NOVARTIS

Travatan (travoprost)

40 mcg/mL eye drops, solution

Basic Succinct Statement

CODE: BSS 759430 – APPR 03 DEC 2018

This material is only meant for Healthcare Professionals

Travatan

Important note: Before prescribing, consult full prescribing information.

Presentation: Oval bottle: Each ml of solution contains 40 micrograms of travoprost.

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

Dosage and administration: ♦Use in adults, including the elderly population: The dose is one drop of TRAVATAN eye drops in the conjunctival sac of the affected eye(s) once daily. Optimal effect is obtained if the dose is administered in the evening. **♦Paediatric population:** The efficacy and safety of TRAVATAN eye drops in patients below the age of 18 years have not been established and its use is not recommended in these patients until further data become available. **♦Hepatic and renal impairment:** TRAVATAN eye drops 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 dosage adjustment is necessary in these patients.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Warnings and Precautions: ■ Eye Colour Changes ♦TRAVATAN* eye drops 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 eye lid changes** ♦Periorbital and/or eyelid skin darkening has been reported in association with the use of TRAVATAN* eye drops. ♦Periorbital and lid changes including deepening of the eyelid sulcus have been observed with prostaglandin analogues. ♦TRAVATAN* eye drops may gradually change eyelashes in the treated eye(s); these changes were observed in about half of the patients in clinical trials and include: increased length, thickness, pigmentation, and/or number of lashes. **■ Aphakic patients** ♦Macular oedema has been reported during treatment with prostaglandin F2a analogues. Use TRAVATAN* eye drops with caution in aphakic patients, pseudophakic patients with torn posterior lens capsule or anterior chamber lenses, or in patients with known risk factors for cystoid macular oedema. **■ Iritis/Uveitis** ♦TRAVATAN* eye drops should be used with caution in patients with active intraocular inflammation, as well as patients with predisposing risk factors for uveitis. **♦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.

Adverse drug reactions: ■The following adverse reactions have been reported during clinical studies with TRAVATAN* 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 ≤1/1000), or very rare (≤1/10,000). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness. **♦Very common:** ocular hyperaemia. **♦Common:** eye pain, eye pruritus, dry eye, eye irritation, iris hyperpigmentation, ocular discomfort. **♦Uncommon:** *Immune system disorders:* hypersensitivity; *Nervous system disorders:* headache; *Eye disorders:* corneal erosion, punctate keratitis, keratitis, iritis, cataract, visual acuity reduced, conjunctivitis, anterior chamber

inflammation, blepharitis, vision blurred, photophobia, periorbital oedema, eyelids pruritus, eye discharge, eyelid margin crusting, lacrimation increased, erythema of eyelid, growth of eyelashes; *Skin and subcutaneous tissue disorders:* skin hyperpigmentation, hypertrichosis ♦**Rare:** *Nervous system disorders:* dizziness, dysgeusia; *Eye disorders:* uveitis, iridocyclitis, ophthalmic herpes simplex, conjunctival follicles, conjunctival oedema, hypoaesthesia eye, eye inflammation, trichiasis, anterior chamber pigmentation, asthenopia, eye allergy, eczema eyelids, eyelid irritation, eyelash hyperpigmentation, eyelash thickening; *Cardiac disorders:* heart rate decreased, palpitations; *Vascular disorders:* hypertension, hypotension; *Respiratory, thoracic and mediastinal disorders:* asthma, dyspnoea, dysphonia, cough, rhinitis allergic, oropharyngeal pain, nasal discomfort, nasal dryness; *Gastrointestinal disorders:* dry mouth, constipation; *Musculoskeletal and connective tissue disorders:* arthralgia, musculoskeletal pain; *General disorders and administration site conditions:* asthenia ■ **Post-Marketing Surveillance:** *Within each System Organ Class adverse reactions are presented in order of decreasing seriousness* ♦**Psychiatric disorders:** Depression, anxiety, insomnia ♦**Eye disorders:** Macular oedema, lid sulcus deepened ♦**Ear and labyrinth disorders:** Tinnitus ♦**Cardiac disorders:** Arrhythmia, tachycardia, chest pain ♦**Respiratory, thoracic and mediastinal disorders:** Epistaxis ♦**Gastrointestinal disorders:** Diarrhoea, vomitting, nausea, abdominal pain ♦**Skin and subcutaneous tissue disorders:** Pruritus ♦**Renal and urinary disorders:** Dysuria, urinary incontinence ♦**Investigations:** Prostatic specific antigen increased.