

RotaTeq(R)

Rotavirus Vaccine, Live, Oral, Pentavalent, MSD

Consumer Medicine Information

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, including vaccines, have risks and benefits. Your doctor has weighed the risks of your child taking RotaTeq against the benefits they expect it will have.

If you have any concerns about this vaccine, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

What RotaTeq is used for

RotaTeq is a viral vaccine that helps protect your child against gastroenteritis (diarrhoea and vomiting) caused by rotavirus infection.

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

Rotavirus 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.

How it works

RotaTeq works by causing your body to produce its own protection (antibodies) against the most common types or "strains" of rotavirus.

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.

Before you take RotaTeq

Before your child starts to take it

Tell your doctor if:

1. Your child has any medical

conditions, especially the following:

- * diseases which decrease the immune system, for example, HIV infection or AIDS
- * cancer
- * blood disorders
- * diarrhoea or vomiting
- * has not been gaining weight
- * is not growing as expected
- * was born with gastrointestinal problems, or has had an intestinal blockage

Tell your doctor if your child has an infection or a high temperature.

Your doctor may decide to delay giving RotaTeq. A mild fever or upper respiratory infection (cold) by itself is not a reason to delay taking the vaccination.

- 2. Your child is taking any medicines that may weaken the immune system**
- 3. Your child 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.**
- 4. Your child has any allergies to any other medicines or vaccines, or any other substances, such as food, preservatives or dyes.**

Tell your doctor if your child has had a blood or plasma transfusion in the last 42 days.

Your doctor may decide to delay vaccination.

When your child must not take 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 the ingredients can be found at the end of this leaflet.

RotaTeq must be used before the expiry date printed on the pack.

Do not take RotaTeq if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether your child should be given RotaTeq, talk to your doctor.

Use in pregnancy and breast feeding

RotaTeq is a paediatric vaccine not intended for adults and should not be given to pregnant or lactating (breast feeding) 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 other vaccines or solutions.

Your doctor will advise you if RotaTeq is to be given with another vaccine.

How RotaTeq is given

How much is given

The entire content of the 2-mL pre-filled unit-dose tube.

How is it given

RotaTeq is given directly to the mouth.

It does not matter if your child is given RotaTeq before or after food.

The vaccine should never be given by injection.

When will it be given

RotaTeq is given in a series of three doses. The first dose is given as early as 6 weeks of age. The next two doses are given one to two months apart.

RotaTeq has not been adequately studied in infants less than 6 weeks of age and more than 32 weeks of age.

After taking RotaTeq

Things you must do for your child

Keep an updated record of your child's vaccinations.

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

It is important that your child takes the follow-up doses of RotaTeq at the appropriate times to make sure the vaccine has the best chance of providing protection against rotavirus gastroenteritis.

Your doctor or nurse will provide instructions regarding your child's return visits for the follow-up doses.

If you miss a dose

If you forget or are not able to make it to your appointment at the planned time, ask your doctor or nurse for advice.

If you are not sure what to do, ask your doctor or nurse.

Side effects

Tell your doctor or pharmacist as soon as possible if your child does not feel well after having RotaTeq.

RotaTeq may have unwanted side effects in a few people. All medicines, including vaccines, can have side effects. Sometimes they are serious, most of the time they are not.

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 or pharmacist if you notice any of the following and they worry you:

- * diarrhoea
- * vomiting
- * fever
- * runny nose
- * sore throat
- * wheezing or coughing
- * ear infection
- * hives
- * Kawasaki disease (a serious condition that may cause high fever and may be accompanied by rash, red eyes, red lips and tongue, swollen glands in the neck, swollen hands and feet).

Other side effects not listed above may occur in some patients. Tell you doctor or pharmacist if you notice any side effects not mentioned in this leaflet.

Storage

RotaTeq is usually stored at the doctor's clinic or at the pharmacy.

If you need to store RotaTeq, always :

- * Keep RotaTeq in the refrigerator stored between 2 to 8 degrees C.
- * Keep RotaTeq out of the reach of children.

- * Protect the vaccine from light by keeping it in the original pack until it is time for it to be given.

Product description

What it looks like

RotaTeq is a pale yellow clear liquid that may have a pink tint, contained in a dosing tube. Each dosing tube contains a single, 2 mL dose of the vaccine.

Ingredients

The active ingredients of RotaTeq are 5 live rotaviruses.

Each 2 mL dose contains the following rotavirus reassortants: G1, G2, G3, G4, and P1[8]. The minimum dose levels of the reassortants are as follows:

G1 2.2 million infectious units

G2 2.8 million infectious units

G3 2.2 million infectious units

G4 2.0 million infectious units

P1[8] 2.3 million infectious units

Inactive ingredients are

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

RotaTeq does not contain any preservatives or thiomersal.

The manufacture of this product includes exposure to bovine derive material. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

Supplier

RotaTeq is supplied in Australia by:-

CSL Biotherapies Pty Ltd
45 Poplar Road
PARKVILLE VIC 3052

This leaflet was prepared in September 2008.

Australian Register Number:
AUST R 120245

(R) Registered Trademark of Merck & Co., Inc., Whitehouse Station, N.J., USA