



Vaccine Safety

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Haemophilus influenzae type b (Hib) Vaccines

Safety Information

About Hib Disease

Hib disease is a serious illness caused by the bacteria *Haemophilus influenzae* type b (Hib). These bacteria most commonly affect children younger than 5 years old. Adults 65 years or older, people who are American Indian or Alaska Native, and people with certain medical conditions are also at increased risk. People can spread the bacteria by coughing or sneezing while in close contact with others.

Hib bacteria can cause mild illness, such as an ear infection or bronchitis, or more severe illness such as pneumonia, meningitis, and infections of the bloodstream. Severe Hib infection, also called invasive Hib disease, requires treatment in a hospital and can sometimes result in death.

[Learn more about Hib disease.](#)

There are safe and effective vaccines that can protect against Hib disease.

Available Vaccines

There are 5 Hib vaccines approved for use in the United States: 3 single antigen vaccines and 2 combination vaccines.

Who Should Get Hib Vaccine

CDC recommends Hib vaccination for all children younger than 5 years old. Children need multiple (3 or 4) shots of a Hib vaccine. CDC recommends shots at the following ages:

- 2 months
- 4 months
- 6 months (if needed; depends on vaccine)
- 12 through 15 months

Older children and adults usually do not need a Hib vaccine. However, CDC recommends Hib vaccination for people with certain medical conditions.

For more information, see [Who should get a Hib vaccine.](#)

Vaccine Information Statements

Vaccine Information Statements (VISs) are information sheets produced by CDC that explain both the benefits and risks of a vaccine.

[Hib VIS](#)

Haemophilus influenzae type b (Hib) Vaccine

Talk with your
healthcare provider
about vaccines.

They can answer questions and
offer advice based on your
specific health needs.



Child and Adult Immunization Schedules

Get CDC’s official recommended immunization schedules for children, adolescents, and adults.

Manufacturer Package Inserts

Single antigen Hib vaccine



The following only contain Hib vaccine:

PedvaxHIB® [PDF–11 Pages] [↗](#) : The Food and Drug Administration (FDA) approved this vaccine in 1989. PedvaxHIB is usually given to children who are 2 through 15 months old.

ActHIB® [PDF–22 Pages] [↗](#) : FDA approved this vaccine in 1993. ActHIB is usually given to children who are 2 through 15 months old.

Hiberix® [PDF–17 Pages] [↗](#) : FDA approved this vaccine in 2009. Hiberix is usually given to children who are 2 through 15 months old.

Combination vaccine with Hib



The following contain Hib vaccine plus other vaccines, combined into a single dose:

Pentacel® [PDF–37 Pages] [↗](#) : FDA approved this vaccine in 2008. Pentacel is usually given to children who are 2 through 18 months old to protect against Hib disease, diphtheria, tetanus, pertussis (whooping cough), and polio.

Vaxelis™ [PDF–20 Pages] [↗](#) : FDA approved this vaccine in 2018. Vaxelis is usually given to children who are 2 through 6 months old to protect against Hib disease, diphtheria, tetanus, pertussis (whooping cough), polio, and hepatitis B.

Common Side Effects

Hib vaccine is safe and effective at preventing Hib disease. Vaccines, like any medicine, can have side effects. The most common side effects are usually mild and go away on their own.



Severe allergic reactions following vaccination are rare, but can be life threatening.
Symptoms of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness.

If such reactions occur, call 9-1-1 and get the person to the nearest hospital.

Single antigen Hib vaccine

- Redness, warmth, or swelling at the site of injection
- Fever
- irritability

Who should not get a single antigen Hib vaccine
This vaccine is not intended for use in children younger than 6 weeks old.

People should not get a single antigen Hib vaccine if they:

- Have had a severe life-threatening allergic reaction after a previous dose or to any component of a Hib vaccine
- Have had a severe allergic reaction to latex

People should talk to their healthcare provider before getting a single antigen Hib vaccine if they:

- Are experiencing a moderate or severe acute illness with or without a fever

In some cases, the healthcare provider may decide to postpone Hib vaccination to a future visit.

Combination vaccine with Hib

- Redness, warmth, or swelling at the site of injection
- Fever

- Irritability

Who should not get a combination vaccine with Hib

This vaccine is not intended for use in children younger than 6 weeks old.

People should not get the combination vaccine with Hib if they:

- Have had a severe life-threatening allergic reaction after a previous dose or to any component of a combination vaccine with Hib
- Developed encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) within 7 days of a previous dose of DTP (Diphtheria, Tetanus, and Pertussis) or DTaP (Diphtheria, Tetanus, and acellular Pertussis).

People should talk to their healthcare provider before getting a combination vaccine with Hib if they:

- Developed a condition called Guillain-Barré syndrome (GBS) within 6 weeks of getting a vaccine containing tetanus-toxoid
- Have a history of Arthus-type hypersensitivity reaction (i.e., severe injection site pain, swelling, and redness) after a previous dose of vaccine that protects against tetanus or diphtheria.
- Are pregnant

In some cases, the healthcare provider may decide to postpone Hib vaccination to a future visit.

More information [about contraindications and precautions](#).

Report Possible Adverse Events To VAERS

The Vaccine Adverse Event Reporting System (VAERS) is an early warning system, co-managed by CDC and FDA, that monitors for potential vaccine safety problems.

Healthcare providers and vaccine manufacturers are required by law to report certain adverse events following vaccination to VAERS; patients and caregivers can also submit reports.

For more information, see [Report an Adverse Event to VAERS](#) .

More Information

[Hib Vaccination: What Everyone Should Know](#)

What everyone should know about Hib and the vaccines that can protect against it.

Who Should Not Get Vaccinated?

Some people should not get certain vaccines or should wait before getting them. Read the CDC Guidelines for each vaccine.

Hib Vaccine – ACIP Recommendations

Official guidance on Hib vaccine from the Advisory Committee on Immunization Practices (ACIP).


Hib Information for Healthcare Professionals

Information for healthcare professionals about Hib vaccination and recommendations.


A Closer Look at the Safety Data

Findings from vaccine safety monitoring systems and scientific studies have shown that Hib vaccines have a favorable safety profile—the body of scientific evidence overwhelmingly supports their safety.


- A study of the safety of Hib vaccines (PedvaxHIB, ActHIB, Hiberix, Pentacel) in VAERS did not find any new or unexpected safety concerns and reconfirmed the safety of Hib vaccines.

Source: [Adverse Events Following Haemophilus Influenzae Type b Vaccines in the Vaccine Adverse Event Reporting System, 1990-2013 \[J Pediatr. 2015\]](#) 

- An observational study using Vaccine Safety Datalink records did not find an increased risk for seizures, meningitis/encephalitis/myelitis, allergic reactions, or fever among children younger than 1 year old.

Source: [Adapting Group Sequential Methods to Observational Postlicensure Vaccine Safety Surveillance: Results of Pentavalent Combination DTaP-IPV-Hib Vaccine Safety Study \[A. J Epidemiol. 2013\]](#) 

Which adverse events are considered “serious?”

By the [Code of Federal Regulations \(CFR\) Title 21](#) , an adverse event is defined as serious if it involves any of the following outcomes:

- Death
- A life-threatening adverse event
- A persistent or significant disability or incapacity
- A congenital anomaly or birth defect
- Hospitalization, or prolongation of existing hospitalization

Learn more [about adverse events](#).

How CDC Monitors Vaccine Safety

CDC and FDA [monitor the safety of vaccines](#) after they are approved or authorized. If a problem is found with a vaccine, CDC and FDA will inform health officials, health care providers, and the public.

CDC uses 3 systems to monitor vaccine safety:

- The [Vaccine Adverse Event Reporting System \(VAERS\)](#): an early warning system, co-managed by CDC and FDA, to monitor for potential vaccine safety problems. Anyone can report possible vaccine side effects to VAERS.
- The [Vaccine Safety Datalink \(VSD\)](#): a collaboration between CDC and 13 healthcare organizations that conducts vaccine safety monitoring and research.

- The [Clinical Immunization Safety Assessment \(CISA\) Project](#): a partnership between CDC and several medical research centers that provides expert consultation and conducts clinical research on vaccine-associated health risks.

Related Scientific Articles

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 Morb Mortal Wkly Rep*. 2020 Feb 7;69:136-139.

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Nelson JC, Yu O, Dominguez-Islas CP, Cook AJ, Peterson D, Greene SK. [Adapting group sequential methods to observational postlicensure vaccine safety surveillance: Results of a pentavalent combination DTaP-IPV-Hib vaccine safety study](#) [↗](#). *Am J Epidemiol*. 2013 Jan 15;177(2):131-41.

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Guerra FA, Blatter MM, Greenberg DP, Pichichero M, Noriega FR. Pentacel Study Group. [Safety and immunogenicity of a pentavalent vaccine compared with separate administration of licensed equivalent vaccines in US infants and toddlers and persistence of antibodies before a preschool booster dose: A randomized, clinical trial](#) [↗](#). *Pediatrics*. 2009 Jan;123(1):301-12.

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Holmes SJ, Fritzell B, Guito KP, Esbenshade JF, Blatter MM, Reisinger KS, et al. [Immunogenicity of *Haemophilus influenzae* type b polysaccharide-tetanus toxoid conjugate vaccine in infants](#) [↗](#). *Am J Dis Child*. 1993 Aug;147(8):832-6.

Decker MD, Edwards KM, Bradley R, Palmer P. [Comparative trial in infants of four conjugate *Haemophilus influenzae* type b vaccines](#) [↗](#). *J Pediatr*. 1992 Feb;120(2 Pt 1):184-9.

Fritzell B, Plotkin S. [Efficacy and safety of a *Haemophilus influenzae* type b capsular polysaccharide-tetanus protein conjugate vaccine](#) [↗](#). *J Pediatr*. 1992 Sep;121(3):355-62.

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