**CLEAN COPY 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.

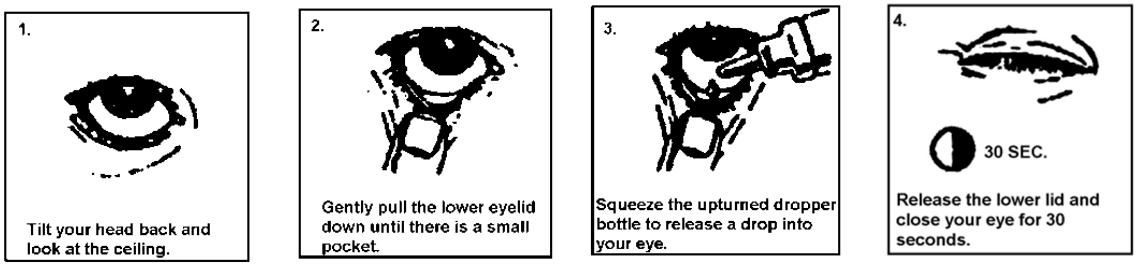
## 3. How to use ACULAR 0,4 %

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 %.

You can also report side effects to AbbVie (Pty) Ltd by sending an e-mail to MEAPV@abbvie.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.

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## Access to the corresponding Professional Information

For the professional information please email medicalinfo.za@abbvie.com