Dietary Supplement Information for Physicians with Naturokinetics®

PRODUCT CODE: P3558

CATEGORY: MOOD*/SLEEP*

Maximum 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 body's regulatory processes, including regulation of glandular secretory functions related to the maintenance of normal sleep/wake cycles and aspects of immune system function.* Supplemental melatonin has been shown to support healthy sleep patterns especially for individuals who are travelling across time zones or working night shifts.*

Structure Formula:

Chemical Name: N-acetyl-5-methoxytryptamine

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

Delivery Form: Vegetable capsules

ROLE AS NUTRIENT AND FUNCTIONS

Melatonin acts as a potent free radical scavenger of reactive oxygen species and as a neuroprotectant.* It influences a variety of biological processes, including circadian rhythm, neuroendocrine, immune and cardiovascular functions.* 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 is generated by neuroendocrine cells in many tissues including those 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 effects on the gastric lining and helps support healthy pH levels as well as normal pepsin and gastrin production.*

NATUROKINETICS®

Liberation. Disintegration of the vegetable capsule occurs between zero and 60 minutes based on USP testing method results.

Absorption. 20 mg melatonin is rapidly absorbed with peak plasma concentration reached approximately one hour and 15 minutes after ingestion (Figure 1).

Distribution. Melatonin is distributed systemically with levels detected in saliva. Melatonin is lipid-soluble and easily crosses the blood-brain barrier.

Metabolism. Endogenous melatonin is metabolized in the liver into 6sulfatoxymelatonin, which then undergoes conjugation and excretion as a

Supplement Facts

Serving Size 1 Veg Capsule

Amount Per Serving

Melatonin

20 mg**

* Daily Value not established.

Other ingredients: Magnesium Citrate, 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. This product is not intended for long-term use. Use beyond 4 consecutive weeks should be only under the supervision of a healthcare practitioner.

sulfate or glucuronide. In the pineal gland and retina, melatonin is metabolized via deacetylation to 5-methoxytryptamine. Tissue uptake requires removal of the phosphate group by plasma membrane tissue nonspecific phosphatase.

Elimination. Melatonin and its metabolite 6-sulfatoxymelatonin are primarily eliminated in the urine.

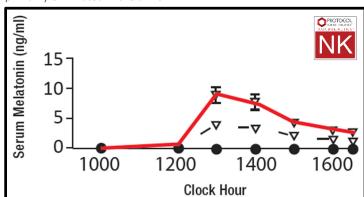


Figure 1: Mean serum melatonin profiles of 20 healthy individuals after ingesting 10 mg (clear triangle), 20 mg (red line) melatonin or placebo (black dash). Melatonin was ingested at 11:45 a.m. Peak plasma concentration was at 1 p.m. Adapted from Dollins et al.

CLINICAL VALIDATION

- Free Radical Scavenger.* A 20 mg daily dose significantly improved oxidative stress markers vs. placebo in 14 healthy male athletes postexercise in a 2-week double-blind, placebo-controlled, randomized clinical trial.* Markers for post-exercise DNA damage were also significantly reduced in the melatonin group vs. placebo.*
- Support of Healthy Sleep Cycle.* The effects of melatonin supplementation on sleep promotion were assessed in eight healthy



Dietary Supplement Information for Physicians with Naturokinetics® PRODUCT CODE: P3558

CATEGORY: MOOD*/SLEEP*

individuals in a double-blind, placebo-controlled crossover study.* A one-time dose of 1 mg, 10 mg, or 40 mg melatonin was provided at 10:00 a.m. and sleep patterns were measured between 12:00 p.m. and 4:00 p.m. Polysomnography measurements showed that all doses of melatonin significantly shortened the latency to sleep onset.* Specifically, melatonin modulated certain sleep stages by increasing stage 2 and decreasing stages 3 and 4 of the sleep cycle, while stage 1 and R.E.M. were unaffected. Sleep following melatonin administration had increased stage 2 and decreased stages 3 and 4, while stage 1 and R.E.M. sleep were unaffected.* These data suggest that melatonin supplementation may help support healthy sleep patterns especially for individuals who are travelling across time zones or working night shifts.*

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 interact with anti-coagulant/anti-platelet, antidepressant, anti-hypertensive, anticonvulsant, and anti-diabetic drugs.

Supplement Interactions: Melatonin may potentiate the effects of supplements with sedative components (e.g. 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 luteinizing hormone serum levels.

STORAGE

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