

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

ROTARIX, ORAL SUSPENSION ROTAVIRUS VACCINE (LIQUID FORMULATION)

Read all of this leaflet carefully before you receive this vaccine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What Rotarix is and what it is used for
2. Before your child receives Rotarix
3. How Rotarix is given
4. Possible side effects
5. How to store Rotarix
6. Further information

1. WHAT ROTARIX IS AND WHAT IT IS USED FOR

Rotarix is a vaccine that helps to protect your child against gastro-enteritis (diarrhoea and vomiting) caused by rotavirus infection.

Rotavirus infection is the most common cause of severe diarrhoea in infants and young children. It is easily spread by hand-to-mouth contact with stool from an infected person. Most children with rotavirus diarrhoea recover without any treatment. Some children become very ill with severe vomiting, diarrhoea and life-threatening loss of fluids that requires hospitalisation.

When someone is vaccinated, the immune system (the body's natural defence system) will make antibodies against the most commonly occurring types of rotavirus. These antibodies protect against disease caused by these types of rotavirus.

Rotarix can only protect your child against rotavirus gastro-enteritis.

Vaccination is the best way to protect against these diseases. However, as with all vaccines, Rotarix may not fully protect all children who are vaccinated.

If your child has recently been vaccinated, it is particularly important to wash your hands after changing their nappy.

2. BEFORE YOUR CHILD RECEIVES ROTARIX

Rotarix should not be given:

- if your child has previously had any allergic reaction to rotavirus vaccines or any ingredient in Rotarix. The ingredients in Rotarix are listed at the end of the leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- if your child has previously had intussusception (a bowel obstruction in which one segment of bowel becomes enfolded within another segment).
- if your child was born with a defect of the gastro-intestinal system.
- if your child has a rare inherited illness which affects their immune system called Severe Combined Immunodeficiency (SCID).

Take special care with Rotarix

- if 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.
- if your child has diarrhoea or is vomiting. It might be necessary to postpone the vaccination until recovery.
- if your child suffers from disorders of the stomach or intestines.
- if your child has any disease or is taking any medicine which reduces his/her resistance to infection.
- if your child has a close contact such as a household member who has any disease or is taking any medicine which reduces his/her resistance to infection.

After your child has received Rotarix, 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.

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

Using other medicines or vaccines

Please tell your doctor if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription or has recently received any other vaccine.

Rotarix may be given at the same time your child receives other normally recommended vaccines, such as diphtheria, tetanus, whooping cough (pertussis), Haemophilus influenzae type b, polio (oral or inactivated), hepatitis B, pneumococcal and meningococcal vaccines.

Taking/Using Rotarix with food and drink

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

Pregnancy and breast-feeding

Rotarix is for use in children only, therefore information on use in pregnancy is not relevant.

Breast-feeding may be continued during the vaccination schedule.

3. HOW ROTARIX IS GIVEN

Your doctor or nurse will give the recommended dose of Rotarix to your child. The vaccine (1.5 ml) is always given into the child's mouth. Under no circumstance should this vaccine be administered by injection.

Your child will receive two doses of the vaccine. The first dose will be given at the earliest at 6 weeks of age. The second dose will be given at least 4 weeks after the first one. The two doses should be given before the age of 24 weeks. Rotarix may be given to infants who were born prematurely following the same vaccination course.

If your child spits out or brings back up the vaccine dose, a single replacement dose may be given at the same visit.

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

If your child misses a dose of Rotarix

It is important that you follow the instructions of your doctor or nurse regarding your child's return visits. If you forget to go back to your doctor at the scheduled time, ask your doctor for advice.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Rotarix can cause side effects, although not everybody gets them.

Side effects that occurred during clinical trials with Rotarix were as follows:

- Common (these may occur with up to 1 in 10 doses of the vaccine):
 - Diarrhoea
 - irritability
- Uncommon (these may occur with up to 1 in 100 doses of the vaccine):
 - pain in the stomach (see also below for signs of very rare side effects of intussusception)
 - flatulence
 - dermatitis

Side effects that occurred during routine use of Rotarix include:

- Rare (these may occur with up to 1 in 1,000 doses of the vaccine):
 - blood in stools
 - children with a rare inherited illness called Severe Combined Immunodeficiency (SCID) may have an inflamed stomach or gut (gastroenteritis) and pass the vaccine virus in their stools. The signs of gastroenteritis may include feeling sick, being sick, stomach cramps or diarrhoea.
- Very rare (these may occur with up to 1 in 10,000 doses of the vaccine):
 - intussusception (part of the intestine gets blocked or twisted). The signs may include severe stomach pain, persistent vomiting, blood in stools, a swollen belly and/or high fever. Contact a doctor/health care professional right away if your child experiences one of these symptoms.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

5. HOW TO STORE ROTARIX

Keep out of the reach and sight of children.

Do not use Rotarix after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

The vaccine must be stored at 2°C - 8°C (in a refrigerator).

The vaccine must not be frozen.

Store in the original package in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.>

6. FURTHER INFORMATION

What Rotarix contains:

- The active substances are:

1 dose (1.5 ml) contains:

Live attenuated human rotavirus RIX4414 strain not less than 106.0 CCID50

- The other ingredients are:

Sucrose, di-sodium adipate, Dulbecco's Modified Eagle Medium (DMEM), sterile water.

What Rotarix looks like and contents of the pack

Rotarix is presented as a suspension for oral administration.

Rotarix is a clear, colourless liquid, free of visible particles, presented in a single dose tube (pack size of 50).

Manufacturer

GlaxoSmithKline Biologicals S. A.

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Belgium.

This leaflet was last approved on

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