

# ROTARIX<sup>®</sup>

Rotavirus Vaccine, live attenuated

## CONSUMER MEDICINE INFORMATION LEAFLET

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### What is in this leaflet?

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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.

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### What is ROTARIX used for?

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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 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 infections 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.

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### Before having ROTARIX

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**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 has a history of chronic gastrointestinal disease.**
- **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.**
- **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.**

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## How is ROTARIX given?

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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 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 between 14 and 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.

Repeat dosing is not indicated if an infant should spit out, regurgitate or vomit during or after a dose of the vaccine. The vaccination course should be completed as recommended above.

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.

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## After having ROTARIX given?

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### Things you must do

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.

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## What are the side-effects?

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**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.

The most commonly reported side-effects are:

- loss of appetite, irritability, fever, fatigue, diarrhoea, vomiting, regurgitation of food, flatulence, abdominal pain, crying, disturbed sleep, sleepiness and constipation.

Rarely reported side-effects are:

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

**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.**

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## How do I store ROTARIX?

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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 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.**

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## Product Description

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### **What ROTARIX looks like**

ROTARIX is supplied as a whitish powder in a single dose glass vial with a separate pre-filled syringe of solvent and an adapter (transfer device) which allows easy transfer of the solvent into the vial containing the powder for mixing the vaccine.

## ***Ingredients***

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

ROTARIX also contains sucrose, dextran 40, sorbitol, amino acids, Dulbecco's Modified Eagle Medium (DMEM), calcium carbonate, xanthan gum and water for injections.

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  
1061 Mountain Highway  
Boronia  
Victoria, 3155  
Australia.

## ***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. Include the following where appropriate: You may also be able to find general information about your disease and its treatment from patient information groups and product specific organisations eg. asthma foundation

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The information provided applies only to: ROTARIX®.

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