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SUMMARY OF CLINICAL STUDIES

Product	Serenity Nightly Nootropic
SKU	SERENITY
Barcode	866033000215
Formula	3
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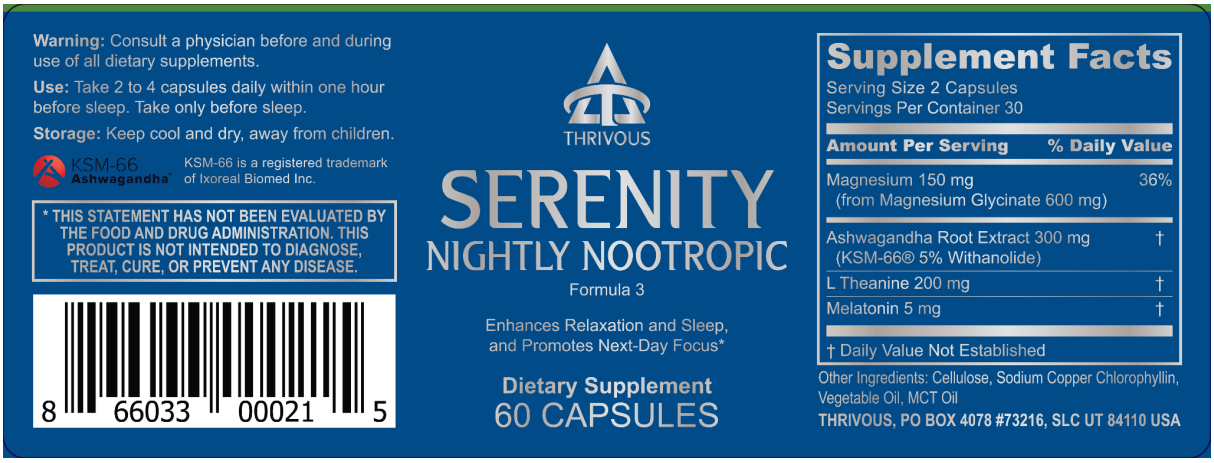
Label



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Ashwagandha to Enhance Relaxation

Ashwagandha supplements may enhance relaxation, according to these clinical studies on humans:

- Efficacy and Safety of Ashwagandha (Withania somnifera) Root Extract in Insomnia and Anxiety: A Double-blind, Randomized, Placebo-controlled Study. In 2019, this study found that "Ashwagandha root extract is a natural compound with sleep-inducing potential, well tolerated and improves sleep quality and sleep onset latency."

- An investigation into the stress-relieving and pharmacological actions of an ashwagandha (Withania somnifera) extract: A randomized, double-blind, placebo-controlled study. In 2019, this study found that Ashwagandha has "stress-relieving effects."

- Adaptogenic and Anxiolytic Effects of Ashwagandha Root Extract in Healthy Adults: A Double-blind, Randomized, Placebo-controlled Clinical Study. In 2019, this study found that "participants receiving Ashwagandha had significant improvement in sleep quality … [and Ashwagandha] was beneficial in reducing stress and anxiety."

- Adjunctive Use of a Standardized Extract of Withania somnifera (Ashwagandha) to Treat Symptom Exacerbation in Schizophrenia: A Randomized, Double-Blind, Placebo-Controlled Study. In 2018, this study found that Ashwagandha "provides significant benefits, with minimal side effects, for … stress."

- Body Weight Management in Adults Under Chronic Stress Through Treatment With Ashwagandha Root Extract: A Double-Blind, Randomized, Placebo-Controlled Trial. In 2017, this study found that “Ashwagandha root extract can be used for body weight management in adults under chronic stress.”

- A Randomized Double Blind Placebo Controlled Study of Ashwagandha on Generalized Anxiety Disorder. In 2013, this study found that participants using “Ashwagandha (Withania somnifera) granules showed a better percentage improvement [in anxious mood].”

- A prospective, randomized double-blind, placebo-controlled study of safety and efficacy of a high-concentration full-spectrum extract of ashwagandha root in reducing stress and anxiety in adults. In 2012, this study found that “Ashwagandha root extract safely and effectively improves an individual's resistance towards stress and thereby improves self-assessed quality of life.”

- Naturopathic care for anxiety: a randomized controlled trial ISRCTN78958974. In 2009, this study found that participants using Ashwagandha “demonstrated a significant decrease in anxiety levels … [and] significant improvements in secondary quality of life measures.”

- Withania somnifera Improves Semen Quality in Stress-Related Male Fertility. In 2009, this study found that Ashwagandha “resulted in a decrease in stress.”

- A Standardized Withania Somnifera Extract Significantly Reduces Stress-Related Parameters in Chronically Stressed Humans: A Double-Blind, Randomized, Placebo-Controlled Study. In 2008, this study found that Ashwagandha “significantly reduces experiential and biochemical indicators of stress without adverse effects.”

- A double-blind, placebo-controlled evaluation of the anxiolytic efficacy ff an ethanolic extract of withania somnifera. In 2000, this study found that Ashwagandha “has useful anxiolytic potential.”

L Theanine to Enhance Relaxation

L Theanine supplements may enhance relaxation, according to these clinical studies on humans:

- Anti-stress effect of theanine on students during pharmacy practice: positive correlation among salivary α-amylase activity, trait anxiety and subjective stress. In 2013, this study found that L-Theanine "intake suppressed initial stress response of students assigned for a long-term commitment of pharmacy practice."

- Effects of l-theanine on attention and reaction time response. In 2011, this study found that L-Theanine "clearly has a pronounced effect on attention performance and reaction time response in normal healthy subjects prone to have high anxiety."

- The effects of L-theanine (Suntheanine®) on objective sleep quality in boys with attention deficit hyperactivity disorder (ADHD): a randomized, double-blind, placebo-controlled clinical trial. In 2011, this study found that L-Theanine "is safe and effective in improving some aspects of sleep quality in boys diagnosed with ADHD."

- L-Theanine reduces psychological and physiological stress responses. In 2007, this study found that "oral intake of [L-Theanine] could cause anti-stress effects via the inhibition of cortical neuron excitation."

- The acute effects of L-theanine in comparison with alprazolam on anticipatory anxiety in humans. In 2004, this study found that L-Theanine "may have some relaxing effects under resting conditions."

- Effects of Theanine on the Release of Brain Alpha Wave in Adult Males. In 2003, this study found that L-Theanine "containing tablets promote the release of alpha waves related to mental relaxation and concentration in young adult males."

Magnesium Glycinate to Enhance Relaxation and Sleep Quality

Approximately 54% of people in the United States consume less than the estimated average requirement for Magnesium from natural sources and fortified foods, and a larger unknown percentage consumes less than optimal amounts, according to these studies:

- Second National Report on Biochemical Indicators of Diet and Nutrition in the U.S. Population. In 2012, this study observed that “dietary deficiencies are well documented, and they have characteristic signs and symptoms. In addition, recent findings have determined that less than optimal biochemical concentrations (representing suboptimal status) have been associated with risks of adverse health effects”.

- Foods, Fortificants, and Supplements: Where Do Americans Get Their Nutrients? In 2011, this study observed that “without enrichment and/or fortification and supplementation, many Americans did not achieve the recommended micronutrient intake levels set forth in the Dietary Reference Intake”.

Magnesium supplements may decrease blood pressure, according to these clinical studies on humans:

- Oral Magnesium Supplementation Reduces Ambulatory Blood Pressure In Patients With Mild Hypertension. In 2009, this study found that Magnesium "is associated with small but consistent ambulatory [blood pressure] reduction in patients with mild hypertension".

- Effects Of Oral Magnesium Supplementation On Insulin Sensitivity And Blood Pressure In Normo-magnesemic Nondiabetic Overweight Korean Adults. In 2009, this study found that Magnesium "does not reduce [blood pressure] and enhance insulin sensitivity in normo-magnesemic nondiabetic overweight people ... however, it appears that magnesium supplementation may lower [blood pressure] in healthy adults with higher [blood pressure]".

- The Effect Of Lowering Blood Pressure By Magnesium Supplementation In Diabetic Hypertensive Adults With Low Serum Magnesium Levels: A Randomized, Double-blind, Placebo-controlled Clinical Trial. In 2009, this study

found that Magnesium "significantly reduces [systolic blood pressure] and [diastolic blood pressure] in diabetic hypertensive adults with hypomagnesaemia".

This clinical study review confirms that Magnesium supplements may decrease blood pressure:

- Effect of magnesium supplementation on blood pressure: a meta-analysis. In 2012, this meta-analysis of 22 studies found that Magnesium "appears to achieve a small but clinically significant reduction in [blood pressure]".

Magnesium supplements may enhance sleep quality, according to these clinical studies on humans:

- A randomized, double-blind, placebo-controlled, multicenter study assessing the efficacy of magnesium oxide monohydrate in the treatment of nocturnal leg cramps. In 2021, this study found that Magnesium “was shown to be effective in the treatment of [nocturnal leg cramps] as well as safe and well-tolerated.”

- Magnesium supplementation improves indicators of low magnesium status and inflammatory stress in adults older than 51 years with poor quality sleep. In 2010, this study found "an association between magnesium status and sleep quality that needs further study to definitively determine whether a low magnesium status is a cause or an effect of poor sleep quality".

- Oral Mg(2+) supplementation reverses age-related neuroendocrine and sleep EEG changes in humans. In 2002, this study found that Magnesium "partially reverses sleep EEG and nocturnal neuroendocrine changes occurring during aging".

Glycine supplements may enhance sleep quality, according to these clinical studies on humans:

- The effects of glycine on subjective daytime performance in partially sleep-restricted healthy volunteers. In 2012, this study found that Glycine "modulates certain neuropeptides in the [suprachiasmatic nucleus] and this

phenomenon may indirectly contribute to improving the occasional sleepiness and fatigue induced by sleep restriction".

- Glycine ingestion improves subjective sleep quality in human volunteers, correlating with polysomnographic changes. In 2007, this study found that Glycine "seems to produce subjective and objective improvement of the sleep quality in a different way than traditional hypnotic drugs such as benzodiazepines".

- Subjective effects of glycine ingestion before bedtime on sleep quality. In 2006, this study found that Glycine "produced a good subjective feeling after awakening from sleep".

Melatonin to Enhance Sleep and Next-Day Focus

Melatonin supplements may enhance sleep, according to these clinical studies on humans:

- High dose melatonin increases sleep duration during nighttime and daytime sleep episodes in older adults. In 2022, this study found that “melatonin significantly increased [sleep efficiency] during both biological day and night.” 12 participants used 5 mg of Melatonin daily for four weeks.

- Effects of melatonin administration on mental health parameters, metabolic and genetic profiles in women with polycystic ovary syndrome: A randomized, double-blind, placebo-controlled trial. In 2019, this study found that “melatonin administration for 12 weeks had beneficial effects on mental health parameters, insulin levels, HOMA-IR, QUICKI, total- and LDL-cholesterol levels, and gene expression of PPAR-γ and LDLR.” 29 participants used 10 mg of Melatonin daily for twelve weeks.

- Melatonin ingestion after exhaustive late-evening exercise improves sleep quality and quantity, and short-term performances in teenage athletes. In 2018, this study found that “improved sleep quality and quantity, selective attention, subjective assessment of the general wellness state, and some short-term

physical performances the following morning in healthy teenagers." 10 participants used 10 mg Melatonin twice.

- The effect of long-term melatonin supplementation on psychosomatic disorders in postmenopausal women. In 2018, this study found that "melatonin supplementation therapy exerts a positive effect on psychosomatic symptoms". 60 participants used 8 mg of Melatonin daily for twelve months.

- Evaluation of sleep, puberty and mental health in children with long-term melatonin treatment for chronic idiopathic childhood sleep onset insomnia. In 2011, this study found that "Melatonin treatment in children can be sustained over a long period of time without substantial deviation of the development of children with respect to sleep quality, puberty development and mental health scores, as compared with the general Dutch population". 51 participants used approximately 2.69 mg of Melatonin daily for approximately 3.1 years.

- The effect of prolonged-release melatonin on sleep measures and psychomotor performance in elderly patients with insomnia. In 2009, this study found that "nightly treatment with [Melatonin] effectively induced sleep and improved perceived quality of sleep in patients with primary insomnia aged > or =55 years", "daytime psychomotor performance was not impaired and was consistently better with [Melatonin] compared with placebo", and Melatonin "was well tolerated with no evidence of rebound effects".

- Long-term effectiveness outcome of melatonin therapy in children with treatment-resistant circadian rhythm sleep disorders. In 2007, this study found that "adverse reaction to melatonin therapy and development of tolerance were not evident [and] better sleep was associated with reported improvement in health, behavior and learning." 44 participants used Melatonin for up to 3.8 years.

- The effects of melatonin on tinnitus and sleep. In 2006, this study found that "the impact of melatonin on sleep was greatest among patients with the worst sleep quality".

- The use of melatonin in Alzheimer's disease. In 2002, this study found that "Melatonin treatment seems to constitute a selection therapy to ameliorate

sundowning and to slow evolution of cognitive impairment". 24 participants used 3 mg or 9 mg of Melatonin daily for 22 to 35 months.

- Melatonin for the prevention and treatment of jet lag. In 2002, this study found that "Melatonin is remarkably effective in preventing or reducing jet-lag, and occasional short-term use appears to be safe".

Melatonin supplements may enhance next-day focus, according to these clinical studies on humans:

- Controlled Release Melatonin in the Treatment of Insomnia in Older Patients: Efficacy and Safety in Patients With History of Use and Non-Use of Hypnotic Drugs. In 2009, this study found that Melatonin provides "shortening of sleep Latency." It also found "improvements in sleep quality and next day alertness and subsequently, quality of life."

- Prolonged-release melatonin improves sleep quality and morning alertness in insomnia patients aged 55 years and older and has no withdrawal effects. In 2007, this study found that Melatonin improves "quality of sleep and morning alertness in primary insomnia patients aged 55 years and older -- suggesting more restorative sleep, and without withdrawal symptoms upon discontinuation".

- Efficacy of Prolonged Release Melatonin in Insomnia Patients Aged 55-80 Years: Quality of Sleep and Next-Day Alertness Outcomes. In 2007, this study found that Melatonin "results in significant and clinically meaningful improvements in sleep quality." It also improves "morning alertness, sleep onset latency and quality of life."

Long term daily supplementation with Melatonin generally is not associated with adverse effects, according to these clinical studies on humans:

- Sleep, Growth, and Puberty After 2 Years of Prolonged-Release Melatonin in Children With Autism Spectrum Disorder. In 2020, this study found that Melatonin "is safe and effective for long-term treatment." Participants used between 2 mg and 10 mg Melatonin daily for up to two years.

- The effect of long-term melatonin supplementation on psychosomatic disorders in postmenopausal women. In 2018, this study found that “melatonin can be safely and permanently used ...” Participants used 8 mg Melatonin daily for one year.

- Evaluation of sleep, puberty and mental health in children with long-term melatonin treatment for chronic idiopathic childhood sleep onset insomnia. In 2011, this study found that “melatonin treatment in children can be sustained over a long period of time without substantial deviation of the development of children.” Participants used between 0.3 mg and 10 mg Melatonin daily for around three years.

- Long-term effectiveness outcome of melatonin therapy in children with treatment-resistant circadian rhythm sleep disorders. In 2007, this study found that “adverse reaction to melatonin therapy and development of tolerance were not evident.” Participants used Melatonin regularly for up to nearly four years.

- The use of melatonin in Alzheimer's disease. In 2002, this study found that “Melatonin improved sleep and suppressed sundowning.” Participants used between 3 mg and 9 mg Melatonin daily for up to three years.