

VACCINE INFORMATION STATEMENT

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 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 U.S. had at least one rotavirus infection before their 5th birthday.

Every year:

- 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.

Rotavirus vaccine has been used since 2006 in the United States. Because children are protected by the 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 of rotavirus vaccine 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)

Rotavirus vaccine is a liquid that is swallowed, not a shot.

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

Rotavirus vaccine is very good at preventing diarrhea and vomiting caused by rotavirus. 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 www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205547.htm.

3 Some babies should not get this vaccine

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

A baby who has a severe (life threatening) allergy to any component 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 probably get the vaccine today. Babies who are moderately or severely ill should probably 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 long-term steroids
 - cancer, or cancer treatment with x-rays or drugs



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

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 very 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

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

Serious problems

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 U.S. infants to 1 in 100,000 U.S. infants who get rotavirus vaccine. Your doctor can give you more information.

5 What if there is a serious reaction?

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 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 **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 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.
- 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 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.

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 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement (Interim) Rotavirus Vaccine

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