

Patient package insert in accordance with the Pharmacists' Regulations (Preparations), 1986

This medicine is dispensed without a doctor's prescription

RAZALAX ADULT RAZALAX CHILDREN Rectal Enema

Active ingredient:

Each single-dose container of rectal enema contains:

Razalax Adult: 6.75 g of glycerin.

Razalax Children: 2.25 g of glycerin.

Inactive ingredients in the medicine, see section 6 "Additional information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to your doctor or pharmacist.

Use this medicine according to the instructions in section 3 "How to use the medicine?" in this leaflet. Consult a pharmacist if you need further information. Refer to a doctor if the symptoms worsen or do not improve after a short period of treatment.

1. WHAT IS THE MEDICINE INTENDED FOR?

This medicine contains glycerin, which facilitates the evacuation of feces. Its laxative effect is obtained due to the ability of glycerin to soften stools and stimulate local intestinal movements.

This medicine is indicated to treat constipation.

2. BEFORE USING THE MEDICINE:

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (Glycerin), or any of the other ingredients this medicine contains (listed in section 6 "Additional information").
- You suffer from rectal and/or anal bleeding or other problems such as inflammation of haemorrhoids or haemorrhagic rectocolitis.

Special warnings regarding the use of this medicine:

Talk to your doctor or pharmacist before using this medicine if:

- The need for a laxative derives from an unforeseen change in intestinal patterns (frequency and nature of evacuations) lasting for more than two weeks (severe constipation).
- You have unexplained anemia (decreased red blood cells or decreased blood hemoglobin levels).
- You have unexplained weight loss.
- You have a fever.
- You have a family history of colon cancer or inflammatory bowel disease.

Do not use laxatives if you experience abdominal pain, nausea, or vomiting.

Children

The use of this medicine in children under 2 years of age will be guided by the attending doctor only and in accordance with the dosage prescribed by him.

Exercise caution if using this medicine for prolonged periods of time as this could lead to dependence, possibly with the need to gradually increase the dose (addiction) or other problems. Overuse or prolonged use may cause diarrhea and loss of fluids and, in severe cases, damage to the intestines.

Drug interactions

If you are taking, or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you might be pregnant or intend to become pregnant, consult your doctor or pharmacist before using this medicine. Glycerin may be used rectally during pregnancy and after giving birth.

Driving and using machines

This medicine does not affect the ability to drive and use machines.

3. HOW TO USE THIS MEDICINE?

You should check with your doctor or pharmacist if you are not sure about the dosage and treatment regimen of the medicine.

The usual dose is:

Razalax Adults:

1 single-dose container for adults, 1 or 2 times daily. If you have not passed stools for more than two weeks (severe constipation), your doctor may advise you to take 2 doses simultaneously.

Do not use for a prolonged period.

Razalax Children (above 2 years):

1 single-dose container for children, 1 or 2 times daily.

If the child did not pass stools for more than two weeks (severe constipation), the doctor may advise giving the child 2 doses simultaneously.

Do not use for a prolonged period.

The use of this medicine in children under 2 years of age will be guided by the attending doctor only and in accordance with the dosage prescribed by him.

Do not exceed the recommended dose.

Do not swallow!

Instructions for use:

Razalax can be used at any time of day.

1. Hold the neck and turn the cap to break the seal.
2. Lift the cap; do NOT grip the squeezable bottle itself at any point as this could cause the product to leak out once opened.
3. Lubricate the cannula with a drop of the solution.
4. Insert the cannula into the rectum and squeeze the bottle.
5. Remove the cannula from the rectum, keep the squeezable bottle depressed, and throw it into the trash.

If you accidentally take a higher dose

If you have taken an overdose or accidental intake or if a child has accidentally swallowed the medicine, proceed immediately to your doctor or go to the nearest hospital and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding the use of this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS:

As with any medicine, the use of Razalax Adult and Razalax Children 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.

Inform your doctor if you notice any reddening, stinging or pain (irritation) in the rectum.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to an online form of adverse events reporting or by entering the following link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed by the doctor!
- Do not use this medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- **Storage condition:** store at temperatures below 25°C.
- Do not discard any medicines 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. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:

Mauve fluid extract, chamomile fluid extract, wheat starch, purified water.

What does the medicine look like and what are the contents of the package:

The single-dose containers contain a yellow to brown viscous liquid.

Approved packaging sizes:

Razalax Adults is available in packages of 6 single-dose 9g containers. Each bottle is a single dose.

Razalax Children is available in packages of 6 single-dose 3g containers. Each bottle is a single dose.

Registration holder and importer:

RAZ PHARMACEUTICS LTD., 31 Geshet Haetz Street, Emek Hefer Industrial Park, Israel

Drug registration numbers at the national drug registry of the Ministry of Health:

Razalax Adult: 158-37-34394-00

Razalax Children: 158-38-34408-00

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