

## FIRST TIME GENERIC APPROVAL

<b>Brand Name</b>	Azopt®
<b>Generic Name</b>	brinzolamide
<b>Drug Manufacturer</b>	Watson Labs, Inc.

### New Drug Approval

#### TYPE OF CLINICAL UPDATE

First time generic

#### FDA APPROVAL DATE

November 27, 2020

#### LAUNCH DATE

March 8, 2021

#### REVIEW DESIGNATION

Standard

#### TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 209406

#### DISPENSING RESTRICTIONS

N/A

### Overview

#### INDICATION FOR USE

Brinzolamide ophthalmic suspension 1% is a carbonic anhydrase inhibitor indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

#### MECHANISMS OF ACTION

Carbonic anhydrase (CA) is an enzyme found in many tissues of the body including the eye. It catalyzes 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 (CA-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 intraocular pressure (IOP).

Brinzolamide ophthalmic suspension 1% contains brinzolamide, an inhibitor of carbonic anhydrase II (CA-II). Following topical ocular administration, brinzolamide inhibits aqueous humor formation and reduces elevated intraocular pressure. Elevated intraocular pressure is a major risk factor in the pathogenesis of optic nerve damage and glaucomatous visual field loss.

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### DOSE FORM AND STRENGTH

Solution containing 10 mg/mL brinzolamide

### DOSE & ADMINISTRATION

- 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 (10) minutes apart.

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