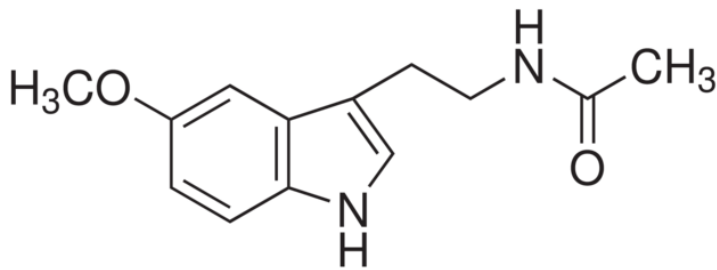


Extra Strength Melatonin

TECHNICAL SUMMARY

Melatonin is a potent free radical scavenger naturally produced in the pineal gland and the GI tract.* It is involved in many of the regulatory processes of the body, including regulation of glandular secretory functions related to the maintenance of normal sleep/wake cycles, maintenance of GI health, and aspects of immune system function.* Supplemental **m**Melatonin has been shown to support healthy sleep patterns especially when travelling across time zones or for shift workers.*

Structure Formula:



Chemical Name: N-Acetyl-5-methoxytryptamine

Allergen and Additive Disclosure: Not manufactured with wheat, gluten, soy, corn, milk, egg, fish, shellfish, or tree nut ingredients. Produced in a GMP facility that processes other ingredients containing these allergens.

Delivery Form: Veg Capsules

ROLE AS NUTRIENT/FUNCTION

Melatonin acts as a potent free radical scavenger of reactive oxygen species and a neuroprotectant.* It influences a variety of biological processes including circadian rhythms, neuroendocrine, immune and cardiovascular function.* Taken at bedtime, melatonin contributes to the ease of falling asleep and alleviates manifestations of poorly coupled circadian rhythms. * In addition to being produced by the pineal gland, melatonin has been shown to be generated locally by neuroendocrine cells in many tissues including in the GI tract.* In the gastric and intestinal mucosa, melatonin acts via specific membrane receptors and also as a free-radical scavenger.* It exerts protective, immune supporting, and free radical scavenging effect on the gastric lining, helps support healthy pH levels as well as normal pepsin and gastrin production.*

NATUROKINETICS®

Liberation. Disintegration of the vegetable capsule is measured in water using a USP testing method with disintegration between zero and 60 minutes.

Absorption. After ingestion of 10 mg melatonin, it is rapidly absorbed with peak plasma concentration reached in 41 minutes and a mean half-life of elimination of 54 minutes. The same study showed that the bioavailability of oral melatonin was around 3% with high inter-individual variability.

Distribution. Melatonin is subject to systemic distribution with levels detected in saliva. Melatonin is lipid-soluble and easily crosses blood-brain barrier.

Supplement Facts

Serving Size 1 Veg Capsule

Amount Per Serving

Melatonin	10 mg**
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** Daily Value not established.

Other ingredients: Microcrystalline Cellulose, Hypromellose (cellulose capsule) and Stearic Acid (vegetable source).

- **Healthy Sleep Cycle***
- **Supports Gastrointestinal Health***

SUGGESTED USAGE: Take 1 capsule prior to bedtime, or as directed by your healthcare practitioner.

Metabolism. Endogenous melatonin is metabolized in the liver into 6-sulfatoxymelatonin which then undergoes conjugation and excretion as a sulfate or glucuronide. In the pineal gland and retina, melatonin is metabolized via deacetylation to 5-methoxytryptamine.

Elimination. Melatonin and its metabolite 6-sulfatoxymelatonin are eliminated via urine. Melatonin is also found in bile.

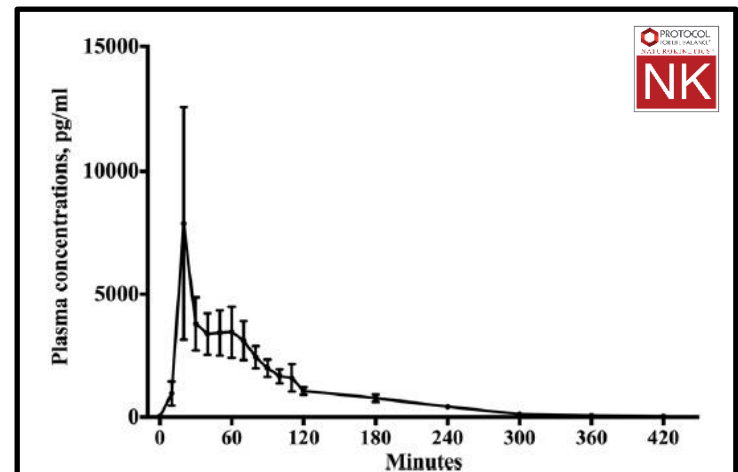


Figure 1: Pharmacokinetic profile of 10 mg of oral melatonin. Dots represent mean values, whiskers represent SEM. Adapted from Andersen et al., 2016.

CLINICAL VALIDATION

- **Free Radical Scavenger,**** In a controlled clinical trial with 29 volunteers, melatonin supplementation (10 mg at 6 PM, for 30 days) resulted in statistically significant support of the body's normal ability to withstand typical oxidative stress, as indicated by SOD (superoxide dismutase) measurements within red blood cells.*
- **Support of Healthy Sleep Cycle,*** In a double-blind, randomized, controlled trial using melatonin versus placebo on ten healthy individuals receiving a single dose of 10 mg melatonin after late-evening exercise, total sleep time ($\Delta = 24.55$ min; $p < 0.001$), sleep efficiency ($\Delta = 4.47\%$; $p < 0.001$), stage-3 sleep (N3 sleep) ($\Delta = 1.73\%$; $p < 0.05$) and rapid-eye-movement sleep ($\Delta = 2.15\%$; $p < 0.001$) were

*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.

significantly higher in the melatonin group.* Moreover, sleep-onset-latency ($\Delta = -8.45\text{min}$; $p < 0.001$), total time of nocturnal awakenings after sleep-onset (NA) ($\Delta = -11\text{ min}$; $p < 0.001$), stage-1 sleep (N1 sleep) ($\Delta = -1.7\%$; $p < 0.001$) and stage-2 sleep (N2 sleep) ($\Delta = -1.9\%$; $p < 0.05$) durations were also significantly lower with melatonin.*

- **Support gastrointestinal health*** In an 11-day controlled clinical trial with 30 healthy volunteers receiving 5 mg melatonin twice daily 30 minutes before taking a compound known to trigger gastric lesions and gastric-micro-bleeding, melatonin subjects presented with significantly fewer gastric lesions and less micro-bleeding than the group receiving the corrosive compound alone, suggesting that melatonin supplementation has a direct gastro-protective properties and/or triggers gastrin release by gastric mucosa.*

SAFETY INFORMATION

Tolerability: Oral melatonin is well tolerated. Doses of melatonin as high as 50 mg/kg of body weight have been used in humans without reported adverse effects.

Contraindications: Do not drive or use machinery for 4 to 5 hours after taking melatonin.

INTERACTIONS

Drug Interactions: Concomitant use of melatonin with alcohol, benzodiazepines, or other similar drugs might cause increased sedation. Melatonin may exhibit interaction with anti-coagulant/anti-platelet medications, antidepressants, anti-hypertensive, anticonvulsants, and anti-diabetes drugs.

Supplement Interactions: Melatonin may potentiate effect of the supplements with sedative component (5-HTP, kava kava, valerian root). Melatonin may increase the effects of herbal supplements that have antiplatelet/anticoagulant properties including angelica, clove, garlic, ginger, ginkgo, *Panax ginseng*, and others.

Interaction with Lab Tests: Melatonin supplementation may increase human growth hormone serum levels and decrease serum luteinizing hormone levels.

STORAGE

Store in a cool, dry place in original sealed container.