

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed without a doctor's prescription

## **Glycerin Suppositories Relief Suppositories**

**Active ingredient:** Each suppository contains 2250 mg glycerol. Glycerol is also called glycerin. These are synonyms for the same active substance.

For the list of inactive ingredients and allergens in this medicine - see section 2 ('Important information about some of this medicine's ingredients'), and section 6 ('Additional information').

**Read the entire leaflet carefully before you start using this medicine.** Keep the leaflet. You may need to read it again.

This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Use this medicine according to the instructions in the section about dose in this leaflet (section 3 'How to use this medicine'). Consult your pharmacist if you need further information. Consult your doctor if the symptoms of illness get worse or do not improve after 7 days.

### **1) What is this medicine intended for?**

The medicine is intended for relief of constipation.

**Therapeutic group:** laxative.

### **2) Before using this medicine:**

**Do not use this medicine:**

- If you are sensitive (allergic) to the active ingredient glycerol (glycerin) or to any of the other ingredients in this medicine (see section 6 'Additional information').
- In case of acute abdominal pain or abdominal pain of unknown origin.
- In case of nausea or vomiting.
- In case of intestinal obstruction or stenosis.
- In case of rectal bleeding of unknown origin.
- In case of acute haemorrhoidal crisis with pain and bleeding.
- In severe states of dehydration.

### **Special warnings about using this medicine:**

- **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 a long period without consulting a doctor.
- **Laxatives should be used as infrequently as possible and for no more than 7 days. Use for longer periods requires a doctor's prescription after appropriate evaluation of the individual case.**
- Treatment of chronic or recurring constipation always requires intervention by the doctor for diagnosis, prescription of drugs and observation during the treatment. Abuse of laxatives can cause persistent diarrhoea, associated with loss of water, mineral salts (especially potassium) and other essential nutrient factors. In more serious cases of abuse, dehydration or hypokalaemia may occur, which may cause cardiac or neuromuscular dysfunction,

especially in cases of concurrent treatment with cardiac glycosides, diuretics or corticosteroids.

- Abuse of laxatives, especially contact laxatives (stimulants), can cause dependency (which may necessitate progressive increase in dosage), chronic constipation and loss of normal bowel function (intestinal atony). In cases of constipation, it is advisable first of all to correct eating habits and integrate adequate intake of fibres and water in the daily diet.
- When using laxatives, it is necessary to drink at least 6-8 glasses of water or other liquids per day for stool softening.
- Consult your doctor when the need for laxatives results from a sudden change in the usual bowel habits (frequency and characteristics of the evacuations) that lasts for more than two weeks or when the use of laxatives is not effective.

### **Children and adolescents:**

This medicine is not usually intended for use in children / infants under 6 years old.

In children under the age of 6, the medicine can be used only after consulting your doctor. It is also advisable for the elderly or people in poor health condition to consult the doctor before using this medicine.

### **Interactions with other medicines:**

**If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.**

No formal studies have been conducted on interactions with other medicines.

### **Pregnancy, breastfeeding and fertility:**

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

Adequate studies on the use of the medicine in pregnant or breastfeeding women have not been carried out. Even if there are no obvious contraindications for use of the medicine during pregnancy or breastfeeding, it is recommended to take the medicine only when needed and under medical supervision.

### **Driving and using machines:**

This medicine does not alter the ability to drive or use machines. However, undesirable side effects may occur during use of the medicine. Therefore, it is advisable to know your reaction to the medicine before you drive or use machines.

### **Important information about some of this medicine's ingredients:**

Each suppository contains 31 mg sodium.

### **3) How to use this medicine?**

Check with your doctor or pharmacist if you are not sure about your dose or about how to use this medicine.

The recommended dose is usually: one suppository per day for adults as needed.

This medicine is not usually intended for use in children / infants under 6 years old.

In children under the age of 6, the medicine can be used only after consulting your doctor. A diet rich in liquids contributes to the effect of the medicine.

**Do not exceed the recommended dose. Consult your doctor when using this medicine for more than 7 consecutive days.** 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 are soft, immerse the container, before opening it, in flowing cold water.

### **If you have accidentally taken a higher dose:**

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. No cases of overdose have been reported. In any case, excessive doses (laxative abuse - frequent or prolonged use or use of 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. Electrolyte imbalance is characterized by the following symptoms: thirst, vomiting, weakness, oedema, pain in the bones (osteomalacia) and hypoalbuminemia. For information on laxative abuse see section 2 'Special warnings about using this medicine'.

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

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

### **4) Side effects:**

As with any medicine, using **Glycerin Suppositories Relief** may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

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

### **Gastrointestinal diseases:**

Isolated crampiform pain or abdominal colic (cramp-like and sudden abdominal pain) and diarrhoea, including 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 you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

### **Reporting side effects:**

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

### **5) How to store the medicine?**

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.

Do not use the medicine after the expiry date (Exp. Date) which is stated on the package. The expiry date refers to the last day of that month.

**Storage conditions:** Store at a temperature below 25°C, in the original package to protect from moisture. Protect from heat source.

After removing the suppository from the aluminium blister, use it immediately. Suppositories kept in blisters can be used until the end of shelf life.

Do not throw away this medicine via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

### **6) Additional information:**

**In addition to the active ingredient, this medicine also contains the following inactive ingredients:**

Sodium Hydrogen Carbonate, Sodium Stearate.

**What the medicine looks like and contents of the pack:** The medicine looks like a colourless or light-yellow suppository. The suppositories are packed in bilateral aluminium blisters. Each aluminium blister contains 6 suppositories. The number of suppositories in each aluminium blister may vary according to the pack size.

**Pack size:** The medicine is supplied in a pack, as detailed below:

- Carton packs containing 1, 2, 3, 4, 5, 10, 15 or 20 aluminium blisters. The number of aluminium blisters in each carton pack may vary according to the pack size. The number of suppositories in each pack is indicated on the carton pack.
- Not all pack sizes may be marketed.

**Registration holder:** Super-Pharm (Israel) Ltd., 16 Arie Shenkar St., Herzliya 4672516.

**Manufacturer:** New.Fa.Dem. S.r.l., Giugliano in Campania, Italy.

Registration number of the medicine in the Ministry of Health National Drug Registry: 176-36-37263-99

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