Opanac® Eye Drops

Nepafenac 0.1% ophthalmic suspension

Description: Non steroidal anti-inflammatory (NSAID) prodrug for ophthalmic use.

Indications: Nepafenac ophthalmic suspension is indicated for the treatment of pain and inflammation associated with cataract surgery.

Dosage: One drop of Nepafenac should be applied to the affected eye(s) three-times-daily beginning 1 day prior to cataract surgery, continued on the day of surgery and through the first 2 weeks of the postoperative period. Nepafenac may be administered in conjunction with other topical ophthalmic medications such as beta-blockers, carbonic anhydrase inhibitors, alpha-agonists, cycloplegics and mydriatics.

Side Effects: The most frequently reported ocular adverse reactions following cataract surgery were capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure and sticky sensation. These reactions occurred in approximately 5 to 10% of patients. Other ocular adverse reactions occurring at an incidence of approximately 1 to 5% included conjunctival edema, corneal edema, dry eye, lid margin crusting, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, photophobia, tearing and vitreous detachment. Some of these reactions may be the consequence of the cataract surgical procedure. Non-ocular adverse reactions reported at an incidence of 1 to 4% included headache, hypertension, nausea/vomiting and sinusitis.

Contraindications: Nepafenac is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formula or to other NSAIDs.

Warning: 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 Nepafenac, 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.

Precaution: Topical nonsteroidal anti-inflammatory drugs (NSAIDs) including Nepafenac, 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 Nepafenac and should be closely monitored for corneal health. 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 may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients. Postmarketing experience with topical NSAIDs also suggests that use more than 1 day prior to

surgery or use beyond 14 days post surgery may increase patient risk for occurrence and severity of corneal adverse events. It is recommended that Nepafenac ophthalmic suspension be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

High Risk Group: Nepafenac should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Nepafenac ophthalmic suspension is administered to a nursing woman. Pediatric Use: The safety and effectiveness of Nepafenac in pediatric patients below the age of 10 years have not been established.

Drug Interactions: No information available.

Pharmaceutical Precautions: Store in a cool and dry place, away from light. Keep out of reach of children. Shake well before each use.

Commercial Pack: Opanac® Eye Drops: Plastic dropper bottle contains 3 ml sterile Suspension. Each ml contains Nepafenac INN 1 mg.

Manufactured by
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