

PART III: CONSUMER INFORMATION**RotaTeq[®]**

rotavirus vaccine, live, oral, pentavalent

This leaflet is part III of a three-part “Product Monograph” published when RotaTeq[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about RotaTeq[®]. Contact your physician or pharmacist if you have any questions about the vaccine.

ABOUT THIS VACCINEWhat the vaccine is used for:

The physician has recommended or administered RotaTeq[®] 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).

What it does:

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

When it should not be used:

Your child should not get the vaccine if he or she:

- 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).

RotaTeq[®] is not intended for adults.

What the medicinal ingredient is:

Five different types of rotavirus

What the important non-medicinal ingredients are: polysorbate

80, sodium citrate, sodium hydroxide, sodium phosphate monobasic monohydrate, sucrose and also 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.

What dosage forms it comes in: Solution 2 mL, to be given by mouth.

WARNINGS AND PRECAUTIONS

BEFORE your child gets RotaTeq[®], talk to your physician or pharmacist if he or she:

- 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.

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.

HOW TO STORE IT

Store refrigerated at 2 °C to 8 °C. Protect from light.

INTERACTIONS WITH THIS VACCINE

Your child may get RotaTeq[®] at the same time as other vaccines, but it should not be mixed with any other vaccines or solutions.

PROPER USE OF THIS VACCINEUsual 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:

There are no known cases of overdose and no information regarding its possible effects.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

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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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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.

Reporting Suspected Vaccine Adverse Events

For the general public:
If you suspect you have had a serious or unexpected event following receipt of a vaccine, please ask your healthcare professional to complete the Adverse Events Following Immunization (AEFI) Form and send it to your local [health unit](#) in your province/territory.

For healthcare professionals:
If a patient experiences an adverse event following immunization, please complete the Adverse Events Following Immunization (AEFI) Form and send it to your local [health unit](#) in your province/territory.

If you have any questions or have difficulty contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada:

Toll-free telephone: 1-866-844-0018
Toll-free fax: 1-866-844-5931
By email: caefi@phac-aspc.gc.ca

NOTE: Should you require information related to the management of the adverse events, please contact your health professional before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.

MORE INFORMATION

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 this Consumer Information by visiting the Health Canada website or Merck Canada website www.merck.ca or by calling Merck Canada at 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

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