

11 years

## VACCINE INFORMATION STATEMENT

# Tdap Vaccine

(Tetanus, Diphtheria,  
and Pertussis)

## 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?

**Tetanus, diphtheria and pertussis** can be very serious diseases, even for adolescents and adults. Tdap vaccine can protect us from these diseases.

**TETANUS** (Lockjaw) causes painful muscle tightening and stiffness, usually all over the body.

- It can lead to tightening of muscles in the head and neck so you can't open your mouth, swallow, or sometimes even breathe. Tetanus kills about 1 out of 5 people who are infected.

**DIPHTHERIA** can cause a thick coating to form in the back of the throat.

- It can lead to breathing problems, paralysis, heart failure, and death.

**PERTUSSIS** (Whooping Cough) causes severe coughing spells, which can cause difficulty breathing, vomiting and disturbed sleep.

- It can also lead to weight loss, incontinence, and rib fractures. Up to 2 in 100 adolescents and 5 in 100 adults with pertussis are hospitalized or have complications, which could include pneumonia or death.

These diseases are caused by bacteria. Diphtheria and pertussis are spread from person to person through coughing or sneezing. Tetanus enters the body through cuts, scratches, or wounds.

Before vaccines, the United States saw as many as 200,000 cases a year of diphtheria and pertussis, and hundreds of cases of tetanus. Since vaccination began, tetanus and diphtheria have dropped by about 99% and pertussis by about 80%.

### 2 Tdap vaccine

Tdap vaccine can protect adolescents and adults from tetanus, diphtheria, and pertussis. One dose of Tdap is routinely given at age 11 or 12. People who did *not* get Tdap at that age should get it as soon as possible.

Tdap is especially important for health care professionals and anyone having close contact with a baby younger than 12 months.

Pregnant women should get a dose of Tdap during *every* pregnancy, to protect the newborn from pertussis. Infants are most at risk for severe, life-threatening complications from pertussis.

A similar vaccine, called Td, protects from tetanus and diphtheria, but not pertussis. A Td booster should be given every 10 years. Tdap may be given as one of these boosters if you have not already gotten a dose. Tdap may also be given after a severe cut or burn to prevent tetanus infection.

Your doctor can give you more information.

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

### 3 Some people should not get this vaccine

- If you ever had a life-threatening allergic reaction after a dose of any tetanus, diphtheria, or pertussis containing vaccine, OR if you have a severe allergy to any part of this vaccine, you should not get Tdap. Tell your doctor if you have any severe allergies.
- If you had a coma, or long or multiple seizures within 7 days after a childhood dose of DTP or DTaP, you should not get Tdap, unless a cause other than the vaccine was found. You can still get Td.
- Talk to your doctor if you:
  - have epilepsy or another nervous system problem,
  - had severe pain or swelling after any vaccine containing diphtheria, tetanus or pertussis,
  - ever had Guillain-Barré Syndrome (GBS),
  - aren't feeling well on the day the shot is scheduled.



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## 4 Risks of a vaccine reaction

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

Brief **fainting spells** can follow a vaccination, leading to injuries from falling. Sitting or lying down for about 15 minutes can help prevent these. Tell your doctor if you feel dizzy or light-headed, or have vision changes or ringing in the ears.

### Mild problems following Tdap

*(Did not interfere with activities)*

- Pain where the shot was given (about 3 in 4 adolescents or 2 in 3 adults)
- Redness or swelling where the shot was given (about 1 person in 5)
- Mild fever of at least 100.4°F (up to about 1 in 25 adolescents or 1 in 100 adults)
- Headache (about 3 or 4 people in 10)
- Tiredness (about 1 person in 3 or 4)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 in 4 adolescents or 1 in 10 adults)
- Chills, body aches, sore joints, rash, swollen glands (uncommon)

### Moderate problems following Tdap

*(Interfered with activities, but did not require medical attention)*

- Pain where the shot was given (about 1 in 5 adolescents or 1 in 100 adults)
- Redness or swelling where the shot was given (up to about 1 in 16 adolescents or 1 in 25 adults)
- Fever over 102°F (about 1 in 100 adolescents or 1 in 250 adults)
- Headache (about 3 in 20 adolescents or 1 in 10 adults)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 or 3 people in 100)
- Swelling of the entire arm where the shot was given (up to about 3 in 100).

### Severe problems following Tdap

*(Unable to perform usual activities; required medical attention)*

- Swelling, severe pain, bleeding and redness in the arm where the shot was given (rare).

A **severe allergic reaction** could occur after any vaccine (estimated less than 1 in a million doses).

## 5 What if there is a serious reaction?

### What should I look for?

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

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

### What should I do?

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

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

## 6 The National Vaccine Injury Compensation Program

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

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

## 7 How can I learn more?

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

## Vaccine Information Statement (Interim) Tdap Vaccine

05/09/2013

42 U.S.C. § 300aa-26





# Meningococcal Vaccines

## What You Need to Know

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### What is meningococcal disease?

Meningococcal disease is a serious bacterial illness. It is a leading cause of bacterial meningitis in children 2 through 18 years old in the United States. Meningitis is an infection of the covering of the brain and the spinal cord.

Meningococcal disease also causes blood infections.

About 1,000–1,200 people get meningococcal disease each year in the U.S. Even when they are treated with antibiotics, 10–15% of these people die. Of those who live, another 11%–19% lose their arms or legs, have problems with their nervous systems, become deaf, or suffer seizures or strokes.

Anyone can get meningococcal disease. But it is most common in infants less than one year of age and people 16–21 years. Children with certain medical conditions, such as lack of a spleen, have an increased risk of getting meningococcal disease. College freshmen living in dorms are also at increased risk.

Meningococcal infections can be treated with drugs such as penicillin. Still, many people who get the disease die from it, and many others are affected for life. This is why preventing the disease through use of meningococcal vaccine is important for people at highest risk.

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### Meningococcal vaccine

There are two kinds of meningococcal vaccine in the U.S.:

- Meningococcal conjugate vaccine (**MCV4**) is the preferred vaccine for people 55 years of age and younger.
- Meningococcal polysaccharide vaccine (**MPSV4**) has been available since the 1970s. It is the only meningococcal vaccine licensed for people older than 55.

Both vaccines can prevent 4 types of meningococcal disease, including 2 of the 3 types most common in the United States and a type that causes epidemics in Africa. There are other types of meningococcal disease; the vaccines do not protect against these.

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### Who should get meningococcal vaccine and when?

#### Routine vaccination

Two doses of MCV4 are recommended for adolescents 11 through 18 years of age: the first dose at 11 or 12 years of age, with a booster dose at age 16.

Adolescents in this age group with HIV infection should get three doses: 2 doses 2 months apart at 11 or 12 years, plus a booster at age 16.

If the first dose (or series) is given between 13 and 15 years of age, the booster should be given between 16 and 18. If the first dose (or series) is given after the 16<sup>th</sup> birthday, a booster is not needed.

#### Other people at increased risk

- College freshmen living in dormitories.
- Laboratory personnel who are routinely exposed to meningococcal bacteria.
- U.S. military recruits.
- Anyone traveling to, or living in, a part of the world where meningococcal disease is common, such as parts of Africa.
- Anyone who has a damaged spleen, or whose spleen has been removed.
- Anyone who has persistent complement component deficiency (an immune system disorder).
- People who might have been exposed to meningitis during an outbreak.

Children between 9 and 23 months of age, and anyone else with certain medical conditions need 2 doses for adequate protection. Ask your doctor about the number and timing of doses, and the need for booster doses.

MCV4 is the preferred vaccine for people in these groups who are 9 months through 55 years of age. MPSV4 can be used for adults older than 55.



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**4****Some people should not get meningococcal vaccine or should wait.**

- Anyone who has ever had a severe (life-threatening) allergic reaction to a previous dose of MCV4 or MPSV4 vaccine should not get another dose of either vaccine.
- Anyone who has a severe (life threatening) allergy to any vaccine component should not get the vaccine. *Tell your doctor if you have any severe allergies.*
- Anyone who is moderately or severely ill at the time the shot is scheduled should probably wait until they recover. Ask your doctor. People with a mild illness can usually get the vaccine.
- Meningococcal vaccines may be given to pregnant women. MCV4 is a fairly new vaccine and has not been studied in pregnant women as much as MPSV4 has. It should be used only if clearly needed. The manufacturers of MCV4 maintain pregnancy registries for women who are vaccinated while pregnant.

Except for children with sickle cell disease or without a working spleen, meningococcal vaccines may be given at the same time as other vaccines.

**5****What are the risks from meningococcal vaccines?**

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of meningococcal vaccine causing serious harm, or death, is extremely small.

Brief fainting spells and related symptoms (such as jerking or seizure-like movements) can follow a vaccination. They happen most often with adolescents, and they can result in falls and injuries.

Sitting or lying down for about 15 minutes after getting the shot—especially if you feel faint—can help prevent these injuries.

**Mild problems**

As many as half the people who get meningococcal vaccines have mild side effects, such as redness or pain where the shot was given.

If these problems occur, they usually last for 1 or 2 days. They are more common after MCV4 than after MPSV4.

A small percentage of people who receive the vaccine develop a mild fever.

**Severe problems**

Serious allergic reactions, within a few minutes to a few hours of the shot, are very rare.

**6****What if there is a serious reaction?****What should I look for?**

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

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

**What should I do?**

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

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**7****The National Vaccine Injury Compensation Program**

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

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

**8****How can I learn more?**

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

**Vaccine Information Statement (Interim)  
Meningococcal Vaccine**

10/14/2011

42 U.S.C. § 300aa-26

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## VACCINE INFORMATION STATEMENT

# HPV Vaccine Gardasil® (Human Papillomavirus)

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## What You Need to Know

### 1 What is HPV?

Genital **human papillomavirus (HPV)** is the most common sexually transmitted virus in the United States. More than half of sexually active men and women are infected with HPV at some time in their lives.

About 20 million Americans are currently infected, and about 6 million more get infected each year. HPV is usually spread through sexual contact.

Most HPV infections don't cause any symptoms, and go away on their own. But HPV can cause **cervical cancer** in women. Cervical cancer is the 2nd leading cause of cancer deaths among women around the world. In the United States, about 12,000 women get cervical cancer every year and about 4,000 are expected to die from it.

HPV is also associated with several less common cancers, such as vaginal and vulvar cancers in women, and anal and oropharyngeal (back of the throat, including base of tongue and tonsils) cancers in both men and women. HPV can also cause genital warts and warts in the throat.

There is no cure for HPV infection, but some of the problems it causes can be treated.

### 2 HPV vaccine: Why get vaccinated?

The HPV vaccine you are getting is one of two vaccines that can be given to prevent HPV. It may be given to both males and females.

This vaccine can prevent most cases of cervical cancer in females, if it is given before exposure to the virus. In addition, it can prevent vaginal and vulvar cancer in females, and genital warts and anal cancer in both males and females.

Protection from HPV vaccine is expected to be long-lasting. But vaccination is not a substitute for cervical cancer screening. Women should still get regular Pap tests.

### 3 Who should get this HPV vaccine and when?

**HPV vaccine is given as a 3-dose series**

1st Dose	Now
2nd Dose	1 to 2 months after Dose 1
3rd Dose	6 months after Dose 1

Additional (booster) doses are not recommended.

#### Routine vaccination

- This HPV vaccine is recommended for girls and boys **11 or 12 years of age**. It *may* be given starting at age 9.

#### Why is HPV vaccine recommended at 11 or 12 years of age?

HPV infection is easily acquired, even with only one sex partner. That is why it is important to get HPV vaccine before any sexual contact takes place. Also, response to the vaccine is better at this age than at older ages.

#### Catch-up vaccination

This vaccine is recommended for the following people who have not completed the 3-dose series:

- Females 13 through 26 years of age.
- Males 13 through 21 years of age.

This vaccine *may* be given to men 22 through 26 years of age who have not completed the 3-dose series.

It is *recommended* for men through age 26 who have sex with men or whose immune system is weakened because of HIV infection, other illness, or medications.

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



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**4****Some people should not get HPV vaccine or should wait.**

- Anyone who has ever had a life-threatening allergic reaction to any component of HPV vaccine, or to a previous dose of HPV vaccine, should not get the vaccine. Tell your doctor if the person getting vaccinated has any severe allergies, including an allergy to yeast.
- HPV vaccine is not recommended for pregnant women. However, receiving HPV vaccine when pregnant is not a reason to consider terminating the pregnancy. Women who are breast feeding may get the vaccine.
- People who are mildly ill when a dose of HPV vaccine is planned can still be vaccinated. People with a moderate or severe illness should wait until they are better.

**5****What are the risks from this vaccine?**

This HPV vaccine has been used in the U.S. and around the world for about six years and has been very safe.

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

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

Several **mild** to **moderate** problems are known to occur with this HPV vaccine. These do not last long and go away on their own.

- Reactions in the arm where the shot was given:
  - Pain (about 8 people in 10)
  - Redness or swelling (about 1 person in 4)
- Fever:
  - Mild (100° F) (about 1 person in 10)
  - Moderate (102° F) (about 1 person in 65)
- Other problems:
  - Headache (about 1 person in 3)
- Fainting: Brief fainting spells and related symptoms (such as jerking movements) can happen after any medical procedure, including vaccination. Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and injuries caused by falls. Tell your doctor if the patient feels dizzy or light-headed, or has vision changes or ringing in the ears.

Like all vaccines, HPV vaccines will continue to be monitored for unusual or severe problems.

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**What should I do?**

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Vaccine Information Statement (Interim)  
**HPV Vaccine (Gardasil)**

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