



PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

ROTARIX LIQUID ORAL VACCINE

Rotavirus vaccine.

Oral suspension.

Contains sugar

(1,073 g of sucrose and 10 µg of glucose per dose).

Read all of this leaflet carefully before your child receives ROTARIX LIQUID ORAL VACCINE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ROTARIX LIQUID ORAL VACCINE** has been prescribed for your child and should not be passed on to others.

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

What is in this leaflet

- What ROTARIX LIQUID ORAL VACCINE is and what it is used for
- What you need to know before you take ROTARIX LIQUID ORAL VACCINE
- How to take ROTARIX LIQUID ORAL VACCINE



- Possible side effects
- How to store ROTARIX LIQUID ORAL VACCINE
- Contents of the pack and other information

1. WHAT ROTARIX LIQUID ORAL VACCINE IS AND WHAT IT IS USED FOR:

- ROTARIX LIQUID ORAL VACCINE 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 hospitalization.

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 LIQUID ORAL VACCINE can only protect your child against gastro-enteritis caused by rotavirus.

Vaccination is the best way to protect against these diseases. However, as with all vaccines, ROTARIX LIQUID ORAL VACCINE may not fully protect all people who are vaccinated.

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

2. WHAT YOU NEED KNOW BEFORE ROTARIX LIQUID ORAL VACCINE IS ADMINISTERED:

ROTARIX LIQUID ORAL VACCINE should not be given:

- if your child has previously had any allergic reaction to rotavirus vaccines or any ingredient in ROTARIX LIQUID ORAL VACCINE. The ingredients in ROTARIX LIQUID ORAL VACCINE are listed at the beginning 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 was born with a defect of the gastro-intestinal system
- if your child has a rare inherited illness which affects his/her immune system called Severe Combined Immunodeficiency (SCID).

Warnings and precautions

Before your child is vaccinated make sure your doctor knows if any of the following apply:

- 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 such as HIV infection, which reduces his/her resistance to infection
- if your child 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 LIQUID ORAL VACCINE, contact your doctor/healthcare 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 ROTARIX LIQUID ORAL VACCINE with food or liquids:

There are no restrictions on taking food or liquids, including breast milk, either before or after vaccination with ROTARIX LIQUID ORAL VACCINE.

Pregnancy and breastfeeding:

ROTARIX LIQUID ORAL VACCINE is for use in children only, therefore information on use in pregnancy is not relevant.

Breastfeeding may be continued during the vaccination schedule.

Using other medicines or vaccines with ROTARIX LIQUID ORAL VACCINE:

Always tell your healthcare professional if you are taking any other medicines (this includes complimentary or traditional medicines).

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 LIQUID ORAL VACCINE 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, hepatitis B, pneumococcal and meningococcal vaccines.

3. HOW TO RECEIVE ROTARIX LIQUID ORAL VACCINE:

Your doctor or nurse will give the recommended dose of ROTARIX LIQUID ORAL VACCINE to your child. The vaccine is always given into the child's mouth. Under no circumstances 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 LIQUID ORAL VACCINE 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.

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

4. POSSIBLE SIDE EFFECTS:

ROTARIX LIQUID ORAL VACCINE can have some side effects.

Not all side effects reported for ROTARIX LIQUID ORAL VACCINE are included in this leaflet. Should your general health worsen, or if your baby experiences any

untoward effects when given this medicine, please consult your doctor, pharmacist, or other healthcare professional for advice.

◆ **Frequent** side effects include:

- diarrhoea
- irritability

◆ **Less frequent** side effects include:

- flatulence, pain in the stomach (**see also below for signs of ‘Other’ side effects of intussusception**)
- dermatitis

◆ **Other** side effects include:

- 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.
- 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 you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:



If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “*Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org)*” found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ROTARIX LIQUID ORAL

5. HOW TO STORE:

DO NOT FREEZE.

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

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

Store all medicines out of reach of children.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

For state packs in tubes only: The colour dot that appears on the label of the vaccine tube, is a Vaccine Vial Monitor (VVM). This is a time-temperature sensitive dot that provides an indication of the total amount of heat to which the tube has been exposed. It will warn you when this exposure to heat is likely to have damaged the vaccine, making the vaccine less effective.

Focus on the square inside the ring. As long as the colour of this square is lighter than the colour of the ring, then the vaccine can be used. As soon as the colour of the square is the same colour as the ring or of a darker colour than the ring, then the vaccine should be returned to your doctor or nurse.

It is absolutely critical to ensure that the storage conditions specified above (+2 °C to +8 °C) are followed.



Inner square lighter than outer circle. **If the expiry date has not been passed, USE the vaccine.**



At a later time, inner square still lighter than outer circle. **If the expiry date has not been passed, USE the vaccine.**



Discard point: Inner square matches colour of outer circle. **DO NOT use the vaccine.**



Beyond the discard point: Inner square darker than outer ring. **DO NOT use the vaccine.**

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ROTARIX LIQUID ORAL VACCINE contains:

One dose (1,5 mL) of ROTARIX LIQUID ORAL VACCINE contains:

- the live attenuated human rotavirus RIX4414 strain as active substance.

ROTARIX LIQUID ORAL VACCINE is presented as a suspension for oral administration.

The other ingredients in the vaccine are:

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



What ROTARIX LIQUID ORAL VACCINE looks like and the contents of the pack

ROTARIX LIQUID ORAL VACCINE is a clear, colourless liquid, free of visible particles, presented in a single dose oral applicator or a single dose tube:

- ROTARIX LIQUID ORAL VACCINE in oral applicator: 1,5 mL of oral suspension in an oral applicator (Type I, Ph. Eur.) with a plunger stopper (butyl rubber). Pack sizes of 1, 5, 10, 25, 50 or 100.
- ROTARIX LIQUID ORAL VACCINE in tube: 1,5 mL of oral suspension in a squeezable tube (LDPE) fitted with a membrane and a cap (polypropylene). Pack sizes of 1, 10 or 25.

HOLDER OF CERTIFICATE OF REGISTRATION:

GlaxoSmithKline South Africa (Pty) Ltd

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Century City

Cape Town

7441

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