PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS (PREPARATIONS) - 1986

This medicine is marketed upon physician's prescription only

RotaTeq® (Rotavirus Vaccine, Live, Oral, Pentavalent)

ORAL SOLUTION

ROTATEQ contains 5 live rotavirus strains (G1, G2, G3, G4, and P1A[8]).

Each dose contains:

Rotavirus G1 Reassortant	not less than 2.2×10^6 IU[1]
Rotavirus G2 Reassortant	not less than 2.8×10^6 IU[1]
Rotavirus G3 Reassortant	not less than 2.2×10^6 IU[1]
Rotavirus G4 Reassortant	not less than 2.0×10^6 IU[1]
Rotavirus P1A[8] Reassortant	not less than 2.3×10^6 IU[1]

[1] Infectious Units

For the list of the inactive ingredients see section 6. "FURTHER INFORMATION". See also section 2.5 "Important information about some of the ingredients of the medicine".

Read all of this leaflet carefully before your child receives each dose of RotaTeq.

- This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their medical condition seems similar.
- The spread of vaccine virus to non-vaccinated contacts has been reported. Tell your doctor if you have someone in your household who has a weak immune system, cancer or is taking medications that can weaken the immune system so that your doctor can provide further advice. Hand washing is recommended after diaper changes to help prevent the spread of vaccine virus.

1. WHAT ROTATEQ IS INTENDED FOR?

RotaTeq is indicated for the prevention of rotavirus gastroenteritis in infants and children caused by types G1, G2, G3, G4, and G9 when administered as a 3-dose series to infants between the ages of 6 to 32 weeks. The first dose of RotaTeq should be administered between 6 and 12 weeks of age.

Therapeutic group: Vaccines, Viral Vaccine ATC code: J07BH02.

Rotavirus infection can cause fever, vomiting, and diarrhea that can be severe and can lead to loss of body fluids (dehydration), hospitalization and even death in some children. RotaTeq may not fully protect all children that get the vaccine, and if your child already has the virus it will not help them.

2. BEFORE YOUR CHILD RECEIVES ROTATEQ

2.1 Do not use ROTATEQ if your child:

- is sensitive (allergic) to any ingredient of this vaccine. For a list of the ingredients, see section 6.
- had an allergic reaction after getting a dose of this vaccine.
- has Severe Combined Immunodeficiency Disease (SCID).
- has ever had intussusception, a form of blockage of the intestines.

2.2 Special warnings regarding the use of ROTATEQ

- **Before your child gets ROTATEQ, tell the doctor if your child:**
  - has illness with fever. A mild fever or cold by itself is not reason to delay taking the vaccine.
  - has diarrhea or has been vomiting.
  - has not been gaining weight or is not growing as expected.
  - has a blood disorder.
  - has any type of cancer.
  - has a weak immune system because of a disease (this includes HIV/AIDS).
  - gets treatment or takes medicines that may weaken the immune system (such as high doses of steroids) or has received a blood transfusion or blood products within the past 42 days.
  - was born with gastrointestinal problems, or has had a blockage or abdominal surgery.
  - has regular close contact with a member of family or household who has a weak immune system such as someone with cancer or someone taking medicines that weaken their immune system.

2.3 Interactions with other medicines

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines (or other vaccines), including non-prescription medicines and nutritional supplements, especially if your child is taking:
Immunosuppressive therapies including irradiation, antimetabolites, alkylating agents, cytotoxic drugs and corticosteroids (used in greater than physiologic doses), may reduce the immune response to vaccines.

Using RotaTeq with other vaccines
RotaTeq may be given at the same time as your child receives other normally recommended vaccinations such as diphtheria and tetanus toxoids and acellular pertussis *(whooping cough)* (DTaP), inactivated poliovirus vaccine (IPV), H. influenzae type b conjugate (Hib), hepatitis B vaccine, and pneumococcal conjugate vaccine.

2.4 Using ROTATEQ with food

There are no restrictions on taking food or liquid, including breast milk, either before or after vaccination with RotaTeq.

2.5 Important information about some of the ingredients of the medicine

RotaTeq contains sucrose
If you have been told that your child has an intolerance to some sugars, inform your doctor/health care professional before the vaccine is administered.

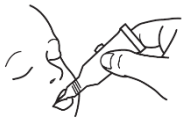
RotaTeq contains sodium
This vaccine contains 37.6 mg sodium (main component of cooking/table salt) in each dose. This is equivalent to 1.88% of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW IS ROTATEQ GIVEN?

The vaccine is given by mouth. Your child will receive 3 doses of the vaccine. The first dose is given when your child is 6 to 12 weeks of age, the second dose is given 4 to 10 weeks later and the third dose is given 4 to 10 weeks after the second dose. The last (third) dose should be given to your child by 32 weeks of age.

Your doctor will gently squeeze the vaccine into your child's mouth (see Figure 1). Your infant may spit out some or all of it. If this happens, the dose does not need to be given again during that visit.

Figure 1:



Administration Instructions for Health care professionals are included in this leaflet (section: "Administration Instructions for Health care professionals")

If your child misses a dose of ROTATEQ

All 3 doses of the vaccine should be given to your child by 32 weeks of age. Your doctor will tell you when your child should come for the follow-up doses. It is important to keep those appointments. If you forget or are not able to go back at the planned time, ask your doctor for advice.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.

If you have further questions on the use of the medicine, consult with a doctor or a pharmacist.

4. SIDE EFFECTS

As with any medicine, **ROTATEQ** may cause side effects, in some users.
Do not be alarmed by reading the list of side effects, your child may not suffer from any of them.

Call your child's doctor or go to the emergency department right away if:

- your child experiences one of the following symptoms:
  - Allergic reactions, which may be severe (anaphylaxis), and may include: allergic swelling that may affect the face, lips, tongue or throat.
  - Bronchospasm. This may present as wheezing, coughing or difficulty breathing.
- your child has any of the following problems after getting RotaTeq, even if it has been several weeks since the last dose because these may be signs of a serious problem called intussusception:
  - bad vomiting
  - bad diarrhea
  - severe stomach pain
  - blood in the stool.

  Intussusception happens when a part of the intestine gets blocked or twisted.

Reports of infants with intussusception following RotaTeq have been received. Intussusception occurred days and sometimes weeks after vaccination. Some infants needed hospitalization, surgery on their intestines, or a special enema to treat this problem. Death due to intussusception has occurred.

A study conducted showed an increased risk of intussusception in the 21 days after the first dose of RotaTeq, but especially in the first 7 days.

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

Additional side effects
- Hives and/or skin rash
- 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 not treated, death can occur).

If a side effect appears, if any of the side effects worsens or if your child suffers from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by using the link "Adverse Drug Reactions Report" at the home page of the Ministry of Health's web site) which refers to the online side effects reporting form, or by using the link:
https://sideeffects.health.gov.il/

5. HOW TO STORE ROTATEQ?
- Avoid Poisoning! This medicine and any other medicine must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the pack. The expiry date refers to the last day of the indicated month.
- **Storage conditions**:
  Store and transport refrigerated at 2-8°C. RotaTeq should be administered as soon as possible after being removed from refrigeration. Protect from light.
- RotaTeq should be discarded in approved biological waste containers according to local regulations.

6. FURTHER INFORMATION

What are the ingredients in RotaTeq?
Active ingredients: 5 live rotavirus strains (G1, G2, G3, G4, and P1A[8]).

In addition to the active ingredients **ROTATEQ** also contains:
Sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80 and also fetal bovine serum.

What ROTATEQ looks like and contents of the pack
RotaTeq, 2 mL, a solution for oral use, is a pale yellow clear liquid that may have a pink tint.

Pack sizes:
Package of 1 individually pouched single-dose tube.
Package of 10 individually pouched single-dose tubes.

Not all pack sizes are marketed.

Marketing authorization holder and importer:
Merck Sharp & Dohme (Israel-1996) Company Ltd., 34 Ha'charash St., Hod-Hasharon.

Drug registration no. listed in the official Registry of the Ministry of Health:
136-76-31569

Approved in November 2025.

Administration Instructions for Health care professionals

The following information is intended for health care professionals only:
Instructions

To administer the vaccine:

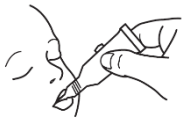
Tear open the pouch and remove the dosing tube.

Clear the fluid from the dispensing tip by holding tube vertically and tapping cap.

Open the dosing tube in 2 easy motions:

1. Puncture the dispensing tip by screwing cap ***clockwise*** until it becomes tight.

2. Remove cap by turning it ***counterclockwise***.



Administer dose by gently squeezing liquid into infant's mouth toward the inner cheek until dosing tube is empty. (A residual drop may remain in the tip of the tube.)

If for any reason an incomplete dose is administered (e.g., infant spits or regurgitates the vaccine), a replacement dose is not recommended, since such dosing was not studied in the clinical trials. The infant should continue to receive any remaining doses in the recommended series.

Discard the empty tube and cap in approved biological waste containers according to local regulations.

See also section 3. HOW IS ROTATEQ GIVEN.