

Ocubrom™ 0.09% Eye Drops

Bromfenac 0.09%
Anti-inflammatory Eye Drops

Bromfenac 0.09% ophthalmic solution is a sterile, nonsteroidal anti-inflammatory drug (NSAID). It blocks prostaglandin synthesis by inhibiting cyclooxygenase-1 and cyclooxygenase-2. Prostaglandin causes disruption of the blood-aqueous humor barrier, vasodilation, increased vascular permeability, leukocytosis, and increased intraocular pressure.

COMPOSITION

Ocubrom™ 0.09% Eye Drops: Each ml contains 0.90 mg Bromfenac Free Acid as Bromfenac Sodium INN.

INDICATION

Ocubrom™ 0.09% Eye Drops is indicated for the treatment of postoperative inflammation and the reduction of ocular pain in patients who have undergone cataract extraction.

DOSAGE AND ADMINISTRATION

Adults: 1 drop to the problem eye 2 times a day; treatment should start 24 hours after surgery and should continue for 2 weeks

Children: Use and dose must be determined by the doctor.

CONTRAINDICATION

Bromfenac ophthalmic solution is contraindicated in patients with known hypersensitivity to any ingredient in the formulation.

WARNING

Bromfenac ophthalmic solution contains Sodium Sulfite, a compound that 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. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.

PRECAUTION

All topical 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. It is recommended that Bromfenac ophthalmic solution be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time. Bromfenac ophthalmic solution should not be administered while wearing contact lenses.

USE IN PREGNANCY AND LACTATION

USFDA 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.

Caution should be exercised when Bromfenac ophthalmic solution is administered to a nursing woman.

Pediatric Use

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

SIDE EFFECT

The most commonly reported adverse experiences are: abnormal sensation in eye, conjunctival hyperemia, eye irritation (including burning/stinging), eye pain, eye pruritus, eye redness, headache, and irisitis.

STORAGE

Store below 30°C protected from light. Do not use after 30 days of first opening. Keep out of reach of children.

HOW SUPPLIED

Ocubrom™ 0.09% Eye Drops: Each container contains 5 ml of Bromfenac 0.09% sterile solution.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH