

BROWN & BURK UK LTD
MODULE 1 ADMINISTRATIVE AND PRESCRIBING INFORMATION
MODULE 1.3 PRODUCT INFORMATION
KETOROLAC TROMETAMOL 0.5%w/v EYE DROPS, SOLUTION

PACKAGE LEAFLET

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Package leaflet: Information for the user

Ketorolac Trometamol 0.5% w/v Eye Drops, solution
ketorolac trometamol (*Referred to as Ketorolac 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, ask your doctor, or 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, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Ketorolac eye drops is and what it is used for

Ketorolac eye drops belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs).

The active ingredient is ketorolac trometamol.

Ketorolac eye drops is used to prevent and relieve eye inflammation following surgery on the eye in adults.

2. What you need to know before you use Ketorolac eye drops

Do not use Ketorolac eye drops

- 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 (acetylsalicylic acid) or other non-steroidal anti-inflammatory drugs (NSAIDs).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Ketorolac eye drops

If you suffer from, or have in the past suffered from:

- corneal damage
- vision or sight disturbances
- viral or bacterial infections of the eye

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- bleeding tendencies (for example, anaemia)
- stomach ulcer
- diabetes
- rheumatoid arthritis
- dry eye syndrome
- asthma after using non-steroidal anti-inflammatory drugs (NSAIDs)
- or if you have had recent eye surgery.

You should also consult your healthcare professional first if you are using:

- other non-steroidal anti-inflammatory drugs (NSAIDs)



Ketorolac eye drops contain the preservative benzalkonium chloride which may cause irritation and discolour soft contact lenses. If you are wearing soft contact lenses, these must be removed before inserting the eye drops and they should not be replaced for at least 15 minutes afterwards.

Children

Ketorolac eye drops should not be prescribed for use in children.

Other medicines and Ketorolac eye drops

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

If you use Ketorolac eye drops with another eye medicine, leave at least 5 minutes between putting in Ketorolac eye drops and the other medicine.

Pregnancy, breast-feeding and fertility

Ketorolac is not recommended for use during pregnancy and should not be used during breast-feeding.

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.

Driving and using machines

Ketorolac eye drops may cause temporary blurred vision. Do not drive or use machinery until your vision has cleared.

Ketorolac eye drops contains benzalkonium chloride

This medicine contains 0.1 mg benzalkonium chloride in each milliliter which is equivalent to 0.1 mg/ml.

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.

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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.

3. How to use Ketorolac eye drops

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

The recommended dose is **1 drop** into the affected eye(s), **3 times a day**, starting 24 hours before surgery and continuing for up to 3 weeks after eye surgery.

INSTRUCTIONS FOR USE

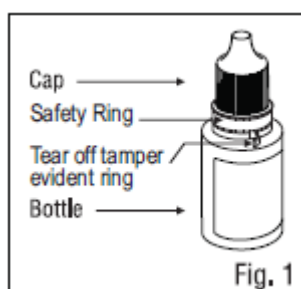
You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it.

Using the drops for the first time: These eye drops come in a bottle with a coned shaped nozzle and screw cap. The inside of the screw cap contains a spike. The screw cap is fitted to the bottle in such a way that there is no contact between the spike and the top of the nozzle of the bottle. In order to open the bottle it is necessary to tighten the screw cap further, so that the edge of the screw cap and the nozzle edge are totally aligned. At this point the screw cap spike will pierce the top of the nozzle of the bottle, which will open the bottle. Once the bottle has been opened in this way, unscrew the screw cap fully to remove it from the bottle and apply the eye drops.

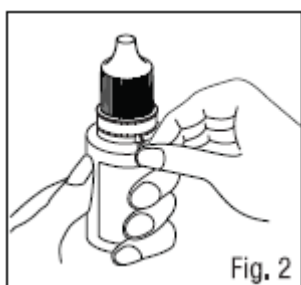
To avoid contamination, Do not touch or allow the dropper tip touch the eye, areas around the eye or any surface. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision.

Opening the bottle before first use

1. Before using the medication for the first time, check that the tear-off tamper evident ring is intact and also that the safety ring connection with the cap has not been broken (Fig.1). You must not use the bottle if the tamper-evident rings on the bottle neck are broken or removed.

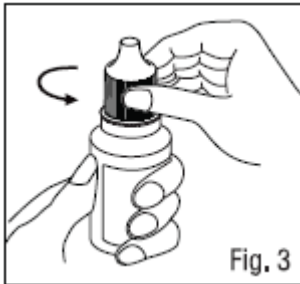


2. Before opening the bottle for the first time, tear off the tamper evident ring to break the seal (Fig.2).

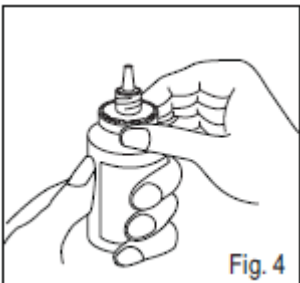


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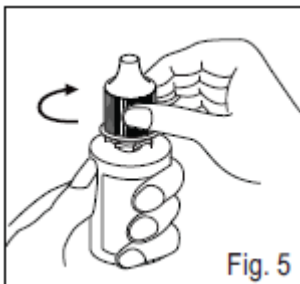
3. To open the bottle, remove the cap by turning it in the counterclockwise direction (Fig.3).



4. After opening the cap remove the safety ring gently (Fig. 4).



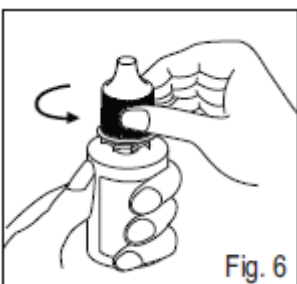
5. Place the cap and tighten the cap on the nozzle completely by turning clockwise. The spike in the cap will pierce the tip of the bottle. (Fig.5).



6. To open the bottle, remove the cap by turning it in the counterclockwise direction (Fig.6).

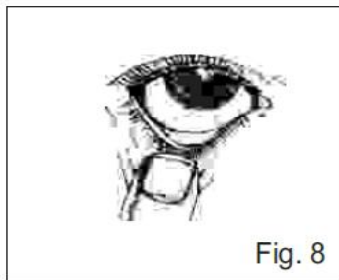
Using your eye drops

7. Wash your hands, tilt your head back and look at the ceiling (Fig.7).

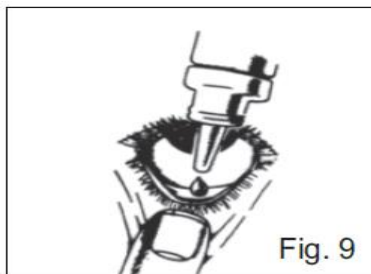


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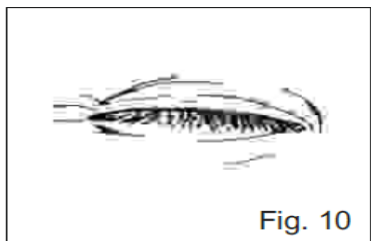
8. Gently pull the lower eyelid down to form a small pocket between the eyelid and the eye. (Fig. 8).



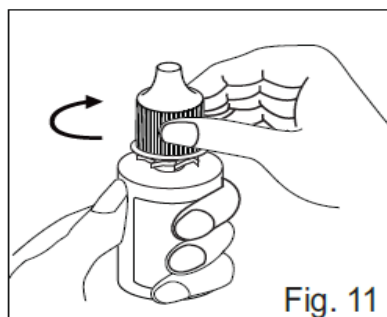
9. Turn the bottle upside down and squeeze it gently to release one drop into each eye that needs treatment. Do not touch your eye or eyelid with the dropper tip (Fig. 9). If a drop misses your eye, try again.



10. Let go of the lower lid, and close your eye for 30 seconds (Fig.10).



11. Reclose the bottle after use (Fig.11).



Wipe off any excess liquid from your cheek with a clean tissue.

The proper application of your eye drops is very important. If you have any questions ask your doctor or pharmacist.

If you use more Ketorolac eye drops than you should

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The application of too many drops is unlikely to lead to unwanted side-effects. Apply your next dose at the normal time. If anyone drinks this medicine they should drink fluids to dilute the medicine in the stomach and contact their doctor for advice.

If you forget to use Ketorolac eye drops

If you forget a dose apply it as soon as you remember, unless it is almost time for your next dose, in which case you should miss out the forgotten dose. Then take your next dose as usual and continue with your normal routine.

Do not use a double dose to make up for a forgotten dose.

If you stop using Ketorolac eye drops

Ketorolac Eye Drops should be used as advised by your doctor.

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

4. Possible Side Effects

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

Side effects related to the cornea (the surface of the eye) may be more likely if Ketorolac Eye Drops is used for longer than two weeks or if you are using topical steroid drops at the same time or if you have a related eye condition. You should see your doctor immediately if you experience pain, increased irritation in the eye or changes in vision.

The **very common side effects** (may affect more than 1 in 10 people):

- Irritation of the eye
- stinging and/or burning in the eye
- eye pain.

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

- allergic reactions,
- eye and/or eyelid swelling/puffiness
- itchy eyes
- red eye
- infection of the eye
- inflammation of the eye (surface or inside)
- bleeding of the retina
- swelling of central retina (light-sensitive layer of the eye)
- headache
- accidental injury caused by the tip of the dropper touching the eye
- increased pressure in the eye
- blurred and/or diminished vision.

Uncommon side effects (may affect up to 1 in 100 people):

- inflammation or damage to the front clear layer of the eye
- eye dryness and/or watery eyes

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Not known side effects (frequency cannot be estimated from the available data):

- damage on the surface of the eye such as thinning
- erosion
- degradation of cell(s)
- difficulty in breathing or wheezing
- aggravation of asthma.
- ulcer-damage to the surface of the eye
- Eye swelling
- redness of eye (Ocular hyperaemia)

Reporting of side effects

If you get any side effects, talk to your doctor or , pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at Website: 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 Ketorolac eye drops

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

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

Throw the bottle away 28 days after opening, even if there is solution remaining.

This product does not require any special storage conditions.

Do not use Ketorolac eye drops if you notice the tamper-proof seal is broken.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ketorolac eye drops contains

- The active substance is Ketorolac Trometamol.
- The other ingredients are benzalkonium chloride, edetate disodium, octoxynol 40, sodium chloride, sodium hydroxide or hydrochloric acid (to adjust pH) and water for injection.

What Ketorolac eye drops looks like and contents of the pack

Ketorolac Eye drops is a clear, colourless to pale yellow solution practically free from particles supplied in either a 3ml, 5 ml or 10 ml in White low density polyethylene (LDPE) container with translucent LDPE block nozzle and white high density polyethylene (HDPE) screw caps.

Pack sizes: 1 x 3ml, 1 x 5ml, 3 x 5ml and 1 x 10ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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