Melatonin (Circadin®) AMBER 0

Indications approved by LSCMMG only – see below

Background

Melatonin is an endogenous hormone which is produced by the pineal gland in the brain and is thought to be a key component in the regulation of circadian rhythm.

Indications (approved for use in Lancashire by LSCMMG. Note: all approved indications are OFF LABEL):

Sleep disorders in children and adults with neurodevelopmental disorders (RAG status: '**Amber 0'**)

Sleep disorders in children with ADHD (RAG status: '**Red';** Blackpool CCG RAG status **'Amber 0'**)

For the Treatment of Rapid Eye Movement (REM) Sleep Behaviour Disorder (RBD) in Parkinson's Disease and Lewy Body Dementia (RAG status: '**Amber 0'**)

Treatment of insomnia in children and adolescents aged 2-18 with Autism Spectrum Disorder (ASD) and or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient (RAG status: '**Amber 0'; Circadin® and Slenyto®**)

Dosage and Administration

The recommended dose is initially 2mg once daily, increased if necessary after 1-2 weeks to 4mg or 6mg once daily as directed by the prescriber.

The dose may be titrated by 2mg every 1-2 weeks according to response to the lowest effective dose. The **maximum dose** is 10mg once daily

(For the Treatment of Rapid Eye Movement (REM) Sleep Behaviour Disorder (RBD) in Parkinson's Disease and Lewy Body Dementia up to 12mg once daily can be used).

The dose should be taken 1-2 hours before bedtime and after food

Tablets **should** be swallowed whole

Advice for Children unable to swallow tablets

Circadin® 2mg MR tablet may be halved using a tablet cutter, and it will retain its slow-release characteristics to some extent.

For children with difficulties swallowing, the tablet can be crushed to a fine powder and mixed with water or jam. Use a small amount of food to ensure that the full dose is taken. Prescribers should be aware that once crushed the tablet will not retain its slow release characteristics. The direction to crush the tablet prior to administration should be included on the prescription where appropriate.

Monitoring

Continued prescribing of melatonin should only occur in patients whose initial response to and progress on this medication is considered satisfactory.

A satisfactory response must be demonstrated by way of a sleep diary and is defined as:

- An increase in sleep duration by 60 minutes or more, **or**
- A significant reduction in the number of night time waking episodes, **or**
- A consistent shift in sleep pattern towards earlier settling to sleep, **or**
- The ability to wake in the morning in order to get to school on time, **or**
- A reported improvement in daytime functioning.

Version: 1.1
Date: June 2022
Review Date: June 2025

Acknowledgements to Lancashire and South Cumbria NHS Foundation Trust

Where patients fail to respond to treatment at the maximum dosage treatment should be discontinued. This can be done abruptly.

Where patients benefit from treatment there should be a review every 6 month to assess continuing need

This should take the form of a treatment holiday: **melatonin should be withdrawn and any changes in sleeping pattern are observed.** At least **three to six months of improved sleep pattern** should elapse before withdrawal takes place.

The speed of withdrawal should be determined using clinical judgment considering knowledge of the child and their family members or carer's ability to engage with ongoing monitoring with the use of a sleep diary. Withdrawal may therefore range from abrupt or gradual discontinuation, typically over a period of 3-4 weeks.

A sleep diary should be kept covering the period of two weeks preceding the gradual withdrawal of melatonin, during discontinuation and for two weeks following discontinuation of treatment

For some, withdrawal is not successful and treatment may need reinstating for a further period

Melatonin therapy should be reinstated only if there is significant deterioration in sleep pattern documented on a sleep diary. Clinically significant deterioration is considered as:

- A decrease in sleep duration of 60 minutes or more
- A significant increase in the number of night time waking episodes
- A consistent shift in sleep patterns towards longer periods to get settled to sleep
- An inability to wake in the morning to get to school on time
- Reported deterioration in daytime functioning

If withdrawal of treatment is unsuccessful then treatment may be reinstated at the lowest effective dosage for a further period of 6 months after which a further treatment holiday should be trialled.

Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. of the SPC

Cautions for Use

Autoimmune disease (manufacturer advises avoid—no information available). Pregnancy and breastfeeding – avoid.
Circadin may cause drowsiness. Therefore,the product should be used with caution if the effects of drowsiness are likely to be associated with a risk to safety.

Circadin contains lactose. Patients with rare hereditary problems of galactose intolerance, the LAPP lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Side Effects

Uncommon (≥1/1,000 to <1/100): Abdominal pain; abnormal dreams; anxiety; chest pain; dizziness; dry mouth; dry skin; dyspepsia; glycosuria; headache; hypertension; irritability; malaise; mouth ulceration; nausea; nervousness; proteinuria; pruritus; rash; restlessness; weight gain.

This is not an exhaustive list of side effects, cautions, contra-indications or interactions please refer to the BNF or Summary of Product Characteristics for more information.

Midlands and Lancashire Commissioning Support Unit,
Jubilee House, Lancashire Business Park, Leyland, PR26 6TR
Tel: 01772 644 400 | www.midlandsandlancashirecsu.nhs.uk

Version: 1.1
Date: June 2022
Review Date: June 2025

Acknowledgements to Lancashire and South Cumbria NHS Foundation Trust