

Brinzolamide USP Sterile Ophthalmic Suspension

DESCRIPTION

Zolopt® is a preparation of Brinzolamide ophthalmic suspension. Brinzolamide is an inhibitor of carbonic anhydrase II. Following topical ocular administration, Brinzolamide inhibits aqueous humor formation and reduces elevated intraocular pressure. Elevated intraocular pressure is a major risk factor in the pathogenesis of optic nerve damage and glaucomatous visual field loss.Carbonic anhydrase (CA) is an enzyme found in many tissues of the body including the eye. It catalyses the reversible reaction involving the hydration of carbon dioxide and the dehydration of carbonic acid. It exists as a number of isoenzymes, the most active being carbonic anhydrase II (CA-II), found primarily in red blood cells, but also in other tissues. Inhibition of carbonic anhydrase in the ciliary processes of the eye decreases aqueous humor secretion, presumably by slowing the formation of bicarbonate ions with subsequent reduction in sodium and fluid transport. Benzalkonium Chloride 0.01% is used as preservative. Carbomer 974P 0.4% is used as vehicle.

INDICATIONS

Zolopt[®] ophthalmic suspension is indicated as monotherapy, or as adjunctive therapy to beta-blockers in the treatment of elevated intraocular pressure in ocular hypertension, or open-angle glaucoma.

DOSAGE AND ADMINISTRATION

The recommended dose is one drops of this eye drop in the conjunctival sac of the affected eye(s) twice daily. Some patients may have a better response with one drop three times a day. If more than one topical ophthalmic drug is being used, the drugs should be administered at least ten minutes apart.

CONTRAINDICATIONS

Hypersensitivity to active component of this product.

SIDE EFFECTS

The most frequent treatment related side effects and local symptoms that may be experienced are taste perversion (bitter, sour or unusual taste) (5.4%) and temporary blurred vision upon instillation, lasting from a few seconds to a few minutes (5.0%).

PRECAUTIONS

Glaucoma caused by accumulation of pigment particles in the drainage channels of the eye (pigmentary glaucoma).

Glaucoma caused as a result of a disorder of part of the eyeball called the ciliary body (pseudoexfoliative glaucoma). Diabetes, Contact lens wearers, Dry eyes.

USE IN PREGNANCY AND LACTATION

Safety in pregnancy and lactation has not been established.

PHARMACEUTICAL PRECAUTION

Store in a dry place and away from light. Keep out of reach of children. Store in an upright position. To prevent contamination of the dropper tip and suspension, care should be taken, not to touch the eyelids, surrounding areas, finger or other surfaces with the dropper tip of the bottle. The bottle should be tightly closed when not in use. Do not use after 4 weeks of first opening.

PACKAGING

Zolopt® Ophthalmic Suspension: Plastic dropper bottle containing 5 mL sterile Ophthalmic Suspension. Each mL contains Brinzolamide USP 10 mg.

SK+F

Manufactured by ESKAYEF BANGLADESH LIMITED

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