

B. PACKAGE LEAFLET

Package leaflet: Information for the user
ACULAR® 0.5% w/v EYE DROPS, SOLUTION
(Ketorolac trometamol)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What ACULAR is and what it is used for
2. What you need to know before you use ACULAR
3. How to use ACULAR
4. Possible side effects
5. How to store ACULAR
6. Contents of the pack and other information

1. What ACULAR is and what it is used for

Acular is used to prevent and reduce eye inflammation following cataract surgery in adults. Acular belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDS).

2. What you need to know before you use ACULAR

Do not use ACULAR

- If you are allergic to ketorolac trometamol or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to aspirin or any other similar drugs, such as other non-steroidal anti-inflammatory drugs.

Warnings and precautions

Talk to your doctor or pharmacist or nurse 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
- diabetes
- rheumatoid arthritis
- dry eye syndrome
- asthma after using non-steroidal anti-inflammatories
- if you have had recent eye surgery
- if you have lost sensitivity in the cornea (the clear surface covering the pupil and iris) or if the normally smooth surface of the cornea is damaged.

Children

ACULAR should not be prescribed for use in children.

Other medicines and ACULAR

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

Driving and using machines

ACULAR may cause blurred vision in some patients. Do not drive or use machinery until the symptoms have cleared.

ACULAR contains Benzalkonium chloride

This medicine contains 0.1 mg benzalkonium chloride in each milliliter which is equivalent to 0.1 mg/ml.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

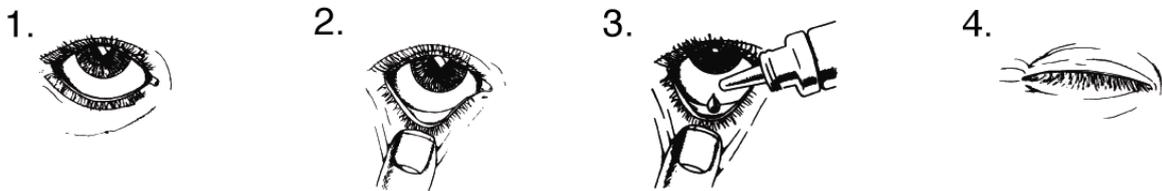
3. How to use ACULAR

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

The recommended dose is 1 drop in the affected eye 3 times a day for 3-4 weeks following cataract surgery, starting 24 hours before surgery.

Instructions for use

Apply your eye drops in the following way:



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.

If a drop misses your eye, try again.

To avoid contamination or injury, do not let the tip of the dropper touch your eye or anything else.

Replace and tighten the cap straight after use.

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

The proper application of your eye drops is very important.
If you have any questions ask your doctor or pharmacist.

If you use more ACULAR than you should

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.

If you forget to use ACULAR

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 stop using ACULAR

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common: may affect more than 1 in 10 people

Irritation of the eye, stinging and/or burning in the eye, eye pain.

Common: may affect up to 1 in 10 people

Allergic reaction, eye and/or eyelid swelling/puffiness, itchy eyes, red eye, infection of the eye, inflammation of the eye (surface or inside), bleeding of the retina, swelling of central retina (light-sensitive layer of the eye), headache, accidental injury caused by the tip of the dropper touching the eye, increased pressure in the eye, blurred and/or diminished vision.

Uncommon: may affect up to 1 in 100 people

Inflammation or damage to the front clear layer of the eye, eye dryness and/or watery eyes.

Not known: frequency cannot be estimated from the available data

Damage on the surface of the eye such as thinning, erosion, perforation, degradation of cell(s), difficulty in breathing or wheezing, aggravation of asthma, swollen face, ulcer-damage to the surface of the eye.

Side effects related to the cornea (the surface of the eye) may be more likely if Acular is used for longer than two weeks or if you are using topical steroid drops at the same time or if you have a related eye condition. You should see your doctor immediately if you experience pain, increased irritation in the eye or changes in vision.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ACULAR

Keep out of the sight and reach of children.

Do not use this medicine 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 25°C.

Do not use this medicine if you notice the tamper-proof seal is broken.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What ACULAR contains

- The active substance is Ketorolac trometamol 0.5% w/v.
- The other ingredients are benzalkonium chloride, disodium edetate, octoxinol 40, sodium chloride, sodium hydroxide or hydrochloric acid (to adjust pH) and purified water.

What ACULAR looks like and contents of the pack

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

Each pack contains a 10ml plastic bottle with a screw cap. Each bottle contains 5ml or 10ml of the eye drops.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Allergan Pharmaceuticals Ireland, Westport, Co. Mayo, Ireland

Tel: +44 (0) 1628 494026, Fax: +44 (0) 1628 494057,

E-mail: uk_medinfo@allergan.com

This medicinal product is authorised in the Member States of the EEA under the following names:

| | |
|---|-------------------------------------|
| Austria | ACULAR 0,5% Augentropfen |
| Belgium, | ACULARE oogdruppels |
| Denmark, Ireland, Italy, United Kingdom | ACULAR |
| Finland | ACULAR 5 mg/ml eye drops |
| France | ACULAR 0,5% |
| Germany | ACULAR 5 mg/ml Augentropfen |
| Greece | ACULAR 0.5% |
| Luxembourg | ACULARE collyre |
| Netherlands | ACULAR oogdruppels 0,5% |
| Portugal | ACULAR 0,5% p/v colírio solução |
| Spain | ACULAR 0,5% p/v colirio en solución |

This leaflet was last revised in April 2019