



Melatonin

This medicine can be prepared by a compounding pharmacist.

Mode of action*

- Endogenous melatonin is associated with control of circadian rhythms and sleep regulation; it acts at MT₁ and MT₂ receptors in the anterior hypothalamus

Indications**

- Short-term use as monotherapy in primary insomnia with poor sleep quality
- Jet lag

Precautions**

- Discourage use in hepatic impairment (no data)
- Short-term use appears safe; long-term safety is not established
- Patients with *epilepsy*
- Patients taking *warfarin*

Paediatric^A

- There is evidence to show melatonin levels are often below average in children with autism spectrum disorders (ASD) compared with healthy children. Recent meta-analysis found that the use of melatonin in ASD is associated with significantly improved sleep duration and sleep onset latency. Furthermore, melatonin appears to improve daytime behaviour in some and has minimal to no side effects. However, additional studies are needed to examine melatonin metabolism in ASD, optimal effective dosing and its long-term adverse effects and safety in ASD.

Pregnancy*

- No clinical data; Australian category B3

Breastfeeding*

- Endogenous melatonin appears in breast milk; no clinical data

Adverse effects*

- Common (>1%) – back pain, arthralgia
- Infrequent (0.1% - 1%) - weakness

Dosage*^{€∞}

- *Primary insomnia*- >55years, 2mg 1-2 hours before bed for up to 13 weeks. The effects of melatonin to improved sleep parameters were found to occur from 0.1 to 20mg by a recent meta-analysis.
- *Children*- refers to paediatrician or sleep physician. Dose will depend on child's age; amount may vary from 0.5 to 6mg around 30-60 minutes before a child goes to bed.

Practice points**

- For all sleep problems, non-drug treatments are first line. Identify specific cause and treat where possible before melatonin is considered as an option. Refer to current clinical guidelines for evaluation and management of insomnia
- Limited evidence suggests that melatonin improves sleep quality in primary insomnia (although many people do not respond); it may be effective in people with delayed sleep phase syndrome
- There do not appear to be any dependence or withdrawal effects, or rebound insomnia

*Source: Australian Medicines Handbook Pty Ltd 2014 [‡]Melatonin CMAJ Nov 2012, 184(17) ^ARossignol & Frye (2011) Melatonin in ASD: meta-analysis DMCN 53(783-792) [€]Ferracioli-Oda et al (2013) Meta-analysis: Melatonin for treatment of primary sleep disorders PLOS 8:5(e63773) [∞]Sleep Health Foundation (2012): Melatonin and Children

- PCCA formula #11162 Melatonin 3mg LoxOral™ Capsules contain NO gluten, casein, sodium lauryl sulfate, lactose, soy, dye and magnesium stearate. *Detailed information regarding the LoxOral™ excipient base is available from the member-only website.* It is highly recommended to use PCCA RAM™ to prepare this formula to ensure content uniformity of the final product. *Detailed information regarding the PCCA RAM™ machine is available from the member-only website.*

PCCA formulas are valid only when PCCA Ingredients, Bases and Equipment are used.

How to Write a Compounded Prescription:

Example prescriptions below

The following formulas are suggested as a guideline for medical practitioners only

Dr. A. Prescriber
99 Station Street
Central NSW 2001
Phone: (99) 9999 9999
Prescriber no.: 123456

Patient's Medicare number: 3,9,0,0,7,2,4,6,5,1,1

Patient's full name: Suzie Citizen
Patient's address: 22 Smith Street, Cityside, Postcode 2001

PBS entitlement number: _____
Safety Net entitlement card holder: Concessional or dependent, RPBS beneficiary or Safety Net concession card holder

PBS Non-PBS Brand substitution not permitted

COMPOUNDED MELATONIN 3mg Capsules with PCCA LoxOral™

Insert required directions

Quantity: _____ Repeats: _____

Pharmacist/patient copy

Privacy note on reverse

Doctor's signature: *A. Prescriber* Date of supply: 03/04/07

I certify that I have received the medication and the information relating to any entitlement to free or concessional pharmaceutical benefits is not false or misleading. 4081 (04/06)

Patient's or agent's signature: _____ Date of supply: / /

Agent's address: _____

Dr. A. Prescriber
99 Station Street
Central NSW 2001
Phone: (99) 9999 9999
Prescriber no.: 123456

Patient's Medicare no.: 3900724651-1

Pharmaceutical benefits entitlement number: _____
 Safety Net entitlement card holder (non-entitled) Concessional or dependent, RPBS beneficiary or Safety Net concession card holder

Patient's name: Suzie Citizen
Address: 22 Smith Street, Cityside NSW 2001

Date: 03/04/07
RPBS non-PBS Brand substitution not permitted

COMPOUNDED MELATONIN 3mg Capsules with PCCA LoxOral™

Insert required directions

Qty: _____ repeat _____
1 item

Dr. A. Prescriber
MBBS

A. Prescriber

Please have scan for privacy code

I certify that I have received the medication and the information relating to any entitlement to free or concessional pharmaceutical benefits is not false or misleading.

Date of supply: / / Patient's or agent's signature: _____

Agent's address: _____ 4081 (04/06)

PCCA ingredients are quality assured for peace of mind. Learn more about PCCA quality by visiting: www.pccarx.com.au/quality



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