Package leaflet: Information for the patient

GLAUMAX, 50 micrograms/ml eye drops, solution
Latanoprost

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or the doctor treating your child, pharmacist or nurse.
- This medicinal product has been prescribed only for you or your child. Do not pass it on to others. The medicinal product may harm them, even if their signs of illness are the same as yours.
- If you or your child get any side effects, talk to your doctor or the doctor treating your child, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What GLAUMAX is and what it is used for

GLAUMAX contains the active ingredient latanoprost, which reduces the intraocular pressure by increasing the natural outflow of aqueous humour.
GLAUMAX is used to reduce the intraocular pressure in patients with open angle glaucoma and ocular hypertension.
GLAUMAX is also used to treat the increased eye pressure and glaucoma in all ages of children and babies.

2. What you need to know before you use GLAUMAX

GLAUMAX can be used in adults, the elderly and in children from birth to 18 years old. GLAUMAX has not been investigated in premature infants (at the gestational age less than 36 weeks).

Do not use GLAUMAX:
- if you or your child are allergic to latanoprost or any of the other ingredients (listed in section 6) of GLAUMAX.

Warnings and precautions
Talk to your doctor or the doctor treating your child, pharmacist or nurse before using GLAUMAX, if any of the following apply to you or your child:
- if you or your child suffer from eye problems such as eye pain, irritation or inflammation, blurred vision;
- if you or your child suffer from dry eyes;
- if you or your child have severe asthma or the asthma is not well controlled;
- if you or your child are about to have or have had eye surgery (including cataract surgery);
- if you or your child wear contact lenses. You can still use GLAUMAX, but follow the instruction for contact lens wearers in section 3;
- if you have suffered or are currently suffering from a viral infection of the eye caused by the *herpes simplex* virus (HSV).

Other medicines and GLAUMAX
GLAUMAX may interact with other medicinal products. Tell your doctor, the doctor treating your child or pharmacist if you or your child are using, have recently used or might use any other medicinal products (or eye drops).

Be sure to tell your doctor, the doctor treating your child or pharmacist if you or your child are taking any of the following types of medicinal products:
- prostaglandins, prostaglandin analogues or prostaglandin derivatives.

Pregnancy, breast-feeding and fertility
Do not use GLAUMAX if you are pregnant or breast-feeding unless your doctor considers it necessary. If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines
Instillation of GLAUMAX eye drops may cause transient blurring of vision. Therefore, while using GLAUMAX do not drive a car or operate machinery until your vision becomes clear again.

GLAUMAX contains benzalkonium chloride and phosphate buffers
This medicine contains 0.2 mg/mL of benzalkonium chloride.
Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. Remove the contact lenses before using this medicine and put them back 15 minutes afterwards the administration.
Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

This medicine contains 4.8 mg/mL phosphates which is equivalent to 0.14 mg/drop.
If you suffer from severe damage to the clear layer at the front of the eye (cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. How to use GLAUMAX

Always use this medicinal product exactly as described in this leaflet or as your doctor or the doctor treating your child, pharmacist or nurse have told you. Check with your doctor, the doctor treating your child, pharmacist or nurse if you are not sure.

Use in adults (including the elderly) and children
The recommended dose is one drop of GLAUMAX in the affected eye(s) once a day in the evenings. More frequent administration reduces the intraocular pressure lowering effect.

Use GLAUMAX always exactly as your doctor or the doctor treating your child has told you, until the end of the use of this medicine.

Contact lens wearers
If you or your child wear contact lenses, they should be removed before using GLAUMAX. Contact lenses may be reinserted after 15 minutes.

Instructions for use
1. Wash your hands and sit or stand comfortably (if necessary, in front of a mirror).
2. Open the dropper-bottle.
3. Hold the dropper-bottle pointing down between your thumb and middle finger.
4. Lean your head backwards. With your clean finger pull the lower eyelid further from the eye to form a “pocket”, where the eye drops can be applied.
5. Place the tip of the bottle close to your eye (if necessary, use the mirror). **Do not touch the eye, eyelids or other surfaces with the tip of the dropper.** The solution may become contaminated.
6. Gently press the sides of the dropper-bottle to release one drop of GLAUMAX at a time.
7. After GLAUMAX instillation, close the eye and press your index finger against the nasal corner of the eyelid.
8. If you need to use eye drops in both eyes, repeat the same techniques.
9. Put the protective cap back on the bottle right after use.

If the drop should miss your eye, try again.

Use with other eye drops
If you are using any other eye drops in addition to GLAUMAX, these medicines must be administered at least 5 minutes apart.

If you use more GLAUMAX than you should
Squeeze the dropper-bottle carefully until only one drop falls into your eye. If you put too many drops into the eye, you may feel some slight transient irritation in the eye. If you become worried, contact your doctor or the doctor treating your child for advice. Contact your doctor or the doctor treating your child as soon as possible if you or your child have accidentally swallowed GLAUMAX.

If you forget to use GLAUMAX

If you have missed one dose of GLAUMAX, treatment should be continued with the next dose at the usual time. Do not use a double dose of eye drops.

If you stop using GLAUMAX
If you wish to stop using GLAUMAX or if you have any further questions on the use of this medicinal product, ask your doctor or the doctor treating your child, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects can occur during the use of GLAUMAX:

Very common side effects (may affect more than 1 in 10 users)
- if you have mixed-colour irises (blue-brown, grey-brown, green-brown or yellow-brown), you are more likely to see a gradual change in eye colour over a long period of time. Any changes in your eye colour may take years to develop although it is normally seen within 8 months of treatment. The iris may become browner and the eye colour may darken. The colour change may be more noticeable if only one eye is treated. In patients with homogeneously grey, blue, green or brown eye colour, this side effect has been reported very rarely. There appears to be no problems associated with the change in eye colour. The eye colour change does not continue after GLAUMAX treatment is stopped;
- redness of the eye(s);
- eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye). If you experience eye irritation severe enough to make your eyes water excessively, or make you consider stopping this medicine, talk to your doctor, the doctor treating your child or nurse promptly. You may need your treatment to be reviewed to ensure you keep receiving appropriate treatment for your condition;
- GLAUMAX may cause increased pigmentation, thickness, length and number of eyelashes (in most cases in patients of Japanese origin).

Common side effects (may affect 1 to 10 users in 100)
- transient scratches to the front part of the eye (punctate epithelial erosions), eyelid inflammation (blepharitis), eye pain, light sensitivity, conjunctivitis.

Uncommon side effects (may affect 1 to 10 users in 1000)
- eyelid(s) swelling, dryness of the eye, inflammation or irritation of the surface of the eye (keratitis), blurred vision, inflammation of the coloured part of the eye, swelling of the retina (macular oedema);
- skin rash;
- chest pain (angina), awareness of heart rhythm (palpitations);
- asthma, shortness of breath;
- chest pain;
- headache, dizziness;

- muscle pain, joint pain.

Rare side effects (may affect 1 to 10 users in 10 000)
- inflammation of the iris, symptomatic swelling and scratches (erosions) to the outer surface of the eye, swelling around the eye, misdirected eyelashes that can sometimes cause eye irritation, appearance of an extra row of eyelashes, scarring of the surface of the eye, fluid filled area within the coloured part of the eye;
- local skin reactions on the eyelids, darkening of the skin of the eyelids;
- worsening of asthma;
- severe itching of the skin;
- developing a viral infection of the eye caused by the *herpes simplex* virus (HSV).

Very rare side effects (may affect less than 1 in 10 000 users)
- worsening of angina in patients who also have heart disease; sunken eye appearance (eye sulcus deepening).

Additional side effects in children
Side effects seen more often in children compared to adults are runny itchy nose and fever.

When used simultaneously with the phosphate containing eye drops, in very rare cases some patients with severe damage to the cornea have developed cloudy patches on the cornea due to calcium build-up during treatment.

Reporting of side effects
If you or your child get any side effects, talk to your doctor or the doctor treating your child, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the www.ravimiamet.ee. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store GLAUMAX

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date "Kõlblik kuni/EXP" which is stated on the bottle label and carton. The expiry date refers to the last day of that month.

Unopened bottle:
Store in a refrigerator (2°C...8°C). Protect from light.

After first opening the bottle:
Store below 25°C and use within 4 weeks after first opening the bottle. Protect from light. Keep the medicinal product tightly closed and upright.

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

6. Contents of the pack and other information

What GLAUMAX contains

- The active substance is latanoprost. Each ml contains 50 micrograms of latanoprost. One drop contains approximately 1.5 micrograms of latanoprost.
- The other ingredients are benzalkonium chloride (0.2 mg/ml), sodium chloride, sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous and water for injections.

What GLAUMAX looks like and contents of the pack

50 micrograms/ml eye drops in dropper-bottle (5ml), dropper, screw cap, tamper-evident. Each dropper-bottle contains 2.5 ml eye drops solution corresponding to approximately 80 drops of solution.

Package size: 1 x 2.5 ml.

Marketing Authorisation Holder and Manufacturer

AS Kevelt
Teaduspargi 3/1
12618 Tallinn
Estonia
Tel: +372 606 6969
E-mail: kevelt@kevelt.ee

This leaflet was last revised in January 2020.