NOVARTIS

BETOPTIC* S (betaxolol hydrochloride)

0.25% suspension

Basic Succinct Statement

CODE: BSS 45477-3; APPR 23 FEB 16

This material is only meant for Healthcare Professionals

BETOPTIC* S

Important note: Before prescribing, consult full prescribing information.

Presentation: 5ml plastic ophthalmic DROP-TAINER* dispenser. 1ml of suspension contains 2.5mg betaxolol base (equivalent to 2.8mg betaxolol hydrochloride). Preservative: 1ml suspension contains 0.1mg benzalkonium chloride.

Indications: BETOPTIC S Suspension has been shown to be effective in lowering intraocular pressure and may be used in patients with chronic open-angle glaucoma and ocular hypertension. It may be used alone or in combination with other intraocular pressure lowering medications.

Dosage and administration: ♦**Use in adults (including elderly):** The recommended dose is one or two drops of BETOPTIC S Suspension in the affected eye(s) twice daily. In some patients, the intraocular pressure lowering responses to BETOPTIC S Suspension may require a few weeks to stabilize. As with any new medication, careful monitoring of patients is advised. If the intraocular pressure of the patient is not adequately controlled on this regimen, concomitant therapy with other anti-glaucoma agents can be instituted. ♦**Use in hepatic and renal impairment:** The safety and efficacy of BETOPTIC S Suspension in patients with hepatic and renal impairment have not been established. ♦**For ocular use.** Shake well before use. To prevent contamination of the dropper tip and suspension, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip. Keep the bottle tightly closed when not in use. If more than one topical ophthalmic product is being used, the products must be administered at least 5 minutes apart. Eye ointments should be administered last.

Contraindications: ♦Hypersensitivity to the active substance or to any of the excipients in this product. ♦Sinus bradycardia, second or third degree atrioventricular block, overt cardiac failure, or cardiogenic shock.

Warnings and Precautions: ♦**General:** Like other topically applied ophthalmic agents, betaxolol is absorbed systemically. Due to the beta-adrenergic component, betaxolol, the same types of cardiovascular, pulmonary and other adverse reactions seen with systemic beta-adrenergic blocking agents may occur. ♦**Cardiac disorders:** BETOPTIC S Suspension has been shown to have a minor effect on heart rate and blood pressure in clinical studies. 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. Treatment with BETOPTIC S Suspension should be discontinued at the first signs of cardiac failure. ♦**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. Caution should be exercised in the treatment of glaucoma patients with excessive restriction of pulmonary function. There have been reports of asthmatic attacks and pulmonary distress during betaxolol treatment. Although re-challenges of some such patients with ophthalmic betaxolol has not adversely affected pulmonary function test results, the possibility of adverse pulmonary effects in patients sensitive to beta-blockers cannot be ruled out.

♦**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 (e.g. tachycardia). Patients suspected of developing thyrotoxicosis should be managed carefully to avoid abrupt withdrawal of beta-adrenergic agents, which might precipitate a thyroid storm. ♦**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). ♦**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 dose of adrenaline used to treat anaphylactic reactions. ♦**Surgical Anaesthesia:** Beta-blocking ophthalmological preparations may block systemic beta-agonist effects e.g. of adrenaline. The anaesthesiologist should be informed when the patient is receiving betaxolol. Consideration should be given to the gradual withdrawal of beta-adrenergic blocking agents prior to general anaesthesia because of the reduced ability of the heart to respond to beta-adrenergically mediated sympathetic reflex stimuli. ♦**Ocular:** When BETOPTIC S Suspension is used to reduce elevated intraocular pressure in angle-closure glaucoma, it should be used with a miotic and not alone. In patients with angle-closure glaucoma, the immediate treatment objective is to reopen the angle by constriction of the pupil with a miotic agent. Betaxolol has little or no effect on the pupil. ♦**Contact lenses:** BETOPTIC S Suspension contains benzalkonium chloride which may cause 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 BETOPTIC S Suspension and wait at least 15 minutes before reinsertion. ♦**Effects on 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 after instillation, the patient must wait until the vision clears before driving or using machinery.

Adverse drug reactions:

The following adverse reactions have been reported during clinical trials with [Betaxolol Eye Drops] 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). Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness. ♦**Very common:** ocular discomfort; ♦**Common:** headache, vision blurred, lacrimation increased, foreign body sensation in eyes; ♦**Uncommon:** bradycardia, tachycardia, punctate keratitis, keratitis, conjunctivitis, blepharitis, visual acuity reduced, visual impairment, photophobia, eye pain, dry eye, asthenopia, blepharospasm, abnormal sensation in eye, eye pruritus, eye discharge, eyelid margin crusting, eye inflammation, eye irritation, conjunctival disorder, conjunctival oedema, ocular hyperaemia, asthma, dyspnoea, rhinitis, respiratory disorder, nausea; ♦**Rare:** atrioventricular block, cardiac failure congestive, syncope, dysgeusia, vertigo, lethargy, myasthenia gravis, parosmia, cataract, eye disorder, cough, rhinorrhoea, bronchospasm, increased viscosity of bronchial secretion, glossitis, dysgeusia, dermatitis, rash, urticaria, toxic epidermal necrolysis, hypotension, anxiety, libido decreased; ♦**Not known:** alopecia. ♦Additional adverse reactions identified from post-marketing surveillance include the following. Frequencies cannot be estimated from the available data: hypersensitivity, insomnia, depression, dizziness, erythema of eyelid, arrhythmia, alopecia, asthenia. ♦Additional medical events reported with other formulations of betaxolol include

hypoaesthesia eye, corneal staining which may appear in dendritic formations, oedema and pupils unequal.

* A trademark of Novartis