Intramol®

Timolol
Eye Drops

Presentation and packaging quantities:
Plastic dropper bottle of 5 ml. Each ml contains Timolol Maleate BP equivalent to Timolol 5.0 mg.

Description
Timolol maleate is a beta1 and beta2 (non-selective) adrenergic receptor-blocking agent, when applied topically to the eye, has the action of reducing elevated, as well as normal, intraocular pressure, whether or not accompanied by glaucoma.

Indications
In the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

Dosage
The dose is one drop of Timolol (either 0.25% or 0.5%) in the affected eye(s) once daily. Because in some patients the intraocular pressure-lowering response to Timolol may require a few weeks to stabilize, evaluation should include a determination of intraocular pressure after approximately 4 weeks of treatment.

Side Effects
Local side-effects of eye drops include ocular stinging, burning, pain, itching, erythema, dry eyes and allergic reactions including anaphylaxis and blepharoconjunctivitis; occasionally corneal disorders have been reported.

Contraindications
(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; or (8) hypersensitivity to any component of this product.

Warning
For topical ophthalmic use only. Not for injection or oral use. As with many topically applied ophthalmic drugs, this drug is absorbed systemically. The same adverse reactions found with systemic administration of beta-adrenergic blocking agents may occur with topical ophthalmic 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 following systemic or ophthalmic administration of timolol maleate.

Precautions
Because of potential effects of beta-adrenergic blocking agents on blood pressure and pulse, these agents should be used with caution in patients with cerebrovascular insufficiency. If signs or symptoms suggesting reduced cerebral blood flow develop following initiation of therapy with Timolol, alternative therapy should be considered. Timolol has little or no effect on the pupil and should not be used alone in the treatment of angle-closure glaucoma. Anaphylaxis: While taking beta-blockers, patients with a history of atopy or a history of severe anaphylactic reactions to a variety of allergens may be more reactive to repeated accidental, diagnostic, or therapeutic challenge with such allergens. Beta-adrenergic blockade has been reported to potentiate muscle weakness consistent with certain myasthenic symptoms (e.g.,diplopia, ptosis, and generalized weakness).Timolol has been reported rarely to increase muscle weakness in some patients with myasthenia gravis or myasthenic symptoms.Patients should also be instructed that ocular solutions, if handled improperly, could become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions. Patients should also be advised that if they have ocular surgery or develop an intercurrent ocular condition (e.g.,trauma or infection), they should immediately seek their physician's advice concerning the continued use of the present multidose container. Patients with bronchial asthma, a history of bronchial asthma, severe chronic obstructive pulmonary disease, sinus bradycardia, second or third degree atrioventricular block, or cardiac failure should be advised not to take this product.

High risk group
Pregnancy Category C. ***Nursing Mothers:***
Timolol maleate has been detected in human milk following oral and ophthalmic drug administration. Because of the potential for serious adverse reactions from Timolol in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Drug Interactions
Patients receiving a beta-adrenergic blocking agent orally and Timolol should be observed for potential additive effects. Patients should not usually receive two topical ophthalmic beta-adrenergic blocking agents concurrently. Caution should be used in the co-administration of beta-adrenergic blocking agents, such as Timolol and oral or intravenous calcium antagonists because of possible atrioventricular conduction disturbances, left ventricular failure, or hypotension. In patients with impaired cardiac function, co-administration should be avoided. Masked symptoms of hypoglycemia in diabetic patients.

Storage
Store in a cool and dry place, away from light. Keep out of reach of children.

How Supplied
Intramol® 0.5% Eye Drops: Dropper bottle containing 5 ml of sterile solution.

BEXIMCO PHARMA
Manufactured by
BEXIMCO PHARMACEUTICALS LTD.
TONGI, BANGLADESH IL 1936 100509