



**Package leaflet:
Information for the patient**

Pilocarpine Hydrochloride 20mg/ml eye drops, solution

Pilocarpine hydrochloride (referred to as Pilocarpine in this leaflet)

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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pilocarpine is and what it is used for
2. What you need to know before you use Pilocarpine
3. How to use Pilocarpine
4. Possible side effects
5. How to store Pilocarpine
6. Contents of the pack and other information

1 What Pilocarpine is and what it is used for

Pilocarpine hydrochloride belongs to a group of medicines called miotics, these medicines affect muscles in the eye causing the pupil of the eye to get smaller.

Pilocarpine is used to treat certain forms of glaucoma (an increase in the pressure within the eye) and to reverse the effect of drugs that cause the pupil of the eye to get bigger.

2 What you need to know before you use Pilocarpine

Do not use Pilocarpine if:

- you are allergic (hypersensitive) to Pilocarpine or any of the other ingredients in this medicine, which are listed in section 6 of this leaflet,
- you are suffering from inflammation of the coloured part of the eye (acute iritis or anterior uveitis),
- you are suffering from eye disorders such as narrow angle glaucoma or secondary glaucoma,
- you are wearing soft contact lenses.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Pilocarpine if:

- you are suffering from any heart problems,
- you have asthma,
- you have Parkinson's disease,
- you have problems in passing urine,
- you have high blood pressure,
- you have a stomach ulcer,
- you are pregnant or are breast-feeding.

If you are unsure about how to use Pilocarpine talk to your doctor, pharmacist or nurse.

Children

Pilocarpine should be given at the lowest available dose at the start of the treatment for children under 18 years of age.

Eye tests

Your doctor may want to check your eyes before and during your therapy particularly if you have had any eye disorders. If you have not had your eyes checked recently, tell your doctor.

Other medicines and Pilocarpine

Tell your doctor, pharmacist or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Some medicines can interfere with your treatment. Tell your doctor if you are taking any of the following:

- antihistamines (medicines used to treat allergies),
- anticholinesterases, (such as neostigmine) which are medicines that affect the muscles and are used to treat diseases like myasthenia gravis,
- medicines used to make the pupil larger and dry up the saliva in your mouth, such as atropine and phenylephrine,
- medicines used to treat Parkinson's disease, anticholinergic drugs such as orphenadrine, procyclidine and trihexyphenidyl,
- antidepressants including tricyclic antidepressants (such as amitriptyline) and monoamine oxidase inhibitors (MAOI's), a type of medicine used to treat severe depression,
- phenothiazines (medicines used to treat serious mental disorders) e.g. chlorpromazine,
- medicines used to treat high blood pressure (adrenergic blockers) such as guanethidine.

If you have any doubts about whether you should use this medicine talk to your doctor, pharmacist or nurse.

Pilocarpine with food, drink and alcohol

You are advised not to drink alcohol during your treatment with Pilocarpine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

If you are pregnant, talk to your doctor before using this medicine as it contains boron which may be harmful to your baby.

Driving and using machines

Pilocarpine can cause difficulty in adapting to the dark. You should not drive or use machinery in poor light. The eye drops may also cause blurred vision. If this happens, you should not drive or operate machinery until you can see clearly.

Pilocarpine contains benzalkonium chloride

This medicine contains 0.1mg benzalkonium chloride in each ml unit of solution.

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.

Pilocarpine contains boric acid

This medicine contains 1.75mg of boron in each ml of solution.

This medicine should not be given to a child younger than 2 years without medical advice, as it contains boron and may impair fertility in the future.

3 How to use Pilocarpine

Always use Pilocarpine exactly as your doctor has told you. Always complete a course of treatment. Do not stop because you feel better.

This medicine is for external use only.

Instructions for use

1. Before opening a new bottle of Pilocarpine, please check that the safety strip on the front of the bottle is unbroken.
2. Tear off the safety strip to break the seal.
3. Wash your hands well before use.
4. Remove the outer cap. If you are putting in the eye drops yourself, you should use a mirror.
5. Tilt your head back and look up at the ceiling.
6. Pull the lower lid of the eye out to form a small pocket between your eyelid and your eye.
7. Hold the container between the thumb and middle finger of the other hand, turn the bottle upside down near to the eye, try not to touch the eye with the nozzle.
8. Apply enough pressure to the bottle to release one to two drops, as directed by your doctor.
9. Blink your eye a few times.
10. If you think that you have missed your eye, then insert another drop.
11. Repeat steps 5-10 above for your other eye if you have been told to use Pilocarpine in both eyes.
12. Replace the outer cap on the bottle, trying not to touch the applicator tip with anything, including the eye or your fingers.
13. Wash your hands.

Always use this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Your doctor will decide how much you need based on the severity of your condition and your response to treatment.

Adults (including the elderly)

The usual dose is two drops three times daily.

Use in children

Lowest available dose and concentration should be used at the start of the treatment for children under 18 years of age.

Your doctor might increase the dose up to the maximum recommended adult dosage of pilocarpine depending on the response and tolerability.

If you use more Pilocarpine than you should

If you are at all concerned that you have used or been given too much of this medicine please tell your doctor.

If you swallow any Pilocarpine

Pilocarpine is for external use only. If you have swallowed or you suspect someone else has swallowed this medicine, contact your doctor or go to the accident and emergency department of your local hospital at once. Always take the container and this leaflet with you if possible, even if empty.

If you forget to take Pilocarpine

If you miss a dose of Pilocarpine, use this medicine as soon as you remember unless it is nearly time for the next dose, then carry on using it as before. Do not take a double dose to make up for one you have missed.

If you stop using Pilocarpine

You should keep using Pilocarpine for as long as your doctor has asked. Your treatment is helping your condition, even if you have not noticed a difference in how you feel. Should you need to stop your treatment, your doctor will advise you how to do this.

If you have any further questions on the use of the medicine, ask your doctor, pharmacist or nurse.

4 Possible side effects

6 Contents of the pack and other information

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

Common (may affect up to 1 in 10 people):

- itching, smarting and a burning sensation around the eye
- a red skin rash with itching (urticaria)
- swelling, redness or soreness of the eyelid
- swelling of the front of the eye (conjunctiva)
- temporarily blurred vision
- temporary short sightedness
- difficulty in seeing in poor light
- enlargement of the veins in the eye
- headache and brow ache (especially in young patients at the beginning of treatment)
- bleeding within the front of the eye
- detachment of the retina (the inner surface of the eye)

Rare (may affect up to 1 in 1,000 people):

- feeling sick (nausea)
- being sick (vomiting)
- diarrhoea
- increase in saliva
- increased flow of tears
- trembling or shaking
- wheezing and breathing difficulties
- change in blood pressure or changes in the way your heart beats

With long term use it is possible that the lens of your eye may change shape resulting in changes to your vision.

You may not know if you have some of the side effects. Your doctor will detect them during examinations.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Pilocarpine

Keep this medicine out of the sight and reach of children.

After first opening, store below 25°C in the original package. Make sure the container is properly closed after each use. Dispose of this medicine 28 days after opening.

Do not use Pilocarpine after the expiry date which is printed on the label. The expiry date refers to the last day of that month.

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

What Pilocarpine contains

The active substance is pilocarpine hydrochloride 20mg/ml.

The other ingredients are benzalkonium chloride, hypromellose, boric acid, sodium citrate, sodium hydroxide and/or hydrochloric acid (for pH adjustment), water for injections.

What Pilocarpine looks like and contents of the pack

Clear solution, free from visible particles.

White 10ml plastic bottle with applicator-dropper closed with a screw cap with a protective strip.

One bottle, together with a patient leaflet, is packaged in a carton box.

Marketing Authorisation Holder

Aspire Pharma Ltd
Unit 4, Rotherbrook Court
Bedford Road
Petersfield
Hampshire
GU32 3QG
United Kingdom

Manufacturer

Antibiotic-Razgrad AD
68 Aprilsko Vastanie Blvd.
7200 Razgrad,
Bulgaria

This leaflet was last revised in 02/2025

1010678- P2.2



Artwork for:	Aspire Pharma Limited
Product name:	Pilocarpine Hydrochloride
	20mg/ml eye drops
Size:	1 x 10ml
PL/PA no:	PL35533/0199
Type:	Leaflet
Artwork dimensions:	160mm x 400mm
Reason for request:	Initial - change cutter Guide
Version no:	2.2
Date of revision:	3.4.25
Colours:	As swatches
Font(s):	Strada Pro Condensed
A/W software:	Indesign CC



PMS Black