Efficacy of Levocabastine Hydrochloride Ophthalmic Suspension in the Conjunctival Allergen Challenge Test in Japanese Subjects with Seasonal Allergic Conjunctivitis

http://www.firstlight.cn 2006-06-13

Background: This study was conducted to investigate the efficacy and safety of 0.025% levocabastine hydrochloride in Japanese subjects with seasonal allergic conjunctivitis and its duration of action using the conjunctival allergen challenge (CAC) test.

Methods: Twenty-four asymptomatic subjects were randomized to instill 0.025% levocabastine ophthalmic suspension in one eye and vehicle in the other eye 10 minutes before the CAC test. Signs and symptoms of allergic conjunctivitis were scored 10, 15, and 25 minutes after the CAC test. The duration of drug effects was also evaluated by allergen rechallenge 4 hours after levocabastine administration. The itching score for each eye as the primary efficacy endpoint was assessed 15 minutes after the CAC test using a 5-point scale.

Results: The mean itching score in the levocabastine-treated group was 0.08 ± 0.06, which was significantly lower than the mean score of 1.98 ± 0.16 in the vehicle group ($P < 0.0001$). The redness and chemosis of the conjunctiva were also improved significantly compared with the vehicle group. Levocabastine showed prolonged efficacy in inhibiting itching (0.42 ± 0.12 vs 0.94 ± 0.17, $P < 0.0002$) and redness (1.04 ± 0.18 vs 1.42 ± 0.22, $P < 0.01$) of the conjunctiva upon the rechallenge test. No significant topical or systemic adverse safety findings were observed in the levocabastine group.

Conclusions: The results indicate that 0.025% levocabastine ophthalmic suspension is effective and safe in the treatment of allergic conjunctivitis with a duration of action of at least 4 h.

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