

## MELATONIN - SAFE PRESCRIBING - DON'T LOSE SLEEP OVER IT

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- ▶ CHECK THE INDICATION
- ▶ EMPHASISE CORRECT TIMING OF DOSES
- ▶ CHECK CONTRAINDICATIONS AND INTERACTIONS
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Melatonin is a hormone that plays a part in the regulation of biological rhythms and the timing of physiological processes. Endogenous melatonin secretion increases soon after the onset of darkness, peaking between 2-3am, and is suppressed by light. There appears to be an age-related decrease in endogenous melatonin production.

**Note:** Melatonin is available in many countries as an over the counter 'nutritional' supplement in varying doses and compositions.

### CHECK THE INDICATION

Short-term use (up to 13 weeks) of slow-release melatonin 2mg (Circadin<sup>®</sup>) taken 1-2 hours before bedtime, is approved for people aged 55 years or over with primary insomnia. A shortened time to sleep onset (by approximately 10 minutes) has been observed with melatonin, compared to placebo, with some improvement in the quality of sleep.

Primary insomnia is sleeplessness that is not associated with another condition. Management should include careful assessment, sleep hygiene techniques and if necessary cognitive behavioural therapy with specialist input. Medication may not be necessary.

Melatonin is available on special authority for children aged 18 years or younger who have persistent, distressing insomnia secondary to a neurodevelopmental disorder, such as autism, or attention deficit hyperactivity disorder, and have not responded successfully to behavioural or environmental approaches. This is an off-label indication.

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.

### EMPHASISE CORRECT TIMING OF DOSES

For insomnia, it is important that melatonin 2mg is taken 1-2 hours before bedtime; if taken at the wrong time of the day or in excessive doses it is likely to cause daytime sleepiness, particularly if combined with other medicines. It is advisable to avoid driving for the remainder of the evening after taking melatonin.

**Note:** Melatonin may cause minor transient adverse effects such as headache, diarrhoea and arthralgia.

### CHECK CONTRAINDICATIONS AND INTERACTIONS

Although occasional short-term monotherapy with melatonin appears to be safe, there is no clear information available about long-term safety or interactions with other medicines.

There is no evidence for its use during pregnancy or breast-feeding and there is currently no data about dosing with renal impairment. Melatonin is not recommended for patients with hepatic impairment.

The efficacy and safety of melatonin combined with other medicines has not been assessed. It is best to avoid combinations with benzodiazepines and other hypnotics, caffeine and alcohol. Melatonin is likely to increase the sedative properties of hypnotics leading to a more pronounced impairment of attention, memory and coordination.

Interactions with melatonin have been identified with fluvoxamine, quinolones (ciprofloxacin), carbamazepine and rifampicin. Melatonin may alter the INR, so caution is advised with warfarin.

### UNDERSTAND ITS PLACE FOR JET LAG

Immediate-release melatonin may be effective for the prevention and reduction of the effects of jet lag, especially if flying across 5 or more time zones in an easterly direction.

**Note:** Immediate-release melatonin is not approved in New Zealand; slow-release may not be as useful for jet lag.

Melatonin is most effective when taken as 0.5-5mg in evening *after* arrival at the destination.

**Note:** Products purchased in other countries should be declared at customs.

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## MELATONIN

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### OBTAIN ADVICE FOR USE IN CHILDREN

Melatonin in combination with sleep hygiene measures can reduce time to sleep onset in children who have neurodevelopmental disorders such as autism or attention deficit hyperactivity disorder and insomnia.

Melatonin is available on special authority by, or on recommendation of a psychiatrist, paediatrician, neurologist or respiratory specialist. Melatonin may be continued by general practitioners under a shared-care arrangement.

Melatonin has been successfully used for blind children and adults with sleep-timing disorders from lack of conscious light perception. It is sometimes used before magnetic resonance imaging (MRI), computed tomography (CT), or electroencephalography (EEG) investigations.

### SLEEP HYGIENE

**ASLEEP is a useful acronym for remembering sleep hygiene tips**

**A**lcohol, caffeine and nicotine should be avoided, especially in the evening

**S**leep and sex should be the only uses of the bed; have a comfortable bed

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

**E**xercise regularly and be active outdoors during the day

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

**P**lan for bedtime – establish a bedtime routine to wind down; have a warm drink or a bath, avoid going to bed until you are drowsy

**T**alk to your doctor about habits which may affect your sleep. Relaxation skills, sleep restriction or cognitive behavioural therapy with a psychologist or sleep specialist can be very helpful.

### REQUIREMENTS FOR UNAPPROVED INDICATIONS

Melatonin 2 mg slow-release tablets are approved for short-term use in New Zealand for people over 55 years with primary insomnia.

For other ages and conditions it is unapproved. Explain this to the patient and discuss the efficacy and safety of melatonin and other options to ensure the expected benefit outweighs potential harm.

The unapproved use of a medicine is considered experimental if there is limited documented evidence supporting its use.<sup>16</sup> If melatonin is regarded 'experimental', obtain signed consent from the patient, and agree how monitoring for safety and efficacy will be arranged.

### KEY REFERENCES

1. Healthcare Logistics. Circadin Prolonged Release Melatonin 2mg Datasheet 23-05-16. [www.medsafe.govt.nz/Profs/Datasheet/c/circadintab.pdf](http://www.medsafe.govt.nz/Profs/Datasheet/c/circadintab.pdf) (Accessed 17-01-19)
2. Bartle A, Wheeler B. Melatonin: Is it worth losing any sleep over? Best Practice Journal 2015;69:18-27 [www.bpac.org.nz/BPJ/2015/August/melatonin.aspx](http://www.bpac.org.nz/BPJ/2015/August/melatonin.aspx) (Accessed 17-01-19)
3. Bartle A, Falloon K. I dream of sleep: managing insomnia in adults Part 2. Best Practice Journal 2017; <https://bpac.org.nz/2017/docs/insomnia-1.pdf> (Accessed 17-01-19)

### ACKNOWLEDGEMENTS

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[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](http://www.saferx.co.nz)

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