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

Read this information carefully before your child receives each dose of RotaTeq® in case any information about the vaccine changes. Your child will need 3 doses of the vaccine over the course of a few months. This leaflet is a summary of certain information about RotaTeq and does not take the place of talking with your child's doctor, who can give you more complete information written for health care professionals.

What is RotaTeq?

RotaTeq is an oral vaccine used to help prevent rotavirus infection in children. Rotavirus infection can cause fever, vomiting, and diarrhea that can be severe and can lead to loss of body fluids (dehydration), hospitalization and even death in some children. RotaTeq may not fully protect all children that get the vaccine, and if your child already has the virus it will not help them.

Who should not receive RotaTeq?

Your child should not get RotaTeq 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.
- He or she has Severe Combined Immunodeficiency Disease (SCID).
- He or she has ever had intussusception, a form of blockage of the intestines.

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

Tell your doctor if your child:

- Has illness with fever. A mild fever or cold by itself is not reason to delay taking the vaccine.
- Has diarrhea or has been vomiting.
- Has not been gaining weight or 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 family or household who has a weak immune system such as someone with cancer or someone taking medicines that weaken their immune system.

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.

Call your child's doctor or go to the emergency department right away if your child has any of the following problems after getting RotaTeq, even if it has been several weeks since the last dose because these may be signs of a serious problem called intussusception:

- bad vomiting
- bad diarrhea

- severe stomach pain
- blood in the stool

Intussusception happens when a part of the intestine gets blocked or twisted.

Since FDA approval, reports of infants with intussusception following RotaTeq have been received by the Vaccine Adverse Event Reporting System (VAERS). Intussusception occurred days and sometimes weeks after vaccination. Some infants needed hospitalization, surgery on their intestines, or a special enema to treat this problem. Death due to intussusception has occurred.

A study conducted after approval of RotaTeq showed an increased risk of intussusception in the 21 days after the first dose of RotaTeq, but especially in the first 7 days.

Other reported side effects include:

- Allergic reactions, which may be severe and may include face and mouth swelling, difficulty breathing, wheezing, hives, and/or skin rash; and
- Kawasaki disease (a serious condition that can affect the heart; symptoms may include fever, rash, red eyes, red mouth, swollen glands, swollen hands and feet and, if not treated, death can occur).

Call your doctor right away if your child has any side effects that concern you or seem to get worse.

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

You, as a parent or guardian, may also report any adverse reactions to your child's doctor or directly to VAERS. The VAERS toll-free number is 1-800-822-7967 or report online to www.vaers.hhs.gov.

What other important information should I know?

Since FDA approval, the spread of vaccine virus to non-vaccinated contacts has been reported. Tell your doctor if you have someone in your household who has a weak immune system, cancer or is taking medications that can weaken the immune system so that your doctor can provide further advice. Hand washing is recommended after diaper changes to help prevent the spread of vaccine virus.

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 doctor will gently squeeze the vaccine into your child's mouth. 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.

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 doctor 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 doctor 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 doctor.

What are the ingredients in RotaTeq?

5 live rotavirus strains (G1, G2, G3, G4, and P1A[8]).

Sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80 and also fetal bovine serum.

Manufactured and Distributed by: Merck Sharp & Dohme LLC
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Revised: 5/2026

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