Latanomia

Sterile Ophthalmic Solution

Composition:
Each 1 ml of **Latanomia** Ophthalmic Solution Contains: Latanoprost 50 mcg, benzalkonium chloride 0.02% as preservative.
Excipients:
Sodium Chloride, dibasic sodium phosphate, monobasic sodium phosphate, Water for injection QS to 2.5 mL

Mechanism of action:
Latanoprost is a prostaglandin F2α analogue that is believed to reduce the IOP by increasing the outflow of aqueous humor. Studies in animals and human suggest that the main mechanism of action is to increase uveoscleral outflow. Elevated IOP represents a major risk factor for glaucomatous field loss. The higher the level of IOP, the greater the likelihood of optic nerve damage and visual field loss.

Pharmacodynamics:
Reduction of intraocular fluid pressure in humans begins about 3-4 hours after administration and the maximum effect is reached after 8-12 hours. Reduction of intraocular fluid pressure is present for at least 24 hours.

Pharmacokinetic:
Absorption:Latanoprost is absorbed through the cornea where the isopropyl ester prodrug is hydrolyzed to the acid form to become biologically active.
Distribution: The distribution volume in humans is 0.16 ± 0.02 L/kg. The acid of latanoprost can be measured in aqueous humor during the first 4 hours, and in plasma only during the first hour after local administration. Studies in human indicate that the peak concentration in the aqueous humor is reached about two hours after topical administration.
Metabolism: Latanoprost, an isopropyl ester prodrug, is hydrolyzed by esterases in the cornea to the biologically active acid. The active acid of latanoprost reaching the systemic circulation is primarily metabolized by the liver to the 1,2-dinor and 1,2,3,4-tetranor metabolites via fatty acid β-oxidation.
Elimination: The elimination of the acid of latanoprost from human plasma is rapid (t = 17 min) after both IV and topical administration. Systemic clearance is approximately 7 mL/min/kg. Following hepatic β-oxidation, the metabolites are mainly eliminated via the kidneys. Approximately 88% and 98% of the administered dose are recovered in the urine after topical and IV dosing, respectively.

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

Contraindications:
Latanomia ophthalmic solution is not indicated when there is known hypersensitivity to latanoprost, benzalkonium chloride, or any other ingredients in this product.

Warnings and precautions:
Pigmentation: **Latanomia** ophthalmic solution has been reported to cause changes to tissues pigmentation. The most frequently reported changes have been increased pigmentation of the iris, periorbital tissue (eyelid), and eyelashes. Pigmentation is expected to increase as long as latanoprost is administered. The pigmentation change is due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. After discontinuation of latanoprost, pigmentation of the iris is likely to be permanent, while pigmentation of the periorbital tissue and eyelash changes have been reported to be reversible in some patients. Patients who receive treatment should be informed of the possibility of increased pigmentation. Beyond 5 years the effects of increased pigmentation are not known. Iris color change may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither nevi nor freckles of the iris appear to be affected by treatment. While treatment with Latanomia can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.
Eyelash Changes: **Latanomia** ophthalmic solution may gradually change eyelashes and vellus hair in the treated eye, these changes include increased length, thickness, pigmentation, the number of lashes or hairs, and misdirected growth of eyelashes. Eyelash changes are usually reversible upon discontinuation of treatment.
Pink Eye: **Latanomia** ophthalmic solution 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 because inflammation may be exacerbated.
Macular Edema: Macular edema, including cystoid macular edema, has been reported during treatment with **Latanomia** ophthalmic solution, Latanoprost should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.
Herpetic Keratitis: Reactivation of herpes simplex keratitis has been reported during treatment with **Latanomia** ophthalmic solution. Latanoprost should be used with caution in patients with a history of herpetic keratitis. Latanoprost should be avoided in cases of active herpes simplex keratitis because inflammation may be exacerbated.
Bacterial Keratitis: There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface.
Contact Lens Use: **Latanomia** ophthalmic solution contains benzalkonium chloride, which may be absorbed by contact lenses. Contact lenses should be removed prior to the administration of **Latanomia** ophthalmic solution, and may be reinserted 15 minutes after administration.

Patient Counseling Information
Possibility of pigmentation: Instruct patients about the possibility of increased brown pigmentation of the iris, which may be permanent. Inform patients of the possibility of eyelid skin darkening, which may be reversible after discontinuation of latanoprost ophthalmic solution
Possible changes in eyelashes: Inform patients of the possibility of changes in eyelash hair and villi in the treated eye during treatment with latanoprost solution. These changes may result in interocular discrepancies in length, thickness, pigmentation, number of eyelashes or villi, and/or the direction of eyelash growth. Eyelash changes can usually be reversed upon discontinuation of treatment.
Use with other eye medications: Inform patients that if more than one topical ophthalmic drug is used, the drugs should be administered at an interval of at least five (5) minutes.

Undesirable effects:
The following adverse reactions were reported:
- Iris pigmentation changes - Darkening of the eyelid skin - Eyelashes changes (increased length, thickness, pigmentation, and number of eyelashes)
- Intraocular inflammation (iritis/ uveitis) - Macular edema, including cystic macular edema

Ocular Adverse Reactions and Ocular Signs/Symptoms Reported by 5-15% of Patients Receiving Latanoprost:
Foreign body sensation, Punctate keratitis, Conjunctival hyperemia, blurred vision, Itching, Burning, Increased pigmentation of the iris.
Adverse Reactions That Were Reported in 1–5% of Patients Receiving Latanoprost:
Excessive tearing, Eyelid discomfort/pain, Dry eye, Eye pain, Eyelid margin crusting, Erythema of the eyelid Photophobia, Eyelid edema, Blepharitis

Pregnancy and lactation:
Pregnancy: There are no adequate and well-controlled studies of Latanomia ophthalmic solution administration in pregnant women.
Lactation: It is not known whether this drug or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when **Latanomia** ophthalmic solution is administered to a nursing woman.
The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for products containing latanoprost and any potential adverse effects on the breastfed child from Latanomia ophthalmic solution.

Children and Elderly people:
- Safety and effectiveness in pediatric patients have not been established.
- Use in elderly people:No overall differences in safety or efficacy were observed between the elderly and younger patients

Dosage and administrations:
- The recommended dosage is one drop in the affected eye(s) once daily in the evening. If one dose is missed, treatment should continue with the next dose as normal.
- The dosage of **Latanomia** ophthalmic solution should not exceed once daily; the combined use of two or more prostaglandins, or prostaglandin analogus including **Latanomia** ophthalmic solution is not recommended. It has been shown that administration of these prostaglandin drug products more than once daily may decrease the IOP lowering effect or cause paradoxical elevations in IOP.
- Reduction of the IOP starts approximately 3 to 4 hours after administration and the maximum effect is reached after 8 to 12 hours.
- **Latanomia** ophthalmic solution may be used concomitantly with other topical ophthalmic drug products to lower IOP. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart. Contact lenses should be removed prior to the administration of **Latanomia** ophthalmic solution.

Over dose:
An intravenous infusion of up to 3 mcg/kg of latanoprost in healthy volunteers produced mean plasma concentrations 200 times higher than during clinical treatment with latanoprost solution and no adverse reactions were observed. IV doses of 5.5 to 10 mcg/kg cause abdominal pain, dizziness, fatigue, hot flashes, nausea, and sweating.

Storage conditions:
- Store unopened bottle(s) under refrigeration at 2°C to 8°C, Protected from light - During shipment to the patient, the bottle may be maintained at temperatures up to 40°C for a period not exceeding 8 days. - Once a bottle is opened for use, it may be stored at room temperature up to 25°C for 6 weeks.

Packaging:
Latanomia ophthalmic solution is supplied in polyethylene bottle 2.5 mL with dropper, tightly sealed with a polyethylene closer, within carton box

Produced by MIAMED Pharmaceutical Industries –Damascus countryside –Syria

This is a medicament
- A medicament is a product but unlike any other products.
- A medicament is a product which affect your health, and its consumption contrary to instructions is dangerous for you.
- follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
Keep medicaments out of reach of children

Council of Arab Health Ministers — Arab pharmacist Association

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