NOVARTIS

AZARGA (brinzolamide and timolol)

10 mg/mL and 5mg/mL eye drops, suspension

Basic Succinct Statement

CODE: BSS RD JAN 2018; APPR 05 DEC 18

This material is only meant for Healthcare Professionals

AZARGA

Important note: Before prescribing, consult full prescribing information.

Presentation: Bottle: 1 ml of suspension contains 10 mg brinzolamide and 5 mg timolol (as timolol maleate).

Indications: Decrease of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.

Dosage and administration: ♦**Use in adults, including the elderly:** The dose is one drop of AZARGA eye drops, suspension in the conjunctival sac of the affected eye(s) twice daily. When substituting another ophthalmic antiglaucoma agent with AZARGA eye drops, suspension, the other agent should be discontinued and AZARGA eye drops, suspension should be started the following day. ♦**Use in paediatric patients:** AZARGA eye drops, suspension is not recommended for use in children below 18 years due to a lack of data on safety and efficacy. ♦**Use in geriatric patients:** No overall differences in safety and effectiveness have been observed between elderly and other adult populations. ♦**Use in patients with hepatic or renal impairment**: No studies have been conducted with AZARGA eye drops, suspension or with timolol 5 mg/ml eye drops in patients with hepatic or renal impairment. No dosage adjustment is necessary in patients with hepatic impairment or in patients with mild to moderate renal impairment. AZARGA eye drops, suspension has not been studied in patients with severe renal impairment (creatinine clearance < 30 ml/min) or in patients with hyperchloraemic acidosis. Since brinzolamide and its main metabolite are excreted predominantly by the kidney, AZARGA eye drops, suspension is therefore contraindicated in patients with severe renal impairment.

Contraindications: ♦Hypersensitivity to the active substances or to any of the excipients. ♦Hypersensitivity to other beta-blockers. ♦Hypersensitivity to sulphonamides. ♦Reactive airway disease including bronchial asthma or a history of bronchial asthma, or severe chronic obstructive pulmonary disease. ♦Sinus bradycardia, sick sinus syndrome, sino-atrial block, second or third degree atrioventricular block, overt cardiac failure or cardiogenic shock. ♦Severe allergic rhinitis. ♦Severe renal impairment. ♦Hyperchloraemic acidosis.

Warnings and Precautions: ♦**General:** •Like other topically applied ophthalmic agents, brinzolamide and timolol are absorbed systemically. Due to beta-adrenergic blocking component, timolol, the same types of cardiovascular, pulmonary and other adverse reactions seen with systemic beta-adrenergic blocking agents may occur. •Hypersensitivity reactions common to all sulphonamide derivates can occur in patients receiving AZARGA eye drops 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). Carbonic anhydrase inhibitors may affect corneal hydration, which may lead to a corneal decompensation and oedema. Careful monitoring of patients with compromised corneas, such as patients with diabetes mellitus or corneal dystrophies, is recommended. •When using nasolacrimal occlusion or closing the eyelids, the systemic absorption is reduced. This may result in a decrease in systemic side effects and an

increase in local activity. •After cap is removed, if tamper evident snap collar is loose, remove before using product. ♦**Cardiac disorders:** In patients with cardiovascular diseases (e.g. coronary heart disease, Prinzmetal's angina and cardiac failure) and hypotension, therapy with beta-blockers should be critically assessed and the therapy with other active substances should be considered. Patients with cardiovascular diseases should be watched for signs of deterioration of these diseases and of adverse reactions. ♦**Vascular disorders:** Patients with severe peripheral circulatory disturbance/disorders (i.e. severe forms of Raynaud's disease or Raynaud's syndrome) should be treated with caution. ♦**Respiratory disorders:** Respiratory reactions, including death due to bronchospasm in patients with asthma, have been reported following administration of some ophthalmic beta-blockers. ♦**Hypoglycaemia/diabetes:** Beta-blockers should be administered with caution in patients subject to spontaneous hypoglycaemia or to patients with labile diabetes as beta-blockers may mask the signs and symptoms of acute hypoglycaemia. ♦**Hyperthyroidism:** Beta-blockers may also mask the signs of hyperthyroidism. ♦**Muscle weakness:** Beta-adrenergic blocking agents have been reported to potentiate muscle weakness consistent with certain myasthenic symptoms (e.g. diplopia, ptosis and generalized weakness). ♦**Other beta-blocking agents:** The effect on intra-ocular pressure or the known effects of systemic beta-blockade may be potentiated when timolol is given to the patients already receiving a systemic beta-blocking agent. The response of these patients should be closely observed. The use of two topical beta-adrenergic blocking agents is not recommended. ♦**Anaphylactic reactions:** While taking beta-blockers, patients with a history of atopy or a history of severe anaphylactic reaction to a variety of allergens may be more reactive to repeated challenge with such allergens and unresponsive to the usual doses of adrenaline used to treat anaphylactic reactions. ♦**Choroidal detachment:** Choroidal detachment has been reported with administration of aqueous suppressant therapy (e.g. timolol, acetazolamide) after filtration procedures. ♦**Surgical anaesthesia:** Beta-blocking ophthalmological preparations may block systemic beta-agonist effects e.g. of adrenaline. The anaesthesiologist should be informed when the patients is receiving timolol. ♦**Contact lenses:** AZARGA eye drops, 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 the application of AZARGA eye drops, suspension and wait at least 15 minutes before reinsertion. ♦**Ability to drive and use machines:** Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient must wait until the vision clears before driving or using machinery. Carbonic anhydrase inhibitors may impair the ability to perform tasks requiring mental alertness and/or physical coordination.

Adverse drug reactions: ♦**Common (≥ 1/100 to <1/10):** Dysgeusia, punctate keratitis, vision blurred, eye pain, eye irritation, heart rate decreased. ♦**Uncommon (≥1/1,000 to <1/100):** white blood cell count decreased, keratitis, dry eye, vital dye staining cornea present, eye pruritus, foreign body sensation in eyes, eye discharge, ocular hyperaemia, conjunctival hyperaemia, blood pressure decreased, cough, blood urine present, malaise. ♦**Rare (≥1/10,000 to <1/1,000):** insomnia, corneal erosion, anterior chamber flare, photophobia lacrimation increased, scleral hyperaemia, erythema of eyelid, eyelid margin crusting, oropharyngeal pain, rhinorrhoea. ♦**Post-Marketing Surveillance:** Anaphylactic shock, hypersensitivity, palpitations, tinnitus, depression, dizziness, headache, paraesthesia, eye allergy, eyelid oedema, visual impairment, conjunctivitis, blood pressure increased, asthma, dyspnoea, epistaixs,

abdominal discomfort, diarrhoea, dry mouth, nausea, alopecia, erythema, rash, pruritus, myalgia, chest pain, fatigue.

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