

**Iowa Department of Public Health
Division of Acute Disease Prevention & Emergency Response**

**Vaccines for Children (VFC) Program
Haemophilus influenzae Type b (Hib) Vaccine Summary
Hiberix
November 2, 2009**

Iowa Vaccines for Children Program Implementation

Effective November 9, 2009, Hiberix (*Haemophilus influenzae* Type b) vaccine, manufactured by GlaxoSmithKline (GSK) will be available through the Iowa VFC Program.

Hiberix Vaccine Recommendations

Food and Drug Administration (FDA) - On August 19, 2009, the FDA approved Hiberix as a booster dose to the *Haemophilus influenzae* Type b (Hib) vaccine series.

ACIP – On September 18, 2009, the Advisory Committee on Immunization Practices recommended Hiberix vaccine for the booster dose of Hib for children 12 months through 4 years of age (prior to 5th birthday) who have received an age-appropriate primary series of any Hib-containing vaccine. Hiberix and other Hib conjugate vaccines can be administered as early as 12 months of age for the booster dose, in accordance with Hib vaccination schedules for routine and catch-up immunization. In usual circumstances an age-appropriate primary series would consist of 3 doses of ActHib or Pentacel, or 2 doses of PedvaxHib or Comvax before the first birthday. However, children who start the Hib series late need fewer doses for an age-appropriate primary series. A child who begins the Hib vaccination series at 12- 14 months needs only 1 dose to complete the primary series. So a “booster dose” can be defined as the last dose in the Hib series in a child who has received at least one prior dose of Hib-containing vaccine.

Recommended Schedule for Hiberix Vaccine

- Booster dose of Hib vaccine in children 12 months through 4 years of age as the last dose in the Hib series for a child who has received at least one prior dose of Hib-containing vaccine.
- Administration/Route: Intramuscular (IM) 0.5 mL injection after reconstitution

Hib Vaccine Series - Age and Minimum Intervals

Vaccine	Age at 1st Dose (Months)	Primary Series	Booster	Booster Dose Vaccine
ActHib or Pentacel (Sanofi)	2-6	3 doses, 2 months apart	12-15 months*	ActHib, Pentacel, PedvaxHib, or Hiberix
	7-11	2 doses, 2 months apart	12-15 months*	
	12-14	1 dose	2 months later*	
	15-59	1 dose	----	----
PedvaxHib or Comvax (Merck)	2-6	2 doses, 2 months apart	12-15 months*	ActHib, Pentacel, PedvaxHib, Comvax or Hiberix
	7-11	2 doses, 2 months apart	12-15 months*	
	12-14	1 dose	2 months later*	
	15-59	1 dose	----	----

* At least 2 months after previous dose

The number of doses in the primary series depends on the type of vaccine used. A booster is recommended at 12-15 months regardless of which vaccine is used for the primary series. Any brand can be used for the booster dose.

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If brands are changed during the primary series, a 3 dose primary series is required (2, 4, 6 months of age) with a booster (12-15 months of age).

Vaccine Storage and Handling

- Store refrigerated at 2 - 8° C, 35 - 46° F.
- Do not freeze.
- After reconstitution, Hiberix should be administered promptly or stored refrigerated and administered within 24 hours. Discard vaccine if not used within 24 hours of reconstitution.
- Lyophilized vaccine vials – store refrigerated at 2 - 8° C, 35 - 46° F; protect from light.
- Diluent - store refrigerated between 2 - 8° C, 35 - 46° F or at a controlled room temperature (68 - 77° F). Do not freeze.

Hiberix is supplied as a lyophilized powder that is reconstituted with saline diluent (provided in a syringe). Hiberix does not contain a preservative (thimerosal) and neither the vial stopper nor the pre-filled diluent syringe contains latex.

IDPH / Immunization Program Recommendations

IDPH Immunization Program routinely follows and promotes the Recommended Immunization Schedule and will implement the Hiberix vaccine in accordance with the ACIP recommendations.

Vaccine Licensure / VFC Implementation

The Advisory Committee on Immunization Practices (ACIP) provides advice and guidance regarding the most appropriate application of vaccines for effective vaccine preventable disease control. The Food and Drug Administration (FDA) is responsible for the licensure of vaccines. Upon FDA approval the ACIP convenes and makes decisions on vaccine recommendations. A VFC resolution vote is required for the inclusion of new vaccines into the VFC Program or the modification of existing resolutions. The Centers for Disease Control and Prevention (CDC) then negotiates a contract for the purchase of vaccines. VFC vaccine must be administered according to the guidelines outlined by the ACIP recommendations and VFC resolutions.

CDC allocates individual state VFC funding based upon eligible populations, anticipated vaccine uptake and negotiated federal contract amounts. CDC establishes monthly vaccine allocations for each vaccine. Additional 317 CDC discretionary funds are used to vaccinate underinsured individuals seen at Local Public Health Agencies (LPHAs) who are not eligible under VFC guidelines. Each state determines the vaccine implementation date based upon the above process which is generally four to six months following vaccine licensure.