



# Temlo<sup>®</sup> Eye Drops

Timolol Maleate

**Anti-glaucoma Eye drops**

## COMPOSITION

Temlo<sup>®</sup> 0.25% Eye Drops : Each ml contains Timolol Maleate BP equivalent to 2.5 mg of Timolol.

Temlo<sup>®</sup> 0.50% Eye Drops : Each ml contains Timolol Maleate BP equivalent to 5.0 mg of Timolol.

## PHARMACOLOGY

Timolol Maleate is a beta-adrenoceptor blocking agent; Temlo<sup>®</sup> has the action of reducing elevated intraocular pressure, whether or not accompanied by glaucoma. The action of Temlo<sup>®</sup> is usually rapid, occurring approximately 20 minutes following ocular instillation and maximum effect occurs in one to two hours. Significant lowering of intraocular pressure has been maintained for periods as long as 24 hours with Temlo<sup>®</sup> 0.25% or 0.50%.

Unlike miotics, Temlo<sup>®</sup> has practically no effect on pupil size. No change in visual acuity has observed.

## INDICATION

1. Ocular hypertension
2. Chronic open-angle glaucoma
3. Aphakic and secondary glaucoma

## DOSAGE AND ADMINISTRATION

The usual starting dose is one drop of 0.25% Temlo<sup>®</sup> in the affected eye twice a day. If the clinical response is not adequate, the dosage may be changed to one drop of 0.50% solution in the affected eye twice a day. Since in some patients the pressure lowering response to Temlo<sup>®</sup> may require a few weeks to stabilize, evaluation should include a determination of intraocular pressure after approximately 4 weeks of treatment with Temlo<sup>®</sup>. If the intraocular pressure is maintained at satisfactory level, the dosage schedule may be changed to one drop once a day.

### *Use in children*

Clinical studies in children have not been conducted. Timolol Maleate is not recommended in premature baby and Newborn.

## CONTRAINDICATION AND PRECAUTION

Timolol Maleate is contraindicated to patients with known hypersensitivity to any of the ingredients of the formulation. Other absolute contraindications

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include bronchial asthma, bronchospasm or severe chronic obstructive pulmonary diseases, uncontrolled congestive cardiac insufficiency, cardiogenic shock, high atrioventricular block and high bradycardia (pulse rate <45 to 50 pulses/min.).

As with other topically applied ophthalmic drugs, this drug may be absorbed systemically and lead to systemic effects of beta blockers. So cardiac insufficiency should be adequately controlled before starting therapy with Timolol Maleate. In patients with a history of severe cardiac disease and in elderly patients, signs of cardiac insufficiency should be watched for and pulse rates should be checked. Patients already receiving a beta-blocker orally and who are given Timolol Maleate should be observed for a potential additive effect either on the intraocular pressure or on the known systemic effects of beta-blockers.

Although Timolol Maleate is well tolerated in glaucomatous patients wearing contact lenses as well as in Aphakic patients, the wear of contact lenses should be avoided due to:

- decrease of lacrimal secretion due to beta-blockers
- absorption on the lens of some components of the drug.

### **SIDE EFFECT**

Timolol Maleate ophthalmic solution is generally well-tolerated. In clinical studies of Timolol Maleate the adverse reactions reported were mainly:

- Ocular: symptoms of ocular irritation including conjunctivitis, blepharitis, keratitis, visual disturbances including refractive changes (due to withdrawal of miotics therapy in some cases).
- Cardiovascular: bradycardia, arrhythmia, hypotension, syncope, heart block, cerebro-vascular accident, cerebral ischemia, congestive heart failure, palpitation, cardiac arrest.
- Respiratory: bronchospasm, respiratory failure and dyspnea.
- Systemic: headache, nausea, dizziness, depression, fatigue.

### **DRUG INTERACTION**

Beta-blocking agents may lead to hypotension and/or severe bradycardia, and when combined with Timolol Maleate may produce additive effects. Ophthalmic supervision is required in case of concomitant therapy with eye drops containing adrenaline (mydriasis may occur).

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### **USE IN PREGNANCY AND LACTATION**

Timolol Maleate has not yet been studied in human pregnancy.

### **STORAGE CONDITION**

The drug is to be used within 30 days after first opening and is to be stored at room temperature. The bottle is to be closed strongly immediately after use. All medicines should be kept out of the reach of children.

### **HOW SUPPLIED**

Temlo<sup>®</sup> 0.25% & 0.5% Eye Drops : Dropper bottle containing 5 ml of sterile solution.

