Bimatol®

Bimatoprost INN and Timolol Maleate BP
Ophthalmic Solution

DESCRIPTION

Bimatol® is a combination ophthalmic solution containing Bimatoprost and Timolol Maleate. Bimatoprost is a synthetic prostamide analogue with potent ocular hypotensive activity. It selectively mimics the effects of a naturally occurring substance, prostamide. Bimatoprost is believed to lower intraocular pressure (IOP) in humans by increasing outflow of aqueous humor through both the trabecular meshwork and uveoscleral routes. Timolol Maleate is a nonselective beta-adrenergic receptor blocking agent that does not have significant intrinsic sympathomimetic, direct myocardial depressant or local anaesthetic (membrane stabilizing) activity. Timolol is thought to work by decreasing the amount of aqueous humor formed in the eye.

INDICATIONS

Bimatol® ophthalmic solution is indicated for the reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.

DOSAGE & ADMINISTRATION

The recommended dose is one drop in the affected eye(s) once daily, either in the morning or in the evening. Use at the same time each day.

CONTRAINDICATIONS

Contraindicated in patients with hypersensitivity to any component of this medication. Also in patients with bronchospasm, bronchial asthma, severe chronic obstructive pulmonary disease, sinus bradycardia, sick sinus syndrome, sino-atrial block, second or third degree atrioventricular block, overt cardiac failure or cardiogenic shock.

SIDE EFFECTS

No adverse drug reactions (ADR's) specific for Bimatoprost and Timolol combination have been observed in clinical studies. The ADR's have been limited to those for Bimatoprost and Timolol. The majority of ADR's are mild in severity and none were serious, e.g., conjunctival hyperaemia, eye Pruritus, burning sensation, foreign body sensation in the eye, erythema of eyelid, eye pain, photophobia, eye irritation, eyelid oedema, lacrimation increased, growth of eyelashes.

PRECAUTION & WARNING

Caution should be exercised in treating patients with severe and uncontrolled cardiovascular disease. Patients with a history of severe cardiac disease should be watched for signs of cardiac failure and have their pulse rates checked. Patients with active intraocular inflammation, corneal diseases should be treated with caution.

USE IN PREGNANCY & LACTATION

There are no adequate and well controlled studies in pregnant women. Consequently, **Bimatol**® should not be used during pregnancy unless clearly necessary.

There are no data on the excretion of Bimatoprost into human milk or on the safety of Bimatoprost exposure in infants. Timolol is excreted in human milk and there is potential for adverse reactions in breastfed infants. **Bimatol**® should not be used by breast-feeding women.

DRUG INTERACTION

Specific drug interaction studies have not been conducted.

PHARMACEUTICAL PRECAUTION

Keep away from light and wet place. Store below 30 °C temperature. Keep out of reach of children. To prevent contamination of the dropper tip and solution, care should be taken. Don't touch the eyelids, surrounding areas, finger or other surfaces with the dropper tip of the bottle. The bottle should be tightly closed when not in use. Do not use after 4 weeks of first opening.

PACKAGING

Bimatol® **Ophthalmic Solution:** Plastic dropper bottle containing 5 mL sterile ophthalmic solution. Each mL contains Bimatoprost INN 0.3 mg and Timolol Maleate BP equivalent to Timolol 5 mg.

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Manufactured by
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