PACKAGE LEAFLET

ACUFIX 0.4% Eye Drops, Solution
Instilled into the eye(s)
Sterile

- ***Active substance:*** Each ml solution contains 4 mg ketorolac trometamol.
- ***Excipients:*** Benzalkonium chloride, sodium chloride, octoxinol 40, disodium EDTA, sodium hydroxide, hydrochloric acid, water for injections.

Read all of this PACKAGE LEAFLET carefully before you start using this medicine because it contains important information for you.
- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the period when you take this medicine, tell your doctor that you take this drug when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or **lower** dose other than recommended to you for this medicine.*

In this leaflet

1. WHAT ACUFIX IS AND WHAT IT IS USED FOR

ACUFIX contains ketorolac trometamol as the active substance. The eye drops solution of 5 ml is presented in an opaque white, low-density polyethylene bottle with a dropper tip and a pink screw cap, packaged in a cardboard box. ACUFIX belongs to the group of medicines called non-steroidal anti-inflammatories that have pain-relieving and inflammation-reducing effects.

ACUFIX is used to treat symptoms such as pain and foreign body sensation, sensitivity to light, burning/stinging and tearing in the eye following eye surgery called refractive corneal surgery.

In addition, it has been shown that ketorolac trometamol does not adversely affect eye pressure.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ACUFIX

Do not use ACUFIX
- If you are allergic to the active substance of this medicinal product or to any of its excipients (see section 4. Possible side effects).

Take special care with ACUFIX
- If you have previously developed allergies to acetylsalicylic acid, phenylacetic acid and its derivatives and other non-steroidal anti-inflammatory drugs, or if you have a history of asthma.
- If you have had a surgical procedure on your eye.

- Some nonsteroidal anti-inflammatory drugs (drugs effective against pain, fever and inflammation) may cause increased bleeding.
- If you are also applying steroids (drugs effective against inflammation) to your eyes during the same period you use ACUFIX.

Locally applied non-steroidal anti-inflammatory drugs and steroids can slow or delay healing when used together.

- Topically applied non-steroidal anti-inflammatory drug use may cause keratitis (inflammation of the anterior layer of the eye (cornea)) and may cause undesirable effects that threaten your vision in the presence of some eye diseases such as complex eye surgeries, nerve loss in the cornea, damage to the outermost layer of the cornea, eye surface diseases (e.g. dry eye syndrome) or eye surgeries repeated over a short period of time, or other diseases such as diabetes or arthritis.
- If you will use your medicine for more than 24 hours before surgery or more than 14 days after surgery.

Long-term use may increase the likelihood and severity of undesirable effects that may occur on the eye surface.

- If you have a tendency to bleed or are taking other medicines that prolong the bleeding time.
- If you are wearing contact lenses.

Since ACUFIX contains benzalkonium chloride as a preservative, it may cause eye irritation. Avoid contact with soft contact lenses. Remove your contact lenses before instillation and wait at least 15 minutes to put your lenses back on. Benzalkonium chloride is known to cause discoloration of soft contact lenses.

If these warnings are applicable for you, even at any time in the past, please consult your doctor.

Using ACUFIX with food and drinks
ACUFIX is not expected to interact with food and drinks.

Pregnancy
Consult your doctor or pharmacist before using this medicine.
Your doctor should make the decision regarding medication use by evaluating risk/benefit ratio. ACUFIX should only be used if its benefit for mother outweighs the possible risk to the fetus. Studies conducted on animals are insufficient. The potential risks to humans are unknown. ACUFIX should not be used in late pregnancy.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breastfeeding
Consult your doctor or pharmacist before using this medicine.
The medicine should be used with caution during breastfeeding.

Driving and using machines
If temporary blurring of vision occurs following instillation, wait until your vision clears before driving or operating machinery.

Important information on some of the ingredients of ACUFIX
ACUFIX may cause eye irritation because it contains benzalkonium chloride. Avoid contact

with soft contact lenses. You should remove contact lenses before using this medicine and put them back at least 15 minutes afterwards. Benzalkonium chloride has been known to discolor soft contact lenses.

Using with other medicines
Use of ACUFIX with some other antiinflammatory eye medicines may cause healing problems.

If ACUFIX is to be used with another eye drops, there should be an interval of at least 5 minutes between the applications of the two medicines.

ACUFIX should be used with caution in patients who have bleeding tendency or are taking other medications that prolong bleeding time.

ACUFIX can safely be used with other eye medicines belonging to the drug groups called alpha agonists, antibiotics, beta-blockers, carbonic anhydrase inhibitors, cycloplegics and mydriatics. There have been no reports of interactions of ketorolac tromethamine (trometamol) ophthalmic solution 0.5% with topical or injectable drugs used in ophthalmology before, during or after surgery, including antibiotics (e.g., gentamicin, tobramycin, neomycin, polymyxin), sedatives (e.g., diazepam, hydroxyzine, lorazepam, promethazine HCl), miotics, mydriatics, cycloplegics (e.g., acetylcholine, atropine, epinephrine, physostigmine, phenylephrine, timolol maleate), hyaluronidase, local anesthetics (e.g., bupivicaine HCl, cyclopentolate HCl, lidocaine HCl, tetracaine), or corticosteroids.

Please inform your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without prescription.

3. HOW TO USE ACUFIX
Instructions for proper use and dose/frequency of administration
For pain and burning/stinging after surgery, 1 drop is applied in the operated eye 4 times a day for 4 days.
Once opened, the product should be used within 4 weeks provided that it is stored below 25°C.

Method and route of administration


Figure 1


Figure 2


Figure 3


Figure 4

1. Wash your hands before using your medicine. Tilt your neck back and look at the ceiling.
2. Gently pull your lower eyelid to form a small pocket.
3. Invert the bottle and squeeze one drop into each eye that needs treatment.
4. Release your eyelid and keep your eyes closed for 30 seconds.

If you could not get the drop in your eye, try again.

Do not allow the dropper tip to contact the eye or its surroundings in order to prevent contamination with bacteria known to cause eye infections. Serious eye damage and loss of vision may occur as a result of using contaminated solutions.

Different age groups
Use in children
This medicinal product should not be used in children under 3 years of age.

Use in elderly
Dose adjustment is not necessary for the elderly.

Special conditions for use
Liver / Kidney failure
There is no specific report in liver/kidney failure regarding the use of the medicine for the eyes.

If you have an impression that the effect of ACUFIX is too strong or too weak, talk to your doctor or pharmacist.

If you used more ACUFIX than you should
If you have used more ACUFIX than you should, wash your eyes with plenty of water. Your doctor will apply the appropriate treatment according to your symptoms.

Talk to a doctor or pharmacist if you have used more ACUFIX than you should.

If you forget to use ACUFIX
Do not apply double doses to make up for forgotten doses.

If you stop using ACUFIX
When ACUFIX treatment is terminated, no adverse effects are expected.

4. POSSIBLE SIDE EFFECTS
Like all medicines, ACUFIX can cause side effects in people with sensitivity to its ingredients.

If you get any of the followings, stop using ACUFIX and contact your doctor or go to your nearest hospital emergency department IMMEDIATELY:
- Swelling of the hands, feet, wrists/ankles, face, lips, or especially swelling of the mouth or throat that makes it difficult to swallow or breathe.

These are all very serious side effects. If you have any of these, it means you are seriously allergic to ACUFIX. You may need urgent medical attention or hospitalization.

Side effects are listed as shown in the following categories:
Very common : may affect at least 1 in 10 patients.
Common : may affect less than 1 in 10 but more than 1 in 100 patients.
Uncommon : may affect less than 1 in 100 but more than 1 in 1,000 patients.
Rare : may affect less than 1 in 1,000 but more than 1 in 10,000 patients.
Very rare : may affect less than 1 in 10,000 patients.
Not known : cannot be estimated from the available data.

Very common
- Temporary burning and stinging following instillation of the medicine
- Conjunctival hyperemia (eye redness)
- Corneal infiltrates (small, blurred, greyish areas on the surface of the eye)
- Headache
- Ocular edema (swelling in the eye)
- Eye pain

Common
- Allergic reactions (swollen eyes, eyelid edema [eyelid swelling] and hyperemia [excessive blood flow to tissues])
- Corneal edema (swelling of the surface of the eye)
- Iritis (inflammation of colored layer of the eye)
- Ocular inflammation (inflammation of the eye)
- Ocular irritation (irritation of the eye)
- Superficial keratitis (inflammation of the surface of the eye)
- Superficial ocular infections (superficial infections of the eye)

Rare
- Corneal ulcer (wound in the transparent layer of the eye)
- Eye dryness
- Vision disorder (blurred vision)

Not known
- Bronchospasm (tightening in the trachea causing breathing difficulty)
- Increase in severity of asthma
- Corneal erosion (superficial damage in the anterior of the eye)
- Corneal perforation (perforation of the eye surface)
- Corneal thinning (thinning of the transparent layer of the eye)
- Corneal melt / Epithelial breakdown (destruction of the surface cells that cover the transparent layer of the eye)

The following serious side effects are mentioned above in the section 'Take special care with ACUFIX':
- Delay in healing
- Cross-sensitivity and hypersensitivity
- Increase in bleeding time
- Effects on the cornea (front layer of the eye)

Reporting of side effects
If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

If you encounter any side effect not listed in this leaflet, inform your doctor or pharmacist.

5. HOW TO STORE ACUFIX

Keep ACUFIX out of the reach and sight of children and in its original package.

Store below 25°C at room temperature.

Once the bottle is opened, the product should be used within 4 weeks if it is stored below 25°C.

Use in accordance with the expiry date.

Do not use ACUFIX after the expiry date, which is stated on the package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Marketing Authorization Holder:
DEVA Holding A.Ş.
Küçükçekmece – İSTANBUL / TÜRKİYE

Manufacturer:
DEVA Holding A.Ş.
Kartepe – KOCAELİ / TÜRKİYE

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