CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ACUVAIL 4,5 mg/ml eye drops, solution

Ketorolac tromethamine

Read all of this leaflet carefully before you start using ACUVAIL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ACUVAIL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ACUVAIL is and what it is used for
2. What you need to know before you use ACUVAIL
3. How to use ACUVAIL
4. Possible side effects
5. How to store ACUVAIL
6. Contents of the pack and other information

1. What ACUVAIL is and what it is used for

ACUVAIL is used to treat pain and inflammation (swelling and redness) following cataract eye surgery in adults. It belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). It works by reducing the release of substances called prostaglandins that

cause inflammation and pain.

2. What you need to know before you use ACUVAIL

Do not use ACUVAIL:

- if you are hypersensitive (allergic) to ketorolac tromethamine or any of the other ingredients of ACUVAIL (listed in section 6).

Warnings and precautions

Take special care with ACUVAIL

Tell your doctor before you use ACUVAIL:

- if you have allergies to aspirin or to any of the other NSAIDs or if you have asthma after using NSAIDs;
- if you bruise easily, or if you have bleeding tendencies, or if you are taking blood thinning medicine. ACUVAIL may cause bleeding in the eyes after eye surgery;
- if you have medical conditions such as diabetes mellitus, dry eye syndrome, rheumatoid arthritis or problems with your cornea (the front part of your eye);
- if you have had recent eye surgery or are planning for eye surgery.

ACUVAIL may slow or delay healing of the eyes.

Do not use ACUVAIL for more than two weeks unless advised by your doctor. There is risk of corneal problems if you use ACUVAIL beyond 14 days after the surgery. Talk to your doctor if your eye does not get better.

Use ACUVAIL single-use vial immediately after opening and discard the remaining solution immediately after use. To avoid eye injury and contamination of the eye drops, do not allow

the tip of the vial to touch the eye or anything else.

Do not use ACUVAIL while wearing contact lenses. If your doctor recommends contact lenses use, remove them before using ACUVAIL. Wait at least 15 minutes after using ACUVAIL before putting your contact lenses back in.

Children

ACUVAIL should not be used in children.

Other medicines and ACUVAIL

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

ACUVAIL can cause increased bleeding in the eye when used with blood thinning medicine.

The use of ACUVAIL with steroid eye drops may increase the potential for healing problems.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using ACUVAIL.

There are no adequate and well-controlled studies of ACUVAIL in pregnant women. ACUVAIL can be excreted in human milk. If you are pregnant or breastfeeding your baby, you should not use ACUVAIL.

Driving and using machines

ACUVAIL may cause blurred vision. Do not drive or use heavy machinery until your vision clears.

3. How to use ACUVAIL

Do not share medicines prescribed for you with any other person.

Always use ACUVAIL exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one drop twice a day in the affected eye.

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 your surgery and for as long as your doctor told you. This may be up to two weeks after cataract surgery.

On the day of your surgery, ACUVAIL will be administered as follows by a healthcare professional:
One drop, two hours before surgery, then approximately every twenty minutes for a total of three drops. One additional drop will be administered before you get discharged.

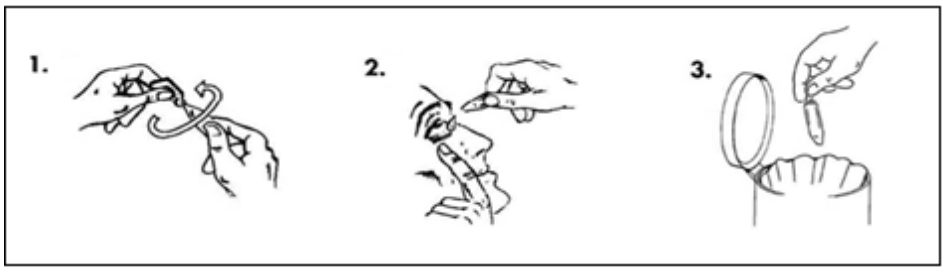
Your doctor will tell you how long your treatment with ACUVAIL will last. Do not stop treatment early or continue treatment for longer than your doctor told you. If you have the impression that the effect of ACUVAIL is too strong or too weak, tell your doctor or pharmacist.

No change in dosage is required for elderly patients.

If you use ACUVAIL with other eye drops, wait at least 5 minutes between using ACUVAIL and the other drops.

To avoid eye injury and contamination of the eye drops, do not allow the tip of the vial to touch the eye or anything else.

Instructions for use:



Use ACUVAIL single-use vial immediately after opening. Wash your hands before opening the vial.

1. Twist off the cap of the single-use vial.
2. Tilt your head back and look at the ceiling.

   Gently pull down the lower eyelid to create a small pocket between your eyelid and your eye.

   Turn the vial upside down and squeeze it gently to release one drop into the eye that needs treatment. If a drop misses your eye, try again.

   Let go of the lower lid and close your eye for 30 seconds.
3. Throw away the single-use vial immediately after you use it, even if there is some solution left.

If you use more ACUVAIL than you should

If you accidentally used too many drops, it is unlikely to lead to unwanted side effects. If anyone drinks ACUVAIL by accident, drink fluids to dilute and contact your health care professional.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use ACUVAIL

If you forget to use ACUVAIL, use it as soon as you remember. However, if it is almost time for the next dose, skip the dose you missed and go back to your regular routine. Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

ACUVAIL can have side effects. Not all side effects reported for ACUVAIL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ACUVAIL, please consult your health care provider for advice.

Frequent side effects

- Increased pressure in the eye
- Eye pain
- Red spot in the white of the eye caused by a broken blood vessel
- Blurred vision

Side effects where the frequency is not known

- Ulcer damage to the surface of the eye

- Eye swelling
- Eyelid swelling
- Red eye

The following additional side effects were seen with other medicines containing different strengths of ketorolac tromethamine and may also occur with ACUVAIL:

- Eye stinging or burning on installation
- Eye irritation, itching or burning
- Inflammation of the eye or iris (coloured part of the eye)
- Side effects related to the cornea (the surface of the eye) such as swelling, inflammation, thinning, erosion, perforation, degradation of cells or particles stuck to the back surface
- Superficial eye infections
- Swelling or bleeding of the back wall (retina) of the eye
- Eye injury
- Headache
- Allergic reactions, including allergic skin reactions (itching, rash, redness or swelling of the skin)
- Difficulty in breathing or wheezing or aggravation of asthma

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side

effects, you can help provide more information on the safety of ACUVAIL.

You can also report side effects to AbbVie (Pty) Ltd by sending an e-mail to MEAPV@abbvie.com

5. How to store ACUVAIL

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store the vials in the foil pouch and fold pouch ends closed to protect it from light.
- You must throw away the single-use vial immediately after use, even if there are still some solution left.
- Do not use after the expiry date stated on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ACUVAIL contains

- The active substance is ketorolac tromethamine. One ml of solution contains 4,5 mg of ketorolac tromethamine.
- The other ingredients are carboxymethylcellulose sodium, sodium chloride, sodium citrate dihydrate and purified water. Small amounts of hydrochloric acid or sodium hydroxide may be added to adjust the pH (acidity level).

What ACUVAIL looks like and the contents of the pack

ACUVAIL is a clear, colourless to pale yellow solution in a clear plastic single-use vial.

Each pack contains 30 single-dose vials in three foil pouches. Each pouch contains 10 single-dose vials. Each single-dose vial contains 0,4 ml solution.

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Access to the corresponding Professional Information

For the professional information please email medicalinfo.za@abbvie.com