®CUSIMOLOL 0.25% and 0.50%
(Timolol maleate)
Eye drops

Composition Each ml contains 2.5 mg and 5 mg respectively of timolol (maleate).

Excipients: s.q. (benzalkonium chloride as preservative).

Properties CUSIMOLOL (timolol maleate) ophthalmic solution reduces intraocular pressure whether or not accompanied by glaucoma. The onset of reduction can be detected approximately 20 minutes after local application. The maximum effect usually occurs in one to two hours after application. With CUSIMOLOL 0.25% and 0.50% ophthalmic solution, a significantly lowering of intraocular pressure can be maintained for periods as long as 24 hours.

Timolol maleate is a nonselective blocking agent of the beta-adrenergic receptors. It has no intrinsic sympathomimetic activity of depressant effect directly on the myocardium nor any local anesthetic activity (membrane stabilizing effect).

The mechanism through which timolol ophthalmic solution acts on ocular hypertension has not been clearly established, though it seems that it could be due to a reduced aqueous formation.

Clinical assays have shown that timolol ophthalmic solution reduces normal and increased intraocular pressure, and that this reduction is not accompanied by changes in the pupil size or by any alteration of the visual acuity. It maintains its therapeutic activity in long-term treatment. Normally, it is tolerated better than pilocarpine and adrenaline. The trials carried out have shown that the adverse reactions are not frequent and if they are produced, they are slight.

Indications Reduction in increased intraocular pressure in conditions such as ocular hypertension, chronic open-angle glaucoma (including aphakic patients) and certain cases of secondary glaucoma.

Dosage Instill one drop of 0.25% solution in the affected eye twice daily.

If the response is not satisfactory, instill one drop of 0.50% solution in the affected eye twice daily.

If a more intense control of the pressure is desired, a concomitant therapy can be initiated with miotics, epinephrine, or carbonic anhydrase inhibitors by systemic route.

If treatment for the ocular pressure results in a satisfactory reduction, many patients can be controlled with a one-drop daily maintenance dose.

Correct administration procedure Separate the eyelids from the eye and instill the drops in the conjunctival sac.

Application of the eye drops should be carried out under hygienic conditions.

Do not touch dropper tip to any surface.

Close bottle after every application.

Discard one month after opening.

Precautions When a patient is transferred from an antiglaucoma agent, continue the medications already being used (at the dosage schedule indicated in DOSAGE). On the following day, discontinue the previously used antiglaucoma agent completely and continue with timolol.

When timolol is to be used concomitantly with other agents, continue at the same dosage schedule. In combined therapy, individualization is required and physician should be able to discontinue some or all of the agents while intraocular pressure is maintained at a satisfactory level.

The effect of timolol may require approximately four weeks to stabilize, evaluation should include a new determination of intraocular pressure after such time. Because of diurnal variations in intraocular pressure, the response should be determined by measuring the intraocular pressure at different times during the day.

There is no experience with the use in pregnancy. Ophthalmic timolol should be used during pregnancy only if the potential benefit justifies the possible risks.

Ophthalmic timolol is not recommended in children due to the lack of experience with the use of this drug.

Warnings Ophthalmic use of timolol can, is some cases, lead to systemic adverse reactions of beta-blocking agents. The medication should be used with caution in cases in which the use of beta-blocking agents by systemic route is contraindicated, such as: bronchial asthma, sinus bradycardia, cardiogenic block, labile diabetes, first-degree atrioventricular block.

Cardiac insufficiency should be adequately compensated before initiating treatment. Patients with a history of severe cardiac disease should be periodically monitored, with blood pressure and pulse, and the possible signs of congestive cardiac insufficiency being controlled.

In patients treated with oral beta-blocking agents, the possible additive effect should be taken into account in the intraocular pressure as well as in the systemic action.

Doping in Sports: due to a component contained in this preparation, the analytical findings of doping controls in sportspersons can be found positive.

This product contains benzalkonium chloride, therefore soft contact lenses should not be worn until at least 20 minutes following the instillation of the drops.

Contraindications Patients with a history of hypersensitivity to timolol.

Interactions Timolol can potentiate the effects of systemic beta-blocking agents (see WARNINGS).

Mydriasis resulting from concomitant therapy with epinephrine has been reported occasionally. The use of timolol alone has generally no effect on pupil size.

Adverse Reactions Timolol is generally well tolerated. Occasional signs and symptoms of ocular irritation may appear, including conjunctivitis, blepharitis, and keratitis. Sometimes visual alterations, including refractive changes can appear that may be due to withdrawal of a previous miotic therapy.

Hypersensitivity, including localized and generalized urticaria or rash are very rarely produced.

On rare occasions, reactions due to the systemic beta-blocking action have been reported (see WARNINGS), among which mild bradycardia, hypotension, bronchospasm (predominantly in patients with asthmatic history), congestive cardiac insufficiency and masked symptoms of hypoglycemia in insulin-dependent diabetics.

The following adverse reactions have been very rarely reported and a causal relationship to therapy with timolol has not been established: headache, dryness of the mouth, anorexia, dyspepsia, nausea, palpitations, hypertension, aphakic cystoid macular edema, and CNS effects (fatigue, confusion, depression, anxiety, somnolence).

Incompatibilities Have not been described.

Overdosage Due to the characteristics of this preparation, intended for topical use, no toxic effects are expected with the use of this product at the recommended dose. Massive ingestion may cause nausea and other cardiocirculatory disorders, depending on the quantity ingested, and which should be symptomatically treated. In the event of overdosage or accidental ingestion, consult physician or a Poison Control Center.

Storage Protect from light. Store below 30° C.

How Supplied 5 ml bottle.

Keep all medication out of the reach of children

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