pharmaniaga®

OptaProst

OphthalmicSolution0.005%w/v

Summary of Product Characteristics

1. Name of the medicinal product:
OptaProst Ophthalmic Solution 0.005% w/v

2. Qualitative and quantitative composition:

[Active Ingredient]
Each mL of eye drops, solution contains 50 micrograms of latanoprost.

Each 2.5mL of eye drops, solution (content of 1 bottle) contains 125 micrograms of latanoprost.

[Excipients]
This product contains preservative as Benzalkonium Chloride 0.01 % w/v.

Route of Administration: Ophthalmic.

For full list of excipients, see section 6.1

3. Pharmaceutical form:
Eye drops, solution.

This product is a clear, colorless, sterile, aqueous ophthalmic solution buffered to approximately pH 6.5 – 6.9.

4. Clinical particulars

4.1 Therapeutic indications:

(1) Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma, chronic angle closure glaucoma, and ocular hypertension.

(2) Reduction of elevated intraocular pressure in paediatric patients with elevated intraocular pressure and paediatric glaucoma

4.2 Posology and method of administration:
Use in adults (including the elderly):

One drop in the affected eye(s) once daily. Optimal effect is obtained if latanoprost is administered in the evening.

The dosage of latanoprost 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.

Latanoprost may be used concomitantly with other classes of 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 minutes apart.

Contact lenses should be removed before instillation of the eye drops and may be reinserted after fifteen minutes.

Pediatric Population

Latanoprost eye drops may be used in paediatric patients at the same posology as in adults. No data are available for preterm infants (less than 36 weeks gestational age). Data in the age group < 1 year are limited.

4.3 Contraindications:
Latanoprost eye drops are contraindicated in patients with known hypersensitivity to latanoprost or to any of the excipients in this product, listed in section 6.1.

4.4 Special warnings and precautions for use:

General:
This product contains benzalkonium chloride, which may be absorbed by contact lenses.

Ocular:
Latanoprost eye drops may produce a gradual increase in the amount of brown pigment in the iris, due to increased melanin content of melanocytes. This change in eye colour is most evident in patients with mixed colour irises, and may be permanent in some patients. The onset of iris pigmentation is usually within the first 8 months of treatment, rarely during the second or third year, and has not been seen after the fourth year of treatment.

Treatment with latanoprost can be continued in patients who develop increased iris pigmentation. These patients should be examined regularly and, depending on the clinical situation, treatment may be stopped.

Increase in brown iris pigment has not been shown to progress further upon discontinuation of treatment, but the resultant color change may be permanent.

Darkening of the palpebral skin (eyelid skin) has been reported in association with the use of latanoprost.

Darkening, thickening, and lengthening of eyelashes may occur and are reversible upon stopping treatment.

The potential for heterochromia exists for patients receiving unilateral treatment.

Macular edema, including cystoid macular edema, has been reported during treatment with latanoprost. These have mainly occurred in aphakic patients, in pseudophakic patients with torn posterior lens capsule, or in patients with known risk factors for macular edema. Caution is recommended when using

latanoprost in these patients.

Concomitant use with other prostaglandins or prostaglandin analogues not recommended.

Use not recommended in those who have active inflammation; intraocular inflammation (iritis/uveitis).

Use with caution in those who have history of intraocular inflammation (iritis/uveitis).

There is limited experience with latanoprost in the treatment of inflammatory neovascular glaucoma. Therefore, it is recommended that latanoprost should be used with caution in these conditions until more experience is obtained.

Latanoprost should be used with caution in patients with a history of herpetic keratitis, and should be avoided in cases of active herpes simplex keratitis and in patients with a history of recurrent herpetic keratitis specifically associated with prostaglandin analogues.

Paediatric Population

Efficacy and safety data in the age group < 1 year (4 patients) are very limited. No data are available for preterm infants (less than 36 weeks gestational age).

In children from 0 to < 3 years old that mainly suffers from PCG (Primary Congenital Glaucoma), surgery (e.g. trabeculotomy/goniotomy) remains the first line treatment.

Long-term safety in children has not yet been established.

4.5 Interaction with other medicinal products and other forms of interaction:

- Paradoxical increases in intra-ocular pressure have been reported after the concomitant ophthalmic use of 2 prostaglandin analogues. Therefore, the use of two or more prostaglandins, prostaglandin analogs, or prostaglandin derivatives is not recommended.

- Concurrent use of thimerosal and latanoprost may result in precipitation in the eye.

4.6 Fertility, pregnancy and lactation:

Pregnancy

There are no adequate and well-controlled studies of latanoprost administration in pregnant women. Therefore, latanoprost should be used during pregnancy only if the maternal benefit justifies the potential fetal risk.

Lactation

Latanoprost and its metabolites may pass into breast milk. Latanoprost should therefore be used with caution in nursing women.

4.7 Effects on ability to drive and use machines:

Instillation of eye drops may cause transient blurring of vision. Until this has resolved, patients should nor drive or use machines.

4.8 Undesirable effects:

Infections and infestations: Herpetic keratitis*

Nervous system disorders: Dizziness*; headache*

Eye disorders: Eye irritation (burning, grittiness, itching, stinging and foreign body sensation); eye pain; eyelash and vellus hair changes of the eyelid (increased length, thickness, pigmentation, and number of eyelashes)*; ocular hyperaemia; iris hyperpigmentation; blepharitis; conjunctivitis*; macular oedema including cystoid macular oedema*; photophobia*; eyelid oedema; keratitis*; uveitis*; corneal oedema*; iritis*; punctate keratitis*; corneal erosion*; trichiasis*; vision blurred*; periorbital and lid changes resulting in deepening of the eyelid sulcus*; darkening of the palpebral skin of the eyelids*; localised skin reaction on the eyelids*; iris cyst* pseudopemphigoid of ocular conjunctiva*

Cardiac disorders: Angina; palpitations*; angina unstable*

Respiratory, thoracic and mediastinal disorders: Asthma*; dyspnoea*; asthma aggravation*; acute asthma attacks*

Skin and subcutaneous tissue disorders: Rash; pruritus

Musculoskeletal and connective tissue disorders: Myalgia*; arthralgia*

General disorders and administration site conditions: Chest pain*

*ADR identified post-marketing

Adverse reactions reported with the use of eye drops containing phosphate buffers

Cases of corneal calcification have been reported very rarely in association with the use of phosphate-containing eye drops in some patients with significantly damaged corneas.

4.9 Overdose:

If overdosage with latanoprost occurs, treatment should be symptomatic.

Apart from ocular irritation and conjunctival hyperemia, no other ocular adverse effects are known if latanoprost is overdosed.

If latanoprost is accidentally ingested the following information may be useful: One 2.5 mL bottle contains 125 micrograms latanoprost. More than 90% is metabolized during the first pass

through the liver.

Intravenous infusion of 3 mcg/kg in healthy volunteers induced no symptoms, but a dose of 5.5 - 10 mcg/kg caused nausea, abdominal pain, dizziness, fatigue, hot flushes and sweating. In patients with moderate bronchial asthma, bronchoconstriction was not induced by latanoprost when applied topically on the eyes in a dose of seven times the clinical dose of Latanoprost.

5. Pharmacological properties

5.1 Pharmacodynamics properties

Latanoprost is a prostaglandin F 2-alpha analogue and a selective FP prostanoid receptor agonist. It reduces intraocular pressure by increasing the outflow of aqueous humor. Studies suggest that the main mechanism of action is increased uveoscleral outflow.

5.2 Pharmacokinetics properties

Absorption

Latanoprost is absorbed through the cornea where the isopropyl ester prodrug is hydrolyzed to the acid form to become biologically active.

The peak concentration in the aqueous humor is reached about two hours after topical administration.

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 four hours, and in plasma only during the first hour after local 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 ß-oxidation.

Elimination

Following hepatic ß-oxidation, the metabolites are mainly eliminated via the kidneys. Approximately 88% and 98% of the administered dose is recovered in the urine after topical and intravenous dosing, respectively. The elimination half-life, t1/2 =17min.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium Chloride
Dibasic Sodium Phosphate Hydrate
Sodium Dihydrogen Phosphate Dihydrate
Polysorbate 80
Disodium Edetate Hydrate
Benzalkonium Chloride Concentrated Solution 50
Hydrochloric Acid
Sodium Hydroxide
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years from manufacturing date.
Shelf life after opening container: 4 weeks

6.4 Special precautions for storage

Unopened bottle:
Store below 30°C. Protect from light.

After first opening:
Store below 30°C. Protect from light.
Use within 4 weeks after first opening the bottle.

6.5 Nature and contents of container

It is supplied as a 2.5 mL ophthalmic solution in a 5 mL sterile polyethylene bottle with a sterile polyethylene dropper tip and a sterile polyethylene cap.

Pack-sizes of 10 bottles in 1 carton.

Pack-sizes of 1 bottle in 1 carton.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Product Registration Holder:

Pharmaniaga Marketing Sdn Bhd
No.7, Lorong Keluli 1B,
Kawasan Perindustrian Bukit Raja Selatan,
Seksyen 7, 40000 Shah Alam,
Selangor Darul Ehsan, Malaysia

8. Manufacturer

Nitto Medic Co., Ltd.
1-14-1, Yasuuchi, Yatsuo-machi,
Toyama-city, Toyama, 939-2366, JAPAN.

9. Date of revision of the text

4th September 2024