

Package leaflet: Information for the patient

Tropicamid Vision 5 mg/ml eye drops, solution Tropicamid Vision 10 mg/ml eye drops, solution Tropicamide

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 Tropicamid Vision is and what it is used for
2. What you need to know before you use Tropicamid Vision
3. How to use Tropicamid Vision
4. Possible side effects
5. How to store Tropicamid Vision
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1. What Tropicamid Vision is and what it is used for

The name of your medicine is Tropicamid Vision, which is intended for use in the eye. It contains tropicamide as an active substance which belongs to a group of medicines known as anticholinergic agents.

This medicine is used:

- To dilate the pupil and relax the eye muscles. This facilitates the examination of your vision.
- Before and after eye surgery.

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

Do not use Tropicamid Vision

- if you are allergic to tropicamide or any of the other ingredients of this medicine (listed in section 6).
- if you have or if you think you may have glaucoma (increased intraocular pressure).

Warnings and precautions

Talk to your doctor or pharmacist before using Tropicamid Vision.

What you need to know before using this product:

- It may increase the intraocular pressure. Before administration, intraocular pressure should be checked, especially in the elderly;
- Dose adjustment may be necessary due to insufficient effect in subjects with a strongly coloured iris and in people of colour;
- May cause behavioural changes (especially in infants and children);
- If you cannot use medicines containing Belladonna alkaloids, you may be more likely to experience side effects.
- This medicine is not suitable for patients with a tendency to psychotic reactions and abnormal behaviour and those with an increased sensitivity to anticholinergic drugs.

This medicine should be used with caution if:

- Your eyes are red;
- You have an enlarged prostate;
- You have high blood pressure;
- You have increased thyroid function;
- You wear contact lenses (see section "Tropicamid Vision contains benzalkonium chloride").

Use in children

- Do not use Tropicamid Vision at a concentration higher than 5 mg/ml in newborns, infants and young children due to the risk of serious side effects.
- This medicine should be used with extreme caution in premature babies, infants, young children, children with Down syndrome, spastic paralysis, brain damage. Talk to your doctor as serious side effects may occur when using this medicine.

Other medicines and Tropicamid Vision

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

If you use other ophthalmic medicines together with Tropicamid Vision, the interval between each application should be at least 5 minutes.

It is especially important to tell your doctor if you are taking medicines to treat:

- allergies;
- depression, anxiety;
- heart disease;
- asthma or other lung problems;
- travel sickness
- Parkinson's disease;
- urinary or gastrointestinal problems.

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 using this medicine.

Pregnancy

The medicine can harm your unborn baby. Tropicamid Vision should only be used during pregnancy if it is absolutely necessary.

Breastfeeding

The medicine can harm your child. In lactating women, Tropicamid Vision should only be used if it is absolutely necessary.

Driving and using machines

Shortly after administration this medicine may cause drowsiness, blurred vision and due to pupil dilation - increased sensitivity to light. You may experience malaise and decrease in blood pressure. Do not drive or use machines until your vision clears fully. Complete recovery can take up to 6 hours after use.

Tropicamid Vision contains benzalkonium chloride

Benzalkonium chloride may cause eye irritation. Avoid contact with soft contact lenses. Remove the contact lenses before administration and wait for at least 15 minutes before re-inserting them. Benzalkonium chloride is known to discolour soft contact lenses.

3. How to use Tropicamid Vision

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

The recommended dose is:

For pupil dilation

One to two drops of solution are placed in the eye 15-20 minutes before the examination.

To relax the eye muscles during examination

One to two drops are placed in the eye, followed by one more drop after 5 minutes.

It is important to maintain hygiene during instillation. Avoid contact between the tip of the bottle and the eye, eyelids, and adjacent surfaces, as it may become contaminated and lead to the development of an eye infection with serious consequences for the eye, even loss of vision. Always wash your hands before using the bottle!

Instructions for use:

1. Before using the bottle for the first time, make sure that the protective strip between the cap and the bottle is not torn. Wash your hands and unscrew the cap.



2. Tilt your head backwards and pull the lower lid down. This forms a "pocket" between the eyelid and the eye. The drop will fall right in this place.

3. Point the bottle downwards. Place the tip of the bottle close to the eye. Use a mirror if it will make it easier for you.

4. Be careful not to touch the eye, eyelids or other surfaces with the tip of the bottle. Gently push the bottom of the bottle to instil a drop of the solution. Only slight pressure on the bottom is required.

5. After instilling the medicine, close the eyelid and press the eye in the corner of the nose for 3 minutes. This will prevent Tropicamid Vision from passing into the nose or leaking out.

6. Close the bottle well immediately after use.

If the drop does not fall into the eye, try again.

Use this bottle only for your eyes!

If you use more Tropicamid Vision than you should

An overdose may occur if you take a higher dose. Symptoms of overdose may include: redness and dryness of the skin (rash may occur in children), blurred vision, rapid and irregular heart beat, fever, abdominal swelling in babies, seizures, hallucinations or loss of coordination.

Rinse the eye(s) with lukewarm water and consult your doctor as soon as possible.

In case of severe overdose or accidental ingestion of the vial contents, seek immediate advice from your doctor or pharmacist, as serious side effects (especially in children) may occur.

4. Possible side effects

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

The following side effects of unknown frequency (cannot be estimated from the available data) may occur: dizziness, headache, blurred vision, light sensitivity, pain and irritation in the eyes, redness, low blood pressure, sometimes with fainting and temporary loss of consciousness (syncope), nausea, rash, pupil dilation.

Nervous system disorders

- psychotic reactions and behavioural disorders.

Other possible side effects that may occur with medicines from this group are:

- increased intraocular pressure that may cause glaucoma in predisposed patients;
- cardiovascular collapse, especially in children;
- redness of the skin, dryness of mucous membranes and skin, irregular heartbeat, decreased secretion of the sweat glands and dry mouth, decreased gastrointestinal motility and constipation, urinary disorders (frequent urination, difficulty urinating, inability to contain urine), decreased nasal, bronchial and lacrimal secretion.

Other effects in children

Tropicamide may cause central nervous system disturbances that may be dangerous in infants and children. Use of medicines from this group can be associated with an increased risk of general toxicity manifested by spastic palsy or brain damage in infants, young or preterm infants or children with Down syndrome.

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 Tropicamid Vision

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

Store in the original package.

Store the bottle tightly closed.

Do not store above 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.

Do not use this medicine if you notice changes in the colour of the solution or the appearance of a sediment (visible solid particles);

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 Tropicamid Vision contains

- The active substance in 1 ml solution Tropicamid Vision 5 mg/ml is 5 mg tropicamide.
- The other ingredients are: benzalkonium chloride, disodium edetate, hydrochloric acid, sodium chloride, sodium hydroxide, water for injections

What Tropicamid Vision looks like and contents of the pack

Clear solution, free of visible particles.

The medicinal product is packaged in a white polyethylene bottle with applicator-dropper, closed with screw cap with protective ring.

One bottle is packed in a carton box.

Marketing Authorisation Holder

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Manufacturer

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