Package Leaflet: Information for the user
RotaTeq oral solution
Rotavirus vaccine (live)

Read all of this leaflet carefully before your child is vaccinated because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What RotaTeq is and what it is used for

RotaTeq is an oral vaccine that helps protect infants and young children against gastroenteritis (diarrhoea and vomiting) caused by rotavirus infection and may be given to infants from the age of 6 weeks to 32 weeks (see section 3). The vaccine contains five types of live rotavirus strains. When an infant is given the vaccine, the immune system (the body's natural defences) will make antibodies against the most commonly occurring types of rotavirus. These antibodies help protect against gastroenteritis caused by these types of rotavirus.

2. What you need to know before your child receives RotaTeq

Do not use RotaTeq if

- your child is allergic to any of the components of this vaccine (see section 6 Contents of the pack and other information).
- your child developed an allergic reaction after receiving a dose of RotaTeq or other rotavirus vaccine.
- your child has previously had intussusception (a bowel obstruction in which one segment of bowel becomes enfolded within another segment).
- your child was born with a malformation of the gastrointestinal system that might predispose for intussusception.
- your child has any disease which reduces his/her resistance to infection.
- your child has a severe infection with a high temperature. It might be necessary to postpone the vaccination until recovery. A minor infection such as a cold should not be a problem, but talk to your doctor first.
- your child has diarrhoea or is vomiting. It might be necessary to postpone the vaccination until recovery.

Warnings and precautions

Talk to your doctor or pharmacist before using RotaTeq if your child:
- has received a blood transfusion or immunoglobulins within the last 6 weeks.
- has a close contact such as a household member who has a weakened immune system, e.g., a person with cancer or who is taking medicines that may weaken the immune system.
- has any disorder of the gastrointestinal system.
- has not been gaining weight and growing as expected.
- or the mother has taken any medicine during pregnancy that weakens the immune system.

After your child has received RotaTeq, contact a doctor/health care professional right away if your child experiences severe stomach pain, persistent vomiting, blood in stools, a swollen belly and/or high fever (see also section 4 “Possible side effects”).

As always, please take care to wash your hands thoroughly after changing soiled nappies.

As with other vaccines, RotaTeq may not completely protect all children who are vaccinated even after all three doses have been given.

If your child has already been infected with rotavirus but is not yet ill when vaccinated, RotaTeq may not be able to prevent the illness.

RotaTeq does not protect against diarrhoea and vomiting due to causes other than rotavirus.

Other medicines and RotaTeq

RotaTeq may be given at the same time as your child receives other normally recommended vaccinations, such as diphtheria, tetanus, pertussis (whooping cough), *Haemophilus influenzae* type b, inactivated or oral poliomyelitis, hepatitis B, pneumococcal conjugate and meningococcus group C conjugate vaccines.

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines (or other vaccines).

RotaTeq with food and drink

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

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 to use RotaTeq

RotaTeq IS FOR ORAL USE ONLY.

A doctor or nurse will administer the recommended doses of RotaTeq to your child. The vaccine will be given by gently squeezing the tube and delivering the vaccine into your child's mouth.
The vaccine can be given without regard to food, liquid, or breast milk.
In case your child spits out or regurgitates most of the vaccine dose, a single replacement dose may be given at the same vaccination visit.

Under no circumstance should this vaccine be administered by injection.

The first dose (2 ml) of RotaTeq may be given from the age of 6 weeks and should be given before 12 weeks of age (about 3 months). RotaTeq may be given to infants who were born early provided that the pregnancy had lasted at least 25 weeks. These infants should receive the first dose of vaccine between 6 and 12 weeks after birth.

Your child will receive 3 doses of RotaTeq given at least four weeks apart. It is important that your child receives all 3 doses of the vaccine for protection against rotavirus. It is preferred that all three doses should be given by the age of 20-22 weeks and at latest all three doses should be given by the age of 32 weeks.

When RotaTeq is given to your child for the first dose, it is recommended that your child also receives RotaTeq (and not another rotavirus vaccine) to complete the vaccination course.

If you forget an appointment for RotaTeq

It is important that you follow the instructions of your doctor/health care professional regarding your child's return visits for the follow-up doses. If you forget or are not able to go back to your doctor/health care professional at the scheduled time, ask him or her for advice.

4. Possible side effects

Like all vaccines and medicines, this vaccine can cause side effects, although not everybody gets them.

Contact a doctor/health care professional right away if your child experiences one of the following symptoms:

- Allergic reactions (frequency cannot be estimated from the available data), which may be severe (anaphylaxis), and may include: allergic swelling that may affect the face, lips, tongue or throat.

- Bronchospasm (rare, may affect up to 1 in 1000 infants). This may present as wheezing, coughing or difficulty breathing.

- Severe stomach pain, persistent vomiting, blood in stools, a swollen belly and/or high fever. These could be symptoms of a very rare (may affect up to 1 in 10,000 infants), but serious, side effect called intussusception (a bowel obstruction in which one segment of bowel becomes enfolded within another segment).

The following other side effects reported with the use of RotaTeq were:

- Very common (may affect more than 1 in 10 infants): fever, diarrhoea, vomiting

- Common (may affect up to 1 in 10 infants): infections of the upper respiratory system

- Uncommon (may affect up to 1 in 100 infants): stomach pains (see also above for signs of a very rare side effect of intussusception), runny nose and sore throat, ear infection, rash, blood in stool

- Rare (may affect up to 1 in 1000 infants): hives

- Not known (frequency cannot be estimated from the available data): irritability

In babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2-3 days after vaccination.

Ask your doctor/health care professional if you want more information about side effects for RotaTeq.

Reporting of side effects
If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store RotaTeq

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Store and transport refrigerated (2 °C to 8 °C). Keep the dosing tube in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What RotaTeq contains

The active substances in RotaTeq are 5 human-bovine reassortant rotavirus strains:
G1 2.2×10^6 Infectious Units
G2 2.8×10^6 Infectious Units
G3 2.2×10^6 Infectious Units
G4 2.0×10^6 Infectious Units
P1A[8] 2.3×10^6 Infectious Units

The other ingredients in RotaTeq are: sucrose, sodium citrate, sodium dihydrogen phosphate monohydrate, sodium hydroxide, polysorbate 80, culture media (containing inorganic salts, amino acids and vitamins), and purified water.

What RotaTeq looks like and contents of the pack

Oral solution

This vaccine is contained in a single-dose tube and is a pale yellow clear liquid that may have a pink tint.

RotaTeq is available in pack size of 1, 10 dosing tubes. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: MSD VACCINS, 162 avenue Jean Jaurès, 69007 Lyon, France.

Manufacturer Responsible for Batch Release: Merck Sharp and Dohme, B.V., Waarderweg, 39, 2031 BN, Haarlem, The Netherlands

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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This leaflet was last revised in:

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu.

The following information is intended for health care professionals only:

Instructions

<table>
<tr><td colspan="2">To administer the vaccine:</td></tr>
<tr><td>  </td><td>Tear open the protective bag and remove the dosing tube.</td></tr>
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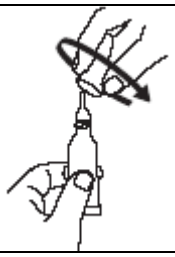
	Clear the fluid from the dispensing tip by holding tube vertically and tapping the twist-off cap.
	Open the dosing tube in 2 easy motions: 1. Puncture the dispensing tip by screwing cap **clockwise** until it becomes tight.
	2. Remove cap by turning it **counterclockwise**.
	Administer dose by gently 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.)
	Discard the empty tube and cap in approved biological waste containers according to local regulations.

Any unused product or waste material should be disposed of in accordance with local requirements.

See also section 3. How to use RotaTeq.