

Package leaflet: Information for the patient

Ketorolac Vision 5 mg/ml eye drops, solution

Ketorolac trometamol

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

1. What Ketorolac Vision is and what it is used for

The name of your medicine is Ketorolac Vision, which is intended for use in the eye. As an active substance, it contains ketorolac trometamol, which belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). It is used in adults to prevent and reduce inflammation and associated symptoms after eye surgery.

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

Do not use Ketorolac Vision

- if you are allergic to ketorolac trometamol or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to aspirin or other similar medicines.

Warnings and precautions

Talk to your doctor or pharmacist before using Ketorolac Vision.

Ketorolac Vision should be used with caution and after consultation with a doctor if you have or have had a history of:

- Viral or bacterial infections of the eye;
- Tendency to bleed (for example, anemia) or stomach ulcers;
- Diabetes;
- Rheumatoid arthritis;
- Dry eye syndrome;
- Asthma after using NSAIDs;
- Recent eye surgery.

This medicine should be used with caution:

- if you are wearing contact lenses (see section "Ketorolac Vision contains benzalkonium chloride").

Use in children

Ketorolac Vision should not be used in children.

Other medicines and Ketorolac Vision

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including medicines obtained without prescription.

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

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.

Ketorolac Vision should not be used during pregnancy and breast-feeding unless your doctor tells you to.

Driving and using machines

Shortly after administration Ketorolac Vision may cause temporary blurred vision. Do not drive or use machines until the symptoms have passed.

Ketorolac 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 Ketorolac 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 1 drop in the affected eye (eyes) 3 times a day, starting 24 hours before the surgery and lasting up to 3 weeks after eye surgery.

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 Ketorolac 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 Ketorolac Vision than you should

It is unlikely that administration of higher doses will lead to side effects. Rinse the eye/eyes with lukewarm water and consult your doctor.

In case of accidental ingestion of the contents of the bottle, take more fluids and seek advice from your doctor or pharmacist.

If you forget to use Ketorolac Vision

If you miss a dose, instil the drops as soon as you remember, unless it is time for the next dose, then continue using the drops as usual. Do not use a double dose to make up for a missed dose.

If you stop using Ketorolac Vision

You should use Ketorolac Vision for as long as it is prescribed by your doctor.

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.

The likelihood of cornea-related side effects (eye surface) increases if Ketorolac Vision is used for more than two weeks or if other topical steroid drops are used at the same time. You should immediately consult your doctor if you experience eye pain, increased irritation, or changes in vision.

Very common side effects (may affect more than 1 in 10 people):

Irritation, stinging, burning sensation and eye pain.

Common side effects (may affect 1 to 10 in 100 people):

Allergic reaction, swelling/puffiness of the eyes and/or eyelids, itching, redness, infection or eye irritation, retinal haemorrhage, central retinal swelling (photosensitive area of the eye), headache, accidental injury caused by the tip of the dropper during eye contact, increased intraocular pressure, blurred vision and/or reduced vision.

Uncommon side effects (may affect 1 to 10 in 1000 patients):

Inflammation or damage to the anterior transparent layer of the eye, dry eyes and/or watery eyes.

Side effects of unknown frequency (cannot be estimated from the available data):

Damage to the surface of the eye such as thinning, erosion, damage to the surface of the cornea, difficulty in breathing or wheezing, worsening of asthma.

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 Ketorolac 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 Ketorolac Vision contains

- The active substance in 1 ml solution is 5 mg ketorolac trometamol.
- The other ingredients are: benzalkonium chloride, disodium edetate, sodium chloride, octoxynol 40, sodium hydroxide and/or hydrochloric acid (for pH adjustment), water for injections

What Ketorolac Vision looks like and contents of the pack

Clear solution, free of visible particles.

White polyethylene bottle with applicator-dropper, closed with screw cap with protective ring.

1 (one) bottle of 3 ml, 5 ml or 10 ml, together with a package leaflet, is packed in a carton box.

Marketing Authorisation Holder

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Manufacturer

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This leaflet was last revised in : November 2018