



Important Information from the San Antonio Metropolitan Health District (SAMHD)

May 17, 2010

FDA Revises Recommendations for Rotavirus Vaccines

This message is to announce the availability of GlaxoSmithKline (GSK) Rotarix® vaccine. In March, the Food and Drug Administration (FDA) made the recommendation to temporarily suspend the use of Rotarix®. On May 14, 2010, the FDA announced the revised recommendations for rotavirus vaccines, and determined that it is appropriate for clinicians and health care professionals to resume the use of Rotarix® and to continue the use of Merck RotaTeq®. This recommendation supersedes FDA's prior recommendation of March 22, 2010, that healthcare practitioners temporarily suspend use of Rotarix® as a precaution, while the FDA learned more about the presence of porcine circovirus type-1 (PCV-1) in the vaccine. The agency reached its decision based on a careful evaluation of information from scientific literature, and input from scientific and public health experts, including members of the FDA's Vaccines and Related Biological Products Advisory Committee that convened on May 7, 2010 to discuss these vaccines.

The FDA also considered the following in its decision:

- Both vaccines have strong safety records, including clinical trials involving tens of thousands of patients as well as clinical experience with millions of vaccine recipients.
- The FDA has no evidence that PCV1 or PCV2 pose a safety risk in humans, and neither is known to cause infection or illness in humans.
- The benefits of the vaccines are substantial, and include prevention of death in some parts of the world and hospitalization for severe rotavirus disease in the United States. These benefits outweigh the risk, which is theoretical.

SAMHD Vaccine Management staff will be contacting VFC provider offices by phone that order Rotarix® vaccine from our program to provide additional guidance. Additional information on the FDA's current recommendation is available at the FDA website: www.fda.gov. In order for GSK to continue to monitor the safety of Rotarix®, providers are encouraged to report any potential vaccine-related adverse events to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967, www.vaers.hhs.gov, and to GSK at 1-888-825-5429. If you have any questions concerning medical or other issues, please contact the GSK Response Center at 1-888-825-5249. CDC has posted a revised Rotavirus VIS for your use at: www.cdc.gov/vaccines/pubs/vis/downloads/vis-rotavirus.pdf

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.

A virus (or parts of the virus) called porcine circovirus is in both rotavirus vaccines. This virus is not known to infect people and there is no known safety risk. For more information, see www.fda.gov.

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 people 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 a common 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.

6 What if there is a moderate or severe reaction?

What should I look for?

Any unusual condition, such as a severe allergic reaction or a high fever. If a severe allergic reaction occurred, it would be within a few minutes

to an hour after the vaccination. Signs of a serious allergic reaction can include difficulty breathing, weakness, hoarseness or wheezing, a fast heart beat, hives, dizziness, paleness, or swelling of the throat.

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 provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website 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

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine may file a claim with VICP by calling **1-800-338-2382** or by visiting their website at www.hrsa.gov/vaccinecompensation.

8 How can I learn more?

- Ask your health care provider. 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



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Vaccine Information Statement (Interim)
Rotavirus 42 U.S.C. §300aa-26 5/14/2010