

ROTAVIRUS VACCINE

WHAT YOU NEED TO KNOW

1 What is rotavirus?

Rotavirus is a virus that causes severe diarrhea, mostly in babies and young children. It is often accompanied by vomiting and fever.

Rotavirus is not the only cause of severe diarrhea, but it is one of the most serious. Each year in the United States rotavirus is responsible for:

- more than 400,000 doctor visits
- more than 200,000 emergency room visits
- 55,000 to 70,000 hospitalizations
- 20-60 deaths

Almost all children in the U.S. are infected with rotavirus before their 5th birthday.

Children are most likely to get rotavirus disease between November and May, depending on the part of the country.

Your child can get rotavirus infection by being around other children who are already infected.

2 Rotavirus vaccine

Better hygiene and sanitation have not been very good at reducing rotavirus disease. Rotavirus vaccine is the best way to protect children against rotavirus disease.

Rotavirus vaccine is an oral (swallowed) vaccine; it is not given by injection.

Rotavirus vaccine will not prevent diarrhea or vomiting caused by other germs, but it is very good at preventing diarrhea and vomiting caused by rotavirus. About 98% of children who get the vaccine are protected from *severe* rotavirus diarrhea, and about 74% do not get rotavirus diarrhea at all.

Children who get the vaccine are also much less likely to be hospitalized or to see a doctor because of rotavirus infection.



3 Who should get rotavirus vaccine and when?

Children should get 3 doses of rotavirus vaccine. They are recommended at these ages:

- First Dose: 2 months of age
- Second Dose: 4 months of age
- Third Dose: 6 months of age

- The first dose should be given between 6 and 12 weeks of age. The vaccine has not been studied when started among children outside that age range.
- Children should have gotten all 3 doses by 32 weeks of age.

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

Children who get the vaccine may be fed normally afterward.

4 Some children should not get rotavirus vaccine or should wait

- A child who has had a severe (life-threatening) allergic reaction to a dose of rotavirus vaccine should not get another dose. A child who has a severe (life threatening) allergy to any component of rotavirus vaccine should not get the vaccine. Tell your doctor if your child has any severe allergies that you know of.
- Children who are moderately or severely ill at the time the vaccination is scheduled should probably wait until they recover. This includes children who have diarrhea or vomiting. Ask your doctor or nurse. Children with mild illnesses should usually get the vaccine.
- Check with your doctor if your child has any ongoing digestive problems.

- Check with your doctor if your child'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
- Check with your doctor if your child recently had a blood transfusion or received any other blood product (such as immune globulin).

In the late 1990s a different type of rotavirus vaccine was used. This vaccine was found to be associated with an uncommon type of bowel obstruction called "intussusception," and was taken off the market.

The new rotavirus vaccine has been tested with more than 70,000 children and has not been associated with intussusception.

However, once a person has had intussusception, from any cause, they are at higher risk for getting it again. So as a precaution, it is suggested that if a child has had intussusception they should not get rotavirus vaccine.

5 What are the risks from rotavirus vaccine?

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

Getting rotavirus vaccine is much safer than getting the disease.

Mild problems

Children are slightly (1-3%) more likely to have mild, temporary diarrhea or vomiting within 7 days after getting a dose of rotavirus vaccine than children who have not gotten the vaccine.

Moderate or severe reactions have not been associated with this vaccine.

If rare reactions occur with any new product, they may not be identified until thousands, or millions, of people have used it. Like all vaccines, rotavirus vaccine will continue to be monitored for unusual or severe problems.

Vaccine Information Statement (Interim)
Rotavirus (4/12/06)

6 What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their website at

www.hrsa.gov/vaccinecompensation.

8 How can I learn more?

- Ask your doctor or nurse. They 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)
 - Visit CDC's National Immunization Program website at: www.cdc.gov/nip



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL IMMUNIZATION PROGRAM