

PNEUMOCOCCAL CONJUGATE VACCINE

WHAT YOU NEED TO KNOW

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

1 Pneumococcal disease

Infection with *Streptococcus pneumoniae* bacteria can make children very sick.

It causes blood infections, pneumonia, and meningitis, mostly in young children. (Meningitis is an infection of the covering of the brain.) Although pneumococcal meningitis is relatively rare (less than 1 case per 100,000 people each year), it is fatal in about 1 of 10 cases in children.

Pneumococcal meningitis can also lead to other health problems, including deafness and brain damage.

Before routine use of pneumococcal conjugate vaccine, pneumococcal infections caused:

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

annually in the United States in children under five.

Children younger than 2 years of age are at higher risk for serious disease than older children.

Pneumococcal bacteria are spread from person to person through close contact.

Pneumococcal infections may be hard to treat because some strains of the bacteria have become resistant to the drugs that are used to treat them. This makes **prevention** of pneumococcal infections through vaccination even more important.

2 Pneumococcal conjugate vaccine (PCV13)

There are more than 90 types of pneumococcal bacteria. The new pneumococcal conjugate vaccine (PCV13) protects against 13 of them. These bacteria types are responsible for most severe pneumococcal infections among children. PCV13 replaces a previous conjugate vaccine (PCV7), which protected against 7 pneumococcal types and has been in use since 2000. During that time severe pneumococcal disease dropped by nearly 80% among children under 5.

PCV13 may also prevent some cases of pneumonia and some ear infections. But pneumonia and ear infections have many causes, and PCV13 only works against the types of pneumococcal bacteria targeted by the vaccine.

PCV13 is given to infants and toddlers, to protect them when they are at greatest risk for serious diseases caused by pneumococcal bacteria.

In addition to receiving PCV13, older children with certain chronic illnesses may get a different vaccine called PPSV23. There is a separate Vaccine Information Statement for that vaccine.

3 Who should get PCV13, and when?

Infants and Children Under 2 Years of Age

PCV13 is recommended as a series of **4 doses**, one dose at each of these ages: 2 months, 4 months, 6 months, and 12 through 15 months

Children who miss their shots at these ages should still get the vaccine. The number of doses and the intervals between doses will depend on the child's age. Ask your health care provider for details.

Children who have begun their immunization series with PCV7 should complete the series with PCV13.

Older Children and Adolescents

- Healthy children between their 2nd and 5th birthdays who have not completed the PCV7 or PCV13 series before age 2 years should get 1 dose.
- Children between the 2nd and 6th birthdays with medical conditions such as:
 - sickle cell disease,
 - a damaged spleen or no spleen,
 - cochlear implants,
 - diabetes,
 - HIV/AIDS or other diseases that affect the immune system (such as cancer, or liver disease), or
 - chronic heart or lung disease,or who take medications that affect the immune system, such as immunosuppressive drugs or steroids, should get **1 dose of PCV 13** (if they received 3

doses of PCV7 or PCV13 before age 2 years), or **2 doses of PCV13** (if they have received 2 or fewer doses of PCV7 or PCV13).

A dose of PCV13 may be administered to children and adolescents 6 through 18 years of age who have certain medical conditions, even if they have previously received PCV7 or PPSV23.

Children who have completed the 4-dose series with PCV7: Healthy children who have not yet turned 5, and children with medical conditions who have not yet turned 6, should get one additional dose of PCV13.

Ask your health care provider if you have questions about any of these recommendations.

PCV13 may be given at the same time as other vaccines.

4 Some children should not get PCV13 or should wait

Children should not get PCV13 if they had a serious (life-threatening) allergic reaction to a previous dose of this vaccine, to PCV7, or to any vaccine containing diphtheria toxoid (for example, DTaP).

Children who are known to have a severe allergy to any component of PCV7 or PCV13 should not get PCV13. Tell your health care provider if your child has any severe allergies.

Children with minor illnesses, such as a cold, may be vaccinated. But children who are moderately or severely ill should usually wait until they recover before getting the vaccine.

5 What are the risks from PCV13?

Any medicine, including a vaccine, could possibly cause a serious problem, such as a severe allergic reaction. However, the risk of any vaccine causing serious harm, or death, is extremely small.

In studies, most reactions after PCV13 were mild. They were similar to reactions reported after PCV7, which has been in use since 2000. Reported reactions varied by dose and age, but on average:

- About half of children were 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.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.

6 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell the doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS website at: <http://www.vaers.hhs.gov>, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine may file a claim with VICP by calling **1-800-338-2382** or visiting their website at <http://www.hrsa.gov/vaccinecompensation>.

8 How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- 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 <http://www.cdc.gov/vaccines>.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Vaccine Information Statement (Interim)

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