PATIENT INFORMATION LEAFLET

SCHEDULING STATUS
Schedule 3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
ACULAR 0,5 % Ketorolac tromethamine 5 mg/ml Ophthalmic Solution

Read all of this leaflet carefully before using ACULAR 0,5 % ophthalmic solution.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ACULAR 0,5 % 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.

1. WHAT ACULAR 0,5 % CONTAINS
- The active ingredient is ketorolac tromethamine 5 mg/ml.
- The other ingredients are benzalkonium chloride, sodium chloride, disodium edetate, octoxynol 40, sodium hydroxide or hydrochloric acid (to adjust pH) and purified water.

2. WHAT ACULAR 0,5 % IS USED FOR
ACULAR 0,5 % belongs to a group of medicines known as non-steroidal anti-inflammatory medicines. ACULAR 0,5 % is used to relieve eye inflammation following cataract surgery.

3. BEFORE YOU TAKE ACULAR 0,5 %
Do not use ACULAR 0,5 %
- If you are allergic to aspirin, ketorolac or any other similar medicines.
- If you are hypersensitive (allergic) to any of the components in this medication (see "WHAT ACULAR 0,5 % CONTAINS").
- If you are pregnant or breast-feeding.
- If you wear soft contact lenses. (The preservative, benzalkonium chloride, can permanently damage this type of lens.)
- ACULAR 0,5 % should not be administered to children.

Take special care with ACULAR 0,5 %
- If you suffer from, or have in the past suffered from, viral or bacterial infections of the eye.
- If you suffer from, or have in the past suffered from, asthma due to an allergy to aspirin or other similar medicines.
- If you develop any kind of corneal (see-through layer covering the eye) disease, inflammation or ulceration, immediately inform your doctor.
- If you have complicated or repeat surgeries of the eye, eye surface diseases, diabetes mellitus or rheumatoid arthritis.

- If you suffer from, or have in the past suffered from, bleeding tendencies (for example, anaemia), stomach ulcers or if you are taking other medicines which may prolong bleeding time or affect blood platelet function.
- As it may slow or delay healing.

Important information about some of the ingredients of ACULAR 0,5 %
Benzalkonium chloride:
A preservative in ACULAR 0,5 % (called benzalkonium chloride) may cause eye irritation and is also known to discolour soft contact lenses. Therefore, do not use the drops while your contact lenses are in your eyes. Wait at least 15 minutes after using the eye drops before putting your lenses back in your eyes.

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 as the preservative benzalkonium chloride can cause damage to your eyes.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using ACULAR 0,5 %

The use of ACULAR 0,5 % during pregnancy and breastfeeding is not recommended. Safety and efficacy during pregnancy has not been established.

Ketorolac tromethamine is excreted in breast milk. ACULAR 0,5 % should not be used by women breastfeeding their infants.

Driving and using machines
ACULAR 0,5 % may cause blurred/abnormal vision. Do not drive or use machinery until these symptoms have cleared.

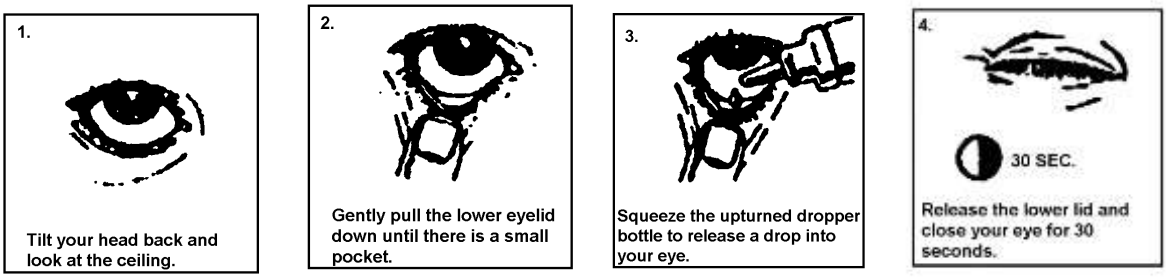
Using other medicines with ACULAR 0,5 %
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

If you are taking other medicines or eye drops on a regular basis, including complementary or traditional medicines, the use of ACULAR 0,5 % 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.

4. HOW TO USE ACULAR 0,5 %
Always use ACULAR 0,5 % exactly as your doctor has instructed you. You should check with

your doctor or pharmacist if you are unsure.

The recommended dose for ACULAR 0,5 % ophthalmic solution is one drop three times a day in the operated eye, starting 24 hours before surgery. Follow the instructions of your eye specialist carefully. 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. Ask your doctor or pharmacist if you have any questions.

If you have the impression that the effect of ACULAR 0,5 % is too strong or too weak, talk to your doctor or pharmacist.

If you use more ACULAR 0,5 % than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use ACULAR 0,5 %
- 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.

5. POSSIBLE SIDE EFFECTS
ACULAR 0,5 % can have side effects. Not all side effects reported for ACULAR 0,5 % are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ACULAR 0,5 %, please consult your doctor, pharmacist or other healthcare professional for advice.

You may commonly experience the following effects:

Stinging or burning when drops are applied, and/or temporary blurred vision. Do not drive or operate machinery if your sight is affected. You may also experience eye irritation (e.g. redness, itchiness, puffiness and pain).

The following side-effects have been reported:
Frequent side effects:

- inflammation of the iris
- particles stuck to the back surface of the cornea
- bleeding on the back wall (retina) of the eye
- retinal swelling
- increase in eye pressure
- headaches.

Side effects with unknown frequency:

- inflammation and ulceration of the cornea (the clear layer in front of the iris and pupil)
- eyelid swelling, eye swelling, red eye, redness of the white part of the eye, eye pain and itchiness of the eye

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

6. STORING AND DISPOSING OF ACULAR 0,5 %

- Store below 25°C. Keep well closed.
- STORE ALL MEDICINES 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.
- Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets). Return all unused medicines to your pharmacist.

7. PRESENTATION OF ACULAR 0,5 %

ACULAR 0,5 % is supplied sterile dropper bottles containing 5 ml solution.

8. IDENTIFICATION OF ACULAR 0,5 %

ACULAR 0,5 % is a clear, colourless to pale yellow solution.

9. REGISTRATION NUMBER

29/15.4/0265

10. NAME, ADDRESS AND TELEPHONE NUMBER OF THE REGISTRATION HOLDER

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11. DATE OF PUBLICATION

Date of registration: 27 November 1995
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Professional Information can be accessed via http://www.allergan.co.za/en-za/products.
In case of an adverse event, please contact +27 11 545 6600 or send an email to SA_Complaints@allergan.com.