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

Read this package insert carefully in its entirety before using this medicine This leaflet has been imprint and checked by health ministry of Israel and approved in 07/2011.

GLYCERIN Suppositories For Adults

GLYCERIN Suppositories For Children

Composition: Each suppository for adults contains: Glycerin 2.16 g

Each suppository for childs contains: Glycerin 1.104 g

The product contains also: Stearin, Sodium Carbonate, Purified Water. Therapeutic activity: Laxative.

Indication: The medicine is indicated to relief of constipation.

When should the preparation not be used?

If you are hypersensitive to one of its ingredients.

Do not use laxatives because bowel movement is missed one or two days. (See also in warning section)

Do not use this medicine in case of congestive heart failure.

Do not use this medicine in case of undiagnosed rectal bleeding or intestinal obstruction or chronic insufficiency of intestine.

Do not use in case of nausea, vomiting, abdominal pains.

Do not use if you have signs of appendicitis.

Do not take this medicine without consulting a doctor before starting treatment:

If you are pregnant or breast-feeding.

If you are suffering, or have suffered in the past, from impaired function of: the heart and/or blood vessels, the digestive system.

If you notice sudden change in the frequency of bowel movement that continues over two weeks.

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

If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine. This product is intended only for constipation that lasts few days. Lack efficacy of bowel movement that lasts only one or two day does not justify the use of the medicine. Do not use this medicine for other indications like "body purification" or like similar.

Drug Interactions: If you are taking another drug concomitantly or if you have just finished treatment with another medicine, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions. This is especially important for other laxative medicines.

Side Effects: In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, for example: skin rash with irritation, nausea, dizziness.

Effects that require special attention:

Local irritation or inflammation or eruption develops at the site of treatment (rare): discontinue treatment and contact your doctor.

Presence of rectal bleeding or lack efficacy of bowel movement after using the laxative medicines: discontinue treatment and contact your doctor. In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Adverse reactions and drug interactions in children and infants: Parents must inform the attending doctor about any side effects, as well as any additional medicine being taken by the child.

Recommended dosage unless otherwise prescribed by your doctor:

<u>Glycerin suppositories for adults:</u> one suppository a day for adults as needed. Do not exceed the recommended dosage.

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

<u>Glycerin suppositories for children</u>: one suppository a day for children as needed. This medicine should not be used on children less than two years of age, except under the prescription of a doctor.

If there is no improvement in the condition of your health within a week, consult your doctor.

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

Directions for Use: Remove the wrapping from the suppository. It is possible to moisten it with some water to facilitate penetration. Lie on your side and introduce the suppository deep into the rectum with the aid of a finger. Wash your hands thoroughly. Bowel movement is usually achieved in 15 - 60 minutes.

How can you contribute to the success of the treatment?

It is recommended that the suppository remain in the rectum for approximately 15 minutes. This treatment should be accompanied by a suitable intake of fluids (1 - 1.5 liter) and suitable dietary habits and physical activity (a fiber-rich diet). Your physician should be consulted if you use this medication for more than a week. Avoid Poisoning!

This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you. <u>Do not induce vomiting</u> unless explicitly instructed to do so by a doctor! <u>Do not take medicines in the dark!</u> Check the label and the dose <u>each time</u> you take your medicine. Wear glasses if you need them. **Storage**: Store at a temperature below 25°C.

Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you. Do not store different medications in the same package. Licence Number:

Glycerin suppositories for adults: 137-97-21926-00 Glycerin suppositories for children: 146-41-33387-00

Manufacturer: Rekah Pharmaceutical Prod. Ltd., 30 Hamelacha St. Holon, Israel.