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# TIMOPTOL*
## (TIMOLOL MALEATE, MSD)

Full prescribing information is available to the physicians and pharmacists.

### COMPOSITION

Eye drops containing 2,5 mg or 5 mg of timolol (as maleate) as active ingredient and 0.1 mg of benzalkonium chloride as a preservative.

### ACTIVITY/USE

Reduces intra-ocular pressure.
Is used in the treatment of elevated pressure (glaucoma).

### INSTRUCTIONS FOR USE

Important: the `Ocumeter' should not be squeezed on the sides.

1. Unscrew the cap without squeezing the sides. Grasp inverted 'Ocumeter' by placing the thumb and middle finger on the rim.
2. Place index finger in the indentation on bottom of `Ocumeter'.
3. Place index finger of other hand just under central portion of lower lid. Pull down gently on skin away from eye (toward the cheek) to form a small pocket.
4. Tilt head back. Look up toward top of head.
5. Apply enough pressure on bottom of `Ocumeter' with the index finger to release a single drop of medication. Instill the drops into the outer lower corner of the eye. Remove the index finger from `Ocumeter'. Do not touch the dropper and do not let it come into contact with the eye (eyelid, eyelashes etc.) in order to maintain the sterility of the contents. Replace the lid on the bottle after use.

### INDICATIONS

Reduction of elevated intraocular pressure.
In clinical trials it has been shown to reduce intraocular pressure in:
patients with open-angle glaucoma;
some patients with secondary glaucoma
Concomitant therapy in patients with pediatric glaucoma, who are inadequately controlled with other antiglaucoma therapy.

### CONTRAINDICATIONS

'Timoptol' is contraindicated in patients with: bronchial asthma or with a history of bronchial asthma, or severe chronic obstructive pulmonary disease; sinus bradycardia; second and third degree atrioventricular block; overt cardiac failure; cardiogenic shock; hypersensivity to any component of this product.

### USE IN PREGNANCY AND DURING LACTATION

There are insufficient data to evaluate the possible harmfulness of this substance when used topically in human pregnancy. To date there has been no evidence of harmfulness in animal trials. The use of `Timoptol' eye drops requires that the anticipated benefit be weighed against possible hazards. If therapy is given, nursing should be discontinued.

### SIDE EFFECTS

The following adverse reactions have been observed either in clinical trials or since the drug has been marketed.
Local
Signs and symptoms of ocular irritation, including conjunctivitis, blepharitis, keratitis, blepharoptosis, and decreased corneal sensitivity. Visual disturbances, including refractive changes (due to withdrawal of miotic therapy in some cases), diplopia, and ptosis.
Cardiovascular
Bradycardia, arrhythmia, hypotension, syncope, heart block, cerebrovascular accident, cerebral ischemia, congestive heart failure, palpitation, cardiac arrest.

Respiratory
Bronchospasm (predominantly in patients with pre-existing bronchospastic disease), respiratory failure, dyspnea.
Body as a Whole
Headache, asthenia, nausea, dizziness, depression, fatigue.
Integumentary
Hypersensitivity reactions, including localized and generalized rash and urticaria, have been reported.

## WARNINGS AND PRECAUTIONS

'Timoptol' may be absorbed systematically.
The same adverse reactions found with systemic administration of beta-adrenergic blocking agents may occur with topical administration.
Cardiac failure should be adequately controlled before beginning therapy with `Timoptol'. In patients with a history of severe cardiac disease, signs of cardiac failure should be watched for and pulse rate should be checked.
Respiratory reactions and cardiac reactions, including death due to bronchospasm in patients with asthma and rarely death in association with cardiac failure, have occurred following administration of `Timoptol'.
Patients who are already receiving a beta-adrenergic blocking agent orally and who are given `Timoptol' should be observed for a potential additive effect either on the intraocular pressure or on the known systemic effects of beta blockade.
In patients with angle-closure glaucoma, the immediate objective of treatment is to reopen the angle. This requires constricting the pupil with a miotic. `Timoptol' has little or no effect on the pupil. In angle-closure glaucoma 'Timoptol' should be used with a miotic and not alone.

## DOSAGE/DURATION OF TREATMENT

The appropriate dosage and duration of treatment will be recommended by the physician.
Adults and children: the usual dosage is one drop of the 2.5 mg or 5 mg once or twice daily.

## PARTICULARS

Therapy should not be stopped without having consulted the physician.

## STORAGE

As indicated on the outer pack of the product.

## THIS IS A MEDICAMENT

Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
The doctor and the pharmacist are experts in medicine, its benefits and risks.
Do not by yourself interrupt the period of treatment prescribed.
Do not repeat the same prescription without consulting your doctor.

**Keep medicament out of reach of children.**

Council Of Arab Health Ministers
Union Of Arab Pharmacists

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**MSD**
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