

GLYCERAZ ADULTS SUPPOSITORIES

Active ingredient:

Each suppository contains:
Glycerol 2,250 mg.

Inactive ingredients and allergens in the medicine – see section 6 "Additional information".

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

You should use the medicine according to the instructions detailed in dosage section in this leaflet (section 3 - "How to use this medicine?").

Consult a pharmacist if you need additional information. Refer to the doctor if the signs illness (symptoms) worsen or do not improve after 7 days.

1. What is this medicine used for?

This medicine is intended for the relief of constipation.

Therapeutic group: laxatives.

2. Before using this medicine

Do not use this medicine:

- * If you are sensitive (allergic) to the active ingredient glycerol or to any of the other ingredients that this medicine contains (see section 6 - "Additional information").
- * In case of acute abdominal pain or of unknown origin.
- * In case of nausea or vomiting.
- * In case of obstruction or intestinal stenosis.
- * In case of rectal bleeding of unknown origin.
- * In the case of hemorrhoids accompanied by an acute attack, pain and bleeding.
- * In severe state of dehydration.

Special warnings regarding the use of this medicine:

Talk to your doctor, pharmacist or nurse before using Glyceraz adults.

Prolonged use may cause dependence on laxatives. Do not use this medicine frequently, or for long period, without consulting a doctor.

Laxatives should be used at the least possible frequency and for not more than 7 days. The use for longer periods of time requires a doctor prescription after proper assessment of individual case.

Treatment of chronic or recurring constipation always requires intervention by the doctor for the diagnosis, prescription of medicines and observation during the treatment. The abuse of laxatives can cause persistent diarrhea with consequential loss of water, mineral salts (especially potassium) and other essential nutrient factors. In more serious cases of abuse, dehydration or hypokalemia may occur, which can cause cardiac or neuromuscular dysfunction, especially in the case of concurrent treatment with cardiac glycosides, diuretics or corticosteroids.

The abuse of laxatives, especially stimulant laxatives, can cause dependency (which may possibly necessitate the progressive increase in dosage), chronic constipation and loss of normal bowel functions (intestinal atony). During episodes of constipation, it is advisable first of all to correct eating habits and integrate at the daily diet with an adequate intake of fiber and water.

When using laxatives, it is necessary to drink at least 6-8 glasses of water, or other fluids, per day so as to favor the relaxation of feces.

Consult your doctor when the need of laxatives is derived from a sudden change of the usual bowel habits (frequency and characteristics of the evacuations) that lasts for more than two weeks or when the use of laxative is not effective.

Children and adolescents

This medicine is not usually intended for administration to children and infants under 6 years old.

In children under the age of 6 years old, the medicine can be used only after consulting with your doctor. It is also advisable that the elderly or people who are not in a good state of health to consult the doctor before using this medicine.

Drug interactions

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

No official studies have been conducted on medicine interactions.

Pregnancy, breastfeeding and fertility

Consult a doctor before using this medicine if you are pregnant, intend to become pregnant or breastfeeding.

Adequate and well-controlled studies on the use of the medicine in pregnancy or lactation have not been carried out. Even if there are no obvious contraindications to the use of the medicinal product in pregnancy and during lactation, it is recommended to take the medication only when needed and under medical supervision.

Effects on ability to drive and use of machines

This medicine does not alter the ability to drive or use machinery. However, it is possible that during the treatment with the medicine some undesirable effects can manifest themselves. Therefore, it is advisable to know the reactions to the medicine before you drive or use machinery.

3. How should you use the medicine?

You should check with the doctor or the pharmacist if you are not sure about the dosage and how to use the medicine.

The usual recommended dose for Glyceraz adults: one suppository a day for adults, as needed.

This medicine is not usually intended for administration to children and infants under 6 years old.

Do not use in children under 6 years old of age without consulting your doctor.

A diet rich in liquids favors the effect of the medicine.

Do not exceed the recommended dose.

If used continuously for more than a week, you should consult a doctor.

Do not swallow! This medicine is intended for rectal use only.

Instructions for use

Remove the suppository from its container and then, if necessary, moisten it to facilitate its insertion in the anus.

If the suppositories appear soft, immerse the container, before opening it, in cold water.

If you have accidentally taken an higher dose

If you have accidentally taken an overdose or if a child has accidentally swallowed the medicine, immediately contact a doctor or go to a hospital emergency room and take the medicine package with you.

No cases of overdose have been reported. In any case, Excessive doses (abuse of laxatives - frequent or prolonged use or with excessive doses) can cause abdominal pain, persistent diarrhea with consequential loss of water, mineral salts (especially potassium) and other essential nutrient factors. The loss of fluids and electrolytes must be replenished. The electrolyte imbalances are characterized by the following symptoms: thirst, vomiting, weakness, edema, pain in the bones (osteomalacia) and hypoalbuminemia. For information on laxatives abuse see section 2 - "Special warnings regarding the use of this medicine".

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

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

4. Side effects

Like with any medicine, the use of this medicine may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

The following undesirable effects of glycerol have been reported. No sufficient data is available to determine the frequency of the individual effects listed.

Gastrointestinal diseases

Pain resulting from spasms in isolated foci or abdominal colics and diarrhoea, with loss of fluids and electrolytes, more frequent in cases of severe constipation, as well as irritation at the rectum.

Compliance with the instructions in the package leaflet reduces the risk of side effects.

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

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) referring to an online form for reporting side effects, or by clicking the link:

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

5. How to store the medicine?

- **Avoid poisoning!** This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. Date) appearing on the outer package. The expiry date refers to the last day of that month.

Storage conditions:

- Store in the original package in order to protect the medicine from moisture and away from direct sources of heat.
- There are no special storage conditions, however, it is recommended to store at room temperature.

The medicine must not be thrown in the waste water and in the household waste bin. Ask your pharmacist how to dispose of medicinal product that are no longer required. This will help to protect the environment.

6. Additional information

In addition to the active ingredient the medicine also contains: Sodium stearate, Sodium hydrogen carbonate.

What does the medicine look like and what is the content of the package:

Torpedo -shaped, clear, homogeneous suppositories with a uniform aspect.

Glyceraz adults is available in a package of 18 or 50 suppositories. Not all package sizes may be marketed.

Name and address of registration holder and importer:

RAZ Pharmaceuticals Ltd., 31 Geshet Haetz Street, Emek Hefer Industrial Park, Israel.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

166-64-35814-00

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