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EFFICACY AND SAFETY OF SILEXAN, A NEW, ORALLY ADMINISTERED LAVENDER OIL PREPARATION, IN SUBTHRESHOLD ANXIETY DISORDER

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A number of studies has been performed recently on the efficacy and tolerability of silexan, a novel preparation from lavender oil for oral use, in the treatment of anxiety disorders and related conditions with particular attention to subthreshold generalized anxiety disorder (GAD). Three randomized, double-blind clinical trials were identified which investigated the efficacy of silexan in subsynromal anxiety disorder (vs. placebo; 10 weeks' treatment), in GAD (vs. lorazepam; 6 weeks), and in restlessness and agitation (vs. placebo; 10 weeks) according to DSM-IV and ICD-10 criteria. One open-label pilot study assessed the potential of the medicinal product in neurasthenia, posttraumatic stress disorder and somatization disorder (6 weeks). All trials assessed the participants' anxiety levels using the Hamilton Anxiety Scale (HAMA) or the State Trait Anxiety Inventory (STAI) as well as measures of co-morbidity and clinical global impressions. Across all trials 280 patients were exposed to silexan 80 mg/day, 37 were treated with lorazepam 0.5 mg/day and 192 received placebo. Average within group HAMA total scores at baseline ranged between 24.7 and 27.1 points. Patients treated with silexan showed average HAMA total score decreases by between 10.4 ± 7.1 and 12.0 ± 7.2 points at week 6 and by between 11.8 ± 7.7 and 16.0 ± 8.3 points at week 10. In subthreshold GAD silexan was significantly superior to placebo, with a mean value difference of at least 4 points (lower bound of 95% confidence interval (CI)) after 10 weeks. In GAD silexan and lorazepam showed comparable HAMA total score reductions (90% CI for mean value difference: -2.3; 2.8 points). The decrease of anxiety levels was accompanied by a reduction of restlessness and co-morbidity, and by improvements in general well-being. The anxiolytic effect of silexan is superior to placebo and comparable to lorazepam in subthreshold and threshold GAD, respectively. The medicinal product also improved associated symptoms like restlessness, disturbed sleep and somatic complaints, and had a beneficial influence on general well-being and quality of life. Silexan may offer interesting perspectives particularly in the treatment of subthreshold GAD.

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