

ACULAR[®] EYE DROPS

(ketorolac trometamol) 5 mg/mL Eye Drops

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ACULAR[®] eye drops, including how to use the eye drops. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using ACULAR[®] eye drops against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What ACULAR[®] eye drops are used for

These eyedrops contain the drug ketorolac trometamol and are used to treat itchy eyes occurring in the condition called seasonal allergic conjunctivitis. They are also used for the relief of swelling and redness after cataract surgery.

Ketorolac trometamol works by decreasing prostaglandin E₂ levels in the eye. Prostaglandins are normally produced by the body and are thought to be associated with pain, itching and inflammation.

ACULAR[®] eye drops are only available with a doctor's prescription from pharmacies.

Ask your doctor if you have any questions about why ACULAR[®] eye drops have been prescribed for you.

Before you use ACULAR[®] eye drops

When you must not use it

Do not use ACULAR[®] eye drops if:

- You have an allergy to ketorolac trometamol or to any of the ingredients listed at the end of this leaflet
- You have ever had an allergic reaction to aspirin or certain types of medicines used for arthritis or pain relief (non steroidal anti-inflammatory drugs)
- The seal around the cap is broken
- The bottle/packaging shows signs of tampering
- The product does not look quite right
- The expiry date on the bottle has passed.

If you use this medicine after the expiry date has passed, it may not work effectively.

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses as the preservative (benzalkonium chloride) in ACULAR[®] eye drops may be deposited and cause discoloration to soft contact lenses. Contact lenses should be removed prior to using ACULAR[®] eye drops. You can put your soft contact lenses back into your eyes 15 minutes after you have used ACULAR[®] eye drops.

Do not allow the tip of the dispensing container to contact the eye to avoid injury of the eye and contamination of the eye drops.

It is not known if ACULAR[®] eye drops are safe and useful for children under 12 years.

These drops are for topical use only.

Before you start to use it

Tell your doctor if:

1. You have had an allergy to any medicines or any other substances, such as foods, preservatives or dyes.
2. You are taking any other prescription or nonprescription

medicine, particularly those which have an effect on bleeding.

3. You have a peptic ulcer or a history of peptic ulcers.
4. You have asthma or a history of asthma.
5. You have defects of the cornea, sugar diabetes, diseases of the eye (e.g. dry eye syndrome), rheumatoid arthritis, or if you have had recent eye surgery.
6. You are pregnant, or intend to become pregnant. ACULAR[®] eye drops are not recommended in pregnancy.
7. You are breastfeeding or intend to breastfeed. ACULAR[®] eye drops are not recommended if you are breastfeeding.
8. You have a condition that causes you to bleed easily.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

It is not expected that ACULAR[®] will interact with other medicines, however you should always ask your optical practitioner, doctor or pharmacist if you have any concerns about using ACULAR[®] eye drops as well as other medications.

How to use ACULAR[®] eye drops

How much to use

Your doctor will tell you how many drops you need to use each day. Use ACULAR[®] eye drops only as prescribed by your doctor.

The usual dose for itchy eyes (seasonal allergic conjunctivitis) is one drop into each eye four times daily for 2-4 weeks.

The usual dose for use before and after eye surgery for cataract removal is one or two drops into each eye four

times daily, starting 24 hours before the surgery and continuing for 2-4 weeks.

Follow all directions given to you by your doctor carefully. The directions may differ from the information contained in this leaflet.

If you are using more than one eye drop product, wait 5 minutes before using the second product.

If you are being changed from one eye drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

How to use it

You may find it easier to put drops in your eye while you are sitting or lying down.

If you are wearing soft contact lenses, remove them before putting the drops in your eye.

To open a new bottle of ACULAR® eye drops first tear off the protective seal from the bottle. The contents are sterile if the seal is intact. The seal will break and you can pull it off and then throw it away.

1. Wash your hands well with soap and water.
2. Remove the lid/cap
3. Hold the bottle upside down in one hand between your thumb and forefinger or index finger.
4. Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.
5. Tilt your head back and look up.
6. Put the tip of the bottle close to your lower eyelid. Do not let it touch your eye.
7. Release one drop into the pouch or pocket formed between your eye and eyelid by gently squeezing the bottle.
8. Close your eye. Do not blink or rub your eye.
9. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose

and throat, from where it can be absorbed into other parts of your body. Ask your doctor for more specific instructions on this technique.

10. Replace the lid/cap, sealing it tightly.
11. Wash your hands again with soap and water to remove any residue.

Wait 15 minutes before replacing your contact lenses.

Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid contaminating the eye drops.

How long to use it

Continue using ACULAR® eye drops for as long as your doctor prescribes. The usual length of use is 2-4 weeks.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use the drops as soon as you remember, and then go back to using them as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not use double the amount to make up for the dose that you missed.

If you use too much (overdose)

If you accidentally put several drops in your eye(s), immediately rinse your eye(s) with warm water.

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of ACULAR® eye drops drink fluids to dilute and immediately telephone your doctor or **Poisons Information Centre (Australia: telephone 13 11 26; New Zealand: telephone 0800 POISON or 0800 764 766)** for advice, or go to casualty at your nearest hospital. Do this even if there are no signs of discomfort or

poisoning.

While you are using ACULAR® eye drops

Things you must do

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

Your doctor may tell you to use a new container of ACULAR® eye drops because of possible contamination of the old one or may advise you to stop your treatment with ACULAR® eye drops.

If you become pregnant while using ACULAR® eye drops tell your doctor immediately.

If you wear soft contact lenses, remove them before using ACULAR® eye drops. Leave your lenses out for at least 15 minutes after putting in the eye drops.

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

If you are about to start any new medicine tell your doctor and pharmacist that you are using ACULAR® eye drops.

Things you must not do

Do not give ACULAR® eye drops to anyone else, even if they have the same condition as you.

Do not stop using ACULAR® eye drops without first talking to your doctor.

Things to be careful of

Your vision may blur for a short time after you put in your ACULAR® eye drops. If this happens you should wait until you can see well again before you drive or use machinery.

ACULAR® eye drops are not expected to cause any problems with your ability to drive a car or operate machinery. However, as a general precaution be careful driving or operating machinery until you know

how ACULAR® eye drops affect you.

Side effects

Tell your optical practitioner, doctor or pharmacist as soon as possible if you do not feel well while you are using ACULAR® eye drops.

Check with your doctor as soon as possible if you have any problems while taking ACULAR® eye drops, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Some side effects of ACULAR® eye drops are:

- burning and stinging of the eye on instillation
- blurring of vision
- infection of the eye or surrounding areas
- inflammation of the front layer of the eyeball or the coloured part of the eye
- conjunctivitis (scratching, foreign body sensation, itching, redness)
- local allergic reactions, such as red eye, stinging of the eye
- irritation of the surface of the eye or feeling of having something in the eye
- pain in the eye
- drooping of the upper eyelid
- swollen eyelid
- uncomfortable sensitivity to light
- eye dryness
- a lesion on the front layer of the eyeball
- increased pressure in the eye
- white spots on the surface of the eye
- headaches
- visual disturbance
- hypersensitivity.

The following side effects were observed in one patient during a controlled clinical studies:

- white deposit on the underside of the front part of the eye
- bleeding of the retina
- swelling of the central area of the retina
- burning eye
- itchy eye
- eye injury.

After using ACULAR® eye drops

Storage

Keep your eye drops in a cool place where the temperature stays below 25°C, and out of the light.

Keep the medicine where children cannot reach it.

Do not leave the top/lid off the bottle for any length of time to avoid contaminating the eye drops.

Disposal

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

Product description

What ACULAR® eye drops look like:

Clear, colourless to pale yellow, sterile solution, supplied in a white opaque plastic bottle with a dropper tip.

Ingredients

Active ingredient:

Ketorolac trometamol 5.0mg/mL

Preservative:

Benzalkonium chloride

Inactive ingredients:

sodium chloride,
edetate disodium
octoxinol 40
purified water
sodium hydroxide and/or

hydrochloric acid may be added to adjust pH

Manufacturer/Supplier

Allergan Australia Pty Ltd
810 Pacific Highway,
Gordon NSW 2072
ABN 85 000 612 831

Toll free: 1800 252 224 (Australia)

Allergan New Zealand Limited
Corner of Manu Tapu Drive and
Joseph Hammond Place
Auckland International Airport
Mangere
AUCKLAND

Freephone: 0800 659 912 (NZ)

ACULAR® eye drops can be identified by registration number: AUST R 63539

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