Senzobrim™

Eye Drops 5mL

(Brinzolamide Ophthalmic Suspension IP 1% w/v)

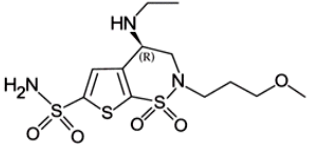
COMPOSITION:

Brinzolamide IP ..... 1.0% w/v
Benzalkonium Chloride Solution IP ..... 0.02% v/v
(As Preservative)
Water for Injections IP ..... q.s.

Description:

Brinzolamide ophthalmic suspension contains brinzolamide, an inhibitor of carbonic anhydrase II. Following topical ocular administration, brinzolamide inhibits aqueous humor formation and reduces elevated IOP. Elevated IOP is a major risk factor in the pathogenesis of optic nerve damage and glaucomatous visual field loss.

Brinzolamide is described chemically as: (R)-(+)-4-Ethylamino-2-(3-methoxypropyl)-3,4-dihydro-2H-thieno [3,2-e]-1,2-thiazine-6-sulfonamide-1,1-dioxide. Its empirical formula is C12H21N3O5S3, and its structural formula is:



Brinzolamide ophthalmic suspension 1% is supplied as a sterile, aqueous suspension of brinzolamide which has been formulated to be readily suspended and slow settling, following shaking.

Mechanism of Action:

Carbonic anhydrase 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. In humans, carbonic anhydrase exists as a number of isoenzymes, the most active being carbonic anhydrase II, found primarily in red blood cells (RBCs), 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. The result is a reduction in IOP.

Pharmacokinetics:

Following topical ocular administration, brinzolamide is absorbed into the systemic circulation. Due to its affinity for carbonic anhydrase II, brinzolamide distributes extensively into the RBCs and exhibits a long half-life in whole blood (approximately 111 days). In humans, the metabolite N-desethyl brinzolamide is formed, which also binds to carbonic anhydrase and accumulates in RBCs. This metabolite binds mainly to carbonic anhydrase I in the presence of brinzolamide. In plasma, both parent brinzolamide and N-desethyl brinzolamide concentrations are low and generally below assay quantitation limits (less than 10 ng/mL). Binding to plasma proteins is approximately 60%. Brinzolamide is eliminated predominantly in the urine as unchanged drug. N-

Desethyl brinzolamide is also found in the urine along with lower concentrations of the N-desmethoxypropyl and O-desmethyl metabolites.

Warnings and Precautions:

Sulfonamide Hypersensitivity Reactions

Brinzolamide ophthalmic suspension is a sulfonamide and although administered topically, it is absorbed systemically. Therefore, the same types of adverse reactions that are attributable to sulfonamides may occur with topical administration of brinzolamide ophthalmic suspension. Fatalities have occurred, although rarely, 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.

Corneal Endothelium:

Carbonic anhydrase activity has been observed in both the cytoplasm and around the plasma membranes of the corneal endothelium. There is an increased potential for developing corneal edema in patients with low endothelial cell counts. Caution should be used when prescribing brinzolamide ophthalmic suspension to this group of patients.

Severe Renal Impairment:

Brinzolamide ophthalmic suspension has not been studied in patients with severe renal impairment [creatinine clearance (CrCl) less than 30 mL/min]. Because brinzolamide ophthalmic suspension and its metabolite are excreted predominantly by the kidney, brinzolamide ophthalmic suspension is not recommended in such patients.

Acute Angle-Closure Glaucoma:

The management of patients with acute angle-closure glaucoma requires therapeutic interventions in addition to ocular hypotensive agents. Brinzolamide ophthalmic suspension has not been studied in patients with acute angle-closure glaucoma.

Contact Lens Wear:

The preservative in brinzolamide ophthalmic suspension, benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of brinzolamide ophthalmic suspension, but may be reinserted 15 minutes after instillation.

Allergies:

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals.

Lactation:

There are no data on the presence of brinzolamide in human milk, the effects on the breastfed infant, or the effects on milk production. Brinzolamide has been detected in the milk of lactating rats.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for brinzolamide ophthalmic suspension and any potential adverse effects on the breast-fed child from brinzolamide ophthalmic suspension.

Paediatric:

Appropriate studies have not been performed on the relationship of age to the effects of brinzolamide eye drops in the paediatric population. Safety and efficacy have not been established.

Geriatric:

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of brinzolamide eye drops in the elderly.

Drug Interactions:

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Aspirin
- Ceritinib
- Memantine
- Topiramate

Other Interactions:

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

Other Medical Problems:

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Allergy to sulfa drugs—Use with caution. May increase risk for more serious side effects.
- Cornea (part of the eye) problems, history of or
- Eye infection or
- Eye surgery, recent—Use with caution. May make these conditions worse.

Kidney disease, severe—Should not be used in patients with this condition

Side Effects:

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

More common:

- Blurred vision

Less common:

- Discharge from the eye
- Dry eyes
- Redness, soreness, irritation, or pain of the eye or eyelid
- Skin rash

Rare:

- Chest pain
- Cough
- Crusting in the corner of the eye
- Difficulty with swallowing
- Dizziness
- Double vision

· Excessive muscle tone
· Eye redness, irritation, or pain
· Fast heartbeat

Storage and handling instructions:
Keep in a cool place
Use the suspension within one month after opening the container.
Do not touch the tip of the container to any surface. Replace cap after using. Protect from light.

KEEP OUT OF REACH OF CHILDREN
NOT FOR INJECTION
FOR EXTERNAL USE ONLY
SHAKE WELL BEFORE USE

Presentation:
Senzobrim is a 5 mL of sterile white to off white colour ophthalmic suspension supplied in opaque plastic dropper bottle with a cap.

Directions for use :


Turn the tamper proof cap anti-clockwise to break the seal.
Remove the cap, dispense drops with gentle pressure.

Replace the cap immediately after every use.

Manufactured in INDIA by :
Senses Pharmaceuticals Pvt. Ltd.,
No.77, 3rd Road, Bommasandra Industrial Area,
Bommasandra 4th Phase, Bengaluru - 560 099.

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