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 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 **www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205547.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.

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

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. Your healthcare provider 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**

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