# Melatonin:
## Safe for Children? What About During Pregnancy?

By Michael T. Murray, ND

Insomnia, for the most part, is uncommon in children, the exception being kids with psychiatric or neurodevelopmental issues such as attention deficit hyperactivity disorder (ADHD), autistic spectrum disorders (ASDs) and epilepsy. While insomnia affects only one to six percent of children without these diagnoses, in those with any of these issues the rate of insomnia jumps to 50 to 75 percent. In other words, insomnia occurs in roughly three out of four kids with ADHD, ASDs or epilepsy. The consequences of this poor sleep quality may include alterations in daytime behavior, memory and learning.

As we explore options that can help alleviate the burden these children are experiencing, we recognize that the use of sedative/hypnotic drugs is not appropriate in these kids, as these drugs have not been sufficiently studied in children. Given their numerous issues in adults (highly addictive, numerous side effects, considerably increased risk for dementia and increased mortality rate associated with chronic use), it makes sense to explore non-drug options such as melatonin.

### Melatonin for Children With ASD, ADHD & Epilepsy

Several very thorough review articles have concluded that melatonin is effective in reducing sleep latency (the time required to go to sleep), reducing nighttime awakenings and improving sleep quality in children with ASD, ADHD and epilepsy. One of the possible reasons for the sleep issues in these children is disturbance in the manufacture of melatonin. In addition to abnormally low levels of melatonin in children with ADHD and ASD, genetic defects in proteins signaled by melatonin have also been noted in these patients.

The clinical studies that have been conducted with melatonin in ASD include four double-blind studies and several open-label trials, all of which showed a significantly shorter time to fall asleep, fewer nighttime awakenings and longer sleep duration with melatonin at dosages of 2-5 mg compared to placebo. Melatonin was usually effective in week one of treatment and maintained effects over time (it did not lose effectiveness with chronic use). And, in addition to showing improvement in sleep, melatonin also improved the behavior of the children leading to a significant reduction in the feelings of stress by the parents.

In a recent double-blind study published in November 2012 in the *British Medical Journal*, melatonin was studied in 146 children aged 3 to 15 years with neurological and developmental disorders and a severe sleep problem (defined as the child not falling asleep within one hour of lights out or having less than six hours of continuous sleep). Immediate release melatonin or matching placebo capsules were administered 45 minutes before the child's bedtime for a 12-week period. All children started with a 0.5 mg capsule, which was increased through 2 mg, 6 mg and 12 mg, depending on their response to treatment. Results indicated that melatonin reduced sleep onset latency by 37.5 minutes, was most effective for children with the longest sleep latency and increased total sleep time by 22.4 minutes. Adverse events were mild (mainly morning sleepiness) and similar between the two groups.

### Melatonin Safety in Children

So melatonin is effective in children, but is it safe? The answer is a definite yes. As melatonin is thought to play a role in the normal rhythm of hormonal secretion, one of the concerns has been that melatonin may impact puberty and/or sexual development. It has been suggested that there is a causal relationship between the onset of puberty and a decrease in pineal melatonin production. Hence, it is thought that the administration of melatonin to adolescents could theoretically delay the onset of puberty. However, puberty is a very tricky situation to examine and it is unlikely, in my opinion, that nature would leave the onset of sexual maturity to a single factor like melatonin levels. Furthermore, it has been suggested that the drop in melatonin levels at the onset of puberty maybe not be causal at all, but rather simply a result of the surge of the hormones of puberty. Only a few studies have looked at the effects of melatonin on sex hormones in adolescents and, based upon existing evidence, there is no effect.

The bottom line is that melatonin appears very helpful in improving childhood insomnia, especially since most cases involve kids with ADHD, ASD and

epilepsy, or some other neurological or developmental disorder. Given the possible benefits, little risk and clear advantages over both OTC and prescription sleeping pills, melatonin appears to be an appropriate choice.

## Melatonin Safety in Pregnancy

The question of melatonin's safety during pregnancy is even more controversial than its use in children. While for many years there was caution against its use, recently there have been numerous studies in animals showing that short-term melatonin therapy is highly effective in reducing complications during pregnancy. There are also a few human studies as well. The occasional negative study in animals has used dosages that are beyond reasonable use in humans. For example, there are a few studies showing dosages of 10 mg per kg body weight produced low birth weight and other negative effects in animals, but these dosages far exceed the usual dosage of 1 to 3 mg in humans. The bottom line is that short-term, occasional use of supplemental melatonin at dosages less than 3 mg per night possess no risk at all to either the mother or fetus (or infant if breastfeeding). In fact, the recent data points to beneficial effects at various stages of pregnancy.

To illustrate the safety of melatonin while breastfeeding, let me offer an interesting study published in the *Journal of Psychosomatic Research* in June 2007. The study was set up to evaluate the effect laughter had on the level of melatonin in breast milk. The mothers viewed either an 87-minute humorous DVD ("Modern Times," featuring Charlie Chaplin) or an 87-minute non-humorous weather information DVD at 8:00 p.m. After viewing, breast milk was collected every two hours for the next 10 hours sequentially from 2200, 2400, 0200, 0400 to 0600 h. Results showed that laughter increased the levels of breast-milk melatonin. And, this effect had clinical benefit in reducing allergic responses in the infants.

The level of elevations in melatonin in the breast milk would be on par with supplementation at recommended dosages and would be no more dangerous to the mother or infant than a good laugh.

## Conclusion

Melatonin has an excellent safety profile. While higher dosages of melatonin (e.g., 5-12 mg) are becoming more popular, there is ample research showing that dosages in the range of 0.5-3 mg 24 to 45 minutes before bedtime is effective. There does not seem to be a physiological or pharmacological reason to go above these dosage levels, especially in children or during pregnancy.

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*(Continued from page 36)*

## Vegetarian & Vegan Supplements

juices and whole foods into nutrient-rich powders that have long shelf lives, original nutrition, vivid colors and flavors—all without needing synthetic additives. These are incredible advancements that increase the potential for supplement products to offer real nutrition from plant sources."

Further, Himalayan's Reisman pointed out that the trend to "strive toward clean" has made consumers aware of the inclusion of artificial excipients and magnesium stearate in their supplements. "Whether it's a tableting agent, a machine lubricant or whatever, if it's not natural, consumers are really growing weary of seeing it on labels," he said. "Vegetarians and vegans are very discriminating shoppers. They read labels and they pay attention to what's going on. It's a big commitment in terms of time, money and speed of production runs to do things right and not let them down."


With that consideration, Himalayan began offering its single herbs (Ashwagandha, Bacopa, Holy Basil, Turmeric and Garcinia) in either VCaps or bound into tablets using the plant matter itself.

"We decided we didn't even want to tablet our single herbs with artificial, non-plant binders, so Himalaya's R&D team in India developed a patented process where we now use a sticky part of the plant itself—a gum resin from the stem, for example—to actually hold the tablet together," he said. "So, unless you've got the time to run out in the woods and chew on some leaves, we're making our pure herb tablets as vegetarian-friendly as we possibly can."

## Conclusion

A challenge for retailers in general is finding a way to better serve their customers. But vegan and vegetarians come with very specific nutrient needs and concerns. Thankfully, according to Kay with Lori's, manufacturers are actively working to help retailers meet them. She noted, for example, that omega-3s, B12 and D3 are areas where this segment hasn't traditionally had a lot of choices. "But the rise in vegan/vegetarian customers has forced manufacturers to look at these customers' needs, and they are responding in kind." **VR**

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