Antigen Hib Vaccine															
	<table><tr><th>Age of Child Starting 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>At 18 months</td></tr><tr><td>7 months up to and including 11 months</td><td>2 doses</td><td>At 18 months</td></tr><tr><td>12 months up to and including 14 months</td><td>1 dose</td><td>At 18 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>	Age of Child Starting Immunization	Primary Series (separate doses by 4 to 8 weeks)	Reinforcing Dose (minimum 8 weeks from previous dose)	2 months up to and including 6 months	3 doses	At 18 months	7 months up to and including 11 months	2 doses	At 18 months	12 months up to and including 14 months	1 dose	At 18 months of age or older	15 months up to and including 59 months	1 dose	None
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	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 appointments. For children who require diphtheria, tetanus, acellular pertussis and polio vaccine refer to the appropriate combined vaccine biological page for further details. - The reinforcing dose of Hib-containing vaccine may be given as early as 15 months of age provided that at least 8 weeks have elapsed since the previous dose. - 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. - 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 <i>Haemophilus influenzae</i> type b (Hib) immunization:																
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See Standard for Immunization of Transplant Candidates and Recipients for the recommended schedule for HSCT and SOT clients.																
Dose	0.5 mL															
Route	IM															
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 individuals who have been immunized 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. Immunize individuals who have recovered from Hib as appropriate for age and risk factors. - Do not give Hib vaccine 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).															

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Possible Reactions	Common: • Pain, redness, swelling or induration. • Fever, irritability, drowsiness, prolonged or abnormal crying, anorexia, diarrhea and vomiting. Rare: • Anaphylaxis, allergic reaction • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.
Pregnancy	Consult with the MOH/designate. • Adequate data is not available for the use of Hib vaccine during pregnancy. • Not routinely recommended in Alberta for pregnant people. • Consult with the MOH/designate if the individual is at high risk of disease. • MOH will make an individual recommendation based on risk of disease versus benefit of vaccine.
Lactation	• May use for people who are lactating and feeding their milk to infants or children. • It is not known if Hib vaccine or corresponding antibodies are excreted in breast milk.
Composition	Each 0.5 mL of reconstituted vaccine contains: • 10 mcg purified polyribosylribitol phosphate capsular polysaccharide (PRP) of <i>Haemophilus influenzae</i> type b • 18-30 mcg tetanus protein • 0.6 mg tris (hydroxymethyl) aminomethane • 42.5 mg sucrose • 2mg sodium chloride • Diluent: 0.4% saline solution
Blood/Blood Products	Does not contain any human blood/blood products.
Bovine/Porcine Products	Does not contain bovine or porcine products.
Latex	The stoppers of the vials containing Act-Hib and the diluent do not contain latex.
Administration with Other Products	• May be given at the same time as other inactivated and live vaccines. • Use a separate needle and syringe for each vaccine. • The same limb may be used if necessary but use different sites on the limb.
Preparation	• Reconstitute the vaccine using only the diluent supplied. • Slowly inject the 0.5 mL of diluent into the freeze-dried vaccine. • Withdraw the entire reconstituted content and inject the entire volume (about 0.5 mL).
Appearance	Clear colourless solution when reconstituted with supplied diluent.
Storage	• Store at +2°C to +8°C • Do not freeze • Do not use beyond the labeled expiry date • Store in original packaging to protect from light.
Vaccine Code	Hib
Antigen Code	Hib
Licensed for	Individuals 2 months of age and older.
Program Notes	• 1987 July: 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. • 1994 August: Hib (PRPT) introduced into routine immunization schedule for 2 month olds in diphtheria, tetanus, pertussis, polio and Hib combination vaccine.

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	2015 February: Act-Hib/Hiberix indicated for individual 5 years and older regardless of previous Hib immunization with specific chronic conditions. 2025 August 1: Removed HIBERIX as this product no longer available in Canada. 2025 December 23 (End date TBD): Targeted use of Hib vaccine as a component of the response strategy for managing the cluster of Hib ST-231 cases amongst individuals experiencing homelessness, unstable or supportive housing. As per CMOH direction, this preventive measure aims to reduce secondary cases in those at elevated risk of exposure.
Related Resources	Haemophilus influenzae type b Conjugate Vaccine Information Sheet
References Alexion Pharma GmbH. (2024, July 24). Soliris (eculizumab for injection). Health Canada drug product database. https://pdf.hres.ca/dpd_pm/00076446.PDF Centers for Disease Control and Prevention. (2024, May 21). Chapter 8: <i>Haemophilus influenzae</i>. In <i>Epidemiology and Prevention of Vaccine-Preventable Diseases (14th ed)</i>. Public Health Foundation. Grabenstein, J. D. (2012). ImmunoFacts: Vaccines and Immunologic Drugs. Facts & Comparisons. Primary and Preventative Health Services. (2022, January). <i>Haemophilus influenzae</i>, Invasive. In <i>Alberta Public Health Disease Management Guidelines</i>. Government of Alberta. Primary and Preventative Health Services. (2026, January 30). Hib Vaccine (<i>Haemophilus influenzae</i> type b Conjugate Vaccine). In <i>Alberta Immunization Policy: Biological Products</i>. Government of Alberta. Primary and Preventative Health Services (2026, January). Adverse Events Following Immunization (AEFI) Policy for Alberta Immunization Providers. In <i>Alberta Immunization Policy: Adverse events - immunization</i>. Government of Alberta. Public Health Agency of Canada. (2024, November 29). <i>Canadian Immunization Guide</i>. Government of Canada. Sanofi Canada Medical Information (manufacturer). Email communication. June 16, 2025. Sanofi Pasteur Limited. (2023, April 4). Act-HIB (<i>Haemophilus b</i> Conjugate Vaccine (Tetanus Protein – Conjugate)). Health Canada drug product database. https://pdf.hres.ca/dpd_pm/00070195.PDF	