NOVARTIS

DuoTrav (travoprost and timolol)

40 mcg/mL + 5mg/ml eye drops, solution

Basic Succinct Statement

CODE: BSS RD FEB 18 - APPR 16 OCT 18

This material is only meant for Healthcare Professionals

DUOTRAV*

Important note: Before prescribing, consult full prescribing information.

Presentation: Oval bottle: Each ml of solution contains 40 micrograms of travoprost and 5 mg of timolol (as timolol maleate).

Indications: Decrease of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.

Dosage and administration: ♦Use in adults, including the elderly population (65 years and above): The dose is one drop of DUOTRAV eye drops in the conjunctival sac of the affected eye(s) once daily, in the morning or evening. It should be administered at the same time each day. If a dose is missed, treatment should be continued with the next dose as planned. The dose should not exceed one drop in the affected eye(s) daily. **♦Special Populations (Hepatic and renal impairment):** No studies have been conducted with DUOTRAV eye drops or with timolol 5 mg/ml eye drops in patients with hepatic or renal impairment. Travoprost alone has been studied in patients with mild to severe hepatic impairment and in patients with mild to severe renal impairment (creatinine clearance as low as 14 ml/min). No dose adjustment was necessary in these patients. Patients with hepatic or renal impairment are unlikely to require dose adjustment with DUOTRAV eye drops. **♦Pediatric population (below 18 years)**: The safety and efficacy of DUOTRAV eye drops in children and adolescents below the age of 18 years have not been established. No data are available.

Contraindications: ♦Hypersensitivity to the active substances, or to any of the excipients. ♦Reactive airway disease including bronchial asthma, a history of bronchial asthma or severe chronic obstructive pulmonary disease. ♦Sinus bradycardia, sick sinus syndrome (including sino-atrial block), second or third degree atrioventricular block, overt cardiac failure, or cardiogenic shock.

Warnings and Precautions: ♦General: Like other topically applied ophthalmic agents, travoprost and timolol are absorbed systemically. Due to the beta-adrenergic blocking component in ophthalmic timolol, the same types of cardiovascular and pulmonary and other adverse reactions seen with systemic beta adrenergic blocking agents may occur. **♦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 for 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).

♦**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. ♦**Ocular effects**: Travoprost may gradually change the eye colour by increasing the number of melanosomes (pigment granules) in melanocytes. Before treatment is instituted, patients must be informed of the possibility of a permanent change in eye colour. The change in iris colour occurs slowly and may not be noticeable for months to years. Periorbital and/or eyelid skin darkening has been reported in association with the use of travoprost. Travoprost may gradually change eyelashes in the treated eye(s); these changes include increased length, thickness, pigmentation, and/or number of lashes. Macular edema has been reported during treatment with prostaglandin F2a analogues. Use travoprost with caution in aphakic patients, pseudophakic patients with torn posterior lens capsule or anterior chamber lenses, or in patients with known risk factors for macular oedema. DUOTRAV eye drops should be used with caution in patients with active intraocular inflammation, as well as patients with predisposing risk factors for uveitis. Periorbital and lid changes including deepening of the eyelid sulcus have been observed with prostaglandin analogues. ♦**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. ♦**Ability to drive and use machines:** As with any eye drop, 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 machines.

Adverse drug reactions: ■ **From clinical trials ♦Very common (≥ 10%):** ocular hyperaemia. ♦**Common (≥ 1/100 to < 1/10):** punctate keratitis, vision blurred, dry eye, eye pain, eye pruritus, ocular discomfort, eye irritation, ♦**Uncommon (≥ 1/1000 to < 1/100):** hypersensitivity, dizziness, headache, keratitis, iritis, conjunctivitis, anterior chamber inflammation, blepharitis, photophobia, visual acuity reduced, asthenopia, eye swelling, lacrimation increased, erythema of eyelid, growth of eyelashes, bradycardia, hypertension, hypotension, dyspnoea, dermatitis contact, hypertrichosis, skin hyperpigmentation (periorbital or eyelid pigmentation) ♦**Rare (≥ 1/10,000 to < 1/1000):** corneal erosion, meibomianitis, conjunctival haemorrhage, eyelid margin crusting, trichiasis, distichiasis, dysphonia, bronchospasm, cough, throat irritation, urticaria, skin discolouration ■ **From spontaneous reports and literature cases (frequency not known):** Depression, macular oedema, eyelid ptosis, lid sulcus deepened, iris hyperpigmentation, chest pain, palpitations, oedema peripheral, dysgeusia, asthma, rash, alopecia.