***Haemophilus* *influenzae* Type b (Hib) Conjugate Vaccine**

**Precautions and Contraindications**

Screen all patients for precautions and contraindications to immunizations.

**Vaccine Information Statements**

Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide a non-English speaking patient with a copy of the VIS in their native language, if one is available and desired; these VISs can be found at <http://www.immunize.org/vis>.

**FDA Approved Indications and Usage (See Package Insert for ActHIB®, current version dated 12/2015**

* **ActHIB**® is a vaccine indicated for the prevention of invasive disease caused by *Haemophilus influenza* type b. **ActHIB**® vaccine is approved for use as a four-dose series in infants and children 2 months through 5 years of age.

**FDA Approved Indications and Usage (See Package Insert for PedvaxHIB®, current version dated 12/2010**

* **PedvaxHIB**® is indicated for routine vaccination against invasive disease caused by *Haemophilus influenza* type b in infants and children 2 to 71 months of age.

**Recommended Schedule**

**ActHIB® (PRP-T)**

**Hib Vaccine Schedule for Unimmunized Children Without Any Previous Doses**

|  |  |  |  |
| --- | --- | --- | --- |
| **Age Receiving 1st Dose** | **Dose** | **Recommended Age** | **Accelerated Schedule** |
| 0 – 6 months | 11 | 2 months | > 6 weeks of age |
| 21 | 4 months | > 1 month after dose #1 |
| 31 | 6 months | > 1 month after dose #2 |
| 4 | 12 through 15 months | > 2 months after previous dose and > 12 months of age |
| 7 – 11 months | 11 | - | 1st visit |
| 21 | - | > 1 month after dose #1 |
| 31 | - | > 2 months after previous dose andbetween 12 through 15 months of age |
| 12 – 14 months | 12 | - | 1st visit |
| 22 | - | > 2 months after previous dose |
| 15 – 59 months | 1 | - | 1st visit |

1 When feasible, use same vaccine for doses 1 – 3.

2 When feasible, use same vaccine for doses 1 – 2.

**Hib Vaccine Schedule (All Hib Formulations) for Partially-Immunized Children,**

**Not Up-To-Date**

|  |  |  |
| --- | --- | --- |
| **Age at Presentation** | **Previous Vaccination History** | **Recommended Regimen** |
| 7 through 11 months | 1 dose of PRP-T, or PRP-OMP 12 doses of PRP-T | 1 dose of conjugate at 7 through 11 months with a booster dose given at least 2 months later, at 12 through 15 months 2Same as above |
| 12 through 14 months | 2 doses before 12 months of PRP-T or PRP-OMP 1 | 1 dose of any licensed conjugate 3 |
| 12 through 14 months | 1 dose before 12 months of PRP-T or PRP-OMP 1 | 2 additional doses of any licensed conjugate, with a minimum interval of 2 months 3 |
| 15 through 59 months | Any incomplete schedule | 1 dose of any licensed conjugate 3 |

 1 PRP-T (ActHIB), PRP-OMP (PedvaxHIB).

2 For the dose given at 7 through 11 months, when feasible, the same vaccine should be used for the dose given at 2 through 6 months. At > 12 months of age, any licensed conjugate can be used.

3 For children 12 through 59 months of age with an underlying condition predisposing them to Hib disease who are not immunized or who have received only 1 dose of conjugate vaccine before 12 months, 2 additional doses of a licensed conjugate vaccine (separated by 2 months) are recommended. If they have received 2 doses before 12 months, only 1 dose is recommended.

**PedvaxHIB® (PRP-OMP) Schedules for
Unimmunized Children Without Any Previous Doses**

|  |  |  |  |
| --- | --- | --- | --- |
| **Age Receiving 1st Dose** | **Dose** | **Recommended Age** | **Accelerated Schedule** |
| 0 through 7 months | 11 | 2 months | > 6 weeks of age |
| 21 | 4 months | > 1 month after dose #1 |
| 3 | 12 through 15 months | > 2 months after previous dose and > 12 months of age |
| 7 through 11 months | 1 | - | 1st visit |
| 2 | - | > 1 months after dose #1 |
| 3 | - | > 2 months after previous dose and between 12 through 15 months of age |
| 12 through 14 months | 1 | - | 1st visit |
| 2 | - | 2 months after the previous dose |
| 15 through 59 months | 1 | - | 1st visit |

 1 When feasible, use the same vaccine for doses 1 – 2.

**Routine vaccination**

* Administer a 2- or 3-dose Hib vaccine primary series and a booster dose (dose 3 or 4 depending on vaccine used in primary series) at age 12 through 15 months to complete a full Hib vaccine series.
* The primary series with **ActHIB**®, HIBERIX®, MENHIBRIX®, or PENTACEL® consists of three doses and should be administered at 2, 4, and 6 months of age. The primary series with **PedvaxHIB**® or COMVAX® consists of 2 doses and should be administered at 2 and 4 months of age; a dose at age 6 months is not indicated.
* One booster dose (dose 3 or 4 depending on vaccine used in primary series) of any Hib vaccine should be administered at age 12 through 15 months.
* Licensed monovalent Hib conjugate vaccines are considered interchangeable for the primary as well as the booster doses (dose 3 or 4, depending on vaccine type used for primary series), [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm).
* Data on the interchangeability of [Hib] combination [conjugate] vaccines with other [Hib] combination [conjugate] vaccines or with monovalent [Hib conjugate] vaccines are limited. Whenever feasible, the same [Hib] combination [conjugate] vaccine should be used for the subsequent doses; however, if a different brand is administered, the dose should be considered valid and need not be repeated, [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm](https://www.cdc.gov/vaccines/terms/USVaccines.html).

NOTE: *Haemophilus influenzae* type b (Hib) conjugate vaccine. (Minimum age: 6 weeks for PRP-T [ACTHIB, DTaP-IPV/Hib (PENTACEL®), HIBERIX® and Hib-MenCY (MENHIBRIX®)], PRP-OMP [**PedvaxHIB**® or **COMVAX**®].

**Recommendations for Routine Vaccination**[http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm)

* ACIP recommends routine administration of a conjugate Hib vaccine series (monovalent vaccine [**PedvaxHIB®** (PRP-OMP) or HIBERIX® or **ActHIB**®, (PRP-T)] or Hib vaccine in combination with HepB [**COMVAX**®], DTaP/IPV [PENTACEL®], or MenCY [MENHIBRIX®]) beginning at age 2 months.
* Infants aged 2 through 6 months should receive a 3-dose series of Hib (PRP-T as **ActHIB**®, PENTACEL®, HIBERIX® or MENHIBRIX®) or a 2-dose series of Hib (PRP-OMP as **PedvaxHIB®** or **COMVAX**®). The first dose can be administered as early as age 6 weeks.
* A booster dose (which will be dose 3 or 4 depending on vaccine type used in primary series) of any licensed conjugate Hib vaccine (monovalent vaccine [**PedvaxHIB**®
(PRP-OMP), **ActHIB**® (PRP-T), or HIBERIX® (PRP-T)] or Hib vaccine in combination with HepB [**COMVAX**®] or DTaP/IPV [PENTACEL®] or MenCY [MENHIBRIX®]) is recommended at age 12 through 15 months and at least 8 weeks after the most recent Hib vaccination).

**Guidance for Routine Vaccination**[http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm](http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/02-13-1-pneumo.pdf)

* Doses for either primary series (2-dose or 3-dose) should be administered 8 weeks apart; however, if necessary, an interval of 4 weeks between doses is acceptable.
* If a PRP-OMP vaccine (**PedvaxHIB**® or **COMVAX**®) is administered for both doses in the primary series, a third primary dose is not indicated.
* If a PRP-OMP vaccine (**PedvaxHIB**® or **COMVAX**®) is not administered for both doses in the primary series or there is uncertainty about which products were administered previously, a third primary series dose of a Hib conjugate vaccine is needed to complete the primary series.
* Any monovalent or combination Hib conjugate vaccine is acceptable for the booster dose (dose 3 or 4 depending on vaccine type used in primary series), regardless of the product used for the primary series.

**Catch-up schedule**

* If dose 1 was administered at ages 12 through 14 months, administer a second (final) dose at least 8 weeks after dose 1, regardless of Hib vaccine used in the primary series.
* If the first 2 doses were PRP-OMP (**PedvaxHIB**® or **COMVAX**®), and were administered at age 11 months or younger, the third (and final) dose should be administered at age 12 through 15 months and at least 8 weeks after the second dose.
* If the first dose was administered at age 7 through 11 months, administer the second dose at least 4 weeks later and a third (and final) at age 12 through 15 months or 8 weeks after second dose, whichever is later, regardless of Hib vaccine used for first dose.
* If the first dose administered is at younger than 12 months of age and second dose administered is between 12 through 14 months of age, a third (and final) dose should be administered 8 weeks later.
* For unvaccinated children aged 15 months or older, administer only one dose.

**Vaccination of children with high-risk conditions (**Patients with functional or anatomic asplenia, HIV infection, immunoglobulin deficiency including Immunoglobulin G2 subclass deficiency, or early component complement deficiency, recipients of a hematopoietic stem cell transplant (HSCT), and those receiving chemotherapy for malignant neoplasms, [http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/02-13-2-hib.pdf](http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf) )

* Children aged 12 through 59 months who are at increased risk for Hib disease, including chemotherapy recipients and those with anatomic or functional asplenia (including sickle cell disease), human immunodeficiency virus (HIV) infection, immunoglobulin deficiency, or early component complement deficiency, who have received either no doses or only 1 dose of Hib vaccine before 12 months of age, should receive 2 additional doses of Hib vaccine 8 weeks apart; children who received 2 or more doses of Hib vaccine before 12 months of age should receive 1 additional dose.
* For patients younger than 5 years of age undergoing chemotherapy or radiation treatment who received a Hib vaccine dose(s) within 14 days of starting therapy or during therapy, repeat the dose(s) at least 3 months following therapy completion.
* Recipients of hematopoietic stem cell transplant (HSCT) should be revaccinated with a
3-dose regimen of Hib vaccine starting 6 to 12 months after successful transplant, regardless of vaccination history; doses should be administered at least 4 weeks apart.
* A single dose of any Hib-containing vaccine should be administered to unimmunized\* children and adolescents 15 months of age and older undergoing an elective splenectomy; if possible, vaccine should be administered at least 14 days before procedure.
* Hib vaccine is not routinely recommended for patients 5 years or older. However, 1 dose of Hib vaccine should be administered to unimmunized\* persons aged 5 years or older who have anatomic or functional asplenia (including sickle cell disease) and unvaccinated persons 5 through 18 years of age with human immunodeficiency virus (HIV) infection.

\* *Patients who have not received a primary series and booster dose or at least one dose of Hib vaccine after 14 months of age are considered unimmunized.* [http://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html](http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html)

**Vaccination of adults with high-risk conditions**

* One dose of Hib vaccine should be administered to persons who have functional or anatomic asplenia or sickle cell disease or are undergoing elective splenectomy if they have not previously received Hib vaccine.
	+ Hib vaccination 14 or more days before splenectomy is suggested.
* Recipients of a hematopoietic stem cell transplant should be vaccinated with a 3-dose regimen 6 to 12 months after a successful transplant, regardless of vaccination history; at least 4 weeks should separate doses
* Hib vaccine is not recommended for adults with HIV infection since their risk for Hib infection is low.

**Hib vaccine is indicated for** **the following groups**

* All infants and children, six weeks of age to less than 59 months of age. The number of doses needed is dependent on the age of the child when the vaccine series is initiated and the type of vaccine given;
* **PedvaxHIB**® (PRP-OMP)is indicated for routine vaccination against invasive disease caused by *Haemophilus influenzae* type b in infants and children 2 to 71 months of age.
* Unimmunized children, aged 5 years and older, with sickle-cell disease, HIV infection, AIDS, severe non-HIV immunosuppressive condition and treatments, functional or anatomic asplenia, renal failure and diabetes;
* Adults with severe non-HIV immunosuppression, after organ transplantation, with functional or anatomic asplenia and chronic immunosuppressive therapy.

**Dosage and Route**

* See the package insert for reconstitution instructions if the **ActHIB**® brand of Hib vaccine is being administered.
* See the package insert for reconstitution instructions if the HIBERIX® brand of Hib vaccine is being administered.
* Administer Hib vaccine 0.5 mL intramuscularly (IM) according to the recommended schedule. **Always check the package insert prior to administration of any vaccine**. Administer IM vaccines at a 90oangle with a 22- to 25-gauge needle.
* See Immunize.org reference below for a table about needle size and length, [http://www.immunize.org/catg.d/p3085.pdf](http://www.merck.com/product/usa/pi_circulars/c/comvax/comvax_pi.pdf)

**Anatomical Site**

* Outer aspect of the deltoid of the upper arm or in the higher anterolateral area of the thigh.

**Precautions**

* Prior to administering the vaccine, obtain a vaccination history to determine any reactions to any vaccine.
* Moderate to severe illness with or without fever (temporary precaution)
* As with other intramuscular injections, use with caution in patients on anticoagulant therapy.

**Contraindications**

* **DO NOT** administer Hib vaccine to individuals with an anaphylactic reaction to a previous dose of Hib, latex (**PedvaxHIB®** and the vial of diluent for **ActHIB**®) or to any other component of the vaccine (see package insert for specific components)

**Adverse Events**

* See the product’s package insert
* See Adverse Events Following Vaccinations page of this section

**Storage and Handling**

* Store in refrigerator at 36oF – 46oF (2oC – 8oC).
* DO NOT FREEZE; discard if product has been frozen.

**Other Important Notes**

* ActHIB vaccine must be used < 24 hours after reconstitution, or be discarded.

**References**

Advisory Committee on Immunization Practices. Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, United States, 2017

<http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>.

Briere EC, Rubin L, Moro PL, Cohn, A, Clark T, Messonnier N. Prevention and Control of *Haemophilus influenzae* Type b Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2014;63(No. RR-1):1-14, <http://www.cdc.gov/mmwr/pdf/rr/rr6301.pdf> .

VFC Resolution 02/13-2 *Haemophilus influenzae* type b,
<http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html>

Package Insert: **ActHIB**® (Dated 12/2015) [https://www.vaccineshoppe.com/image.cfm?doc\_id=11167&image\_type=product\_pdf](https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf?doc_id=11167&image_type=product_pdf).

Package Insert: **COMVAX**® (Dated 12/2010) [http://www.merck.com/product/usa/pi\_circulars/c/comvax/comvax\_pi.pdf](http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf).

Package Insert: HIBERIX® (Dated 12/2010) [https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\_Information/Hiberix/pdf/HIBERIX.PDF](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm).

Package Insert: MENHIBRIX® (Dated 11/2013) [https://gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\_Information/Menhibrix/pdf/MENHIBRIX.PDF](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a4.htm).

Package Insert: **PedvaxHIB**® (Dated 12/2015) [http://www.merck.com/product/usa/pi\_circulars/p/pedvax\_hib/pedvax\_pi.pdf](http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf).

Package Insert: PENTACEL® (Dated 10/2013) [https://www.vaccineshoppe.com/image.cfm?doc\_id=11169&image\_type=product\_pdf](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6007a1.htm?doc_id=11169&image_type=product_pdf).

Immunize.org. Administering Vaccines: Dose, Route, Site, and Needle Size, Item #P3085 (11/15), [http://www.immunize.org/catg.d/p3085.pdf](http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/02-13-2-hib.pdf)

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