

# Relye

Bromfenac 0.09%

Sterile and Pyrogen free Eye Drops

## Compositions

Each ml contains Bromfenac Sodium INN equivalent to Bromfenac 0.9 mg. Preservative: Benzalkonium Chloride BP 0.1 mg.

## Description

It is a sterile and pyrogen free ophthalmic solution containing Bromfenac-a non steroidal anti- inflammatory drug for topical administration to the eyes.

## Clinical Pharmacology

Bromfenac is a nonsteroidal anti-inflammatory drug (NSAID). The mechanism of anti-inflammatory activity is thought to be due to its ability to block prostaglandin synthesis by inhibiting cyclooxygenase 1 and 2.

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, vasodilation, increased vascular permeability, leukocytosis and increased intraocular pressure.

## Indications

This ophthalmic solution is indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone ocular surgery (cataract extraction, IOL implantation etc).

## Dosage & Administration

For the treatment of postoperative inflammation, one drop of Bromfenac 0.09% ophthalmic solution should be applied to the affected eye(s) two times daily beginning 24 hours after ocular surgery and continuing through the first 2 weeks of the postoperative period.

## Contraindications

Known hypersensitivity to Bromfenac, benzalkonium chloride or any other ingredients in this product.

## Precautions

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.

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.

## Use In Pregnancy and Lactation

Pregnancy: There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: 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.

## Side-Effects

The most commonly reported adverse reactions following use of Bromfenac after cataract surgery include: abnormal sensation in eye, conjunctival hyperemia, eye irritation (including burning/stinging), eye pain, eye pruritus, eye redness, headache and iritis. These events were reported in 2-7% of patients.

## Overdosage

Specific studies are not available.

## Pharmaceutical Precautions

Store in a cool and dry place. Do not touch the dropper tip to any surface. It is desirable that the contents should not be used more than one month after first opening of the bottle.

## Commercial Pack

Plastic dropper bottle of 5 ml.

## Manufactured by

Popular Pharmaceuticals Ltd. for



For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.