

PATIENT INFORMATION LEAFLET

ENFLUAT 0.4 % Sterile Eye Drops

Applied dropwise to the eye.

- **Drug substance:** Each 1ml contains 4 mg ketorolac tromethamine.
- **Excipient(s):** Benzalkonium chloride, sodium chloride, disodium edetate, octoxinol 40, for pH adjustment sodium hydroxide and/or hydrochloric acid and pure water.

Read all of this 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 individually. Do not pass it on to others.*
- *During the use of this drug, tell your doctor that you are using this medicine when you go to a doctor or hospital.*
- *Please follow what is written in these instructions exactly. Do not use **high or low dose** except the recommended dose of drug.*

In this leaflet:

- 1. What ENFLUAT is and what is it used for?*
- 2. What you need to know before you use ENFLUAT?*
- 3. How to use ENFLUAT*
- 4. What are the possible side effects?*
- 5. How to store ENFLUAT*

1. What ENFLUAT is and what it is used for?

- ENFLUAT is an eye drop containing ketorolac tromethamine as active ingredient and is founded in 5ml transparent LDPE bottles.
- ENFLUAT belongs to a group of medicines known as non-steroidal anti-inflammatory drugs.
- ENFLUAT is used to reduction of ocular symptoms such as ocular pain and foreign object sensation, photophobia, burning/stinging and lachrymation following eye operations called refractive surgery.

Furthermore it has been shown that ketorolac tromethaminine does not affect eye-pressure.

2. What you need to know before you use ENFLUAT?

DO NOT USE ENFLUAT following conditions

- If you are allergic (hypersensitive) to it's active ingredient, or any of the excipients of it.

TAKE SPECIAL CARE with ENFLUAT in following conditions

If:

- You are using contact lenses: Must not be used while using contact lenses. Preservative substance in it can irritate eye. Avoid contact with contact lenses. Take out the contact lenses 15 minutes before the administration. ENFLUAT is known to discolour soft contact lenses.
- You have bleeding tendencies,
- You had an eye operations recently and you have eye surface sicknesses like cornea sickness, diabetes, rheumatoid arthritis, dry eye syndrome,
- You are using medicines that extends bleeding time,
- You had cornea (transparent layer covering the colored side of the eye) sicknesses before,
- You are allergic to acetylsalicylic acid, phenylacetic acid derivatives and other non-steroidal anti-inflammatories (NSAIDs).

If you suffer, or have suffered from in the past, talk to your doctor.

Using of ENFLUAT with food and drink

There is no interaction with food and drink due to usage way.

Pregnancy

Ask your doctor or pharmacist for advice before using the medicine.

ENFLUAT is decided to be used after the risk/benefit evaluations of the doctor.

Please consult your doctor immediately if you notice that you are pregnant during treatment.

Breast-feeding

Ask your doctor or pharmacist for advice before using the medicine.

Must be used carefully during breast feeding.

Driving and using machines

ENFLUAT may cause temporary blurred vision. Do not drive or use machinery until the symptoms have been cleared.

Important information about some of the ingredients of ENFLUAT

The preservative in ENFLUAT, benzalkonium chloride, is known to discolor soft contact lenses. It may cause eye irritation. Contact with soft contact lenses must be avoided. Contact lenses must be removed prior to application, with at least a 15-minute wait before reinsertion.

Using other medicines

Using together with other eye medicines may cause recovery problems.

ENFLUAT is not recommended to be used on patients with bleeding tendency and patients using medicines that extend bleeding time.

If you use ENFLUAT with another eye medicine, leave at least 5 minutes between putting in ENFLUAT and the other medicine.

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

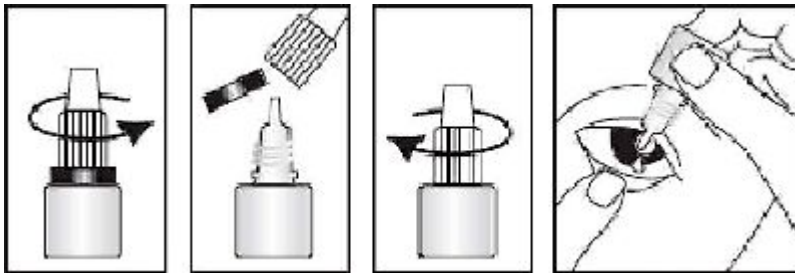
3. How to use ENFLUAT

Instructions for appropriate usage and dose/frequency of application:

It is applied one drop for 4 times a day for up to 4 days following surgery.

Must be used in 4 weeks after opened.

Method of administration



Wash your hands before using the eye drop.

1. Spin the cap and open it.
2. Take out the safety ring on the bottle.
3. Put the cap on the bottle again and spin it. Make sure you close it tight. The tooth inside the cap will pierce the tip of the dropper and ENFLUAT will be ready to be dropped. You don't need to repeat this in the following usages.
4. Tilt your head back and gently pull the lower eyelid down until there is a small pocket
5. DO NOT LET THE DROPPER TOUCH YOUR EYE OR EYELID
6. Turn the bottle upside down and squeeze it to release one drop into each eye that needs treatment
7. Let go of the lower lid, and close your eye for 30 seconds
8. Close the bottle

If a drop misses your eye, try again.

Different age groups:

Children: It is not recommended for use in children younger than 3 years old.

Elderly: There is no need for a special dose for elderly.

Special uses:

Kidney and liver failure:

There is no need for a special dosing of ocular usage in patients with renal or hepatic insufficiency.

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

If you use more ENFLUAT than you should:

If you use more ENFLUAT than you should, talk your doctor or pharmacist.

If you forget to use ENFLUAT:

Do not take a double dose to make up for a forgotten dose.

If you stop using ENFLUAT:

No adverse side effects are expected when ENLUAT treatment ends.

4. Possible side effects

Like all medicines, ENFLUAT can cause side effects in people who are sensitive to its ingredients.

If any of the below effects occur stop using ENFLUAT and IMMEDIATELY inform your doctor or attend to an emergency service of the closest hospital.

- Inflation in hands, feet, wrists, face, lips or especially mouth and throat that can make swallowing and breathing difficult.

These are all very serious side effects. If any of these occur, you are seriously allergic to ENFLUAT.

You may need immediate medical attention or hospital care.

The frequency of adverse reactions is given below and is defined as follows:

Very Common: occurring in more than 1 in 10 patients

Common : occurring in between 1 and 10 patients in every 100

Uncommon : occurring in between 1 and 10 patients in every 1,000

Rare : occurring in between 1 and 10 patients in every 10,000 patients

Very rare : occurring in less than 1 in every 10,000 patients

Not Known : cannot be estimated from available data

Very common:

- Stinging and/or burning in the eye

Common:

- Death of cells on the surface of the eye, allergic reaction, eye and/or eyelid swelling/puffiness, irritation of the eye, itchiness, redness, infection of the eye, inflammation of the eye.

Uncommon:

- Eye rash
- Blurred greyish fields on eye surface
- Headache
- Eye inflation
- Ache in eye
- Allergic reaction
- Eye infection
- Eye irritation
- Eye inflammation

Not known:

- Slimming of transparent layer of eye,
- Pierce in eye surface,
- Superficial damage in front side of eye

Reporting of side effects

If you feel any side effects listed or not listed in this leaflet speak to a doctor, pharmacist or nurse. Furthermore report the side effects you feel by clicking “Reporting Medicine Side Effect” in www.titck.gov.tr or by calling 0 800 314 00 08 side effect report line Turkey Pharmacovigilance Center. By reporting side effects you can help provide more information on the safety of this medicine

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

5. How to store ENFLUAT

Keep out of the sight and reach of children and store in the original pack.

Store the medicine at room temperature below 25°C.

Should be used in 4 weeks after opening.

Please use in accordance with expiration date.

Do not use ENFLUAT after the expiry date on the packaging

Registration Holder: Biem İlaç San. ve Tic. A.Ş.
Turgut Reis Cad. No: 21 06570
Tandođan – Ankara / TURKEY
Tel: 0312 230 29 29
Faks: 0312 230 68 00

Manufacturer: Mefar İlaç Sanayii A.Ş.
Ramazanođlu Mah. Ensar Cad. No: 20
Kurtköy – Pendik / İstanbul

This leaflet was approved on 06/05/2015