Nepagen TS

Nepafenac

Sterile Ophthalmic Suspension

Presentation

Nepagen TS: Each ml sterile Ophthalmic Suspension contains Nepafenac INN 3 mg. *Preservative*: Benzalkonium Chloride 0.005%

Pharmacological Action

Nepafenac is a nonsteroidal anti-inflammatory drug (NSAID) that inhibits the action of cyclooxygenase (COX) enzymes which are responsible for biosynthesis of prostaglandins. Ocular hydrolases convert nepafenac to amfenac which is also a NSAID. Both nepafenac and amfenac inhibit the action of COX-1 and COX-2 with more selectivity for COX-1.

Indications

Nepagen TS ophthalmic suspension is indicated for management of pain and inflammation associated with cataract surgery.

Dosage and Application

One drop of Nepagen TS ophthalmic suspension should be applied to the affected eye(s) once daily beginning 1 day prior to cataract surgery, and continued on the day of surgery for up to 2 weeks of the postoperative period. An additional drop should be administered 30 to 120 minutes prior to surgery.

Contraindications

Nepagen TS ophthalmic suspension is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formulation or to other NSAIDs.

Side Effects

The most common side effects include eye pain, abnormal sensation in the eye, crusty eyelids, and eye surface inflammation.

Less common side effects include eye surface damage with loss of cells, blurred vision, eye itching, dry eye, eye discharge, increased tear production, eyelid inflammation, sensitivity to light, eye allergy.

Precautions

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, and corneal ulceration.

Drug Interactions

Nepagen TS ophthalmic suspension may be administered in conjunction with other topical ophthalmic medications such as beta-blockers, carbonic anhydrase inhibitors, alpha-agonists, cycloplegics, and mydriatics.

Use in Pregnancy and Lactation

Pregnancy Category C

It is not known whether this drug is excreted in human milk. So caution should be exercised when Nepafenac ophthalmic suspension is administered to a nursing mother.

Pediatric Use

The safety and effectiveness of Nepafenac ophthalmic suspension in pediatric patients below the age of 10 years have not been established.

Over Dose

A topical over dosage may be flushed from the eye(s) with warm tap water.

Storage Conditions

Store the dropper between 2 to 25°C. Keep out of reach of children. Do not touch the dropper tip to surfaces since this may contaminate the solution. After one month of the opening do not use the medicine of dropper.

Commercial Pack

Napagen TS: Each plastic dropper bottle containing 5 ml Sterile Ophthalmic Suspension.

Manufactured by :



Revision.: 00 22060259