Herefordshire and Worcestershire Medicines and Prescribing Committee

NHS
Herefordshire and Worcestershire
Clinical Commissioning Group

Melatonin Prescribing Position Statement

Key Points

- All patients should be counselled that they will need to use the melatonin **for short term use** to get back into a good sleep regime and then stop, or at least take regular treatment breaks.
- Sleep Hygiene measures should be tried before prescribing. If ineffective alone, sleep hygiene must continue as well as any agreed further treatment.
- Evidence of beneficial effect is limited mostly showing moderate benefit in initiating sleep. Melatonin is expensive. Consider cost vs benefit carefully before commencing prescribing.
- First prescribing choice should be Circadin®, either whole (MR) or crushed (immediate release or swallowing issues).
- Any liquid melatonin prescribed will be more expensive than solid dosage form.
- Review of benefits and treatment breaks are essential to ensure ongoing need. Longer term use needs a break and review of effect at least annually (see below).

Information

- Generic drug name: MELATONIN
- Melatonin should only be used in conjunction with sleep hygiene measures in order to restore the normal circadian rhythm of sleep (if sleep hygiene has not proven to be adequate alone).
- Licensed formulations:
    - 2mg modified-release tablets (Circadin®). Circadin® brand is licensed in UK for adults over 55 for 13 weeks.
    - 1mg and 5mg modified release tablets (Slenyto®). ONLY recommended for use in Herefordshire and Worcestershire for children who cannot tolerate crushed tablets and who would otherwise be prescribed liquid.
    - Colonis 3mg tablets and liquid 1mg/ml. NOT recommended for use in Herefordshire and Worcestershire.
- NICE does not recommend the use of melatonin in people with dementia.
- A recently licensed indication for melatonin for treating Jet lag (Colonis Pharma Ltd 3mg tabs and 1mg/ml liquid) is NOT an approved NHS use within Herefordshire and Worcestershire and therefore this indication is included within the Do Not Prescribe List.
    - The liquid contains sorbitol and propylene glycol which may cause abdominal pain and diarrhoea in some children.
    - Prescribing melatonin liquid 1mg/ml in primary care will lead to Colonis liquid being dispensed as it is the only licensed liquid available at that strength.
    - If an unlicensed melatonin liquid is required, community pharmacists may request confirmation from the prescriber of the intention for an unlicensed product to be dispensed, before it can be ordered from their wholesaler.
- As a more cost effective alternative to the prescribing of a liquid melatonin preparation:
    - Crushed Circadin® is encouraged to be used where immediate release characteristics are required, or where swallowing difficulties are identified. Note that crushing the tablet renders it unlicensed, and patients/carers should be made aware of this.
    - There have been no reports of problems with crushed Circadin® for use with a gastrostomy.

Sleep Problems in Adults

- All patients should receive sleep hygiene advice (as appropriate to the person's cognitive ability) and should try using it for at least four weeks before receiving a prescription.
- There is insufficient evidence to assess the effectiveness of sleep hygiene as a single intervention; however its use is widely supported by expert opinion in current literature and guidelines. https://bestpractice.bmj.com/topics/en-gb/227
- A sleep hygiene sheet is available from www.choiceandmedication.org/worcestershire/generate/handyfactsheetsleephygiene.pdf
- If someone has a diagnosis of dementia and has a continuing sleep problem, refer them to your local secondary care community mental health team.
- Sleep apps can be accessed in the NHS app library: https://www.nhs.uk/apps-library/category/sleep/

Sleep Problems in Children

- Most involve difficulties initiating and maintaining sleep because of behavioural insomnia of childhood (sleep association and/or limit-setting disorder), for which sleep hygiene measures should be implemented.
- Neurodevelopmental difficulties such as Autistic Spectrum Disorder and Attention Deficit Hyperactivity Disorder are commonly associated with sleep problems.
- Some sleep problems are due to sleep apnoea, which should be treated where possible before commencing melatonin.
- Refer to the BMJ Best Practice guide for further information https://bestpractice.bmj.com/topics/en-gb/781
- Sleep hygiene measures must have been tried. Early Intervention Family Support services can help families to implement sleep hygiene routines.

Evidence for Effectiveness

- Is limited for melatonin and prescribing costs are significant (www.cks.nice.org.uk/insomnia).
- In 2020, around £1.2 million was spent in Herefordshire and Worcestershire. We spend more than most CCGs in England.
- Limited evidence suggests up to an average of only 15-20 minutes benefit may be observed, for this expensive medication. www.nice.org.uk/advice/esuom2/chapter/Key-points-from-the-evidence
- Melatonin appears to help most with improving the timing of onset of sleep rather than length of sleep.

Cautions and Contraindications

- See SmPC www.medicines.org.uk/emc

Typical Doses

- Recommended starting dose: 2mg once daily, 1-2 hours before bedtime and after food. (Commonly, 1 hour when crushed, 2 hours when taken whole as a modified release preparation.)
- Sleep hygiene is essential. Ask the patient, family or carers to use it alongside the melatonin.
- Usual response time: 7 – 14 days.
- After an appropriate time period, specialists may recommend a higher dose if no response. Doses are typically lower than 6mg per day.
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Undesirable Effects

- Melatonin is generally well tolerated with only a few adverse side-effects having been reported. Most commonly reported side-effects include sleepiness, tiredness, mood swings, headache, irritability, aggression and feeling hungover.
- For less common side effects, see SmPC. www.medicines.org.uk/emc

Review Period and Treatment Break

- All patients should be counselled that they will need to use the melatonin to get back into a good sleep regime and then stop, or at least take regular treatment breaks.
- "Treatment breaks" are an important component of prescribing this product, and best practice supports the use of treatment breaks.
- Stopping melatonin does not mean that it will be less effective when restarting.
- From local specialist experience; when restarting melatonin, a slightly lower dose may be as effective as that which was last used.
- If the patient has been using sleep hygiene techniques, these will probably have been working better than the melatonin.

Adults over 55	All other patients
• Review at 3 weeks. • If effective at that point, melatonin can be continued for a further 10 weeks then stopped. • In patients with dementia, it would not be expected that melatonin would be prescribed for longer than 3 months. This is because this is the average time that most behavioural and psychological symptoms persist in dementia.	• First review should occur within 3 months, and stop if no clinical benefit. Then review at least once every year. • The yearly review should incorporate at least a week's break. If there is no change in sleep onset, morning wake time or quality of sleep during this break, then melatonin should be stopped.

Table 1

Treatment Breaks
• Ensure breaks happen at least once a year. • Pick a time that is least stressful for carers e.g. school holidays, no big events planned. • It is not absolutely vital that the break is carried out 12 monthly, so if it is carried out at 9 months or 14 months, that will be fine. • The break can happen at any dose. No titration is necessary. • If there is no clear benefit, the melatonin can be stopped. • Consider using a rating scale for the quality of sleep before and after the treatment break, for example the NHS sleep self assessment. https://www.nhs.uk/conditions/insomnia • If it decided to restart the melatonin: Clinicians have found that melatonin can be more effective when it is restarted after a break, so consider restarting at a lower dose.

Table 2

Use in ICU

Melatonin 2mg MR may be used in Intensive care to improve synchronisation of the circadian system and promote a normal sleep pattern.

Diurnal sleep patterns have been reported to be consistently or periodically disturbed in 65-75% of critical care patients, and melatonin secretion is reduced in patients in critical care, especially those on mechanical ventilation, with the normal nocturnal peak absent or flattened.

Use should **be reviewed before discharge from hospital** or after 3 weeks.

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