PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: Melatonin (AR)
Form: Oral Capsule

Drug Class: Neurohormone/chronobiotic agent

Mechanism of Action[1]:
Melatonin is intended to:

- Regulate circadian rhythm by binding MT1 and MT2 melatonin receptors in the suprachiasmatic nucleus (SCN) of the hypothalamus to synchronize biological clock.
- Enhance sleep propensity and reduce sleep latency by signaling night-time physiology.
- Scavenge free radicals and upregulate antioxidant enzymes to potentially provide neuroprotective and anti-aging effects.
- Modulate immune response by influencing cytokine release and immune cell activity, with ongoing research in inflammation and oncology.

Indications Commonly Prescribed for:

- Short-term treatment of insomnia.
- Circadian rhythm sleep–wake disorders (delayed sleep phase syndrome, non-24-hour sleep–wake disorder, jet lag, shift-work disorder).

Before Use: Let your health care provider know if you have any medication allergies before you take this compounded preparation. Let your health care provider know if you have any liver or kidney problems. Let your healthcare provider know of all supplements you are currently taking.

Contraindications:

- Hypersensitivity to melatonin.
- Caution in autoimmune diseases — theoretical risk of immune stimulation.

Cautions: Let your Healthcare provider know if you experience any adverse side effects.

How to Use: This compounded preparation is in the form of an oral capsule. Swallow the capsule whole with a glass of water. Do not chew or crush the capsule. If you miss a dose, take as soon as you remember, but not at the time for the next dose. Desired results may take up to several weeks.

Warnings and Precautions:

- Daytime drowsiness: May impair alertness; advise caution with driving or machinery.
- Hormonal effects: May influence puberty onset and reproductive hormones with long-term use in children.

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Adverse Reactions:

- Common
  - Headache, Dizziness
  - Drowsiness
  - Nausea
- Rare:
  - Irritability
  - GI upset, endocrine effects
  - Vivid dreams

Interactions:

- Sedatives / CNS depressants: Additive effects (benzodiazepines, alcohol, antihistamines).
- Anticoagulants / antiplatelets: Potential increased bleeding risk.
- Immunosuppressants: Possible antagonism due to immune-modulating effects.
- CYP1A2 metabolism: Inhibitors (e.g., fluvoxamine, cimetidine) increase melatonin levels; inducers (e.g., smoking) decrease levels.

Use in Specific Populations:

- Pregnancy/Lactation: Limited data; avoid unless benefit outweighs risk.
- Pediatrics: Used in neurodevelopmental sleep disorders; long-term safety not fully established.
- Older adults: Lower endogenous production; melatonin often more effective and well tolerated.
- Hepatic impairment: Avoid in severe liver disease due to altered metabolism.

Storage:

- Store in original container at room temperature (up to 30°C or 86°F)
- Store in a cool dry place away from heat, sunlight, and moisture

Monitoring Parameters:

- Clinical: Sleep onset latency, total sleep time, nighttime awakenings, daytime alertness.
- Safety: Monitor for next-day sedation, mood changes, or abnormal dreams.
- Special populations: In pediatrics, consider monitoring growth/puberty markers with prolonged use.

Citations:

1. Ferracioli-Oda E, Qawasmi A, Bloch MH. Meta-Analysis: Melatonin for the Treatment of Primary Sleep Disorders. PLOS ONE. 2013 May 17;8(5):e63773. doi:10.1371/journal.pone.0063773.