

Rotavirus 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?

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.



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

5. What if there is a serious problem?

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 or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members 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. 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 or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- 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.
- 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.





**Addendum to Rotavirus Vaccine:
What You Need to Know
Vaccine Information Statement**

1. I agree that the person named below will get the vaccine checked below.
2. I received or was offered a copy of the Vaccine Information Statement (VIS) for the vaccine listed above.
3. I know the risks of the disease this vaccine prevents.
4. I know the benefits and risks of the vaccine.
5. I have had a chance to ask questions about the disease the vaccine prevents, the vaccine, and how the vaccine is given.
6. I know that the person named below will have the vaccine put in his/her body to prevent the disease this vaccine prevents.
7. I am an adult who can legally consent for the person named below to get the vaccine. I freely and voluntarily give my signed permission for this vaccine.

Vaccine to be given: Rotavirus Vaccine

| Information about person to receive vaccine (Please print) | | | | |
|---|-------|----------------|-------------------------|---------------------|
| Name: Last | First | Middle Initial | Birthdate (mm/dd/yy) | Sex (circle one) |
| | | | | M F |
| Address: Street | City | County | State TX | Zip |
| Signature of person to receive vaccine or person authorized to make the request (parent or guardian): | | | | |
| x _____ | | | Date: _____ | |
| x _____ | | | Date: _____ | |
| Witness | | | | |

PRIVACY NOTIFICATION - With few exceptions, you have the right to request and be informed about information that the State of Texas collects about you. You are entitled to receive and review the information upon request. You also have the right to ask the state agency to correct any information that is determined to be incorrect. See <http://www.dshs.texas.gov> for more information on Privacy Notification. (Reference: Government Code, Section 552.021, 552.023, 559.003, and 559.004)

Privacy Notice: I acknowledge that I have received a copy of my immunization provider's HIPAA Privacy Notice.

For Clinic / Office Use Only

| | |
|--------------------------|-------------------------------------|
| Clinic / Office Address: | Date Vaccine Administered: |
| | Vaccine Manufacturer: |
| | Vaccine Lot Number: |
| | Site of Injection: |
| | Title of Vaccine Administrator: |
| | Signature of Vaccine Administrator: |
| | Date VIS Given: |

Notice: Alterations or changes to this publication is prohibited.

Instructions: File this consent statement in the patient's chart.