Benozol BR™

Brinzolamide 1% +
Brimonidine Tartrate 0.2%

Sterile Ophthalmic Suspension

Description:
Benozol BR is a sterile ophthalmic suspension containing Brinzolamide + Brimonidine for topical administration to the eye.

Composition:
Each ml contains:
Active substance: Brinzolamide USP 10 mg and Brimonidine Tartrate INN 2 mg
Preservative: Benzalkonium Chloride 0.03 mg.

Clinical Pharmacology:
Benozol BR is comprised of two components: 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.
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. Brinzolamide has a peak ocular hypotensive effect occurring at 2 to 3 hours post-dosing.
Fluorophotometric studies in animals and humans suggest that Brimonidine Tartrate has a dual mechanism of action by reducing aqueous humor production and increasing uveoscleral outflow. Brimonidine Tartrate has a peak ocular hypotensive effect occurring at two hours post-dosing. The result is a reduction in intraocular pressure (IOP).

Indications and Uses:
Benozol BR is a fixed combination of a carbonic anhydrase inhibitor and an alpha 2 adrenergic receptor agonist indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

Dosage and Administration:
Shake well before use.
Instill one drop in the affected eye(s) three times daily. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart.

Contraindications:
It is contraindicated in patients who are hypersensitivity to Brinzolamide, Brimonidine Tartrate, or to any ingredient in the formulation and Neonates and Infants (under the age of 2 years).

Drug Interactions:
In patients treated with Benozol BR rare instances to drug interactions have occurred with high-dose salicylate therapy, CNS Depressants, Antihypertensives/Cardiac Glycosides, Tricyclic Antidepressants, Monoamine Oxidase Inhibitors. Therefore, the potential for such drug interactions should be considered in patients receiving Benozol BR .

Warning:
Benozol 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 Benozol 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.
Brimonidine Tartrate also may potentiate syndromes associated with vascular insufficiency. Benozol BR should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, or thromboangitis obliterans. anemia, and other blood dyscrasias. Brinzolamide and its metabolite are excreted predominantly by the kidney, Benozol BR is not recommended in renal impairment patients. The preservative in Benozol BR, benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of Benozol BR but may be reinserted 15 minutes after.

Adverse Reactions:
The most frequently reported adverse reactions in patients treated with Benozol BR occurring in approximately 3 to 5% of patients were blurred vision, eye irritation, dysgeusia (bad taste), dry mouth, and eye allergy.
Other adverse reactions that have been reported with the individual components during clinical trials are listed below.

Brinzolamide 1% :
The most frequently reported adverse reactions reported with Brinzolamide in 5 to 10% of patients were blurred vision and bitter, sour or unusual taste. Adverse reactions occurring in 1 to 5% of patients were blepharitis, dermatitis, dry eye, foreign body sensation, headache, hyperemia, ocular discharge, ocular discomfort, ocular keratitis, ocular pain, ocular pruritus and rhinitis.

Brimonidine Tartrate 0.2% :
Adverse reactions occurring with Brimonidine Tartrate in approximately 10 to 30% of the subjects, in descending order of incidence, included oral dryness, ocular hyperemia, burning and stinging, headache, blurring, foreign body sensation, fatigue/drowsiness, conjunctival follicles, ocular allergic reactions, and ocular pruritus.

Special Populations
Use in Pregnancy: Pregnancy Category C
Benozol BR should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in Nursing Mothers:
It is not known whether Benozol BR 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 in nursing infants from Benozol BR , 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.

Use in Pediatrics:
The individual component, Brinzolamide, has been studied in pediatric glaucoma patients 4 weeks to 5 years of age. The individual component, Brimonidine Tartrate, has been studied in pediatric patients 2 to 7 years old. Somnolence (50-83%) and decreased alertness was seen in patients 2 to 6 years old. Benozol BR is contraindicated in children under the age of 2 years

Use in Geriatrics:
No overall differences in safety or effectiveness have been observed between elderly and adult patients.

Overdosage:
Although no human data are available, electrolyte imbalance, development of an acidotic state, and possible nervous system effects may occur following an oral overdose of Brinzolamide. Serum electrolyte levels (particularly potassium) and blood pH levels should be monitored.
Very limited information exists on accidental ingestion of Brimonidine Tartrate in adults; the only adverse event reported to date has been hypotension. Symptoms of Brimonidine Tartrate overdose have been reported in neonates, infants, and children receiving Brimonidine Tartrate as part of medical treatment of congenital glaucoma or by accidental oral ingestion. Treatment of an oral overdose includes supportive and symptomatic therapy; a patent airway should be maintained.

Pharmaceutical Precautions:
Store at room temperature & protect from light. Do not touch dropper tip to any surface. It is desirable that the contents should not be used more than one month after first opening of the bottle. Shake well before use & do not freeze.

Commercial Pack:
A sterile ophthalmic suspension in 5 ml plastic dropper bottle.

Manufactured by :

POPULAR

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TONGI, GAZIPUR, BANGLADESH

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