FIRST TIME GENERIC APPROVAL

Brand Name	Combigan®
Generic Name	brimonidine-timolol
Drug Manufacturer	Apotex Corp

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

December 13, 2021

LAUNCH DATE

January 19, 2022

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 212592

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Brimonidine Timolol is indicated for the reduction of elevated intraocular pressure (IOP) in patients with glaucoma or ocular hypertension.

MECHANISMS OF ACTION

Brimonidine and timolol decrease elevated intraocular pressure by reducing aqueous humor secretion. Reduction of elevated or normal intraocular pressure occurs irrespective of the presence of glaucoma.

Brimonidine*:* Brimonidine is a potent, selective alpha-2-agonist that is 1000-fold more selective for the alpha-2 versus the alpha-1 receptor. When brimonidine is compared to clonidine and apraclonidine, it is 7-12 and 23-32 times, respectively, more selective for the alpha-2 receptor. Brimonidine decreases IOP, without causing mydriasis, by reducing aqueous humor production and increasing uveoscleral aqueous humor outflow.

Timolol: Timolol is a non-selective beta-blocker. The exact mechanism by which beta-blockers lower intraocular pressure has not been clearly defined. However, studies suggest that they may block catecholamine-stimulated increases in cyclic AMP within ciliary processes, with subsequent reduction in aqueous humor formation. Visual acuity, pupil size, and accommodation do not appear to be affected by timolol.

DOSE FORM AND STRENGTH

Brimonidine Tartrate 0.2%, Timolol Maleate 0.5% Ophthalmic drops, solution.

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DOSE & ADMINISTRATION

2 drops/day per affected eye.

- If more than one topical ophthalmic drug product is being used, the drugs should be administered at least 5 minutes apart.
- Contact lenses should be removed prior to administration. Lenses may be reinserted 15 minutes following administration.
- To prevent contamination, do not touch the tip of the dropper to the eye, fingertips, or other surface. To avoid contamination or the spread of infection, do not use dropper for more than one person.