EyeKare

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For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Travoprostin™

TRAVOPROST EYE DROPS IP 0.004% w/v

COMPOSITION :

Travoprost IP 0.004% w/v, Water for Injections IP q.s. In a specially designed container to avoid preservative use.

PHARMACOLOGICAL ACTION : Pharmacodynamic properties : Travoprost, a prostaglandin F2alpha analogue, is a selective agonist with affinity for the prostaglandin FP-receptor. The exact mechanism of action by which travoprost reduces IOP has not been fully elucidated. As with other topical prostaglandin analogues, travoprost is believed to increase uveoscleral outflow.

Pharmacokinetic Properties : Travoprost is an ester prodrug. It is absorbed through the cornea where the isopropyl ester is hydrolysed to the free acid. Metabolism is the major route of elimination of both travoprost and the active free acid. The systemic metabolic pathways parallel those of endogenous prostaglandin- F2alpha, which are characterised by reduction of the 13-14 double bond, oxidation of the 15-hydroxyl and beta-oxidative cleavages of the upper side chain.

INDICATIONS : TRAVOPROSTIN eye drops is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension who are intolerant of or insufficiently responsive to another intraocular pressure lowering medication, as monotherapy or as adjunctive therapy.

CONTRA-INDICATIONS :

- Hypersensitivity to TRAVOPROST or any of the excipients.
- Pregnant women or women attempting to become pregnant as teratogenicity has been demonstrated in experimental animals.
- Breast-feeding women.
- Children, as safety and efficacy has not been proven.

Use in children and adolescents: The efficacy and safety of TRAVOPROSTIN eye drops in patients below the age of 18 have not been established and its use is not recommended in these patients until further data become available.

Women of childbearing potential: TRAVOPROSTIN must not be used in women who may become pregnant unless adequate contraceptive measures are in place.

Nursing women: Animal studies indicate that travoprost and its metabolites may pass into breast milk and TRAVOPROSTIN must therefore not be used in breast-feeding women.

WARNINGS : TRAVOPROSTIN 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. TRAVOPROSTIN 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 TRAVOPROSTIN.

TRAVOPROSTIN may gradually change eyelashes in the treated eye; these changes include increased length, thickness, pigmentation and/or number of eyelashes. Patients who are expected to receive treatment in only one eye should be informed about the potential for increased brown pigmentation of the iris, periorbital and/or eyelid tissue and eyelashes in the treated eye and thus heterochromia between the eyes. They should also be advised of the potential for a disparity between the eyes in length, thickness, and/or number of eyelashes.

PRECAUTIONS

General : Patients may slowly develop increased brown pigmentation of the iris. This change may not be noticeable for months to years (see Warnings). Iris pigmentation changes may be more noticeable in patients with mixed coloured irides, i.e., blue-brown, grey-brown, yellow brown and green-brown; however, it has also been observed in patients with brown eyes. The colour change is believed to be due to increased melanin content in the stromal melanocytes of the iris. The exact mechanism of action is unknown at this time. Typically the brown pigmentation around the pupil spreads concentrically towards the periphery in affected eyes, but the entire iris or parts of it may become more brownish. Until more information about increased brown pigmentation is available, patients should be examined regularly and depending on the situation, treatment may be stopped if increased pigmentation ensues. TRAVOPROSTIN should be used with caution in patients with active intraocular inflammation (iritis/uveitis). Macular oedema, including cystoid macular oedema, has been reported during treatment with prostaglandin F2alpha analogues. These reports have mainly occurred in aphakic patients, pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular oedema. TRAVOPROSTIN should be used with caution in these patients. TRAVOPROSTIN has not been evaluated for the treatment of angle closure, inflammatory or neovascular glaucoma. TRAVOPROSTIN has not been studied in patients with renal or hepatic impairment and should be used with caution in such patients. TRAVOPROSTIN should not be administered while wearing contact lenses. Contact lenses should be removed prior to the administration of the solution. Lenses may be reinserted 15 minutes following administration of TRAVOPROSTIN.

INFORMATION FOR PATIENTS : Patients should be advised concerning all the information contained in the Warning and Precautions sections. Patients also should be advised that if they develop an intercurrent ocular condition (e.g. trauma or infection) or have ocular surgery, they should immediately seek their physician's advice concerning the continued use of the multi-dose container. Patients should be advised that if they develop any ocular reactions, particularly conjunctivitis and lid reactions, they should immediately seek their physician's advice.

INSTRUCTIONS FOR USE AND HANDLING : Since prostaglandins are biologically active materials and since they 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 vial. In case of accidental contact with the contents of the vial, thoroughly rinse the exposed area immediately.

DOSAGE AND DIRECTIONS FOR USE: The recommended dose is one drop of TRAVOPROSTIN in the conjunctival sac of the affected eye(s) once daily in the evening. If more than one topical ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart. When substituting another ophthalmic antiglaucoma agent with TRAVOPROSTIN, discontinue the other agent and start the following day with TRAVOPROSTIN.

METHOD OF ADMINISTRATION : To prevent contamination of the dropper tip and solution, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip of the vial.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS :

Side-Effects : The most frequently reported treatment-related side-effect was ocular hyperaemia, which was reported in 35% to 50% of patients. Approximately 3% of patients discontinued treatment due to conjunctival hyperaemia. The following undesirable effects assessed as definitely, probably or possibly related to treatment were reported during clinical trials with TRAVOPROSTIN. Their incidence was either very common (greater than 10.0%), common (1.0% to 10%), or uncommon (0.2% to less than 1.0%). All other effects were single reports, of which none were serious or related.

Ocular effects Very common: ocular hyperaemia.
Common: ocular pruritus, ocular discomfort (transient burning or stinging upon instillation), ocular pain, iris discolouration, dry eye, foreign body sensation, photophobia, keratitis and flare, tearing, blurred vision, conjunctivitis, eyelash lengthening, ocular irritation, iritis, lid oedema, sticky sensation, conjunctival follicles, abnormal vision, blepharitis, brow-ache and conjunctival papillae, cataracts, lid margin crusting, subconjunctival haemorrhage.

Systemic effects Body as a whole: Common: headache.
Cardiovascular: Uncommon: hypotension and bradycardia.
Skin and appendages: Uncommon: periorbital tissue and/or eyelid discolouration. Interaction with other medicinal products and other forms of interaction. Data on adjunctive administration of TRAVOPROSTIN with timolol and with brimonidine eye drops confirmed the additive effect of TRAVOPROSTIN with these glaucoma medications. No data are available on adjunctive use with other ocular hypotensive medications. Data on concomitant administration with brimonidine are limited. Interactions of TRAVOPROSTIN with other medications have not been specifically evaluated.

Effects on ability to drive and use machines : As with any eye drop, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient must wait until the vision clears before driving or using machinery.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
If overdosage with TRAVOPROSTIN occurs, treatment should be symptomatic.

PRESENTATION : 5 ml available in 5ml Vial specially designed to avoid contamination of the contents.

STORAGE INSTRUCTIONS : Store at a temperature not exceeding 30°C and protect from light. Use the solution within one month after opening the container.
For external use only.
KEEP OUT OF REACH OF CHILDREN.

INSTRUCTIONS FOR USE

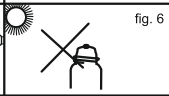
Rotate cap anticlockwise to break the seal.

The vial is now ready for use; turn it up side down. Hold the blue tip in center of the eye and squeeze the walls of the vial gently to deliver sterile drop into the eye.

Replace the cap. Tighten it firmly and keep the vial closed for subsequent use.

Do not touch the nozzle.

Do not rinse the nozzle.



Do not expose to Sunlight.

State of the art technology from Eyekare Ltd.

™ Trade Mark applied for

Marketed by:
EyeKare
Division of :
Kilitch Healthcare India Ltd.

Manufactured in India by:
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