PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a physician's prescription only

Rotarix Suspension

Oral suspension

Each dose (1.5 ml) contains:
Human rotavirus RIX4414 strain (live, attenuated)
not less than $10^{6.0}$ $CCID_{50}$
For the list of inactive and allergenic ingredients in the preparation, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".
Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.
This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Rotarix is intended for active vaccination of infants from the age of 6 weeks, to prevent gastroenteritis caused by the rotavirus.
Clinical trials have proven its efficacy against gastroenteritis caused by the G1P[8], G2P[4], G3P[8], G4P[8] and G9P[8] types of rotavirus.
The use of Rotarix should be based on official recommendations.

Therapeutic group: Live vaccines against the rotavirus.

Rotavirus infection is the most common cause of severe diarrhea in infants and young children. Rotavirus is easily spread from hand to mouth due to contact with stools from an infected person. Most children with rotavirus diarrhea recover on their own. However, some children become very ill and suffer from severe vomiting, diarrhea and life-threatening loss of fluids that requires hospitalization.
When a person is given the vaccine, the immune system (the body's natural defenses) makes 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 were vaccinated against the rotavirus infections the vaccine is intended to prevent.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- your child has previously had any allergic reaction to rotavirus vaccines or any of the additional ingredients contained in the vaccine (listed in section 6). Signs of an allergic reaction can include: itchy skin rash, shortness of breath and swelling of the face or tongue.
- your child has previously had intussusception (a bowel obstruction in which one segment of the bowel becomes enfolded within another segment).
- your child was born with a malformation of the gut that could lead to intussusception.
- your child has a rare inherited illness which affects the immune system called: Severe combined immunodeficiency (SCID).
- your child has a severe infection with a high fever. It might be necessary to postpone the vaccination until recovery. A minor infection, such as a cold, should not be a problem, but refer to your physician first.
- your child has diarrhea or is vomiting. It might be necessary to postpone the vaccination until recovery.

Special warnings regarding use of the medicine
Before your child is vaccinated with Rotarix, tell the physician or pharmacist if:
- he has a close contact, such as, with a household member who has a weakened immune system, e.g., a person with cancer or a person who is taking medicines that weaken the immune system.
- he has any disorder of the gastrointestinal system.
- he has not been gaining weight and growing as expected.
- he has a disease or is taking any medicine which reduces his resistance to infection or his mother has taken during pregnancy any medicine that may weaken the immune system.

After your child has been vaccinated with Rotarix, contact a physician 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 – "Side effects").
As always, please take care to wash your hands after changing soiled diapers.

Drug interactions
If your child is taking, or has recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist.
Tell the physician if your child has recently received any other vaccine.
Rotarix may be given to your child at the same time with other recommended vaccines, such as diphtheria, tetanus, pertussis (whooping cough), *Haemophilus influenzae* type b, oral or inactivated polio, hepatitis B vaccines, as well as pneumococcal and meningococcal serogroup C conjugate vaccines.

Use of the medicine and food
There are no restrictions on your child's consumption of food or liquids, either before or after vaccination.

Pregnancy and breastfeeding
Based on evidence from clinical trials, breastfeeding does not reduce the protection against gastroenteritis afforded by Rotarix vaccine. Therefore, breastfeeding may be continued during the vaccination schedule.

Important information about some of the ingredients of the medicine
Rotarix contains sucrose, glucose, phenylalanine and sodium.
If you have been told by the physician that the child being vaccinated has an intolerance to some sugars, contact the physician before your child receives the vaccine.
The vaccine contains 0.15 microgram phenylalanine in each dose. Phenylalanine may be harmful if your child has phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
The vaccine contains 32 mg sodium (the main component of cooking/table salt) in each dose.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the physician only.
The physician or nurse will administer the recommended dose of Rotarix to your child. The vaccine (1.5 ml liquid) will be given **orally**. Under no circumstance should this vaccine be administered by injection.
The usual dosage is generally:
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 may be given from the age of 6 weeks. The two doses of the vaccine must have been given by the age of 24 weeks, although they should preferably have been given before 16 weeks of age.
Rotarix may be given according to the same vaccination course to infants who were born prematurely, provided that the pregnancy lasted at least 27 weeks.
In case your child spit out or regurgitated most of the vaccine dose, a single replacement dose may be given at the same visit.
When the first dose of Rotarix is given to your child, it is recommended that your child also receive Rotarix (and not another rotavirus vaccine) for the second dose.
It is important that you follow the instructions of the physician or nurse regarding return visits. If you forget to go back to the physician at the scheduled time, ask the physician for advice.

Do not exceed the recommended dose.
Adhere to the treatment regimen as recommended by the physician.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Rotarix may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
The following side effects may happen with this vaccine:

Common side effects
These may occur with **up to 1 in 10** doses of the vaccine:
- diarrhea
- irritability

Uncommon side effects
These may occur with **up to 1 in 100** doses of the vaccine:
- abdominal pain (see also below for signs of very rare side effects of intussusception)
- flatulence
- inflammation of the skin

Side effects that have been reported during marketed use of Rotarix include:
- Very rare side effects: hives (urticaria).
- Very rare side effects: 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 physician right away if your child experiences one of these symptoms.**
- blood in stools
- 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.
- 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 diarrhea.

If a side effect occurs, if one of the side effects worsens, or if your child suffers from side effects not mentioned in the leaflet, consult with the physician.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il/

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in a refrigerator (between 2°C and 8°C). Do not freeze.
- Store in the original package to protect from light.
- The vaccine should be used immediately after opening.
- Do not discard medicines in the wastewater or household waste. Consult the pharmacist about how to dispose of medicines that are not in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredients, the medicine also contains: Sucrose, Di-sodium adipate, Dulbecco's modified Eagle Medium (DMEM) (containing phenylalanine, sodium, glucose, and other substances), Water for injection.

  Also see section 2 in the leaflet – "Important information about some of the ingredients of the medicine".
- What the medicine looks like and the contents of the package: **Oral** suspension.

  Rotarix is a clear, colourless liquid supplied in a single-use pre-filled applicator (1.5 ml) or in a squeezable, single-use, ready-to-use tube.

  Package sizes:

  Ready-to-use tube: Packs of 1, 10 or 50 units.

  Pre-filled single-use applicator: Packs of 1 or 10 units.

  Not all package sizes may be marketed.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Biologicals S.A., Rixensart, Belgium.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 143-49-32971

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