

Nepafenac INN Sterile Ophthalmic Suspension

## Composition:

Nevan Sterile Ophthalmic Suspension: Each ml contains Nepafenac INN 1 mg.

Nevan TS Sterile Ophthalmic Suspension: Each ml contains Nepafenac INN 3 mg.

### Vehicle:

Nevan TS Sterile Ophthalmic Suspension: Carbomer 980 USP 0.4%. Nevan TS Sterile Ophthalmic Suspension: Carbomer 980.

## Pharmacology:

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Nepafenac 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:

  Nevan Sterile Ophthalmic Suspension
  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).

  Nevan TS Sterile Ophthalmic SuspensionPost-operative pain and inflammation associated with cataract surgery.

### Dosage & administration:

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Nevan Sterile Ophthalmic Suspension: For post-operative pain & inflammation: Instill 1 drop 3 times daily 1 day prior to cataract surgery and continued on the day of surgery and through the first 2 weeks of the post-operative period.
For surgery induced miosis: Instill 1 drop 3 times daily 1 day before surgery & on the day of surgery.
For prevention of post-operative CME: Instill 1 drop 3 times daily 1 day before surgery and continued on the day of surgery and through the first 6 weeks of the post-operative period.

Nevan TS Sterile Ophthalmic Suspension: For post-operative pain & inflammation: Instill 1 drop once daily 1 day prior to cataract surgery and continued on the day of surgery and through the first 2 weeks of the post-operative period. An additional drop should be administered 30 to 120 minutes prior to surgery.

Contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formulation or to other NSAIDs.

Side effects:
Reported side effects are foreign body sensation, lid margin crusting, ocular discomfort, ocular hyperemia etc.

# Precautions:

Nepafenac should be used with caution in patients with known bleeding tendencies or who are receiving medications which may prolong bleeding time.

Use in special group:
Use in 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.

been in actation. 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.

Safety and effectiveness in pediatric patients below 18 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

# Storage:

- Store below 30°C, protect from light.
   Do not use longer than 30 days after first opening.
   Keep out of the reach of children.

Packing:
Nevan Sterile Ophthalmic Suspension: Each plastic dropper bottle contains 5 ml sterile ophthalmic suspension.
Nevan TS Sterile Ophthalmic Suspension: Each plastic dropper bottle contains 5 ml sterile ophthalmic suspension.

**ARISTOVISION** 

