

AZOPRES

BRINZOLAMIDE USP

Compositions:

<p>Azopres Eye Suspension : Each ml contains Brinzolamide USP 10 mg.</p>

Pharmacology:

Brinzolamide is an inhibitor of carbonic anhydrase II (CA-II). 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 intraocular pressure (IOP).

Indications:

Indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

Dosage And Administration:

Instill 1 drop 3 times daily in the affected eye(s). If more than one topical ophthalmic drug is being used, the drugs should be administered at least ten (10) minutes apart.

Contraindications:

Brinzolamide ophthalmic suspension 1% is contraindicated in patients who are hypersensitive to any component of this product.

Warning And Precaution:

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.

Side Effects:

The following adverse reactions were reported at an incidence below 1 % allergic reactions, alopecia, chest pain, conjunctivitis, diarrhea, diplopia, dizziness, dry mouth, dyspnea, dyspepsia, eye fatigue, hypertonia, keratoconjunctivitis, keratopathy, kidney pain, lid margin crusting or sticky sensation, nausea, pharyngitis, tearing and urticaria.

Use in Pregnancy and Lactation:

There are no adequate and well-controlled studies in pregnant women. Brinzolamide ophthalmic suspension 1% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Brinzolamide ophthalmic suspension 1%, 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.

Drug Interaction:

There is a potential for an additive effect on the known systemic effects of carbonic anhydrase inhibition in patients receiving an oral carbonic anhydrase inhibitor and Brinzolamide ophthalmic suspension 1%. The concomitant administration of Brinzolamide ophthalmic suspension 1% and oral carbonic anhydrase inhibitors is not recommended.

Overdosage:

Although no human data are available, electrolyte imbalance, development of an acidotic

state, and possible nervous system effects may occur following oral administration of an overdose. Serum electrolyte levels (particularly potassium) and blood pH levels should be monitored.

Storage:

Store in a cool, dry place and protected from light. Keep out of reach of children. Discard the container 4 weeks after opening.

Packing:

<p>Azopres Eye Suspension : Each plastic dropper bottle contains 5 ml sterile Eye Suspension.</p>

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.