



Bromfenac Eye Drops 0.09%

COMPOSITION

Each mL contains:

Bromfenac Sodium equivalent to Bromfenac	0.09%
Benzalkonium chloride Solution IP (As preservative)	0.01% w/v
Aqueous Buffered Vehicle	q.s.

DESCRIPTION

OCUBRO (Bromfenac) **Eye Drops 0.09%** is a sterile, topical, nonsteroidal anti-inflammatory drug (NSAID) for ophthalmic use.

CLINICAL PHARMACOLOGY

Mechanism of Action

Prostaglandins have been shown in many animal models to be mediators of certain kinds of intraocular inflammation. In studies performed in animal eyes, prostaglandins have been shown to produce disruption of the blood-aqueous humor barrier; cause vasodilation, increased vascular permeability, leukocytosis, and increased intraocular pressure. Bromfenac has analgesic and anti-inflammatory activity. The mechanism of its action is thought to be due to its ability to block prostaglandin synthesis by inhibiting cyclooxygenase 1 and 2.

Pharmacokinetics

The plasma concentration of bromfenac following ocular administration of 0.09% **Bromfenac Eye Drops** in humans is unknown. Based on the maximum proposed dose of one drop to each eye (0.09mg) and PK information from other routes of administration, the systemic concentration of bromfenac is estimated to be below the limit of quantification (50 ng/mL) at steady-state in humans.

Studies with **Bromfenac Eye Drops** in both animals and humans have demonstrated that the drug penetrates rapidly and extensively into all ocular tissues after ophthalmic application. Two animal studies have demonstrated that Bromfenac rapidly achieves measurable levels in all major ocular tissues and that detectable levels are sustained over 24 hours. According to one human study, **Bromfenac Eye Drops** undergoes rapid absorption (within 15 mins), achieves peak aqueous humor concentration of Bromfenac at 150 to 180 minutes after instillation and remains at therapeutic concentrations in the aqueous humor for at least 12 hours.

INDICATIONS

OCUBRO Eye Drops is indicated for the treatment of:

- Postoperative inflammation and reduction of ocular pain in patients who have undergone cataract extraction
- Cystoid Macular Edema (CME) following cataract extraction
- Anterior Uveitis
- Scleritis and Episcleritis

DOSAGE & ADMINISTRATION

For the treatment of postoperative inflammation and the reduction of ocular pain in patients who have undergone cataract extraction, one drop of **OCUBRO Eye Drops** should be applied to the affected eye(s) two times daily beginning 24 hours after cataract surgery and continuing through the first 2 weeks of the postoperative period.

CONTRAINDICATIONS

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

WARNINGS & PRECAUTIONS

OCUBRO Eye Drops contains sodium sulfite. A sulfite may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other NSAIDs. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.

With some NSAIDs, there exists the potential for increased bleeding time due to interference with platelet aggregation. There have been reports that ocularly applied NSAIDs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery.

All topical nonsteroidal anti-inflammatory drugs (NSAIDs) may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs and should be closely monitored.

Postmarketing experience with topical NSAIDs suggests that 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.

Postmarketing experience with topical NSAIDs also suggests that more than 24 hours use prior to surgery or use beyond 14 days post surgery may increase patient risk for the occurrence and severity of corneal adverse events.

It is recommended that **OCUBRO Eye Drops** be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

OCUBRO Eye Drops should not be administered while wearing contact lenses.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term carcinogenicity studies in rats and mice given oral doses of bromfenac up to 0.6 mg/kg/day (360 times the recommended human ophthalmic dose) revealed no significant increases in tumor incidence. Bromfenac did not show mutagenic potential in various mutagenicity studies. Bromfenac did not impair fertility when administered orally to male and female rats at doses up to 0.9 mg/kg/day and 0.3 mg/kg/day, respectively.

Pregnancy and lactation: Pregnancy Category C

There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, the drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Because of the known effects of prostaglandin biosynthesis inhibiting drugs on the fetal cardiovascular system (closure of ductus arteriosus), the use of **Bromfenac Eye Drops** during late pregnancy should be avoided.

Caution should be exercised when **Bromfenac Eye Drops** is administered to a nursing woman.

Pediatric Use

Safety and efficacy in pediatric patients below the age of 18 have not been established.

Geriatric Use

There is no evidence that the efficacy or safety profiles for **Bromfenac Eye Drops** differ in patients 65 years of age and older compared to younger adult patients.

ADVERSE REACTIONS

The most commonly reported adverse reactions reported following use of **Bromfenac Eye Drops** after cataract surgery include: abnormal sensation in eye, conjunctival hyperemia, eye irritation (including burning/stinging), eye pain, eye pruritus, eye redness, headache, and iritis.

PRESENTATION

OCUBRO Eye Drops are available in 5 mL bottles

STORAGE

Store below 30°C protected from light. Do not freeze.