ZULTAN

Latanoprostene Bunod 0.024%

Ophthalmic Solution

Composition:
Zultan Ophthalmic Solution: Each ml contains Latanoprostene Bunod INN 0.24 mg.

Preservative:
Benzalkonium Chloride.

Pharmacology:
Latanoprostene bunod is thought to lower intraocular pressure via a dual mechanism of action since the medication is metabolized into two relevant moieties upon administration: (1) latanoprost acid, and (2) Butanediol mononitrate
As a prostaglandin F2-alpha analog, the latanoprost acid moiety operates as a selective PGF2-alpha (FP) receptor agonist which reduces the intraocular pressure (IOP) by increasing the outflow of aqueous humor through uveoscleral outflow.
Butanediol Mononitrate consequently enters the cells of the Trabecular Meshwork and inner wall of Schlemm's canal, decreases the cell contractility and volume, This allows for enhanced conventional outflow of aqueous humor through Trabecular Meshwork.

Indications:
Zultan ophthalmic solution is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

Dosage and Administration:
The recommended dosage is one drop in the conjunctival sac of the affected eye(s) once daily in the evening.

Contraindications:
Latanoprostene Bunod eye drops is contraindicated in patients who are hypersensitive to any component of this preparation.

Adverse Effects:
The reported most common ocular adverse reaction is: Pigmentation, Eyelash Changes, Intraocular Inflammation, Macular Edema, Bacterial Keratitis etc.

Precautions:
- For ophthalmic use only.
- To avoid possible contamination of the drops, do not touch the dropper tip.
- Should be used with caution in patients with a history of intraocular inflammation (iritis/uveitis) and should generally not be used in patients with active intraocular inflammation.
- May cause changes to pigmented tissues, gradually change eyelashes and vellus hair in the treated eye.
- Contact lenses should be removed before the administration of Latanoprostene Bunod and may be reinserted 15 minutes after administration.
- Latanoprostene Bunod can be used with other topical eye drug products, but they should be administered at least 5 minutes apart from each other.

Overdose:
Do not administer Latanoprostene Bunod ophthalmic solution more than once daily since it has been shown that more frequent administration of prostaglandin analogs may lessen the intraocular pressure lowering effect.

Use in Special Groups:
Use in Pregnancy: There are no available human data for using Latanoprostene Bunod during pregnancy to inform any drug-associated risks.
Lactation: There are no data on the presence of Latanoprostene Bunod in human milk, the effects on the breastfed infant, or the effects on milk production.
Use in the Paediatric population: Paediatric patients aged 16 years and younger are not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.
Use in Geriatric Patients: No overall clinical differences in safety or effectiveness have been observed between elderly and other adult patients.

Storage:
- Protect from light. Store at 2°C to 8°C.
- Once a bottle is opened it may be stored at 2° to 25°C.
- Keep out of the reach of children.

Packing:
Zultan Ophthalmic Solution: Each LDPE dropper bottle contains 3 ml Sterile Eye Drops.

ARISTOVISION

Manufactured by:
ARISTOPHARMA LTD.
GAZIPUR, BANGLADESH

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