



LIFESTYLE  
SPECTRUM

## Clinical Applications

- Helps to maintain normal circadian rhythm – the natural daily cycle of hormone secretion
- Nutritionally augments the natural function of the pineal gland
- Helps to regulate sleep patterns
- Promotes restful sleep

Melatonin is a hormone produced by the pineal gland located in the brain. It plays a vitally important role in controlling the body's circadian rhythm and, thus, the wake/sleep cycle. Normal melatonin secretion is suppressed by light and stimulated by periods of darkness. Nocturnal secretion of melatonin is at its highest during childhood, and then decreases with age. Supplemental intake of melatonin has been shown to regulate circadian rhythm in individuals who have disrupted sleep patterns.<sup>[1,3]</sup> More recently, research has shown that melatonin also functions as an important antioxidant, and is involved in the body's immune response.<sup>[4,5]</sup>

Melatonin Meets or Exceeds cGMP quality Standards

## Discussion

**Effect on Sleep Patterns** Melatonin is best known for its ability to help regulate sleep patterns and promote a restful night's sleep. Research indicates that low levels of melatonin may be a frequent cause of insomnia in the elderly. A review of several studies suggests that melatonin supplementation can be helpful in inducing and maintaining sleep in patients suffering from insomnia, particularly when the pineal gland's own production is very low.<sup>[6]</sup> Additionally, individuals who have unusual work hours, such as night shift workers, or people experiencing jet lag, in particular those who regularly travel across time zones, may benefit from melatonin supplementation.<sup>[7,8]</sup> Melatonin may also be helpful in treating circadian rhythm sleep disorders in blind people lacking light perception.<sup>[9]</sup>

**Sleeplessness** Studies on the effects of melatonin in patients with insomnia have demonstrated improvements in overall sleep activity.<sup>[6]</sup> Reported improvements include the ability to fall asleep faster, fewer nighttime awakenings, and increases in sleep efficiency (percent of time asleep to total time in bed). In one study, sleep onset and sleep maintenance were improved in elderly people with insomnia following one week of supplementation. Patients given a sustained-released preparation experienced further improvements in sleep onset over a two-month period.<sup>[1]</sup> Melatonin has also been shown to benefit medically ill hospitalized patients with insomnia. Patients given melatonin fell asleep faster and slept longer than those given placebo.<sup>[2]</sup>

**Jet Lag**, is due to the desynchronization between various body rhythms and environmental rhythm as a result of traveling across time zones. Individuals with jet lag may experience disturbed sleep, increased irritability, as well as difficulties in falling to sleep and maintaining restful sleep. Melatonin supplementation may help to alleviate or prevent jet lag by helping to speed up the shifting of the body clock from the time zone to the next.

A review of 10 trials of which nine compared melatonin with placebo and one with the drug zolpidem, a hypnotic, found melatonin to be highly effective in preventing or reducing jet lag. Study subjects included airline passengers, airline staff, or military personnel.<sup>[7]</sup> Daily doses between 0.5mg to 5mg taken at bedtime were found to be similarly effective at preventing or reducing jet lag, however the effects were greater at the higher dose. According to this review doses higher than 5mg do not appear to demonstrate any increased benefit.

**Antioxidant Activity and Effect on the Immune System** In addition to its role in regulating the wake/sleep cycle, melatonin has been shown to possess antioxidant and anti-aging effects.<sup>[4,10,11]</sup> Through its free radical scavenging activity, melatonin helps to protect cells from molecular damage and dysfunction. Cellular damage caused by free radicals is believed to accelerate the aging process and to be the basis for many disease states. Melatonin supplementation has been reported to provide some benefit to individuals who have a high burden of oxidative stress by reducing the severity of illness.<sup>[11]</sup>

Finally, evidence suggests that melatonin may also have immunotherapeutic potential.<sup>[5]</sup> Activation of melatonin receptors has been shown to enhance cytokine release in human monocytes. This activity suggests that melatonin may help to support the body's natural resistance to pathogens.



# Supplement Facts

Serving Size: 1 Lozenge  
Servings Per Container: 60

|           | Amount Per Serving | %Daily Value |
|-----------|--------------------|--------------|
| Melatonin | 3 mg               | **           |

\*\* Daily Value not established.

**Other Ingredients:** Xylitol, stearic acid, mannitol, silica, vegetable magnesium stearate, natural peppermint flavor and Soolite™.

## Dosing

Take one to two lozenges 15 to 60 minutes before bedtime, or as directed by your healthcare practitioner.

## References

1. Haimov I, et al. Melatonin replacement therapy in elderly insomniacs. *Sleep* 1995;18:598-602
2. Andrade C, et al. Melatonin in medically ill patients with insomnia: a double blind, placebo-controlled study. *J Clin Psychiatry* 2001;62:41-45.
3. Kayumov L. et al. A randomized, double-blind placebo controlled crossover study of the effect of exogenous melatonin on delayed sleep phase syndrome. *Psychosom Med* 2001;63:40-48.
4. Olde Rikkert MG, Rigaud AS. Melatonin in elderly patients with insomnia. A systematic review. *Z Gerontol Geriatr* 2001 Dec;34(6): 491-7.
5. Herxheimer A. Petrie KJ. Melatonin for the prevention and treatment of jet lag. *Chocrane Database Syst Rev* 2002;(2):CD001520.
6. Herxheimer A. The prevention and treatment of jet lag. *BMJ* 2003;326:296-297.
7. Sack RI, Lewy AJ. Circadian Rhythm disorders: lessons from the blind. *Sleep Med Rev* 2001;5(3):189-206.
8. Reiter RJ, et al. A review of the evidence supporting melatonin's role as an antioxidant. *J Pineal Res* 1995;18:1-11
9. Maestroni GJ. The immuotherapeutic potential of melatonin. *Expert Opin Investg Drugs* 2001;939:190-199.
10. Oxenkrug G, et al. Antioxidant and anti-aging activity of Nacetylserotonin and melatonin in the vivo models. *Ann NY Acad Sci*;939:190-199.
11. Reiter RJ, et al. Melatonin: reducing molecular pathology and dysfunction due to free radicals and associated reactants. *Neuroendocrinol Lett* 2002 Apr;23 Suppl 1:3-8.

## Cautions

Consult your healthcare practitioner before use. Keep out of reach of children. If you have any autoimmune disease do not use melatonin.\*

Additional references available upon request

\*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.

