VACCINE INFORMATION STATEMENT

Pneumococcal Conjugate Vaccine

What You Need to Know

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.
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.

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?

- 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.

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.

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) or
  - Visit CDC’s website at www.cdc.gov/vaccines