

ZolamidTM Plus Sterile Ophthalmic Suspension

Brinzolamide 1% &
Brimonidine Tartrate 0.2%

Presentation

ZolamidTM Plus Sterile Ophthalmic Suspension: Each ml contains Brinzolamide USP 10 mg and Brimonidine Tartrate BP 2 mg.

Description

Zolamid Plus is a combination of a carbonic anhydrase inhibitor, brinzolamide and an alpha 2 adrenergic receptor agonist, brimonidine tartrate. Each of these two components decreases elevated intraocular pressure. Brinzolamide inhibits carbonic anhydrase in the ciliary processes of the eye to decrease aqueous humor secretion. Brimonidine tartrate has a dual mechanism of action by reducing aqueous humor production and increasing uveoscleral outflow.

Indication and Uses

It is a fixed combination of a carbonic anhydrase inhibitor and an alpha 2 adrenergic receptor agonist indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

Dosage and Administration

The recommended dose is one drop of this eye drop in the affected eye(s) three times daily. Shake well before use.

If more than one topical ophthalmic drug is being used, the drugs should be administered at least five minutes apart.

Side Effects

The most frequent reactions of this combination are blurred vision, eye irritation, dysgeusia (bad taste), dry mouth and eye allergy.

Use in Pregnancy and Lactation

Pregnancy: Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. It should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

Lactation: It is not known whether brinzolamide and brimonidine tartrate are excreted in human milk following topical ocular administration. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions from this combination in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in children below the age of 2 years have not been established.

Contraindications

Contraindicated in patients who are hypersensitive to any component of this product and in neonates and infants (under the age of 2 years).

Drug Interactions

Monoamine oxidase inhibitors may result in increased hypotension. Tricyclic antidepressants may potentially blunt the hypotensive effect of systemic clonidine. As brimonidine tartrate may reduce blood pressure, caution in using drugs such as antihypertensives / cardiac glycosides is advised. Use with CNS depressants may result in an additive or potentiating effect. The concomitant administration of topical and oral carbonic anhydrase inhibitors is not recommended as there is a potential for an additive effect. The potential for acid-base and electrolyte alterations with high-dose salicylate therapy should be considered.

Precautions

Due to presence of brinzolamide, a sulfonamide, if signs of serious reactions or hypersensitivity occur, discontinue the use of this preparation. There is an increased potential for developing corneal edema in patients with low endothelial cell counts.

Since brinzolamide and its metabolite are excreted predominantly by the kidney, it is not recommended in patients with severe renal impairment (CrCl < 30 mL/min).

Due to presence of Brimonidine tartrate, caution should be exercised in treating patients with severe cardiovascular disease, vascular insufficiency, CNS disease and hepatic impairment.

Overdose

No information is available on overdose with these drops in humans.

Storage

- Store in a cool & dry place, protected from light
- Keep out of reach of children
- Shake well before using.

Commercial Pack

ZolamidTM Plus Sterile Ophthalmic Suspension: Each plastic dropper bottle contains 5 ml of sterile ophthalmic suspension.