

Pilocarpine Eye Drops 1.0%, 2.0% and 4.0% w/v

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

What is in this leaflet:

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

1. What Pilocarpine Eye Drops are and what are they 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 Eye Drops are 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 Eye Drops

Do not use Pilocarpine Eye Drops 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 or pharmacists before taking Pilocarpine eye drops 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 Eye Drops talk to your doctor or pharmacist.

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

Please tell your doctor or pharmacist 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 or pharmacist.

Pilocarpine Eye Drops with food, drink and alcohol

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

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 taking this medicine.

Driving and using machines

Pilocarpine Eye Drops 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 eye drops contains benzalkonium

This medicine contains benzalkonium chloride which may cause eye irritation and is known to discolour soft contact lenses.

Soft contact lenses must not be worn during treatment with Pilocarpine Eye Drops.

3. How to use Pilocarpine Eye Drops

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

Pilocarpine Eye Drops are for external use only.

Instructions for use

1. Before opening a new bottle of Pilocarpine Eye Drops, 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 Eye Drops 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 or pharmacist 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.

Continued overleaf

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 the 2 % Pilocarpine eye drops depending on the response and tolerability.

If you use more Pilocarpine Eye Drops 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 Eye Drops

Pilocarpine Eye Drops are for external use only. If you have swallowed or you suspect someone else has swallowed any Pilocarpine Eye Drops, 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 Eye Drops

If you miss a dose of Pilocarpine Eye Drops, use them 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 Eye Drops

You should keep using Pilocarpine Eye Drops 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 or pharmacist.

4. Possible side effects

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

Common side effects (may affect 1 and 10 in every 100 patients):

- 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

Reporting suspected adverse reactions after authorisation 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 via the Yellow Card Scheme Website: <http://www.mhra.gov.uk/yellowcard>.

5. How to store Pilocarpine Eye Drops

Keep this medicine out of the sight and reach of children

Make sure the container is properly closed after each use.

Store Pilocarpine Eye Drops in their original container to protect from moisture and away from direct light. Store below 25°C.

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

Dispose of this medicine 28 days after opening.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Pilocarpine Eye Drops contain

The active substance is Pilocarpine hydrochloride 1.0%, 2.0% or 4.0% w/v

The other ingredients are benzalkonium chloride and purified water.

What Pilocarpine Eye Drops look like and contents of the pack

Pilocarpine Eye Drops are a clear, colourless and sterile solution supplied in a plastic dropper bottle. Each bottle contains 10ml of the solution.

Marketing Authorisation Holder:

Martindale Pharmaceuticals Ltd
T/a Martindale Pharma
Bampton Road
Harold Hill
Romford Essex RM3 8UG UK

Manufacturers:

Tubilux Pharma S.p.A.
Via Costarica 20/22
00071 Pomezia (RM)
ITALY

Marketing Authorisation numbers:

Pilocarpine Eye Drops 1.0% w/v PL
00156/0079
Pilocarpine Eye Drops 2.0% w/v PL
00156/0080
Pilocarpine Eye Drops 4.0% w/v PL
00156/0078

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