

Romfen®

Bromfenac Sodium INN
Sterile Ophthalmic Solution

DESCRIPTION

Romfen® is a preparation of Bromfenac ophthalmic solution. Bromfenac is a nonsteroidal anti-inflammatory drug (NSAID) that has 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. Prostaglandins have been shown 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, vasodilatation, increased vascular permeability, leukocytosis, and increased intraocular pressure.

INDICATIONS

Romfen® ophthalmic solution is indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract extraction.

DOSAGE & ADMINISTRATION

For the treatment of postoperative inflammation in patients who have undergone cataract extraction, one drop of **Romfen®** ophthalmic solution should be applied to the affected eye(s) once daily beginning 1 day prior to cataract surgery, continued on the day of surgery, and through the first 14 days of the postoperative period.

CONTRAINDICATIONS

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

SIDE EFFECTS

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

PRECAUTION & WARNING

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.

USE IN PREGNANCY & LACTATION

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 have not been established.

PHARMACEUTICAL PRECAUTION

Store in a cool (below 30°C), dry place and away from light. Keep out of reach of children. To prevent contamination of the dropper tip and solution, care should be taken. Don't touch the eyelids, surrounding areas, finger or other surfaces with the dropper tip of the bottle. The bottle should be tightly closed when not in use. Do not use after 4 weeks of first opening.

PACKAGING

Romfen® Ophthalmic Solution: Plastic dropper bottle containing 5 ml sterile ophthalmic solution. Each ml contains Bromfenac Sodium INN equivalent to Bromfenac 0.9 mg.

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Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

GAZIPUR, BANGLADESH

® REGD. TRADEMARK

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