BRIMOMIA 0.2%

Sterile Ophthalmic Solution

COMPOSITION:
Each 1 mL of BRIMOMIA 0.2% ophthalmic solution contains Brimonidine tartrate 2mg
EXCIPIENTS:
Benzalkonium chloride,Citric acid, Polyvinyl alcohol, Sodium chloride, Sodium citrate, water for injection
INDICATIONS:
Brimonidine tartrate is indicated for lowering intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.
The IOP lowering efficacy of Brimonidine tartrate diminishes over time in some patients. This loss of effect appears with a variable time of onset in each patient and should be closely monitored.
DOSAGE AND ADMINISTRATION:
The recommended dose is one drop of Brimonidine tartrate in the affected eye(s) three times daily, approximately 8 hours apart.
Brimonidine tartrate may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic product is to be used, the different products should be instilled at least 5 minutes apart.
CONTRAINDICATIONS:
Neonates and Infants (under the age of 2 years):
Brimonidine tartrate is contraindicated in neonates and infants (under the age of 2 years).
Hypersensitivity Reactions:
Brimonidine tartrate is contraindicated in patients who have exhibited a hypersensitivity reaction to any component of this medication in the past.
WARNINGS AND PRECAUTIONS:
Potentiation of vascular insufficiency:
Brimonidine tartrate may potentiate syndromes associated with vascular insufficiency.
Brimonidine tartrate should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, or thromboangiitisobliterans.
Severe cardiovascular disease:
Although Brimonidine tartrate ophthalmic solution had minimal effect on the blood pressure of patients in clinical studies, caution should be exercised in treating patients with severe cardiovascular disease.
Contamination of topical ophthalmic products after use:
There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in
most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface.
Use with contact lenses:
The preservative in Brimonidine tartrate, benzalkonium chloride, may be absorbed by soft contact lenses. Patients wearing soft contact lenses should be instructed to wait at least 15 minutes after instilling Brimonidine tartrate to insert soft contact lenses.
ADVERSE REACTIONS:
Adverse reactions occurring in approximately 10% to 30% of the subjects (in descending order):
Oral dryness, ocular hyperemia, burning and stinging, headache, blurring, foreign body sensation, fatigue/drowsiness, conjunctival follicles, ocular allergic reactions, and ocular pruritus.
Adverse reactions occurring in approximately 3% to 9% of the subjects (in descending order):
Corneal staining/erosion, photophobia, eyelid erythema, ocular ache/pain, ocular dryness, tearing, upper respiratory symptoms, eyelid edema, conjunctival edema, dizziness, blepharitis, ocular irritation, gastrointestinal symptoms, asthenia, conjunctival blanching, abnormal vision and muscular pain.
Adverse reactions reported < 3% of the patients:
Lid crusting, conjunctival hemorrhage, abnormal taste, insomnia, conjunctival discharge, depression, hypertension, anxiety, palpitations/arrhythmias, nasal dryness and syncope.
DRUG INTERACTIONS:
Antihypertensive/Cardiac Glycosides:
Because Brimonidine tartrate may reduce blood pressure, caution in using drugs such as antihypertensive and/or cardiac glycosides with Brimonidine tartrate is advised.
CNS Depressants:
Although specific drug interaction studies have not been conducted with Brimonidine tartrate, the possibility of an additive or potentiating effect with CNS depressants (alcohol, barbiturates, opiates, sedatives, or anesthetics) should be considered.
Tricyclic Antidepressants:
Tricyclic antidepressants have been reported to blunt the hypotensive effect of systemic clonidine. It is not known whether the concurrent use of these agents with Brimonidine tartrate in humans can lead to resulting interference with the IOP lowering effect. Caution is advised in patients taking tricyclic antidepressants, which can affect the metabolism and uptake of circulating amines.
Monoamine Oxidase Inhibitors:
Monoamine oxidase (MAO) inhibitors may theoretically interfere with the metabolism of Brimonidine tartrate and potentially result in an increased systemic side-effect such as hypotension. Caution is advised in patients taking MAO inhibitors which can affect the metabolism and uptake of circulating amines.
PREGNANCY:
Pregnancy Category B.
Brimonidine tartrate should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.
NURSING MOTHERS:
It is not known whether Brimonidine tartrate is excreted in human milk, although in animal studies, Brimonidine tartrate has been shown to be excreted in breast milk. Because of the potential for serious adverse reactions from Brimonidine tartrate 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:
Brimonidine tartrate is contraindicated in children under the age of 2 years.
GERIATRIC USE:
No overall differences in safety or effectiveness have been observed between elderly and other adult patients.
OVERDOSAGE:
Very limited information exists on accidental ingestion of Brimonidine tartrate in adults; the only adverse reaction reported to date has been hypotension. Symptoms of Brimonidine tartrate overdose have been reported in neonates, infants, and children receiving Brimonidine tartrate as part of medical treatment of congenital glaucoma or by accidental oral ingestion. Treatment of an oral overdose includes supportive and symptomatic therapy; a patent airway should be maintained.
STORAGE CONDITION:
Store at (20°–25°) C.
PACKAGING:
BRIMOMIA 0.2% ophthalmic solution is supplied in polyethylene bottle 5 mL with dropper, tightly sealed with a polyethylene closer within carton box.

Produced by MIAMED Pharmaceutical Industries –Damascus countryside –Syria

This is a medicament
- A medicament is a product but unlike any other products.
- A medicament is a product which affect your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
Keep medicaments out of reach of children

Council of Arab Health Ministers Arab pharmacist Association

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