Melatonin Use in Pediatric Populations

A Comprehensive Resource for Pediatric Clinicians

Melatonin is increasingly used to treat sleep difficulties in children, but its use requires careful clinical evaluation and ongoing supervision. This guide provides evidence-based recommendations for assessment, prescription, and monitoring of melatonin in typically developing children and those with neurodevelopmental conditions.

Important: *Melatonin should be treated as a medication requiring medical supervision, not a natural remedy. It should only be used alongside behavioral interventions.*

CLINICAL CONTRAINDICATIONS

Before recommending melatonin, ensure it is appropriate:

- Generally not recommended for children under 2 years (very rare exceptions require sleep medicine specialist supervision)
- Should only be used for behavioral insomnia and circadian rhythm disorders, not other sleep disorders
- Not appropriate for children without genuine sleep complaints or to "make sleep better" in children with normal sleep

SLEEP HISTORY ASSESSMENT

Conducting a thorough clinical sleep evaluation ensures behavioral interventions are appropriately matched and melatonin use is appropriate.

- Document sleep schedule and duration (weekend/weekday), sleep onset latency, night awakenings, daytime sleepiness, and naps.
- Ask what typically happens in the hour before bed, as some patients may not identify a specific “bedtime routine.” Explore behaviors that may support or interfere with sleep (e.g., electronic use, consistency of evening activities), and evaluate the sleep environment (e.g., whether the child sleeps alone, and if the room is quiet and dark).
- Screen for other sleep disorder symptoms, including snoring, restless sleep, leg discomfort, nightmares.
- Consider secondary effects of medications or illnesses, specifically late-day stimulants, ASMs, asthma/allergy medicines (e.g., albuterol, steroids, montelukast), chronic pain, anxiety, depression, and other psychiatric conditions.

MELATONIN DOSING GUIDELINES

Age Group	Starting Dose	Maximum Dose	Titration
Toddlers (2-3 years)	0.5 mg	2-3 mg	If there is no improvement, increase by 0.5 mg every 3 days (up to age)
Preschoolers (4-5 years)	0.5 mg	4-5 mg	
School-age (6-10 years)	2.5 mg	6-10 mg	
Adolescents (11+ years)	2.5 mg	10 mg	
Never exceed the child's age in milligrams. Children with neurodevelopmental disorders may benefit from slightly higher doses than their age but do not need an excess of 10 mg. Dosing should be based on clinical responsiveness.			

Important: If melatonin appears ineffective, verify timing is appropriate (20-60 minutes before bedtime; shorter is more effective) before increasing dose.

TIMING AND ADMINISTRATION

While guidelines recommend administering melatonin 20–60 minutes before desired bedtime, clinical experience indicates most children benefit from dosing closer to bedtime rather than earlier in the night. Optimal timing is essential to align with circadian rhythms and maximize therapeutic effect.

Formulations

- Immediate-release (alternative): First-line for sleep onset delay
- Extended-release: Consider for night wakings and circadian rhythm disturbances (limited data in typically developing children)

PRODUCT SAFETY

- Keep in child-proof containers, away from children
- Provide psychoeducation on dosing and framing. Avoid referring to melatonin as a "gummy" or treat; emphasize it should be treated as a medication to reduce risk of accidental ingestion or overdose.
- Screen for hidden sources of melatonin. Check night cough syrups and relaxation aids

Safety Monitoring	Key Points
Common Side Effects (Generally Mild)	Headache, fatigue, dizziness, GI upset, vivid dreams, irritability, bedwetting (in children)
Potential Long-Term Concerns	Possible delayed puberty (long-term use >7 years); theoretical concerns about bone health; increased fracture risk in older adults
Drug Interactions - Increased Melatonin	Tricyclic antidepressants, fluvoxamine, cimetidine, ciprofloxacin, oral contraceptives
Drug Interactions - Decreased Melatonin	Carbamazepine, omeprazole, beta-blockers, NSAIDs, alcohol, smoking
Enhanced sedation risk	Benzodiazepines, zolpidem
Overdose/Accidental Ingestion	Emergency visits ↑ 530% (2012–2021); can lead to hospitalization, ICU, rarely death; stress poison control and safe storage

USE USP-VERIFIED PRODUCTS ONLY

Natrol & Nature's Made are currently the only USP-certified brands. Avoid non-verified retailers.

Why This Matters

- OTC melatonin content varies 74%-347% of labeled amount
- 88% of products are inaccurately labeled
- Some products contain CBD or serotonin contamination
- Chewable tablets show greatest variability

WHEN TO REFER TO A SPECIALIST

If melatonin fails (child still cannot fall asleep or continues waking through the night), consider referral to rule out other sleep issues:

- Low ferritin levels (significant negative correlation with sleep disturbances)
- Obstructive sleep apnea (can contribute to sleep maintenance issues)
- Other underlying sleep disorders

MONITORING AND FOLLOW-UP

- Monitor closely with regular follow-up to assess efficacy and side effects
- Periodically pause use ("melatonin-free holidays") to evaluate continued need
- Long-term use is rarely indicated in neurotypical youth; typical duration is 3-6 months
- Refer to a sleep specialist if long-term use is being considered

References

Abramova, R., Campbell, P., Baron, J., Patel, K., & Parmar, S. (2020). Review of Melatonin Supplementation for Sleep Disorders in Pediatric Special Populations. *Journal of Pharmacy Practice*, *33*(4), 533–539. https://doi.org/10.1177/0897190019845982

Cohen, P. A., Avula, B., Wang, Y.-H., Katragunta, K., & Khan, I. (2023). Quantity of Melatonin and CBD in Melatonin Gummies Sold in the US. *JAMA*, *329*(16), 1401–1402. https://doi.org/10.1001/jama.2023.2296

Cortese, S., Konofal, E., Bernardina, B. D., Mouren, M.-C., & Lecendreux, M. (2009). Sleep disturbances and serum ferritin levels in children with attention-deficit/hyperactivity disorder. *European Child and Adolescent Psychiatry*, *18*(7), 393–399. https://doi.org/10.1007/s00787-009-0746-8

Cuomo, B. M., Vaz, S., Lee, E. A. L., Thompson, C., Rogerson, J. M., & Falkmer, T. (2017). Effectiveness of Sleep-Based Interventions for Children with Autism Spectrum Disorder: A Meta-Synthesis. *Pharmacotherapy: The Journal of Human Pharmacology and Drug Therapy*, *37*(5), 555–578. https://doi.org/10.1002/phar.1920

Force, M. T., Owens, J., Simakajornboon, N., Kotagal, S., Gringras, P., & International Pediatric Sleep Association. (2025). Melatonin use in typically developing (TD) children: International Pediatric Sleep Association (IPSA) expert consensus recommendations for healthcare providers. *Sleep Medicine*, *128*, 127–129.

Giambersio, D., Marzulli, L., Margari, L., Matera, E., Nobili, L., De Grandis, E., Cordani, R., Barbieri, A., Peschechera, A., Margari, A., & Petruzzelli, M. G. (2023). Correlations between Sleep Features and Iron Status in Children with Neurodevelopmental Disorders: A Cross-Sectional Study. *Journal of Clinical Medicine*, *12*(15), Article 15. https://doi.org/10.3390/jcm12154949

Givler, D., Givler, A., Luther, P. M., Wenger, D. M., Ahmadzadeh, S., Shekoohi, S., Edinoff, A. N., Dorius, B. K., Jean Baptiste, C., Cornett, E. M., Kaye, A. M., & Kaye, A. D. (2023). Chronic Administration of Melatonin: Physiological and Clinical Considerations. *Neurology International*, *15*(1), Article 1. https://doi.org/10.3390/neurolint15010031

Goldman, R. D., Bongiorno, P. B., Olcese, J. M., Witt-Enderby, P. A., & Shatkin, J. P. (2021). Myths and Evidence Regarding Melatonin Supplementation for Occasional Sleeplessness in the Pediatric Population. *Pediatric Annals*, *50*(9). https://doi.org/10.3928/19382359-20210823-01

Grigg, -Damberger Madeleine M., & Ianakieva, D. (n.d.). Poor Quality Control of Over-the-Counter Melatonin: What They Say Is Often Not What You Get. *Journal of Clinical Sleep Medicine*, *13*(02), 163–165. https://doi.org/10.5664/jcsm.6434

Haendel, M. N., Andersen, H. K., Ussing, A., Virring, A., Jennum, P., Debes, N. M., Laursen, T., Baandrup, L., Gade, C., & Dettmann, J. (2023). The short-term and long-term adverse effects of melatonin treatment in children and adolescents: A systematic review and GRADE assessment. *EClinicalMedicine*, *61*.

Pawar, R. S., Coppin, J. P., Khanna, S., & Parker, C. H. (n.d.). A Survey of Melatonin in Dietary Supplement Products Sold in the United States. *Drug Testing and Analysis*, *n/a*(n/a). https://doi.org/10.1002/dta.3823

Rolling, J., Rabot, J., & Schroder, C. M. (2022). Melatonin Treatment for Pediatric Patients with Insomnia: Is There a Place for It? *Nature and Science of Sleep*, *14*, 1927–1944. https://doi.org/10.2147/NSS.S340944