

# Melatonin in the Treatment of Insomnia.

*By Current Medical Research and Opinion*

Insomnia is a chronic inability to obtain or sustain sleep. While everyone occasionally experiences sleeplessness, chronic insomnia is an ongoing, often debilitating condition. After a night of inadequate sleep, those with insomnia report impaired mental and physical abilities, diminished memory, reduced alertness, and impaired reaction time. Chronic lack of sleep threatens the well being, productivity, and safety of millions of Americans including teenagers. Researchers found insomnia increased the risk for hypertension. Insomnia is not a disease but a condition associated with a number of physical and emotional disorders even including depression. The incidence of insomnia is higher among people with chronic illnesses, such as hyperthyroidism, renal insufficiency, multiple sclerosis, and Alzheimer's disease. Pregnancy, alcohol intake, stress, and depression are also leading causes of insomnia.

Melatonin is a hormone that is produced by the pineal gland in the brain. For years, scientists have known that melatonin's main function was in the control of our sleep patterns. However, more recent research has revealed that it also functions as an important antioxidant.<sup>(1)</sup> After puberty melatonin output begins a gradual steady decline. Adults experience about a 37 percent decline in daily melatonin output between the ages of 20 and 70 with the majority of the decline occurring after age 40. In 1994, melatonin became a sensation when studies revealed that supplementation provided significant life extension in several different species of laboratory animals. Although long-term studies on humans have not been conducted, melatonin became a popular product in health food stores and pharmacies throughout the country.

A current study sought to investigate the efficacy and safety of prolonged release melatonin. The study also evaluated whether age affects how well prolonged release melatonin works in people with insomnia. The study included 791 adults between the ages of 18 and 80 years with primary insomnia. The participants completed a two week, single-blind placebo run-in period followed by three weeks double-blind treatment with prolonged release melatonin or placebo, one tablet per day at 2 hours before bedtime. Patients taking the prolonged release melatonin continued whereas placebo completers were re-randomized 1:1 to prolonged release melatonin or placebo for 26 weeks followed by two weeks run-out on placebo. A total of 746 participants completed the three week trial and 555 completed the six month trial. The main reason for participant drop-out was patient decision. The results revealed that after three weeks significant differences in sleep latency in favor of prolonged release melatonin versus placebo treatment were found for the 55 to 80 year old group, but not in the 18 to 80 year old group. Participants in both groups experienced improved sleep quality and quality of life with few adverse reactions. The noted improvements were maintained or enhanced over the six month period with no signs of increased tolerance. No withdrawal symptoms or rebound insomnia were found in any of the participants. These findings suggest that prolonged release melatonin may be a safe and effective treatment for primary insomnia for all adults, but may work even better in those over 55 years of age.

Wade AG, Crawford G, Ford I, et al. Prolonged release melatonin in the treatment of primary insomnia: evaluation of the age cut-off for short- and long-term response. *Curr Med Res Opin.* Jan2011;27(1):87-98.