Bimator[™] Eye Drops

Bimatoprost 0.03% & Timolol 0.5%

Sterile Eye Drops

COMPOSITION

Bimator™ Eye Drops: Each ml contains Bimatoprost INN 0.3 mg & Timolol 5 mg as Timolol Maleate BP.

INDICATION

Bimator[™] Eye Drops is indicated for the reduction of intraocular pressure in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to mono-therapy.

DOSAGE & ADMINISTRATION

The recommended dose is one drop in the affected eye(s) once-daily.



Pierce the container by screwing the Two- parts



Open the upper part of the cap only



Use the required amount of medication



Close the upper part of the cap with the container just after the use

CONTRAINDICATION

It is contraindicated in patients with known hypersensitivity to any ingredient of this formulation.

WARNING & PRECAUITON

Like other topically applied ophthalmic medicinal products, the active substances Timolol/ Bimatoprost may be absorbed systemically. Due to the beta-adrenergic component, Timolol, the same types of cardiovascular, pulmonary and other adverse reactions as seen with systemic beta-blockers may occur. Caution should be exercised in treating patients with severe or unstable and uncontrolled cardiovascular Disease.

DRUG INTERACTION

There is a potential for bradycardia when ophthalmic beta-blockers solution is administered concomitantly with oral calcium channel blockers, guanethidine, beta-adrenergic blocking agents, parasympathomimetics, anti-arrhythmics and digitalis glycosides. Concomitant ocular medications should be administered at least 5 min apart from the instillations of **Bimator**TM Eye Drops.

USE IN PREGNANCY & LACTATION

Use in Pregnancy: There are no adequate data from the use of the Bimatoprost / timolol fixed combination in pregnant women. It should not be used during pregnancy unless clearly necessary. Use in Lactation: Animal studies showed Bimatoprost is excreted in rat's milk. & Timolol is excreted in human milk. Therefore, Bimatoprost / Timolol should not be used during breastfeeding.

PEDIATRIC & GERIATRIC USE

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 other adult patients.

SIDE EFFECT

In clinical trials, Ocular hyperemia was reported in approximately 26% of patients. 5 to 10 % in these clinical studies included decreased visual acuity, eye discomfort, foreign body sensation, pain and pruritis.

STORAGE

Store below 25°C in a dry place protected from light. Keep out of reach of children. Solution can be used up to 28 days after first opening.

HOW SUPPLIED

3 ml of **Bimator**™ Eye Drops is supplied in a 5 ml LDPE bottle.

Manufactured by

