

0.07%
Xirom
Bromfenac 0.07%
Eye Drops

Composition:

Xirom 0.07% Eye Drops: Each ml contains Bromfenac Sodium INN equivalent to Bromfenac 0.7 mg.

Preservative: Sodium Perborate BP 0.02%

Vehicle: Povidone BP 1%.

Pharmacology:

Bromfenac is a nonsteroidal anti-inflammatory drug (NSAID) for ophthalmic use. It has anti-inflammatory potency higher than diclofenac. The mechanism of its action is thought to be due to its ability to block prostaglandin synthesis by inhibiting cyclooxygenase (COX) 1 and 2 enzyme.

Indications: Xirom Eye Drops is indicated for-

- treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery
- treatment of cystoid macular edema (CME) and
- treatment of external or anterior ocular inflammatory diseases

Dosage & administration:

For the treatment of postoperative inflammation in patients who have undergone cataract extraction, instill one drop into the affected eye once daily beginning 1 day prior to surgery, continued on the day of surgery, and through the first 14 days post-surgery.

Treatment of cystoid macular edema (CME): 1 drop for 16 days, beginning day before surgery.

Contra-indications:

Bromfenac Eye Drops is contraindicated in patients with known hypersensitivity to any ingredient in the formulation.

Adverse reactions:

The most commonly reported adverse experiences include: foreign body sensation, photophobia, anterior chamber inflammation and vision blurred.

Warnings and Precautions:

Use of topical NSAIDs in patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients.

All topical nonsteroidal anti-inflammatory drugs (NSAIDs) may slow or delay healing.

It is recommended that Bromfenac eye drops should be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

Bromfenac eye drops should not be administered while wearing contact lenses.

Use in Special group:

Pregnancy: Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Caution should be exercised when Bromfenac Eye Drops is administered to a nursing woman.

Pediatric Use: Safety and efficacy in pediatric patients have not been established.

Geriatric Use: There is no evidence that the efficacy or safety profiles for Bromfenac differ in patients 70 years of age and older compared to younger adult patients.

Storage:

- Store below 30°C temperature in a dry place, protect from light.
- Do not use longer than 30 days after first opening.
- Keep out of the reach of children.

Packing:

Xirom 0.07% Eye Drops: Each LDPE dropper bottle contains 5 ml Sterile Eye Drops.



Manufactured by:
ARISTOPHARMA LTD.
GAZIPUR, BANGLADESH

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