INTEGRATIVE NEUROENDOCRINE™

LAVELA WS 1265™

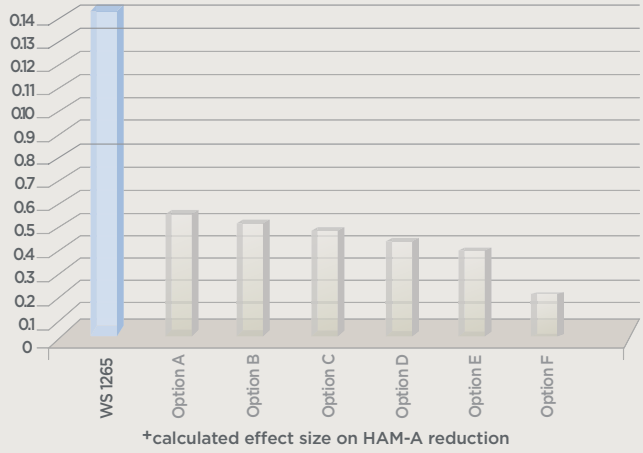
CLINICALLY STUDIED LAVENDER OIL

Lavela WS 1265 is an exclusive lavender (*Lavandula angustifolia*) essential oil, known as Silexan™. Indicated for occasional anxiety, Lavela WS 1265 has been shown to promote relaxation and calm nervousness with safety and efficacy, as demonstrated in controlled trials published in peer-reviewed medical journals.*[1,2,4]

Comparison to Alternative Options

Lavela WS 1265 offers relief without the side effects commonly seen in other options. Taken just one to two times per day, this gentle, yet powerful, essential oil is non-habit-forming and well-tolerated. Clinical trials and a comparative analysis suggest that the effects of Lavela WS 1265 compare favorably to other options (see chart).*[1,3]

CLINICAL EFFICACY+



+calculated effect size on HAM-A reduction

wheat free · gluten free · corn free · dairy free

1. Kasper S, Gastpar M, Müller WE, et al. *Int Clin Psychopharmacol* 2010 Sep;25(5):277-87. 2. Woelk H, Schälfke S. *Phytomedicine* 2010;17:94–99.
3. Hidalgo RB, Tupler LA, Davidson JR. *J Psychopharmacol* 2007;21:864 72. 4. Kasper S, Gastpar M, Müller WE, et al. Lavender oil preparation Silexan is effective in generalized anxiety disorder-a randomized, double-blind comparison to placebo and paroxetine. *Int J Neuropsychopharmacol.* 2014 Jun;17(6):859-69.

LAVELA WS 1265™

Lavela WS 1265 Clinical Overview

Several clinical studies show the benefit of Lavela WS 1265 as compared to reference or placebo. The results were statistically significant and the response rate to treatment is high.

Comparison to conventional options
Researchers Woelk and Schläfke conducted a multi-center, double-blind, randomized study of Lavela WS 1265 in comparison to a conventional agent for promoting relaxation.[2] The Hamilton Anxiety Rating Scale (HAM-A total score) was used as the primary objective measurement to monitor changes in the level of tension and relaxation beginning at baseline through week 6 of the trial. Additional data was collected using the Self-Rating Anxiety Scale, Penn State Worry Questionnaire, SF 36 Health Survey Questionnaire, and specific sections of the Clinical Global Impressions.

A total of 77 female (76.6%) and male (23.4%) subjects 18-65 years of age were randomized into groups. Participants were eligible for the study if they met the inclusion criteria of a HAM-A total score of greater than 18 as well as a score equal to or greater than 2 on both anxious mood and tension items. Secondary objective outcome data were obtained from responder and remission rate comparisons made between the two treatment groups. In order for a participant to qualify as having a significant response to treatment they were required to have a reduction of at least 50% in the HAM-A total score during the 6 week trial. Remission was defined as a HAM-A total score of less than ten points at the end of the 6 week study. The clinical results demonstrated that WS 1265 was comparable to the conventional approach. The HAM-A total score decreased by 45% in the WS 1265 group and decreased by 46% in the conventional group. At the conclusion of the 6 week intervention, 40% of the WS 1265 group and 27% of the conventional treatment group were determined to be in remission. The WS 1265 group had a response rate of 52.5% compared to only 40.5% taking the conventional option. Adverse effects in the WS 1265 group were uncommon and included nausea (5.2%), eructation (3.9%), and dyspepsia (2.6%).

Kasper evaluated Lavela WS 1265 in two doses against placebo and a conventional agent for promoting contentment. Additional data was collected using the Hamilton Rating Scale for Depression (HAMD) and other questionnaires.

A total of 539 female (71.4%) and male (28.6%) subjects 18-65 years of age were randomized into groups.[4] Participants were eligible for the study if they met the inclusion criteria of a HAM-A total score of equal to or greater than 18. Two arms of the trial evaluated WS 1265: one at 80 mg per day and another at 160 mg per day. A third arm received the conventional approach and a fourth arm received a placebo. The clinical results demonstrated that WS 1265 was superior to the conventional approach. The HAM-A total score decreased by 14.1±9.3 in the 160 mg group, 12.8±8.6 in the 80 mg group, 11.3±8.0 and 9.5±9.0 for the conventional and placebo group respectively. Adverse effects in the WS 1265 group were uncommon, and less common than placebo, and included gastrointestinal effects (4.4% in the 160 mg group and 4.5% in the 80 mg group).

Efficacy of WS® 1265

Another study was performed to investigate the efficacy of WS 1265 in comparison to placebo in a primary care setting.[1] In 27 general and psychiatric practices, 221 adults reporting unspecified anxiety were randomized to receive 80 mg per day of WS 1265 or placebo for 10 weeks with office visits every 2 weeks. A baseline HAM-A total score of ≥18 and a total score > 5 for the Pittsburgh Sleep Quality Index (PSQI) were required. The primary outcome measures were HAM-A and PSQI total score decrease between baseline and week 10. Secondary efficacy measures included the Clinical Global Impressions scale, the Zung Self-Rating Anxiety Scale, and the SF–36 (Quality of Life) Health Survey Questionnaire. Subjects taking WS 1265 showed a total score decrease by 16.0± 8.3 points (mean± SD, 59.3%) for the HAM-A and by 5.5± 4.4 points (44.7%) for the PSQI compared to 9.5± 9.1 (35.4%) and 3.8± 4.1 points (30.9%) in the placebo group ($P < 0.01$ one-sided, intention to treat). WS 1265 was superior to placebo regarding the percentage of responders (76.9 vs. 49.1%, $P< 0.001$) and remitters (60.6 vs. 42.6%, $P=0.009$). Adverse effects were uncommon and included dyspepsia (4.7% in the treatment group vs 1.8% in the placebo group) and eructation (3.7% in the treatment group and none in the placebo group).

Lavela WS 1265 had a significant beneficial influence on quality and duration of sleep and improved general mental and physical health without causing any unwanted sedative effects.* Researchers concluded that Lavela WS 1265 was "both efficacious and safe" for the relief of occasional anxiety not otherwise specified.* It has a clinically demonstrable relaxing effect and was found to support restful sleep.*[1]

Comparison to conventional alternatives
Conventional approaches have mean HAM-A reductions in the range of 11 to 15.3 points, suggesting comparable to superior efficacy of WS 1265 without the side effects associated with those options.[1-2, 5-6]

Safety

The safety profile and evaluation report for WS 1265 showed no serious adverse events during either of the studies discussed above. Lavela WS 1265, when taken at the recommended dose of 80 mg or 160 mg per day, is safe and well-tolerated, without sedative action on the body, and no known potential for abuse.

References

1. Kasper S, Gastpar M, Müller WE, et al. *Int Clin Psychopharmacol* 2010;25:277–87.
2. Woelk H, Schläfke S. *Phytomedicine* 2010;17:94–9.
3. Hidalgo RB, Tupler LA, Davidson JR. *J Psychopharmacol* 2007;21:864 72.
4. Woelk H, Kapoula O, Lehr S, Schröter K, Weinholz P (1999). *Healthnotes Review* 6:265–70.
5. Bielski RJ, Bose A, Chang CC. *Ann Clin Psychiatry* 2005 Apr-Jun;17(2):65–9.
6. Allgulander C, Hartford J, Russell J, et al. *Curr Med Res Opin* 2007 Jun;23(6):1245–52. Epub 2007 Apr 25.

Supplement Facts

Serving Size 1 softgel

Amount per softgel	
Lavender (*Lavandula angustifolia*) Oil (Silexan™ brand)	80 mg**

**Daily Value not established.

Other ingredients: canola oil, gelatin (capsule), glycerin, sorbitol, and annato extract color.

Contains no: sugar, salt, yeast, wheat, gluten, corn, dairy products, artificial flavoring, or preservatives.

Recommendations: Take 1 softgel, 1-2 times daily with a full glass of water, or as recommended by your healthcare professional.

Caution: Not to be used during pregnancy, lactation, or by persons under 18 years of age. If you are taking prescription medications, consult with your healthcare professional before using this product. Lavender eructation has been reported in a small number of users and is a normal effect of the product.

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