

Lavender oil Silexan®: new safety data from two state-of-the-art clinical trials

No impairment on ability to drive and no abuse potential

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Anxiolytic drugs often may have sedative effects that impair the ability to drive as well as a potential for abuse. These aspects were investigated in two new studies of modern anxiolytic Silexan, a proprietary essential oil from *Lavandula angustifolia*.

A double-blind, randomized crossover clinical trial investigated the effect of Silexan on driving performance in healthy volunteers. Driving performance was assessed in a validated, alcohol calibrated simulator test. The primary outcome was the standard deviation of the lane position (SDLP). Secondary outcomes included driving errors and sleepiness. First part demonstrated the equivalence between 80 mg/d Silexan and placebo, whereas second part demonstrated the superiority of 160 and 320 mg Silexan over 1 mg Lorazepam [1].

Another double-blind, five-way crossover clinical study in healthy users of recreational CNS depressants was carried out to investigate the potential for abuse of Silexan. The participants received single oral doses of 80 mg (therapeutic dose) and 640 mg Silexan, 2 mg and 4 mg Lorazepam (active control) and placebo in randomized order, with 4-14-day washout periods between treatments. Pharmacodynamic measures included among others validated visual analogue scales (VAS) assessing positive, negative and sedative drug effects and balance of effects. The primary outcome measure was the individual maximum value on the Drug Liking VAS during 24 hours post-dose. In intraindividual head-to-head comparisons of the Drug Liking VAS maximum value both doses of Silexan were rated similar to placebo whereas differences were observed between Silexan and lorazepam and between placebo and lorazepam ($p < 0.001$) [2].

The first study showed that Silexan has no adverse effect on driving performance. The second study showed that Silexan has no abuse potential and is unlikely to be recreationally abused. Those aspects underlining favorable safety profile of Silexan, especially comparing to the synthetic anxiolytics.

1. Möller HJ, Volz HP, Seifritz E, et al. 2020 Silexan does not affect driving performance after single and multiple dose applications: results from a double-blind, placebo and reference-controlled study in healthy volunteers. [manuscript submitted 2020]
2. Seifritz E, Möller, HJ, Volz HP et al. 2020 No abuse potential of Silexan in healthy recreational drug users: a randomised controlled trial. [Manuscript submitted 2020]