

**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**

**The active ingredient:**

Each single-dose container of rectal enema contains:

Razalax Adult: 6.75 g of glycerin.

Razalax Children: 2.25 g of glycerin.

For the list of inactive ingredients, see section 6.

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

Use the medicine correctly. Refer to your pharmacist if you need further information. Inform your doctor if 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 thanks 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 allergic to the active ingredient, or any of the other ingredients of this medicine (listed in section 6).
- You suffer from rectal and/or anal bleeding or other problems such as inflammation of haemorrhoids or haemorrhagic rectocolitis.

**Specials 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).
- Unexplained anemia (decreased red blood cells or decreased blood hemoglobin levels).
- Unexplained weight loss.
- Fever.
- Family history of colon cancer or inflammatory bowel disease.

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

**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.**

**The use with other medicines**

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

**Pregnancy and lactation**

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 SHOULD YOU USE THE MEDICINE?**

You should check with your doctor or pharmacist if you are unsure.

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. Use only for short periods of time.

**Razalax Children:**

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 to give the child 2 doses simultaneously.

Use only for short periods of time.

**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, keeping the squeezable bottle depressed, and throw away.

**If you accidentally take a higher dose**

In case of overdose or accidental intake, contact your doctor immediately or go to the nearest hospital.

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.

**Reporting side effects:**

You can report side effects to the Ministry of Health by clicking the "report side effects due to medication" in the homepage of the Ministry of Health ([www.health.gov.il](http://www.health.gov.il)) referring to an online form for reporting side effects, or by clicking the link:

<https://sideeffects.health.gov.il>

### **5. HOW SHOULD THE MEDICINE BE STORED?**

- Avoid poisoning! This medicine and any other must be kept out of the reach 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) that appears on the package. The expiry date refers to the last day of that month.
- Do not store at temperatures exceeding 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. FURTHER INFORMATION**

Razalax Adult contains 6.75 g of glycerin.

Razalax Children contains 2.25 g of glycerin.

**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:**

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

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

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

**License holder:**

Raz Pharmaceuticals Ltd, 6 Hamatechet St., Kadima, Israel

**Manufacturer:**

A.C.R.A.F. S.p.A., Via Vecchia del Pinocchio 22 - 60131 Ancona, Italy.

**Drug registration numbers:**

Razalax Adult: 158-37-34394-00

Razalax Children: 158-38-34408-00

**This leaflet was checked and approved by the Israeli Ministry of Health in April 2017, and was updated according to MOH instructions in September 2019**

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