

# Glucovis Eye Drops

Betaxolol 0.25%

**Description:** Betaxolol Hydrochloride Ophthalmic Solution has the action of reducing elevated as well as normal intraocular pressure, whether or not accompanied by glaucoma. Ophthalmic betaxolol has minimal effect on pulmonary and cardiovascular parameters.

**Indications:** In lowering intraocular pressure and in the treatment of ocular hypertension and chronic open-angle glaucoma. It may be used alone or in combination with other anti-glaucoma drugs.

**Dosage and Administration:** The recommended dose is one to two drops of Betaxolol Hydrochloride Ophthalmic Solution in the affected eye(s) twice daily.

**Side Effects:** Discomfort, rare instances of decreased corneal sensitivity, erythema, itching sensation, corneal punctate staining, keratitis, anisocoria, edema, photophobia, blurred vision, foreign body sensation, dryness of the eyes, inflammation, discharge, ocular pain, decreased visual acuity, and crusty lashes, bradycardia, heart block and congestive failure, pulmonary distress characterized by dyspnea, bronchospasm, thickened bronchial secretions, asthma and respiratory failure.

**Contraindications:** Hypersensitivity to any component of this product. Betaxolol Hydrochloride Ophthalmic Solution is contraindicated in patients with sinus bradycardia, greater than a first degree atrioventricular block, cardiogenic shock, or patients with overt cardiac failure.

**Warning:** Topically applied beta-adrenergic blocking agents may be absorbed systemically. The same adverse reactions found with systemic administration of beta-adrenergic blocking agents may occur with topical administration. For example, severe respiratory reactions and cardiac reactions, including death due to bronchospasm in patients with asthma, and rarely death in association with cardiac failure, have been reported with topical application of beta-adrenergic blocking agents. Betaxolol Hydrochloride Ophthalmic Solution has been shown to have a minor effect on heart rate and blood pressure in clinical studies. Caution should be used in treating patients with a history of cardiac failure or heart block. Treatment with Betaxolol Hydrochloride Ophthalmic Solution should be discontinued at the first signs of cardiac failure.

**Precaution:** Use cautiously in diabetes mellitus, thyrotoxicosis, muscle weakness, major surgery, pulmonary, risk from anaphylactic reaction, carcinogenesis, mutagenesis, impairment of fertility.

**High Risk Group:** Pregnancy: There are no adequate and well-controlled studies in pregnant women. Betaxolol Hydrochloride Ophthalmic Solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Nursing Mothers: It is not known whether betaxolol HCl is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Betaxolol Hydrochloride Ophthalmic Solution is administered to nursing women. Pediatric Use: Safety and effectiveness in pediatric patients have not been established. Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and younger patients.

**Drug Interactions:** Patients who are receiving a beta-adrenergic blocking agent orally and Betaxolol Hydrochloride Ophthalmic Solution should be observed for a potential additive effect either on the intraocular pressure or on the known systemic effects of beta blockade. Close observation of the patient is recommended when a beta blocker is administered to patients receiving catecholamine-depleting drugs such as reserpine, because of possible additive effects and the production of hypotension and/or bradycardia. Caution should be exercised in patients using concomitant adrenergic psychotropic drugs. In patients with angle-closure glaucoma, the immediate treatment objective is to reopen the angle by constriction of the pupil with a miotic agent. Betaxolol has little or no effect on the pupil. When Betaxolol Hydrochloride Ophthalmic Solution is used to reduce elevated intraocular pressure in angle-closure glaucoma, it should be used with a miotic and not alone.

**Pharmaceutical Precautions:** Store in a cool and dry place, away from light. Keep out of reach of children. Store below 30°C

**Commercial Pack:** Glucovis® 0.25% Eye Drops: Plastic dropper bottle containing 5 ml sterile solution. Each ml contains: Betaxolol Hydrochloride BP equivalent to Betaxolol 2.5 mg.

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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