Travopta™

Travoprost 0.004% w/v Eye Drops

1. Generic Name

Travoprost

2. Qualitative and Quantitative composition

Travoprost 0.004% w/v

3. Dosage form and strength

Ophthalmic solution containing travoprost 0.04 mg/mL

4. Clinical particulars

4.1 Therapeutic indication

TRAVOPTA PF EYE DROP is a prostaglandin analogue indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension

4.2 Posology and method of administration

One drop in the affected eye(s) once daily in the evening

4.3 Contraindication

None

4.4 Special warnings and precautions for use

- Pigmentation: Pigmentation of the iris, periorbital tissue (eyelid) and eyelashes can occur. Iris pigmentation likely to be permanent.
- Eyelash Changes: Gradual change to eyelashes including increased length, thickness and number of lashes. Usually reversible.

- Macular Edema: Macular edema, including cystoid macular edema, has been reported during treatment with travoprost ophthalmic solution. TRAVOPTA PF EYE DROP 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.
- Angle-closure, Inflammatory or Neovascular Glaucoma : TRAVOPTA PF EYE DROP has not been evaluated for the treatment of angle-closure, inflammatory or neovascular glaucoma.
- 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
- Use with Contact Lenses: Contact lenses should be removed prior to instillation of TRAVOPTA PF EYE DROP and may be reinserted 15 minutes following its administration.

4.5 Drug interactions

There are no drug interactions associated with the Travoprost

4.6 Use in special population

- **Pediatric patients:**

Use in paediatric patients below the age of 16 years is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.

- **Geriatric patients:**

No overall clinical differences in safety or effectiveness have been observed between elderly and other adult patients.

- **Liver impairment:**

Travoprost ophthalmic solution 0.004% has been studied in patients with hepatic impairment. No clinically relevant changes in haematology, blood chemistry, or urinalysis laboratory data were observed in these patients.

- **Renal failure:**

Patients with the renal impairment have been studied, no clinically relevant changes in the urinalysis, haematology observed in these patients.

- **Pregnancy and lactation:**

Pregnancy Category C. TRAVOPTA PF EYE DROP should be administered during pregnancy only if the potential benefit justifies the potential risk to the foetus.

- **Lactating Women:**

A study in lactating rats demonstrated that radiolabel travoprost and/or its metabolites were excreted in milk. 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 TRAVOPTA PF EYE DROP is administered to a nursing woman

4.7 Effects on ability to drive and use machine

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to Travopta eye drops is known.

4.8 Undesirable effects

Most common adverse reaction (30% to 50%) is conjunctival hyperemia.

4.9 Overdose

This medicine may be harmful if swallowed. If swallowing or overdose of TRAVOPTA PF EYE DROP is suspected, contact physician immediately

5. Pharmacological properties

5.1 Mechanism of action

Travoprost, a prostaglandin F2α analogue, is a highly selective full agonist which has a high affinity for the prostaglandin FP receptor, and facilitates reductions in intraocular pressure by increasing the outflow of aqueous humour via trabecular meshwork and uveoscleral pathways. Reduction of the intraocular pressure in man starts about 2 hours after administration and maximum effect is reached after 12 hours. Significant lowering of intraocular pressure can be maintained for periods exceeding 24 hours with a single dose

5.2 Pharmacodynamic properties

Travoprost, an isopropyl ester prodrug, it is a synthetic prostaglandin F2 alpha analogue that is rapidly hydrolyzed by esterases in the cornea to its biologically active free acid Label. The travoprost free acid is potent and highly selective for the FP prostanoid receptor. Travoprost is believed to reduce intraocular pressure by increasing uveoscleral outflow. The exact mechanism of action is unknown at this time.

5.3 Pharmacokinetic properties

Travoprost is absorbed through the cornea and is hydrolyzed to the active free acid. Data from 4 multiple dose pharmacokinetic studies (totalling 107 subjects) have shown that plasma concentrations of the free acid are below 0.01 ng/mL (the quantitation limit of the assay) in two-thirds of the subjects. In those individuals with quantifiable plasma concentrations (N=38), the mean plasma Cmax was 0.018 ± 0.007 ng/mL (ranged 0.01 to 0.052 ng/mL) and was reached within 30 minutes. From these studies, travoprost is estimated to have a plasma half-life of 45 minutes. There was no difference in plasma concentrations between Days 1 and 7, indicating steady-state was reached early and that there was no significant accumulation. Travoprost, an isopropyl ester prodrug, is hydrolyzed by esterases in the cornea to its biologically active free acid. Systemically, travoprost free acid is metabolized to inactive metabolites via beta-oxidation of the α(carboxylic acid) chain to give the 1,2-dinor and 1,2,3,4-tetranor analogues, via oxidation of the 15-hydroxyl moiety, as well as via reduction of the 13, 14 double bond. The elimination of travoprost free acid from plasma was rapid and levels were generally below the limit of quantification

within one hour after dosing. The terminal elimination half-life of travoprost free acid was estimated from fourteen subjects and ranged from 17 minutes to 86 minutes with the mean half-life of 45 minutes. Less than 2% of the topical ocular dose of travoprost was excreted in the urine within 4 hours as the travoprost free acid.

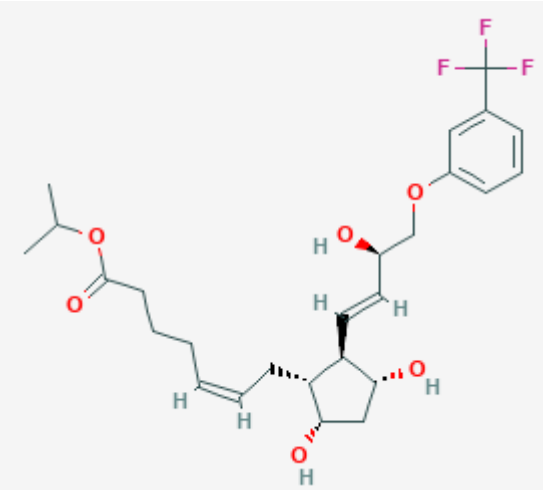
6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

NA.

7. Description

Travoprost is a synthetic lipophilic isopropyl ester prodrug of the active compound travoprost free acid a prostaglandin F2alpha analog with anti-glaucoma property[12].Travoprost is a clear, colorless to slightly yellow oil that is very soluble in acetonitrile, methanol, octanol, and chloroform. It is practically insoluble in water.



8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

24 months

8.3 Packaging Information

TRAVOPTA PF EYE DROP is available LDPE Vial of 3ml.

8.4 Storage and handling instructions

Store between 2°C - 25°C away from light and moisture. Keep medicine away from children.

9. Patient Counselling Information

NA

9.1 Adverse reactions

Refer 4.8

9.2 Drug Interactions

Refer 4.5

9.3 Dosage

One drop in the affected eye(s) once daily in the evening.

9.4 Storage

Refer 8.4

9.5 Risk factors

Refer 4.4

9.6 Self-monitoring information

NA

9.7 Information on when to contact a health care provider or seek emergency help

Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8 Contraindications

None

10. Manufactured by CENTAUR PHARMACEUTICALS PVT. LTD. and DCI Pharmaceuticals

11. Details of permission or license number with date

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12. Date of revision January 2021