



Drug information question: Is melatonin supplementation useful for insomnia in children with attention deficit hyperactivity disorder (ADHD)?

Conclusion: In children with ADHD and co-occurring insomnia, the limited available evidence indicates that melatonin reduces the amount of time it takes to fall asleep by approximately 20 minutes. Long-term efficacy and safety information is not available. Melatonin is not known to cause serious adverse events at usual doses. However, the safe storage of melatonin supplements is important, as adverse outcomes from accidental pediatric poisonings are increasing.

Efficacy

A 2022 systematic review considered clinical trials of melatonin in a variety of pediatric neurodevelopmental disorders, including autism, insomnia, and ADHD.¹ The review identified three short-term trials enrolling children with ADHD. In the largest trial, melatonin reduced time to sleep onset by approximately 20 minutes compared to a placebo.² The effect of melatonin on children experiencing insomnia as a consequence of medication prescribed for ADHD (e.g., methylphenidate, amphetamines, atomoxetine) is less certain as this population was excluded from the largest trial.

Guidelines

Current ADHD guidelines offer varying recommendations for melatonin. Canadian ADHD guidelines (by CADDRA) cautiously recommend melatonin as a second-line treatment for insomnia if behavioural interventions are ineffective.³ The National Institute for Health and Care Excellence (NICE) declined to recommend melatonin for treatment of ADHD, as current evidence does not indicate that the supplement improves quality of life or core ADHD symptoms.⁴

Dose

A clear dose-response effect or optimal dosing time for melatonin has not been identified, despite significant variability in doses and administration times tested in clinical trials.^{1,5,6} In the United Kingdom, a melatonin product recently obtained regulatory approval for ADHD-related insomnia in children aged 6 to 17.⁷ The prescribing information recommends a starting dose of 1 to 2 mg given 30 to 60 minutes before bedtime, with gradual titration up to a maximum dose of 5 mg.

Safety

Short-term trials do not implicate melatonin in serious adverse events.⁸ Daytime somnolence and fatigue are reported inconsistently.^{1,8} Uncertainties remain due to a lack of long-term safety data and reports of suboptimal product quality control.^{8,9} In the United States, there are increasing reports of adverse outcomes when melatonin is ingested unintentionally by children at doses higher than recommended.¹⁰

¹SALANITRO Neurosci Biobehav Rev 2022 (PMID: 25691474); ²VAN DER HEIJDEN J Am Acad Child Adolesc Psychiatry 2007 (PMID: 17242627); ³Canadian ADHD Practice Guidelines 2020 Edition 4.1; ⁴National Institute for Health and Care Excellence NICE guideline [NG87] 2021; ⁵VAN GEIJLSWIJK Psychopharmacol 2010 (PMID: 20668840); ⁶AYYASH Expert Rev Neurother 2015 (PMID: 25938708); ⁷United Kingdom Electronic Medical Compendium; ⁸BESAG CNS Drugs 2019 (PMID: 31722088); ⁹ERLAND J Clin Sleep Med 2017 (PMID: 27855744); ¹⁰CDC Morbidity and Mortality Weekly Report (MMWR) June 3, 2022