Sensonac® Forte

Eye Drops

(Nepafenac Ophthalmic Suspension 0.3% w/v)

COMPOSITION:

Nepafenac	0.3% w/v
Benzalkonium Chloride Solution IP (as preservative)	0.01% v/v
Water for Injections IP	q.s.

Pharmacological Action

Sensonac Forte Eye Drops contains Nepafenac (0.3%), 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 (0.3%) 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 (CYPlA2, 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 oculat TID dosing of Nepafenac 0.3% 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 Forte Eye Drops is indicated for the inhibition and treatment of pain and inflammation associated with cataract surgery.

Dosage and Administration

Shake well before use. Dosage: One drop of Nepafenac ophthalmic suspension, 0.3% should be applied to the affected eye one-time-daily beginning 1 day prior to cataract surgery, continued on the day of surgery and through the first 2 weeks of the postoperative period. An additional drop should be administered 30 to 120 minutes prior to surgery, or as directed by the Ophthalmologist.

Sensonac Forte 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 Forte 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 Forte, 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 Forte, 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 Forte 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

Store below 30°C, Do Not Freeze. Use the suspension within one month after opening the container. If the suspension becomes dark brown, it should be discarded. Protect from light.

KEEP OUT OF REACH OF CHILDREN

NOT FOR INJECTION

FOR EXTERNAL USE ONLY

SHAKE WELL BEFORE USE

PRESENTATION

Sensonac Forte contains is 5 mL of greenish yellow colour sterile suspension supplied in opaque dropper bottle with cap.

Directions for use:

Turn the tamper proof cap anti clockwise to break the seal and remove the cap.

Remove and discard the tamper proof ring from the container.

Tilt your head back. Gently pull your lower eyelid downwards to form a pocket between your eyelid and your eye, look up.

Turn the container upside down, place the dropper tip close to your eye but be careful not to touch your eye with it and gently press the container with thumb and index finger to dispense the drop.

Replace the cap by turning clockwise direction until it is firmly touching the bottle. Do not overtighten the cap.

Manufactured in INDIA by :

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