BIMONID™

(Brimonidine Tartrate)
Ophthalmic Solution

5mL
10mg/5mL
0.2% w/v

بیمونِڈ

اوپتھیلمک سلوشن ۵ ملی لیٹر
(برائیمونیڈین ٹارٹریٹ) ۱۰ ملی گرام/۵ ملی لیٹر

Qualitative And Quantitative Composition:
Each mL contains:
Brimonidine Tartrate U.S.P. 2mg
Innovator's Specifications

Description:
Bimonid™ 0.2% is an alpha-adrenergic agonist indicated for lowering intraocular pressure (IOP) in patients with open angle glaucoma or ocular hypertension.

Clinical Pharmacology:
Mechanism of action
Bimonid™ 0.2% is a relatively selective alpha-2 adrenergic receptor agonist with a peak ocular hypotensive effect occurring at two hours post-dosing.
Fluorophotometric studies in animals and humans suggest that brimonidine tartrate has a dual mechanism of action by reducing aqueous humor production and increasing uveoscleral outflow.
Pharmacodynamics
Brimonidine is a highly selective alpha-2 adrenergic receptor agonist that is 1000-fold more selective for the alpha2-adrenergic receptor than the alpha1-adrenergic receptor. his characteristic gives the drug some therapeutic advantages, since it reduces the risk of systemic side effects, such as systemic hypotension, bradycardia, and sedation. In addition, there is a reduction in the risk for developing alpha-1 mediated ocu-lar unwanted effects, such as conjunctival blanching, mydriasis, and eyelid retraction. However, despite high alpha-2 receptor specificity, brimonidine may still produce alpha-1 adrenoceptor-mediated ocular ef-fects, such as conjunctival vasoconstriction. Brimonidine has a peak ocular hypotensive effect occurring at two hours post-dosing.

Pharmacokinetics
Absorption: After ocular administration of a 0.2% solution, plasma concentrations peaked within 1 to 4 hours and declined with a systemic half-life of approximately 3 hours.
Distribution: The protein binding of brimonidine has not been studied.
Metabolism: In humans, brimonidine is extensively metabolized by the liver.
Excretion: Urinary excretion is the major route of elimination of brimonidine and its metabolites. Approxi-mately 87% of an orally-administered radioactive dose of brimonidine was eliminated within 120 hours, with 74% found in the urine.
Preclinical safety data: Preclinical safety data is not available.

Indications:
Bimonid™ (brimonidine tartrate ophthalmic solution) 0.2% is indicated for lowering intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. The IOP lowering efficacy of Bimonid™ 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.

Contraindications:
Neonates and Infants (under the age of 2 years).
Bimonid™ is contraindicated in neonates and infants (under the age of 2 years).

Hypersensitivity Reactions:
Bimonid™ is contraindicated in patients who have exhibited a hypersensitivity reaction to any component of this medication in the past.

Interactions:
Antihypertensives/Cardiac Glycosides
Because Bimonid™ may reduce blood pressure, caution in using drugs such as antihypertensives and/or car-diac glycosides with Bimonid™ is advised.
CNS Depressants
Although specific drug interaction studies have not been conducted with Bimonid™, 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 Bimonid™, 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 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.

Special Warnings And Precautions For Use:
Potentiation of Vascular Insufficiency
Bimonid™ may potentiate syndromes associated with vascular insufficiency.
Bimonid™ should be used with caution in patients with depression, cerebral or coronary insufficiency, Ray-naud's phenomenon, orthostatic hypotension, or thromboangiitis obliterans.
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 cas-es, had a concurrent corneal disease or a disruption of the ocular epithelial surface.
Use with Contact Lenses
The preservative in Bimonid™, 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 Bimonid™ to in-sert soft contact lenses.

Use In Specific Population:
Pregnancy: There are no adequate and well-controlled studies in pregnant women; however, in animal studies, brimonidine crossed the placenta and entered into the fetal circulation to a limited extent. Because animal reproduction studies are not always predictive of human response, Bimonid™ 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 ani-mal studies, brimonidine tartrate has been shown to be excreted in breast milk. Because of the potential for serious adverse reactions from Bimond in nursing infants, a decision should be made whether to discon-tinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
Pediatric Use: The safety and effectiveness of brimonidine tartrate have not been studied in children below the age of 2 years.
Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and other adult patients.

Adverse Reactions:
- Potentiation of Vascular Insufficiency
- Severe Cardiovascular Disease
- Contamination of Topical Ophthalmic Products after Use
- Neonates and Infants (under the age of 2 years)

Dosage And Administration:
The recommended dose is one drop of Bimonid™ 0.2% in the affected eye(s) three times daily, approximately 8 hours apart. Bimonid™ ophthalmic solution 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.

Instructions:
Store below 30°C. Protect from heat & light. Shake well before use. Use within 4 weeks after first opening the container. Keep out of the sight and reach of children. Tighten the cap securely after use.

For Ophthalmic Use Only

Presentation:
Bimonid™ (Brimonidine Tartrate) 10mg/5mL Ophthalmic Solution is packed in 5mL labeled LDPE bottle with dropper Nozzle in a Carton.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔ **ہدایات:** ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ روشنی اور گرمی سے محفوظ رکھیں۔ استعمال سے پہلے بوتل کو اچھی طرح ہلالیں۔ بوتل کھولنے کے بعد چار ہفتوں سے زیادہ استعمال نہ کریں۔ تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔ استعمال کے بعد ڈھکن کو مضبوطی سے بند کریں۔

صرف آنکھوں کے استعمال کیلئے۔

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