

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 and How Does it Work?

RotaTeq helps protect against an infection that nearly all children get called rotavirus. Rotavirus can cause fever, vomiting, and diarrhea which may 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.

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 other important information should I know?

Call your child's doctor right away if, following any dose of RotaTeq, 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. Intussusception is a serious and life-threatening event that occurs when a part of the intestine gets blocked or twisted and it requires immediate medical attention. Intussusception can occur when no vaccine has been given and the cause is usually unknown.

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

Before FDA approval, RotaTeq was studied in 35,000 infants and no increased risk of intussusception was found compared to 35,000 infants who did not receive RotaTeq.

Contact your doctor if your child has any symptoms of intussusception, even if it has been several weeks since the last vaccine dose.

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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 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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