

ROTARIX

Human Rotavirus (live attenuated oral vaccine) oral liquid

CONSUMER MEDICINE INFORMATION LEAFLET

What is in this leaflet?

Please read this leaflet carefully before your child receives ROTARIX vaccine.

This leaflet answers some common questions about ROTARIX. It does not contain all of 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 expected benefits of your child having ROTARIX against the possible risks.

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

Keep this leaflet with the vaccine.

You may need to read it again.

What is ROTARIX used for?

ROTARIX is a viral 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. Rotavirus is easily spread by hand-to-mouth contact with stool from an infected person. Most children with rotavirus diarrhoea recover on their own. Some children become very ill with severe vomiting, diarrhoea and life-threatening loss of fluids

that requires hospitalisation. Rotavirus infections are responsible for hundreds of thousands of deaths worldwide every year especially in developing countries, where nutrition and health care are not optimal.

When a person 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 may help protect against disease caused by these types of rotavirus.

As with all vaccines, ROTARIX may not completely protect all people who are vaccinated against the disease it is intended to prevent. The vaccine will not protect against gastro-enteritis caused by other types of viruses or organisms.

ROTARIX is not addictive.

Before having ROTARIX

ROTARIX should not be given if:

- **your child has previously had an allergic reaction to ROTARIX or any of the ingredients listed toward the end of this leaflet. (See "Ingredients") Signs of an allergic reaction include itchy skin rash, shortness of breath and swelling of the face or tongue.**
- **your child was born with a defect of the gastro-intestinal system.**
- **your child has a rare inherited illness which**

affects their immune system called Severe Combined Immunodeficiency (SCID).

- **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.**
- **your child has previously had intussusception (part of the intestine gets blocked or twisted).**
- **the expiry date (EXP) printed on the pack has passed.**
- **the packaging is torn or shows signs of tampering.**

Tell your doctor if:

- **your child is allergic to foods, dyes, preservatives or any other medicines.**

In these cases, your doctor can determine the right time of vaccination for your child.

- **your child is taking any prescription or OTC (over-the-counter) medicines. Some vaccines may be affected by other vaccines or medicines. Your doctor, nurse or pharmacist will be able to tell you what to do if ROTARIX is to be given with another vaccine or medicine.**
- **your child has a history of chronic gastrointestinal disease.**

How is ROTARIX given?

The doctor or nurse will administer the recommended dose of ROTARIX to your child. **THE VACCINE WILL BE GIVEN ORALLY.**

How much is given

ROTARIX is given as a 1.5 mL liquid dose.

How it is given

ROTARIX is given into the mouth. Under no circumstance should this vaccine be given by injection.

When will it be given?

Your child will receive two doses of the vaccine. Each dose will be given on a separate occasion with an interval of at least 4 weeks between the two doses. The first dose will be given between 6 and 14 weeks of age and the second dose must be given by 24 weeks of age.

There are no restrictions on your child's consumption of food or liquids, including breast milk, either before or after vaccination.

In the unlikely event that an infant spits out or regurgitates most of the vaccine dose, a single replacement dose may be given at the same vaccination visit.

It is important that you follow the instructions of your doctor or nurse regarding return visits for the follow-up dose.

IF A DOSE IS MISSED

If you forget to go back to your doctor at the scheduled time, ask your doctor for advice.

After having ROTARIX

Things you must do

After your child has received ROTARIX, contact your 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.

If you are in close contact with a recently vaccinated baby/child, ensure your hands are washed thoroughly:

- after changing nappies
- before eating or handling food.

What are the side-effects?

Check with your doctor as soon as possible if you think your child is experiencing any side effects or allergic reactions due to having ROTARIX, even if the problem is not listed below.

Like other medicines, ROTARIX can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

Side effects that occurred during clinical trial use of ROTARIX include:

The most commonly reported side-effects are:

- loss of appetite, irritability, fever, fatigue, diarrhoea, vomiting, regurgitation of food, flatulence, abdominal pain (see also below for signs of very rare side effects of intussusception), crying, disturbed sleep, sleepiness and constipation.

Rarely reported side-effects are:

- chest infection, hoarseness, runny nose, dermatitis, rash and muscle cramp.

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.

Tell your doctor immediately if you notice any of the following:

- **Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be symptoms of an allergic reaction.**

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor or pharmacist if you notice any side effects from

your child's vaccine which are not mentioned here.

Do not be alarmed by this list of possible side-effects. Your child may not experience any of them.

How do I store ROTARIX?

ROTARIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store ROTARIX always:

- Keep ROTARIX in the refrigerator stored between +2 C and +8 C. Do not freeze. Do not store it in the bathroom, or leave it in the car. Avoid exposing the vaccine to sunlight. **HEAT CAN DESTROY THE VACCINE.**
- Keep the vaccine out of the reach of children.
- Keep ROTARIX in the original pack until it is time for it to be given.

Ask your pharmacist what to do with any left over ROTARIX that has expired or has not been used.

Product Description

What ROTARIX looks like

ROTARIX is presented as a suspension for oral administration.

ROTARIX is supplied as a clear, colourless liquid, free of visible particles, presented in a single dose squeezable tube (fitted with a membrane and a cap), or as 5 single dose tubes (connected by a bar – pack size of 50 tubes) or a single dose oral applicator (syringe type applicator with a plunger stopper).

Ingredients

The active ingredient of ROTARIX is live attenuated human rotavirus RIX4414 strain.

ROTARIX also contains sucrose, di-sodium adipate, Dulbecco's Modified Eagle Medium (DMEM), and sterile water.

The manufacture of this product includes exposure to bovine derived materials. 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

Your ROTARIX is supplied by:

GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street
Abbotsford, Victoria, 3067
Australia.

Distributed in New Zealand by:
GlaxoSmithKline NZ Ltd
Private Bag 106600
Downtown Auckland
Ph: (09) 367 2900
Fax: (09) 367 2910

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

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