For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

Sensonac™

Eye Drops

(Nepafenac Ophthalmic Suspension)

COMPOSITION:

Nepafenac ..... 0.1% w/v
Benzalkonium chloride Solution IP..... 0.01% v/v
(As preservative)
Water for Injections IP ..... q.s.

Pharmacological Action

SENSONAC Eye Drops contains Nepafenac (0.1%), a nonsteroidal anti-inflammatory and analgesic prodrug. After topical ocular dosing, nepafenac penetrates the cornea and is converted by ocular tissue hydrolases to amfenac, a potent nonsteroidal anti-inflammatory drug. Amfenac is thought to inhibit the action of prostaglandin H synthase (cyclooxygenase) an enzyme required for prostaglandin production. In rabbits, a single topical ocular dose of nepafenac (0.1%) leads to a uniform inhibition (80% to 100%) of prostaglandin formation by the iris/ciliary body. Suppression of prostaglandin E2 synthesis is maintained for a period of greater than 6 hours and is accompanied by a nearly 8 hour suppression of trauma induced vascular leakage of the blood aqueous barrier.

Pharmacokinetics

Drug-Drug Interaction: Nepafenac at concentrations up to 300mg/mL did not inhibit the in vitro metabolism of 6 specific marker substrates of cytochrome P450 (CYP) isozymes (CYPIA2, CYP2C9, CYP2C19, CYP2D6, CYP2E1, and CYP3A4). Therefore, drug-drug interactions involving CYP-mediated metabolism of concomitantly administered drugs are unlikely. Drug-drug interactions mediated by protein binding are also unlikely.

Gender: Data in healthy subjects indicate no clinically relevant or significant gender difference in the steady-state pharmacokinetics of amfenac following three-times- daily dosing.

Low but quantifiable plasma concentrations of nepafenac and amfenac were observed in the majority of subjects 2 and 3 hours postdose, respectively, following bilateral topical ocular TID dosing of Nepafenac 0.1% Eye Drops. The mean steady- state Cmax for Nepafenac and for amfenac were 0.310 ± 0.104 mg/mL and 0.422 ± 0.121mg/mL, respectively, following ocular administration.

Indications

SENSONAC 0.1% Eye Drops is indicated for the inhibition and treatment of pain and inflammation associated with cataract surgery.

Dosage and Administration

Shake well before use. One drop of SENSONAC 0.1% Eye Drops should be applied to the affected eye(s) three-times-daily beginning 1 day prior to cataract surgery, and continued on the day of surgery and through the first 2 weeks of the postoperative period.

SENSONAC has been safely administered in conjunction with other ophthalmic medications such as antibiotics, anesthetics, beta-blockers, carbonic anhydrase inhibitors, alpha-agonists, cycloplegics, and mydriatics.

Contraindications

SENSONAC 0.1% Eye Drops is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formulation or to other NSAIDs.

Warnings

For topical use only and not for injection or oral use.

Precautions

General: There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other nonsteroidal anti-inflammatory agents. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.

With some nonsteroidal anti-inflammatory drugs including SENSONAC, there exists the potential for increased bleeding time due to interference with thrombocyte aggregation. There have been reports that ocularly applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery. Topical nonsteroidal anti-inflammatory drugs (NSAIDs) including SENSONAC, 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. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs including SENSONAC and should be closely monitored for corneal health.

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.

STORAGE

Keep in a cool place. Use the suspension within one month after opening the container.

Protect from light.

KEEP OUT OF REACH OF CHILDREN

NOT FOR INJECTION

FOR EXTERNAL USE ONLY

SHAKE WELL BEFORE USE

PRESENTATION

SENSONAC is a sterile suspension supplied in plastic opaque dropper bottle with a cap, containing 5ml of the suspension.

Directions for use:

Turn the tamper proof cap anti-clockwise to break the seal.

Remove the cap, dispense drops with gentle pressure.

Replace the cap immediately after every use.

Manufactured in INDIA by :

Senses Pharmaceuticals Pvt. Ltd.,

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