



## ASSURING THE SAFE USE OF MELATONIN IN CHILDREN

### Issue:

Melatonin is regulated by the Food and Drug Administration as a dietary supplement and is a widely available over-the-counter sleep aid for adults and children.

During 2012–2021, the annual number of pediatric ingestions of melatonin increased 530% with a total of 260,435 ingestions reported. Pediatric hospitalizations and more serious outcomes also increased, primarily because of an increase in unintentional melatonin ingestions in children aged  $\leq 5$  years.<sup>1</sup>

### Action:

- Review safe medication storage practices with patients and caregivers to prevent accidental ingestions.
- Specify on prescriptions that a USP verified supplement be used to fill the prescription to assure product quality. If a patient prefers to purchase the product independently, counsel them to select USP verified OCT supplements and look for the USP seal on the supplement bottle.

### Issue:

Increasing use of over-the-counter melatonin might place children at risk for potential adverse events. This communication is an initiative focusing on raising awareness of increasing melatonin ingestions among children to improve the way Melatonin is prescribed through clinical practice guidelines.

### Action:

- Consider reserving melatonin for sleep disorders in children most likely to benefit (i.e., problems with sleep onset in patients with delayed sleep phase syndrome, blindness, and perhaps autism, ADHD, and developmental disorders)<sup>2</sup>
- Most children who do benefit from melatonin—even those with ADHD—don't need more than 3 to 6 mg of melatonin.<sup>3</sup>

### Dosing Recommendation:<sup>2</sup>

Patient Age or Weight	Max Recommended Daily Dose	Notes
Infants >6 months	1mg	Many children will respond to 0.5 mg or 1 mg when taken 30 to 90 minutes before bedtime.
Children < 40kg	3mg	
Children >40kg	5mg	

### References:

1. <https://www.cdc.gov/mmwr/volumes/71/wr/mm7122a1.htm>
2. Clinical Resource, Considerations for use of Melatonin. Pharmacist's Letter/Prescriber's Letter. March 2022. [380302]
3. <https://www.healthychildren.org/english/healthy-living/sleep/pages/melatonin-and-childrens-sleep.aspx>