A good night’s sleep is important for optimal health, daytime functioning, and brain chemistry. Insomnia or sleeplessness is when a person is having difficulty falling asleep or staying asleep throughout the night. Sleeping problems can be linked to pain and often thought of as a sign and/or symptom of physical, emotional, and/or mental health. Somnicin was designed by pharmacists and health professionals in order to help promote effective sleep by using a combination of natural ingredients. In addition to aiding sleep, it may aid in reducing anxiety and/or depression.

**Dietary Supplement:**
- Melatonin 2 mg
- 5-HTP (5-hydroxytryptophan) 50 mg
- L-tryptophan 100 mg
- Vitamin B6 (pyridoxine) 10 mg
- Magnesium 50 mg

**Suggested Use:** Take one capsule 30 to 90 minutes before bedtime or as directed by your physician. May increase to 2 capsules if tolerating and need additional benefit.

**Mechanism of Action:**

**Melatonin,** also chemically known as N-acetyl-5-methoxytryptamine, is a natural compound found in animals and plants. Melatonin is also a hormone produced by the pineal gland of humans. The changes in circulating levels of melatonin correlate with our circadian rhythm. While most studies find efficacy in patients with jet lag and those who are on their night shifts, it can also benefit in helping reduce sleep onset latency (time it takes to fall asleep).

**5-HTP (5-hydroxytryptophan)** is a naturally occurring amino acid precursor and intermediate in the biosynthesis of other important neurotransmitters as shown below. More specifically, with increased 5-HTP comes increased serotonin levels. Besides helping with insomnia, studies have shown that 5-HTP is also beneficial in the following conditions: primary fibromyalgia syndrome, depression, and anxiety.

**L-tryptophan** is one of the 20 standard amino acids in the human body. It plays a key part in the synthesis of many neurotransmitters and is a key component in many bodily functions. While studies have shown it to be useful as a sleep aid, it does not cross the blood brain barrier as well as 5-HTP.

**Vitamin B6 (pyridoxine)** plays an important role in the metabolism of these previously mentioned ingredients as well as many other functions. It plays a crucial role in the production of serotonin via activating aromatic-L-amino-acid decarboxylase and has been found to be effective in the treatment of nocturnal leg cramps. It also is essential for red blood cell formation, which can increase the oxygen in the blood and therefore, aid in a more healthy and restful sleep.

**Magnesium** helps relax smooth muscles (vasodilation) to increase blood flow while asleep and promotes relaxation.

**Benefits:** This is a non-habit forming sleep aid that promotes and supports a calm and relaxed mood. Unlike conventional medications like nonbenzodiazepine hypnotics (i.e Ambien, Lunesta) or benzodiazepine hypnotics (i.e flurazepam, temazepam), Somnicin does not have addictive or habit forming properties. Therapeutic administration of 5-HTP has been shown to be effective in a wide variety of conditions, including depression, fibromyalgia, insomnia, and chronic headaches. Oral 5-HTP is absorbed well; roughly 70% of it ends up in the bloodstream. One important benefit of this medication involves the metabolism of these ingredients in the body. Some patients have reduced enzyme activity that is responsible
for converting L-tryptophan to 5-HTP (tryptophan hydroxylase). Therefore, this formulation bypasses this rate-limiting step by including 5-HTP along with the other ingredients. There is evidence that illnesses, old age, and stressful life conditions can decrease the levels of melatonin in the brain. Consuming a safe and trusted melatonin sleep aid like Somnicin can be helpful in restoring and reinforcing the body's capacity of producing melatonin itself. Vitamin B6 aids this process and magnesium relaxes smooth muscles in the blood vessels allowing adequate blood flow to the brain and body. See below for information on interactions because this product also can theoretically help some patients reduce dosing of concurrent SSRI or SNRI use.

**Adverse Reactions:** Nausea is the most common side effect. Somnicin may be taken with a snack or small meal if nausea occurs. Other effects such as headache, abdominal cramps, fatigue, or dizziness may occur. If any of these effects persists or worsens, contact your physician or pharmacist immediately. If any serious side effects such as nausea, vomiting, diarrhea, fever, or severe stomach aches persist; discontinue use immediately and contact your pharmacist or physician. This is not a complete list of all side effects that may occur. You may report side effects to the FDA at 800-FDA-1088 or at http://www.fda.gov/medwatch.

**Interactions:** Avoid taking MAO inhibitors (isocarboxazid, linezolid, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranylcypromine) during treatment and for two weeks before and after treatment with this medication. In some cases a serious (possibly fatal) drug interaction may occur.

Before using Somnicin, report the use of other drugs that increase serotonin, such as dextromethorphan, lithium, St. John's wort, sibutramine, tramadol, tryptophan, certain antidepressants including SSRIs (such as sertraline, citalopram, paroxetine) and SNRIs (such as duloxetine, venlafaxine), “triptans” used to treat migraine headaches (such as eletriptan, sumatriptan), among others. The risk of serotonin syndrome may be more likely when you start or increase the dose of these medications. However, patients not on maximum SSRI dosing (i.e. citalopram 20 mg, fluoxetine 20 mg) or patients that have been on therapy for more than 2-3 months may start this medication as long as they are counseled on such risks. As with any other minor/moderate interaction, these are considered for use with caution, and not an absolute contraindication. Also, the individual ingredient dosing in this product is lower than any of these ingredients sold independently on the market (upper limits sold independently are Melatonin 10mg, 5-HTP 300mg, L-tyrptophan 1200mg. Regardless, symptoms such as tremor, fever, nausea, vomiting, diarrhea, increased blood pressure, and/or mental status changes should be reported to a physician immediately.

Tell your doctor or pharmacist if you are taking other products that cause drowsiness including alcohol, antihistamines (such as cetirizine, diphenhydramine), drugs for sleep or anxiety (such as alprazolam, diazepam, zolpidem), muscle relaxants, and narcotic pain relievers (such as codeine). Ask your pharmacist about using those products safely. This is not a complete list.

**Precautions:**
- Not intended for use by pregnant or nursing women
- Consult your physician if you are taking any other medications, such as MAO-inhibitors or SSRIs, or if any serious adverse reactions occur
- Patients with hypersensitivity to any of the active ingredients listed above should not use this product before checking with your physician or pharmacist.
- Do not drive, operate machinery, or consume alcohol when taking this product
- Not intended for use in persons under the age of 18
- Do not use if imprinted neck seal is broken or missing
- Store at room temperature in a dry and cool place
- Do not expose to excessive heat
- **Keep out of reach of children**

**In Case of Ingestion or Overdose,** get medical help or contact a Poison Control Center (800-222-1222) right away.

**Inactive Ingredients:** Hydroxypropylmethylcellulose (HPMC or plant-derived cellulose) and Magnesium Stearate.