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## INSOMNITOL™

NATURAL SUPPORT FOR QUALITY SLEEP  
60 VEGETARIAN CAPSULES | NPN80051334 | INSM60-CN

**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.<sup>1</sup>

### 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
- Helps re-set the body's sleep-wake cycle
- Helps reduce the time it takes to fall asleep

### 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 nervine botanicals known for their relaxant properties and ability to help reduce tension and promote quality sleep, without causing morning drowsiness.<sup>4</sup>

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.<sup>5</sup> Valerian root has been shown to be an appropriate 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.<sup>5,6</sup>

### GAMMA-AMINO BUTYRIC 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, promoting a normal response to stress.

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.

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## 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.<sup>9,10</sup> 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.”<sup>11</sup> 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.<sup>11,12</sup> Human EEG studies show “L-theanine significantly increases activity in the alpha frequency band which indicates that it relaxes the mind without inducing drowsiness,”<sup>13</sup> making it a valuable tool for relieving feelings of stress while not negatively impacting alertness and focus.

## 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.<sup>15</sup>

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.<sup>16</sup> 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.<sup>17</sup>

## 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.<sup>18</sup> 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.<sup>18</sup> 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).



### Medicinal Ingredients (per capsule):

Valerian ( <i>Valeriana officinalis</i> ) (8% Valerenic Acid 8:1).....	200 mg
Chamomile ( <i>Matricaria chamomilla</i> -Flower) (1.2% Apigenin 6:1).....	100 mg
Lemon balm ( <i>Melissa officinalis</i> -Herb Top) (3% Rosemarinic Acid 5:1).....	100 mg
Passion Flower ( <i>Passiflora incarnata</i> -Herb top) (3.5% Bioflavonoids 6:1).....	100 mg
GABA (Gamma-Aminobutyric Acid).....	50 mg
L-5-HTP ( <i>Griffonia simplicifolia</i> -Seed).....	50 mg
L-Theanine.....	50 mg
Vitamin B6 (Pyridoxal 5-phosphate).....	5 mg
Melatonin (N-Acetyl-5-methoxytryptamine).....	1.5 mg

### Non-Medicinal Ingredients: Hypromellose, magnesium stearate (vegetable source), silicon dioxide. **Recommended Dose:**

Adults: Take 2 capsules per day 30-45 minutes before bedtime, or as directed by your health care practitioner. Do not drive or use machinery for 5 hours after taking melatonin. For use beyond 4 weeks, consult a health care practitioner. 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.

### CONTRAINDICATIONS FOR MELATONIN USE:

- 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.
- 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
- See label for full risk information

### REFERENCES

For a list of references cited in this document, please visit: <https://www.designsforhealth.com/techsheet-references/Insomnitrol-Capsules-References.pdf>



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## INSOMNITOL™

NATURAL PROMOTION OF QUALITY SLEEP  
60 VEGETARIAN CAPSULES | NPN80051334 | INSM60-CN

Our bodies require a good night's sleep for optimal performance during the day. We all go to bed with the hope of sleeping well, but on occasion our minds will not settle or we wake up throughout the night, and thus do not get the sleep we need.

**Insomnitol™** is a formulary blend of botanicals and nutrients designed to support quality sleep and promote calm brain activity. It is ideal for those who occasionally have difficulty getting to sleep, or staying asleep through the night.

### INSOMNITOL™ CONTAINS:

- A unique herbal blend of valerian root, passion flower, lemon balm, and chamomile to provide relaxation without impairing memory or causing drowsiness upon awakening
- L-theanine, an amino acid that can help promote calmness and improve the quality of sleep
- Gamma aminobutyric acid (GABA), the main calming agent in the body. It assists with the ability to get to sleep and stay asleep. This formula provides a novel, proprietary form of GABA that is naturally manufactured via a fermentation process and considered more effective than other traditional, chemically-produced synthetic forms.
- Melatonin, a multifunctional hormone whose main role is to help regulate sleep by controlling our day and night biological rhythms, known as the 'circadian rhythm' or our 24-hour biological clock
- 5-HTP supports further melatonin production during the night to help with staying asleep. 5-HTP is a precursor to serotonin — the body's mood and sleep regulator.
- Vitamin B6, an essential nutrient for the conversion of 5-HTP and melatonin to serotonin

### BENEFITS OF A GOOD NIGHT'S SLEEP:

- Supports a healthy immune system
- Supports proper cardiovascular function
- Supports clear mind and focus for better memory and learning
- Promotes proper growth hormones
- Promotes healthy metabolism
- Encourages proper reflexes, reactions and judgments

**Recommended Dose:** Adults: Take 2 capsules per day 30-45 minutes before bedtime, or as directed by your health care practitioner. **Note:** If using a prescription drug, consult your health care practitioner prior to using this product. Do not take this product if you are pregnant, lactating or planning to become pregnant, suffer from an autoimmune disease, depression, diabetes, or any endocrine disorders. Do not use this product while operating a motorized vehicle or heavy machinery.

Consult with your healthcare practitioner about your specific circumstances and any questions you may have.

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