ACULAR® OPHTHALMIC SOLUTION *Consumer Medication Information Leaflet (RiMUP)*

Ketorolac tromethamine (0.5% w/v)

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What ACULAR® is used for

ACULAR® ophthalmic solution is indicated for the short-term relief of itchy eyes due to seasonal eye allergy and for the prevention and relief of eye inflammation following eye surgery.

How ACULAR® works

ACULAR® belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). The active ingredient in **ACULAR®** is ketorolac tromethamine.

The eye solution of Ketorolac tromethamine works by decreasing prostaglandin E2 levels in the eye.

Prostaglandins are normally produced by the body, but in the eye they are thought to be associated with pain, itching and inflammation.

Before you use ACULAR®

- *When you must not use it*

If you are allergic (hypersensitive to ketorolac, or any of the other ingredients of **ACULAR®**. (for a full list of ingredients, see section 8 "PRODUCT DESCRIPTION").

If you are hypersensitive to, or have had an allergic reaction to aspirin or other NSAIDs.

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

- *Pregnancy and lactation*

Ask your doctor or pharmacist for advice before using any medicine.

ACULAR® should not be used if you are pregnant or might become pregnant or are breast feeding, unless your doctor recommends it.

- *Children*

The use of **ACULAR®** in children has not been studied.

- *Before you start use it*

Take special care with **ACULAR®**.

If any of the following apply, talk to your doctor before using **ACULAR®**.

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

- Viral or bacterial infections of the eye - Bleeding tendencies (for example, anaemia) or stomach ulcers
- or if you have had recent eye surgery
- you have had an allergy to any medicines or any other substances, such as foods, preservatives or dyes.
- you have defects of the cornea, diseases of the eye , or if you have had recent eye surgery.
- you have asthma or a history of asthma.

- *Taking other medicines*

Please tell your doctor or pharmacist if you are using or have recently used any other medicine, including medicines obtained without a prescription.

Some medicines when taken with **ACULAR®** may interfere with each other. These include:
- topical corticosteroid

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

How to use ACULAR®

- *How much to use*

Always use **ACULAR®** exactly as your doctor has told you.

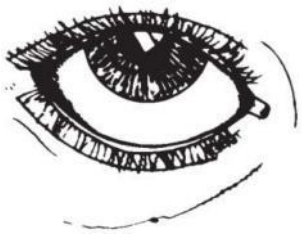
You should check with your doctor or pharmacist if you are not sure.

To relieve itchy eyes due to seasonal eye allergy, the recommended dose is 1 drop into the affected eye(s), 4 times a day.

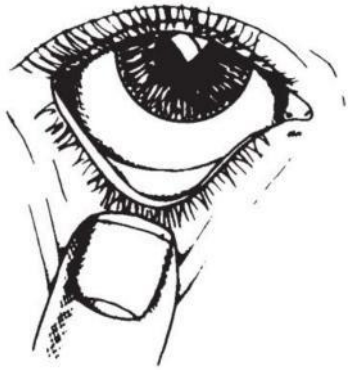
For prevention and relief of eye inflammation following eye surgery, the usual dose is 1 drop into the affected eye(s), 3 times a day, starting 24 hours before surgery and continuing for up to 3 weeks after eye surgery.

- *Instructions for use*

1. Wash your hands. Tilt your head back and look at the ceiling



2. Gently pull the lower eyelid down until there is a small pocket



3. Turn the bottle upside down and squeeze it to release one drop into each eye that needs treatment.



4. Let go of the lower lid, and close your eye for 30 seconds



- *When to use it*

ACULAR® should be used as advised by your doctor. If you have any further questions on the use of this product, ask your doctor or pharmacist.

- *How long to use it*

ACULAR® should be used as advised by your doctor. If you have any further questions on the use of this product, ask your doctor or pharmacist.

- *If you forget to use it*

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 take a double dose to make up for a forgotten dose.

- *If you use too much (overdose)*

The application of too many drops is unlikely to lead to unwanted side-effects.

Apply your next dose at the normal time. If, by accident, anyone drinks this medicine, drink fluids to dilute and contact your doctor.

While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking **ACULAR®**.

Tell your doctor immediately if you become pregnant while taking this medication.

If you develop an eye infection, receive an eye injury, or have eye surgery tell your doctor.

Tell your doctor if your condition gets worse or does not get better while using **ACULAR®** eye drops.

- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

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

- *Things to be careful of*

If you wear contact lenses you should remove them prior to application and wait at least 15 minutes before reinsertion.

The preservative in **ACULAR®** benzalkonium chloride, may cause eye irritation and can permanently damage this type of lens. **ACULAR®** is known to discolour soft contact lenses.

Avoid contact with soft contact lenses.

Driving and using machine:
ACULAR® may cause temporary blurred vision. Do not drive or use machinery until the symptoms have cleared.

Side effects

Like all medicines, **ACULAR®** can cause side effects, but not everyone gets them.

The most frequently reported side effects include stinging and burning.

Others include eye irritation, allergic reactions, infection of the eye surface, inflammation of the eye surface, blurred vision, conjunctivitis (infection of the eye or surrounding areas), iritis (inflammation of the front layer of the eyeball or the coloured part of the eye), local allergic reactions, such as red eye, stinging of the eye, increased pressure in the eye, headaches, bleeding of the retina.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public-Reporting Medicinal Problems /Side Effects / AEFI)

Storage and Disposal of ACULAR®

- *Storage*

Keep out of the reach and sight of children.

Do not use **ACULAR®** after the expiry date which is stated on the bottle label and the bottom of the 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. Store below 30°C. Protect from light.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

Product Description

- *What it looks like*

ACULAR® is a clear, colourless to slightly yellow solution in a plastic bottle.

Each pack contains 1 plastic bottle with a screw cap.

Each bottle is about half full and contains 3ml, 5 ml or 10ml of the eye drops as written on the front of the pack.

Not all pack sizes may be marketed.

- *Ingredients*
  - Active ingredient
    Ketorolac tromethamine

  - Inactive ingredients
    Benzalkonium chloride, disodium edetate, octoxinol 40, sodium chloride, sodium hydroxide or hydrochloric acid (to adjust pH) and purified water.

- *MAL number:*
  MAL20013345ARZ

Manufacturer

Allergan Pharmaceuticals Ireland
Castlebar Road, Westport County
Mayo
Ireland

Product Registration Holder

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