

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrACULAR® / PrACULAR LS®

ketorolac tromethamine ophthalmic solution

Read this carefully before you start taking **ACULAR** or **ACULAR LS** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ACULAR** or **ACULAR LS**.

What are ACULAR or ACULAR LS used for?

- ACULAR is used to prevent and treat inflammation in your eyes after having cataracts removed. A cataract is the clouding of the lens of the eye.
- ACULAR LS is used to manage eye pain and other symptoms that may occur after vision correction surgery. It may reduce eye pain, burning, stinging, sensitivity to light and the feeling that something is in your eye.

How does ACULAR or ACULAR LS work?

ACULAR and ACULAR LS belong to a family of drugs known as non-steroidal anti-inflammatory drugs (NSAIDs). These drugs reduce certain substances (called prostaglandins). When prostaglandin levels are reduced, the intensity of pain, and inflammation is reduced as well.

What are the ingredients in ACULAR and ACULAR LS?

Medicinal ingredient: Ketorolac tromethamine

Non-medicinal ingredients:

ACULAR: Benzalkonium chloride 0.01% w/v as the preservative, edetate disodium, octoxynol 40, purified water, sodium chloride and sodium hydroxide and/or hydrochloric acid solution to adjust the pH to 7.4.

ACULAR LS: Benzalkonium chloride 0.006% w/v as the preservative, edetate disodium, octoxynol 40, purified water, sodium chloride and sodium hydroxide and/or hydrochloric acid to adjust the pH to 7.4.

ACULAR and ACULAR LS come in the following dosage forms:

ACULAR: ophthalmic solution 0.5%, w/v.

ACULAR LS: ophthalmic solution 0.4%, w/v.

Do not use ACULAR or ACULAR LS if:

- you are allergic to ketorolac tromethamine or any of the other ingredients (see section above **What are the ingredients in ACULAR and ACULAR LS?**).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ACULAR or ACULAR LS. Talk about any health conditions or problems you may have, including if you:

- are allergic to acetylsalicylic acid (e.g. Aspirin®) or to any of the other non-steroidal anti-inflammatory drugs (NSAID).
- have a past medical history of asthma.
- are pregnant or are planning to become pregnant. ACULAR and ACULAR LS are not recommended during pregnancy.
- are breast-feeding, or are planning to breast-feed. ACULAR and ACULAR LS are not recommended for nursing mothers.
- have had recent eye surgery or are planning for eye surgery.
- have medical conditions such as diabetes mellitus, dry eye syndrome, rheumatoid arthritis or any issues with your cornea (the front part of your eye).
- have bleeding problems, as ACULAR may cause bleeding in the eyes when associated with eye surgery.

Other warnings you should know about:

ACULAR and ACULAR LS may cause blurred vision. Do not drive or use heavy machinery until your vision clears.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ACULAR or ACULAR LS:

- Non-steroidal anti-inflammatory drugs (NSAID) such as aspirin.

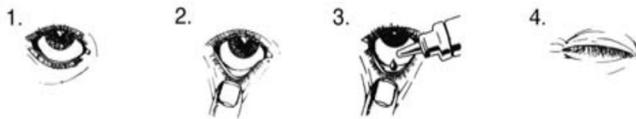
How to take ACULAR or ACULAR LS:

- Remove your contact lenses before using ACULAR or ACULAR LS. You may re-insert them 15 minutes after taking ACULAR or ACULAR LS.
- ACULAR and ACULAR LS both contain benzalkonium chloride, which may discolour soft contact lenses.
- Always use ACULAR and ACULAR LS exactly as your doctor has instructed you.
- If you use ACULAR or ACULAR LS with another eye drop, leave at least five minutes between putting in ACULAR or ACULAR LS and then the other drops.
- To help prevent infections, do not let the tip of the bottle touch your eye or anything else. Put the cap back on and close the bottle immediately after you have used it.
- ACULAR and ACULAR LS should only be applied to the eye.

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

Follow these steps to use ACULAR and ACULAR LS properly:

- Wash your hands. Tilt your head back and look at the ceiling. (See illustration 1)
- Gently pull down the lower eyelid to create a small pocket. (See illustration 2)
- Turn the bottle upside down and squeeze it gently to release one drop into the eyelid pocket. If a drop misses your eye, try again. (See illustration 3)
- Let go of the lower lid and close your eye for 30 seconds. (See illustration 4)



Repeat steps 1 – 4 in the other eye if both eyes need treatment.

Usual dose:

ACULAR: Instill 1 or 2 drops in your affected eye(s) 3 or 4 times daily or as directed by your doctor.

ACULAR LS: Instill 1 drop in your affected eye(s) 4 times daily for up to 4 days.

Overdose:

If ingested accidentally, drink a lot of fluids.

If you think you, or a person you are caring for, have taken too much ACULAR or ACULAR LS, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to apply ACULAR or ACULAR LS at your normal time, simply apply them as soon as you remember, and then go back to your regular routine. Do not take two doses to make up for the one that you missed.

What are possible side effects from using ACULAR or ACULAR LS?

These are not all the possible side effects you may have when taking ACULAR or ACULAR LS. If you experience any side effects not listed here, tell your healthcare professional.

Common with ACULAR:

- Irritation of the eye (stinging, burning, redness)
- Itchy and/or swollen eye

- Blurred vision after instillation of the eye drops
- Eye pain
- Conjunctivitis (pink eye)

Common with ACULAR LS:

- Eye pain

Uncommon with ACULAR LS:

- Headache

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
delay wound healing in those with serious eye conditions including corneal thinning, erosion, perforation or ulceration, and cause these conditions to worsen and may affect sight		√	
bronchospasm (shortness of breath) and worsen asthma symptoms		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

ACULAR and ACULAR LS should be stored in the original container at room temperature (15 – 30 °C) and protected from light. Discard unused solution 28 days after opening.

Keep out of reach and sight of children.

If you want more information about ACULAR or ACULAR LS:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

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