Timolat

Timolol Maleate

Composition

1 ml contains

Active Substance	: 0.25% 0.5%
Timolol Maleate BP	: 3.4 mg6.8 mg
Quantity equivalent to Timolol Base	: 2.5 mg5.00 mg
Excipieants	: Disodium hydrogen phosphate, Sodium dihydrogen phosphate, Benzalkonium chloride and purified water.

Description

Timolat is a non-selective beta adrenergic blocking agent, supplied as a sterile isotonic buffered aqueous solution of Timolol Maleate.

Pharmacology/Description

The ocular hypotensive action of Timolol may be related to reduced aqueous formation. However, in some studies a slight increase in out flow facility was also observed. The maximum effect usually occurs in one to two hours and significant lowering of intraocular pressure can be maintained for period as long as 24 hours with a single dose.

Indication and usage

Ophthalmic solution is indicated in the treatment of elevated intraocular pressure with ocular hypertension associated with open angle glaucoma and aphakic glaucoma.

Dosage and administration

The usual starting dose is one drop of 0.25% Timolat in affected eyes twice a day. If the clinical response is not adequate the dose may be changed to one drop of 0.5% solution in the affected eyes twice a day. If necessary the physician may institute a concomitant therapy: Systemically administered carbonic anhydrase inhibitor, in order to obtain a better response. But concomitant use of two topical beta adrenergic blocking agents is not recommended. In some patients the pressure lowering response to Timolat may require a few weeks to stabilize. If IOP is maintained at satisfactory levels, the dosage schedule may be changed to one drop once a day in affected eyes.

Contraindications

Timolat is contraindicated in patients with bronchial asthma, a history of bronchial asthma, severe chronic obstructive pulmonary diseases, sinus bradycardia, second or third degree atrioventricular block, overt cardiac failure, cardiogenic shock or hypersensitivity to any component of this product.

Warnings

As with many topically applied drugs, this absorb systemically. Same adverse reactions found with systemic administration of beta adrenergic blocking agents may occur with topical administration.

Cardiac failure
Sympathetic stimulation may be essential for support of the circulation in individuals with diminished myocardial contractility or its inhibition by beta adrenergic receptor blockade may precipitate more severe failure. At the first sign or symptom of cardiac failure Timolat should be discontinued.

Pulmonary function
Patients with chronic obstructive pulmonary disease (e.g. chronic bronchitis, emphysema) of mild or moderate severity bronchospastic disease or a history of bronchospastic disease should, in general, not receive beta blocker, including Timolat.

Major surgery
If necessary during surgery, the effects of beta adrenergic blocking agents may be reversed by sufficient dose of adrenergic agonists.

Diabetes Mellitus
Beta adrenergic receptor blocking agents may mask the signs and symptoms of acute hypoglycemia so it should be administered with caution specially in case of those who are receiving insulin.

Calcium antagonist
Caution should be used in co-administration of beta adrenergic blocking agents such as Timolat in ocudoses and oral or IV calcium antagonists, because of possible atrioventricular condition disturbance.

Precautions
These agents should be used with caution in patients with cerebro vascular insufficiency. Timolol Maleate has little or no effect on the pupil, so Timolat should not be used alone in treatment of angle closure glaucoma because in this case immediate objective is to reopen the angle which requires constricting the pupil.

Information for patients
Patients should be instructed to avoid allowing the tip of the dispensing container to contact with the eye or surrounding structures.

Teratogenic effect
Pregnancy category C. Teratogenicity studies with Timolol in mice, rats and rabbits at oral dosage upto 50 mg/kg/day (7000 times the systemic exposure following the maximum recommended human ophthalmic dose) demonstrated to evidence of fetal malformations.

Nursing mother
A decision should be made whether to discontinue nursing or to discontinue the drug. Because Timolol Maleate has been detected in human milk following ophthalmic administration.

Adverse reaction
The most frequently reported adverse experiences have been burning and stinging upon instillation.

Presentation
Timolat eye drops: Dropper bottle contains 5 ml drops.

Manufactured by
The **IBN SINA** Pharmaceutical Industry Ltd.
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