

# Vaccine Information Statements

## Please Read!

Age: \_\_\_\_\_ Date: \_\_\_\_\_

### Check-up and Immunization Schedule

Age	Check-up*	Immunizations/Tests Due
2 wk.	within 3 days	Hep B #1 (if not given in hospital)
2 mo.	within 1 week	Pentacel #1; Hep B #2; Prevnar #1; Rotavirus #1 Maternal Depression Screen
4 mo.	within 2 weeks	Pentacel #2; Prevnar #2; Rotavirus #2 Maternal Depression Screen
6 mo.	within 3 weeks	Pentacel #3; Prevnar #3; Rotavirus #3 OAE Hearing & Spot Vision Screens Maternal Depression Screen
9 mo.	within 3 weeks	Hep B #3 Developmental Screen
12 mo.	MUST be after 1 yr. b'day	MMR #1; Varicella #1 OAE Hearing & Spot Vision Screens; CBC Lead Screen (if indicated)
15 mo.	within 3 weeks	Prevnar #4; Hep A #1
18 mo.	within 3 weeks	Pentacel #4 Developmental Screen
2 yr.	within 2 mo.	Hep A #2 Developmental Screen Anemia Screen w/CBC (if indicated)
30 mo.	within 2 mo.	Developmental Screen Anemia Screen w/CBC (if indicated)
3 yr.	within 2 mo.	OAE Hearing & Spot Vision Screens Anemia Screen w/CBC (if indicated)
4 yr.	MUST be after 4 yr. b'day	MMR #2; Varicella #2; Quadracel Hearing & Spot Vision Screens Anemia Screen w/CBC (if indicated)

\*Time specified can either be before or after date of the specified age.

#### Vaccines

Hep A/B=Hepatitis A/B  
DTaP=Diphtheria, Tetanus, Pertussis  
IPV=Inactivated Polio Vaccine  
MMR=Measles, Mumps, Rubella  
Pentacel=DTaP, Polio, Hib  
Prevnar=Pneumococcal Vaccine  
Td=Tetanus, Diphtheria  
Tdap=Tetanus, Diphtheria, Pertussis  
Quadracel=DTaP, Polio

Age	Check-up*	Immunizations/Tests Due
5 yr.	yearly	Hearing & Titmus Vision Screens Anemia Screen w/CBC (if indicated)
6 yr.	yearly	Hearing & Titmus Vision Screens Anemia Screen w/CBC (if indicated)
7 yr.	yearly	-----
8 yr.	yearly	Hearing & Vision Screens Anemia Screen w/CBC (if indicated)
9 yr.	yearly	-----
10 yr.	yearly	Hearing & Vision Screens Anemia Screen w/CBC (if indicated) Lipid Panel
11 yr.	yearly	Tdap; Meningococcal #1; HPV Series Anemia Screen w/CBC (if indicated)
12-21 yrs.	yearly	Anemia Screen w/CBC (if indicated) 12, 15, 18 yrs. Hearing & Vision Screens 13 & up Adolescent Confidential Questionnaire 16 yr. Meningococcal #2 17 yr. Lipid Panel 21 yr. Td HPV Series if not already completed
ALL		Flu vaccine yearly for all patients 6 mos. & older

#### Tests

CBC=Complete Blood Count  
OAE=Otoacoustic Emissions

- 1) Please scan this QR code with phone's camera and click on the link.
- 2) Click on "Vaccine Information Statements" located under "Schedule of Visits" for very important information about your child's vaccines.
- 3) The Vaccine Information Statements are available via our website: [northsidepediatrics.com](http://northsidepediatrics.com). Go to Services --> Well Visits --> click on "Vaccine Information Statements" located under "Schedule of Visits".



## Vaccine Safety: The Facts

Some people have expressed concerns about vaccine safety. **The fact is vaccines save lives and protect against the spread of disease.** If you decide not to immunize, you're not only putting your child at risk to catch a disease that is dangerous or deadly but also putting others in contact with your child at risk. Getting vaccinated is much better than getting the disease.

Indeed, some of the most devastating diseases that affect children have been greatly reduced or eradicated completely thanks to vaccination.

**Today, we protect children and teens from [16 diseases](#) that can have a terrible effect on their young victims if left unvaccinated.**



Your pediatrician knows that you care about your child's health and safety. That's why you need to get all the scientific facts from a medical professional you can trust before making any decisions based on stories you may have seen or heard on TV, the Internet, or from other parents.

**Your pediatrician cares about your child, too, and wants you to know that...**

- **Vaccines work.** They have kept children healthy and have saved millions of lives for more than 50 years. Most childhood vaccines are 90% to 99% [effective in preventing disease](#). And if a vaccinated child does get the disease, the symptoms are usually less serious than in a child who hasn't been vaccinated. There may be mild side effects, like swelling where the shot was given, but they do not last long. And it is [rare for side effects to be serious](#).
- **Vaccines are safe.** Before a vaccine is licensed in the United States, the Food and Drug Administration (FDA) reviews all aspects of development, including where and how the vaccine is made and the studies that have been conducted in people who received the vaccine. The FDA will not license a vaccine unless it meets standards for effectiveness (how well the vaccine works) and safety. Results of studies get reviewed again by the Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics, and the American Academy of Family Physicians before a licensed vaccine is officially recommended to be given to children. Every lot of vaccine is tested to ensure quality (including safety) before the vaccine reaches the public. In addition, FDA regularly inspects places where vaccines are made.

Watch the Journey of Your Child's Vaccine @ <https://youtu.be/Fcvgp6gNh6o>.

Learn about the three phases of clinical trials, vaccine licensing and manufacturing, how a vaccine is added to the U.S. Recommended Immunization Schedule, and how FDA and CDC monitor vaccine safety after the public begins using the vaccine.

- **Vaccines are necessary.** Your pediatrician believes that your children should receive [all recommended childhood vaccines](#). In the United States vaccines have protected children and continue to protect children from many diseases. However, in many parts of the world many vaccine-preventable diseases that are rarely seen in the United States are still common. Since some vaccine-preventable diseases still occur in the United States and others may be brought

into the United States by Americans who travel abroad or from people visiting areas with current disease outbreaks, it's important that your children are vaccinated.

- **Vaccines are studied.** To monitor the safety of vaccines after licensure, the FDA and the CDC created the Vaccine Adverse Event Reporting System (VAERS). All doctors must report certain side effects of vaccines to VAERS. Parents can also file reports with VAERS. For more information about VAERS, visit [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call the toll-free VAERS information line at 800/822-7967. Other systems exist to further study vaccine safety concerns if they are identified in VAERS by FDA and CDC.

### **Protection for everyone**

Just as important as the initial vaccinations are the booster shots. These are designed to continue immunity by building on the previous vaccines' effectiveness. Unfortunately, some parents forget or skip the boosters, which undercut the effectiveness of a very important concept in vaccination: *herd immunity*. Herd immunity is the benefit everyone receives from a vaccinated population once immunization reaches a critical level. When enough people are vaccinated, everyone—including those who are [too young](#) or too sick to be immunized—receives some protection from the spread of diseases. However, relying on herd immunity to keep your child safe is risky. The more parents that follow this way of thinking, the fewer vaccinated children we will have, and the more likely a serious disease will return and infect all of those unvaccinated.

In the rare case that a child has serious side effects to a vaccine, parents can contact the National Vaccine Injury Compensation Program (VICP) at 800/338-2382 or [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation). This federal program was created to help pay for the care of people who have been harmed.

If you have any additional questions or concerns, feel free to ask your pediatrician.

### **Additional Information & Resources:**

- [Vaccine Studies: Examine the Evidence](#)
- [Vaccines Your Child Needs](#)
- [Weighing the Risks and Benefits](#)
- [www.fda.gov](http://www.fda.gov) (Food and Drug Administration)
- [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines) (Centers for Disease Control and Prevention)

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Source: Adapted from Healthy Children E-Magazine, Back to School 2012

# Your Child's First Vaccines:

## What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

The vaccines included on this statement are likely to be given at the same time during infancy and early childhood. There are separate Vaccine Information Statements for other vaccines that are also routinely recommended for young children (measles, mumps, rubella, varicella, rotavirus, influenza, and hepatitis A).

### Your child is getting these vaccines today:

☐ DTaP      ☐ Hib      ☐ Hepatitis B      ☐ Polio      ☐ PCV13

(Provider: Check appropriate boxes.)

## 1. Why get vaccinated?

Vaccines can prevent disease. Childhood vaccination is essential because it helps provide immunity before children are exposed to potentially life-threatening diseases.

### Diphtheria, tetanus, and pertussis (DTaP)

- **Diphtheria (D)** can lead to difficulty breathing, heart failure, paralysis, or death.
- **Tetanus (T)** causes painful stiffening of the muscles. Tetanus can lead to serious health problems, including being unable to open the mouth, having trouble swallowing and breathing, or death.
- **Pertussis (aP)**, also known as “whooping cough,” can cause uncontrollable, violent coughing that makes it hard to breathe, eat, or drink. Pertussis can be extremely serious especially in babies and young children, causing pneumonia, convulsions, brain damage, or death. In teens and adults, it can cause weight loss, loss of bladder control, passing out, and rib fractures from severe coughing.

### Hib (*Haemophilus influenzae* type b) disease

*Haemophilus influenzae* type b can cause many different kinds of infections. These infections usually affect children under 5 years of age but can also affect adults with certain medical conditions. Hib bacteria can cause mild illness, such as ear infections

or bronchitis, or they can cause severe illness, such as infections of the blood. Severe Hib infection, also called “invasive Hib disease,” requires treatment in a hospital and can sometimes result in death.

### Hepatitis B

**Hepatitis B** is a liver disease that can cause mild illness lasting a few weeks, or it can lead to a serious, lifelong illness. Acute hepatitis B infection is a short-term illness that can lead to fever, fatigue, loss of appetite, nausea, vomiting, jaundice (yellow skin or eyes, dark urine, clay-colored bowel movements), and pain in the muscles, joints, and stomach. Chronic hepatitis B infection is a long-term illness that occurs when the hepatitis B virus remains in a person's body. Most people who go on to develop chronic hepatitis B do not have symptoms, but it is still very serious and can lead to liver damage (cirrhosis), liver cancer, and death.

### Polio

**Polio** (or poliomyelitis) is a disabling and life-threatening disease caused by poliovirus, which can infect a person's spinal cord, leading to paralysis. Most people infected with poliovirus have no symptoms, and many recover without complications. Some people will experience sore throat, fever, tiredness, nausea, headache, or stomach pain.



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A smaller group of people will develop more serious symptoms: paresthesia (feeling of pins and needles in the legs), meningitis (infection of the covering of the spinal cord and/or brain), or paralysis (can't move parts of the body) or weakness in the arms, legs, or both. Paralysis can lead to permanent disability and death.

### **Pneumococcal disease**

**Pneumococcal disease** refers to any illness caused by pneumococcal bacteria. These bacteria can cause many types of illnesses, including pneumonia, which is an infection of the lungs. Besides pneumonia, pneumococcal bacteria can also cause ear infections, sinus infections, meningitis (infection of the tissue covering the brain and spinal cord), and bacteremia (infection of the blood). Most pneumococcal infections are mild. However, some can result in long-term problems, such as brain damage or hearing loss. Meningitis, bacteremia, and pneumonia caused by pneumococcal disease can be fatal.

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## **2. DTaP, Hib, hepatitis B, polio, and pneumococcal conjugate vaccines**

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**Infants and children** usually need:

- 5 doses of **diphtheria, tetanus, and acellular pertussis vaccine (DTaP)**
- 3 or 4 doses of **Hib vaccine**
- 3 doses of **hepatitis B vaccine**
- 4 doses of **polio vaccine**
- 4 doses of **pneumococcal conjugate vaccine (PCV13)**

Some children might need fewer or more than the usual number of doses of some vaccines to be fully protected because of their age at vaccination or other circumstances.

**Older children, adolescents, and adults** with certain health conditions or other risk factors might also be recommended to receive 1 or more doses of some of these vaccines.

These vaccines may be given as stand-alone vaccines, or as part of a combination vaccine (a type of vaccine that combines more than one vaccine together into one shot).

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## **3. Talk with your health care provider**

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Tell your vaccination provider if the child getting the vaccine:

### **For all of these vaccines:**

- Has had an **allergic reaction after a previous dose of the vaccine**, or has any **severe, life-threatening allergies**

### **For DTaP:**

- Has had an **allergic reaction after a previous dose of any vaccine that protects against tetanus, diphtheria, or pertussis**
- Has had a **coma, decreased level of consciousness, or prolonged seizures within 7 days after a previous dose of any pertussis vaccine (DTP or DTaP)**
- Has **seizures or another nervous system problem**
- Has ever had **Guillain-Barré Syndrome** (also called “GBS”)
- Has had **severe pain or swelling after a previous dose of any vaccine that protects against tetanus or diphtheria**

### **For PCV13:**

- Has had an **allergic reaction after a previous dose of PCV13, to an earlier pneumococcal conjugate vaccine known as PCV7, or to any vaccine containing diphtheria toxoid** (for example, DTaP)

In some cases, your child's health care provider may decide to postpone vaccination until a future visit.

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

Your child's health care provider can give you more information.

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## 4. Risks of a vaccine reaction

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### For all of these vaccines:

- Soreness, redness, swelling, warmth, pain, or tenderness where the shot is given can happen after vaccination.

### For DTaP vaccine, Hib vaccine, hepatitis B vaccine, and PCV13:

- Fever can happen after vaccination.

### For DTaP vaccine:

- Fussiness, feeling tired, loss of appetite, and vomiting sometimes happen after DTaP vaccination.
- More serious reactions, such as seizures, non-stop crying for 3 hours or more, or high fever (over 105°F) after DTaP vaccination happen much less often. Rarely, vaccination is followed by swelling of the entire arm or leg, especially in older children when they receive their fourth or fifth dose.

### For PCV13:

- Loss of appetite, fussiness (irritability), feeling tired, headache, and chills can happen after PCV13 vaccination.
- Young children may be at increased risk for seizures caused by fever after PCV13 if it is administered at the same time as inactivated influenza vaccine. Ask your health care provider for more information.

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

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## 5. What if there is a serious problem?

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An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

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## 6. The National Vaccine Injury Compensation Program

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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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation) or call **1-800-338-2382** to learn about the program and about filing a claim.

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## 7. How can I learn more?

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- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at [www.fda.gov/vaccines-blood-biologics/vaccines](http://www.fda.gov/vaccines-blood-biologics/vaccines).
- 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](http://www.cdc.gov/vaccines).





# Hepatitis B Vaccine:

## *What You Need to Know*

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Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

### 1 Why get vaccinated?

**Hepatitis B vaccine** can prevent **hepatitis B**.

Hepatitis B is a liver disease that can cause mild illness lasting a few weeks, or it can lead to a serious, lifelong illness.

- **Acute hepatitis B infection** is a short-term illness that can lead to fever, fatigue, loss of appetite, nausea, vomiting, jaundice (yellow skin or eyes, dark urine, clay-colored bowel movements), and pain in the muscles, joints, and stomach.
- **Chronic hepatitis B infection** is a long-term illness that occurs when the hepatitis B virus remains in a person's body. Most people who go on to develop chronic hepatitis B do not have symptoms, but it is still very serious and can lead to liver damage (cirrhosis), liver cancer, and death. Chronically-infected people can spread hepatitis B virus to others, even if they do not feel or look sick themselves.

Hepatitis B is spread when blood, semen, or other body fluid infected with the hepatitis B virus enters the body of a person who is not infected. People can become infected through:

- Birth (if a mother has hepatitis B, her baby can become infected)
- Sharing items such as razors or toothbrushes with an infected person
- Contact with the blood or open sores of an infected person
- Sex with an infected partner
- Sharing needles, syringes, or other drug-injection equipment
- Exposure to blood from needlesticks or other sharp instruments

Most people who are vaccinated with hepatitis B vaccine are immune for life.

### 2 Hepatitis B vaccine

Hepatitis B vaccine is usually given as 2, 3, or 4 shots.

**Infants** should get their first dose of hepatitis B vaccine at birth and will usually complete the series at 6 months of age (sometimes it will take longer than 6 months to complete the series).

**Children and adolescents** younger than 19 years of age who have not yet gotten the vaccine should also be vaccinated.

Hepatitis B vaccine is also recommended for certain **unvaccinated adults**:

- People whose sex partners have hepatitis B
- Sexually active persons who are not in a long-term monogamous relationship
- Persons seeking evaluation or treatment for a sexually transmitted disease
- Men who have sexual contact with other men
- People who share needles, syringes, or other drug-injection equipment
- People who have household contact with someone infected with the hepatitis B virus
- Health care and public safety workers at risk for exposure to blood or body fluids
- Residents and staff of facilities for developmentally disabled persons
- Persons in correctional facilities
- Victims of sexual assault or abuse
- Travelers to regions with increased rates of hepatitis B
- People with chronic liver disease, kidney disease, HIV infection, infection with hepatitis C, or diabetes
- Anyone who wants to be protected from hepatitis B

Hepatitis B vaccine may be given at the same time as other vaccines.



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### 3 Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of hepatitis B vaccine**, or has any **severe, life-threatening allergies**.

In some cases, your health care provider may decide to postpone hepatitis B vaccination to a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting hepatitis B vaccine.

Your health care provider can give you more information.

### 4 Risks of a vaccine reaction

- Soreness where the shot is given or fever can happen after hepatitis B vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

### 5 What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff 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. Visit the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation) or call **1-800-338-2382** to learn about the program and about filing a claim. There is a time limit to file a claim for compensation.

### 7 How can I learn more?

- Ask your healthcare provider.
- 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 [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)

Vaccine Information Statement (Interim)  
**Hepatitis B Vaccine**



Office use only

8/15/2019 | 42 U.S.C. § 300aa-26



# DTaP (Diphtheria, Tetanus, Pertussis) Vaccine: *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

## 1. Why get vaccinated?

DTaP vaccine can prevent **diphtheria, tetanus, and pertussis**.

Diphtheria and pertussis spread from person to person. Tetanus enters the body through cuts or wounds.

- **DIPHTHERIA (D)** can lead to difficulty breathing, heart failure, paralysis, or death.
- **TETANUS (T)** causes painful stiffening of the muscles. Tetanus can lead to serious health problems, including being unable to open the mouth, having trouble swallowing and breathing, or death.
- **PERTUSSIS (aP)**, also known as “whooping cough,” can cause uncontrollable, violent coughing that makes it hard to breathe, eat, or drink. Pertussis can be extremely serious especially in babies and young children, causing pneumonia, convulsions, brain damage, or death. In teens and adults, it can cause weight loss, loss of bladder control, passing out, and rib fractures from severe coughing.

## 2. DTaP vaccine

DTaP is only for children younger than 7 years old. Different vaccines against tetanus, diphtheria, and pertussis (Tdap and Td) are available for older children, adolescents, and adults.

It is recommended that children receive 5 doses of DTaP, usually at the following ages:

- 2 months
- 4 months
- 6 months
- 15–18 months
- 4–6 years

DTaP may be given as a stand-alone vaccine, or as part of a combination vaccine (a type of vaccine that combines more than one vaccine together into one shot).

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

## 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of any vaccine that protects against tetanus, diphtheria, or pertussis**, or has any **severe, life-threatening allergies**
- Has had a **coma, decreased level of consciousness, or prolonged seizures within 7 days after a previous dose of any pertussis vaccine (DTP or DTaP)**
- Has **seizures or another nervous system problem**
- Has ever had **Guillain-Barré Syndrome** (also called “GBS”)
- Has had **severe pain or swelling after a previous dose of any vaccine that protects against tetanus or diphtheria**

In some cases, your child’s health care provider may decide to postpone DTaP vaccination until a future visit.

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

Your child’s health care provider can give you more information.



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## 4. Risks of a vaccine reaction

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- Soreness or swelling where the shot was given, fever, fussiness, feeling tired, loss of appetite, and vomiting sometimes happen after DTaP vaccination.
- More serious reactions, such as seizures, non-stop crying for 3 hours or more, or high fever (over 105°F) after DTaP vaccination happen much less often. Rarely, vaccination is followed by swelling of the entire arm or leg, especially in older children when they receive their fourth or fifth dose.

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

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## 5. What if there is a serious problem?

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An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

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## 6. The National Vaccine Injury Compensation Program

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## 7. How can I learn more?

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- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at [www.fda.gov/vaccines-blood-biologics/vaccines](http://www.fda.gov/vaccines-blood-biologics/vaccines).
- 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](http://www.cdc.gov/vaccines).



# Polio Vaccine:

## *What You Need to Know*

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### 1. Why get vaccinated?

**Polio vaccine** can prevent **polio**.

Polio (or poliomyelitis) is a disabling and life-threatening disease caused by poliovirus, which can infect a person's spinal cord, leading to paralysis.

Most people infected with poliovirus have no symptoms, and many recover without complications. Some people will experience sore throat, fever, tiredness, nausea, headache, or stomach pain.

A smaller group of people will develop more serious symptoms that affect the brain and spinal cord:

- Paresthesia (feeling of pins and needles in the legs),
- Meningitis (infection of the covering of the spinal cord and/or brain), or
- Paralysis (can't move parts of the body) or weakness in the arms, legs, or both.

Paralysis is the most severe symptom associated with polio because it can lead to permanent disability and death.

Improvements in limb paralysis can occur, but in some people new muscle pain and weakness may develop 15 to 40 years later. This is called "post-polio syndrome."

Polio has been eliminated from the United States, but it still occurs in other parts of the world. The best way to protect yourself and keep the United States polio-free is to maintain high immunity (protection) in the population against polio through vaccination.

### 2. Polio vaccine

**Children** should usually get 4 doses of polio vaccine at ages 2 months, 4 months, 6–18 months, and 4–6 years.

Most **adults** do not need polio vaccine because they were already vaccinated against polio as children. Some adults are at higher risk and should consider polio vaccination, including:

- People traveling to certain parts of the world
- Laboratory workers who might handle poliovirus
- Health care workers treating patients who could have polio
- Unvaccinated people whose children will be receiving oral poliovirus vaccine (for example, international adoptees or refugees)

Polio vaccine may be given as a stand-alone vaccine, or as part of a combination vaccine (a type of vaccine that combines more than one vaccine together into one shot).

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



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### 3. Talk with your health care provider

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Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of polio vaccine**, or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone polio vaccination until a future visit.

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

Not much is known about the risks of this vaccine for pregnant or breastfeeding people. However, polio vaccine can be given if a pregnant person is at increased risk for infection and requires immediate protection.

Your health care provider can give you more information.

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### 4. Risks of a vaccine reaction

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- A sore spot with redness, swelling, or pain where the shot is given can happen after polio vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

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### 5. What if there is a serious problem?

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An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

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### 6. The National Vaccine Injury Compensation Program

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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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation) or call **1-800-338-2382** to learn about the program and about filing a claim.

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### 7. How can I learn more?

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- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at [www.fda.gov/vaccines-blood-biologics/vaccines](http://www.fda.gov/vaccines-blood-biologics/vaccines).
- 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](http://www.cdc.gov/vaccines).



# *Haemophilus influenzae* type b (Hib) Vaccine: What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

## 1. Why get vaccinated?

**Hib vaccine** can prevent *Haemophilus influenzae* type b (Hib) disease.

*Haemophilus influenzae* type b can cause many different kinds of infections. These infections usually affect children under 5 years of age but can also affect adults with certain medical conditions. Hib bacteria can cause mild illness, such as ear infections or bronchitis, or they can cause severe illness, such as infections of the blood. Severe Hib infection, also called “invasive Hib disease,” requires treatment in a hospital and can sometimes result in death.

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 infection 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

## 2. Hib vaccine

Hib vaccine is usually given in 3 or 4 doses (depending on brand).

**Infants** will usually get their first dose of Hib vaccine at 2 months of age and will usually complete the series at 12–15 months of age.

**Children between 12 months and 5 years of age** who have not previously been completely vaccinated against Hib may need 1 or more doses of Hib vaccine.

**Children over 5 years old and adults** usually do not receive Hib vaccine, but it might be recommended for older children or adults whose spleen is damaged or has been removed, including people with sickle cell disease, before surgery to remove the spleen, or following a bone marrow transplant. Hib vaccine may also be recommended for people 5 through 18 years old with HIV.

Hib vaccine may be given as a stand-alone vaccine, or as part of a combination vaccine (a type of vaccine that combines more than one vaccine together into one shot).

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

## 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of Hib vaccine**, or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone Hib vaccination until a future visit.

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

Your health care provider can give you more information.



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## 4. Risks of a vaccine reaction

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- Redness, warmth, and swelling where the shot is given and fever can happen after Hib vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

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## 5. What if there is a serious problem?

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An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

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## 6. The National Vaccine Injury Compensation Program

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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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation) or call **1-800-338-2382** to learn about the program and about filing a claim.

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## 7. How can I learn more?

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- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at [www.fda.gov/vaccines-blood-biologics/vaccines](http://www.fda.gov/vaccines-blood-biologics/vaccines).
- 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](http://www.cdc.gov/vaccines).



# Pneumococcal Conjugate Vaccine: *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

## 1. Why get vaccinated?

Pneumococcal conjugate vaccine can prevent pneumococcal disease.

**Pneumococcal disease** refers to any illness caused by pneumococcal bacteria. These bacteria can cause many types of illnesses, including pneumonia, which is an infection of the lungs. Pneumococcal bacteria are one of the most common causes of pneumonia.

Besides pneumonia, pneumococcal bacteria can also cause:

- Ear infections
- Sinus infections
- Meningitis (infection of the tissue covering the brain and spinal cord)
- Bacteremia (infection of the blood)
- Anyone can get pneumococcal disease, but children under 2 years old, people with certain medical conditions or other risk factors, and adults 65 years or older are at the highest risk.

Most pneumococcal infections are mild. However, some can result in long-term problems, such as brain damage or hearing loss. Meningitis, bacteremia, and pneumonia caused by pneumococcal disease can be fatal.

## 2. Pneumococcal conjugate vaccine

Pneumococcal conjugate vaccine helps protect against bacteria that cause pneumococcal disease. There are three pneumococcal conjugate vaccines (PCV13, PCV15, and PCV20). The different vaccines are recommended for different people based on their age and medical status.

### PCV13

- **Infants and young children** usually need 4 doses of PCV13, at ages 2, 4, 6, and 12–15 months.
- **Older children (through age 59 months)** may be vaccinated with PCV13 if they did not receive the recommended doses.
- **Children and adolescents 6–18 years of age** with certain medical conditions should receive a single dose of PCV13 if they did not already receive PCV13.

### PCV15 or PCV20

- **Adults 19 through 64 years old** with certain medical conditions or other risk factors who have not already received a pneumococcal conjugate vaccine should receive either:
  - a single dose of PCV15 followed by a dose of pneumococcal polysaccharide vaccine (PPSV23), or
  - a single dose of PCV20.
- **Adults 65 years or older** who have not already received a pneumococcal conjugate vaccine should receive either:
  - a single dose of PCV15 followed by a dose of PPSV23, or
  - a single dose of PCV20.

Your health care provider can give you more information.



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### 3. Talk with your health care provider

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Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of any type of pneumococcal conjugate vaccine (PCV13, PCV15, PCV20, or an earlier pneumococcal conjugate vaccine known as PCV7), or to any vaccine containing diphtheria toxoid** (for example, DTaP), or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone pneumococcal conjugate vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover.

Your health care provider can give you more information.

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### 4. Risks of a vaccine reaction

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- Redness, swelling, pain, or tenderness where the shot is given, and fever, loss of appetite, fussiness (irritability), feeling tired, headache, muscle aches, joint pain, and chills can happen after pneumococcal conjugate vaccination.

Young children may be at increased risk for seizures caused by fever after PCV13 if it is administered at the same time as inactivated influenza vaccine. Ask your health care provider for more information.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

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### 5. What if there is a serious problem?

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An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call **1-800-822-7967**.

*VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

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### 6. The National Vaccine Injury Compensation Program

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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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation) or call **1-800-338-2382** to learn about the program and about filing a claim.

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### 7. How can I learn more?

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- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at [www.fda.gov/vaccines-blood-biologics/vaccines](http://www.fda.gov/vaccines-blood-biologics/vaccines).
- 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](http://www.cdc.gov/vaccines).



# Rotavirus Vaccine:

## *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

### 1. Why get vaccinated?

**Rotavirus vaccine** can prevent **rotavirus disease**.

Rotavirus commonly causes severe, watery diarrhea, mostly in babies and young children. Vomiting and fever are also common in babies with rotavirus. Children may become dehydrated and need to be hospitalized and can even die.

### 2. Rotavirus vaccine

Rotavirus vaccine is administered by putting drops in the child's mouth. Babies should get 2 or 3 doses of rotavirus vaccine, depending on the brand of vaccine used.

- The first dose must be administered before 15 weeks of age.
- The last dose must be administered by 8 months of age.

Almost all babies who get rotavirus vaccine will be protected from severe rotavirus diarrhea.

Another virus called "porcine circovirus" can be found in one brand of rotavirus vaccine (Rotarix). This virus does not infect people, and there is no known safety risk.

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

### 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of rotavirus vaccine**, or has any **severe, life-threatening allergies**
- Has a **weakened immune system**
- Has **severe combined immunodeficiency (SCID)**
- Has had a type of bowel blockage called "**intussusception**"

In some cases, your child's health care provider may decide to postpone rotavirus vaccination until a future visit.

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

Your child's health care provider can give you more information.

### 4. Risks of a vaccine reaction

- Irritability or mild, temporary diarrhea or vomiting can happen after rotavirus vaccine.

Intussusception is a type of bowel blockage that is treated in a hospital and could require surgery. It happens naturally in some infants every year in the United States, and usually there is no known reason for it. There is also a small risk of intussusception from rotavirus vaccination, usually within a week after the first or second vaccine dose. This additional risk is estimated to range from about 1 in 20,000 U.S. infants to 1 in 100,000 U.S. infants who get rotavirus vaccine. Your health care provider can give you more information.

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



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## 5. What if there is a serious problem?

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For intussusception, look for signs of stomach pain along with severe crying. Early on, these episodes could last just a few minutes and come and go several times in an hour. Babies might pull their legs up to their chest. Your baby might also vomit several times or have blood in the stool, or could appear weak or very irritable. These signs would usually happen during the first week after the first or second dose of rotavirus vaccine, but look for them any time after vaccination. If you think your baby has intussusception, contact a health care provider right away. If you can't reach your health care provider, take your baby to a hospital. Tell them when your baby got rotavirus vaccine.

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

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## 6. The National Vaccine Injury Compensation Program

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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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation) or call **1-800-338-2382** to learn about the program and about filing a claim.

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## 7. How can I learn more?

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- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at [www.fda.gov/vaccines-blood-biologics/vaccines](http://www.fda.gov/vaccines-blood-biologics/vaccines).
- 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](http://www.cdc.gov/vaccines).





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

Many vaccine information statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

## 1. Why get vaccinated?

MMR vaccine can prevent **measles, mumps, and rubella**.

- **MEASLES (M)** causes fever, cough, runny nose, and red, watery eyes, commonly followed by a rash that covers the whole body. It can lead to seizures (often associated with fever), ear infections, diarrhea, and pneumonia. Rarely, measles can cause brain damage or death.
- **MUMPS (M)** causes fever, headache, muscle aches, tiredness, loss of appetite, and swollen and tender salivary glands under the ears. It can lead to deafness, swelling of the brain and/or spinal cord covering, painful swelling of the testicles or ovaries, and, very rarely, death.
- **RUBELLA (R)** causes fever, sore throat, rash, headache, and eye irritation. It can cause arthritis in up to half of teenage and adult women. If a person gets rubella while they are pregnant, they could have a miscarriage or the baby could be born with serious birth defects.

Most people who are vaccinated with MMR will be protected for life. Vaccines and high rates of vaccination have made these diseases much less common in the United States.

## 2. MMR vaccine

**Children** need 2 doses of MMR vaccine, usually:

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

**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. These children should still get 2 additional doses at the recommended ages for long-lasting protection.

**Older children, adolescents, and adults** also need 1 or 2 doses of MMR vaccine if they are not already

immune to measles, mumps, and rubella. Your health care provider can help you determine how many doses you need.

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

MMR vaccine may be given at the same time as other vaccines. Children 12 months through 12 years of age might receive MMR vaccine together with varicella vaccine in a single shot, known as MMRV. Your health care provider can give you more information.

## 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of MMR or MMRV vaccine**, or has any **severe, life-threatening allergies**
- Is **pregnant** or thinks they might be pregnant—pregnant people should not get MMR vaccine
- Has a **weakened immune system**, or has a **parent, brother, or sister with a history of hereditary or congenital immune system problems**
- Has ever had a **condition that makes him or her bruise or bleed easily**
- Has recently **had a blood transfusion or received other blood products**
- Has **tuberculosis**
- Has **gotten any other vaccines in the past 4 weeks**

In some cases, your health care provider may decide to postpone MMR vaccination until a future visit.



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

Your health care provider can give you more information.

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## 4. Risks of a vaccine reaction

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- Sore arm from the injection or redness where the shot is given, fever, and a mild rash can happen after MMR vaccination.
- Swelling of the glands in the cheeks or neck or temporary pain and stiffness in the joints (mostly in teenage or adult women) sometimes occur after MMR vaccination.
- More serious reactions happen rarely. These can include seizures (often associated with fever) or temporary low platelet count that can cause unusual bleeding or bruising.
- In people with serious immune system problems, this vaccine may cause an infection that may be life-threatening. People with serious immune system problems should not get MMR vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

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## 5. What if there is a serious problem?

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An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

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## 6. The National Vaccine Injury Compensation Program

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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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation) or call **1-800-338-2382** to learn about the program and about filing a claim.

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## 7. How can I learn more?

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- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at [www.fda.gov/vaccines-blood-biologics/vaccines](http://www.fda.gov/vaccines-blood-biologics/vaccines).
- Contact the Centers for Disease Control and Prevention (CDC):
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  - Visit CDC's website at [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines).



# Varicella (Chickenpox) Vaccine:

## What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

### 1. Why get vaccinated?

**Varicella vaccine** can prevent **varicella**.

**Varicella**, also called “chickenpox,” causes an itchy rash that usually lasts about a week. It can also cause fever, tiredness, loss of appetite, and headache. It can lead to skin infections, pneumonia, inflammation of the blood vessels, swelling of the brain and/or spinal cord covering, and infections of the bloodstream, bone, or joints. Some people who get chickenpox get a painful rash called “shingles” (also known as herpes zoster) years later.

Chickenpox is usually mild, but it can be serious in infants under 12 months of age, adolescents, adults, pregnant people, and people with a weakened immune system. Some people get so sick that they need to be hospitalized. It doesn't happen often, but people can die from chickenpox.

Most people who are vaccinated with 2 doses of varicella vaccine will be protected for life.

### 2. Varicella vaccine

**Children** need 2 doses of varicella vaccine, usually:

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

**Older children, adolescents, and adults** also need 2 doses of varicella vaccine if they are not already immune to chickenpox.

Varicella vaccine may be given at the same time as other vaccines. Also, a child between 12 months and 12 years of age might receive varicella vaccine together with MMR (measles, mumps, and rubella) vaccine in a single shot, known as MMRV. Your health care provider can give you more information.

### 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of varicella vaccine**, or has any **severe, life-threatening allergies**
- Is **pregnant** or thinks they might be pregnant—pregnant people should not get varicella vaccine
- Has a **weakened immune system**, or has a **parent, brother, or sister with a history of hereditary or congenital immune system problems**
- Is **taking salicylates** (such as aspirin)
- Has recently **had a blood transfusion or received other blood products**
- Has **tuberculosis**
- Has **gotten any other vaccines in the past 4 weeks**

In some cases, your health care provider may decide to postpone varicella vaccination until a future visit.

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

Your health care provider can give you more information.



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## 4. Risks of a vaccine reaction

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- Sore arm from the injection, redness or rash where the shot is given, or fever can happen after varicella vaccination.
- More serious reactions happen very rarely. These can include pneumonia, infection of the brain and/or spinal cord covering, or seizures that are often associated with fever.
- In people with serious immune system problems, this vaccine may cause an infection that may be life-threatening. People with serious immune system problems should not get varicella vaccine.

It is possible for a vaccinated person to develop a rash. If this happens, the varicella vaccine virus could be spread to an unprotected person. Anyone who gets a rash should stay away from infants and people with a weakened immune system until the rash goes away. Talk with your health care provider to learn more.

Some people who are vaccinated against chickenpox get shingles (herpes zoster) years later. This is much less common after vaccination than after chickenpox disease.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

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## 5. What if there is a serious problem?

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An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

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## 6. The National Vaccine Injury Compensation Program

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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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation) or call **1-800-338-2382** to learn about the program and about filing a claim.

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## 7. How can I learn more?

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- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at [www.fda.gov/vaccines-blood-biologics/vaccines](http://www.fda.gov/vaccines-blood-biologics/vaccines).
- Contact the Centers for Disease Control and Prevention (CDC):
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  - Visit CDC's website at [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines).



# Hepatitis A Vaccine:

## What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

### 1 Why get vaccinated?

**Hepatitis A vaccine** can prevent **hepatitis A**.

**Hepatitis A** is a serious liver disease. It is usually spread through close personal contact with an infected person or when a person unknowingly ingests the virus from objects, food, or drinks that are contaminated by small amounts of stool (poop) from an infected person.

Most adults with hepatitis A have symptoms, including fatigue, low appetite, stomach pain, nausea, and jaundice (yellow skin or eyes, dark urine, light colored bowel movements). Most children less than 6 years of age do not have symptoms.

A person infected with hepatitis A can transmit the disease to other people even if he or she does not have any symptoms of the disease.

Most people who get hepatitis A feel sick for several weeks, but they usually recover completely and do not have lasting liver damage. In rare cases, hepatitis A can cause liver failure and death; this is more common in people older than 50 and in people with other liver diseases.

Hepatitis A vaccine has made this disease much less common in the United States. However, outbreaks of hepatitis A among unvaccinated people still happen.

### 2 Hepatitis A vaccine

**Children** need 2 doses of hepatitis A vaccine:

- First dose: 12 through 23 months of age
- Second dose: at least 6 months after the first dose

**Older children and adolescents** 2 through 18 years of age who were not vaccinated previously should be vaccinated.

**Adults** who were not vaccinated previously and want to be protected against hepatitis A can also get the vaccine.

Hepatitis A vaccine is recommended for the following people:

- All children aged 12–23 months
- Unvaccinated children and adolescents aged 2–18 years
- International travelers
- Men who have sex with men
- People who use injection or non-injection drugs
- People who have occupational risk for infection
- People who anticipate close contact with an international adoptee
- People experiencing homelessness
- People with HIV
- People with chronic liver disease
- Any person wishing to obtain immunity (protection)

In addition, a person who has not previously received hepatitis A vaccine and who has direct contact with someone with hepatitis A should get hepatitis A vaccine within 2 weeks after exposure.

Hepatitis A vaccine may be given at the same time as other vaccines.

### 3 Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of hepatitis A vaccine, or has any severe, life-threatening allergies.**

In some cases, your health care provider may decide to postpone hepatitis A vaccination to a future visit.



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People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting hepatitis A vaccine.

Your health care provider can give you more information.

## 4 Risks of a vaccine reaction

- Soreness or redness where the shot is given, fever, headache, tiredness, or loss of appetite can happen after hepatitis A vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

## 5 What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff 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. Visit the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation) or call **1-800-338-2382** to learn about the program and about filing a claim. There is a time limit to file a claim for compensation.

## 7 How can I learn more?

- Ask your health care provider.
- 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](http://www.cdc.gov/vaccines)

Vaccine Information Statement (Interim)  
**Hepatitis A Vaccine**



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07/28/2020 | 42 U.S.C. § 300aa-26

# Tdap (Tetanus, Diphtheria, Pertussis) Vaccine: *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

## 1. Why get vaccinated?

**Tdap vaccine** can prevent **tetanus, diphtheria, and pertussis**.

Diphtheria and pertussis spread from person to person. Tetanus enters the body through cuts or wounds.

- **TETANUS (T)** causes painful stiffening of the muscles. Tetanus can lead to serious health problems, including being unable to open the mouth, having trouble swallowing and breathing, or death.
- **DIPHTHERIA (D)** can lead to difficulty breathing, heart failure, paralysis, or death.
- **PERTUSSIS (aP)**, also known as “whooping cough,” can cause uncontrollable, violent coughing that makes it hard to breathe, eat, or drink. Pertussis can be extremely serious especially in babies and young children, causing pneumonia, convulsions, brain damage, or death. In teens and adults, it can cause weight loss, loss of bladder control, passing out, and rib fractures from severe coughing.

## 2. Tdap vaccine

Tdap is only for children 7 years and older, adolescents, and adults.

**Adolescents** should receive a single dose of Tdap, preferably at age 11 or 12 years.

**Pregnant people** should get a dose of Tdap during every pregnancy, preferably during the early part of the third trimester, to help protect the newborn from pertussis. Infants are most at risk for severe, life-threatening complications from pertussis.

**Adults** who have never received Tdap should get a dose of Tdap.

Also, **adults should receive a booster dose of either Tdap or Td** (a different vaccine that protects against tetanus and diphtheria but not pertussis) **every 10 years**, or after 5 years in the case of a severe or dirty wound or burn.

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

## 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of any vaccine that protects against tetanus, diphtheria, or pertussis**, or has any **severe, life-threatening allergies**
- Has had a **coma, decreased level of consciousness, or prolonged seizures within 7 days after a previous dose of any pertussis vaccine (DTP, DTaP, or Tdap)**
- Has **seizures or another nervous system problem**
- Has ever had **Guillain-Barré Syndrome** (also called “GBS”)
- Has had **severe pain or swelling after a previous dose of any vaccine that protects against tetanus or diphtheria**

In some cases, your health care provider may decide to postpone Tdap vaccination until a future visit.

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

Your health care provider can give you more information.



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## 4. Risks of a vaccine reaction

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- Pain, redness, or swelling where the shot was given, mild fever, headache, feeling tired, and nausea, vomiting, diarrhea, or stomachache sometimes happen after Tdap vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

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## 5. What if there is a serious problem?

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An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

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## 6. The National Vaccine Injury Compensation Program

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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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation) or call **1-800-338-2382** to learn about the program and about filing a claim.

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## 7. How can I learn more?

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- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at [www.fda.gov/vaccines-blood-biologics/vaccines](http://www.fda.gov/vaccines-blood-biologics/vaccines).
- 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](http://www.cdc.gov/vaccines).



# Meningococcal ACWY Vaccine:

## What You Need to Know

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Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

### 1. Why get vaccinated?

**Meningococcal ACWY vaccine** can help protect against **meningococcal disease** caused by serogroups A, C, W, and Y. A different meningococcal vaccine is available that can help protect against serogroup B.

**Meningococcal disease** can cause meningitis (infection of the lining of the brain and spinal cord) and infections of the blood. Even when it is treated, meningococcal disease kills 10 to 15 infected people out of 100. And of those who survive, about 10 to 20 out of every 100 will suffer disabilities such as hearing loss, brain damage, kidney damage, loss of limbs, nervous system problems, or severe scars from skin grafts.

Meningococcal disease is rare and has declined in the United States since the 1990s. However, it is a severe disease with a significant risk of death or lasting disabilities in people who get it.

Anyone can get meningococcal disease. Certain people are at increased risk, including:

- Infants younger than one year old
- Adolescents and young adults 16 through 23 years old
- People with certain medical conditions that affect the immune system
- Microbiologists who routinely work with isolates of *N. meningitidis*, the bacteria that cause meningococcal disease
- People at risk because of an outbreak in their community

### 2. Meningococcal ACWY vaccine

**Adolescents** need 2 doses of a meningococcal ACWY vaccine:

- First dose: 11 or 12 years of age
- Second (booster) dose: 16 years of age

In addition to routine vaccination for adolescents, meningococcal ACWY vaccine is also recommended for **certain groups of people**:

- People at risk because of a serogroup A, C, W, or Y meningococcal disease outbreak
- People with HIV
- Anyone whose spleen is damaged or has been removed, including people with sickle cell disease
- Anyone with a rare immune system condition called “complement component deficiency”
- Anyone taking a type of drug called a “complement inhibitor,” such as eculizumab (also called “Soliris”®) or ravulizumab (also called “Ultomiris”®)
- Microbiologists who routinely work with isolates of *N. meningitidis*
- Anyone traveling to or living in a part of the world where meningococcal disease is common, such as parts of Africa
- College freshmen living in residence halls who have not been completely vaccinated with meningococcal ACWY vaccine
- U.S. military recruits



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### 3. Talk with your health care provider

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Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of meningococcal ACWY vaccine**, or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone meningococcal ACWY vaccination until a future visit.

There is limited information on the risks of this vaccine for pregnant or breastfeeding people, but no safety concerns have been identified. A pregnant or breastfeeding person should be vaccinated if indicated.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting meningococcal ACWY vaccine.

Your health care provider can give you more information.

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### 4. Risks of a vaccine reaction

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- Redness or soreness where the shot is given can happen after meningococcal ACWY vaccination.
- A small percentage of people who receive meningococcal ACWY vaccine experience muscle pain, headache, or tiredness.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

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### 5. What if there is a serious problem?

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An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

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### 6. The National Vaccine Injury Compensation Program

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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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation) or call **1-800-338-2382** to learn about the program and about filing a claim.

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### 7. How can I learn more?

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- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at [www.fda.gov/vaccines-blood-biologics/vaccines](http://www.fda.gov/vaccines-blood-biologics/vaccines).
- 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](http://www.cdc.gov/vaccines).





# HPV (Human Papillomavirus) Vaccine: *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

## 1. Why get vaccinated?

HPV (human papillomavirus) vaccine can prevent infection with some types of human papillomavirus.

HPV infections can cause certain types of cancers, including:

- cervical, vaginal, and vulvar cancers in women
- penile cancer in men
- anal cancers in both men and women
- cancers of tonsils, base of tongue, and back of throat (oropharyngeal cancer) in both men and women

HPV infections can also cause anogenital warts.

HPV vaccine can prevent over 90% of cancers caused by HPV.

HPV is spread through intimate skin-to-skin or sexual contact. HPV infections are so common that nearly all people will get at least one type of HPV at some time in their lives. Most HPV infections go away on their own within 2 years. But sometimes HPV infections will last longer and can cause cancers later in life.

## 2. HPV vaccine

HPV vaccine is routinely recommended for adolescents at 11 or 12 years of age to ensure they are protected before they are exposed to the virus. HPV vaccine may be given beginning at age 9 years and vaccination is recommended for everyone through 26 years of age.

HPV vaccine may be given to adults 27 through 45 years of age, based on discussions between the patient and health care provider.

Most children who get the first dose before 15 years of age need 2 doses of HPV vaccine. People who get the first dose at or after 15 years of age and younger people with certain immunocompromising conditions need 3 doses. Your health care provider can give you more information.

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

## 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of HPV vaccine**, or has any **severe, life-threatening allergies**
- Is **pregnant**—HPV vaccine is not recommended until after pregnancy

In some cases, your health care provider may decide to postpone HPV vaccination until a future visit.

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

Your health care provider can give you more information.



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## 4. Risks of a vaccine reaction

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- Soreness, redness, or swelling where the shot is given can happen after HPV vaccination.
- Fever or headache can happen after HPV vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

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## 5. What if there is a serious problem?

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An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

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- Contact the Centers for Disease Control and Prevention (CDC):
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  - Visit CDC's website at [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines).



# Meningococcal B Vaccine:

## What You Need to Know

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### 1. Why get vaccinated?

**Meningococcal B vaccine** can help protect against **meningococcal disease** caused by serogroup B. A different meningococcal vaccine is available that can help protect against serogroups A, C, W, and Y.

**Meningococcal disease** can cause meningitis (infection of the lining of the brain and spinal cord) and infections of the blood. Even when it is treated, meningococcal disease kills 10 to 15 infected people out of 100. And of those who survive, about 10 to 20 out of every 100 will suffer disabilities such as hearing loss, brain damage, kidney damage, loss of limbs, nervous system problems, or severe scars from skin grafts.

Meningococcal disease is rare and has declined in the United States since the 1990s. However, it is a severe disease with a significant risk of death or lasting disabilities in people who get it.

Anyone can get meningococcal disease. Certain people are at increased risk, including:

- Infants younger than one year old
- Adolescents and young adults 16 through 23 years old
- People with certain medical conditions that affect the immune system
- Microbiologists who routinely work with isolates of *N. meningitidis*, the bacteria that cause meningococcal disease
- People at risk because of an outbreak in their community

### 2. Meningococcal B vaccine

For best protection, more than 1 dose of a meningococcal B vaccine is needed. There are two meningococcal B vaccines available. The same vaccine must be used for all doses.

Meningococcal B vaccines are recommended for people 10 years or older who are at increased risk for serogroup B meningococcal disease, including:

- People at risk because of a serogroup B meningococcal disease outbreak
- Anyone whose spleen is damaged or has been removed, including people with sickle cell disease
- Anyone with a rare immune system condition called “complement component deficiency”
- Anyone taking a type of drug called a “complement inhibitor,” such as eculizumab (also called “Soliris”®) or ravulizumab (also called “Ultomiris”®)
- Microbiologists who routinely work with isolates of *N. meningitidis*

These vaccines may also be given to anyone 16 through 23 years old to provide short-term protection against most strains of serogroup B meningococcal disease, based on discussions between the patient and health care provider. The preferred age for vaccination is 16 through 18 years.



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### 3. Talk with your health care provider

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Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of meningococcal B vaccine**, or has any **severe, life-threatening allergies**
- Is **pregnant or breastfeeding**

In some cases, your health care provider may decide to postpone meningococcal B vaccination until a future visit.

Meningococcal B vaccination should be postponed for pregnant people unless the person is at increased risk and, after consultation with their health care provider, the benefits of vaccination are considered to outweigh the potential risks.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting meningococcal B vaccine.

Your health care provider can give you more information.

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### 4. Risks of a vaccine reaction

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- Soreness, redness, or swelling where the shot is given, tiredness, headache, muscle or joint pain, fever, or nausea can happen after meningococcal B vaccination. Some of these reactions occur in more than half of the people who receive the vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

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### 5. What if there is a serious problem?

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An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

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### 7. How can I learn more?

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- Contact the Centers for Disease Control and Prevention (CDC):
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# Td (Tetanus, Diphtheria) Vaccine: *What You Need to Know*

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## 1. Why get vaccinated?

**Td vaccine** can prevent **tetanus** and **diphtheria**.

Tetanus enters the body through cuts or wounds.

Diphtheria spreads from person to person.

- **TETANUS (T)** causes painful stiffening of the muscles. Tetanus can lead to serious health problems, including being unable to open the mouth, having trouble swallowing and breathing, or death.
- **DIPHTHERIA (D)** can lead to difficulty breathing, heart failure, paralysis, or death.

## 2. Td vaccine

Td is only for children 7 years and older, adolescents, and adults.

Td is usually given as a **booster dose every 10 years**, or after 5 years in the case of a severe or dirty wound or burn.

Another vaccine, called “Tdap,” may be used instead of Td. Tdap protects against pertussis, also known as “whooping cough,” in addition to tetanus and diphtheria.

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

## 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of any vaccine that protects against tetanus or diphtheria**, or has any **severe, life-threatening allergies**
- Has ever had **Guillain-Barré Syndrome** (also called “GBS”)
- Has had **severe pain or swelling after a previous dose of any vaccine that protects against tetanus or diphtheria**

In some cases, your health care provider may decide to postpone Td vaccination until a future visit.

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

Your health care provider can give you more information.



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## 4. Risks of a vaccine reaction

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- Pain, redness, or swelling where the shot was given, mild fever, headache, feeling tired, and nausea, vomiting, diarrhea, or stomachache sometimes happen after Td vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

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An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

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- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at [www.fda.gov/vaccines-blood-biologics/vaccines](http://www.fda.gov/vaccines-blood-biologics/vaccines).
- 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](http://www.cdc.gov/vaccines).



# Pneumococcal Polysaccharide Vaccine (PPSV23): *What You Need to Know*

Many Vaccine Information Statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

## 1 Why get vaccinated?

**Pneumococcal polysaccharide vaccine (PPSV23)** can prevent **pneumococcal disease**.

**Pneumococcal disease** refers to any illness caused by pneumococcal bacteria. These bacteria can cause many types of illnesses, including pneumonia, which is an infection of the lungs. Pneumococcal bacteria are one of the most common causes of pneumonia.

Besides pneumonia, pneumococcal bacteria can also cause:

- Ear infections
- Sinus infections
- Meningitis (infection of the tissue covering the brain and spinal cord)
- Bacteremia (bloodstream infection)

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

Most pneumococcal infections are mild. However, some can result in long-term problems, such as brain damage or hearing loss. Meningitis, bacteremia, and pneumonia caused by pneumococcal disease can be fatal.

## 2 PPSV23

PPSV23 protects against 23 types of bacteria that cause pneumococcal disease.

PPSV23 is recommended for:

- All **adults 65 years or older**,
- Anyone **2 years or older with certain medical conditions that can lead to an increased risk for pneumococcal disease**.

Most people need only one dose of PPSV23. A second dose of PPSV23, and another type of pneumococcal vaccine called PCV13, are recommended for certain high-risk groups. Your health care provider can give you more information.

People 65 years or older should get a dose of PPSV23 even if they have already gotten one or more doses of the vaccine before they turned 65.

## 3 Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of PPSV23**, or has any **severe, life-threatening allergies**.

In some cases, your health care provider may decide to postpone PPSV23 vaccination to a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting PPSV23.

Your health care provider can give you more information.



**U.S. Department of Health and Human Services**  
Centers for Disease Control and Prevention

## 4 Risks of a vaccine reaction

- Redness or pain where the shot is given, feeling tired, fever, or muscle aches can happen after PPSV23.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

## 5 What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **[www.vaers.hhs.gov](http://www.vaers.hhs.gov)** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff do not give medical advice.*

## 6 How can I learn more?

- Ask your health care provider.
- 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](http://www.cdc.gov/vaccines)**

Vaccine Information Statement  
**PPSV23 Vaccine**

10/30/2019



Office use only

# Influenza (Flu) Vaccine (Inactivated or Recombinant): *What you need to know*

Many vaccine information statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

## 1. Why get vaccinated?

**Influenza vaccine** can prevent **influenza (flu)**.

**Flu** is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years and older, pregnant people, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections, and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer, or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

In an average year, **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

## 2. Influenza vaccines

CDC recommends everyone 6 months and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against the influenza viruses believed to be likely to cause disease in the upcoming flu season.

Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine **does not cause flu**.

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

## 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**
- Has ever had **Guillain-Barré Syndrome** (also called "GBS")

In some cases, your health care provider may decide to postpone influenza vaccination until a future visit.

Influenza vaccine can be administered at any time during pregnancy. People who are or will be pregnant during influenza season should receive inactivated influenza vaccine.

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

Your health care provider can give you more information.



**U.S. Department of Health and Human Services**  
Centers for Disease Control and Prevention

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## 4. Risks of a vaccine reaction

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- Soreness, redness, and swelling where the shot is given, fever, muscle aches, and headache can happen after influenza vaccination.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

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## 5. What if there is a serious problem?

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An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

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## 6. The National Vaccine Injury Compensation Program

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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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation) or call **1-800-338-2382** to learn about the program and about filing a claim.

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## 7. How can I learn more?

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- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at [www.fda.gov/vaccines-blood-biologics/vaccines](http://www.fda.gov/vaccines-blood-biologics/vaccines).
- 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/flu](http://www.cdc.gov/flu).





**FACT SHEET FOR RECIPIENTS AND CAREGIVERS  
EMERGENCY USE AUTHORIZATION OF THE MODERNA COVID-19 VACCINE TO  
PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS  
6 MONTHS THROUGH 5 YEARS OF AGE**

**FOR 6 MONTHS THROUGH 5 YEARS OF AGE**

**Your child is being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.**

**This Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Moderna COVID-19 Vaccine for use in individuals 6 months through 5 years of age.<sup>1</sup>**

**The Moderna COVID-19 Vaccine has received EUA from FDA to provide a two-dose primary series to individuals 6 months through 5 years of age.**

**The Moderna COVID-19 Vaccine has also received EUA from FDA to provide a third primary series dose to individuals 6 months through 5 years of age who have been determined to have certain kinds of immunocompromise.**

**The Moderna COVID-19 Vaccine is not FDA-approved for use in individuals 6 months through 5 years of age.**

This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which your child may receive because there is currently a pandemic of COVID-19. Talk to your child's vaccination provider if you have questions.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit [www.modernatx.com/covid19vaccine-eua](http://www.modernatx.com/covid19vaccine-eua).

**WHAT YOU NEED TO KNOW BEFORE YOUR CHILD GETS THIS VACCINE**

**WHAT IS COVID-19?**

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-

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<sup>1</sup> You may receive this Fact Sheet even if your child is 6 years old. Children who will turn from 5 years to 6 years of age between doses in the primary series may receive, for any dose, either: (1) the Moderna COVID-19 Vaccine authorized for use in individuals 6 months through 5 years of age; or (2) Moderna COVID-19 Vaccine authorized for use in individuals 6 years through 11 years of age.

19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

### **WHAT SHOULD YOU MENTION TO YOUR CHILD'S VACCINATION PROVIDER BEFORE YOUR CHILD GETS THE VACCINE?**

Tell the vaccination provider about all of your child's medical conditions, including if your child:

- has any allergies
- has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- has a fever
- has a bleeding disorder or is on a blood thinner
- is immunocompromised or is on a medicine that affects your child's immune system
- has received another COVID-19 vaccine
- has ever fainted in association with an injection

### **WHO SHOULD NOT GET THE VACCINE?**

Your child should not get the vaccine if your child:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

### **WHAT ARE THE INGREDIENTS IN THE VACCINE?**

The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, and sucrose.

### **HOW IS THE VACCINE GIVEN?**

The Moderna COVID-19 Vaccine will be given to your child as an injection into the muscle.

The vaccine is administered as a two-dose series, 1 month apart. A third primary series dose may be administered at least 1 month after the second dose to individuals who are determined to have certain kinds of immunocompromise.

### **HAS THE VACCINE BEEN USED BEFORE?**

Millions of individuals 18 years of age and older have received the Moderna COVID-19 Vaccine under EUA since December 18, 2020. In a clinical trial, approximately 5,000 individuals 6 months through 5 years of age have received at least 1 dose of Moderna COVID-19 Vaccine. In other clinical trials, approximately 4,000 individuals 6 years through 11 years of age and 30,000 individuals 12 years of age and older have received at least 1 dose of the vaccine.

### **WHAT ARE THE BENEFITS OF THE VACCINE?**

The vaccine has been shown to prevent COVID-19. The duration of protection against COVID-19 is currently unknown.

## **WHAT ARE THE RISKS OF THE VACCINE?**

There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your child's vaccination provider may ask your child to stay at the place where your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is very low. You should seek medical attention right away if your child has any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after your child receives a dose of the vaccine:

- Chest pain
- Shortness of breath or difficulty breathing
- Feelings of having a fast-beating, fluttering, or pounding heart
- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

Side effects that have been reported in clinical trials with the vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection or in the groin, redness, and swelling (hardness)
- General side effects: fatigue, headache, muscle pain, chills, nausea and vomiting, fever, joint pain, irritability/crying, sleepiness, and loss of appetite

Side effects that have been reported during post-authorization use of the vaccine include:

- Severe allergic reactions
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

## **WHAT SHOULD I DO ABOUT SIDE EFFECTS?**

If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your child's healthcare provider if your child has any side effects that bother your child or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include "Moderna COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

You may also be given an option to enroll in **v-safe**. **V-safe** is a voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).

## **WHAT IF I DECIDE NOT TO HAVE MY CHILD GET THE MODERNA COVID-19 VACCINE?**

Under the EUA, there is an option to accept or refuse receiving the vaccine. Should you decide for your child not to receive it, it will not change your child's standard medical care.

## **ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?**

Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

## **CAN MY CHILD RECEIVE THE MODERNA COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?**

Data have not yet been submitted to FDA on administration of Moderna COVID-19 Vaccine at the same time as other vaccines. If you are considering having your child receive the Moderna COVID-19 Vaccine with other vaccines, discuss your options with your child's healthcare provider.

## **WHAT IF MY CHILD IS IMMUNOCOMPROMISED?**

If your child is immunocompromised, you may be given the option to have your child receive a third primary series dose of the vaccine. The third dose may still not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to have your child maintain physical precautions to help prevent COVID-19. In addition, your child's close contacts should be vaccinated as appropriate.

## **WILL THE VACCINE GIVE MY CHILD COVID-19?**

No. The vaccine does not contain SARS-CoV-2 and cannot give your child COVID-19.


## **KEEP YOUR CHILD’S VACCINATION CARD**

When your child gets the first dose, you will get a vaccination card to show when to return for your child’s next dose(s) of the vaccine. Remember to bring the card when your child returns.

## **ADDITIONAL INFORMATION**

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

<b>Moderna COVID-19 Vaccine website</b>	<b>Telephone number</b>
<a href="http://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a> 	1-866-MODERNA (1-866-663-3762)

## **HOW CAN I LEARN MORE?**

- Ask the vaccination provider
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>
- Visit FDA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- Contact your state or local public health department

## **WHERE WILL MY CHILD’S VACCINATION INFORMATION BE RECORDED?**

The vaccination provider may include your child’s vaccination information in your state/local jurisdiction’s Immunization Information System (IIS) or other designated system. This will ensure that your child receives the same vaccine when your child returns for the second dose. For more information about IISs, visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

## **CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?**

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients).

## **WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?**

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.



## **WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?**

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit [www.hrsa.gov/cicp/](http://www.hrsa.gov/cicp/) or call 1-855-266-2427.

## **WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?**

An EUA is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic. A product authorized for emergency use has not undergone the same type of review by FDA as an FDA approved product.

FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

An EUA is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of this product, unless terminated or revoked (after which the product may no longer be used).

Moderna US, Inc.  
Cambridge, MA 02139

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Patent(s): [www.modernatx.com/patents](http://www.modernatx.com/patents)  
Revised: June/17/2022



Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

GDTI: 0886983000516

**VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS  
ABOUT THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT  
CORONAVIRUS DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS  
5 THROUGH 11 YEARS OF AGE**

**FOR 5 THROUGH 11 YEARS OF AGE**

**Your child is being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.**

**This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine for use in individuals 5 through 11 years of age.<sup>1</sup>**

**The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide a two-dose primary series to individuals 5 through 11 years of age.**

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which your child may receive because there is currently a pandemic of COVID-19. Talk to your child's vaccination provider if you have questions.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see [www.cvdvaccine.com](http://www.cvdvaccine.com).

**WHAT YOU NEED TO KNOW BEFORE YOUR CHILD GETS THIS VACCINE**

**WHAT IS COVID-19?**

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness leading to death. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

For more information on EUA, see the **"What is an Emergency Use Authorization (EUA)?"** section at the end of this Fact Sheet.

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<sup>1</sup> You may receive this Vaccine Information Fact Sheet even if your child is 12 years old. Children who will turn from 11 years to 12 years of age between their first and second dose in the primary regimen may receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 5 through 11 years of age; or (2) COMIRNATY or one of the Pfizer-BioNTech COVID-19 Vaccine formulations authorized for use in individuals 12 years of age and older.

## **WHAT SHOULD YOU MENTION TO YOUR CHILD'S VACCINATION PROVIDER BEFORE YOUR CHILD GETS THE VACCINE?**

**Tell the vaccination provider about all of your child's medical conditions, including if your child:**

- has any allergies
- has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- has a fever
- has a bleeding disorder or is on a blood thinner
- is immunocompromised or is on a medicine that affects your child's immune system
- is pregnant
- is breastfeeding
- has received another COVID-19 vaccine
- has ever fainted in association with an injection

## **HOW IS THE VACCINE GIVEN?**

The Pfizer-BioNTech COVID-19 Vaccine will be given to your child as an injection into the muscle.

The vaccine is administered as a 2-dose series, 3 weeks apart.

The vaccine may not protect everyone.

## **WHO SHOULD NOT GET THE VACCINE?**

Your child should not get the vaccine if your child:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

## **WHAT ARE THE INGREDIENTS IN THE VACCINE?**

The vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), tromethamine, tromethamine hydrochloride, sucrose, and sodium chloride.

## **HAS THE VACCINE BEEN USED BEFORE?**

Millions of individuals 12 years of age and older have received the Pfizer-BioNTech COVID-19 Vaccine under EUA since December 11, 2020. In a clinical trial, approximately 3,100 individuals 5 through 11 years of age have received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine. In other clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the vaccine. The vaccine that is authorized for use in children 5 through 11 years of age includes the same mRNA and lipids but different inactive ingredients compared to the vaccine that has been used under EUA in individuals 12 years of age and older and that has been studied in clinical trials. The use of the different inactive ingredients helps stabilize the vaccine under refrigerated temperatures and the formulation can be readily prepared to deliver appropriate doses to the 5 through 11 year-old population.

## **WHAT ARE THE BENEFITS OF THE VACCINE?**

The vaccine has been shown to prevent COVID-19.

The duration of protection against COVID-19 is currently unknown.

## **WHAT ARE THE RISKS OF THE VACCINE?**

There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your child's vaccination provider may ask your child to stay at the place where your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of the face and throat
- A fast heartbeat
- A bad rash all over the body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if your child has any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported with the vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain

- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- decreased appetite
- diarrhea
- vomiting
- arm pain
- fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

#### **WHAT SHOULD I DO ABOUT SIDE EFFECTS?**

If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your child's healthcare provider if your child has any side effects that bother your child or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
<a href="http://www.pfizersafetyreporting.com">www.pfizersafetyreporting.com</a>	1-866-635-8337	1-800-438-1985

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).



**WHAT IF I DECIDE NOT TO HAVE MY CHILD GET THE PFIZER-BIONTECH COVID-19 VACCINE?**

Under the EUA, there is an option to accept or refuse receiving the vaccine. Should you decide for your child not to receive it, it will not change your child's standard medical care.

**ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE?**

For children 5 through 11 years of age, there are no other COVID-19 vaccines available under Emergency Use Authorization and there are no approved COVID-19 vaccines.

**CAN MY CHILD RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?**

Data have not yet been submitted to FDA on administration of the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering to have your child receive the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss the options with your child's healthcare provider.

**WHAT ABOUT PREGNANCY OR BREASTFEEDING?**

If your child is pregnant or breastfeeding, discuss the options with your healthcare provider.

**WILL THE VACCINE GIVE MY CHILD COVID-19?**

No. The vaccine does not contain SARS-CoV-2 and cannot give your child COVID-19.


**KEEP YOUR CHILD'S VACCINATION CARD**

When your child gets the first dose, you will get a vaccination card to show when to return for your child's next dose(s) of the vaccine. Remember to bring the card when your child returns.

**ADDITIONAL INFORMATION**

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
<a href="http://www.cvdvaccine.com">www.cvdvaccine.com</a> 	1-877-829-2619 (1-877-VAX-CO19)

## **HOW CAN I LEARN MORE?**

- Ask the vaccination provider.
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>.
- Visit FDA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.
- Contact your local or state public health department.

## **WHERE WILL MY CHILD'S VACCINATION INFORMATION BE RECORDED?**

The vaccination provider may include your child's vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that your child receives the same vaccine when your child returns for the second dose. For more information about IISs visit:

<https://www.cdc.gov/vaccines/programs/iis/about.html>.

## **CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?**

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

## **WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?**

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or <https://TIPS.HHS.GOV>.

## **WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?**

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit [www.hrsa.gov/cicp/](http://www.hrsa.gov/cicp/) or call 1-855-266-2427.

## **WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?**

An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based

on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.



Manufactured by  
Pfizer Inc., New York, NY 10017

**BIONTECH**

Manufactured for  
BioNTech Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz, Germany

LAB-1486-0.3

Revised: 29 October 2021



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Barcode Date: 09/30/2021

**VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS  
ABOUT COMIRNATY (COVID-19 VACCINE, mRNA)  
AND THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS  
DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 12 YEARS OF AGE AND  
OLDER**

**FOR 12 YEARS OF AGE AND OLDER**

**You are being offered either COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.**

**This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and also includes information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA) for use in individuals 12 years of age and older.**

**The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the two formulations of Pfizer-BioNTech COVID-19 Vaccine authorized for Emergency Use Authorization (EUA) for ages 12 years and older, when prepared according to their respective instructions for use, can be used interchangeably.<sup>1</sup>**

**COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older. It is also authorized under EUA to provide:**

- a 2-dose primary series to individuals 12 through 15 years;**
- a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and**
- a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY:**
  - 65 years of age and older**
  - 18 through 64 years of age at high risk of severe COVID-19**

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<sup>1</sup> When prepared according to their respective instructions for use, the FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the two EUA-authorized formulations of Pfizer-BioNTech COVID-19 Vaccine for ages 12 years of age and older can be used interchangeably without presenting any safety or effectiveness concerns.

- 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. **Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series.**

**The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide:**

- a 2-dose primary series to individuals 12 years of age and older;
- a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
- a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or **COMIRNATY:**
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. **Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series.**

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19. Talk to your vaccination provider if you have questions.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see [www.cvdvaccine.com](http://www.cvdvaccine.com).

## **WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE**

### **WHAT IS COVID-19?**

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness leading to death. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

## **WHAT IS COMIRNATY (COVID-19 VACCINE, mRNA) AND HOW IS IT RELATED TO THE PFIZER-BIONTECH COVID-19 VACCINE?**

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine when prepared according to their respective instructions for use, can be used interchangeably.

For more information on EUA, see the “**What is an Emergency Use Authorization (EUA)?**” section at the end of this Fact Sheet.

## **WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE VACCINE?**

**Tell the vaccination provider about all of your medical conditions, including if you:**

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

## **HOW IS THE VACCINE GIVEN?**

The Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY will be given to you as an injection into the muscle.

**Primary Series:** The vaccine is administered as a 2-dose series, 3 weeks apart. A third primary series dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

**Booster Dose:**

- A single booster dose of the vaccine may be administered at least 6 months after completion of a primary series to individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- A single booster dose of the vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster dose.

The vaccine may not protect everyone.



## **WHO SHOULD NOT GET THE VACCINE?**

You should not get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

## **WHAT ARE THE INGREDIENTS IN THE VACCINES?**

COMIRNATY (COVID-19 Vaccine, mRNA) and the authorized formulations of the vaccine include the following ingredients:

- mRNA and lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol).

Pfizer-BioNTech COVID-19 vaccines for individuals 12 years of age and older contain 1 of the following sets of additional ingredients; ask the vaccination provider which version is being administered:

- potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose

OR

- tromethamine, tromethamine hydrochloride, and sucrose

COMIRNATY (COVID-19 Vaccine, mRNA) contains the following additional ingredients: potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

## **HAS THE VACCINE BEEN USED BEFORE?**

Yes. In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the vaccine. Data from these clinical trials supported the Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccines and the approval of COMIRNATY (COVID-19 Vaccine, mRNA). Millions of individuals have received the vaccine under EUA since December 11, 2020. The vaccine that is authorized for use in individuals 12 years and older includes two formulations; one that was studied in clinical trials and used under EUA, and one with the same mRNA and lipids but different inactive ingredients. The use of the different inactive ingredients helps stabilize the vaccine under refrigerated temperatures and the formulation can be administered without dilution.

## **WHAT ARE THE BENEFITS OF THE VACCINE?**

The vaccine has been shown to prevent COVID-19.

The duration of protection against COVID-19 is currently unknown.

## **WHAT ARE THE RISKS OF THE VACCINE?**

There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported with the vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- decreased appetite
- diarrhea
- vomiting
- arm pain
- fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

### **WHAT SHOULD I DO ABOUT SIDE EFFECTS?**

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include either “COMIRNATY (COVID-19 Vaccine, mRNA)” or “Pfizer-BioNTech COVID-19 Vaccine EUA”, as appropriate, in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
<a href="http://www.pfizersafetyreporting.com">www.pfizersafetyreporting.com</a>	1-866-635-8337	1-800-438-1985

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).

#### **WHAT IF I DECIDE NOT TO GET COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?**

Under the EUA, it is your choice to receive or not receive the vaccine. Should you decide not to receive it, it will not change your standard medical care.

#### **ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?**

Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

#### **CAN I RECEIVE THE COMIRNATY (COVID-19 VACCINE, mRNA) OR PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?**

Data have not yet been submitted to FDA on administration of COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering receiving COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

#### **WHAT IF I AM IMMUNOCOMPROMISED?**

If you are immunocompromised, you may receive a third dose of the vaccine. The third dose may still not provide full immunity to COVID-19 in people who are

immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate.

### **WHAT IF I AM PREGNANT OR BREASTFEEDING?**

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

### **WILL THE VACCINE GIVE ME COVID-19?**

No. The vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.


### **KEEP YOUR VACCINATION CARD**

When you get your first dose, you will get a vaccination card to show you when to return for your next dose(s) of the vaccine. Remember to bring your card when you return.

### **ADDITIONAL INFORMATION**

If you have questions, visit the website or call the telephone number provided below.

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- Ask the vaccination provider.
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### **CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?**

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a

COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

#### **WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?**

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#### **WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?**

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit [www.hrsa.gov/cicp/](http://www.hrsa.gov/cicp/) or call 1-855-266-2427.

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The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.



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