

## Patient Medication Information

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

## RotaTeq®

rotavirus vaccine, live, oral, pentavalent

This patient medication information is written for the person who will be taking **RotaTeq®**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this vaccine. If you have more questions about this vaccine or want more information about **RotaTeq®**, talk to a healthcare professional.

### What RotaTeq® is used for:

RotaTeq® is a live virus vaccine to help protect your child against rotavirus infection, a viral infection of the digestive tract and a major cause of gastroenteritis (inflammation of the stomach and intestines which causes diarrhea and vomiting).

### How RotaTeq® works:

RotaTeq® works by helping the body develop natural defenses against the most common types or “strains” of rotavirus.

### The ingredients in RotaTeq® are:

Medicinal ingredients: Five different types of rotavirus.

Non-medicinal ingredients: polysorbate 80, sodium citrate, sodium hydroxide, sodium phosphate monobasic monohydrate, sucrose and culture media. There are no preservatives or thimerosal present.

The vaccine contains DNA (very small parts) from porcine circoviruses type 1 and type 2 (viruses that infect pigs). These viruses are not known to cause infection or illness in people and there is no known safety risk in people.

Tell the physician if your child has ever had an allergic reaction to these ingredients.

### RotaTeq® comes in the following dosage form:

Solution 2 mL, to be given by mouth.

### Do not use RotaTeq® if:

Your child:

- has an allergic reaction after getting a dose of the vaccine.
- is allergic to any of the ingredients of the vaccine. A list of ingredients can be found in the following section.
- has Severe Combined Immunodeficiency Disease (SCID).
- has uncorrected congenital malformation (such as Meckel’s diverticulum) of the gastrointestinal tract that would predispose for intussusception, a form of blockage of the intestines.

- has a history of intussusception.

RotaTeq® is not intended for adults.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take RotaTeq®. Talk about any health conditions or problems your child may have, including if your child:**

- has any illness with fever. A mild fever or upper respiratory infection (cold) by itself is not a reason to delay taking the vaccination.
- has diarrhea or is vomiting.
- has not been gaining weight.
- is not growing as expected.
- has a blood disorder.
- has any type of cancer.
- has an immune system that is weakened because of a disease (this includes HIV infection or AIDS).
- gets treatment or takes medicines that may weaken the immune system.
- was born with gastrointestinal problems, or has had an intestinal blockage.
- 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.

**Other warnings you should know about:**

As with other vaccines, RotaTeq® may not fully protect all those who get it. Some children may already have the virus but not yet show signs of being sick. In those cases, the vaccine may not be able to prevent the illness.

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

Hand washing is recommended after diaper changes to help prevent the spread of vaccine virus.

**Use in pregnancy and breast-feeding:**

RotaTeq® is a pediatric vaccine not intended for adults and should not be given to pregnant or lactating women. There are no data available on the use during pregnancy or lactation in humans.

**Tell your healthcare professional about all the medicines your child is taking, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with RotaTeq®:**

RotaTeq® may be given at the same time your child receives other vaccines, but it should not be mixed with any other vaccines or solutions.

**How to take RotaTeq®:**

RotaTeq® will be given to your child by a healthcare professional in a healthcare setting.

**Usual dose:**

The vaccine is given by mouth and is a series of 3 doses. The first dose is given as early as 6 weeks of age. The next two doses are given one to two months apart.

### Overdose:

If you think you, or a person you are caring for, have taken too much **RotaTeq®** contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

### Missed Dose:

Your child needs 3 doses of the vaccine. It is important that you follow the instructions of your health care provider regarding your child's return visits for the follow-up doses. It is important to keep those appointments. If you forget or are not able to go back to your health care provider at the planned time, ask your health care provider for advice.

### Possible side effects from using RotaTeq®:

These are not all the possible side effects you may have when taking **RotaTeq®**. If you experience any side effects not listed here, tell your healthcare professional.

Like all vaccines, RotaTeq® may have side effects. The side effects of RotaTeq® are usually mild and do not last long. In addition, these side effects have not been reported much more frequently than when a placebo (an oral solution without vaccine) was given. Side effects reported with the use of RotaTeq® were diarrhea, vomiting, fever, runny nose and sore throat, wheezing or coughing, and ear infection.

Other reported side effects include allergic reactions, which may be severe (anaphylaxis), allergic swelling, hives.

Tell your doctor immediately or go to the emergency at your nearest hospital if you notice any of the following:

- Severe stomach pain or distress, swollen belly, persistent vomiting, blood in the stool, bad diarrhea and/or high fever in your child after receiving RotaTeq®. These symptoms and signs may be indicative of intussusception, an uncommon but serious and life-threatening problem, which happens when a part of the intestine gets blocked or twisted. Intussusception can happen even when no vaccine has been given and the cause is usually unknown.

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.

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

If you noticed any side effects not mentioned in this leaflet, please inform your physician or pharmacist. If the condition persists or worsens, seek medical attention.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

If your child has a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

**Reporting suspected side effects for vaccines**

**For the general public:** Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Merck Canada cannot provide medical advice.

**For healthcare professionals:** If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory ([Reporting Adverse Events Following Immunization \(AEFI\) in Canada](#)) and send it to your local Health Unit.

**Storage:**

Store refrigerated at 2°C to 8°C. Protect from light.  
Keep out of reach and sight of children.

**If you want more information about RotaTeq®:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada website: ([Drug Product Database: Access the database](#)); the manufacturer's website [www.merck.ca](http://www.merck.ca), or by calling 1-800-567-2594.

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