Binzotim®

Brinzolamide USP and Timolol Maleate BP
Sterile Ophthalmic Suspension

DESCRIPTION

Binzotim® is a combined preparation of Brinzolamide and Timolol. Brinzolamide is a potent inhibitor of human carbonic anhydrase II (CA-II), the predominant iso-enzyme in the eye. Inhibition of CA-II in the ciliary processes of the eye decreases aqueous humour secretion, presumably by slowing the formation of bicarbonate ions with subsequent reduction in sodium and fluid transport. Timolol is a non-selective beta-adrenergic blocking agent that has no intrinsic sympathomimetic, direct myocardial depressant or membrane-stabilising activity. Tonography and fluorophotometry studies in man suggest that its predominant action is related to reduce aqueous humour formation and a slight increase in outflow facility. These two components decrease elevated intraocular pressure (IOP) primarily by reducing aqueous humour secretion, but do so by different mechanisms of action. The combined effect of these two active substances results in additional IOP reduction compared to either compound alone. Benzalkonium Chloride 0.01% is used as preservative. Carbomer 974P 0.4% is used as vehicle.

INDICATIONS

Decrease of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.

DOSAGE & ADMINISTRATION

The recommended dosage is one drop in the conjunctival sac of the affected eye(s) twice daily.

CONTRAINDICATIONS

A history of hypersensitivity to Brinzolamide and other Sulphonamides, Timolol, or any other component of the medication.

SIDE EFFECTS

Blurred vision, Eye pain, Eye irritation, Foreign body sensation in eyes etc.

PRECAUTION & WARNING

Acid-base disturbances have been reported with oral carbonic anhydrase inhibitors. If signs of serious reactions or hypersensitivity occur, discontinue use of this medicine. Due to the beta-adrenergic component, Timolol, the same types of cardiovascular and pulmonary adverse reactions as seen with systemic beta-adrenergic blocking agents may occur. Cardiac failure should be adequately controlled before beginning therapy with Timolol. Patients with a history of severe cardiac disease should be watched for signs of cardiac failure and have their pulse rates checked.

USE IN PREGNANCY & LACTATION

Pregnancy Category C. There are no adequate data from the use of Brinzolamide in pregnant women. Studies in animals have shown reproductive toxicity. The potential risk for humans is unknown. Data on a limited number of exposed pregnancies indicate no adverse effects of Timolol in eye drops on pregnancy or on the health of the foetus but bradycardia and arrhythmia have been reported in one case in the foetus of a woman treated with Timolol eye drops. It is not known whether Brinzolamide is excreted in human breast milk. Animal studies have shown excretion of Brinzolamide in breast milk. Timolol does appear in human breast milk; however, at therapeutic doses of brinzolamide and Timolol ophthalmic suspension, no effects on the breastfed infants are anticipated. Brinzolamide and Timolol ophthalmic suspension can be used during breast-feeding.

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

Binzotim® Ophthalmic Suspension: Plastic dropper bottle containing 5 mL sterile ophthalmic suspension. Each mL contains Brinzolamide USP 10 mg and Timolol Maleate BP equivalent to Timolol 5 mg.

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Manufactured by
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GAZIPUR, BANGLADESH

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