SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Latanoprost eye drops 50mcg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Latanoprost 50mcg
Benzalkonium Chloride 0.02%w/v
(As preservative)

3. PHARMACEUTICAL FORM

Ophthalmic Solution
A clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology
Adults and elderly
Recommended therapy is one eye drop in the affected eye(s) once daily. Optimal effect is obtained if Latanoprost Eye Drops, Solution is administered in the evening. The dosage of Latanoprost Eye Drops, Solution should not exceed once daily since it has been shown that more frequent administration decreases the intraocular pressure lowering effect.
Precautions to be taken before handling or administering the medicinal product.
As with any eye drops, to reduce possible systemic absorption, it is recommended that the lachrymal sac be 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.

4.3 Contraindications

Hypersensitivity to the active substance latanoprost or to any of the excipients listed.

4.4 Special warnings and precautions for use

Latanoprost Eye Drops, Solution may gradually change eye colour by increasing the amount of brown pigment in the iris. Pigmentation is expected to increase as long as Latanoprost is administered. The color change is permanent after discontinuation of Latanoprost.
If irritation persists or increases discontinue the use and consult Physician.
Do not touch the dropper tip to any surface since this may contaminate the solution. Use the solution within one month after opening the container.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.
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.

4.6 Fertility, pregnancy and lactation

Fertility

Latanoprost has not been found to have any effect on male or female fertility in animal.
Pregnancy

The safety of this 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 Eye Drops, Solution should not be used during pregnancy.

Breast-feeding

Latanoprost and its metabolites are may pass into breast milk and Latanoprost Eye Drops, Solution should therefore not be used in breast-feeding women or breast feeding should be stopped.

4.7 Effects on ability to drive and use machines

Latanoprost eye drop has minor effect or monderate influence on ability to drive and use machine as in common with other eye preparations, instillation of eye drops may cause transient blurring of vision. Until this has resolved patient should not drive or use machine.

4.8 Undesirable effects

- Iris pigmentation changes.
- Eyelid skin darkening
- Eyelash changes (increased length, thickness, pigmentation, and number of lashes)
- Intraocular inflammation (iritis/uveitis)
- Macular edema, including cystoid macular edema & ect.

4.9 Overdose

Symptoms
Apart from ocular irritation and conjunctival hyperaemia, no other ocular side effects are known if Latanoprost Eye Drops, Solution is overdosed.

Management
If Latanoprost Eye Drops, Solution is accidentally ingested the following information may be useful: One bottle contains 125 micrograms latanoprost. More than 90% is metabolised during the {rst pass through the liver. Intravenous infusion of 3 micrograms/kg in healthy volunteers produced mean plasma concentrations 200 times higher than during clinical treatment and induced no symptoms, but a dose of 5.5-10 micrograms/kg caused nausea, abdominal pain, dizziness, fatigue, hot |ushes and sweating. In monkeys, latanoprost has been infused intravenously in doses of up to 500 micrograms/kg without major effects on the cardiovascular system. Intravenous administration in monkeys has been associated with transient bronchoconstriction.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Antiglaucoma preparation and miotics, prostaglandin analogues.
ATC code: S01 EE01.

Mechanism of action
The active substance latanoprost, a prostaglandin F2α analogue, is a selective prostanoid FP receptor agonist which reduces the intraocular pressure by increasing the out|ow of aqueous

humour. 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.

5.2 Pharmacokinetic properties

Latanoprost (mw 432.58) is an isopropyl ester prodrug which per se is inactive, but after hydrolysis to the acid of latanoprost becomes biologically active.

5.3 Preclinical safety data

Not Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium Chloride, Sodium Chloride, Water for Injection, Potassium dihydrogen Orthophosphate Anhydrous, Disppodium hydrogen Orthophosphate Anhydrous, Polyoxyl 4C Hydrogenated Castor oil (Cremophor RH 40).

6.2 Incompatibilities

Not known

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store in Refrigerator between 2°C to 8°C . Protect from light.after first opening the bottle: do not store above 25°C. Keep out of reach of children.

6.5 Nature and contents of container and special equipment for use, administration or implantation

2.5ml filled in 5ML LDPE White Plastic Bottle.

6.6 Special precautions for disposal and other handling

None.

7. MARKETING AUTHORISATION HOLDER

Ciron Drugs & Pharmaceuticals Pvt. Ltd.
C- 1101 /1102, Lotus Corporate Park, Graham Firth Steel Compound,
Jay Coach Junction, Western Express Highway, Goregaon (East)
Mumbai- 400 063, India.

8. MARKETING AUTHORISATION NUMBER(S)

CIR/IND/21

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24.02.2020

10. DATE OF REVISION OF THE TEXT

14/07/2023

11. Reference

https://www.medicines.org.uk/emc/product/2983/smpc#gref