

Information for Parents and Caregivers **About RotaTeq® (Rotavirus Vaccine, Live, Oral, Pentavalent)**

On May 14, 2010, the US Food and Drug Administration (FDA) recommended that health care professionals continue the use of RotaTeq, the rotavirus vaccine made by Merck.

For background, DNA from 2 types of a virus called porcine circovirus (PCV) – PCV1 and PCV2 – was found in RotaTeq. In making its recommendation for health care professionals to continue the use of RotaTeq, the FDA carefully studied scientific information and laboratory results from both Merck and its own laboratories, and got input from scientific and public health experts. The FDA stated that it has no evidence that either PCV1 or PCV2 poses a safety risk. FDA also stated that neither PCV1 nor PCV2 is known to cause infection or illness in people. The FDA further noted that the benefits of rotavirus vaccines are large as compared to the lack of known health risks from PCV in people.

The FDA has determined that children who received RotaTeq need no additional medical follow-up and that RotaTeq can continue to be used in infants.

Merck remains confident in the safety profile and quality of RotaTeq. The safety profile of the vaccine was evaluated in a large clinical study that included tens of thousands of infants and will continue to be monitored by FDA and Merck.

Here is additional information in response to some questions you may have:

My child received RotaTeq. Do I need to do anything?

According to the FDA, children who received RotaTeq need no additional medical follow-up. At this time, there is no evidence that PCV1 and PCV2 pose a safety risk in people, and neither is known to cause infection or illness in people. If you have further questions about RotaTeq, please discuss these questions with your child's health care professional.

What is rotavirus?

Rotavirus is very easy to catch and can cause severe diarrhea in infants and young children. Nearly all children are infected with rotavirus by 5 years of age.

How does rotavirus spread?

Rotavirus is usually spread through contaminated hands or objects, and can remain on surfaces for a long time.

What are the symptoms of rotavirus?

Common symptoms of rotavirus include vomiting, watery diarrhea, and fever. Some children with rotavirus infection show little or no symptoms, while others may experience severe, dehydrating diarrhea and vomiting. The most severe cases of rotavirus occur most often in children between 6 months and 2 years of age.

A severe case of rotavirus may lead to hospitalizations or may require fluids in the emergency room.

Why is it important to vaccinate against rotavirus?

An important reason to vaccinate is to help protect your baby against a severe case of rotavirus disease. You should talk to your child's health care professional about rotavirus vaccination.

DNA=deoxyribonucleic acid.



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What is RotaTeq® (Rotavirus Vaccine, Live, Oral, Pentavalent)?

RotaTeq is a vaccine that can help protect babies against common types of rotavirus. RotaTeq is not a shot; it is a vaccine given by mouth in three doses. The first dose is given when your child is 6 to 12 weeks of age, the second dose is given 4 to 10 weeks after the first dose, and the last (third) dose should be given by 32 weeks of age. RotaTeq may not fully protect all children who get the vaccine.

Who should not receive RotaTeq?

RotaTeq should not be given to infants who are allergic to any part of the vaccine. Your child should not get RotaTeq if he or she has Severe Combined Immunodeficiency Disease (SCID).

What are the possible side effects of RotaTeq?

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

Other reported side effects include: hives; 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 untreated, can be life threatening).

What other important information should I know?

Call your child's doctor or go to the emergency department right away if, following any dose of RotaTeq, your child has vomiting, diarrhea, severe stomach pain, blood in their stool or change in bowel movements. These may be signs of a serious and life-threatening problem called intussusception. Intussusception can happen even when no vaccine has been given and the cause is usually unknown.

Contact your doctor or go to the emergency department right away if your child has any symptoms of intussusception, even if it has been several weeks since the last vaccine dose.

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

There are some important things your doctor needs to know about your baby. Tell your doctor:

- If your baby is sick with fever, diarrhea, or vomiting, or is not growing or gaining weight as expected.
- If your baby or someone in regular close contact with your baby has a weakened immune system from a disease (like cancer, HIV/AIDS, or a blood disorder) or from medicine (such as steroids).
- If your baby has received a blood transfusion or blood products recently or if he or she was born with gastrointestinal problems, had a blockage, or had abdominal surgery.

Please read the [Patient Product Information](#) and discuss it with your doctor or health care professional. Also available is the physician [Prescribing Information](#).

To learn more about RotaTeq, please visit RotaTeq.com. If you have additional questions, please talk with your child's health care professional.

Additional information is also available at www.fda.gov.



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