NOVARTIS

TIMOLAST* (timolol maleate 0.5%)

5mg/mL ophthalmic gel forming solution

Basic Succinct Statement

CODE: BSS RD MAR 18; APPRV 09 OCT 2018

This material is only meant for Healthcare Professionals

TIMOLAST

Important note: Before prescribing, consult full prescribing information.

Presentation: DROP-TAINER™ dispenser. Each ml of gel forming solution 5 mg timolol and benzododecinium bromide 0.012% as preservative.

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

Dosage and administration: The dose is one drop of TIMOLAST* ophthalmic gel forming solution in the affected eye(s) once daily. Because in some patients the intraocular pressure-lowering response to TIMOLAST* ophthalmic gel forming solution may require a few weeks to stabilize, evaluation should include a determination of intraocular pressure after approximately 4 weeks of treatment with TIMOLAST* ophthalmic gel forming solution. Dosages higher than one drop of 0.5% TIMOLAST* ophthalmic gel forming solution once daily have not been studied. If the patient's intraocular pressure is still not at a satisfactory level on this regimen, concomitant therapy can be considered. Other topically applied ophthalmic medications should be administered at least 10 minutes before TIMOLAST* ophthalmic gel forming solution. ♦**How to transfer patients from other therapy**: When a patient is transferred from Timolol Maleate Ophthalmic Solution to Timolol Gel Forming Solution (TIMOLAST), Timolol Maleate Ophthalmic Solution should be discontinued after proper dosing on one day, and treatment with 0.5% TIMOLAST started on the following day. ♦When a patient is transferred from another topical ophthalmic β adrenergic blocking agent, that agent should be discontinued after proper dosing on one day treatment with 0.50% TIMOLAST started on the following day with 1 drop of 0.50% TIMOLAST in the affected eye once a day. ♦When a patient is transferred from a single antiglaucoma agent, other than a topical ophthalmic β adrenergic blocking agent, continue the agent and add 1 drop of 0.50% TIMOLAST to each affected eye once a day. On the following day, discontinue the previously used anti-glaucoma agent and continue 0.50% TIMOLAST.

Contraindications: ♦Hypersensitivity to the active substance or to any of the excipients. ♦Reactive airway disease including bronchial asthma or a history of bronchial asthma, 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.

Warnings and Precautions: ♦**General:** Like other topically applied ophthalmic agents, timolol is absorbed systemically. Due to the beta-adrenergic blocking component in ophthalmic timolol, the same types of cardiovascular, 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. ♦**Hypoglycemia/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 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. ♦**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.

Adverse drug reactions: ¤The following adverse reactions have been reported during clinical trials with TIMOLAST* ophthalmic gel forming solution 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. ♦**Common:** vision blurred, eye pain, eye irritation, ocular discomfort, ocular hyperaemia ♦**Uncommon:** headache, corneal erosion, punctate keratitis, keratitis, iritis, conjunctivitis, blepharitis, reduced visual acuity, photophobia, dry eye, lacrimation increased, eye discharge, eye pruritus, eyelid margin crusting, anterior chamber inflammation, eyelid oedema, conjunctival hyperaemia, bradycardia, hypotension, asthma, bronchitis, dyspnoea, dysgeusia, fatigue ♦**Rare:** depression, cerebral ischaemia, dizziness, migraine, uveitis, diplopia, asthenopia, eczema of eyelids, erythema of eyelid, eyelid pruritus, conjunctival oedema, corneal pigmentation, myocardial infarction, blood pressure increased, oedema peripheral, peripheral coldness, chronic obstructive pulmonary disease, bronchospasm, cough, wheezing, nasal congestion, dyspepsia, abdominal discomfort, dry mouth, swelling face, erythema, asthenia, chest discomfort ¤Additional adverse reactions identified from post-marketing surveillance include the following. Frequencies cannot be estimated from the available data. Within each System Organ Class adverse reactions are presented in order of decreasing seriousness. ♦**Immune system disorders:** angioedema, hypersensitivity ♦**Metabolism and nutrition disorders:** hypoglycaemia ♦**Psychiatric disorders:** insomnia, amnesia, nightmares ♦**Nervous system disorders:** cerebrovascular accident, syncope, paraesthesia ♦**Eye disorders:** choroidal detachment (following filtration surgery), eyelid ptosis ♦**Cardiac disorders:** cardiac arrest, atrioventricular block (complete, lower degree or aggravation), congestive cardiac failure (aggravation), arrhythmia, palpitations ♦**Vascular disorders:** Raynaud's phenomenon ♦**Gastrointestinal disorders:** vomiting, diarrhoea, nausea ♦**Skin and subcutaneous tissue disorders:** urticaria, psoriasis, rash, alopecia ♦**Musculoskeletal and connective tissue disorders:** arthropathy ♦**Reproductive system and breast disorder:** sexual dysfunction