Safety and efficacy of triple fixed-combination bimatoprost 0.01%/brimonidine 0.15%/timolol 0.5% twice daily in patients with glaucoma or ocular hypertension previously treated with brimonidine 0.2% and timolol 0.5% twice-daily: A multicenter, open-label study
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**Purpose:** To evaluate the efficacy and safety of a new, triple fixed-combination bimatoprost/brimonidine/timolol ophthalmic solution in Indian patients with glaucoma or ocular hypertension (OHT) previously treated with brimonidine 0.2% and timolol 0.5% as a fixed combination or adjunctive monotherapies.

**Methods:** In this multicenter, open-label study, patients who had elevated intraocular pressure (IOP) after receiving dual combination therapy twice daily for ≥1 month transitioned to treatment with the triple fixed-combination therapy twice daily in each eye for 12 weeks. IOP and safety were assessed at baseline, and weeks 4, 8, and 12. The primary efficacy variable was mean diurnal IOP change from baseline in the study eye at week 12 in the modified intent-to-treat population (mITT), which was confirmed in the per-protocol (PP) population.

**Results:** Overall, 126 patients were enrolled in the study, 121 were included in the mITT and safety populations, and 103 were included in the PP population; 109 (90.1%) patients completed the study. In the mITT and safety populations, the mean (SD) age was 58.6 (11.44) years. The specific diagnoses were open angle glaucoma (51.2%), angle closure glaucoma with patent iridotomy (36.4%), and OHT (13.2%). At week 12, triple fixed-combination therapy provided clinically meaningful and statistically significant IOP reductions from the dual combination-treated baseline; changes from baseline in mean diurnal IOP were -3.98 and -4.22 mmHg in the mITT and PP populations, respectively (p < 0.001). The most frequent (≥3%) treatment-related adverse events (AEs) were conjunctival hyperemia (14.0%), dry eye (4.1%), conjunctival follicles (3.3%), eye pain (3.3%), and increased lacrimation (3.3%). Seven (5.8%) patients discontinued due to AEs (all ocular).

**Conclusions:** In Indian patients with glaucoma or OHT with elevated IOP, bimatoprost/brimonidine/timolol provides a clinically meaningful and statistically significant additional IOP reduction from the dual combination-treated baseline, and has an acceptable safety/tolerability profile.