

RotaTeq[®]

rotavirus vaccine, live, oral, pentavalent

Single dose 2 mL unit dosing tube

What is in this leaflet

This leaflet answers some common questions about RotaTeq. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the risks of your child being given RotaTeq against the benefits they expect it will have for them.

If you have any concerns about your child being given this vaccine, ask your doctor.

Keep this leaflet with the medicine. You may need to read it again.

What RotaTeq is used for

RotaTeq (Rotavirus Vaccine, Live, Oral, Pentavalent) is a viral vaccine that helps protect your child against gastroenteritis (diarrhoea and vomiting) caused by rotavirus infection.

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

The doctor 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 diarrhoea and vomiting). 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. The vaccine course is completed by the time your child is 32 weeks of age.

Rotavirus gastroenteritis may cause fever, vomiting, and diarrhoea. These symptoms can lead to the loss of body fluids (dehydration) and even to death.

It is the chief cause of severe dehydrating diarrhoea among infants and young children around the world. Before the vaccine was used, the virus was the cause for about 25 million physician visits per year. It also accounted for 2.1 million hospital admissions, and 352,000 to 592,000 deaths per year worldwide.

Rotavirus infects the small intestine and usually starts with fever and vomiting, followed by diarrhoea. The diarrhoea can be mild to severe and generally lasts 3-9 days. Severe vomiting and diarrhoea (more than 5 times each day) lasts an average of 3-6 days. Nearly all children are infected with rotavirus by the time they are 5 years old. This is true even where standards of hygiene are high.

Before you are given RotaTeq

When your child should not be given it

Your child should not get the vaccine if:

- he or she has an allergic reaction after getting a dose of the 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).

Before your child is given it

Tell your doctor 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 diarrhoea 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 infections 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 diarrhoea 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 Breastfeeding

RotaTeq is a paediatric 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.

Having other vaccines

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

How to take RotaTeq

How much is given

The dose for children is 2 mL.

How it is given

The vaccine is given by mouth and is a series of 3 doses.

Vaccination schedule

The first dose is given as early as 6 weeks of age. The next two doses are given one to two months apart. The vaccination course is completed by the time your child is 32 weeks of age.

If you miss a 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.

After you have been given RotaTeq

Things you must do

Keep your child's follow-up appointments with their doctor or clinic.

Adverse Effects

Like all medicines, RotaTeq can 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.

Tell your doctor if you notice any of the following and they worry you:

- diarrhoea
- vomiting
- fever
- runny nose
- sore throat
- wheezing or coughing
- ear infection

Other side effects also reported:

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

Product description

What it looks like

RotaTeq comes as a single dose 2 mL unit dosing tube.

Ingredients

Active ingredient:

- 5 live rotaviruses

Inactive ingredients:

- sucrose
- sodium citrate
- sodium phosphate monobasic monohydrate
- sodium hydroxide
- polysorbate 80
- culture media

There are no preservatives or thimerosal present.

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

Supplier

RotaTeq is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited
P O Box 99851
Newmarket
Auckland
NEW ZEALAND
Tel: 0800 500 673

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