Med Choice
Vision Care

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Latanoprost
Latadin®

50 mcg/mL (0.005% w/v)
Sterile Ophthalmic Solution
(Eye Drops)
PROSTAGLANDIN ANALOGUE (ANTIGLAUCOMA)
FOR EXTERNAL USE ONLY

FORMULATION:
Each mL contains:
Latanoprost ..... 50 mcg

PRODUCT DESCRIPTION:
A clear solution filled in a tight, light resistant plastic dropper bottles.

PHARMACOLOGICAL PROPERTIES:
Pharmacodynamic properties
The active substance latanoprost, a prostaglandin F2 α analogue, is a selective prostanoid FP receptor agonist which reduces the intraocular pressure by increasing the outflow of aqueous humor.
Reduction of the intraocular pressure in man starts about three to four hours after administration and maximum effect is reached after eight to twelve hours. Pressure reduction is maintained for at least 24 hours.
Mild to moderate conjunctival or episcleral hyperemia may occur during topical treatment.
Latanoprost has not induced fluorescein leakage in the posterior segment of pseudophakic human eyes during short-term treatment.
Pharmacokinetic properties
Latanoprost (mw 432.58) is an isopropyl ester prodrug which per se is inactive, but after hydrolysis to the acid of latanoprost, it becomes biologically active. The prodrug is well-absorbed through the cornea and all drugs that enter the aqueous humor are hydrolyzed during the passage through the cornea. There is practically no metabolism of the acid of latanoprost in the eye. The main metabolism occurs in the liver. The
half-life in plasma is 17 minutes in man. The main metabolites, the 1, 2-dinor and 1, 2, 3, 4-tetranor metabolites, exert no or only weak biological activity in animal studies and are excreted primarily in the urine.

INDICATIONS:
Reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension.

DOSAGE AND ADMINISTRATION:
Recommended dosage for adults (including the elderly):
Recommended therapy is: One eye drop in the affected eye(s) once daily.
Optimal effect is obtained if Latanoprost (Latadin®) is administered in the evening.
The dosage of Latanoprost (Latadin®) should not exceed once daily since it has been shown that more frequent administration decreases the intraocular pressure lowering effect.
If one dose is missed, treatment should continue with the next dose as normal.
As with any eye drops, to reduce possible systemic absorption, it is recommended that the lacrimal sac is compressed at the medial canthus (punctal occlusion) for one minute.
This should be performed immediately following the instillation of each drop.
Contact lenses should be removed before instillation of the eye drops and may be reinserted after 15 minutes.
If more than one topical ophthalmic drug is being used, the drugs should be administered at least five minutes apart.
Children:
Safety and effectiveness in children has not been established. Therefore, Latanoprost (Latadin®) is not recommended for use in children.

CONTRAINDICATIONS:
Known hypersensitivity to any component in Latanoprost (Latadin®).

SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE:
Latanoprost may gradually change eye color by increasing the amount of brown pigment in the iris. Before treatment is instituted, patients should be informed of the possibility of a permanent change in eye color.
Unilateral treatment can result in permanent heterochromia.
This change in eye color has predominantly been seen in patients with mixed colored irides, i.e. bluebrown, grey-brown, yellow-brown and green-brown. In patients with homogeneously blue eyes, no change has been observed and in patients with homogeneously grey, green or brown eyes, the change has only rarely been seen.
The color change is due to increased melanin content in the stromal melanocytes of the iris and not due to an increase in number of melanocytes. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery in affected eyes, but the entire iris or parts of it may become more brownish. No further increase in brown iris pigment has been observed after discontinuation of treatment.
Neither nevi nor freckles of the iris have been affected by treatment. Accumulation of pigment in the trabecular meshwork or elsewhere in the anterior chamber has not been observed in clinical trials.
Based on 5 years clinical experience, increased iris pigmentation has not been shown to have any negative clinical sequelae.
Latanoprost (Latadin®) can be continued if iris pigmentation ensues. However, patients should be monitored regularly and if the clinical situation warrants, Latanoprost (Latadin®) treatment may be discontinued.
There is limited experience of Latanoprost in chronic angle closure glaucoma, open angle glaucoma of pseudophakic patients and in pigmentary glaucoma.
There is no experience of Latanoprost in inflammatory and neovascular glaucoma, inflammatory ocular conditions, or congenital glaucoma. Latanoprost has no or little effect on the pupil, but there is no experience in acute attacks of closed angle glaucoma.
Therefore, it is recommended that Latanoprost (Latadin®) should be used with caution in these conditions until more experience is obtained.
There are limited study data on the use of Latanoprost during the peri-operative period of cataract surgery.
Latanoprost (Latadin®) should be used with caution in these patients. Reports of macular edema have occurred mainly in aphakic patients, in pseudophakic patients with torn posterior lens capsule or anterior chamber lenses, or in patients with known risk factors for cystoid macular edema (such as diabetic retinopathy and retinal vein occlusion).
Latanoprost (Latadin®) should be used with caution in aphakic patients, in pseudophakic patients with torn posterior lens capsule or anterior chamber lenses, or in patients with known risk factors for cystoid macular edema.
In patients with known predisposing risk factors for iritis/uveitis, Latanoprost (Latadin®) can be used with caution.
There is limited experience from patients with asthma, but some cases of exacerbation of asthma and/or dyspnea were reported in post- marketing experience.
Asthmatic patients should therefore be treated with caution until there is sufficient experience.
Periorbital skin discoloration has been observed, the majority of reports being in Japanese patients.
Experience to date shows that periorbital skin discoloration is not permanent and in some cases has reversed while continuing treatment with Latanoprost.
Latanoprost may gradually change eyelashes and vellus hair in the treated eye and surrounding areas; these changes include increased length, thickness, pigmentation, number of lashes or hairs and misdirected growth of eyelashes. Eyelash changes are reversible upon discontinuation of treatment.
Latanoprost (Latadin®) contains benzalkonium chloride, which is commonly used as a preservative in ophthalmic products.
Benzalkonium chloride has been reported to cause punctate keratopathy and/or toxic ulcerative keratopathy, and it may cause eye irritation and is known to discolor soft contact lenses.
Close monitoring is required with frequent or prolonged use of Latanoprost (Latadin®) in dry eye patients, or in conditions where the cornea is compromised.
Contact lenses may absorb benzalkonium chloride and these should be removed before applying Latanoprost (Latadin®) but may be reinserted after 15 minutes.

DRUG INTERACTIONS:
Definitive drug interaction data are not available.
There have been reports of paradoxical elevations in intraocular pressure following the concomitant ophthalmic administration of two prostaglandin analogues.
Therefore, the use of two or more prostaglandins, prostaglandin analogues, or prostaglandin derivatives is not recommended.

PREGNANCY AND LACTATION:
Pregnancy
The safety of this medicinal product for use in human pregnancy has not been established.
It has potential hazardous pharmacological effects with respect to the course of pregnancy, to the unborn or the neonate.
Therefore, Latanoprost (Latadin®) should not be used during pregnancy.

Lactation
Latanoprost and its metabolites may pass into breast milk and therefore Latanoprost (Latadin®) should not be used in nursing women or breastfeeding should be stopped.

Effects on ability to drive and use machines
In common with other eye preparations, instillation of eye drops may cause transient blurring of vision. Until this has resolved, patients should not drive or use machines.

ADVERSE DRUG REACTIONS:
The majority of adverse events relate to the ocular system.
Adverse events are categorized by frequency as follows: Very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1000, < 1/100), rare (< 1/1000) and very rare (< 1/10,000). Not known (cannot be estimated from the available data).
Eye Disorders:
Very common: Increased iris pigmentation; mild to moderate conjunctival hyperemia, eye irritation (burning grittiness, itching, stinging, and foreign body sensation); eyelash and vellus hair changes (increased length, thickness, pigmentation, and number) (vast majority of reports in Japanese population).
Common: Transient punctate epithelial erosions, mostly without symptoms; blepharitis; eye pain.
Uncommon: Eyelid edema; dry eye; keratitis; blurred vision; conjunctivitis.
Rare: Iritis/uveitis (the majority of reports in patients with concomitant predisposing factors); macular edema; symptomatic corneal edema and erosions; periorbital edema; misdirected eyelashes sometimes resulting in eye irritation; extra row of cilia at the aperture of the meibomian glands (distichiasis).
Not known: Iris cyst.
Nervous System Disorders:
Not known: Headache, dizziness.
Cardiac Disorders:
Very rare: Aggravation of angina in patients with pre-existing disease.
Not known: Palpitations.
Respiratory, Thoracic and Mediastinal Disorders:
Rare: Asthma, asthma exacerbation and dyspnea.
Skin and Subcutaneous Tissue Disorders:
Uncommon: Skin rash.
Rare: Localized skin reaction on the eyelids; darkening of the palpebral skin of the eyelids.
Musculoskeletal and Connective Tissue Disorders:
Not known: Myalgia; arthralgia.
General Disorders and Administration Site Conditions:
Very rare: Chest pain.

OVERDOSE AND TREATMENT:
Apart from ocular irritation and conjunctival hyperemia, no other ocular side effects are known if
Latanoprost (Latadin®) is overdosed.
If overdosage with Latanoprost (Latadin®) occurs, treatment should be symptomatic.

CAUTION:
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription

"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

Seek medical attention immediately at the first sign of any adverse drug reaction."

STORAGE CONDITION:
Store between 2°C and 8°C (under refrigeration, no freezing).
Keep out of reach of children.

AVAILABILITY:
LDPE white opaque plastic droptainer in 2.5 mL [net content] Box of 1's.

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