

15 months

VACCINE INFORMATION STATEMENT

Hib Vaccine

(*Haemophilus
Influenzae* Type b)

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Haemophilus influenzae type b (Hib) disease is a serious disease caused by bacteria. It usually strikes children under 5 years old.

Your child can get Hib disease by being around other children or adults who may have the bacteria and not know it. The germs spread from person to person. If the germs stay in the child's nose and throat, the child probably will not get sick. But sometimes the germs spread into the lungs or the bloodstream, and then Hib can cause serious problems.

Before Hib vaccine, Hib disease was the leading cause of bacterial meningitis among children under 5 years old in the United States. Meningitis is an infection of the lining of the brain and spinal cord. It can lead to brain damage and deafness. Hib disease can also cause:

- pneumonia
- severe swelling in the throat, making it hard to breathe
- infections of the blood, joints, bones, and covering of the heart
- death

Before Hib vaccine, about 20,000 children in the United States under 5 years old got life-threatening Hib disease each year, and about 3% – 6% of them died.

Hib vaccine can prevent Hib disease. Since use of Hib vaccine began, the number of cases of invasive Hib disease has decreased by more than 99%. Many more children would get Hib disease if we stopped vaccinating.

2 Hib vaccine

Several different brands of Hib vaccine are available. Your child will receive either 3 or 4 doses, depending on which vaccine is used.

Doses of Hib vaccine are usually recommended at these ages:

- First Dose: 2 months of age
- Second Dose: 4 months of age
- Third Dose: 6 months of age (if needed, depending on brand of vaccine)
- Final Dose: 12–15 months of age

Hib vaccine may safely be given at the same time as other vaccines.

Hib vaccine may be given as part of a combination vaccine. Combination vaccines are made when two or more types of vaccine are combined together into a single shot, so that one vaccination can protect against more than one disease. Ask your doctor for more information.

People over 5 years old usually do not need Hib vaccine. But it may be given to older children or adults before surgery to remove the spleen or following a bone marrow transplant. It may also be given to anyone with certain health conditions such as sickle cell disease or HIV/AIDS. Ask your doctor for details.

3 Some people should not get this vaccine

Hib vaccine should not be given to infants younger than 6 weeks of age.

Tell your doctor:

- **If the patient has any severe (life-threatening) allergies.** If the patient has ever had a life-threatening allergic reaction after a dose of Hib vaccine, or has a severe allergy to any part of this vaccine, he or she should not get a dose.
- **If the patient is not feeling well.** Your doctor might suggest waiting until the patient feels better. But you should come back.



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4 Risks of a vaccine reaction

With a vaccine, like any medicine, there is a chance of side effects. These are usually mild and go away on their own.

Serious side effects are also possible, but are very rare.

Most people who get Hib vaccine do not have any problems with it.

Mild Problems following Hib vaccine:

- redness, warmth, or swelling where the shot was given
- fever

These problems are uncommon. If they occur, they usually begin soon after the shot and last 2 or 3 days.

Problems that could happen after any vaccine:

- Brief fainting spells can happen after any medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if the patient appears to feel dizzy, or have vision changes or ringing in the ears.
- Severe shoulder pain and reduced range of motion in the arm where a shot was given can happen, very rarely, after a vaccination.
- Severe allergic reactions from a vaccine are very rare, estimated at less than 1 in a million doses. If one were to occur, it would usually be within a few minutes to a few hours after the vaccination.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5 What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS is only for reporting reactions. They do not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

7 How can I learn more?

- Ask your doctor.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO)
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement (Interim)
Hib Vaccine

2/04/2014

42 U.S.C. § 300aa-26

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VACCINE INFORMATION STATEMENT

Pneumococcal Conjugate Vaccine

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☒ Your doctor recommends that you, or your child, get a dose of PCV13 today.

1 Why get vaccinated?

Pneumococcal conjugate vaccine (called PCV13 or Prevnar® 13) is recommended to protect infants and toddlers, and some older children and adults with certain health conditions, from **pneumococcal disease**.

Pneumococcal disease is caused by infection with *Streptococcus pneumoniae* bacteria. These bacteria can spread from person to person through close contact.

Pneumococcal disease can lead to severe health problems, including pneumonia, blood infections, and meningitis.

Meningitis is an infection of the covering of the brain. Pneumococcal meningitis is fairly rare (less than 1 case per 100,000 people each year), but it leads to other health problems, including deafness and brain damage. In children, it is fatal in about 1 case out of 10.

Children younger than two are at higher risk for serious disease than older children.

People with certain medical conditions, people over age 65, and cigarette smokers are also at higher risk.

Before vaccine, pneumococcal infections caused many problems each year in the United States in children younger than 5, including:

- more than 700 cases of meningitis,
- 13,000 blood infections,
- about 5 million ear infections, and
- about 200 deaths.

About 4,000 adults still die each year because of pneumococcal infections.

Pneumococcal infections can be hard to treat because some strains are resistant to antibiotics. This makes **prevention through vaccination** even more important.

2 PCV13 vaccine

There are more than 90 types of pneumococcal bacteria. PCV13 protects against 13 of them. These 13 strains cause most severe infections in children and about half of infections in adults.

PCV13 is routinely given to children at 2, 4, 6, and 12–15 months of age. Children in this age range are at greatest risk for serious diseases caused by pneumococcal infection.

PCV13 vaccine may also be recommended for some older children or adults. Your doctor can give you details.

A second type of pneumococcal vaccine, called PPSV23, may also be given to some children and adults, including anyone over age 65. There is a separate Vaccine Information Statement for this vaccine.

3 Precautions

Anyone who has ever had a life-threatening allergic reaction to a dose of this vaccine, to an earlier pneumococcal vaccine called PCV7 (or Prevnar), or to any vaccine containing diphtheria toxoid (for example, DTaP), should not get PCV13.

Anyone with a severe allergy to any component of PCV13 should not get the vaccine. Tell your doctor if the person being vaccinated has any severe allergies.

If the person scheduled for vaccination is sick, your doctor might decide to reschedule the shot on another day.

Your doctor can give you more information about any of these precautions.



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4 What are the risks of PCV13 vaccine?

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Reported problems associated with PCV13 vary by dose and age, but generally:

- About half of children became drowsy after the shot, had a temporary loss of appetite, or had redness or tenderness where the shot was given.
- About 1 out of 3 had swelling where the shot was given.
- About 1 out of 3 had a mild fever, and about 1 in 20 had a higher fever (over 102.2°F).
- Up to about 8 out of 10 became fussy or irritable.

Adults receiving the vaccine have reported redness, pain, and swelling where the shot was given. Mild fever, fatigue, headache, chills, or muscle pain have also been reported.

Life-threatening allergic reactions from any vaccine are very rare.

5 What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

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- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

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