NOVARTIS

SIMBRINZA® (brinzolamide 10 mg/mL /brimonidine 2 mg/mL)
Eye drops, suspension

Basic Succinct Statement (BSS)

CODE: BSS RD 22 MAR 19; APPR 03 DEC 19

This material is only meant for Healthcare Professionals

SIMBRINZA®

Important note: Before prescribing, consult full prescribing information.

Presentation: 8 mL round opaque low density polyethylene (LDPE) bottle with a LDPE dropper tip and white polypropylene screw cap (Drop-Tainer) containing 5 mL suspension. Each ml of suspension contains 10 mg of brinzolamide and 2 mg of brimonidine tartrate equivalent to 1.3 mg of brimonidine as well as 0.03mg of benzalkonium chloride as preservative.

Indications: SIMBRINZA eye drops contains brinzolamide, a carbonic anhydrase (CA-II) inhibitor, and brimonidine tartrate, an alpha-2 adrenergic agonist. Decrease of elevated 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 recommended dose is 1 drop of SIMBRINZA eye drops in the affected eye(s) 2 times daily. ♦**Paediatric population**: The safety and efficacy of SIMBRINZA in children and adolescents aged 2 to 17 years have not been established. No data are available. SIMBRINZA is contraindicated in neonates and infants aged less than 2 years in the decrease of elevated intraocular pressure (IOP) with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction because of safety concerns. ♦ **Hepatic and/or renal impairment:** SIMBRINZA eye drops has not been studied in patients with hepatic impairment and caution is therefore recommended in this population. SIMBRINZA eye drops has not been studied in patients with severe renal impairment (CrCl < 30 ml/min) or in patients with hyperchloraemic acidosis. Since the brinzolamide component of SIMBRINZA eye drops and its metabolite are excreted predominantly by the kidney, SIMBRINZA eye drops is contraindicated in such patients.

Contraindications: ♦Hypersensitivity to the active substances or to any of the excipients. ♦Hypersensitivity to sulphonamides. ♦Patients receiving monoamine oxidase (MAO) inhibitor therapy. ♦Patients on antidepressants which affect noradrenergic transmission (e.g. tricyclic antidepressants and mianserin). ♦Patients with severe renal impairment. ♦Patients with hyperchloraemic acidosis. ♦Neonates and infants under the age of 2 years.

Warnings and precautions: ♦In case of allergic reactions due to brimonidine tartrate or brinzolamide (a sulphonamide derivative), treatment should be discontinued. ♦Risk of delayed ocular hypersensitivity reactions associated with an increase in IOP. ♦If signs of serious reactions or hypersensitivity occur, discontinue the use of the product. ♦Careful monitoring of patients with compromised corneas, such as patients with diabetes mellitus or corneal dystrophies, is recommended. ♦Caution in patients with risk of renal impairment because of the possible risk of metabolic acidosis. ♦Caution in patients with risk of hepatic impairment ♦Caution in patients with severe cardiovascular disorders and in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension or thromboangiitis obliterans. ♦Benzalkonium chloride may cause eye irritation and is known to discolor soft contact lenses. ♦Contact lenses must be removed before administration and wait at least 15 minutes before reinsertion. ♦Caution in patients who drive and use machines due to temporary blurred vision or other visual disturbances, patient must wait until the vision clears before driving or using machinery. ♦Caution in patients who engage in hazardous activities due to potential for a decrease in mental alertness.

Pediatric population: Simbrinza is not recommended in children 2 years and above because of the potential for CNS related side effects.

Adverse drug reactions: ■ In clinical trials involving SIMBRINZA dosed twice-daily the most common adverse reactions were ocular hyperaemia and ocular allergic type reactions occurring in approximately 6-7% of patients, and dysgeusia (bitter or unusual taste in the mouth following instillation) occurring in approximately 3% of patients. ♦**Common (≥ 1/100 to < 1/10):** somnolence[1], dizziness[3], dysgeusia[1], eye allergy[1], keratitis[1], eye pain[1], ocular discomfort[1], blurred vision[1], abnormal vision[3], ocular hyperaemia[1], conjunctival blanching[3], dry mouth[1]. ♦**Uncommon (≥ 1/1000 to < 1/100):** nasopharyngitis[2], pharyngitis[2], sinusitus[2], red blood cell decreased[2], blood chloride increased[2], hypersensitivity[3], apathy[2], depression[2,3], depressed mood[2], insomnia[1], libido decreased[2], nightmares[2], nervousness[2], headache[1], motor dysfunction[2], amnesia[2], memory impairment[2], paraesthesia[2], : corneal erosion[1], corneal oedema[2], blepharitis[1], corneal deposits (keratic precipitates) [1], conjunctival disorder (papillae) [1], photophobia[1], photopsia[2], eye swelling[2], eyelid oedema[1], conjunctival oedema[1], dry eye[1], eye discharge[1], visual acuity reduced[2], lacrimation increased[1], pterygium[2], erythema of eyelid[1], meibomianitis[2], diplopia[2], glare[2], hypoaesthesia eye[2], scleral pigmentation[2], subconjunctival cyst[2],abnormal sensation in eye[1], asthenopia[1], vertigo[1], tinnitus[2], cardio-respiratory distress[2], angina pectoris[2], arrhythmia[3], palpitations[2,3], heart rate irregular[2], bradycardia[2,3], tachycardia[3], hypotension[1], dyspnoea[2], bronchial hyperactivity[2], pharyngolaryngeal pain[2], dry throat[1], cough[2], epistaxis[2], upper respiratory tract congestion[2], nasal congestion[1], rhinorrhoea[2], throat irritation[2], nasal dryness[1], postnasal drip[1], sneezing[2], dyspepsia[1], oesophagitis[2], abdominal discomfort[1], , diarrhoea[2], vomiting[2], nausea[2], frequent bowel movements[2], flatulence[2], hypoaesthesia oral[2], paraesthesia oral[1], dermatitis contact[1], urticaria[2], rash[2], rash maculopapular[2], pruritus generalized[2], alopecia[2], skin tightness[2], back pain[2], muscle spasms[2], myalgia[2], renal pain[2], erectile dysfunction[2], pain[2], chest discomfort[2], feeling abnormal[2], feeling jittery[2], irritability[2], medication residue[1]. ♦**Very rare (< 1/10,000):** syncope[3], uveitis[3], miosis[3], hypertension[3]. ♦**Not known:** rhinitis[2], tremor[2], hypoaesthesia[2], ageusia[2], visual disturbances[2], madarosis[2], asthma[2], liver function test abnormal[2], face oedema[3], dermatitis[2,3], erythema[2,3], arthralgia[2], pain in extremity[2], pollakiuria[2], chest pain[2], peripheral oedema[2,3].

[1] adverse reaction observed with SIMBRINZA
[2] additional adverse reaction observed with brinzolamide monotherapy
[3] additional adverse reaction observed with brimonidine monotherapy