

SUMMARY PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GLYCERIN, 1.0 G OR 2.11 G, RECTAL SUPPOSITORIES

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains the:

Active substance: Glycerol 1.0 g or 2.11 g

For excipients, see 6.1

3. PHARMACEUTICAL FORM

Rectal Suppositories.

Transparent or translucent suppositories, almost colorless, or with a yellowish-brown-shade with a smearing surface, hygroscopic, torpedo shaped. Turbidity of suppositories, slight softening of the surface layer and moisturization of primary packaging is allowed. Allowed presence of air rod.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of constipation of various etiologies, including during pregnancy and breastfeeding.

Prevention of constipation in patients who cannot strain during defecation.

4.2 Posology and method of administration

Adults: 1-2 suppository 2.11 g as needed

Children: 1 suppository 1.0 g as needed

It is necessary to keep the suppository in the right colon as long as possible before defecation.

4.3 Contraindications

Hypersensitivity to the components of the drug, intestinal obstruction, haemorrhoids in the acute stage, inflammatory diseases and tumors of the rectum, undiagnosed abdominal pain.

4.4 Special Warning and precautions for use

It is used with caution in case of renal insufficiency.

Systematic use is not recommended. Treatment is discontinued after the restoration of normal intestinal motility.

Do not lubricate suppositories with mineral liquid or solid oils.

When used, the remains of the suppository are excreted from the intestine with feces.

Use in children

Use in children under 3 years of age is possible only after consulting a doctor and excluding diseases that could affect the delay in bowel movement.

Use of the drug in children must be carried out under the supervision of a doctor.

4.5 Interaction with other medicinal products and other forms of interaction

Suppositories with glycerin may weaken the effect of medications that are used rectally.

If it is necessary to use other rectal medications, an interval of at least 1 hour should be observed between their uses.

4.6 Fertility, Pregnancy and lactation

The safety of Glycerin Suppositories during pregnancy and lactation has not been established.

Use only under a doctor's instruction.

Fertility

There is no information on the effects of drug on human fertility.

4.7 Effects on the ability to drive and use machines

The use of the drug does not affect the ability to drive vehicles or operate machinery.

4.8 Undesirable effects

Classification of the frequency of development of side effects recommended by the World Health Organization (WHO): very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$), frequency not known (cannot be estimated from the available data).

MedDRA System Organ Class	Incidence	Adverse reactions
<i>Disorders of the Immune System</i>	frequency not known	allergic reactions
<i>General disorders and administration site conditions</i>		local reactions at the site of suppository administration (feeling of discomfort, itching, burning); intestinal spasms. With prolonged use – weakening of the physiological process of defecation.

In patients with dehydration, severe dehydration may develop after using glycerin in the form of suppositories, leading to cardiovascular failure and pulmonary edema. Cases of necrotic hyperosmolar hyperglycemic coma, which can lead to death, have been described.

Reporting of suspected adverse reactions

*Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions online to the **Center of Drug and Medical Technologies Expertise** of MoH of RA via www.pharm.am or call the hotline numbers: (+374 10) 20 05 05 and (+374 96) 22 05 05.*

4.9 Overdose

Overdose cases are unknown.

When using the drug in accordance with the instructions for use, an overdose is unlikely.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other drugs for constipation

ATC code: A06AX01

5.1 Pharmacodynamic properties

Laxative, softens and lubricates hardened fecal masses, facilitates their passage through the colon, irritates the mucous membrane intestinal, reflex stimulating intestinal motility.

5.2 Pharmacokinetic properties

Following rectal administration is poorly absorbed.

5.3 Preclinical safety data

In preclinical data obtained from the results of standard studies of pharmacological safety, repeated administration toxicity, genotoxicity, carcinogenic potential and reproductive and ontogenetic toxicity, no special harm to humans was identified.

6. PHARMACEUTICAL PARTICULAR**6.1 List of excipients**

Excipients: gelatine fish, sodium stearate, purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25 °C. Do not freeze.

Keep out of reach of children.

6.5 Nature and contents of the container

5 rectal suppositories in a strip, 2 strips and leaflet insert in a paperboard box

6.6 Special precautions for disposal and other handling

For rectal use only.

7. MANUFACTURER AND MARKETING AUTHORIZATION HOLDER

«Medical Horizon» Ltd

RA, Ararat province, Masis city, Hrant Vardanyan 22

8. DATE OF (PARTIAL) REVISION OF THE TEXT

October 2024