

Hepatitis B Vaccine

What You Need to Know

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

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

1 Why get vaccinated?

Hepatitis B is a serious disease that affects the liver. It is caused by the hepatitis B virus. Hepatitis B can cause mild illness lasting a few weeks, or it can lead to a serious, lifelong illness.

Hepatitis B virus infection can be either acute or chronic.

Acute hepatitis B virus infection is a short-term illness that occurs within the first 6 months after someone is exposed to the hepatitis B virus. This can lead to:

- fever, fatigue, loss of appetite, nausea, and/or vomiting
- jaundice (yellow skin or eyes, dark urine, clay-colored bowel movements)
- pain in muscles, joints, and stomach

Chronic hepatitis B virus 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
- death

Chronically-infected people can spread hepatitis B virus to others, even if they do not feel or look sick themselves. Up to 1.4 million people in the United States may have chronic hepatitis B infection. About 90% of infants who get hepatitis B become chronically infected and about 1 out of 4 of them dies.

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 with the virus through:

- Birth (a baby whose mother is infected can be infected at or after birth)
- 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

Each year about 2,000 people in the United States die from hepatitis B-related liver disease.

Hepatitis B vaccine can prevent hepatitis B and its consequences, including liver cancer and cirrhosis.

2 Hepatitis B vaccine

Hepatitis B vaccine is made from parts of the hepatitis B virus. It cannot cause hepatitis B infection. The vaccine is usually given as 2, 3, or 4 shots over 1 to 6 months.

Infants should get their first dose of hepatitis B vaccine at birth and will usually complete the series at 6 months of age.

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

Hepatitis B vaccine is recommended for unvaccinated **adults** who are at risk for hepatitis B virus infection, including:

- 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, or diabetes
- Anyone who wants to be protected from hepatitis B

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



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

3**Some people should not get this vaccine**

Tell the person who is giving the vaccine:

- **If the person getting the vaccine has any severe, life-threatening allergies.**
If you ever had a life-threatening allergic reaction after a dose of hepatitis B vaccine, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Ask your health care provider if you want information about vaccine components.
- **If the person getting the vaccine is not feeling well.**
If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.

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.

Most people who get hepatitis B vaccine do not have any problems with it.

Minor problems following hepatitis B vaccine include:

- soreness where the shot was given
- temperature of 99.9°F or higher

If these problems occur, they usually begin soon after the shot and last 1 or 2 days.

Your doctor can tell you more about these reactions.

Other problems that could happen after this vaccine:

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

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

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

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

What should I look for?

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

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would 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 to the nearest hospital. Otherwise, call your clinic.

Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

6**The National Vaccine Injury Compensation Program**

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

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7**How can I learn more?**

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement
Hepatitis B Vaccine



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10/12/2018 | 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

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

1 Why get vaccinated?

DTaP vaccine can help protect your child from diphtheria, tetanus, and pertussis.

- **DIPHTHERIA (D)** can cause breathing problems, paralysis, and heart failure. Before vaccines, diphtheria killed tens of thousands of children every year in the United States.
- **TETANUS (T)** causes painful tightening of the muscles. It can cause “locking” of the jaw so you cannot open your mouth or swallow. About 1 person out of 5 who get tetanus dies.
- **PERTUSSIS (aP)**, also known as Whooping Cough, causes coughing spells so bad that it is hard for infants and children to eat, drink, or breathe. It can cause pneumonia, seizures, brain damage, or death.

Most children who are vaccinated with DTaP will be protected throughout childhood. Many more children would get these diseases if we stopped vaccinating.

2 DTaP vaccine

Children should usually get 5 doses of DTaP vaccine, one dose at each of the following ages:

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

DTaP may be given at the same time as other vaccines. Also, sometimes a child can receive DTaP together with one or more other vaccines in a single shot.

3 Some children should not get DTaP vaccine or should wait

DTaP is only for children younger than 7 years old. DTaP vaccine is not appropriate for everyone—a small number of children should receive a different vaccine that contains only diphtheria and tetanus instead of DTaP.

Tell your health care provider if your child:

- Has had an **allergic reaction after a previous dose of DTaP**, or has any **severe, life-threatening allergies**.
- Has had a **coma or long repeated seizures within 7 days after a dose of DTaP**.
- Has **seizures or another nervous system problem**.
- Has had a condition called **Guillain-Barré Syndrome (GBS)**.
- Has had **severe pain or swelling after a previous dose of DTaP or DT vaccine**.

In some cases, your health care provider may decide to postpone your child’s DTaP vaccination to 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 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, soreness, swelling, and tenderness where the shot is given are common after DTaP.
- Fever, fussiness, tiredness, poor appetite, and vomiting sometimes happen 1 to 3 days 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, the vaccine is followed by swelling of the entire arm or leg, especially in older children when they receive their fourth or fifth dose.
- Long-term seizures, coma, lowered consciousness, or permanent brain damage happen extremely rarely after DTaP vaccination.

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 child 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 child to the nearest hospital.

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

Serious reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor will usually file this report, or you can do it yourself. Visit www.vaers.hhs.gov or call 1-800-822-7967. *VAERS is only for reporting reactions, it does not give medical advice.*

6 The National Vaccine Injury Compensation Program

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

Vaccine Information Statement (Interim)
DTaP (Diphtheria, Tetanus,
Pertussis) Vaccine



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VACCINE INFORMATION STATEMENT

Hib Vaccine

What You Need to Know

(*Haemophilus
Influenzae* Type b)

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

1 Why get vaccinated?

Haemophilus influenzae type b (Hib) disease is a serious disease caused by bacteria. It usually affects children under 5 years old. It can also affect adults with certain medical conditions.

Your child can get Hib disease by being around other children or adults who may have the bacteria and not know it. The germs spread from person to person. If the germs stay in the child's nose and throat, the child probably will not get sick. But sometimes the germs spread into the lungs or the bloodstream, and then Hib can cause serious problems. This is called invasive Hib disease.

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 disease 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

Before Hib vaccine, about 20,000 children in the United States under 5 years old got Hib disease each year, and about 3% - 6% of them died.

Hib vaccine can prevent Hib disease. Since use of Hib vaccine began, the number of cases of invasive Hib disease has decreased by more than 99%. Many more children would get Hib disease if we stopped vaccinating.

2 Hib vaccine

Several different brands of Hib vaccine are available. Your child will receive either 3 or 4 doses, depending on which vaccine is used.

Doses of Hib vaccine are usually recommended at these ages:

- First Dose: 2 months of age
- Second Dose: 4 months of age
- Third Dose: 6 months of age (if needed, depending on brand of vaccine)
- Final/Booster Dose: 12-15 months of age

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

Hib vaccine may be given as part of a combination vaccine. Combination vaccines are made when two or more types of vaccine are combined together into a single shot, so that one vaccination can protect against more than one disease.

Children over 5 years old and adults usually do not need Hib vaccine. But it may be recommended for older children or adults with asplenia or sickle cell disease, before surgery to remove the spleen, or following a bone marrow transplant. It may also be recommended for people 5 to 18 years old with HIV. Ask your doctor for details.

Your doctor or the person giving you the vaccine can give you more information.



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3**Some people should not get this vaccine**

Hib vaccine should not be given to infants younger than 6 weeks of age.

A person who has ever had a life-threatening allergic reaction after a previous dose of Hib vaccine, OR has a severe allergy to any part of this vaccine, should not get Hib vaccine. *Tell the person giving the vaccine about any severe allergies.*

People who are mildly ill can get Hib vaccine. People who are moderately or severely ill should probably wait until they recover. Talk to your healthcare provider if the person getting the vaccine isn't feeling well on the day the shot is scheduled.

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. Serious reactions are also possible but are rare.

Most people who get Hib vaccine do not have any problems with it.

Mild Problems following Hib vaccine:

- redness, warmth, or swelling where the shot was given
- fever

These problems are uncommon. If they occur, they usually begin soon after the shot and last 2 or 3 days.

Problems that could happen after any vaccine:

Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

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

Older children, adolescents, and adults might also experience these problems after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.

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

5**What if there is a serious reaction?**

What should I look for?

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

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

What should I do?

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

VAERS does not give medical advice.

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7**How can I learn more?**

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
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 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement
Hib Vaccine

4/02/2015

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VACCINE INFORMATION STATEMENT

Polio Vaccine

What You Need to Know

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1 Why get vaccinated?

Vaccination can protect people from **polio**. Polio is a disease caused by a virus. It is spread mainly by person-to-person contact. It can also be spread by consuming food or drinks that are contaminated with the feces of an infected person.

Most people infected with polio have no symptoms, and many recover without complications. But sometimes people who get polio develop paralysis (cannot move their arms or legs). Polio can result in permanent disability. Polio can also cause death, usually by paralyzing the muscles used for breathing.

Polio used to be very common in the United States. It paralyzed and killed thousands of people every year before polio vaccine was introduced in 1955. There is no cure for polio infection, but it can be prevented by vaccination.

Polio has been eliminated from the United States. But it still occurs in other parts of the world. It would only take one person infected with polio coming from another country to bring the disease back here if we were not protected by vaccination. If the effort to eliminate the disease from the world is successful, some day we won't need polio vaccine. Until then, we need to keep getting our children vaccinated.

2 Polio vaccine

Inactivated Polio Vaccine (**IPV**) can prevent polio.

Children

Most people should get IPV when they are children. Doses of IPV are usually given at 2, 4, 6 to 18 months, and 4 to 6 years of age.

The schedule might be different for some children (including those traveling to certain countries and those who receive IPV as part of a combination vaccine). Your health care provider can give you more information.

Adults

Most adults do not need IPV because they were already vaccinated against polio as children. But 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 polio virus, and
- health care workers treating patients who could have polio.

These higher-risk adults may need 1 to 3 doses of IPV, depending on how many doses they have had in the past.

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

3 Some people should not get this vaccine

Tell the person who is giving the vaccine:

- **If the person getting the vaccine has any severe, life-threatening allergies.**
If you ever had a life-threatening allergic reaction after a dose of IPV, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Ask your health care provider if you want information about vaccine components.
- **If the person getting the vaccine is not feeling well.**
If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.

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.

Some people who get IPV get a sore spot where the shot was given. IPV has not been known to cause serious problems, and most people do not have any problems with it.



U.S. Department of
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Centers for Disease
Control and Prevention

Other problems that could happen after this vaccine:

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

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

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

5

What if there is a serious problem?

What should I look for?

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

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would 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 to the nearest hospital. Otherwise, call your clinic.

Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

6

The National Vaccine Injury Compensation Program

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

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7

How can I learn more?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement Polio Vaccine

7/20/2016

42 U.S.C. § 300aa-26

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VACCINE INFORMATION STATEMENT

Pneumococcal Conjugate Vaccine (PCV13)

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

1 Why get vaccinated?

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

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

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

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

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

Before there was a vaccine, the United States saw:

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

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

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

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

2 PCV13 vaccine

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

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

3 Some people should not get this vaccine

Anyone who has ever had a life-threatening allergic reaction to a dose of this vaccine, to an earlier pneumococcal vaccine called PCV7, or to any vaccine containing diphtheria toxoid (for example, DTaP), should not get PCV13.

Anyone with a severe allergy to any component of PCV13 should not get the vaccine. *Tell your doctor if the person being vaccinated has any severe allergies.*

If the person scheduled for vaccination is not feeling well, your healthcare provider might decide to reschedule the shot on another day.

4 Risks of a vaccine reaction

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

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

- About half became drowsy after the shot, had a temporary loss of appetite, or had redness or tenderness where the shot was given.
- About 1 out of 3 had swelling where the shot was given.
- About 1 out of 3 had a mild fever, and about 1 in 20 had a fever over 102.2°F.
- Up to about 8 out of 10 became fussy or irritable.

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

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



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

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some older children and adults get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

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

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

5

What if there is a serious reaction?

What should I look for?

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

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

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.

Reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

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Vaccine Information Statement
PCV13 Vaccine

11/05/2015

42 U.S.C. § 300aa-26

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VACCINE INFORMATION STATEMENT

Rotavirus Vaccine

What You Need to Know

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1 Why get vaccinated?

Rotavirus is a virus that causes diarrhea, mostly in babies and young children. The diarrhea can be severe, and lead to dehydration. Vomiting and fever are also common in babies with rotavirus.

Before rotavirus vaccine, rotavirus disease was a common and serious health problem for children in the United States. Almost all children in the United States had at least one rotavirus infection before their 5th birthday.

Every year before the vaccine was available:

- more than 400,000 young children had to see a doctor for illness caused by rotavirus,
- more than 200,000 had to go to the emergency room,
- 55,000 to 70,000 had to be hospitalized, and
- 20 to 60 died.

Since the introduction of the rotavirus vaccine, hospitalizations and emergency visits for rotavirus have dropped dramatically.

2 Rotavirus vaccine

Two brands of rotavirus vaccine are available. Your baby will get either 2 or 3 doses, depending on which vaccine is used.

Doses are recommended at these ages:

- First Dose: 2 months of age
- Second Dose: 4 months of age
- Third Dose: 6 months of age (if needed)

Your child must get the first dose of rotavirus vaccine before 15 weeks of age, and the last by age 8 months. Rotavirus vaccine may safely be given at the same time as other vaccines.

Almost all babies who get rotavirus vaccine will be protected from severe rotavirus diarrhea. And most of these babies will not get rotavirus diarrhea at all.

The vaccine will not prevent diarrhea or vomiting caused by other germs.

- Another virus called porcine circovirus (or parts of it) can be found in both rotavirus vaccines. This is not a virus that infects people, and there is no known safety risk. For more information, see <http://wayback.archive-it.org/7993/20170406124518/https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm212140.htm>

3 Some babies should not get this vaccine

A baby who has had a life-threatening allergic reaction to a dose of rotavirus vaccine should not get another dose.

A baby who has a severe allergy to any part of rotavirus vaccine should not get the vaccine. *Tell your doctor if your baby has any severe allergies that you know of, including a severe allergy to latex.*

Babies with "severe combined immunodeficiency" (SCID) should not get rotavirus vaccine.

Babies who have had a type of bowel blockage called "intussusception" should not get rotavirus vaccine.

Babies who are mildly ill can get the vaccine. Babies who are moderately or severely ill should wait until they recover. This includes babies with moderate or severe diarrhea or vomiting.

Check with your doctor if your baby's immune system is weakened because of:

- HIV/AIDS, or any other disease that affects the immune system
- treatment with drugs such as steroids
- cancer, or cancer treatment with x-rays or drugs

4 Risks of a vaccine reaction

With a vaccine, like any medicine, there is a chance of side effects. These are usually mild and go away on their own. Serious side effects are also possible but are rare.

Most babies who get rotavirus vaccine do not have any problems with it. But some problems have been associated with rotavirus vaccine:

Mild problems following rotavirus vaccine:

- Babies might become irritable, or have mild, temporary diarrhea or vomiting after getting a dose of rotavirus vaccine.



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Serious problems following rotavirus vaccine:

- Intussusception is a type of bowel blockage that is treated in a hospital, and could require surgery. It happens “naturally” in some babies 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 1st or 2nd vaccine dose. This additional risk is estimated to range from about 1 in 20,000 to 1 in 100,000 US infants who get rotavirus vaccine. Your doctor can give you more information.

Problems that could happen after any vaccine:

- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and usually happen within a few minutes to a few hours after the vaccination.

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

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

5 What if there is a serious problem?

What should I look for?

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 1st or 2nd dose of rotavirus vaccine, but look for them any time after vaccination.

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

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, or unusual sleepiness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

If you think it is **intussusception**, call a doctor right away. If you can't reach your doctor, take your baby to a hospital. Tell them when your baby got the rotavirus vaccine.

If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 or get your baby to the nearest hospital.

Otherwise, call your doctor.

Afterward, the reaction should be reported to the “Vaccine Adverse Event Reporting System” (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

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

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement Rotavirus Vaccine

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