

PACKAGE LEAFLET: Information for the user

PILOKARPINE

Eye drops, solution – 20 mg / ml (2 %)

(Pilocarpine hydrochloride)

Read this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. What Pilocarpine is and what it is used for
2. Before you use Pilocarpine
3. How to use Pilocarpine
4. Possible side effects
5. How to store Pilocarpine
6. Other information

1. WHAT PILOKARPINE IS AND WHAT IT IS USED FOR

Pilocarpine is an alkaloid with a vegetal origin. In the human organism it acts by directly stimulating the cholinergic receptors of M type and by causing similar effects with the activation of the parasympathetic system. These effects are more expressed in the eye and in the sweating and salivary glands.

Pilocarpine, can also antagonize the mydriatic effect of sympathomimetics and of atropine.

It is used for the treatment of simple chronic open angle glaucoma and of acute closed angle glaucoma. Pilocarpine is used alone or combined with other myotics, beta-blockers, carbonic anhydrase inhibitors, sympathomimetics or hyperosmotic substances, to reduce the intraocular

pressure before surgical interventions and to cause myosis (constriction of the pupilla) in order to antagonize the effects of the mydriatic and cycloplegic eye drops substances (both cause dilatation of the pupilla).

2. BEFORE YOU USE PILOKARPINE

Do not use Pilokarpine if you:

- are hypersensitive (allergic) to pilocarpine hydrochloride or to any of the excipients of Pilokarpine;
- have ever had retina detachment;
- have secondary glaucoma where use is not indicated;
- have acute iritis;
- have anterior uveitis;
- use soft contact lenses, because Pilokarpine contains benzalkonium chloride as preservative and contact lenses should be removed before treatment with Pilokarpine eye drops.

Take special care with Pilokarpine

Before the beginning of the treatment, all patients should examine fundus oculi, because there is a risk for retina detachment.

Ask your doctor before using Pilokarpine if:

- you suffer from acute cardiac failure, bronchial asthma, peptic ulcer, hypertension, hypotension, urinary tract obstruction and Parkinson disease;
- you take it in high doses, because caution should be taken with systemic reactions.

During treatment it is advised to control regularly intraocular pressure and visive parameters.

Children or adolescents

The safety and efficacy of pilocarpine eye drops, solution 2 % after thorough controls has not been clinically approved for children and adolescents. Therefore, in case of necessity, the use must be only after recommendation and under strict medical supervision.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by pilocarpine.

Please contact with your doctor or pharmacist if you are taking / using or have recently taken / used other drugs, including those taken without a prescription. Do not forget to inform your doctor for the treatment with Pilocarpine if you have been given any other drug during treatment. It is especially important that in case of pilocarpine use (eye drops), your doctor knows that you are being treated at the same time with:

- adrenaline (it may cause further decrease of the intraocular pressure);
- beta-blockers (increased risk of arrhythmias from pilocarpine);
- timolol (decreased intraocular pressure);
- carbonic anhydrase inhibitors (further decreased intraocular pressure may occur);
- atropine or drugs with cholinolytic effects, phenothiazines, antihistamines (they antagonize the effects of pilocarpine);
- drugs like: clozapine, disopyramide, amitriptyline, amoxapine, bupropione, etc. (they antagonize the effect of pilocarpine).

Pregnancy

Inform your doctor or pharmacist before using this medication.

Because no data is available, it is better to avoid Pilocarpine during pregnancy. In necessary cases when benefit outweighs the risk, it can be used under medical control.

Breastfeeding

Pilocarpine passes into breast milk. In this case, ask your doctor before using it.

Driving and using machines

Pilocarpine may reduce your ability to drive or use machinery.

Do not drive or use machinery immediately after the application of Pilocarpine and especially without knowing how it affects your vision.

Important information about some of the excipients of Pilokarpine

Pilokarpine contains 0.1 mg benzalkonium chloride in 1 ml eye drops.

Remove contact lenses prior to application and wait at least 15 minutes before reinsertion.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

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.

3. HOW TO USE PILOKARPINE

Always use Pilokarpine as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. If you feel that the effects of pilocarpine are too strong or too weak, talk to your doctor or pharmacist.

Dosage:

- for the treatment of chronic glaucoma and myosis induction are used 1 – 2 drops of the 2 % solution, 4 times daily;
- for the treatment of acute closed angle glaucoma, is initiated with 1 drop of the 2 % solution every 10 minutes, during 1 hour, and then it is continued with 1 – 2 drops every 1 – 3 hours, until intraocular pressure decreases.

The way of administration of Pilokarpine 2% eye drops is:

- Wash your hands.
- Do not touch the point of exit of the drops.
- Look upward.
- Low the lower lid of the eye to form a groove.
- Put the dropper as close as possible to the groove, but without touching it.
- Put the right amount of the drops in the groove.
- Close the eye for about 2 minutes. To avoid for the medication to be absorbed by the organism press the corner of the eye near the nose for about 1 – 2 minutes.

- The excess of solution may be removed with a sterile gauze.

If you use more Pilokarpine than you should

If you use more Pilokarpine than you should or if the children have taken this drug incorrectly, please contact your doctor, hospital, or call the emergency to take an opinion for the risk and advice for the actions to be taken.

Cases of overdose are observed if Pilokarpine is taken incorrectly by mouth.

In this case the symptoms are: sweating, blurred vision, increased salivation, faint, nausea, vomiting, diarrhea, etc.

If you forget to use Pilokarpine

If you forget a dose (or more doses), use the following dose when it is time to use it usually.

Do not use a double dose (or higher) to make up for the forgotten dose (doses).

If you have any other question on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Pilokarpine may cause side effects, although not everyone manifests them.

The main side effects are: burning, pain, itching, conjunctival vascular congestion, ciliary spasms, reduced visual acuity in conditions of a poor illumination, headache, retinal detachment and vitreous haemorrhage.

Systemic side effects are rare: hypertension, tachycardia, bronchial spasms, nausea, vomiting, etc.

Other side effects that may occur are diarrhea, hypersalivation, tear flow, hyperhidrosis, pulmonary oedema, bradycardia, hypotension, sensitization, pupillary block, eye disorders, lens changes in long-term use.

If you notice adverse effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE PILOKARPINE

Keep out of the reach and sight of children!

Do not use Pilocarpine after the expiry date which is stated on the package.

Store between 10°C - 25°C!

Store in the original packaging to protect it from light.

6. OTHER INFORMATION

What Pilocarpine eye drops, solution contains:

The active substance is pilocarpine hydrochloride.

1 ml solution contains 20 mg pilocarpine hydrochloride (2%).

The excipients are: sodium chloride, borax, boric acid, disodium EDTA, benzalkonium chloride, water for injection.

Package content:

Carton box with one sterile plastic dropper vial of 10 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in January 2024.