

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrACUVAIL®

Ketorolac tromethamine ophthalmic solution

Read this carefully before you start taking **ACUVAIL** 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 **ACUVAIL**.

What is ACUVAIL used for?

- ACUVAIL is used to treat pain and inflammation (swelling and redness) following cataract eye surgery.

How does ACUVAIL work?

ACUVAIL is a non-steroidal anti-inflammatory drug (NSAID). It works by reducing the release of substances called prostaglandins that cause inflammation, and pain.

What are the ingredients in ACUVAIL?

Medicinal ingredient: ketorolac tromethamine

Non-medicinal ingredients: carboxymethylcellulose sodium, sodium chloride, sodium citrate, purified water with hydrochloric acid and/or sodium hydroxide to adjust pH.

ACUVAIL comes in the following dosage forms:

Ophthalmic solution 0.45% w/v

Do not use ACUVAIL if:

- you are allergic (hypersensitive) to ketorolac tromethamine or any of the other ingredients (see section **What are the ingredients in ACUVAIL?**);
- you are allergic to other nonsteroidal anti-inflammatory medicines such as acetylsalicylic acid, diflunisal, fenoprofen, flurbiprofen, ketoprofen, indomethacin, mefenamic acid, piroxicam, sulindac, tiaprofenic acid or tolmetin.

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

- have any allergies to acetylsalicylic acid or to any of the other non-steroidal anti-inflammatory drugs (NSAIDs) or have asthma after using NSAIDs;
- bruise easily, or if you have bleeding problems, or if you are taking blood thinning medication. ACUVAIL may cause bleeding in the eyes with eye surgery;

- have medical conditions such as diabetes mellitus, dry eye syndrome, rheumatoid arthritis or problems with your cornea (the front part of your eye);
- have had recent eye surgery or are planning for eye surgery;
- are pregnant or intend to become pregnant;
- are breast-feeding or intend to breast-feed.

Other warnings you should know about:

While using ACUVAIL talk to your healthcare professional if you are not getting relief, your symptoms worsen or new eye problems develop.

Do not use ACUVAIL more than two weeks unless advised by your doctor. There is risk of corneal problems if you use ophthalmic non-steroidal anti-inflammatory drugs such as ACUVAIL beyond 14 days after the surgery.

ACUVAIL eye drop may slow or delay healing of the eyes.

Driving and Using Machines:

ACUVAIL 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 ACUVAIL:

- blood thinning medication such as warfarin.

How to take ACUVAIL:

- If you use ACUVAIL with other eye drops, wait 5 minutes between using ACUVAIL and the other drops.
- Use ACUVAIL single-use vial immediately after opening.
 - Discard the remaining product immediately after use.
- Do not allow the tip of the vial to touch the eyes or eyes lids, eyelashes, fingers, counter surface or anything else.
 - Contact with any surface can contaminate the product which may infect your eyes later on.
- Remove your contact lenses before using ACUVAIL. You may put them back in 15 minutes after using ACUVAIL.

Follow the following steps to help you use ACUVAIL properly:

- Wash your hands well with soap and water before you start.
- Tilt your head back or lie down.
- Gently pull down the lower eyelid to create a small “pocket” between the eyelid and your eye. The drop will go in here.

- Hold the unit-dose vial, tip pointing down. While looking up, gently squeeze the vial to release one drop into each eye that needs treatment.
- Let go of the lower lid, and close your eye for 30 seconds, longer is better (up to 5 minutes). Try not to blink or squeeze your eyelids.

Usual dose:

Patient dosing (18 years of age and older):

One day before your cataract surgery, apply one drop of ACUVAIL to the affected eye twice daily. Continue to apply one drop to the affected eye twice daily on the day of cataract surgery and for as long as your doctor told you. This maybe up to two weeks after cataract surgery.

Dosing on the day of cataract surgery by healthcare professional:

Administer one drop two hours before surgery, then approximately every twenty minutes for a total of three drops. Before discharge administer one additional drop.

Overdose:

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

If you accidentally swallow ACUVAIL eye drops, drink fluids to dilute and contact your local poison centre or doctor.

Missed Dose:

If you miss a dose of ACUVAIL, use the missed dose as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not double dose.

What are possible side effects from using ACUVAIL?

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

The most common side effects with treatment of ACUVAIL include eye pain, abnormal sensation in the eye, increased fluid pressure inside the eye(s), and pupil disorder.

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	
UNKNOWN			
Ulcerative keratitis [open sores and swelling of the cornea (clear window in the front of the eye)]: a feeling that a foreign object is trapped in your eye, blurred vision, decreased vision, excess tearing, eye pain, eye redness, increased sensitivity to light			✓
Corneal perforation (hole in the cornea): decreased vision, eye pain, excess tearing, increased sensitivity to light			✓

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:

Store at room temperature (15 - 30°C). Store the vials in the pouch. Protect from light.

Keep out of reach and sight of children.

If you want more information about ACUVAIL:

- 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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