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THERAPEUTICS™

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LAVELA WS 1265™

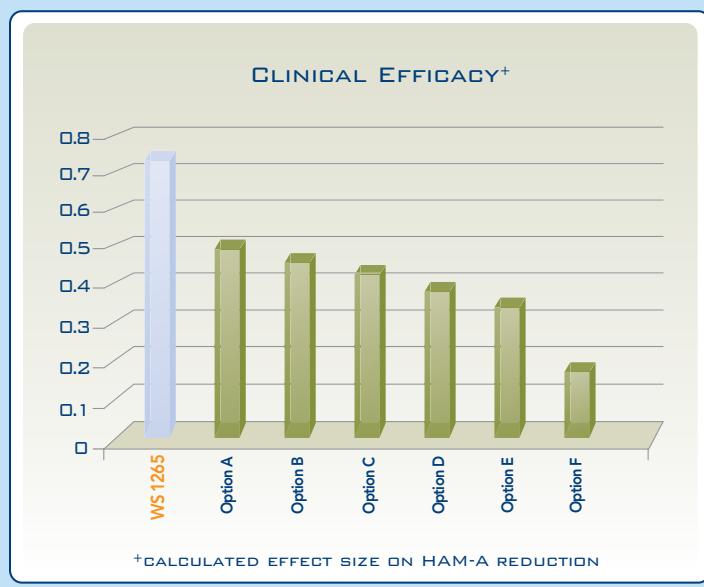
CLINICALLY STUDIED LAVENDER OIL

AN ANXIOLYTICALLY AWAITED SOLUTION

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}

COMPARISON TO ALTERNATIVE OPTIONS

Lavela WS 1265 offers relief without the side effects commonly seen in other options. Taken just once a 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}



(HAM-A = Hamilton Anxiety Scale) additional study detail provided on back

CLINICALLY DOCUMENTED RELIEF

- Exclusive, safe and effective option
- Non-habit forming, non-sedating relief of occasional anxiety*
- Convenient, once daily dosing

1. Kasper S, Gastpar M, Müller WE, et al. Silexan, an orally administered *Lavandula* oil preparation, is effective in the treatment of 'subsyndromal' anxiety disorder: a randomized, double-blind, placebo controlled trial. *Int Clin Psychopharmacol* 2010 Sep;25(5):277-87.

2. Woelk H, Schäfke S. A multi-center, double-blind, randomised study of the Lavender oil preparation Silexan in comparison to Lorazepam for generalized anxiety disorder. *Phytomedicine* 2010;17:94-99.

3. Hidalgo RB, Tupler LA, Davidson JR. An effect-size analysis of pharmacologic treatments for generalized anxiety disorder. *J Psychopharmacol* 2007;21:864-72.

TECHNICAL DATA

Background

Mild or occasional anxiety is a common complaint. Herbal preparations have long been a mainstay for maintaining a healthy, adaptive response to everyday stress and promoting restful sleep.

Lavandula angustifolia is the most common species of lavender utilized for health purposes.¹ Lavender is native to the Mediterranean, the Arabian Peninsula, Russia and Africa. Throughout history, lavender has been cultivated for its flowers and oils and used both cosmetically and medicinally. Lavender has a high concentration of volatile oils; these oils are regularly used in aromatherapy to relieve mild anxiety.* Lavender has been also used internally for mood imbalances such as restlessness, occasional sleeplessness, and gastrointestinal complaints related to nervousness.*² Lavender essential oil is obtained from steam distillation processing of the flowering tops of *L. angustifolia*.

Lavela WS 1265™:

Lavela WS 1265 is an exclusive, proprietary lavender (*Lavandula angustifolia*) essential oil, indicated for occasional anxiety.* Clinically shown to be comparable in efficacy to commonly used conventional and alternative options, Lavela WS 1265 offers safe and effective relief.

- Exclusive, safe and effective option
- Non-habit forming, non-sedating relief of occasional anxiety*
- Convenient, once-daily dosing

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.³ 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 six week trial. Remission was defined as a HAM-A total score of less than ten points at the end of the six 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 six 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%).

Efficacy of WS® 1265

Another study was performed to investigate the efficacy of WS 1265 in comparison to placebo in a primary care setting.⁴ 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 HAMA 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 \pm 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.*⁴

LAVELA WS 1265™

CLINICALLY STUDIED LAVENDER OIL

LAVELA WS 1265™ CLINICALLY STUDIED LAVENDER OIL

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 annatto extract color.

Contains no: sugar, salt, yeast, wheat, gluten, corn, dairy products, artificial flavoring, or preservatives. This product contains natural ingredients; color variations are normal.

Recommendations: Take one softgel daily with a full glass of water, or as recommended by your healthcare practitioner.

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 practitioner before using this product. Lavender eructation has been reported in a small number of users and is a normal effect of the product.

Integrative Therapeutics: 60ct / 70662

Emerson Ecologies: I06620

Natural Partners: IT0084

Comparison to kava and conventional alternatives

Kava kava (*Piper methysticum*) was among better studied herbs for supporting relaxation, until concerns about liver toxicity prompted many companies to discontinue offering it. In a 6-week study, kava was found to produce a mean reduction of the HAM-A score of 10 points, whereas the mean reduction of that score from WS 1265 has ranged from 11.3 points (6 week study)³ to 16 points (10 week study).⁴ Other 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.³⁻⁷

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 per day, is safe and well-tolerated, without sedative action on the body, and no known potential for abuse.

Conclusion

Lavela WS 1265 offers a safe and effective solution for occasional anxiety.* It also promotes relaxation and restful sleep.* Taken just once a day, this gentle yet powerful botanical essential oil is non-habit-forming and well-tolerated, with efficacy demonstrated in controlled clinical trials published in peer-reviewed medical journals.

References

1. Basch E, Foppa I, Liebowitz R, et al. Monograph: *Lavandula angustifolia*. *J Herbal Pharmacother* 2004;4(2) 63-78.
2. Blumenthal M, ed. Lavender flower. In: *The Complete German Commission E Monographs*. Austin, TX, American Botanical Council, 1998:159-60.
3. Woelk H, Schläfke S. A multi-center, double-blind, randomized study of the Lavender oil preparation Silexan in comparison to Lorazepam for generalized anxiety disorder. *Phytomedicine* 2010;17:94-9.
4. Kasper S, Gastpar M, Müller WE, et al. Silexan, an orally administered *Lavandula* oil preparation, is effective in the treatment of 'subsyndromal' anxiety disorder: a randomized, double-blind, placebo-controlled trial. *Int Clin Psychopharmacol* 2010;25:277-87.
5. Woelk H, Kapoula O, Lehr S, Schröter K, Weinholz P (1999). A comparison of Kava special extract WS 1490 and benzodiazepines in patients with anxiety. *Healthnotes Review* 6:265-70.
6. Bielski RJ, Bose A, Chang CC. A double-blind comparison of escitalopram and paroxetine in the long-term treatment of generalized anxiety disorder. *Ann Clin Psychiatry* 2005 Apr-Jun;17(2):65-9.
7. Allgulander C, Hartford J, Russell J, et al. Pharmacotherapy of generalized anxiety disorder: results of duloxetine treatment from a pooled analysis of three clinical trials. *Curr Med Res Opin* 2007 Jun;23(6):1245-52. Epub 2007 Apr 25.

WHAT IS LAVELA WS 1265?

Each softgel of Lavela WS 1265 contains 80 mg of a unique lavender essential oil that has been proven effective in clinical research. Lavela WS 1265 relieves occasional anxiety and restlessness.*

WHAT CAN I EXPECT WHEN TAKING THE PRODUCT?

Research shows Lavela WS 1265 not only calms occasional nervousness, but also enhances the quality and duration of sleep, thereby helping patients wake up refreshed and rested.* Lavela WS 1265 has also been shown to improve both mental and physical health without causing the side effects commonly seen with other options.* Clinically and statistically significant improvements were achieved in a six week study.*

HOW SHOULD I TAKE LAVELA WS 1265?

Take one softgel (80 mg) daily with a full glass of water, or as recommended by your healthcare practitioner. Lavela WS 1265 should not be used during pregnancy, lactation, or by persons under 18 years of age. If you are taking prescription medications, consult with your healthcare practitioner before using this product.

Integrative Therapeutics™ is North America's leading manufacturer and distributor of proprietary, natural, dietary supplements for medical professionals and their patients. Every day, more than 50,000 doctors recommend our products to their patients—an indicator of trust, quality and value.

As the cornerstone of our commitment to quality, Integrative Therapeutics products are the B.E.S.T. that science and nature have to offer:

- **BIOAVAILABLE** – Bioavailability testing via dissolution and disintegration methods ensures nutrients are released for absorption in the body
- **EFFECTIVE** – Every lot of raw material must be tested to confirm identity, potency and purity delivering efficacy you can trust
- **SAFE** – Safety and stability protocols ensure products retain full potency throughout product shelf-life
- **TRUSTED** – When Results Matter™ you can trust a high quality, consistent product - bottle to bottle, and capsule to capsule

An Anxiously Awaited Solution



ARE YOU WIRED, BUT TIRED?

Economic challenges, work-home life imbalances, and health-related issues are commonly reported worries in today's world. Concerns for what lies ahead keep many individuals awake at night. As a result, more and more patients are turning to their physicians for help in managing symptoms of stress and occasional anxiety.

WORK-RELATED STRESS

LOSS OF JOB

ECONOMIC UNCERTAINTY

HEALTH CONCERNs

LAVELA
WS 1265™

TENSION

RESTLESSNESS

OCCASIONAL SLEEPLESSNESS

CIRCLING THOUGHTS

LACK OF CONCENTRATION

Herbs and botanicals have been used for centuries to quiet the mind and calm the body. Among these, lavender has been a mainstay and provides a wide-range of health benefits. Lavender oils are regularly used in aromatherapy to relieve mild anxiety. Oral lavender supplements have also been used to treat mood imbalances, such as restlessness, occasional sleeplessness, and gastrointestinal irritability related to nervousness.*

LAVELA WS 1265™

An Anxiously Awaited Solution

Lavela WS 1265 contains an exclusive lavender (*Lavandula angustifolia*) essential oil, known as WS 1265, or Silexan™, in the research. Indicated for occasional anxiety, Lavela WS 1265 has been shown to safely and effectively promote relaxation and calm nervousness, as demonstrated in controlled trials published in peer-reviewed medical journals.*^{1,2}

SAFE & NON-HABIT FORMING

Lavela WS 1265 offers gentle relief that supports healthy relaxation and adaptation to stress.* Taken just once a day, this botanical extract is non-habit forming and well-tolerated. Clinical research shows Lavela WS 1265 is an effective and convenient solution for occasional anxiety and restlessness.*^{1,2}

