

Natural support for quality sleep*

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Insomnitol™ is a blend of botanicals, nutrients, and neurotransmitter precursors designed to support quality, restful sleep.* By providing nutritional support for calm brain activity through promoting GABAergic and serotonergic activities, Insomnitol™ helps promote the body's natural ability to fall asleep and stay asleep.*

The key ingredients in this comprehensive formula include botanicals that support nervous system function, PharmaGABA® (a proprietary form of GABA), L-theanine, melatonin, 5-HTP, and the activated form of vitamin B6, pyridoxal-5-phosphate (P-5-P). By combining the various interventions typically used in natural promotion of quality sleep in one product, Insomnitol™ is a convenient option that may help improve patient compliance and clinical outcome.* A pilot study of participants who supplemented with a combination of melatonin, vitamin B6 and calming botanical extracts including lemon balm and passionflower for two weeks demonstrated significant improvements in sleep quality, sleep onset latency, total sleep duration, and sleep-related daytime parameters.¹

Proprietary Herbal Blend

Insomnitol™ contains 400 mg valerian root (*Valeriana officinalis*) standardized to contain 0.8% valerenic acid, 200 mg passion flower (*Passiflora incarnata*) standardized to contain 3.5% flavonoids, 200 mg of lemon balm (*Melissa officinalis*) standardized to have 3% rosmarinic acid, and 200 mg chamomile (*Matricaria chamomilla*). All of these are considered safe nervine botanicals known for their relaxant properties and ability to help reduce tension and promote quality sleep, without causing morning drowsiness.⁴

Valerian root has demonstrated sedative effects due to the synergistic effects of its chemical composition, including the upregulation of gamma-aminobutyric acid (GABA), as well as the activities of the volatile oil valerenic acid.⁵ Valerian root has been shown to be a safe sedative choice in subjects with mild to moderate insomnia, having improved subjective sleep experience when taken over the course of one to two weeks without causing sleepiness upon waking (a side-effect of many common anti-anxiety medications).^{5,6}

It has been suggested that the bioactive constituents in valerian root, passion flower, and chamomile bind to central benzodiazepine receptors, possibly causing anxiolytic effects (reducing anxiety symptoms) without impairing memory, diminishing motor skills, or causing drowsiness upon waking.^{4,7,8} Lemon balm has been suggested to improve calmness via the inhibitory action of GABA, similar to benzodiazepine, but without the overt side effects of these medications.

Gamma-Aminobutyric Acid (as PharmaGABA®)

Direct stimulation of GABA, the naturally-occurring amino acid and the main inhibitory neurotransmitter in the central nervous system, is provided with PharmaGABA®, a proprietary form of GABA naturally manufactured via a fermentation process and considered more effective than other traditional, chemically produced synthetic forms. Being an inhibitory neurotransmitter, GABA blocks nerve impulses, slowing down the activity of nerve cells and preventing them from over-firing. Frequent over-firing of brain cells can lead to cell death, meaning that stress can actually kill brain cells. Keeping GABA levels optimal can help prevent this from occurring. Thus, GABA serves as a critical calming agent for the body, helping to combat stress and anxiety.*

Certain GABA receptors are highly expressed in the thalamus, the part of the brain that is distinctively important in the control of sleep and wakefulness. GABAergic inhibition in the thalamus is known to play a principal role in the generation of sleep brain waves. Thus, PharmaGABA® is suitable to take before bedtime to help promote a good night's sleep and may be ideal for stress-induced insomnia.*

L-Theanine

L-Theanine is an amino acid that has been shown to help promote calmness and improve the quality of sleep.* It has been demonstrated in human studies to significantly reduce cortisol response and subjective stress response to cognitive stressors, and to suppress the stimulatory effect of caffeine.^{9,10} Theanine crosses the blood-brain barrier and is known to block the binding of glutamic acid to glutamate receptors in the brain "and has been considered to cause anti-stress effects by inhibiting cortical neuron excitation."¹¹ Studies in healthy adults show that L-theanine reduces anxiety and attenuates blood pressure increases under conditions of physical or psychological stress, and animal studies suggest that L-theanine increases brain levels of serotonin, dopamine, and GABA.^{11,12} Human EEG studies show "L-theanine significantly increases activity in the alpha frequency band which indicates that it relaxes the mind without inducing drowsiness,"¹³ making it a valuable tool for relieving feelings of anxiety or stress while not negatively impacting alertness and focus. More research is needed, but mechanistic explanations support a potential therapeutic role for L-theanine in anxiety and panic disorders, obsessive-compulsive disorder (OCD), schizophrenia, ADHD and more.¹⁴

Insomnitol™ Benefits:*

- Serves as a natural sleep aid and general relaxant without disrupting the body's circadian rhythm
- Provides a natural sedative effect without causing drowsiness upon waking
- Reduces generalized anxiety symptoms
- Improves pain tolerance in chronic pain syndromes, increasing the ability to sleep throughout the night^{2,3}

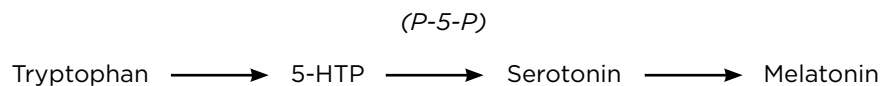
Melatonin

Melatonin is a multifunctional hormone secreted by the pineal gland whose main role is to help regulate sleep by controlling the body's day and night biological rhythms, known as the 'circadian rhythm' or 24-hour biological clock. Melatonin mediates the body's response to variations of natural light availability from indoor/outdoor exposure or due to seasons (winter/summer). Darkness into the eye tells the brain to make melatonin so the body can prepare for sleep mode. A meta-analysis showed that melatonin supplementation significantly reduced sleep latency, increased total sleep time, and increased total sleep quality compared to placebo.¹⁵

Various dietary and lifestyle factors may reduce the production of melatonin such as poor sleep hygiene, inadequate darkness throughout the night, insufficient exposure to natural light during daytime, excessive stress, and high caffeine or alcohol consumption too close to bedtime. Additionally, inadequate brain availability of precursors or cofactors necessary for melatonin synthesis (vitamin B6, SAMe, folate, and iron), and the use of certain medications such as benzodiazepines, beta-blockers, aspirin, and loop diuretics contribute greatly to low melatonin production. By age 60, the body's production may fall to close to 50% of youthful levels.¹⁶ Due to its effects on sleep and many other metabolic functions, it is hypothesized that restoring melatonin to youthful levels may have a multitude of benefits. A systematic review and meta-analysis of clinical trials exhibited melatonin supplementation to significantly reduce pro-inflammatory mediators, TNF-alpha and IL-6, suggesting that melatonin may attenuate sleep disorders associated with chronic inflammation.¹⁷

5-HTP & Pyridoxal-5-Phosphate (P-5-P)

5-HTP can be used in conjunction with melatonin, as a precursor to serotonin, which can support further endogenous melatonin production during the night to help with staying asleep.¹⁸ Serotonin is a very important calming neurotransmitter known as "the feel-good hormone." In the central nervous system, serotonin has been implicated in the regulation of sleep, depression, anxiety, aggression, appetite, temperature, sexual behavior, and pain sensation.¹⁸ When using 5-HTP for enhancing serotonin and melatonin production to promote calmness, healthy mood and sleep, the addition of P-5-P is needed to catalyze the conversion of 5-HTP to serotonin (5-HT).



Supplement Facts

Serving Size 2 capsules
Servings Per Container 30

Amount Per Serving		% Daily Value
Vitamin B-6 (as Pyridoxal-5-Phosphate)	10 mg	588%
Valerian (<i>Valeriana officinalis</i>)(root) [standardized to contain 0.8% valerenic acid]	400 mg	*
Passion Flower (<i>Passiflora incarnata</i>) (flower) [standardized to contain 3.5% flavonoids]	200 mg	*
Lemon Balm (<i>Melissa officinalis</i>)(leaves) [standardized to contain 3% rosmarinic acid]	200 mg	*
Chamomile (<i>Matricaria chamomilla</i>)(flower)	200 mg	*
gamma-Aminobutyric acid (as PharmaGABA®)	100 mg	*
L-Theanine	100 mg	*
5-HTP (5-Hydroxytryptophan)	100 mg	*
Melatonin	3 mg	*

*Daily Value not established.

Other Ingredients: Cellulose (capsule), vegetable stearate, silicon dioxide.

Recommended Use:

- Take two capsules per day 30-60 minutes before bedtime, or as directed by your health care practitioner.
- Due to the inclusion of GABA, this product is not recommended for pregnant or lactating women, as well as young children, unless under the guidance of a health care practitioner.

Contraindications for Melatonin Use:

- Autoimmune conditions such as lupus or arthritis, because the immune stimulatory effect of melatonin may exacerbate the action of certain types of lymphocytes or B-cells involved in the pathogenic course of these diseases
- Immune-related cancers such as lymphoma and leukemia
- Pregnancy, lactation or during the time where fertility is desired
- Interactions with drug therapy: melatonin may not be suitable to administer along with MAO inhibitors and corticosteroid therapy

For a list of references cited in this document, please visit:

<https://www.designsforhealth.com/api/library-assets/literature-reference---insomnitol-capsules-tech-sheet-references>

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Dosing recommendations are given for typical use based on an average 150 pound healthy adult. Health care practitioners are encouraged to use clinical judgement with case-specific dosing based on intended goals, subject body weight, medical history, and concomitant medication and supplement usage. Any product containing botanical substances has the potential for causing individual sensitivities, appropriate monitoring, including liver function tests (LFT) is recommended.

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

To contact Designs for Health, please call us at (860) 623-6314, or visit us on the web at www.designsforhealth.com.