

Package leaflet: Information for the patient

Atropin Vision 10 mg/ml eye drops, solution

Atropine sulfate

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 pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Atropin Vision is and what it is used for
2. What you need to know before you use Atropin Vision
3. How to use Atropin Vision
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1. What Atropin Vision is and what it is used for

Your medicine contains the active substance atropine sulfate, which widens the pupil when instilled into the eye. This is necessary in order to enable the eye specialist to examine your eyes more closely. This medicine is also used in the treatment of some eye diseases in combination with other medicines.

Atropin Vision is indicated in adults, children and the elderly.

2. What you need to know before you use Atropin Vision

Do not use Atropin Vision

- if you are allergic to atropine sulfate or any of the other ingredients of this medicine (listed in section 6).
- If you have an increased pressure in the eye (suffer from closed angle glaucoma).
- If an eye specialist has told you that you have a narrow drainage angle.

Warnings and precautions

Talk to your doctor or pharmacist before using Atropin Vision.

You need to talk to your doctor:

- if you have an increased pressure in the eye or suffer from glaucoma;
- if you have a disease of the cornea (keratoconus);
- if you have or have recently had eye inflammation;
- if you currently have a fever;
- if you have heart disease or increased heart rate;
- if you wear soft contact lenses. Your doctor will ask you to remove your contact lenses prior to the administration of the drops. Do not wear your contact lenses until the effects of the medicine have completely worn off.

You should be aware that this medicine is intended only for use in the eye. After using the drops you should wash your hands thoroughly to avoid contact of the medicine with your mouth.

Other medicines and Atropin Vision

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

It is important for you to know that this medicine may change the effects of other medicines when used concomitantly. That is why it is very important to tell your doctor if you take:

- medicines which belong to the antimuscarinic and anticholinergic group (scopolamine, tropicamide, cyclopentolate). Your medicine may increase their effect.
- medicines used to treat glaucoma. Atropine may reduce their effect.
- carbachol, physostigmine or pilocarpine. These medicines may reduce the effect of atropine.

Tell your doctor if you are taking anti-sickness medicines or some medicines which belong to the group of phenothiazines or barbiturates, because interactions with atropine cannot be completely ruled out.

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 or pharmacist for advice before taking this medicine.

Your doctor will decide if it is possible for you to use this medicine if you are pregnant. He will evaluate the ratio between the benefit to you and the risks to your baby.

Your doctor will decide if you should stop breastfeeding during the treatment with this medicine.

Driving and using machines

As with other eye drops, the use of this medicine may cause temporary blurred vision or other disturbances that may affect the ability to drive or operate machinery.

After using Atropin Vision in your eye, you should wait until your vision clears before you start operating machines or driving.

Atropin Vision contains benzalkonium chloride

This medicine contains benzalkonium chloride which may cause eye irritation.

Avoid contact with soft contact lenses. Remove the contact lenses before using the drops.

Benzalkonium chloride is known to discolour soft contact lenses.

3. How to use Atropin Vision

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

Your doctor will decide whether you should use Atropin Vision in one or both eyes.

Usually this medicine is placed as 1 drop, 2 to 3 times daily. Your doctor will determine the appropriate dose and duration of administration.

If another medicine for use in the eye is administered concomitantly, the two applications should be at least 5 minutes apart.

It is important to maintain hygiene while using the drops. Do not let the tip of the bottle touch the eye, eyelid and adjacent surfaces because it may get contaminated and in turn cause eye infection with serious consequences for the eye, and even loss of vision. Always wash your hands before using the bottle!

If you think that your bottle is contaminated, contact your doctor before you continue to use the eye drops.

While using Atropin Vision, especially in children and most adults, it is important to press the inner corner of your eye for three minutes after instillation; that will reduce the possibility of the medicine to drain into the nose (read carefully the information in the Instructions for Use)

Instructions for use

1. Before you start using the bottle, make sure that the protective strip between the cap and the bottle is not broken. Wash your hands and unscrew the cap.



2. Tilt your head backwards and pull the lower eyelid downwards to form a pouch between the eyelid and the eye. The eye drop will fall just into this place.

3. Point the bottle downwards. Place the tip close to the eye. Use a mirror if it helps.

4. Pay attention not to touch the tip of the bottle to the eye, eyelid or adjacent surfaces. Gently press the bottom of the bottle to release one drop of solution. Only a slight pressure on the bottom is needed.

5. Once the medicine is dropped, close your eyelid and press the inner corner of your eye with your finger for three minutes. This will help stop Atropin Vision draining into the nose or out of your eye.

6. If you should use the drops in both eyes, repeat all previous steps for your other eye.

7. Close the bottle tightly immediately after use.

If the eye drop misses your eye, try again.

Use this bottle of Atropin Vision for your eyes only!

If you use more Atropin Vision than you should

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

If you have used more than the recommended dose, rinse thoroughly your eye/eyes with lukewarm water. If you accidentally swallow the contents of the bottle, talk to your doctor.

The doctor will decide whether treatment is necessary if you have used a higher dose.

If you forget to use Atropin Vision

Do not use a double dose to make up for the missed dose. Place the dose as soon as you remember. If it is time for your next dose, continue as per your regular dosing schedule.

If you stop using Atropin Vision

Your doctor will decide when you should stop using this product. Do not stop using this medicine unless your doctor has told you to do so.

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

4. Possible side effects

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

During treatment with atropine sulfate, the following adverse reactions might occur:

Common (may affect up to 1 in 100 and less than 1 in 10 people using the medicine):

- blurred vision, increased sensitivity to light;

Uncommon (may affect up to 1 in 1000 and less than 1 in 100 people using the medicine) or rare (may affect up to 1 in 10 000 or less than 1 in 1000 people using the medicine):

- pain, eye irritation, swelling of the eyelid, redness, itching, especially with repeated doses, increased pressure in the eye, particularly in patients with glaucoma;
- skin rashes;
- dry mouth and difficulty speaking and swallowing, flushing of the face, dry skin, fever, difficulty passing urine, constipation;
- nausea, vomiting
- palpitations
- confusion (most common in the elderly), vertigo, fatigue, hallucinations, excitement.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Bulgarian Drug Agency
8 Damyan Gruev Street
1303 Sofia
Tel.: +35 928903417
Website: www.bda.bg.

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

5. How to store Atropin Vision

Keep this medicine out of the sight and reach of children.
Store in the original package.
Store below 25 °C.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Use this medicine within 28 days after first opening of the bottle.

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 Atropin Vision contains

- The active substance in 1 ml solution is atropine sulfate 10 mg.
- The other ingredients are: benzalkonium chloride, boronic acid, hypromellose, hydrochloric acid, sodium hydroxide and water for injection

What Atropin Vision looks like and contents of the pack

Atropine Vision is a clear liquid.

Sterile white plastic bottles of 10 ml, closed with sterile plastic applicator-droppers and sealed with sterile screw caps with a protective ring.

1 (one) bottle with the package leaflet is packed in a carton box.

Marketing Authorisation Holder and Manufacturer

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