NOVARTIS

AZOPT (brinzolamide 1%)

Ophthalmic suspension

Basic Succinct Statement

CODE: BSS RD 31 JAN 17 - APPR 07 FEB 19

This material is only meant for Healthcare Professionals

AZOPT

Important note: Before prescribing, consult full prescribing information.

Presentation: Plastic DROP-TAINER* dispensers with a controlled dispensing-tip. Each ml of AZOPT 1% contains 10 mg brinzolamide. Benzalkonium chloride 0.01% is added as a preservative.

Indications: Treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

Dosage and administration: ♦When used as monotherapy or adjunctive therapy, the dose is one drop of AZOPT Ophthalmic Suspension in the conjunctival sac of the affected eye(s) twice daily. Some patients may have a better response with one drop three times a day. If a dose is missed, treatment should be continued with the next dose as planned. The dose should not exceed 1 drop in the affected eye(s) 3 times daily.

Contraindications: ♦Hypersensitivity to the active substance, to any of the excipients or to sulphonamides. ♦Severe renal impairment. ♦Hyperchloraemic acidosis.

Warnings and Precautions: ♦Hypersensitivity reactions common to all sulphonamide derivatives can occur in patients receiving AZOPT* 10mg/ml Ophthalmic Suspension as it is absorbed systemically. If signs of serious reactions or hypersensitivity occur, discontinue the use of this product. ♦Acid-base disturbances have been reported with oral carbonic anhydrase inhibitors. Use with caution in patients with risk of renal impairment because of the possible risk of metabolic acidosis. ♦The possible role of brinzolamide on corneal endothelial function has not been investigated in patients with compromised corneas (particularly in patients with low endothelial cell count). Careful monitoring of patients with compromised corneas, such as patients with diabetes mellitus or corneal dystrophies, is recommended. ♦AZOPT* 10mg/ml Ophthalmic Suspension contains benzalkonium chloride which may cause eye irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses. Patients must be instructed to remove contact lenses prior to application of AZOPT* 10mg/ml Ophthalmic Suspension and wait at least 15 minutes before reinsertion.

Adverse drug reactions: ●The following adverse reactions have been reported during clinical studies with AZOPT* 10mg/ml Ophthalmic Suspension and are classified according to the subsequent convention: very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000) and very rare (<1/10,000). ♦**Common:** vision blurred, eye irritation, eye pain, ocular discomfort, ocular hyperaemia, dysgeusia ♦**Uncommon:** depression, dizziness, paresthesia, headache, corneal erosion, punctate keratitis, keratitis, conjunctivitis, conjunctivitis allergic, blepharitis, photophobia, dry eye, asthenopia, eye pruritus, lacrimation increased, eye discharge, eyelid margin crusting, dyspnoea, epistaxis, rhinorrhoea, oropharyngeal pain, upper airway cough syndrome, throat irritation, nausea, diarrhoea, dyspepsia, abdominal discomfort, dry mouth, rash, fatigue ♦**Rare:** insomnia, memory impairment, somnolence, corneal oedema, diplopia, visual acuity reduced, photopsia, hypoaesthesia eye, periorbital oedema, tinnitus, angina pectoris, heart rate irregular, bronchial hyperreactivity, upper respiratory tract congestion, sinus congestion, nasal congestion, cough, nasal dryness, urticaria, alopecia, pruritus generalised, chest pain, feeling jittery, asthenia,

irritability. •Additional adverse reactions identified from post-marketing surveillance include the following. Frequencies cannot be estimated from the available data: decreased appetite, hypoaesthesia, blood pressure decreased, arthralgia.

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