HAEMOPHILUS B VACCINE

Haemophilus b Vaccine

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On January 5, 2026, the US Department of Health and Human Services (HHS) announced the approval of a revised US childhood and adolescent immunization schedule ([Web]). Under the revised recommendations, CDC continues to organize the childhood immunization schedule in three distinct categories (Immunizations Recommended for All Children, Immunizations Recommended for Certain High-Risk Groups or Populations, and Immunizations Based on Shared Clinical Decision-Making) but changes individual vaccine placement within those categories. For additional information, see [Web] .

Introduction

Haemophilus b (Hib) vaccine is an inactivated (polysaccharide) vaccine that is used to stimulate active immunity to invasive disease caused by *Haemophilus influenzae* type B (Hib).[144,174,223]

Uses

Prevention of Haemophilus Influenzae Type B Infection

Haemophilus influenzae type b (Hib) conjugate vaccines are used to stimulate active immunity to invasive disease caused by Hib.[144,174,223] Hib vaccines will not provide protection against other types of *H. influenzae* (e.g., nonencapsulated [nontypeable] strains) or against other microorganisms that cause meningitis, sepsis, or other invasive infections.[144] In the US, the Hib vaccine is available as 2 different vaccine types: Hib conjugate vaccine (meningococcal protein conjugate) (PRP-OMP; PedvaxHIB®) and Hib conjugate vaccine (tetanus toxoid conjugate) (PRP-T; ActHIB®, Hiberix®).[174,223] PRP-OMP (PedvaxHIB®) is FDA-labeled for use in infants and children 2 to 71 months of age.[144] PRP-T (ActHIB®) is labeled for use in infants and children 2 months through 5 years of age, and PRP-T (Hiberix®) is FDA-labeled for use in children 6 weeks through 4 years of age.[174,223] PRP-T is also commercially available in a fixed-combination vaccine containing diphtheria, tetanus, pertussis, poliovirus, and Hib antigens (DTaP-IPV/Hib; Pentacel®) for use in children 6 weeks through 4 years of age,[224] and PRP-OMP is also commercially available in a fixed-combination vaccine containing diphtheria, tetanus, pertussis, poliovirus, Hib, and hepatitis B (HepB) antigens for use in children 6 weeks through 4 years of age (DTaP-IPV/Hib/HepB; Vaxelis®).[236]

Hib is a gram-negative bacterium that causes meningitis and other serious infections (e.g., pneumonia, epiglottitis, sepsis, cellulitis, septic arthritis, osteomyelitis, endocarditis, purulent pericarditis), principally in infants and children younger than 5 years of age.[105,166] Prior to the availability of Hib vaccine, Hib was the most common cause of bacterial meningitis and other invasive bacterial disease in young children worldwide; however, the incidence of invasive Hib disease in the US decreased by 99% (to <1 case per 100,000 children <5 years of age in 2019) following the introduction of Hib conjugate vaccines.[105,166] After receiving a primary series of 2 or 3 doses of Hib conjugate vaccine, over 95% of infants develop protective antibody levels against Hib; however, the exact duration of immunity following immunization is unknown.[300] Most cases now occur in infants and children who are unvaccinated or incompletely vaccinated, including infants younger than 6 months of age who are too young to have received a complete vaccination series; American Indian and Alaska Native children also experience higher rates of invasive disease from *H. influenzae* compared to other populations in the US.[105,166]

Primary and Booster Vaccination

The Centers for Disease Control and Prevention (CDC)'s Advisory Committee on Immunization Practices (ACIP) and other organizations (e.g., American Academy of Pediatrics [AAP]) provide recommendations for the prevention of Hib.[105,159,199,237] These organizations recommend that all infants receive primary and booster immunization against Hib disease initiated at 2 months of age (minimum age 6 weeks) with an appropriate Hib vaccine.[105,159,199,237] Primary immunization against Hib infection can be integrated with age-appropriate primary immunization against diphtheria, tetanus, pertussis, hepatitis B, influenza, pneumococcal disease, poliomyelitis, rotavirus, measles, mumps, rubella, and varicella.[105,159,199,243]

Depending on the specific Hib vaccine administered, patients will receive either a 2-dose or 3-dose primary Hib vaccine series plus a booster dose at 12–15 months of age.[159,199,237] The Hib conjugate vaccine (meningococcal protein conjugate) (PRP-OMP; PedvaxHIB®) is given as a 2-dose primary series, administered at 2 and 4 months of age, and a booster dose at 12–15 months of age.[159,199,237] The Hib conjugate vaccines (tetanus toxoid conjugate) (PRP-T; ActHIB®, Hiberix®) are given as a 3-dose primary series, administered at 2, 4, and 6 months of age, followed by a booster dose at 12–15 months of age.[159,199,225,237] In pediatric patients with HIV, the Hib vaccine should be administered following the same routine schedule as for individuals who are not infected with HIV.[156] Medically stable preterm infants generally should receive primary immunization against Hib infection at the usual chronologic age.[159] Due to differences in immunogenicity among the available Hib vaccines, and the fact that PRP-OMP vaccines provide a protective antibody response after the first dose, vaccines with a PRP-OMP Hib component (PedvaxHIB® and the combination vaccine Vaxelis®) are preferentially recommended for primary vaccination among American Indian/Alaska Native patients.[159,199,236,237]

Pediatric patients <24 months of age who develop systemic Hib infection may be at risk of developing a second episode of the disease since most pediatric patients in this age group fail to develop adequate immunity following natural infection.[105,159] Such children should be considered unvaccinated, regardless of prior doses of Hib vaccine, and should receive age-appropriate primary immunization as if they had received no previous doses of Hib vaccine; the immunization series should be initiated 1 month (4 weeks) after disease onset or as soon as possible thereafter.[105,159]

The ACIP makes recommendations regarding vaccination of internationally adopted children and other immigrants.[245] In such patients, when the immunogenicity of vaccines previously received or the completeness of a vaccine series is in question, healthcare providers can repeat the vaccinations or utilize serologic testing to determine which vaccines may be needed (if serologic tests are available to document protection against infection).[245] In the case of the Hib vaccine, interpretation of serologic tests can be difficult.[245] Because the number of vaccinations needed for protection against Hib decreases with age and because adverse events are uncommon, age-appropriate vaccination should be provided.[245] Hib vaccination is not routinely recommended for patients who are ≥5 years of age.[245]

Catch-Up Vaccination

Children who are <5 years of age who have not been fully immunized against Hib should follow the recommended catch-up vaccination schedule based on how many doses they have had previously and their age at the time of vaccination (see Table 1).[159,199,237] Catch-up vaccination is not required in previously unvaccinated children who are ≥5 years of age and are not considered high-risk.[159,199,237]

Table 1. Recommendations for Hib Catch-up Vaccination[159,199,237]

NUMBER OF PREVIOUS DOSES	AGE WHEN PREVIOUS DOSE(S) ADMINISTERED	RECOMMENDATION FOR CATCH-UP VACCINATION
0	Unvaccinated at age 15–59 months	Administer 1 dose
1	7–11 months	Dose 2: ≥4 weeks after dose 1 Dose 3 (final dose): Administer at 12–15 months of age or 8 weeks after dose 2 (whichever is later)
1	12–14 months	Dose 2 (final dose): ≥8 weeks after dose 1
1	≥15 months	No further doses needed
2	Dose 1 at <12 months Dose 2 at <15 months	Dose 3 (final dose): ≥8 weeks after dose 2
2 (PedvaxHIB®)	<12 months	Dose 3 (final dose): Administer at age 12–59 months and ≥8 weeks after dose 2

Hib Vaccination in At-Risk Populations

The ACIP and AAP make specific recommendations for Hib vaccination in certain populations who are considered to be at increased risk for invasive Hib disease (i.e., those with functional or anatomic asplenia, sickle cell disease, HIV infection, immunoglobulin deficiency [including immunoglobulin G_2 subclass deficiency] or early component complement deficiency, recipients of a hematopoietic stem cell transplant, and those receiving chemotherapy or radiation for malignant neoplasms).[159,199,200,237] Patients with these conditions who are <12 months of

age should follow routine Hib vaccination recommendations.[159,199,200,237] Recommendations for at-risk patients who are 12–59 months of age are described below (see Table 2).[159,199,200,237]

Table 2. Recommendations for Hib Vaccination in At-Risk Populations: 12–59 Months of Age.[156,159,199,200,237]

POPULATION	VACCINATION STATUS	RECOMMENDATION
Chemotherapy or radiation treatment[a] Anatomic or functional asplenia[b] HIV infection Immunoglobulin deficiency, early component complement deficiency, or early component complement inhibitor use	≤1 dose before 12 months of age	Administer 2 doses, 8 weeks apart
Chemotherapy or radiation treatment[a] Anatomic or functional asplenia[b] HIV infection Immunoglobulin deficiency, early component complement deficiency, or early component complement inhibitor use	≥2 doses before 12 months of age	Administer 1 dose ≥8 weeks after the last dose
Hematopoietic stem cell transplant	All patients (regardless of Hib vaccination history)	Administer 3-dose series 4 weeks apart, starting 6–12 months after successful transplant
Elective splenectomy	Unvaccinated[c] patients ≥15 months of age	Administer 1 dose[d]

[a] Doses administered within 14 days of starting therapy or during therapy should be repeated at least 3 months after completion. [b] Includes sickle cell disease. [c] Unvaccinated is defined as having fewer than the recommended number of doses in those ≤14 months of age or no doses of Hib vaccine in those ≥15 months of age. [d] If possible, administer dose ≥14 days prior to procedure.

ACIP and AAP also recommend use of Hib vaccine in certain ***individuals 5 years of age and older [off-label]†*** *at increased risk for invasive Hib disease because of certain medical conditions (see Table 3).[159,199,200,237]*

Table 3. Recommendations for Hib Vaccination in At-Risk Populations: ≥5 Years of Age [off-label]† [155,156,159,199,200,237]

POPULATION	VACCINATION STATUS/AGE AT TIME OF VACCINATION	RECOMMENDATION
Hematopoietic stem cell transplant	All patients (regardless of Hib vaccination history)	Administer 3-dose series 4 weeks apart, starting 6–12 months after successful transplant
Anatomic or functional asplenia[a]	Unvaccinated[b] patients ≥5 years of age	Administer 1 dose
Elective splenectomy	Unvaccinated[b] patients ≥15 months of age	Administer 1 dose[c]
HIV infection	Unvaccinated[b] pediatric patients 5–18 years of age	Administer 1 dose
HIV infection	Adults	Hib vaccination not recommended

[a] Includes sickle cell disease. [b] Unvaccinated is defined as having no doses of Hib vaccine in those ≥15 months of age. [c] If possible, administer dose ≥14 days prior to procedure.

Combination Vaccines Containing Hib Vaccine and Other Antigens

PRP-T Hib vaccine is also commercially available in a combination vaccine that contains diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed (DTaP), poliovirus vaccine inactivated (IPV), and Hib antigens (DTaP-IPV/Hib; Pentacel®)[224], and a fixed-combination vaccine containing DTaP, IPV, Hib, and HepB antigens (DTaP-IPV/Hib/HepB; Vaxelis®).[236]

> *When indicated based on the age and vaccination status of the child and when there are no contraindications to any of the individual components, combination vaccines containing Hib and other antigens can be used instead of separate injections.[105,166] ACIP, AAP, and other organizations state that a combination vaccine generally is preferred over separate injections of the equivalent component vaccines; considerations include provider assessment (e.g., number of injections, vaccine availability, likelihood of improved coverage, likelihood of patient return, storage requirements, cost), patient preference, and potential for adverse effects.[105,243]*
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> *DTaP-IPV/Hib (Pentacel®) can be used when doses of DTaP, IPV, and Hib vaccine are indicated in pediatric patients 6 weeks through 4 years of age and there are no contraindications to any of the individual components.[224] For prevention of Hib, ACIP states that Pentacel® may be used for the primary immunization doses at 2, 4, and 6 months of age and the booster dose at 12–15 months of age.[199] Pentacel® can be used to complete the vaccination series in pediatric patients previously vaccinated with ≥1 doses of Hib conjugate vaccine (either administered separately or as part of another combination vaccine) who are scheduled to receive the other antigens in Pentacel®; however, data on immunogenicity and safety of Pentacel® are not available in such patients.[224] If different brands of Hib vaccines are administered to complete the series, 3 primary immunizing doses are needed, followed by a booster dose.[224]*
>
> *The commercially available fixed-combination vaccine containing DTaP, Hib, HepB, and IPV antigens (DTaP-IPV/Hib/HepB; Vaxelis®) can be used for a 3-dose immunization series in infants and children 6 weeks through 4 years of age when there are no contraindications to any of the individual components.[236] Vaxelis® may be administered to pediatric patients who have received 1 or 2 doses of Hib vaccine and are also scheduled to receive the other antigens in Vaxelis®; however, data on effectiveness and safety of Vaxelis® are not available in such patients.[236] Vaxelis® is not recommended for use as a booster dose; a different Hib-containing vaccine should be used for the booster dose.[199]*

Postexposure Prophylaxis

Whenever a case of invasive Hib disease is identified, unvaccinated or incompletely vaccinated children who are daycare or preschool contacts of the infected individual should receive a dose of Hib vaccine and be scheduled to complete the recommended age-specific Hib vaccination schedule.[105]

If a case of Hib is diagnosed, rifampin postexposure prophylaxis is recommended for all household contacts (regardless of age) in households with children younger than 4 years of age who are unvaccinated or incompletely vaccinated against Hib and for all household contacts in households with an immunocompromised individual younger than 18 years of age.[105,159] In childcare settings, rifampin postexposure prophylaxis should be considered for all attendees and childcare providers if 2 or more cases of invasive Hib disease have occurred within 60 days and unvaccinated or incompletely vaccinated children attend the facility.[105,159] Rifampin eradicates nasopharyngeal carriage of Hib in approximately 95% of carriers and decreases the risk of secondary invasive disease in exposed household contacts.[105]

Dosage and Administration

■ General

Pretreatment Screening

- Prior to administration of Haemophilus b (Hib) conjugate vaccine (meningococcal protein conjugate) (PRP-OMP; PedvaxHIB®), Hib conjugate vaccine (tetanus toxoid conjugate) (PRP-T; ActHIB®, Hiberix®), or combination Hib vaccine containing PRP-T, take all known precautions to prevent adverse reactions, including a review of the patient's history with respect to health status and possible sensitivity to the vaccine or similar vaccines.[144,174,223]

Other General Considerations

- Syncope (vasovagal or vasodepressor reaction; fainting) may occur following vaccination.[134,223] Procedures should be in place to avoid a falling injury from syncope.[134,223]

- Have epinephrine and other appropriate agents and equipment available for immediate treatment if an anaphylactic or other serious allergic reaction occurs.[144,174,223]

■ Administration

Haemophilus b (Hib) conjugate vaccine (meningococcal protein conjugate) (PRP-OMP; PedvaxHIB®)[144] and Hib conjugate vaccine (tetanus toxoid conjugate) (PRP-T; ActHIB®, Hiberix®)[174,223] are administered by IM injection.

The fixed-combination vaccine containing diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed (DTaP), poliovirus vaccine inactivated (IPV), and Hib conjugate

vaccine (DTaP-IPV/Hib; Pentacel®) and the fixed-combination vaccine containing DTaP, hepatitis B (HepB), poliovirus, and Hib antigens (DTaP-IPV/Hib/HepB; Vaxelis®) are also administered by IM injection.[224,236] Consult the prescribing information for these fixed-combination vaccines for additional information.[224,236]

Monovalent Hib vaccine and combination vaccines containing Hib and other antigens should *not* be given IV, subcutaneously, or intradermally.[144,174,223,224,236]

Depending on patient age, IM injections should be made into the anterolateral muscles of the thigh or deltoid muscle of the arm.[134,144,174,223]

In infants younger than 12 months of age, IM injections should preferably be made into the anterolateral thigh; in certain circumstances (e.g., physical obstruction at other sites and no reasonable indication to defer the vaccine dose), IM injections can be made into the gluteal muscle using care to identify anatomical landmarks prior to injection.[134]

In infants and children 1 through 2 years of age, the anterolateral thigh is preferred; alternatively, IM injections can be made into the deltoid muscle if muscle mass is adequate.[134]

In adults, adolescents, and children 3 years of age or older, IM injections should preferably be made into the deltoid muscle; IM injections also can be made into the anterolateral thigh.[134]

To ensure delivery into muscle, IM injections should be made at a 90° angle to the skin using a needle length appropriate for the individual's age and body mass, the thickness of adipose tissue and muscle at the injection site, the volume to be injected, and the injection technique.[134]

Some manufacturers state that Hib vaccine should not be injected into the gluteal area or any area where there may be a major nerve trunk.[144]

Hib vaccine may be given concurrently with other age-appropriate vaccines.[243] Use of fixed-combination vaccines can reduce the number of injections a patient receives and alleviate concerns about the number of injections.[243] When multiple vaccines are administered during a single health-care visit, each parenteral vaccine should be given using separate syringes and different injection sites.[134] The injection sites should be separated by at least 1 inch (if anatomically feasible) to allow appropriate attribution of any local adverse effects that may occur.[134] For infants and younger children receiving >2 vaccines in a single limb, the thigh is the preferred site due to greater mass.[134] For older children and adults, more than one IM injection can be administered into the deltoid muscle.[134]

PRP-OMP (PedvaxHIB®)

PRP-OMP (PedvaxHIB®) is administered undiluted.[144]

Single-dose vials of PRP-OMP should be shaken well prior to withdrawing the dose.[144] Thorough agitation is necessary to maintain a suspension; the vaccine should appear as a slightly opaque white suspension.[144]

PRP-OMP (PedvaxHIB®) should be refrigerated at 2–8°C and should not be frozen.[144]

PRP-T (ActHIB®)

Single-dose vials of lyophilized PRP-T (ActHIB®) should be reconstituted by adding 0.6 mL of the 0.4% sodium chloride diluent supplied by the manufacturer.[174] The vial should be agitated thoroughly to ensure complete reconstitution; the reconstituted vaccine should appear clear and colorless.[174] The manufacturer's labeling should be consulted for additional information regarding reconstitution of ActHIB®.[174]

PRP-T should be administered promptly after reconstitution or may be stored at 2–8°C and administered within 24 hours after reconstitution.[174] The reconstituted vaccine should be shaken well prior to use.[174]

PRP-T should not be mixed with any other vaccine or solution.[174]

Lyophilized PRP-T (ActHIB®) and the 0.4% sodium chloride diluent provided by the manufacturer should be refrigerated at 2–8°C and should not be frozen.[174] The vaccine contains no preservatives.[174]

PRP-T (Hiberix®)

PRP-T (Hiberix®) is supplied in 2 presentations: a vial and vial presentation and a vial and prefilled syringe presentation.[223] For both presentations, the lyophilized antigen component should be reconstituted only with the accompanying saline diluent.[223] The reconstituted vaccine should be a clear and colorless solution.[223] The manufacturer's labeling should be consulted for additional information regarding reconstitution of Hiberix®.[223]

PRP-T should be administered promptly after reconstitution.[223]

Lyophilized PRP-T (Hiberix®) should be stored at 2–8°C and protected from light.[223] The 0.9% sodium chloride diluent supplied by the manufacturer should be stored at 2–8°C or at room temperature between 2 and 25°C.[223] The diluent should not be frozen and should be discarded if freezing occurs.[223]

Dosage

The dosage schedule (i.e., number of doses) recommended for primary immunization against Hib infection varies according to the specific Hib vaccine administered and the age at which vaccination is started.[144,159,174,223] The age-appropriate recommendations for the specific preparation used should be followed.[144,159,174,223]

Monovalent PRP-OMP and monovalent PRP-T are considered interchangeable for both primary and booster immunization.[159,166] If the primary immunization series included both PRP-OMP and PRP-T or if there is uncertainty about which vaccine type was administered previously, 3 primary doses and a booster dose are needed to complete the series.[159,166]

The Centers for Disease Control and Prevention (CDC)'s Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics (AAP) state that use of PRP-OMP (available as a monovalent vaccine [PedvaxHIB®] or as part of a fixed-combination vaccine [Vaxelis®]) is preferred for primary immunization in American Indian and Alaskan native children.[199,237]

If interruptions or delays result in an interval between Hib vaccine doses longer than recommended, it is not necessary to administer additional doses or start the vaccination series over.[199]

The usual dose of PRP-OMP (PedvaxHIB®) or PRP-T (ActHIB®, Hiberix®) is 0.5 mL.[144,174,223]

Pediatric Patients

PRP-OMP (PedvaxHIB®) is labeled by FDA for use in infants and children 2 through 71 months of age.[144]

PRP-T (ActHIB®) is labeled by FDA for use in infants and children 2 months through 5 years of age.[174]

PRP-T (Hiberix®) is labeled by FDA for use in infants and children 6 weeks through 4 years of age.[223]

Primary and Booster Vaccination

Routine primary immunization in early infancy using PRP-T (ActHib®; Hiberix®) consists of a series of 3 doses and a booster dose.[199,237] ACIP, AAP, and other organizations recommend that doses be given at 2, 4, 6, and 12 through 15 months of age.[199,237] The manufacturers recommend that doses be given at 2, 4, 6, and 15 through 18 months of age.[174,223] The initial dose may be given as early as 6 weeks of age.[199,237]

Routine primary immunization in early infancy using PRP-OMP (PedvaxHIB®) consists of a series of 2 doses and a booster dose.[144,199,237] The manufacturer, ACIP, AAP, and other organizations recommend that doses be given at 2, 4, and 12 through 15 months of age.[144,199,237] The initial dose may be given as early as 6 weeks of age.[199,237]

Catch-up Vaccination

For catch-up vaccination in infants who received their first dose at 7–11 months of age, ACIP, AAP, and other organizations recommend that a second dose be given at least 4 weeks after the first dose.[159,199,237] The third dose should be given at 12–15 months of age or 8 weeks after the second dose, whichever is later.[159,199,237]

For catch-up vaccination in infants who received 2 doses of PRP-OMP (PedvaxHIB®) before 12 months of age, the third and final dose should be given at 12–59 months of age, and at least 8 weeks after the second dose.[159,199,237]

For catch-up vaccination in infants who received their first dose at 12–14 months of age, ACIP, AAP, and other organizations recommend that a second dose be given at least 8 weeks after the first dose.[159,199,237] A third dose is not necessary.[159,199,237]

For catch-up vaccination in infants and children who previously received 2 doses (first dose before 12 months of age and second dose before 15 months of age), give a third (final dose) at least 8 weeks after the second dose.[159,199,237]

In previously unvaccinated infants and children 15 through 59 months of age, give a single dose.[159,199,237]

In previously unvaccinated children 60 months of age and older, catch up vaccination for Hib is not required.[159,199,237]

Vaccination in At-Risk Populations

> *ACIP, AAP and other organizations recommend that children 12 through 59 months of age who are at an increased risk for Hib disease (i.e., those with functional or anatomic asplenia, HIV infection, immunoglobulin deficiency [including immunoglobulin G_2 subclass deficiency] or early component complement deficiency, recipients of a hematopoietic stem cell transplant [HSCT], and those receiving chemotherapy or radiation for malignant neoplasms) and who received no doses or only 1 dose of Hib vaccine before 12 months of age should receive 2 additional doses separated by 8 weeks; children who received ≥2 doses before 12 months of age should receive 1 additional dose, at least 8 weeks after the last dose (see Table 2).[159,199,237] In children undergoing chemotherapy or radiation therapy, if the Hib vaccine was administered ≥14 days prior to initiation of therapy, no additional Hib doses are necessary.[159,199,237] Any doses administered within 14 days of starting therapy or during therapy should be repeated at least 3 months after completion of chemotherapy or radiation.[159,199,237] Regardless of Hib vaccination history, children who receive HSCT should repeat a 3-dose series starting 6–12 months post-transplant with doses separated by 4 weeks.[159,199,237]*
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> *ACIP, AAP, and other organizations recommend that children ≥15 months of age undergoing elective splenectomy who are unvaccinated, defined as having fewer than the recommended number of doses in those ≤14 months of age or no doses of Hib vaccine in those ≥15 months of age, should receive 1 dose (preferably ≥14 days before the procedure).[159,199,237]*
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> *In unvaccinated children **5 years of age and older [off-label]**† at increased risk for invasive Hib disease because of HIV infection or anatomic or functional asplenia, ACIP, AAP, and other organizations recommend 1 dose of Hib vaccine.[159,199,237] Regardless of Hib vaccination history, recipients of HSCT should repeat a 3-dose Hib series starting 6–12 months post-transplant with doses separated by 4 weeks.[159,199,237]*

Adults

In unvaccinated **adults [off-label]**† undergoing elective splenectomy or with functional or anatomic asplenia (including sickle cell disease), ACIP and other organizations recommend 1 dose of Hib vaccine.[159,200] The dose of vaccine should be administered ≥14 days prior to the elective splenectomy.[159,200] Regardless of Hib vaccination history, ACIP and other experts recommend that adult recipients of HSCT repeat a 3-dose Hib series starting 6–12 months post-transplant with doses separated by 4 weeks.[159,200] In adults with HIV infection, Hib vaccination is not recommended unless the patient has concomitant anatomic or functional asplenia.[155,159,200]

■ Special Populations

Hepatic Impairment

Manufacturers make no specific dosage recommendations for patients with hepatic impairment.[144,174,223]

Renal Impairment

Manufacturers make no specific dosage recommendations for patients with renal impairment.[144,174,223]

Geriatric Patients

Manufacturers make no specific dosage recommendations for geriatric patients.[144,174,223]

Cautions

■ Contraindications

- Haemophilus b (Hib) conjugate vaccine (meningococcal protein conjugate) (PRP-OMP; PedvaxHIB®): hypersensitivity to any vaccine component.[144]
- Hib conjugate vaccine (tetanus toxoid conjugate) (PRP-T; ActHIB®, Hiberix®): severe allergic reaction (e.g., anaphylaxis) after dose of any Hib vaccine, dose of any vaccine containing tetanus toxoid, or any component in PRP-T.[174,223]

■ Warnings/Precautions

Management of Acute Allergic Reactions

Prior to administration of a Hib vaccine, clinicians should review the patient's history regarding possible sensitivity and any previous adverse reactions and should take all precautions known for prevention of allergic or any other adverse effects.[144,174,223] Epinephrine and other appropriate agents and equipment should be available for immediate treatment if an anaphylactic or other serious allergic reaction occurs.[144,174,223]

Latex Sensitivity

Some packaging components of PRP-OMP (PedvaxHIB®) (i.e., vial stoppers) contain natural rubber latex, which may cause sensitivity reactions in susceptible individuals.[144]

Individuals with Altered Immunocompetence

If Hib vaccines are used in patients with malignancies, those receiving immunosuppressant therapy, or those who are otherwise immunocompromised, the expected immune response may not be achieved.[144]

The manufacturer of PRP-T (Hiberix®) states that safety and efficacy of the vaccine have not been evaluated in immunosuppressed children.[223]

Guillain-Barré Syndrome

If Guillain-Barré syndrome (GBS) occurred within 6 weeks of receipt of a vaccine containing tetanus toxoid, the manufacturers state that a decision to administer a dose of PRP-T (ActHIB®, Hiberix®) should be based on careful consideration of potential benefits and possible risks.[174,223]

Syncope

Syncope (fainting) may occur following vaccination; such reactions may be accompanied by transient neurologic signs (e.g., visual disturbance, paresthesia, tonic-clonic limb movements).[223] Procedures should be in place to avoid a falling injury and to restore cerebral perfusion following syncope.[223]

Apnea in Premature Infants

Apnea has been reported following IM administration of vaccines in some infants born prematurely.[223] Decisions regarding when to administer an IM vaccine in infants born prematurely should be based on consideration of the individual infant's medical status and potential benefits and possible risks of vaccination.[223]

Individuals at Increased Bleeding Risk

Individuals who have bleeding disorders or are receiving anticoagulant therapy should be advised about the risk of hematoma from IM injections.[245]

ACIP states that IM vaccines may be given to individuals who have bleeding disorders or are receiving anticoagulant therapy if a clinician familiar with the patient's bleeding risk determines that the vaccine can be administered IM with reasonable safety.[245] In these cases, a fine needle (23 gauge or smaller) should be used to administer the vaccine and firm pressure should be applied to the injection site (without rubbing) for at least 2 minutes.[245] In individuals receiving therapy for hemophilia, IM vaccines can be scheduled for shortly after a dose of such therapy.[245] If possible, IM vaccines should be scheduled before the use of anticoagulant therapy.[245]

Limitations of Vaccine Effectiveness

Hib vaccines may not protect all vaccine recipients against invasive Hib disease.[144,174]

Hib vaccines will not provide protection against other types of *H. influenzae* (e.g., nonencapsulated [nontypeable] strains) or against other pathogens that cause meningitis, septicemia, or other invasive disease.[144]

Hib vaccine does not result in protective antibodies immediately following vaccination.[144]

Although PRP-OMP contains Hib antigen conjugated to outer membrane protein complex (OMPC) of *Neisseria meningitidis* and antibodies to OMPC have been demonstrated in individuals who received the vaccine, the clinical relevance of these antibodies has not been established.[144]

Although PRP-T contains Hib antigen conjugated to tetanus toxoid, the vaccine is not a substitute for routine immunization against tetanus.[223]

Specific Populations

Pregnancy

Hib vaccines are not labeled by FDA for use in adolescents or adults,[144,223] as Hib disease is uncommon in this age group.[159]

Animal reproduction studies have not been performed with Hib vaccines.[174,223] It is not known whether the vaccines can cause fetal harm when administered to pregnant women or whether they can affect fertility.[144,174,223]

According to ACIP, there is no evidence of risk to the fetus when inactivated vaccines are administered during pregnancy.[245]

Lactation

Hib vaccines are not labeled by FDA for use in adolescents or adults,[144,174,223] as Hib disease is uncommon in this age group.[159]

It is not known whether antigens contained in Hib vaccines are distributed into human milk, affect milk production, or affect the breast-fed infant.[223]

ACIP states that administration of an inactivated vaccine to a woman who is breast-feeding does not pose any safety concerns for the woman or the breast-fed infant.[245]

Pediatric Use

PRP-OMP (PedvaxHIB®): Safety and efficacy have not been established in infants younger than 6 weeks of age or in children 6 years of age or older.[144] *The manufacturer states that administration of PRP-OMP before 6 weeks of age may result in immunologic tolerance to the vaccine (i.e., impaired ability to respond to subsequent exposure to PRP antigen).*[144]

PRP-T (ActHIB®): Safety and efficacy have not been established in infants younger than 6 weeks of age or in children and adolescents 6 years of age or older.[174]

PRP-T (Hiberix®): Safety and efficacy have not been established in infants younger than 6 weeks of age or in children and adolescents 5–16 years of age.[223]

ACIP and AAP state that immunization against Hib infection using an age-appropriate vaccine can be initiated as early as 6 weeks of age.[159,199] *Hib vaccines should not be administered to infants younger than 6 weeks of age.*[144,159]

Apnea has been reported following IM administration of vaccines in some infants born prematurely.[223] *Decisions regarding when to administer an IM vaccine in infants born prematurely should be based on consideration of the individual infant's medical status and potential benefits and possible risks of vaccination.*[223]

Geriatric Use

Safety and efficacy of Hib vaccines have not been established in adults, including geriatric adults,[144,223] *and these vaccines are not usually used in this age group.*[105,144,159,200]

■ Common Adverse Effects

Adverse effects reported in more than 1% of pediatric patients receiving PRP-OMP (PedvaxHIB®) vaccine in clinical studies were irritability, sleepiness, injection site pain/soreness, injection site erythema, injection site swelling/induration, unusual high-pitched crying, prolonged crying (>4 hours), diarrhea, vomiting, crying, pain, otitis media, rash, and upper respiratory infection.[144]

The most common adverse effects following a single dose of PRP-T (ActHIB®) vaccine in pediatric patients 2–16 months of age were fussiness/irritability (75%), inconsolable crying (58%), and decreased activity/lethargy (51%).[174] In pediatric patients 15–20 months of age, tenderness (20%) was the most common local reaction following administration of ActHIB®.[174]

Adverse effects reported in at least 20% of pediatric patients receiving PRP-T (Hiberix®) vaccine include pain and redness at the injection site, irritability, drowsiness, fever, loss of appetite, fussiness, and restlessness.[223]

Drug Interactions

■ Immunosuppressive Agents

Individuals receiving immunosuppressive therapy (e.g., alkylating agents, antimetabolites, corticosteroids, cytotoxic drugs, radiation therapy) may have reduced immune responses to vaccines, including *Haemophilus influenzae* type b (Hib) vaccine.[174,223] Inactivated vaccines generally should be administered at least 2 weeks prior to initiation of immunosuppressive therapy.[159]

■ Tests to Diagnose Hib Disease

Haemophilus b (Hib) capsular polysaccharide has been detected in urine following administration of Hib conjugate vaccine.[174,223] Therefore, urine antigen detection may not have a diagnostic value in evaluating suspected Hib disease in children if performed within 1–2 weeks following administration of a Hib vaccine.[174,223]

■ Vaccines

The Hib vaccine does not interfere with the immune response to other live and non-live vaccines and can be administered simultaneously.[243] Manufacturers state that, when administering Hib concomitantly with other injectable vaccines, each parenteral vaccine should be administered using a different syringe and injection site.[144,174,223]

Description

Haemophilus b conjugate (meningococcal protein conjugate) vaccine (PRP-OMP) and haemophilus b conjugate (tetanus toxoid conjugate) vaccine (PRP-T) are used to stimulate active immunity to *Haemophilus influenzae* type b (Hib) infection by inducing production of specific antibodies.[144,174,223]

In a clinical study using PRP-OMP (PedvaxHIB®), 80% of infants developed protective antibody levels (anti-PRP greater than 1 mcg/mL) after a primary series of 2 doses initiated at 2–3 months of age and 95% had protective antibody levels approximately 1 month after a booster dose given at 12–15 months of age.[144]

In clinical studies using PRP-T (ActHIB®, Hiberix®), 81–97% of infants developed protective antibody levels (anti-PRP 1 mcg/mL or greater) after a primary immunization series of 3 doses given at 2, 4, and 6 months of age, and 98–100% had protective antibody levels 1 month after a booster dose given at 15–23 months of age.[174,223]

Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from MedlinePlus (in English and Spanish; written at a 6th- to 8th-grade reading level).

- Prior to administration of each vaccine dose, provide a copy of the appropriate CDC Vaccine Information Statement (VIS) to the patient or patient's legal representative as required by the National Childhood Vaccine Injury Act ([Web]).[144,174,223]
- Advise patient and/or patient's caregiver of the risks and benefits of vaccination against Hib.[144,174,223]
- Advise patient and/or patient's caregiver that it is important to receive the complete primary vaccination series to ensure the highest level of protection against Hib.[144,174]
- Advise patients and caregivers to inform their clinician of any latex allergy prior to vaccination.[144] Use caution when vaccinating latex-sensitive individuals with PRP-OMP (PedvaxHIB®) since the vial stopper contains dry natural latex rubber that may cause allergic reactions.[144]
- Advise patients and caregivers to inform their clinician if any severe or unusual adverse reactions occur.[203,223] Clinicians or individuals can report any adverse reactions that occur following vaccination to the Vaccine Adverse Event Reporting System (VAERS) at 800-822-7967 or [Web] .[203]
- Advise patients to inform their clinician if they are or plan to become pregnant or plan to breast-feed.[144,174,223]
- Advise patients to inform their clinician of existing or contemplated concomitant therapy, including prescription and OTC drugs and dietary and herbal supplements, as well as any concomitant illnesses.[144,174,223]
- Advise patients of other important precautionary information.[144,174,223]

Additional Information

The American Society of Health-System Pharmacists, Inc. represents that the information provided in the accompanying monograph was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are advised that decisions regarding use of drugs are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and that the information contained in the monograph is provided for informational purposes only. The manufacturer's labeling should be consulted for more detailed information. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. The information contained in the monograph is not a substitute for medical care.

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) (PRP-OMP)

ROUTES	*FORMS*	*STRENGTHS*	*BRAND NAMES*	*MANUFACTURER*
Parenteral	*Injectable suspension, for IM use*	*7.5 mcg of Haemophilus b capsular polysaccharide conjugated to 125 mcg of Neisseria meningitidis OMPC protein carrier per 0.5 mL*	*PedvaxHIB Liquid®*	*Merck*

Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) (PRP-T)

ROUTES	FORMS	STRENGTHS	BRAND NAMES	MANUFACTURER
Parenteral	*For injectable suspension, for IM use*	*10 mcg of Haemophilus b capsular polysaccharide conjugated to 24 mcg of tetanus toxoid protein carrier per 0.5 mL*	*ActHIB®*	*Sanofi Pasteur*
Parenteral	*For injection, for IM use*	*10 mcg of Haemophilus b capsular polysaccharide conjugated to 25 mcg of tetanus toxoid protein carrier per 0.5 mL*	*Hiberix®*	*GlaxoSmithKline*

Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine (DTaP-IPV/Hib)

ROUTES	FORMS	STRENGTHS	BRAND NAMES	MANUFACTURER

Diphtheria and Tetanus Toxoids and Acellular Pertussis, Inactivated Poliovirus and Haemophilus b Conjugate and Hepatitis B Vaccine (DTaP-IPV/Hib/HepB)

ROUTES	FORMS	STRENGTHS	BRAND NAMES	MANUFACTURER
Parenteral	*Injectable suspension, for IM use*	*Diphtheria Toxoid 15 Lf units, Tetanus Toxoid 5 Lf units, Acellular Pertussis Vaccine 48 mcg (of pertussis antigen), Poliovirus Type 1 29 DU, Poliovirus Type 2 7 DU, Poliovirus Type 3 26 DU, and Hepatitis B Surface Antigen 10 mcg per 0.5 mL*	*Vaxelis®*	*Sanofi Pasteur*

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

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