

Package leaflet: information for the user

ACULAR® 0.5% w/v Eye Drops, solution (ketorolac trometamol)

Your medicine is available using the above name but will be referred to as Acular throughout this leaflet.

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Acular is and what it is used for
2. Before you use Acular
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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. Before you use Acular

Do not use Acular

- If you are allergic (hypersensitive) to ketorolac, or any of the other ingredients of Acular.
- If you are allergic to aspirin or any other similar drugs, such as other non-steroidal anti-inflammatory drugs.

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
- 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.

Using other medicines

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

Ask your doctor or pharmacist for advice before using any medicine. Acular should not be used if you are pregnant or breast-feeding, unless your doctor recommends it.

Children

Acular should not be prescribed for use in children.

Driving and using machines

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

Important information about some of the ingredients of Acular

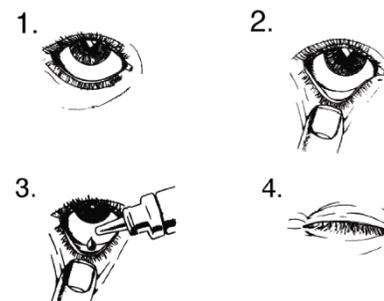
- If you wear soft (hydrophilic) contact lenses you should remove them prior to application and wait at least 15 minutes before reinsertion.
- The preservative in Acular, benzalkonium chloride, may cause eye irritation and can permanently damage this type of lens. Acular is known to discolour soft contact lenses.
- Avoid contact with soft contact lenses.

3. How to use Acular

Always use Acular exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual 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, Acular can cause side effects, although not everybody gets them.

The **very common side effects** (occurring in more than 1 in 10 patients) are: irritation of the eye, stinging and/or burning in the eye, eye pain.

Common side effects (occurring in between 1 and 10 patients in every 100) are: 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 side effects (occurring in between 1 and 10 patients in every 1,000) are: inflammation or damage to the front clear layer of the eye, eye dryness and/or watery eyes.

Not known side effects (cannot be estimated from the available data) are: damage on the surface of the eye such as thinning, erosion, perforation, degradation of cell(s), difficulty in breathing or wheezing, aggravation of asthma.

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, pharmacist or nurse. 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.

Store below 25°C.

Do not use Acular after the expiry date (EXP) which is stated on the carton and bottle label. The expiry date refers to the last day of that month.

If your eye drops appear to be discoloured, damaged or show any other signs of deterioration, please return these to your pharmacist who will advise you further.

Throw the bottle away 15 days after opening, even if there is solution remaining.

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

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.

If you have any left-over/unused eye drops, please return these to your pharmacist for safe disposal.

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 pale yellow aqueous solution.

Your medicine is available in plastic bottles containing 5ml of solution in an overlabelled outer carton.

Manufacturer

Manufactured by: Allergan Pharmaceuticals Ireland, Westport, Co Mayo, Ireland.

Procured from within the EU by and repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

PPA1151/142/001

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 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 colírio en solución

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ACULAR® is a registered trademark of Allergan, Inc.

Blind or partially sighted?

Is this leaflet hard to see or read?

Call +44 (0) 1302 365000 (Regulatory)

Please be ready to give the following information:

Product name: ACULAR 0.5% w/v Eye Drops, solution

Reference No: PPA1151/142/001