BRM T EYE DROPS

(Brimonidine Tartrate 0.2% + Timolol 0.5%)

COMPOSITION

Each mL contains Brimonidine Tartrate 2 mg (0.2% w/v) and Timolol 5 mg (0.5% w/v), as timolol maleate. Excipients: as per approved formulation.

DESCRIPTION

BRM T is a combination ophthalmic solution containing brimonidine, an alpha-2 adrenergic agonist, and timolol, a nonselective beta-adrenergic blocker.

CLINICAL PHARMACOLOGY

Both substances lower intraocular pressure (IOP) by reducing aqueous humour production; brimonidine also increases uveoscleral outflow. Their combined activity reduces elevated IOP in glaucoma and ocular hypertension.

INDICATIONS

Reduction of elevated IOP in patients with glaucoma or ocular hypertension requiring adjunctive or replacement treatment because IOP is not adequately controlled.

DOSAGE AND ADMINISTRATION

Instil ONE drop in the affected eye(s) TWICE DAILY approximately 12 hours apart. Separate different topical ophthalmic medicines by at least 5 minutes. Use exactly as prescribed.

METHOD OF USE

For topical ophthalmic use only. Wash hands. Do not touch the bottle tip to eyes, skin or other surfaces. Close cap after each use. Do not use if cloudy or discoloured.

CONTRAINDICATIONS

Hypersensitivity to either active ingredient or an excipient; bronchial asthma or history of asthma; severe chronic obstructive pulmonary disease; sinus bradycardia; second- or third-degree atrioventricular block; overt cardiac failure; cardiogenic shock; neonates and infants under 2 years.

WARNINGS AND PRECAUTIONS

Timolol can be absorbed systemically and may cause serious respiratory or cardiac reactions, including bronchospasm and bradycardia. Avoid use in patients with listed contraindications. Use caution with milder obstructive pulmonary disease, cardiovascular disease, hypotension and vascular insufficiency.

OTHER PRECAUTIONS

Beta-blockade may mask signs of low blood glucose and thyrotoxicosis, aggravate myasthenic weakness and alter response to anaesthesia. Tell the anaesthetist before surgery. Patients with a history of severe allergy may be less responsive to usual adrenaline doses.

OCULAR PRECAUTIONS

Ocular allergy may develop and IOP may rise. Avoid dropper contamination, which can result in bacterial keratitis and sight-threatening infection. Seek medical advice for eye pain, swelling, discharge or visual deterioration.

CONTACT LENSES

If the formula contains benzalkonium chloride, remove soft contact lenses before application and wait 15 minutes before reinsertion; verify excipients on the market pack.

DRUG INTERACTIONS

Concomitant oral or ophthalmic beta-blockers may increase beta-blocking effects. Use caution with calcium-channel blockers, digoxin, other antihypertensives and catecholamine-depleting drugs due to possible bradycardia or hypotension. CYP2D6 inhibitors may increase systemic timolol effects. Alcohol, sedatives and other CNS depressants may add to drowsiness. Tricyclic antidepressants and monoamine oxidase inhibitors may affect brimonidine response.

PREGNANCY

Human pregnancy data are insufficient to define drug-associated risk. Use only after the physician has assessed maternal benefit and potential fetal risk.

LACTATION

Timolol may enter breast milk. There are insufficient human data for brimonidine. Consider the benefit of breastfeeding, clinical need for treatment and potential effects on the infant.

PEDIATRIC USE

Contraindicated in children under 2 years. Safety and efficacy below 18 years have not been established for this fixed combination. Marked somnolence and systemic adverse effects are possible in young children.

GERIATRIC USE

No overall age-related differences in safety or effectiveness were identified in clinical studies; assess each patient individually.

DRIVING / MACHINERY

Blurred vision, fatigue or somnolence may impair performance. Avoid driving until these effects resolve.

ADVERSE REACTIONS

Commonly reported: allergic conjunctivitis, conjunctival follicles, conjunctival redness, eye itching, ocular burning or stinging. Other effects: eyelid inflammation/swelling, eye irritation or dryness, watery eyes, foreign-body sensation, blurred vision, headache, dry mouth, fatigue and somnolence.

SERIOUS ADVERSE EFFECTS

Rare but important systemic beta-blocker effects include slow heart rate, low blood pressure, breathing difficulties, heart failure and severe allergic reactions. Stop the medicine and obtain urgent care for wheezing, fainting, breathing difficulty or severe allergy.

OVERDOSAGE

Overdose or accidental ingestion may cause hypotension, bradycardia, respiratory depression, drowsiness, hypothermia and other serious reactions, especially in children. Seek emergency medical attention immediately. Treatment is supportive.

STORAGE CONDITIONS

Store under conditions approved for the marketed formulation; protect from light and contamination. Keep the bottle securely closed and out of reach of children. Do not use after the expiry date.

PRESENTATION

BRM T Eye Drops, sterile ophthalmic solution, Brimonidine Tartrate 0.2% + Timolol 0.5%. Pack size: as indicated on carton.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd. 30 Km, Multan Road, Lahore - Pakistan.