

Immunization Protocol

***Haemophilus influenzae* type b (Hib) Conjugate Vaccines and Combination Vaccines (ActHIB^{®1}, PedvaxHIB^{®3}, HIBERIX^{®2}, Pentacel^{®4}, VAXELIS^{™5})**

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1. What's new

Added new, hexavalent, DTaP, IPV, Hib and HepB combination vaccine, VAXELIS.

2. Oregon immunization protocol

- A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
- B. Screen clients for contraindications and precautions.
- C. Provide a current Vaccine Information Statement (VIS), answering any questions.
- D. Record all required data elements in the client's permanent health record.
- E. Verify needle length for intramuscular (IM) injection.
- F. Administer a 0.5-mL dose of Hib-containing vaccine IM according to age and vaccine-specific schedule.
- G. Hib-containing vaccines can be given with all other routinely recommended vaccines.
- H. To avoid injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks and use proper IM administration technique.
- I. Ask client to remain seated in the clinic for 15 minutes after vaccination to decrease the risk of injury should they faint.

Health Officer Signature

Date

Health Officer Signature

Date

3. Vaccine schedule for *Haemophilus influenzae* type b vaccines⁶

Dose and Route - 0.5 mL, IM			
Dose	Preferred age	Minimum acceptable age	Minimum acceptable spacing
1	2 months	6 weeks	
2	4 months	10 weeks	4 weeks dose 1 to dose 2
3	6 months	14 weeks	4 weeks dose 2 to dose 3
4	15 months	12 months	8 weeks dose 3 to dose 4

4. Licensed *Haemophilus influenzae* type b vaccines

Product Name	Vaccine Components	Presentation	Acceptable Age Range	Thimerosal
ActHIB ¹ (PRP-T)	Hib	0.5-mL single-dose vials	6 weeks – 5 years	None
HIBERIX ² (PRP-T)	Hib		6 weeks – 4 years	
PedvaxHIB ³ (PRP-OMP)	Hib		6 weeks – 5 years	
Pentacel ⁴ (PRP-T)	DTaP-IPV-Hib		6 weeks – 4 years	
VAXELIS ⁵ (PRP-OMP)	DTaP-IPV-Hib-Hep. B		6 weeks – 4 years	

5. Recommendations for use⁶

Hib (PRP-T), single-antigen (ActHIB, HIBERIX) or combination (Pentacel)			
Dose	Preferred Age	Minimum Acceptable Age	Minimum Acceptable Spacing
1	2 months	6 weeks	
2	4 months	10 weeks	4 weeks dose 1 to dose 2
3	6 months	14 weeks	4 weeks dose 2 to dose 3
4	15 months	12 months	8 weeks dose 3 to dose 4
Hib (PRP-OMP),* single-antigen (PedvaxHIB)			
Dose	Preferred Age	Minimum Acceptable Age	Minimum Acceptable Spacing
1	2 months	6 weeks	
2	4 months	10 weeks	4 weeks dose 1 to dose 2
3	15 months	12 months	8 weeks dose 2 to dose 3
Hib (PRP-OMP),* combination (VAXELIS)			
Dose	Preferred Age	Minimum Acceptable Age	Minimum Acceptable Spacing
1	2 months	6 weeks	

2	4 months	10 weeks	4 weeks dose 1 to dose 2
3 [◇]	6 months	6 months	4 weeks dose 2 to dose 3

*PRP-OMP-containing vaccines are preferred for Native American/Alaskan Native children to provide early protection, due to their higher incidence of disease, because these vaccines produce a protective antibody response after the first dose,
[◇]A total of 4 doses of Hib-containing vaccine are needed if VAXELIS was used for any doses. Any other single-antigen hib vaccine is acceptable.⁹

Catch-Up for Healthy Children⁶

Hib (ActHIB, HIBERIX, Pentacel, VAXELIS, Mixed Brands, or Unknown Product)		
Age at First Dose	Total Number of Doses	Minimum Acceptable Spacing
<7 months	4	Doses 1, 2 and 3: 4-week intervals between each Dose 4: 12–15 months of age and at least 8 weeks after dose 3
7–11 months	3	Doses 1 and 2: 4-week interval Dose 3: 12–15 months of age and at least 8 weeks after dose
12–14 months	2	Dose 2: at least 8 weeks after dose 1
15–59 months	1	Complete
Hib (PedvaxHIB)		
Age at First Dose	Total Number of Doses	Minimum Acceptable Spacing
≤11 months	3	Doses 1 and 2: 4-week intervals between each Dose 3: 12–15 months of age and at least 8 weeks after dose 2
12–14 months	2	Dose 2: at least 8 weeks after dose 1
15–59 months	1	Complete

Unvaccinated children >60 months of age and not considered to be at high risk do not require catch-up vaccination.

Catch-Up for Children at High-Risk⁶

High-Risk Group	Vaccine Guidance
Patients aged <60 months undergoing chemotherapy or radiation therapy.	If routine Hib doses administered ≥14 days before starting therapy, revaccination not required. If doses administered within 14 days of starting therapy or given during therapy, repeat doses starting at least 3 months following therapy completion.

Patients aged ≥ 15 months undergoing elective splenectomy	If unimmunized, 1 dose prior to procedure.
Asplenic patients 5 years of age or older	If unimmunized, 1 dose.
HIV-infected children 5-18 years of age	If unimmunized, 1 dose.
HIV-infected persons ≥ 19 years of age	Hib immunization is not recommended.
Hematopoietic stem cell transplantation (HSCT)	3 doses beginning 6–12 months after HSCT regardless of prior Hib vaccine history

6. Contraindication

Severe allergic reaction to any component of the vaccine.

Components of Hib-Containing Vaccines	
Vaccine ⁷	Contains
Hib (ActHIB)	Sodium chloride, formaldehyde, sucrose
Hib (HIBERIX)	Formaldehyde, sodium chloride, lactose
Hib (PedvaxHIB)	Amorphous aluminum hydroxyphosphate sulfate, sodium chloride
DTaP-IPV/Hib (Pentacel)	Aluminum phosphate, polysorbate 80, sucrose, formaldehyde, glutaraldehyde, bovine serum albumin, 2-phenoxyethanol, neomycin, polymyxin B sulfate
DTaP-IPV-Hib-Hep B (VAXELIS)	Polysorbate 80, formaldehyde, glutaraldehyde, bovine serum albumin, neomycin, streptomycin sulfate, polymyxin B sulfate, ammonium thiocyanate, yeast protein, aluminum

7. Warnings and precautions

Pentacel⁴, VAXELIS⁵

- A. A history of fever $\geq 40.5^{\circ}\text{C}$ (104.9°F), hypotonic-hyporesponsive episode, or persistent inconsolable crying lasting ≥ 3 hours within 48 hours after receipt of a pertussis-containing vaccine.
- B. Encephalopathy within 7 days of a previous dose of pertussis-containing vaccine.
- C. History of Guillain-Barré syndrome within 6 weeks of a prior vaccine containing tetanus toxoid.
- D. For PedvaxHIB, use caution when vaccinating latex-sensitive individuals since the vial stopper contains dry natural latex rubber that may cause allergic reactions.

8. Other considerations

- A. The 4th dose in a 4-dose series and the 3rd dose in a 3-dose series are considered booster doses. Any licensed single-antigen Hib vaccine can be given for these doses, regardless of previous brand of Hib received.⁶
- B. All monovalent Hib vaccines are interchangeable, but if brands are mixed or unknown, a 4-dose series is recommended.⁶
- C. In immunosuppressed persons, including those receiving immunosuppressive therapy, the expected antibody responses may not be obtained.¹⁻⁵
- D. For retrospective checking, doses that violate the minimum spacing or age by 4 or fewer days do not need to be repeated. Doses administered 5 days or earlier than the minimum interval or age should be repeated as age appropriate.⁸
- E. Fever-reducing medications like acetaminophen, should not be used before or at the same time as vaccinations. They can be used for fever or discomfort that develops after vaccination. These medications have not shown to prevent febrile seizures in children with a history of febrile seizures.⁸

9. Side effects and adverse reactions

Hib, single-antigen (ActHib ¹ , HIBERIX ² , PedvaxHIB ³)	
Any local reaction—pain, redness, induration or swelling at injection site	Up to 49%
Severe pain, induration or swelling at injection site	Up to 4%
Any systemic reaction—Irritability, drowsiness, loss of appetite, fever.	Up to 70%
Severe (grade 3) systemic reactions—irritability, drowsiness	Up to 6%
Hib, combination (Pentacel ⁴ , VAXELIS ⁵)	
Any local reaction—pain, redness, induration or swelling at injection site	Up to 30%
Any systemic reaction—Irritability, inconsolable crying, loss of appetite, fever.	Up to 50%

10. Storage and handling

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
All ¹⁻⁵	2°– 8°C	Protect from light. Do not freeze.	HIBERIX ² – discard if the diluent has been frozen.

11. Adverse events reporting

Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at <https://vaers.hhs.gov/reportevent.html>. VAERS Reporting Table: <https://vaers.hhs.gov/resources/infoproviders.html>.

Event and interval from vaccination
A. Shoulder Injury Related to Vaccine Administration (7 days)
B. Vasovagal syncope (7 days)
C. Any acute complication or sequelae (including death) of above events (interval not applicable)
D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval – see package insert).

12. References

1. ActHIB[®] package insert. 17 May 2019. Available at www.fda.gov/media/74395/download. Accessed 14 July 2021.
2. HIBERIX[®] package insert. April 2018. Available at www.fda.gov/media/77017/download. Accessed 14 July 2021.
3. PedvaxHIB[®] package insert. No date. Available at www.fda.gov/media/80438/download. Accessed 14 July 2021.
4. Pentacel[®] package insert. February 2021. Available at www.fda.gov/media/74385/download. Accessed 14 July 2021.
5. VAXELIS[™] package insert. October 2020. Available at www.fda.gov/media/119465/download. Accessed 14 July 2021.
6. 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: www.cdc.gov/mmwr/PDF/rr/rr6301.pdf. Accessed 14 July 2021.
7. CDC. Vaccine Excipient Table. February 2020. Available at: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. Accessed 14 July 2021.
8. Ezeanolue E, Harriman K, Hunter P, Kroger A, Pellegrini C. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html. Accessed 14 July 2021.
9. Oliver SE, Moore KL. Licensure of a diphtheria and tetanus toxoids and acellular pertussis, inactivated poliovirus, *Haemophilus influenzae* type b conjugate, and

hepatitis B vaccine, and guidance for use in infants. MMWR 2020; 69:136–9.
Available at:
www.cdc.gov/mmwr/volumes/69/wr/mm6905a5.htm?s_cid=mm6905a5_w.
Accessed 14 July 2021.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971-673-0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this standing order is available at: [standing orders](#)

13. Appendix

Not applicable.