# Optafenac™ TS

Nepafenac 0.3%

Sterile Ophthalmic Suspension

**Description**
Optafenac TS is a sterile ophthalmic suspension containing nepafenac 0.3%- a non steroidal anti-inflammatory drug for topical administration to the eyes.

**Composition**
Each ml Optafenac TS ophthalmic suspension contains:
Active Substance: Nepafenac INN 3 mg.
Preservative: Benzalkonium Chloride 0.05 mg.

**Clinical Pharmacology**
Optafenac TS is a nonsteroidal anti-inflammatory prodrug (NSAID). After instillation in the eye, it penetrates the cornea and is converted by ocular tissue hydrolase to Amfenac, a potent nonsteroidal anti-inflammatory drug. Amfenac is thought to inhibit the action of cyclooxygenase enzyme. This enzyme is required for prostaglandin synthesis.

**Indications and Uses**
Optafenac TS ophthalmic suspension is indicated for:
- The treatment of post-operative ocular pain and inflammation including cataract surgery
- Inhibition of surgery induced miosis and
- Prevention of post-operative cystoid macular edema (CME)

**Dosage and Administration**
One drop of Optafenac TS ophthalmic suspension 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.

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

**Warning & Precautions**
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, so nepafenac should be used with caution in patients with known bleeding tendencies.

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. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs including Nepafenac and should be closely monitored for corneal health.

**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.

**Use in special groups**
*Pregnancy:* There are no adequate and well-controlled studies in pregnant women. Nepafenac should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

*Lactation:* 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.

*Use in children:* Safety and effectiveness in pediatric patients below 10 years of age have not been established.

*Use in elderly patients:* No overall differences in safety or effectiveness have been observed between elderly and younger patients.

**Drug Interactions**
Specific drug interaction studies have not been conducted with Nepafenac ophthalmic suspension.

**Overdosage**
No data are available in humans regarding overdosage by accidental or deliberate ingestion.

**Pharmaceutical Precautions**
Store at room temperature, protect from light and freezing. It is desirable that the contents should not be used more than 1 month after first opening of the bottle.

**Commercial Pack**
A sterile ophthalmic suspension in 5 ml plastic dropper bottle.

Manufactured by :

POPULAR

***POPULAR PHARMACEUTICALS LTD.***
TONGI, GAZIPUR, BANGLADESH

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