Travolar[™] 0.004% Eye Drops

Travoprost USP 0.004% Sterile Solution

Travoprost is a highly selective, potent agonist for the FP prostanoid receptor. FP receptor agonists reduce intraocular pressure (IOP) by increasing the outflow of aqueous humor, primarily by increased uveoscleral outflow.

COMPOSITION

TravolarTM 0.004% Eye Drops: Each ml contains Travoprost USP 0.04 mg.

INDICATION

TravolarTM 0.004% Eye Drops is indicated for the reduction of intraocular pressure in adult patients with open-angle glaucoma or ocular hypertension.

DOSAGE AND ADMINISTRATION

The recommended dosage is one drop in the affected eye(s) once-daily. Optimal effect is observed with evening dosing.



Pierce the container by screwing the Two- parts Cap clock-wise.



Open the upper part of the cap only



Use the required amount of medication.



Close the upper part of the cap with the container just after the use.

CONTRAINDICATION

It is contraindicated in patients with known hypersensitivity to any ingredient of this formulation.

WARNING & PRECAUITON

Prostaglandin analogues, including travoprost ophthalmic solution, 0.004% have 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.

DRUG INTERACTION

Concomitant ocular medications should be administered at least 5 min apart from

the instillations of **Travolar**™ 0.004% Eve Drops to avoid washout effects.

USE IN PREGNANCY AND LACTATION

Use in Pregnancy: Pregnancy Category C. Animal studies showed teratogenic effects in rats with the active ingredient. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Use in Lactation: Animal studies showed this drug is excreted in rat's milk. It is not known whether this drug or its metabolites are excreted in human milk. Caution should be exercised when **Travolar**TM is administered to a nursing woman.

PEDIATRIC AND GERIATRIC USE

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 other adult patients.

SIDE EFFECT

Ocular hyperemia, decreased visual acuity, eye discomfort, foreign body sensation, pain and pruritus, redness may be seen in few cases.

STORAGE

Store below 25° C in a dry place. Keep out of reach of children. Solution can be used up to 30 days after first opening.

HOW SUPPLIED

TravolarTM 0.004% Eye Drops is supplied as 3 ml solution in a 5 ml LDPE container.

Manufactured by

