Zolopt BR®

Brinzolamide USP & Brimonidine Tartrate BP
Ophthalmic Suspension

DESCRIPTION

Zolopt BR® is a combined preparation of Brinzolamide & Brimonidine Tartrate. Brinzolamide (carbonic anhydrase inhibitor) and Brimonidine Tartrate (alpha 2 adrenergic receptor agonist). Each of these two components decreases elevated intraocular pressure. Elevated intraocular pressure is a major risk factor in the pathogenesis of optic nerve damage and glaucomatous visual field loss. The higher the level of intraocular pressure, the greater the likelihood of glaucomatous field loss and optic nerve damage. Brinzolamide inhibits carbonic anhydrase in the ciliary processes of the eye to decrease aqueous humor secretion, presumably by slowing the formation of bicarbonate ions with subsequent reduction in sodium and fluid transport.

INDICATIONS

Zolopt BR® (Brinzolamide/Brimonidine Tartrate ophthalmic suspension) 1%/0.2% 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 **Zolopt BR®** in the affected eye(s) three times daily. Shake well before use. **Zolopt BR®** ophthalmic suspension may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart.

CONTRAINDICATIONS

Hypersensitivity

Zolopt BR® is contraindicated in patients who are hypersensitive to any component of this product.

Neonates and Infants

Zolopt BR® is contraindicated in neonates and infants (under the age of 2 years).

SIDE EFFECTS

- Blurred vision
- Eye irritation
- Dysgeusia (bad taste)
- Dry mouth
- Eye allergy

PRECAUTIONS AND WARNINGS

Zolopt BR® contains Brinzolamide, a sulfonamide and although administered topically is absorbed systemically. Therefore, the same types of adverse reactions that are attributable to sulfonamides may occur with topical administration of **Zolopt BR®**. Fatalities have occurred due to severe reactions to sulfonamides including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia, and other blood dyscrasias. Sensitization may recur when a sulfonamide is re-administered irrespective of the route of administration. If signs of serious reactions or hypersensitivity occur, discontinue the use of this preparation.

USE IN PREGNANCY AND LACTATION

Pregnancy category C. There are no adequate and well-controlled studies in pregnant women. **Zolopt BR®** should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether Brinzolamide and Brimonidine Tartrate are excreted in human milk following topical ocular administration.

PHARMACEUTICAL PRECAUTION

Keep upright, away from light and wet place. Keep out of reach of children. 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 BR® Ophthalmic Suspension: Plastic dropper bottle containing 5 mL sterile ophthalmic suspension. Each mL contains Brinzolamide USP 10 mg and Brimonidine Tartrate BP 2 mg.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
TONGI, GAZIPUR, BANGLADESH
® REGD. TRADEMARK
PM05057 V01