

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) - 1986**

This medicine is to be supplied without doctor's prescription

GLYCERAZ ADULTS

Composition:

Each suppository contains:

Active ingredient: glycerol 2250 mg.

For the list of inactive ingredients – see section 6, "Additional information".

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

You should take the medicine in a proper manner. Consult a pharmacist if you need additional information. Refer to the doctor if the signs of the illness (symptoms) worsen or do not improve after 7 days.

1. What is this medicine used for?

For 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 abdominal pain acute 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 case of acute haemorrhoidal crisis with pain and bleeding,
- * in severe state of dehydration.

Warnings:

Talk to your doctor, pharmacist or nurse before using this medicine.

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

Treatment of chronic or recurring constipation always requires intervention by the doctor for the diagnosis, prescription of drugs 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 contact laxatives (stimulants), 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 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 liquids, per day so as to favor the relaxation of faeces.

* consult your doctor when the need of the laxative 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/infants under 6 years old. In children under the age of 6, the medicinal product can be used only after consulting your doctor. It is also appropriate that the elderly or people not in a good state of health to consult the doctor before using this medicine.

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

Pregnancy, breastfeeding and fertility

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

This medicine does not alter the ability to drive or use machinery. However, it is possible that during the treatment some undesirable effects can manifest themselves.

Therefore it is advisable to know the reactions to the medicinal product before you drive or use machinery.

3. How should you use the medicine?

Use the medicine always according to your doctor's instructions. 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/infants under 6 years old. In children under 6 years old, the medicinal product can be used only after consulting your doctor. A diet rich in liquids favors the effect of the product.

Do not exceed the recommended dose.

Laxatives should be used in the least possible frequently and for not more than seven days. The use for longer periods of time requires a doctor's prescription after proper assessment of each individual case.

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 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 diarrhoea 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 "Warnings".

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 further questions regarding the use of this medicine, consult the doctor or the pharmacist.

4. Side effects

Like 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

Isolated crampiform pain 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 contained in the package leaflet reduces the risk of side effects.

If any of the side effects becomes worse, or if you notice any side effects not listed in this leaflet, please 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.

- 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 medicinal products must not be thrown in the waste water and in household waste. Ask your pharmacist how to dispose the medicinal products 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:

Suppositories - pack of 18 or 50 suppositories.

Manufacturer:

Laboratorio Chimico Farmaceutico A. Sella S.r.l., Via Vicenza, Schio (VI), Italy.

Marketing Authorization Holder:

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

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

166-64-35814-00

Revised in February 2021 according to MOHs guidelines.

RAZP0136/43-00