VENAC EYE DROPS

Nepafenac Ophthalmic Suspension
0.1% (5 mL) and 0.3% (3 mL)

COMPOSITION

Venac 0.1%: Each 1 mL contains Nepafenac 1 mg.
Venac 0.3%: Each 1 mL contains Nepafenac 3 mg.
Other ingredients are as per the approved formulation.

THERAPEUTIC CLASS

Topical ophthalmic non-steroidal anti-inflammatory drug (NSAID); prodrug. Medical segment: Ophthalmology, particularly cataract surgery.

PHARMACOLOGY

Nepafenac penetrates ocular tissues and is converted by ocular hydrolases to amfenac, which inhibits cyclooxygenase and prostaglandin synthesis. It reduces postoperative ocular pain and inflammation.

INDICATIONS

Treatment of pain and inflammation associated with cataract surgery in patients for whom nepafenac ophthalmic treatment is appropriate. Other indications, including prevention of postoperative macular oedema in selected patients, depend on country-specific approval.

DOSAGE: VENAC 0.1%

Instil **one drop into the affected eye three times daily**, beginning one day before cataract surgery, continuing on the day of surgery and through the first two weeks after surgery, unless the ophthalmologist directs otherwise.

DOSAGE: VENAC 0.3%

Instil **one drop into the affected eye once daily**, beginning one day before cataract surgery, continuing on the day of surgery and through the first two weeks after surgery. Administer **one additional drop 30 to 120 minutes before surgery**, as directed by the ophthalmologist.

METHOD OF ADMINISTRATION

For ophthalmic use only. **Shake well before use** if supplied as a suspension. Wash hands; tilt head back and pull lower lid down; instil the prescribed drop without touching the tip to the eye or any surface. Close the eye gently. Separate other topical ophthalmic medications by at least five minutes. Do not inject or swallow.

CONTRAINDICATIONS

Known hypersensitivity to nepafenac, any formulation ingredient or other NSAIDs.

WARNINGS: CORNEAL EFFECTS

Topical NSAIDs may cause keratitis and, in susceptible patients, epithelial breakdown, corneal thinning, erosion, ulceration or perforation, potentially threatening sight. Stop treatment and obtain urgent ophthalmic assessment if corneal damage is suspected.

WARNINGS: HEALING AND BLEEDING

Topical NSAIDs may slow or delay healing. Concomitant topical corticosteroids can increase healing problems. Ocular bleeding, including hyphema, may occur; use caution in patients with bleeding disorders or taking medicines that prolong bleeding time.

ADDITIONAL PRECAUTIONS

Patients with complicated ocular surgery, corneal denervation or epithelial defects, diabetes, rheumatoid arthritis, dry-eye disease or repeated surgery may have increased risk of corneal adverse events. Prolonged use beyond the recommended perioperative period may increase risk. Avoid contaminating the bottle.

CONTACT LENSES

Contact lenses should not be worn during treatment unless the ophthalmologist specifically advises otherwise. Follow preservative-specific instructions for lens use if relevant.

DRUG INTERACTIONS

Concomitant topical corticosteroids may increase the potential for healing complications. Use caution with systemic anticoagulants or other drugs affecting bleeding. Tell the prescriber about all ocular and systemic medications.

PREGNANCY AND LACTATION

Use during pregnancy only if clearly needed after medical assessment. NSAID-related fetal risks, particularly later in pregnancy, should be considered. Human milk excretion after ophthalmic use is uncertain; use caution while breastfeeding.

PAEDIATRIC AND ELDERLY USE

Paediatric safety and effectiveness may not be established for all formulations. Clinical experience in older adults has not identified a consistent difference in response; follow approved labeling and clinical judgment.

ADVERSE REACTIONS

Possible reactions include eye discomfort, foreign-body sensation, blurred or reduced vision, increased intraocular pressure, sticky sensation, conjunctival irritation and hypersensitivity. Serious corneal injury and ocular bleeding require urgent evaluation.

OVERDOSAGE

Excess topical dosing may increase local adverse effects. If accidentally swallowed, seek medical advice. Management is supportive and based on clinical assessment.

STORAGE

Store according to the approved Venac product specifications. Keep tightly closed and protected from contamination. Follow the validated discard period after opening; keep out of reach of children.

PRESENTATION

Venac Eye Drops 0.1%: 5 mL bottle.
Venac Eye Drops 0.3%: 3 mL bottle.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.