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

The medicine is dispensed with a doctor's prescription only.

GLAUTAN Eye Drops

Composition:

Latanoprost 50 mcg/ml

For the list of inactive ingredients, please see section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm even if it seems to you that their medical condition is similar. This medicine is intended for treatment of adults over 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Therapeutic activity:

For reducing intraocular pressure in patients with open-angle glaucoma and ocular hypertension.

Therapeutic group:

Prostaglandin F2 analog.

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:

- you are sensitive (allergic) to latanoprost or to any of the additional ingredients contained in the medicine (see section 6: "Further Information").
- you are pregnant or are planning to become pregnant.
- you are breastfeeding.

Special warnings regarding use of the medicine:

❗ Before treatment with Glautan, tell the doctor if:

- you are about to have or have recently had eye surgery (including cataract surgery).
- you are suffering, or have suffered in the past, from impaired eye function (such as eye pain, irritation or inflammation, blurred vision, infection (e.g., herpes), severe narrow-angle glaucoma, ocular lens damage, etc.).
- you are suffering, or have suffered in the past, from dry eyes.
- you are suffering, or have suffered in the past, from impaired heart function.
- you are suffering, or have suffered in the past, from disease of the liver, kidney.
- you suffer from severe asthma or from uncontrolled asthma.
- you wear contact lenses. You can use **Glautan**, but follow the instructions in Section 3.

During the course of treatment with this medicine, the pigmentation of the iris should be monitored.

❗ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:

acetazolamide - diuretics, cholinergic agents (pilocarpine), beta blockers (timolol), dipivefrin and epinephrine - adrenergic agonists, prostaglandins, prostaglandin analogs or derivatives.

❗ Pregnancy and breastfeeding – do not use the medicine if you are pregnant. Refer to a doctor immediately if you are pregnant, planning to become pregnant or think you are pregnant.

Do not use the medicine if you are breastfeeding.

❗ Driving and operating machinery – use of this medicine may cause blurred vision for a short period of time. If this happens, avoid driving or operating dangerous machinery for as long as your vision is blurred.

❗ Important information about some of the ingredients of the medicine - this medicine contains a preservative called benzalkonium chloride. This substance may cause irritation or damage to the cornea (the surface of the eye). The substance may be absorbed by contact lenses and cause discoloration of soft contact lenses. Therefore, avoid contact between the preparation and soft contact lenses.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are unsure.

The dosage and the treatment regimen will be determined by the doctor only.

The usual dosage is generally one drop, once a day, preferably in the evening.

Do not exceed the recommended dose.

Wash your hands thoroughly. Tilt your head backwards or lie down on a bed, and with the aid of a finger pull the lower eyelid slightly away from the eye. Instill the medicine into the space that has formed. Press the finger on the corner of the eye near the nose for about a minute, while keeping the eye closed. Do not blink. In order to prevent contamination of the solution, make sure not to allow the tip of the bottle to come into contact with any surface including the finger or the eye and close the bottle tightly. Do not use the medicine for more than a month after the bottle is first opened. When used in combination with other eye drops, wait 5 minutes between treatments.

If you wear contact lenses, remove the lenses before use of the preparation; they may be reinserted no less than 15 minutes after instilling the medicine into the eye.

If you accidentally took a higher dosage (you put too many drops into the eye), local irritation of the eye may occur (manifested by reddening of the eye and tearing). This effect should pass, but if you are concerned, refer to a doctor. If a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the required time, take the next dose at the regular time. Do not take two doses together to compensate for a forgotten dose!

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

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

If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Glautan** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Side effects that occur frequently:

- A gradual change in eye color by an increase in the brown pigment in the iris. Patients with mixed-color eyes (blue-brown, gray-brown, yellow-brown or green-brown) are more likely to see the color change than patients with a uniform eye color (blue, gray, green or brown). The changes in color may develop after years, although it can usually be seen within approximately 8 months of treatment. The color change may be permanent and may be noticeable if you use **Glautan** in only one eye. The change in color seemingly does not cause any problems. The eye color does not continue to change if you stop treatment with the medicine.
- Redness of the eye.
- Eye irritation (a feeling of burning, grittiness, itching, stinging, sensation of a "foreign body" in the eye).
- A gradual change in the eyelashes of the treated eye and fine hairs around the treated eye (seen mostly in patients of Japanese origin). These changes include a change in color (darkening), length, thickness and number of eyelashes.
- Irritation or damage of the surface of the eye, eyelid inflammation, eye pain.

Side effects that occur infrequently:

- Eyelid swelling, dryness of the eye, inflammation or irritation of the cornea (the surface of the eye), blurred vision, conjunctivitis.
- Skin rash.

Side effects that occur rarely:

- Inflammation of the iris, swelling of the retina, symptoms of swelling or scratching/damage to the surface of the eye, swelling around the eye, misdirected eyelash growth or an extra row of eyelashes, photophobia (light sensitivity).
- Darkening of, or changes in, the skin of the eyelids.
- Asthma or worsening of preexisting asthma and shortness of breath.

Side effects that occur very rarely:

- Worsening of angina in patients with heart diseases; chest pain; sunken eye appearance (eye sulcus deepening).

Side effects of unknown frequency:

Iris cysts, headaches, dizziness, palpitations, muscle pains, joint pains, development of an infection of the eye caused by the herpes simplex virus (HSV), runny nose, fever.

In very rare cases, some patients with severe damage to the cornea developed cloudy patches on the iris due to calcium sedimentation during treatment.

If one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in a refrigerator, at a temperature of 2-8°C, protected from light. After opening, can be stored at room temperature (below 25°C) for up to 4 weeks. Discard the remains.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Disodium hydrogen phosphate anhydrous, Sodium dihydrogen phosphate monohydrate, Benzalkonium chloride, Sodium chloride, Purified water.

What the medicine looks like and the contents of the package:

Glautan is packaged in a vial provided in a carton pack. Each **Glautan** vial has 2.5 ml solution.

The solution is clear and colorless.

License holder: Unipharm Ltd., P.O.B. 21429 Tel Aviv, 6121301.

Manufacturer and address: Vitamed Ltd., Binyamina.

This leaflet was checked and approved by the Ministry of Health in March 2014.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 139 75 31597 00

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