OCUBRO™

Composition:

Each ml of Ocubro eye drops contains:

Bromfenac	0.09% w/v
Benzalkonium chloride	0.01% w/v
Sterile aqueous vehicle	q.s

Pharmacokinetic properties:

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.

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, leucocytosis, 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.

Indication:

- Post-operative inflammation
- Cystoid macular edema
- Uveitis
- Scleritis

Contraindication:

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

Adverse effects:

The most commonly reported adverse reactions reported following use of Ocubro 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.

Warnings and 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. 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.

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.

Post marketing 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.

Post marketing 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.

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

Use in special population:

1. **Pediatric**

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

2. **Geriatric**

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.

3. **Liver impairment**

No data available.

4. **Renal failure**

No data available.

5. **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.

Dosage:

As directed physician.

Presentation:

5ml in plastic bottle.

Storage and handling:

Store at 2°C- 25°C (36°F - 77°F).