

MELATONIN - DON'T LOSE SLEEP OVER IT

- ▶ MELATONIN IS AVAILABLE ON PRESCRIPTION ONLY
- ▶ APPROVED FOR PRIMARY INSOMNIA IN THOSE OVER 55 YEARS
- ▶ CONSIDERED USEFUL FOR JET LAG
- ▶ LONG-TERM SAFETY AND INTERACTION DATA ARE LACKING
- ▶ CAN CAUSE DAYTIME DROWSINESS AND IMPAIRED CONCENTRATION
- ▶ SAFETY IN CHILDREN HAS NOT BEEN ESTABLISHED

Melatonin plays a part in the regulation of biological rhythms and the timing of physiological processes. Endogenous secretion increases soon after the onset of darkness, with production being suppressed by light. There appears to be an age-related decrease in endogenous melatonin production.

MELATONIN IS AVAILABLE ON PRESCRIPTION ONLY

Melatonin 2mg Prolonged Release tablet (CIRCADIN[®]) was approved in New Zealand in 2011, as monotherapy for the short-term treatment of primary insomnia in patients who are aged 55 or over.

Melatonin is available in some other countries as an over the counter 'nutritional' supplement in varying doses and compositions, leading to unregulated and uncontrolled use. There is very little robust clinical evidence available about long-term use.

Melatonin has been extensively studied in New Zealand for sleep timing disorders in the blind and visually impaired, and has been considered very useful for this group.

APPROVED FOR PRIMARY INSOMNIA IN THOSE OVER 55 YEARS

Short-term use (up to 13 weeks) has demonstrated benefits in primary insomnia for those over 55 years.

A 2mg dose as monotherapy taken 1-2 hours before bedtime has been shown to improve quality of sleep and morning alertness. A shortened time to sleep onset (by 9 to 11 minutes) has been observed, although in those over 55 years, time to sleep onset is usually normal.

Note: Primary insomnia is sleeplessness that is not associated with another medical or psychological condition, and could arise as a result of prolonged periods of stress. It may not always require drug treatment and could be managed by careful assessment and 'sleep hygiene' methods or cognitive behavioural therapy with specialist input. (See over for 'sleep hygiene' tips).

CONSIDERED USEFUL FOR JET LAG

Melatonin may be effective in reducing jet lag especially if it has been experienced previously, and if flying across five or more time zones (particularly in an easterly direction). Normal release preparations may be more useful than prolonged release for jet lag but are not approved. Other measures to alleviate jet lag should also be recommended, for example exposure to natural daylight and eating meals at regular times after arriving at the destination.

The timing of the melatonin dose is critical; it is most effective when taken as 0.5-3mg one to two hours prior to bedtime on the day of arrival at the destination, and on the following 2-5 days at the same time.

Note: This indication has not been approved in New Zealand.

LONG-TERM SAFETY AND INTERACTION DATA ARE LACKING

There is no clear data about long-term safety or interactions with other medications, so some of the following is theoretical.

Melatonin is best avoided in people with epilepsy, hypertension and diabetes, and could potentially worsen symptoms of depression. There is no evidence for use in pregnancy, breast-feeding, renal or hepatic impairment. Efficacy and safety in combination with other agents has not been assessed. Benzodiazepines and other hypnotics including alcohol are best avoided; melatonin can further increase sedation, impair attention, memory and coordination.

Oestrogen-containing preparations may also increase melatonin levels, so are best avoided. Interactions have been identified in combination with fluvoxamine, quinolones, carbamazepine and rifampicin. Melatonin could lead to an increased risk of bleeding, so caution is advised in combination with warfarin or other anticoagulants.

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MELATONIN

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CAN CAUSE DAYTIME DROWSINESS AND IMPAIRED CONCENTRATION

Melatonin taken at the wrong time of the day or at excessive doses is likely to cause daytime sleepiness, particularly if combined with other medications. Melatonin can increase fatigue and impair concentration; driving or use of machinery should be avoided for 4 to 5 hours. There have been reports of transient anxiety, irritability and confusion, headache, insomnia, rash, upset stomach, and nightmares.

SAFETY IN YOUNG CHILDREN HAS NOT BEEN ESTABLISHED

There is insufficient safety and efficacy data to recommend use in those under 18 years. Despite this, it may be useful for specific sleep disturbances associated with central nervous system disorders and developmental disabilities (e.g. cerebral palsy and mental retardation) to reduce the time to sleep onset and minimise nighttime awakenings. Melatonin has also been used successfully in blind children and adults with sleep-timing disorders due to a lack of conscious light perception.

KEY REFERENCES

Healthcare Logistics. Circadin Prolonged Release Melatonin 2mg Datasheet 28-06-11. <http://www.medsafe.govt.nz/Profs/Datasheet/c/circadintab.pdf> (Accessed 21-03-12)

Warman GR, Pawley MDM, Bolton C et al. Circadian-related sleep disorders and sleep medication use in the New Zealand blind population: An observational prevalence survey. PLoSONE 2011;6(7):e22073 (Accessed 23-03-12)

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Sleep Hygiene

ASLEEP is a useful acronym for remembering sleep hygiene tips

Alcohol, caffeine and nicotine should be avoided, especially in the evening

Sleep and sex should be the only uses of the bed; make sure your bed environment is comfortable

Leave laptops, TV and paperwork out of the bedroom and keep clocks out of sight; blue light from phones, computers and TV can exacerbate insomnia

Exercise regularly and be active during the day, spending time outdoors if possible

Early rising – avoid sleeping-in or daytime naps; get up at the same time each day

Plan for bedtime – establish a bedtime routine to wind down such as having a warm drink or a bath; avoid going to bed until you are drowsy

Talk to your doctor about changing specific habits that may affect your sleep. It can be very helpful to learn relaxation skills or try other techniques such as sleep restriction or cognitive behavioural therapy, which may need referral to a psychologist or sleep specialist.

Adapted from Cape G BPJ 2008;14:6-11

[CLICK HERE FOR FURTHER INFORMATION ON MELATONIN AND A FULL REFERENCE LIST](#)

For further information on other high-risk medicines visit our website at: www.saferx.co.nz

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