
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ACULAR 0,4 %, 4 mg/ml ophthalmic solution Ketorolac tromethamine

Read all of this leaflet carefully before you start using ACULAR 0,4 %

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ACULAR 0,4 % 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.

What is in this leaflet

1. What ACULAR 0,4 % is and what it is used for
2. What you need to know before you use ACULAR 0,4 %
3. How to use ACULAR 0,4 %
4. Possible side effects
5. How to store ACULAR 0,4 %

1. What ACULAR 0,4 % is and what it is used for

ACULAR 0,4 % belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). ACULAR 0,4 % is used to reduce eye pain and burning/stinging following corneal refractive surgery.

2. What you need to know before you use ACULAR 0,4 %

Do not use ACULAR 0,4 %

- If you are hypersensitive (allergic) to ketorolac tromethamine or any of the other ingredients of ACULAR 0,4 % (listed in section 6);
- If you are pregnant or breastfeeding your baby;
- While you are wearing contact lenses, the preservative, benzalkonium chloride, may be absorbed and cause discolouration of soft contact lenses;
- ACULAR 0,4 % should not be used in children.

Warnings and precautions

Take special care with ACULAR 0,4 %:

- If you have previously exhibited sensitivity to aspirin, phenylacetic acid derivatives or non-steroidal anti-inflammatory drugs (NSAIDs) due to the potential for cross-

sensitivity;

- If you have asthma (or used to) because ACULAR 0,4 % can bring on an attack;
- If you develop any kind of corneal (see-through layer covering the eye) problem, stop using ACULAR 0,4 % and any other eye drops in the same class (non-steroidal anti-inflammatory drugs (NSAIDs) and immediately inform your doctor;
- If you have known bleeding tendencies, or if you are taking other medicines which may prolong bleeding time or affect blood platelet function;
- If you have had complicated eye surgeries, or repeated eye surgeries within a short period of time;
- If you have corneal denervation, corneal epithelial defects, diabetes mellitus, eye surface diseases (e.g. dry eye syndrome) or rheumatoid arthritis;
- Do not use ACULAR 0,4 % more than 24 hours prior to surgery or use beyond 14 days after surgery.

Children

ACULAR 0,4 % should not be used in children.

Other medicines and ACULAR 0,4 %

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

This is particularly true if you are using other non-steroidal anti-inflammatory drugs (NSAIDs), cortisone eye medicines, or you are taking medicines that may prolong bleeding time, such as warfarin, medicines that prevent blood clotting, coumarin- or indandione-derivative, heparin or antiplatelet medicines, all of which may increase the risk of bleeding after ocular surgery.

Please consult your doctor, pharmacist or other healthcare professional for advice.

Pregnancy and breastfeeding

The use of ACULAR 0,4 % during pregnancy and breastfeeding is contraindicated (see 'Do not use ACULAR 0,4 %').

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using ACULAR 0,4 %.

Driving and using machines

Your sight may become blurred for a short time just after using ACULAR 0,4 %. Do not drive or use machines until the symptoms have cleared.

ACULAR 0,4 % contains benzalkonium chloride

Do not use ACULAR 0,4 % while you are wearing contact lenses. The preservative, benzalkonium chloride, may be absorbed and cause discolouration of contact lenses. Wait at least 15 minutes after using ACULAR 0,4 % before putting your lenses back into your eyes.

Special care should be taken if you have an extensive eye surface disease. Do not use ACULAR 0,4 % for a prolonged period of time as it may worsen the eye surface disease, and have regular eye examinations.

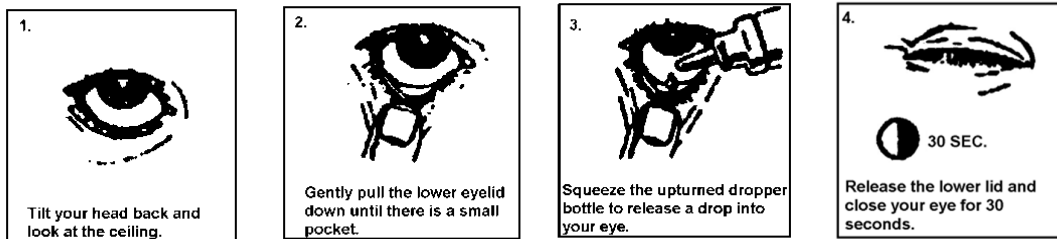
3. How to use ACULAR 0,4 %

Do not share medicines prescribed for you with any other person.

Always use ACULAR 0,4 % exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose 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.

Your doctor will tell you how long the treatment with ACULAR 0,4 % will last. Do not stop treatment early or use the drops for longer than recommended. If you have the impression that the effect of ACULAR 0,4 % is too strong or too weak for you, tell your doctor or pharmacist.

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

Wash your eye with water. If, by accident, anyone drinks ACULAR 0,4 %, drink fluids to dilute and contact your doctor.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison 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 use 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.

4. Possible side effects

ACULAR 0,4 % can have side effects.

Not all side effects reported for ACULAR 0,4 % are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ACULAR 0,4 %, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

Frequent side effects

- Eye stinging or burning upon installation,
- Inflammation of the eye, cornea (see-through layer covering the eye) or iris (the coloured part of the eye),
- Swelling of the cornea,
- Eye irritation or eye pain,
- Superficial eye infections,
- Hypersensitivity (allergic) skin reactions (itching, rash, redness or swelling of the skin).

Less frequent side effects

- Headache

Side effects of which the frequency is unknown

- Corneal (clear surface of the eye) erosion (partial failure of the outermost layer of cells (epithelium) to attach to the underlying membrane),
- Corneal perforation (penetration),
- Corneal thinning,
- Breakdown of the epithelium,
- Ulcer-damage to the surface of the eye,
- Swelling of the eye or eyelid,

- Eye redness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ACULAR 0,4 %.

In case of a side effect, please contact +27 11 545 6600 or send an email to SA_Complaints@Allergan.com

5. How to store ACULAR 0,4 %

- Store at or below 25 °C.
- Do not store in the fridge or freezer.
- Store all medicines out of reach of children.
- Do not use later than 30 days after first 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 medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ACULAR 0,4 % contains

- The active substance is ketorolac tromethamine 4 mg/ml.
- The other ingredients are benzalkonium chloride 0,006 % m/v as preservative, disodium edetate, octoxynol 40, sodium chloride, sodium hydroxide or hydrochloric acid (to adjust pH) and purified water.

What ACULAR 0,4 % looks like and contents of the pack

ACULAR 0,4 % is a clear, colourless to pale yellow solution in a white opaque plastic bottle with a white controlled dropper tip and a grey screw cap. Each pack contains one bottle containing 5 ml solution in a 10 ml bottle.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Professional Information can be accessed via <http://www.allergan.co.za/en-za/products> or by contacting +27 11 545 6600.