5.4 Use with Contact Lenses

Disease or a disruption of the ocular epithelial surface

These containers had been inadvertently contaminated for Brimonidine Tartrate Ophthalmic Solution 0.2%.

For Topical Use

Initial U.S. Approval: 1996

**5.3 Contamination of Topical Ophthalmic Products After Use**

**5.4 Use with Contact Lenses**

**5.2 Severe Cardiovascular Disease**

Brimonidine Tartrate Ophthalmic Solution may potentiate syndromes associated with vascular insufficiency. Brimonidine Tartrate Ophthalmic Solution is contraindicated in patients who have exhibited a hypersensitivity reaction to any component of this medication in the past. [see Warnings and Precautions (5.2)]

**5.1 Potentiation of Vascular Insufficiency**

The IOP-lowering efficacy of Brimonidine Tartrate Ophthalmic Solution has been shown in patients with open-angle glaucoma or ocular hypertension. [see Warnings and Precautions (5.1)]

**5.7 Individual Variability**

The IOP-lowering effect of Brimonidine Tartrate Ophthalmic Solution 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.

**5.1 Potentiation of Vascular Insufficiency**

Although Brimonidine Tartrate Ophthalmic Solution had minimal effect on the disposition of drugs in clinical studies, caution should be exercised in treating patients with severe cardiovascular disease.

**5.6 Ophthalmic Herpes Simplex**

Brimonidine Tartrate Ophthalmic Solution is contraindicated in patients with a past history of ocular herpes simplex. 

**5.4 Use with Contact Lenses**

**5.3 Contamination of Topical Ophthalmic Products After Use**

These solutions are intended for use with Bausch & Lomb disposable single-use or multiple-use contact lens storage containers and single-use contact lens cases. Contact lens cases should not be reused.

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Brimonidine tartrate was not mutagenic or clastogenic in a series of in vitro and in vivo studies including the Ames bacterial reversion test, chromosomal aberration assays in Chinese Hamster Ovary (CHO) cells, and three in vivo studies in ≥12 mice: a host-mediated assay, cytogenetic study, and dominant lethal assay. A reproduction and fertility study in rats with brimonidine tartrate demonstrated no adverse effect on male or female fertility at oral doses up to 1 mg/kg/day, estimated as approximately 200 times the systemic exposure (AUC) following the maximum recommended human ophthalmic dose of Brimonidine Tartrate Ophthalmic Solution 0.5%.

14 CLINICAL STUDIES

Elevated IOP presents a major risk factor in glaucomatous field loss. The higher the level of IOP, the greater the likelihood of optic nerve damage and visual field loss. Brimonidine has the action of a 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 increases aqueous humor production and increasing uveoscleral outflow. The selective alpha-2 adrenergic receptor agonist action is responsible for a decrease in mental alertness. As with other similar medications, Brimonidine Tartrate Ophthalmic Solution may cause fatigue and/or drowsiness in some patients. Children who engage in hazardous activities of the potential for a decrease in mental alertness.

Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC

Brimonidine Tartrate Ophthalmic Solution has been studied in therapeutic human trials.

Brimonidine Tartrate Ophthalmic Solution has not been studied in pediatric glaucoma patients (ages 2 to 7 years) the most commonly observed adverse reactions with Brimonidine Tartrate Ophthalmic Solution 0.2% discontinued from the study due to somnolence.

In patients (ages 2 to 7 years) the most commonly observed adverse reactions with Brimonidine Tartrate Ophthalmic Solution 0.2% discontinued from the study due to somnolence.

In a well-controlled clinical study conducted in pediatric glaucoma patients, brimonidine tartrate was shown to be safe and well-tolerated when used for the control of intraocular pressure. The safety and effectiveness of brimonidine tartrate have not been studied in children below the age of 2 years.

No overall differences in safety or effectiveness have been observed between elderly and other adult patients.

The structural formula of brimonidine tartrate is:

\[
\text{Molecular Weight: } 442.22 \text{ g/mol} \\
\text{Molecular Formula: } C_{11}H_{10}BrN_5 \cdot C_4H_6O_6
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