FERTEX
Instructions
on medical use of the drug

Trade name of the drug: Fertex.
INN: Ketorolac trometamol.
Dosage form: Eye drops.
Pharmacotherapeutic group: NSAIDs.
Composition: *1 ml of the drug contains:*
Ketorolac trometamol 5 mg.
Pharmacological properties:
Pharmacodynamics:
Ketorolac trometamol is an NSAID that has an analgesic, anti-inflammatory and antipyretic effect, which is due to its ability to suppress the biosynthesis of prostaglandins. When applied topically to the eye, ketorolac reduces the level of prostaglandin E2 in the aqueous humor of the eye.
Ketorolac trometamol does not have a significant effect on intraocular pressure, but changes in intraocular pressure are possible after cataract surgery.
Pharmacokinetics:
Ketorolac trometamol has no significant effect on intraocular pressure. A very low level of ketorolac in the blood plasma or a level that is not detectable after instillation into the conjunctival sac indicates minimal absorption of the drug into the systemic circulation after topical application.
Indications for use:

- Pain and inflammation after cataract surgery;
- Treatment of non-infectious inflammatory eye diseases;
- To reduce the risk of developing macular edema in patients with diabetes after cataract surgery;
- Symptomatic treatment of pain, foreign body sensation, burning sensation in the eye, photophobia, lacrimation after refractive surgery on the cornea.

Mode of application:
For topical use only. The drug is used by adults and children over 12 years of age.
Instillation, into the conjunctival sac.
Before surgery: 1 drop 5 times within 3 hours before surgery. In the postoperative period: 1 drop 3 times a day immediately after surgery, then 1 drop 4 times a day for the time required for treatment (7-10 days).
In the treatment of inflammatory pain syndrome, to relieve tingling in the eyes with seasonal allergic conjunctivitis: 1 drop 4 times a day until clinical cure, but not more than 10 days.
After refractive surgery on the cornea, it is instilled locally into the conjunctival sac of the operated eye 4 times a day to eliminate symptoms for 4 days after surgery.
Children: the safety and effectiveness of the drug in children have not been studied, therefore Fertex should not be used in pediatric practice.
Contraindications:
- hypersensitivity to any of the components of the drug;
- cerebral hemorrhages;
- pregnancy and lactation;
- children's age up to 12 years.

Side effects:
The most common side effects reported in 1–6% of patients were increased intraocular pressure, conjunctival hyperemia and/or hemorrhage, corneal edema, eye pain, headache, lacrimation and blurred vision. Some of these effects may result from cataract surgery.
Special instructions:
Delayed wound healing: Topical NSAIDs may slow or delay the healing process of wounds. Patients should be advised of the possibility of delayed or delayed healing when using NSAIDs.
Occurrence of cross-sensitivity: The drug should be used with caution to treat individuals who have previously been sensitive to acetylsalicylic acid, phenylacetic acid derivatives and other NSAIDs.
Increased bleeding time: With some NSAIDs, there is a risk of increased bleeding time due to interference with platelet aggregation. It has been reported that NSAIDs, which are used to treat eye diseases, may cause increased bleeding in the ocular tissues (including hemorrhages in the anterior chamber of the eye) in combination with ocular surgery.
It is recommended to use the drug with caution in patients who have a tendency to bleed or are taking other medications that may prolong bleeding time.
Corneal effects: The use of topical NSAIDs may result in keratitis. In some susceptible patients, long-term use of topical NSAIDs can lead to epithelial stratification, thinning, erosion, ulceration, and corneal perforation. This can lead to the risk of vision loss. Patients with signs of corneal epithelial separation should immediately discontinue use of topical NSAIDs and undergo a corneal examination.
Intercurrent ocular conditions: Patients should be advised that in the event of intercurrent ocular conditions (for example, injury or infection) or ophthalmic surgery, they should contact an ophthalmologist to determine the possibility of further treatment with the drug.
Concomitant local therapy: Fertex can be used in conjunction with other local ophthalmic drugs, such as α- agonists, β-adrenergic blockers, drugs for the treatment of paralysis of accommodation and mydriatic agents.
If the patient uses more than one ophthalmic drug, an interval of at least 5 minutes between instillations should be observed.
Use when wearing contact lenses: The drug should not be used when wearing contact lenses.
Prevention of microbial contamination of the drug: Do not allow the tip of the bottle to touch your eyes or the surface around the eyes, as this may lead to contamination with bacteria that cause eye infections. Serious eye damage with subsequent loss of vision may result from the use of contaminated solutions.
Use during pregnancy or breastfeeding:
Adequate and strictly controlled studies have not been conducted in pregnant women. The drug should be used during pregnancy only if the expected benefit to the mother outweighs the potential risk to the fetus.
Due to the effect of prostaglandin inhibitors on the fetal cardiovascular system (closure of the ductus arteriosus), the use of the drug should be avoided in late pregnancy. Since most drugs are excreted into breast milk, the drug should be used with caution in breastfeeding women.
The ability to influence reaction speed when driving vehicles or other mechanisms. Adverse effects are not expected to occur when driving or operating machinery, although patients should be warned about the possibility of blurred vision when using the drug.
Drug interactions:
Concomitant ophthalmic medications should be used at least 5 minutes after instillation of Fertex .

Topical corticosteroids are also known to slow down or delay the healing process of wounds. Concomitant treatment with topical NSAIDs and topical steroids may increase the risk of healing problems.
There is a risk of cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives and other NSAIDs.

Overdose:

Usually an overdose does not lead to serious consequences.

Release form:

Eye drops in a bottle of 5 ml.

Storage conditions:

Store at a temperature not exceeding 25 °C.
After opening the bottle, the drug can be used for 4 weeks.

Vacation conditions:

By doctor's prescription.

Made for:
MAXX PHARM LTD.
London, Great Britain