

Patient Information
RotaTeq[®] (pronounced "RŌ-tuh-tek")
rotavirus vaccine, live, oral, pentavalent

You should read this information before your child receives the RotaTeq vaccine and ask your child's doctor any questions you may have. Your child will need 3 doses of the vaccine over the course of a few months. So read the leaflet before your child receives each dose of the vaccine in case any of the information about the vaccine changes. This leaflet is a summary of certain information about the vaccine. If you would like additional information, your health care provider can give you more complete information about this vaccine that is written for health care professionals. This leaflet does not take the place of talking with your child's doctor.

What is RotaTeq and How Does it Work?

RotaTeq is a vaccine that can help protect your child from getting a virus infection that can cause fever, vomiting, and diarrhea. The vaccine is given by mouth at 3 different times, each about one to two months apart. Nearly all children become infected with the rotavirus by the time they are 5 years old.

RotaTeq helps protect against diarrhea and vomiting only if they are caused by the rotavirus. It does not protect against diarrhea and vomiting that are caused by anything else.

RotaTeq may not fully protect all children that get the vaccine, and if your child already has the virus it will not help them.

What are the Symptoms of a Rotavirus Infection?

Infection with the Rotavirus is the most common cause of severe diarrhea in infants. Sometimes the diarrhea and vomiting can be severe and lead to the loss of body fluids (dehydration) and even to death.

Signs that your infant is dehydrated include:

- Sleepiness
- Dry mouth and tongue
- Fussiness
- Dry diaper for several hours

If your infant shows signs that they are dehydrated, you should call the doctor immediately.

What should I tell the doctor before my child gets RotaTeq?

There are some things your doctor should know before your child gets the vaccine. You should tell your doctor if your child:

- Has any illness with fever. A mild fever or cold by itself is not a reason to delay taking the vaccination.
- Has diarrhea or has been vomiting.
- Has not been gaining weight.

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- Is not growing as expected.
- Has a blood disorder.
- Has any type of cancer.
- Has a weak immune system because of a disease (this includes HIV/AIDS).
- Gets treatment or takes medicines that may weaken the immune system (such as high doses of steroids) or has received a blood transfusion or blood products within the past 42 days.
- Was born with gastrointestinal problems, or has had a blockage or abdominal surgery.
- Has regular close contact with a member of the family or household who has a weakened immune system. For example, a person in the house with cancer or one who is taking medicines that may weaken their immune system.

Who should not receive RotaTeq?

Your child should not get the vaccine if:

- He or she had an allergic reaction after getting a dose of this vaccine.
- He or she is allergic to any of the ingredients of the vaccine. A list of ingredients can be found at the end of this leaflet.

What important information should I know about RotaTeq?

Intussusception is a serious and life-threatening event that occurs when a part of the intestine (the tube that goes from the stomach to the anus) gets blocked or twisted. Cases of intussusception can occur when no vaccine has been given and the cause is usually unknown. However, a different rotavirus vaccine was associated with intussusception and is no longer available.

In clinical trials, RotaTeq was studied in 70,000 infants (35,000 infants received RotaTeq and 35,000 received placebo), and no increased risk of intussusception was found. However, since RotaTeq has been on the market, cases of intussusception in infants who received RotaTeq have been reported to the Vaccine Adverse Event Reporting System (VAERS). Intussusception occurred at various times after vaccination with RotaTeq. Some of these infants required hospitalization and surgery on their intestine or a special enema to treat this problem.

Call your child's doctor right away if your child has vomiting, diarrhea, severe stomach pain, blood in their stool or change in their bowel movements as these may be signs of intussusception. It is important to contact your doctor if you have questions or if your child has any of these symptoms, at any time after vaccination, even if it has been several weeks since the last vaccine dose.

What are the possible side effects of RotaTeq?

The most common side effects reported after taking RotaTeq were diarrhea, vomiting, fever, runny nose and sore throat, wheezing or coughing, and ear infection.

Other reported side effects include hives.

These are NOT all the possible side effects of RotaTeq. You can ask your doctor or health care provider for a more complete list.

If your child seems to be having any side effects that are not mentioned in this leaflet, please call your doctor or other health care provider. If the condition continues or worsens, you should seek medical attention.

You, as a parent or guardian, may also report any adverse reactions to your child's health care provider or directly to the Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to www.vaers.hhs.gov.

Can RotaTeq be given with other vaccines?

Your child may get RotaTeq at the same time as other childhood vaccines.

How is RotaTeq given?

The vaccine is given by mouth. Your child will receive 3 doses of the vaccine. The first dose is given when your child is 6 to 12 weeks of age, the second dose is given 4 to 10 weeks later and the third dose is given 4 to 10 weeks after the second dose. The last (third) dose should be given to your child by 32 weeks of age.

Your health care provider will gently squeeze the vaccine into your child's mouth (see Figure 1). Your infant may spit out some or all of it. If this happens, the dose does not need to be given again during that visit.

Figure 1:



What do I do if my child misses a dose of RotaTeq?

All 3 doses of the vaccine should be given to your child by 32 weeks of age. Your health care provider will tell you when your child should come for the follow-up doses. It is important to keep those appointments. If you forget or are not able to go back at the planned time, ask your health care provider for advice.

What else should I know about RotaTeq?

This leaflet gives a summary of certain information about the vaccine. If you have any questions or concerns about RotaTeq, talk to your health care provider. You can also visit www.rotateq.com.

What are the ingredients in RotaTeq?

Active Ingredient: 5 live rotavirus strains (G1, G2, G3, G4, and P1).

Inactive Ingredients: sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80 and also fetal bovine serum.

Rx only

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Issued September 2007

Manuf. and Dist. by:
 **MERCK & CO., INC.**, Whitehouse Station, NJ 08889, USA