

Rotarac[®] LS

Bromfenac 0.07% eye drops

Description

Rotarac[®] LS eye drops is a sterile, topical ophthalmic solution containing Bromfenac which is a nonsteroidal anti-inflammatory drug (NSAID). It works by blocking prostaglandin synthesis by inhibiting cyclooxygenase (COX) 1 and 2, thus reduces pain and inflammation.

Indications

Rotarac[®] LS eye drops is indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

Dosage & administration

Recommended dosing in adults: One drop 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 postoperative period.

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

Geriatric use: No overall difference in safety or effectiveness has been observed between elderly and younger 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 eye drops is administered to a lactating mother.

Side effects

The most common side effects include abnormal sensation in eye, conjunctival hyperemia, eye irritation (including burning / stinging), eye pain, eye pruritus, eye redness, headache and iritis.

Contraindications

Bromfenac eye drops is contraindicated in patients with known hypersensitivity to Bromfenac or any of its ingredients.

Precautions

Topical NSAIDs should be used with caution in 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. This may increase risk of corneal adverse effects which may become sight threatening. It is recommended that Bromfenac eye drops should be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

Warnings

Bromfenac eye drops should not be administered while wearing contact lenses.

Drug interactions

Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

Overdose

Not known and not likely.

Pharmaceutical precautions

- Store in a cool and dry place protected from light.
- Do not use after one month once the cap is opened.

Presentation

Rotarac[®] LS eye drops: Each ml contains Bromfenac 0.7 mg as Sodium INN.

Package quantities

Rotarac[®] LS eye drops: Plastic dropper bottle of 5 ml.

® Registered Trade Mark



ACI Limited
Narayanganj, Bangladesh