Protocol for Haemophilus influenzae type b Vaccines (ActHIB®, HIBERIX®, PedvaxHIB®)

1. What's New

A. Contraindications- Latex (Removed for ActHib®)[1]

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of Hib vaccine to persons ≥7 years of age according to high-risk group indication.

B. Hib vaccines can be given with all other routinely recommended vaccines.

3. Vaccine Schedule

A. Not routinely recommended. See recommendations for use for guidance for high-risk groups.

Hib Vaccine (ActHIB®, HIBERIX®, PedvaxHIB®)[1-3] Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥7 years	
2		28 days
3		28 days

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
ActHIB®[1] (PRP-T)	Hib (tetanus toxoid conjugate)	0.5-mL lyophilized single-dose vials packaged with single-dose diluent	6 weeks – 5 years*	None
HIBERIX®[2] (PRP-T)	Hib (tetanus toxoid conjugate)		6 weeks – 4 years*	
PedvaxHIB®[3] (PRP-OMP)	Hib (meningococcal protein conjugate)	0.5-mL single-dose suspension	6 weeks – 5 years*	

*Any licensed product presentation may be used for Catch-Up for Persons at High Risk

5. Recommendations for Use

A. **Routinely Recommended Use**- N/A

B. **Catch-Up for Healthy Children**- N/A

C. **Catch-Up for Persons at High-Risk**[4]

High-Risk Group	Vaccine Guidance
Patients aged ≥7 years undergoing elective splenectomy	If unimmunized, 1 dose at least 14 days prior to procedure
Asplenic patients ≥7 years	If unimmunized, 1 dose
HIV-infected children 7-18 years	If unimmunized, 1 dose
HIV-infected persons ≥19 years	Hib immunization is not recommended
Hematopoietic stem cell transplantation (HSCT) ≥7 years	3 doses (4-week intervals) beginning 6–12 months after HSCT regardless of prior Hib vaccine history

6. Contraindications[5]

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component, including latex (PedvaxHIB®[3]).

Vaccine	Contains
Hib (ActHIB®[1])	Sodium chloride, formaldehyde, sucrose
Hib (HIBERIX®[2])	Formaldehyde, sodium chloride, lactose
Hib (PedvaxHIB®[3])	Amorphous aluminum hydroxyphosphate sulfate, sodium chloride

7. Warnings and Precautions

A. N/A

8. Other Considerations [1-3]

A. In immunosuppressed persons, including those receiving immunosuppressive therapy, the expected antibody responses may not be obtained.

9. Side Effects and Adverse Reactions

Adverse Event	Frequency
Any systemic reaction—Irritability, drowsiness, loss of appetite, fever	Very common, up to 70%
Any local reaction—pain, redness, induration or swelling at injection site	Very common, up to 49%
Severe (grade 3) systemic reactions—irritability, drowsiness	Uncommon, up to 6%
Severe pain, induration or swelling at injection site	Uncommon, up to 4%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
ActHIB®[1]	2°to 8°C (36° to 46°F) vaccine & diluent	Do not freeze.	
HIBERIX®[2]	2°to 8°C (36° to 46°F) vaccine 2°to 25°C (36° to 77°F) diluent	Protect from light. Do not freeze.	Discard if the diluent has been frozen.
PedvaxHIB®[3]	2°to 8°C (36° to 46°F) vaccine	Do not freeze.	

11. References

1. ActHIB® package insert. 2022. Available at https://www.fda.gov/media/74395/download. Accessed 22 August 2022.

2. HIBERIX® package insert. April 2018. Available at https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Package-Insert---HIBERIX.pdf. Accessed 22 August 2022.
3. PedvaxHIB® package insert. No date. Available at https://www.fda.gov/media/80438/download. Accessed 22 August 2022.
4. Briere EC, Rubin L, Moro P, et al. Prevention and control of Haemophilus influenzae type b disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2014; 63(RR-1). Available at: https://www.cdc.gov/mmwr/PDF/rr/rr6301.pdf. Accessed 22 August 2022.
5. CDC. Vaccine Excipient Table. 1 November 2021. Available at: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. Accessed 22 August 2022.
6. Kroger A, Bahta L, Hunter P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/. Accessed 22 August 2022.

12. Appendix

A. N/A