

Clinical Studies on Alluna™ Sleep

Sleep						
Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Fussel <i>et al.</i> , 2000	Sleep	PS n=30	2 wks	2 tablets in the evening (1000 mg valerian extract and 240 mg hops extract per day)	Ze 91019 Alluna™ (US) Ivel® (Germany) Redormin® (Switzerland) (500 mg valerian extract and 120 mg hops extract)	Polysomnography data on patients with mild to moderate, non-organic insomnia were recorded on baseline and after 2 weeks. Sleep latency was reduced statistically significantly while sleep efficiency increased. An increase in slow wave sleep was recorded. In a self-assessment patients reported an improvement of feeling refreshed in the morning after 2 weeks. No adverse events were recorded.
Vonderheid-Guth <i>et al.</i> , 2000	Sleep	R, SB, CO 2 studies n=12	1, 2, and 4 hours after application in each study, studies spaced 3 months apart	1st dosage: 1 tablet vs. placebo; 2nd dosage: 3 tablets (1500 mg valerian extract and 360 mg hops extract per day) vs. placebo	Ze 91019 Alluna™ (US) Ivel® (Germany) Redormin® (Switzerland) (500 mg valerian extract and 120 mg hops extract)	The study concluded that pharmaco-dynamic responses could be repeated. The quantitative topo-graphical EEG demonstrated a visible effect on the CNS, especially after intake of the high dosage of the valerian-hops combination.
Kammer <i>et al.</i> , 1996	Sleep	R, DB, CO n=18	21 days	2 tablets in the evening, or placebo	Ze 91019 Alluna™ (US) Ivel® (Germany) Redormin® (Switzerland)	The study concluded that the combination did not produce significant adverse effects and did not impair psychometrically measured fitness and subjective state of health. In addition, no significant interaction with alcohol is to be expected.
Lataster and Brattström, 1996	Sleep	MC, OL n=3447	4–6 wks	2 tablets in the evening	Ze 91019 Alluna™ (US) Ivel® (Germany) Redormin® (Switzerland)	The efficacy of the combination was evaluated as good to very good by 75% of the physicians. The number of patients who slept through the night rose from 24.4% to 77.4%. The self-efficacy report of feeling rested upon awakening rose from 26.5% to 64.9%.

KEY: C – controlled, CC – case-control, CH – cohort, CI – confidence interval, Cm – comparison, CO – crossover, CS – cross-sectional, DB – double-blind, E – epidemiological, LC – longitudinal cohort, MA – meta-analysis, MC – multi-center, n – number of patients, O – open, OB – observational, OL – open label, OR – odds ratio, P – prospective, PB – patient-blind, PC – placebo-controlled, PG – parallel group, PS – pilot study, R – randomized, RC – reference-controlled, RCS – retrospective cross-sectional, RS – retrospective, S – surveillance, SB – single-blind, SC – single-center, U – uncontrolled, UP – unpublished, VC – vehicle-controlled.