

Important: Read Carefully!

XolamolTM

dorzolamide hydrochloride, timolol maleate

Sterile Ophthalmic Solution

DESCRIPTION: XolamolTM is the combination of a topical carbonic anhydrase inhibitor and a topical beta-adrenergic receptor blocking agent.

COMPOSITION: Each ml of XolamolTM contains 22.26 mg dorzolamide hydrochloride equivalent to 20 mg dorzolamide and 6.84 mg timolol maleate equivalent to 5 mg timolol. Inactive ingredients are sodium citrate, hydroxypropylmethylcellulose, sodium hydroxide, mannitol, and water for injection. Benzalkonium chloride 0.0075% (w/v) is added as a preservative.

MECHANISM OF ACTION: XolamolTM is comprised of two components: dorzolamide hydrochloride and timolol maleate. Each of these two components decreases elevated intraocular pressure, whether or not associated with glaucoma, by reducing aqueous humor secretion.

Dorzolamide hydrochloride is an inhibitor of human carbonic anhydrase II. Inhibition of carbonic anhydrase in the ciliary processes of the eye decreases aqueous humor secretion, presumably by slowing the formation of bicarbonate ions with subsequent reduction in sodium and fluid transport. Timolol maleate is a beta₁ and beta₂ (non-selective) adrenergic receptor blocking agent that does not have significant intrinsic sympathomimetic, direct myocardial depressant or local anesthetic (membrane-stabilizing) activity. The combined effect of these two agents administered as XolamolTM b.i.d results in additional intraocular pressure reduction compared to either component administered alone.

INDICATIONS AND USAGE: XolamolTM is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to beta-blockers (failed to achieve target IOP determined after multiple measurements over time).

CONTRAINDICATIONS: XolamolTM is contraindicated in patients with:

- (1) bronchial asthma. (2) a history of bronchial asthma. (3) severe chronic obstructive pulmonary disease.
- (4) sinus bradycardia. (5) second or third degree atrioventricular block. (6) overt cardiac failure.
- (7) cardiogenic shock (8) hypersensitivity to any component of this product.

WARNING: Not for injection into the eye.

PRECAUTIONS: As it is absorbed, systemic effects may arise after instillation of XolamolTM in the eyes, thus most precautions taken after administration of beta blocking agents should be considered. Cardiac and respiratory reactions may arise in patients suffering from bronchospasm. Monitoring of these patients should be done from time to time and withdrawal of the drug may be the only solution in some cases.

Potential additive effects in patients receiving oral or parenteral beta-blocker and XolamolTM is sure. XolamolTM is not advised in pregnant or lactating women.

USE IN PEDIATRICS: Safety & efficacy has not been established.

SIDE EFFECTS: Any medication may have some undesirable effects, so called side effects. You may experience temporary eye symptoms such as burning, stinging, redness of the eye (s), blurred vision, tearing or itching. You may sense bitter taste after instillation.
Other side effects : shortness of breath, stomach upset.

EFFECTS ON ABILITY TO DRIVE OR OPERATE MACHINES: There are side effects associated with the medication-blurred vision that may affect your ability to drive and operate machinery.

STORAGE: Store at 15 - 25° C. Discard after 30 days of opening.

DOSAGE & ADMINISTRATION:

One drop of XolamolTM into the affected eye(s) 2 times daily.

HOW SUPPLIED: XolamolTM Sterile Ophthalmic Solution, 5 ml in LDPE bottles.

THIS IS A MEDICAMENT

- Medicament is a product that 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 the reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists

 **Ophthalmics**
XolamolTM is a quality product manufactured by:



جمجوم فارما
Jamjoom Pharma

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