Travasenz®

Eye Drops 3ml

(Travoprost Eye Drops IP)

COMPOSITION:

Travoprost IP	0.004% w/v
Benzalkonium chloride Solution IP (as preservative)	0.02% v/v
Water for Injections IP	q.s.

Pharmacological Action:

Travoprost free acid, a prostaglandin analog is a selective FP prostanoid receptor agonist which is believed to reduce intraocular pressure by increasing uveoscleral outflow. The exact mechanism of action is unknown at this time.

Pharmacokinetics:

Travoprost is absorbed through the cornea and is hydrolyzed to the active free acid. Data from four multiple dose pharmacokinetic studies (totaling 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 a(carboxylic acid) chain to give the 1 ,2-dinor and 1,2,3,4-tetranor analogs, 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.

Indications:

Travasenz Eye Drops is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

Dosage and Administration:

The recommended dosage is one drop in the affected eye(s) once daily in the evening. Travasenz (Travoprost Eye Drops) should not be administered more than once daily since it has been shown that more frequent administration of prostaglandin analogs may decrease the intraocular pressure lowering effect.

Reduction of the intraocular pressure starts approximately 2 hours after the first administration with maximum effect reached after 12 hours.

Travasenz may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart.

Patients should remove contact lenses prior to administration of the solution. Lenses may be reinserted 15 minutes following administration of Travasenz Eye Drops.

Contraindications: None.

Pregnancy

Pregnancy Category C

No adequate and well-controlled studies have been performed in pregnant women. Travoprost, like all FP agonists, may interfere with the maintenance of pregnancy and should not be used by women during pregnancy or by women attempting to become pregnant. Since prostaglandins are biologically active and may be absorbed through the skin, women who are pregnant or attempting to become pregnant should exercise appropriate precautions to avoid direct exposure to the contents of the bottle. In case of accidental contact with the contents of the bottle, thoroughly cleanse the exposed area with soap and water immediately.

Lactation: A study in lactating rats demonstrated that radio labeled 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 Travasenz Eye Drops is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use : No overall differences in safety or effectiveness have been observed between elderly and younger patients.

Warnings:

Travasenz Eye Drops has been reported to cause changes to pigmented tissues. The most frequently reported changes have been increased pigmentation of the iris and periorbital tissue (eyelid) and increased pigmentation and growth of eyelashes. These changes may be permanent.

Travasenz Eye Drops may gradually change eye colour. increasing the amount of brown pigmentation in the iris by increasing the number of melanosomes (pigment granules) in melanocytes. The long-term effect on the melanocytes and the consequences of potential injury to the melanocytes and/or deposition of pigment granules to other areas of the eye are currently unknown. The change in iris colour occurs slowly and may not be noticeable for months to years. Patients should be informed of the possibility of iris colour change.

Eyelid skin darkening has been reported in association with the use of Travasenz Eye Drops.

Travasenz Eye Drops may gradually change eyelashes in the treated eye; these changes include increased length, thickness, pigmentation and/or number of eyelashes.

Storage:

Keep in cool place. Use the solution within one month after opening the container.

PROTECT FROM LIGHT

KEEP OUT OF REACH OF CHILDREN

NOT FOR INJECTION

FOR EXTERNAL USE ONLY

Presentation:

Travasenz is a sterile ophthalmic solution supplied in a sterile plastic opaque dropper bottle with a cap containing 3ml of the solution

Directions for use :

Turn the tamper proof cap anti-clockwise to break the seal.

Remove the cap, dispense drops with gentle pressure.

Replace the cap immediately after every use.

Manufactured in INDIA by :

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TVZPI-02

Month of publication of pack insert: April 2021