

## **Patient Medication Information**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

Pr **ACULAR®**

#### **ketorolac tromethamine ophthalmic solution**

This Patient Medication Information is written for the person who will be taking **ACULAR**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **ACULAR**, talk to a healthcare professional.

#### **What ACULAR is 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.

#### **How ACULAR works:**

ACULAR belongs 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 inflammation is reduced as well.

#### **The ingredients in ACULAR are:**

Medicinal ingredient: Ketorolac tromethamine

Non-medicinal ingredients:

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 comes in the following dosage form:**

ophthalmic solution 0.5%, w/v.

**Do not use ACULAR if:**

- you are allergic to ketorolac tromethamine or any of the other ingredients (see section above: The ingredients in ACULAR are).

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ACULAR. 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 is not recommended during pregnancy.
- are breast-feeding, or are planning to breast-feed. ACULAR is 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 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:**

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

**How to take ACULAR:**

- Remove your contact lenses before using ACULAR. You may re-insert them 15 minutes after taking ACULAR.
- ACULAR contains benzalkonium chloride, which may discolour soft contact lenses.
- Always use ACULAR exactly as your doctor has instructed you.
- If you use ACULAR with another eye drop, leave at least five minutes between putting in ACULAR 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 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 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:**

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

#### **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 contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

#### **Missed dose:**

If you missed a dose of this medication, take it as soon as you remember. But if it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose. Go back to the regular dosing schedule. Do not take two doses at the same time.

#### **Possible side effects from using ACULAR:**

These are not all the possible side effects you may have when taking ACULAR. 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)

#### Serious side effects and what to do about them

| Frequency/Side Effect/Symptom                                                                                                                                                      | Talk to your healthcare professional |              | Stop taking this 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 ([canada.ca/drug-device-reporting](http://canada.ca/drug-device-reporting)) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

**Storage:**

ACULAR 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:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website ([Drug Product Database: Access the database](#)); the manufacturer's website [www.abbvie.ca](http://www.abbvie.ca); or by calling 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

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