

ROTAVIRUS VACCINE

WHAT YOU NEED TO KNOW

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

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. Before rotavirus vaccine was used, rotavirus was responsible for:

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

in the United States each year.

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

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

Your baby can become infected by being around other children who have rotavirus diarrhea.

2 Rotavirus vaccine

Better hygiene and sanitation have not reduced rotavirus diarrhea very much in the United States.

The best way to protect your baby is with rotavirus vaccine.

Rotavirus vaccine is an oral (swallowed) vaccine, not a shot.

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. Most babies who get the vaccine will not get rotavirus diarrhea at all, and almost all of them will be protected from *severe* rotavirus diarrhea.

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



3 Who should get rotavirus vaccine and when?

There are two brands of rotavirus vaccine. A baby should get either 2 or 3 doses, depending on which brand is used.

The 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)

The first dose may be given as early as 6 weeks of age, and should be given by age 14 weeks 6 days. The last dose should be given by 8 months of age.

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

Babies who get the vaccine may be fed normally afterward.

4 Some babies should not get rotavirus vaccine or should wait

- 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 who are moderately or severely ill at the time the vaccination is scheduled should probably wait until they recover. This includes babies who have moderate or severe diarrhea or vomiting. Ask your doctor or nurse. Babies with mild illnesses should usually get the vaccine.

- 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

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 it was taken off the market.

The new rotavirus vaccines have not been associated with intussusception.

However, babies who have had intussusception, from any cause, are at higher risk for getting it again. If your baby has ever had intussusception, discuss this with your doctor.

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 any vaccine causing serious harm, or death, is extremely small.

Most babies who get rotavirus vaccine do not have any problems with it.

Mild problems

Babies may be slightly more likely to be irritable, or to have mild, temporary diarrhea or vomiting after getting a dose of rotavirus vaccine than babies who did not get the vaccine.

Rotavirus vaccine does not appear to cause any serious side effects.

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 (8/28/08)

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

A federal program has been created to help people who may have been harmed by a vaccine.

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/vaccines



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through the end of 2008 in order to allow providers to complete the series for any child who started with Rotateq.

In the next few weeks you will be receiving a supply of new Vaccine Order Forms (VOFs) that include space for these 2 new vaccines. Once you receive the new VOFs, please discard any old versions you have in stock. When reporting doses administered data for Rotavirus, you can combine any doses administered for both Rotateq and Rotarix in the space provided-you do not need to separate out the data by vaccine.

Update on Hib Vaccine Supply

CDC expects the Hib shortage to ease with the reintroduction of Merck Hib vaccine in the last quarter of 2008. For the time being we have sufficient inventory of ActHiB to support provider vaccine orders of the current 3 dose series and will do our best to accommodate your request but may need at times to modify orders based on provider usage and inventory. We will continue to monitor inventory levels on a month to month basis. We will not be offering the DTaP/IPV/Hib (Pentacel) combination vaccine product at this time. As a reminder providers should continue to defer the booster dose of Hib for healthy children 12-15 months of age.

New Vaccine Information Statement

Enclosed please find a camera-ready copy of the new Vaccine Information Statement (VIS) for Rotavirus. The VIS statements are also available electronically through the CDC website at <http://www.cdc.gov/vaccines/pubs/vis/default.htm>. There is no VIS revision planned for the new DTaP/IPV combination vaccine; continue to use the current VIS for DTaP and Polio vaccines. Also enclosed is an updated Vaccine Eligibility Criteria with a list of all vaccines currently provided by the Immunization Program.

As always, if you have any questions please call the State Immunization Program at (860) 509-7929.