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■ Herz-Kreislauf-Therapeutika · Kardiaka ·
Koronar-Therapeutika

■ Cardiac Drugs · Cardiac Stimulants ·
Coronary Drugs

Uchida, T., Toki, Y., Fukami, Y., Kamiya, H., E 383
Matsui, H., Okumura, K., Ito T., Hayakawa, T.
Relative Bedeutung von Kalzium-aktivierten
Kalium-Kanälen für die Nipradilol-induzierte
Erschlaffung der Aorta bei Ratten
*Relative Importance of Calcium-activated
Potassium Channels in Nipradilol-induced Aortic
Relaxation in Rats*

■ Antiallergika · Antiasthmatica · Antitussiva ·
Bronchodilatoren · Bronchosekretolytika · Mukolytika

■ Antiallergic Drugs · Antiasthmatics · Antitussives ·
Bronchodilators · Bronchosecretogogues · Mucolytics

Falser, N., Wober, W., Rahlfs, V. W., Baehre, M. E 387
Vergleich der Wirksamkeit und Verträglichkeit
von Azelastin- und Levocabastin-Nasenspray bei
Patienten mit saisonaler allergischer Rhinitis
*Comparative Efficacy and Safety of Azelastine
and Levocabastine Nasal Sprays in Patients with
Seasonal Allergic Rhinitis*

■ Antiemetika · Magen-Darm-Therapeutika · Urologika

■ Antiemetics · Gastrointestinal Drugs · Urologic Drugs

Dalrymple, P. D., Beeby, T. L., Mukai, H., E 394
Chasseaud, L. F.

Pharmakokinetik von NS-49, einem α_{1A} -
Adrenozeptor-Agonisten der Phenethylamin-
Gruppe / 4. Mitteilung; Gewebeverteilung,
Plazentatransfer und Milchsekretion von Radio-
aktivität bei Ratten nach einmaliger oraler
Verabreichung von ^{14}C -NS-49 sowie Auswirkungen
wiederholter Verabreichung auf die Pharma-
kokinetik

*Pharmacokinetics of NS-49, a Phenethylamine
Class α_{1A} -Adrenoceptor Agonist / 4th Communica-
tion: Tissue distribution, placental transfer and
milk secretion of radioactivity in rats after a
single oral administration of ^{14}C -NS-49, and ef-
fects of repeated administration on its pharmaco-
kinetics*

Koike, T., Kitazumi, H., Mukai, H. E 402

Gewebeverteilung von NS-49, einem α_{1A} -
Adrenozeptor-Agonisten der Phenethylamin-
Klasse, bei Pigment-Ratten
*Tissue Distribution of NS-49, a Phenethylamine
Class α_{1A} -Adrenoceptor Agonist, in Pigmented
Rats*

■ Analgetika · Antiphlogistika · Antirheumatika

■ Analgesics · Antiphlogistics · Antirheumatic Drugs

Fang, J.-Y., Sung, K. C., Hu, O. Y.-P., E 408
Chen, H.-Y.

Transdermale Permeation von Nalbuphin und
Nalbuphinpivalat aus Hydrogelen durch passive
Diffusion und Iontophorese
*Transdermal Delivery of Nalbuphine and
Nalbuphine Pivalate from Hydrogels by Passive
Diffusion and Iontophoresis*

E = Publication in English. G = Publication in German.

■ Hämostyptika

■ Haemostyptic Drugs

Bianchini, P., Parma, B. E 414
Studie zur immunologischen Sicherheit einer
hämostatisch wirksamen Wundaufgabe aus
Pferdecollagen
*Immunological Safety Evaluation of a Horse
Collagen Haemostatic Pad*

■ Antibiotika · Chemotherapeutika · Virustatika ·
Zytostatika

■ Antibiotics · Antiviral Drugs · Chemotherapeutics ·
Cytostatics

Küçükbay, H., Durmaz, R., Güven, M., E 420
Günel, S.
Synthese von Benzimidazol-Derivaten und ihre
antibakterielle und antimykotische Aktivität
*Synthesis of Some Benzimidazole Derivatives and
their Antibacterial and Antifungal Activities*

Guzmán, A., García, C., Paz Marín, A., E 425
Demestre, I.
4-wöchige orale Toxizitätsstudien mit dem
neuen antibakteriell wirksamen Chinolon
Cetefloxacin Tosylat an Ratten und Krallenaffen
*Four-week Oral Toxicity Studies of the New
Quinolone Antibacterial Agent Cetefloxacin
Tosylate in Rats and Marmoset Monkeys*

Poli, G., Dall'Ara, P., Binda, S., Santus, G., E 433
Poli, A., Cocilovo, A., Ponti, W.
Auswertung des Meerschweinchenrückenhaut-
modells bei der Auswahl topischer Virustatika für
die Behandlung von rezidivierendem Herpes
simplex Typ 1
*Value of the Dorsal Cutaneous Guinea Pig Model
in Selecting Topical Antiviral Formulations for
the Treatment of Recurrent Herpes simplex Type 1
Disease*

■ Patentinformationen

■ Information on Patents

Habernickel, V. J. E 439
Der Pharmamarkt im Spiegel der Patente / Wirk-
stoffe zur Behandlung von Diabetes und Folge-
erkrankungen, Antinflammatorika, Arthritis-
mittel
*The Pharma Market as Reflected by Patents /
Agents for treating diabetes and related diseases,
agents for the treatment of inflammation, agents
for the treatment of arthritis*

■ Ankündigungen

■ Announcements

444

■ Buchbesprechungen

■ Book Reviews

444

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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