
PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before using ACULAR 0,4% ophthalmic solution.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME AND DOSAGE FORM

ACULAR 0,4% (ophthalmic solution)

Ketorolac tromethamine 4 mg/ml.

WHAT ACULAR 0,4% CONTAINS

- The active ingredient is ketorolac tromethamine 4 mg/ml.
- The other ingredients are benzalkonium chloride, disodium edetate, octoxynol 40, sodium chloride, sodium hydroxide or hydrochloric acid (to adjust pH) and purified water.

WHAT ACULAR 0,4% IS USED FOR

ACULAR 0,4% is administered to relieve eye pain and burning/stinging following corneal refractive surgery.

BEFORE YOU TAKE ACULAR 0,4%

Do not use ACULAR 0,4%

- If you are hypersensitive (allergic) to any of the components in this medication (see “WHAT ACULAR 0,4% CONTAINS”).
- If you wear contact lenses (The preservative, benzalkonium chloride, can permanently damage this type of lens).
- ACULAR 0,4% should not be administered to children under the age of 3 years.

Take special care with ACULAR 0,4%

- If you develop any kind of corneal (see-through layer covering the eye) disease, immediately inform your doctor.
- Do not use this medication more than 24 hours prior to surgery or use beyond 14 days after surgery.

Important information about some of the ingredients of ACULAR 0,4%

Benzalkonium chloride: Special care should be taken if you have an extensive eye surface disease. Do not use this medicine for a prolonged period of time and have regular eye examinations.

Pregnancy and breast feeding

The use of ACULAR 0,4% during pregnancy and breast feeding is not recommended.

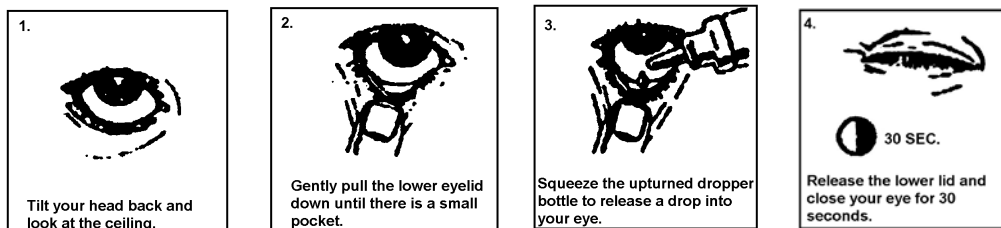
Using other medicines with ACULAR 0,4%

If you are taking other medicines or eye drops on a regular basis, including complementary or traditional medicines, the use of ACULAR 0,4% with these medicines may cause undesirable interactions. This is particularly true if you are taking medicines which may prolong bleeding time, such as Warfarin. Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW TO USE ACULAR 0,4%

The recommended dose for ACULAR 0,4% ophthalmic solution is one drop four times a day in the operated eye as needed for pain and burning/stinging. It can be instilled for up to 4 days following surgery.

Apply your eye drops in the following way:



Avoid touching the dropper tip against your eye or any other surface.

Replace and tighten the cap straight after use.

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

The proper application of your eye drops is very important.

If you have the impression that the effect of ACULAR 0,4% is too strong or too weak, talk to your doctor or pharmacist.

If you use more ACULAR 0,4% than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to use ACULAR 0,4%

- Use the eye drops as soon as you remember, and then go back to using them as you would normally.
- If it is almost time for your next dose, ignore the dose you missed and put the drops in when you are meant to.
- Do not take a double dose to make up for the dose that you missed.
- If you have missed several doses, consult your doctor.
- If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

POSSIBLE SIDE EFFECTS

ACULAR 0,4% can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while using this medicine, please consult your doctor, pharmacist or other health care professional for advice.

You may commonly experience the following effects:

Stinging or burning upon installation, corneal (see-through layer covering the eye) inflammation or pain, headache or hypersensitivity (allergic) reactions.

STORING AND DISPOSING OF ACULAR 0,4%

- Store below 25°C. Keep well closed.
- KEEP OUT OF REACH OF CHILDREN.
- Do not use more than 30 days after opening.
- Discard any unused portion.
- To avoid contamination of the solution, keep container tightly closed and do not touch dropper tip to any surface.
- Contents are sterile if seal is intact.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

PRESENTATION OF ACULAR 0,4%

ACULAR 0,4% is supplied sterile in a white, plastic bottle with a controlled dropper tip and a white cap. The pack size is 5 ml in a 10 ml bottle.

IDENTIFICATION OF ACULAR 0,4%

ACULAR 0,4% is a clear, colourless to pale yellow solution.

REGISTRATION NUMBER / REFERENCE NUMBER

A40/15.4/0282

NAME AND ADDRESS OF REGISTRATION HOLDER

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