



**Code:** 9286 **NPN:** 80036635  
**Size:** 180 sublingual tablets  
**Actual Size:** 8.01 mm diameter



# Melatonin

## Fall Asleep and Stay Asleep • 10 mg

- Sublingual tablets provide fast and superior melatonin absorption, bypassing liver and gastrointestinal metabolism - pharmacokinetic studies indicate that 30 to 60% of an oral dose of melatonin is metabolized via the liver<sup>1</sup> and overall gastrointestinal absorption is variable<sup>2,3</sup>
- A singular high-potency sublingual tablet is optimal for those who need higher doses of melatonin (10–20 mg)
- Derived from non-animal sources
- Refreshing, natural peppermint flavour
- Non-habit forming

### PRODUCT SUMMARY

Sleep is a vital part of health and many of us are not getting enough. The 2002 Canadian Community Health Survey found about 1 in 7 adults has difficulty falling asleep or staying asleep. Insomnia affects 1 in 3 seniors and is 40% more common in women. Changes in sleeping patterns are largely reflective of our circadian rhythms, which are guided by the pineal hormone, melatonin. Melatonin is known to decline as we age, which accounts for a number of the sleep changes we see throughout life. Additionally, jet lag and shift work can significantly alter circadian rhythms and thus melatonin secretion.<sup>4-6</sup>

Melatonin has shown clinical benefit for inducing sleep or adjusting sleep cycles,<sup>7</sup> reducing sleep onset latency and improving perceived quality of sleep, without impairing daytime psychomotor performance.<sup>8,9</sup> In fact, supplemental melatonin and bright light therapy are considered standard medical treatment for cases of jet lag, shift work, age-related insomnia, delayed sleep-phase disorder, advanced sleep-phase disorder, and non-24-hour sleep-wake disorder.<sup>10</sup> Chronic sleep disturbance is a risk factor for premature aging, diabetes, obesity, cardiovascular disease and certain cancers,<sup>11</sup> demonstrating just how important it is to maintain normal melatonin levels to enhance sleep quality.



## MELATONIN

FALL ASLEEP AND STAY ASLEEP · 10 MG

**Serving Size:** 1 sublingual tablet

**Servings per Container:** 180

**Each Sublingual Tablet Contains:**

Melatonin (vegetarian source)..... 10 mg

**Non-medicinal Ingredients:** Lactose monohydrate, microcrystalline cellulose, natural peppermint flavour, croscarmellose sodium, vegetable grade magnesium stearate (lubricant).

**Recommended Adult Dose:** Do not drive or use machinery for 5 hours after taking melatonin. Dissolve 1 tablet under the tongue at bedtime once per day or as directed by a health care practitioner. Consult a health care practitioner for use beyond 4 weeks.

**Recommended Use:** Helps increase the total sleep time (aspect of sleep quality) in people suffering from occasional sleep restriction or altered sleep schedule (e.g., shift-work and jet lag). Supports alertness during waking hours and helps reduce the time it takes to fall asleep. Supports the body's sleep-wake cycle.

**Contraindications:** Do not use if you are taking immunosuppressive drugs and/or if you are pregnant or breastfeeding. Do not drive or use machinery for 5 hours after taking melatonin.

**Caution:** Consumption with alcohol, other medications or natural health products with sedative properties is not recommended. Consult a health care practitioner prior to use if you have one of the following conditions: asthma, cardiovascular disease, chronic kidney disease, depression, diabetes or hypoglycaemia, hormonal disorder, immune system disease, liver disease, migraine, or seizure disorders, or if you are taking one of the following medications: anticoagulant, anticonvulsant, blood pressure medications, immunosuppressive medications, sedative, hypnotic or psychotropic medications, or steroids. Do not use if you are pregnant or breastfeeding. Mild gastrointestinal symptoms (nausea, vomiting, or cramping) and rare allergic reactions have been known to occur, in which case discontinue use. If symptoms persist continuously for more than 4 weeks (chronic insomnia), consult your health care practitioner. Keep out of reach of children.

**Drug Interactions:** Melatonin may impair glucose utilization and increase insulin resistance in diabetic patients. However, the clinical significance of this effect on diabetics is unknown.<sup>12</sup> Contraceptive drugs can increase endogenous melatonin levels. Theoretically, this may increase the effects and adverse effects of oral melatonin use.<sup>13</sup> Fluvoxamine significantly inhibits the elimination of melatonin,<sup>14</sup> which some researchers believe could be helpful in the treatment of refractive insomnia.<sup>15</sup> However, this interaction may also cause excessive unwanted drowsiness and other adverse effects. Melatonin production and release may be inhibited by beta-blockers<sup>16</sup> and non-steroidal anti-inflammatory drugs<sup>17</sup>.

**Contains no artificial colours, preservatives, or sweeteners; no starch, sugar, wheat, gluten, yeast, soy, egg, fish, shellfish, salt, tree nuts, or GMOs. Suitable for vegetarians.** Sealed for your protection. Do not use if seal is broken. For freshness, store in a cool, dry place.

### References

1. Lane, E.A., & Moss, H.B. (1985). Pharmacokinetics of metabolism in man: first pass hepatic metabolism. *J Clin Endocrinol Metab.* 61, 1214-1216.
2. Kovacs, J., Brodner, W., Kirchlechner, V. et al. (2000). Measurement of urinary melatonin: a useful tool for monitoring serum melatonin after its oral administration. *J Clin Endocrinology Metabolism*, 85(2), 666-670.
3. Waldhauser, F., Waldhauser, M., Lieberman, H.R., et al. (1984). Bioavailability of oral melatonin in humans. *Neuroendocrinology*. 1984; 39(4), 307-13.
4. Karasek, M. & Winczyk, K. (2006). Melatonin in humans. *J Physiol Pharmacol.* 57 Suppl 5:19-39.
5. Zawilska, J.B., Skene, D.J., & Arendt, J. (2009). Physiology and pharmacology of melatonin in relation to biological rhythms. *Pharmacol Rep.* 61(3), 383-410.
6. Alternative Medicine Review. (2005). Melatonin Monograph. *Altern Med Rev.* 10(4), 326-336.
7. Kunz, D., Mahlberg, R., Muller, C., et al. (2004). Melatonin in patients with reduced REM sleep duration: two randomized controlled trials. *J Clin Endocrinol Metab.* 89(1), 128-34.
8. Wade, A.G., Ford, I., Crawford, G., et al. (2007). Efficacy of prolonged release melatonin in insomnia patients aged 55-80 years: quality of sleep and next day alertness outcomes. *Curr Med Res Opin.* 23(10), 2597-605.
9. Wade, A.G., Ford, I., Crawford, G., et al. (2010). Nightly treatment of primary insomnia with prolonged release melatonin for 6 months: a randomized placebo controlled trial on age and endogenous melatonin as predictors of efficacy and safety. *BMC Med.* 8, 51.
10. Bjorvatn, B., & Pallesen, S. (2009). A practical approach to circadian rhythm sleep disorders. *Sleep Med Rev.* 13(1), 47-60.
11. Litinski, M., Scheer, F.A., Shea, S.A. (2009). Influence of the circadian system on disease severity. *Sleep Med Clin.* 4(2), 143-163.
12. Cagnacci, A., Arangino, S., Renzi, A., et al. Influence of melatonin administration on glucose tolerance and insulin sensitivity of postmenopausal women. *Clin Endocrinol (Oxf).* 54(3), 339-46.
13. Wright Jr, K.P., Myers, B.L., Plenzler, S.C., et al. (2000). Acute effects of bright light and caffeine on nighttime melatonin and temperature levels in women taking and not taking oral contraceptives. *Brain Res.* 873(2), 310-7.
14. Hartter, S., Grozinger, M., Weigmann, H., et al. (2000). Increased bioavailability of oral melatonin after fluvoxamine coadministration. *Clin Pharmacol Ther.* 67(1), 1-6.
15. Grozinger, M., Hartter, S., Wang, X., et al. (2000). Fluvoxamine strongly inhibits melatonin metabolism in a patient with low-amplitude melatonin profile. *Arch Gen Psychiatry.* 57(8), 812-3.
16. Stoschitzky, K., Sakotnik, A., Lercher, P., et al. (1999). Influence of beta-blockers on melatonin release. *Eur J Clin Pharmacol.* 55, 111-5.
17. Murphy, P.J., Myers, B.L., Badia, P. (1996). Nonsteroidal anti-inflammatory drugs alter body temperature and suppress melatonin in humans. *Physiol Behav.* 59, 133-9.



· GUARANTEED ·

Bioclinic Naturals® products are guaranteed to meet or exceed Good Manufacturing Practices (GMP) of the U.S. Food and Drug Administration (FDA), Health Canada, and the Therapeutic Goods Administration (TGA) of Australia.



PRODUCT OF CANADA  
Bioclinic Naturals® Canada  
Burnaby, BC V3N 4T6  
bioclinicnaturals.com

FOR PROFESSIONAL USE ONLY. This product is not intended to diagnose, treat, cure or prevent any disease.

© All Rights Reserved Bioclinic Naturals® 2020. January 29, 2020. 50270

Bioclinic Naturals is distributed by Assured Natural Distribution Inc.

Head office Assured Natural Distribution Inc., 104 – 3686 Bonneville Place, Burnaby, BC, Canada V3N 4T6 | U.S. Distribution office 14224 167<sup>th</sup> Avenue SE, Monroe, WA, USA 98272

Customer Service 1-888-826-9625 · Fax 1-844-384-7503 · Email customercare@assurednatural.com