



Clinical Applications

- Support Synchronization of the Body's Daily Biorhythms*
- Support Restful Sleep*
- Direct and Indirect Antioxidant Support*
- Support Healthy Immune Response*
- Support Brain Health*

*Pure Sleep is a vegetarian formula with a biphasic delivery system that releases melatonin quickly and then steadily. Melatonin is naturally produced in the pineal gland in response to changes in light exposure; it helps promote healthy sleep patterns as well as antioxidant and immune activities. Pure Sleep can support these functions by helping to maintain normal levels of melatonin in the body.**

All New Foundation Medicine Formulas Meet or Exceed cGMP Quality Standards

Discussion

Melatonin is a neurohormone produced from tryptophan by the pineal gland when it is stimulated by darkness. While melatonin regulates many other hormones; its primary function appears to be regulation of the body's daily and annual biological rhythms.*

Oral supplementation has been shown to have some benefit with regard to time to sleep onset, total sleep time, and sleep efficiency.^[1] Noteworthy advantages over pharmaceutical sleep aids are improved performance upon waking and the absence of memory impairment.^[2,3] According to studies, daytime melatonin supplementation by travelers crossing time zones and/or shift workers also promotes sleep.*^[4]

Research has shown that melatonin not only fights free radicals during sleep, but also stimulates the body's own antioxidant systems. For example, it reduced harmful oxidized cholesterol (LDL) in post-menopausal women.^[5] Melatonin's antioxidant capacity also accounts for its role as a neuroprotectant. By delivering antioxidant benefits and correcting the circadian rhythm, melatonin could support cognitive function.*^[6,7]

A decrease in plasma melatonin correlates with a decline in immune function in some individuals beginning around the age of sixty. Interestingly, lymphoid cells are an important physiological source of melatonin in humans. The hormone appears to stimulate production of T helper (TH) cells and their release of interleukin-2, gamma interferon and opioid peptides.^[8] Considering the decline in melatonin synthesis with age, exogenous supplementation with the hormone has long been of interest in anti-aging protocols.*^[9,10]

The addition of pyridoxine in this formula supports the biosynthesis of melatonin and may also enhance dream recall.*

The biphasic delivery system consists of 1mg of melatonin in the coating solution and the remainder in the tablet core. The melatonin in the coating solution is immediately released upon digestion. The melatonin in the tablet core is released over a 6-hour period. The tablet core contains a tableting agent, hydroxypropyl methylcellulose that works by forming a gel layer when hydrated. This gel layer acts as a diffusion barrier to control the rate of release of the melatonin in the tablet core. As the tablet travels through the intestine, the gel layer slowly erodes to release the melatonin, which then is available for absorption in the intestine.*

***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.**



Supplement Facts

Serving Size: 1 Tablet
Servings Per Container: 90

| | Amount Per Serving | %DV |
|--------------------------------|--------------------|------|
| Vitamin B6 (as pyridoxine HCl) | 10 mg | 500% |
| Melatonin | 5 mg | ** |

** Daily Value (DV) not established.

Other Ingredients: Cellulose, dibasic calcium phosphate, hypromellose, magnesium stearate, stearic acid, silica, methylcellulose, and glycerin.

Directions

Take one tablet with water 20 minutes before bedtime, or as directed by your healthcare practitioner.

References

1. Brzezinski A, Vangel MG, Wurtman RJ, et al. Effects of exogenous melatonin on sleep: a meta-analysis. *Sleep Med Rev.*2005;9:41-50. [PMID: 15649737]
2. Paul MA, et al. Melatonin and zopiclone as pharmacologic aids to facilitate crew rest. *Aviat Space Environ Med.* 2001 Nov;72(11):974-84. [PMID: 11718517]
3. Wesensten NJ, Balkin TJ, Reichardt RM et al. Daytime sleep and performance following a zolpidem and melatonin cocktail. *Sleep.* 2005;28:93-103. [PMID: 15700725]
4. Srinivasan V, et al. Jet lag: therapeutic use of melatonin and possible application of melatonin analogs. *Travel Med Infect Dis.* 2008 Jan-Mar;6(1-2):17-28.[PMID: 18342269]
5. Wakatsuki A, et al. Melatonin inhibits oxidative modification of low-density lipoprotein particles in normolipidemic post-menopausal women. *J Pineal Res.* 2000;28:136-142 [PMID: 10739299]
6. Peck JS, et al. Cognitive effects of exogenous melatonin administration in elderly persons: a pilot study. *Am J Geriatr Psychiatry.* 2004;12:432-436. [PMID: 15249281]
7. Asayama K, Yamadera H, Ito T, et al. Double blind study of melatonin effects on the sleep-wake rhythm, cognitive and noncognitive functions in Alzheimer type dementia. *J Nippon Med Sch.* 2003;70:334-341. [PMID: 12928714]
8. Cardinali DP, et.al. Melatonin and the immune system in aging. *Neuroimmunomodulation.* 2008;15(4-6):272-8. [PMID: 19047804]
9. Armstrong SM, Redman JR. Melatonin: A chronobiotic with anti-aging properties? *Med Hypotheses* 1991;34: 300-9 [PMID: 1865836]
10. Rozencwaig R, Grad BR, Ochoa J. The role of melatonin and serotonin in aging. *Med Hypotheses* 1987;23: 337-52 [PMID: 2889131]
11. Miyamoto A, et.al. Serum melatonin kinetics and long-term melatonin treatment for sleep disorders in Rett syndrome. *Brain Dev.* 1999 Jan;21(1):59-62 [PMID: 10082254]
12. Arendt J. Safety of melatonin in long-term use. *J Biol Rhythms* 1997;12:673-681 [PMID: 9406044]
13. Voordouw BC, et.al. Melatonin and melatonin-progestin combinations alter pituitary-ovarian function in women and can inhibit ovulation. *J Clin Endocrinol Metab.* 1992 Jan;74(1):108-17. [PMID: 1727807]
14. Abd-Allah AR, et al. Effect of melatonin on estrogen and progesterone receptors in relation to uterine contraction in rats. *Pharmacol Res.* 2003 Apr;47(4):349-54 [PMID: 12644393]

Does Not Contain

Wheat, gluten, corn, yeast, soy, animal or dairy products, fish, shellfish, peanuts, tree nuts, egg, artificial colors, artificial sweeteners, or preservatives.

Cautions

If you are under medical supervision or using any tranquilizers or sedatives, seek the advice of your healthcare practitioner prior to using. Consult your healthcare practitioner before using if you have an autoimmune condition or depressive disorder or are a pregnant or lactating woman. Not for use by children under 12 years of age. Do not take when operating machinery or driving a vehicle.

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