

VACCINE INFORMATION STATEMENT

Pneumococcal Conjugate Vaccine (PCV13)

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?

Vaccination can protect both children and adults from **pneumococcal disease**.

Pneumococcal disease is caused by bacteria that can spread from person to person through close contact. It can cause ear infections, and it can also lead to more serious infections of the:

- Lungs (pneumonia),
- Blood (bacteremia), and
- Covering of the brain and spinal cord (meningitis).

Pneumococcal pneumonia is most common among adults. Pneumococcal meningitis can cause deafness and brain damage, and it kills about 1 child in 10 who get it.

Anyone can get pneumococcal disease, but children under 2 years of age and adults 65 years and older, people with certain medical conditions, and cigarette smokers are at the highest risk.

Before there was a vaccine, the United States saw:

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

in children under 5 each year from pneumococcal disease. Since vaccine became available, severe pneumococcal disease in these children has fallen by 88%.

About 18,000 older adults die of pneumococcal disease each year in the United States.

Treatment of pneumococcal infections with penicillin and other drugs is not as effective as it used to be, because some strains of the disease have become resistant to these drugs. This makes prevention of the disease, through vaccination, even more important.

2 PCV13 vaccine

Pneumococcal conjugate vaccine (called PCV13) protects against 13 types of pneumococcal bacteria.

PCV13 is routinely given to children at 2, 4, 6, and 12–15 months of age. It is also recommended for children and adults 2 to 64 years of age with certain health conditions, and for all adults 65 years of age and older. Your doctor can give you details.

3 Some people should not get this vaccine

Anyone who has ever had a life-threatening allergic reaction to a dose of this vaccine, to an earlier pneumococcal vaccine called PCV7, 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 not feeling well, your healthcare provider might decide to reschedule the shot on another day.

4 Risks of a vaccine reaction

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

Problems reported following PCV13 varied by age and dose in the series. The most common problems reported among children were:

- About half 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 fever over 102.2°F.
- Up to about 8 out of 10 became fussy or irritable.

Adults have reported pain, redness, and swelling where the shot was given; also mild fever, fatigue, headache, chills, or muscle pain.

Young children who get PCV13 along with inactivated flu vaccine at the same time may be at increased risk for seizures caused by fever. Ask your doctor for more information.



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Problems that could happen after any vaccine:

- People sometimes faint after a 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 you feel dizzy, or have vision changes or ringing in the ears.
- Some older children and adults get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very small chance of a vaccine causing a serious injury or death.

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 unusual behavior.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness—usually within 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.

Reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should 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 does 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. There is a time limit to file a claim for compensation.

7

How can I learn more?

- Ask your healthcare provider. He or she 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 www.cdc.gov/vaccines

Vaccine Information Statement
PCV13 Vaccine

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VACCINE INFORMATION STATEMENT

Varicella (Chickenpox) Vaccine: What You Need to Know

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

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

1 Why get vaccinated?

Varicella (also called chickenpox) is a very contagious viral disease. It is caused by the varicella zoster virus. Chickenpox is usually mild, but it can be serious in infants under 12 months of age, adolescents, adults, pregnant women, and people with weakened immune systems.

Chickenpox causes an itchy rash that usually lasts about a week. It can also cause:

- fever
- tiredness
- loss of appetite
- headache

More serious complications can include:

- skin infections
- infection of the lungs (pneumonia)
- inflammation of blood vessels
- swelling of the brain and/or spinal cord coverings (encephalitis or meningitis)
- blood stream, bone, or joint infections

Some people get so sick that they need to be hospitalized. It doesn't happen often, but people can die from chickenpox. Before varicella vaccine, almost everyone in the United States got chickenpox, an average of 4 million people each year.

Children who get chickenpox usually miss at least 5 or 6 days of school or childcare.

Some people who get chickenpox get a painful rash called shingles (also known as herpes zoster) years later.

Chickenpox can spread easily from an infected person to anyone who has not had chickenpox and has not gotten chickenpox vaccine.

2 Chickenpox vaccine

Children 12 months through 12 years of age should get 2 doses of chickenpox vaccine, usually:

- First dose: 12 through 15 months of age
- Second dose: 4 through 6 years of age

People 13 years of age or older who didn't get the vaccine when they were younger, and have never had chickenpox, should get 2 doses at least 28 days apart.

A person who previously received only one dose of chickenpox vaccine should receive a second dose to complete the series. The second dose should be given at least 3 months after the first dose for those younger than 13 years,

and at least 28 days after the first dose for those 13 years of age or older.

There are no known risks to getting chickenpox vaccine at the same time as other vaccines.

There is a combination vaccine called **MMRV** that contains both chickenpox and MMR vaccines. MMRV is an option for some children 12 months through 12 years of age. There is a separate Vaccine Information Statement for MMRV. Your health care provider can give you more information.

3 Some people should not get this vaccine

Tell your vaccine provider if the person getting the vaccine:

- **Has any severe, life-threatening allergies.** A person who has ever had a life-threatening allergic reaction after a dose of chickenpox vaccine, or has a severe allergy to any part of this vaccine, may be advised not to be vaccinated. Ask your health care provider if you want information about vaccine components.
- **Is pregnant, or thinks she might be pregnant.** Pregnant women should wait to get chickenpox vaccine until after they are no longer pregnant. Women should avoid getting pregnant for at least 1 month after getting chickenpox vaccine.
- **Has a weakened immune system** due to disease (such as cancer or HIV/AIDS) or medical treatments (such as radiation, immunotherapy, steroids, or chemotherapy).
- **Has a parent, brother, or sister with a history of immune system problems.**
- **Is taking salicylates (such as aspirin).** People should avoid using salicylates for 6 weeks after getting varicella vaccine.
- **Has recently had a blood transfusion or received other blood products.** You might be advised to postpone chickenpox vaccination for 3 months or more.
- **Has tuberculosis.**



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- **Has gotten any other vaccines in the past 4 weeks.** Live vaccines given too close together might not work as well.
- **Is not feeling well.** A mild illness, such as a cold, is usually not a reason to postpone a vaccination. Someone who is moderately or severely ill should probably wait. Your doctor can advise you.

4 Risks of a vaccine reaction

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

Getting chickenpox vaccine is much safer than getting chickenpox disease. Most people who get chickenpox vaccine do not have any problems with it.

After chickenpox vaccination, a person might experience:

Minor events:

- Sore arm from the injection
- Fever
- Redness or rash at the injection site

If these events happen, they usually begin within 2 weeks after the shot. They occur less often after the second dose.

More serious events following chickenpox vaccination are rare. They can include:

- Seizure (jerking or staring) often associated with fever
- Infection of the lungs (pneumonia) or the brain and spinal cord coverings (meningitis)
- Rash all over the body

A person who develops a rash after chickenpox vaccination might be able to spread the varicella vaccine virus to an unprotected person. Even though this happens very rarely, anyone who gets a rash should stay away from people with weakened immune systems and unvaccinated infants until the rash goes away. Talk with your health care provider to learn more.

Other things that could happen after this vaccine:

- People sometimes faint after medical procedures, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting and injuries caused by a fall. Tell your doctor if you feel dizzy or have vision changes or ringing in the ears.
- Some people get shoulder pain that can be more severe and longer-lasting than routine soreness that can follow injections. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions to a vaccine are estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

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

5 What if there is a serious problem?

What should I look for?

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

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 and get to the nearest hospital. Otherwise, call your health care provider.

Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should 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 does 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. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your health care provider. He or she 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 www.cdc.gov/vaccines

Vaccine Information Statement Varicella Vaccine

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VACCINE INFORMATION STATEMENT

MMR (Measles, Mumps, and Rubella) Vaccine: *What You Need to Know*

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

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1 Why get vaccinated?

Measles, mumps, and rubella are viral diseases that can have serious consequences. Before vaccines, these diseases were very common in the United States, especially among children. They are still common in many parts of the world.

Measles

- Measles virus causes symptoms that can include fever, cough, runny nose, and red, watery eyes, commonly followed by a rash that covers the whole body.
- Measles can lead to ear infections, diarrhea, and infection of the lungs (pneumonia). Rarely, measles can cause brain damage or death.

Mumps

- Mumps virus causes fever, headache, muscle aches, tiredness, loss of appetite, and swollen and tender salivary glands under the ears on one or both sides.
- Mumps can lead to deafness, swelling of the brain and/or spinal cord covering (encephalitis or meningitis), painful swelling of the testicles or ovaries, and, very rarely, death.

Rubella (also known as German Measles)

- Rubella virus causes fever, sore throat, rash, headache, and eye irritation.
- Rubella can cause arthritis in up to half of teenage and adult women.
- If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

These diseases can easily spread from person to person. Measles doesn't even require personal contact. You can get measles by entering a room that a person with measles left up to 2 hours before.

Vaccines and high rates of vaccination have made these diseases much less common in the United States.

2 MMR vaccine

Children should get 2 doses of MMR vaccine, usually:

- First dose: 12 through 15 months of age
- Second dose: 4 through 6 years of age

Infants who will be traveling outside the United States when they are between 6 and 11 months of age should get a dose of MMR vaccine before travel. This can provide temporary protection from measles infection, but will not

give permanent immunity. The child should still get 2 doses at the recommended ages for long-lasting protection.

Adults might also need MMR vaccine. Many adults 18 years of age and older might be susceptible to measles, mumps, and rubella without knowing it.

A third dose of MMR might be recommended in certain mumps outbreak situations.

There are no known risks to getting MMR vaccine at the same time as other vaccines.

There is a combination vaccine called **MMRV** that contains both chickenpox and MMR vaccines. MMRV is an option for some children 12 months through 12 years of age. There is a separate Vaccine Information Statement for MMRV. Your health care provider can give you more information.

3 Some people should not get this vaccine

Tell your vaccine provider if the person getting the vaccine:

- **Has any severe, life-threatening allergies.** A person who has ever had a life-threatening allergic reaction after a dose of MMR vaccine, or has a severe allergy to any part of this vaccine, may be advised not to be vaccinated. Ask your health care provider if you want information about vaccine components.
- **Is pregnant, or thinks she might be pregnant.** Pregnant women should wait to get MMR vaccine until after they are no longer pregnant. Women should avoid getting pregnant for at least 1 month after getting MMR vaccine.
- **Has a weakened immune system** due to disease (such as cancer or HIV/AIDS) or medical treatments (such as radiation, immunotherapy, steroids, or chemotherapy).
- **Has a parent, brother, or sister with a history of immune system problems.**
- **Has ever had a condition that makes them bruise or bleed easily.**
- **Has recently had a blood transfusion or received other blood products.** You might be advised to postpone MMR vaccination for 3 months or more.



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- **Has tuberculosis.**
- **Has gotten any other vaccines in the past 4 weeks.** Live vaccines given too close together might not work as well.
- **Is not feeling well.** A mild illness, such as a cold, is usually not a reason to postpone a vaccination. Someone who is moderately or severely ill should probably wait. Your doctor can advise you.

4 Risks of a vaccine reaction

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

Getting MMR vaccine is much safer than getting measles, mumps, or rubella disease. Most people who get MMR vaccine do not have any problems with it.

After MMR vaccination, a person might experience:

Minor events:

- Sore arm from the injection
- Fever
- Redness or rash at the injection site
- Swelling of glands in the cheeks or neck

If these events happen, they usually begin within 2 weeks after the shot. They occur less often after the second dose.

Moderate events:

- Seizure (jerking or staring) often associated with fever
- Temporary pain and stiffness in the joints, mostly in teenage or adult women
- Temporary low platelet count, which can cause unusual bleeding or bruising
- Rash all over body

Severe events occur very rarely:

- Deafness
- Long-term seizures, coma, or lowered consciousness
- Brain damage

Other things that could happen after this vaccine:

- People sometimes faint after medical procedures, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting and injuries caused by a fall. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.
- Some people get shoulder pain that can be more severe and longer-lasting than routine soreness that can follow injections. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions to a vaccine are estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

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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?

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Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should 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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Vaccine Information Statement MMR Vaccine

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