

Nesudil

Netarsudil INN 0.02% &
Latanoprost USP 0.005% *Plus*
Ophthalmic Solution

Composition:

Nesudil Plus Ophthalmic Solution: Each ml contains Netarsudil Dimesylate INN equivalent to Netarsudil 0.20 mg and Latanoprost USP 0.05 mg.

Preservative: Sodium Perborate BP 0.01%

Pharmacology:

Nesudil Plus is a fixed-dose combination of a Rho kinase inhibitor and a Prostaglandin F_{2α} analogue. Netarsudil is a Rho kinase inhibitor, works at the cellular level within the trabecular outflow pathway to relax actin-myosin. This causes relaxation within the trabecular meshwork and the inner wall of Schlemm's canal, and decrease episcleral venous pressure (EVP).

Latanoprost is a selective FP receptor agonist which reduces the intraocular pressure (IOP) by increasing the outflow of aqueous humor through uveoscleral outflow.

Indications:

Nesudil Plus is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

Dosage and Administration:

The recommended dosage is one drop in the affected eye(s) once daily in the evening.

Contraindication:

This eye drops is contraindicated in patients who are hypersensitive to any component of this preparation.

Side Effects:

The most common ocular adverse reaction observed in controlled clinical studies with Netarsudil & Latanoprost was conjunctival hyperemia, instillation site pain, corneal verticillata, instillation site discomfort, foreign body sensation and blurred visions were reported in few patients.

Precautions:

- For ophthalmic use only
- To avoid possible contamination of the drops, do not touch the dropper tip or to any surface
- Should be used with caution in patients with active intraocular inflammation (e.g., iritis/uveitis)
- May cause changes to pigmented tissues, gradually change eyelashes and vellus hair in the treated eye
- Cystoid macular edema, has been reported during treatment with Latanoprost. Reactivation of Herpes Simplex keratitis may occur
- Netarsudil & Latanoprost combination can be used with other topical eye drug products, but they should be administered at least 5 minutes apart from each other

Use in special group:

Pregnancy: There are no adequate and well-controlled studies of Netarsudil & Latanoprost combination in pregnant women to inform any drug associated risk.

Lactation: There are no data on the presence of Netarsudil or Latanoprost in human milk, the effects on the breastfed infant, or the effects on milk production.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Use in elderly patients: No overall differences in safety and effectiveness have been observed between elderly and other adult patients.

Storage:

- Store at 2°-8°C in a dry place, protect from light until opened.
- After opening the product may be kept at 2°-25°C for upto 6 weeks.
- Keep out of the reach of children.

Packing:

Nesudil Plus Ophthalmic Solution: Each LDPE dropper bottle contains 3 ml Sterile Eye Drops.



Manufactured by:
ARISTOPHARMA LTD.
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