BRM EYE DROPS

(Brimonidine Tartrate 0.2% w/v)

COMPOSITION

Each mL contains Brimonidine Tartrate 2 mg (0.2% w/v). Other ingredients: as per approved formulation.

DESCRIPTION

BRM Eye Drops contain brimonidine tartrate, an alpha-2 adrenergic receptor agonist for topical ophthalmic administration.

CLINICAL PHARMACOLOGY

Brimonidine reduces intraocular pressure (IOP) principally by decreasing aqueous humour production and increasing uveoscleral outflow. The IOP-lowering effect may diminish over time in some patients; continued monitoring is essential.

INDICATIONS

Reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. May be used alone or with other IOP-lowering ophthalmic medications.

DOSAGE AND ADMINISTRATION

Instil one drop into the affected eye(s) three times daily, approximately 8 hours apart, or as directed by the physician. When more than one topical ophthalmic medicine is used, separate instillations by at least 5 minutes.

METHOD OF ADMINISTRATION

For ophthalmic use only. Wash hands before use. Avoid touching the dropper tip to the eye, fingers or any surface. Close the cap promptly after use.

CONTRAINDICATIONS

Contraindicated in neonates and infants under 2 years and in patients with known hypersensitivity to brimonidine or any component of the formulation.

WARNINGS AND PRECAUTIONS

Use with caution in patients with severe cardiovascular disease, depression, cerebral or coronary insufficiency, Raynaud’s phenomenon, orthostatic hypotension or thromboangiitis obliterans. Brimonidine may worsen vascular insufficiency.

PREVENTION OF CONTAMINATION

Contamination of multidose eye-drop bottles may cause bacterial keratitis and serious ocular harm. Do not touch the dropper tip. Do not use if the solution is cloudy or discoloured. If eye surgery, injury or infection occurs, consult the physician about continued use.

CONTACT LENSES

Remove contact lenses before instillation; wait at least 15 minutes before reinsertion. This precaution is especially important where the product contains benzalkonium chloride; confirm the specific excipients on the product carton.

DRIVING / MACHINERY

Fatigue, drowsiness and blurred vision can occur. Patients should avoid driving or operating machinery until their response to the medicine is known.

MONITORING

Intraocular pressure should be reassessed periodically. Consult the treating ophthalmologist if control becomes inadequate.

DRUG INTERACTIONS

Caution with antihypertensive agents and cardiac glycosides because blood-pressure effects may be additive. Alcohol, sedatives, opioids, anaesthetics and other CNS depressants may increase sedation. Tricyclic antidepressants may interfere with adrenergic effects. Use caution with monoamine oxidase inhibitors due to possible hypotension.

PREGNANCY

Adequate controlled studies in pregnant women are lacking. Use during pregnancy only if the potential benefit justifies possible fetal risk, after medical assessment.

LACTATION

It is not known whether brimonidine is excreted in human milk. The physician should decide whether to discontinue nursing or the medicine, considering the importance of treatment to the mother.

PEDIATRIC USE

Contraindicated below 2 years of age. Use with caution in older children; significant somnolence, lethargy and systemic effects have been reported, especially in young children.

GERIATRIC USE

No overall clinically significant safety or efficacy differences have been identified between elderly and other adult patients; individual monitoring is recommended.

RENAL / HEPATIC IMPAIRMENT

Brimonidine has not been adequately studied in patients with hepatic or renal impairment. Use cautiously on medical advice.

ADVERSE REACTIONS

Frequently reported reactions include ocular redness, burning or stinging, ocular itching, foreign-body sensation, blurred vision, allergic conjunctivitis, conjunctival follicles, dry mouth, headache, fatigue and drowsiness. Other possible effects include eyelid swelling, tearing, dizziness and altered taste. Discontinue and seek medical attention for severe allergy or significant eye irritation.

OVERDOSAGE

Ocular overdose: rinse with lukewarm water if excess drops are instilled. Accidental ingestion, particularly by children, can cause serious systemic effects including hypotension, bradycardia, drowsiness, respiratory depression and altered consciousness. Seek emergency medical care immediately; treatment is supportive.

STORAGE CONDITIONS

Store according to the conditions stated on the approved pack label. Protect the bottle from contamination. Keep tightly closed and out of reach of children. Do not use after the expiry date.

PRESENTATION

BRM Eye Drops 0.2% w/v, sterile ophthalmic solution. Bottle size: as stated on the market pack.

MANUFACTURED BY

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