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Comparative Efficacy and Safety of Azelastine and Levocabastine Nasal Sprays in Patients with Seasonal Allergic Rhinitis

Norbert Falser^a, Wolfgang Wober^{b †}, Volker W. Rahlfs^c, and Martin Baehre^d

Ear Nose Throat Specialist Practice^a, Innsbruck (Austria), Institute for Medical Research^b, Munich (Germany),
idv-Datenanalyse und Versuchsplanung^c, Gauting/Munich (Germany), and ASTA Medica^d,
Frankfurt/Main (Germany)

Summary

The aim of the present investigation was to compare the efficacy and tolerability of azelastine (CAS 58581-89-8) (1.12 mg/day) and levocabastine (CAS 79547-78-7) (0.4 mg/day) nasal spray administered twice daily to patients with seasonal allergic rhinitis. A total of 180 patients participated in a 4-week, double-blind, parallel group (n = 90 each) study. Symptom severity of nasal, ocular and other symptoms were recorded, out of which a total symptom score (TSS) was calculated. Physicians assessed symptoms at baseline and at days 7, 14, and 28, patients and physicians evaluated the efficacy and tolerability. After 4 weeks of treatment with azelastine the mean overall TSS was reduced from a baseline score of 18.7 to 4.2, after levocabastine from 17.8 to 5.9. Patients morning scores for treatment days 1 to 28 gave a mean total score of

212.4 for the azelastine group and 230.6 for the levocabastine group; the equivalent evening scores yielded a mean total score of 115.5 and 175.6 respectively. Global efficacy was judged by physicians as either 'very good' or 'good' for 90 % of azelastine patients and for 74 % of the levocabastine group; 92 % of azelastine patients and 76 % of levocabastine patients judged treatment to be either 'very good' or 'good'. No serious adverse events were reported, all adverse events were related to nasal symptoms. Both azelastine and levocabastine administered twice daily as a nasal spray provide effective and well tolerated symptomatic treatment of seasonal allergic rhinitis. Azelastine, however, was statistically superior in efficacy as well as in safety (PWeilachin < 0.0001, combined results).

Key words

- Azelastine, clinical study, nasal symptom score, safety
- CAS 58581-89-8
- CAS 79547-78-7
- Levocabastine, clinical study, nasal symptom score, safety
- Rhinitis, seasonal allergic

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Zusammenfassung

Vergleich der Wirksamkeit und Verträglichkeit von Azelastin- und Levocabastin-Nasenspray bei Patienten mit saisonaler allergischer Rhinitis

Ziel der vorliegenden Untersuchung war es, die Wirksamkeit und Verträglich-

keit von Azelastin (CAS 58581-89-8) (1,12 mg/Tag) und Levocabastin (CAS 79547-78-7) (0,4 mg/Tag), jeweils in Form eines Nasensprays 2mal täglich appliziert, bei Patienten mit saisonaler allergischer Rhinitis zu vergleichen. Insgesamt 180 Patienten nahmen an einer 4-wöchigen,

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