

## MELATONIN CONSENSUS STATEMENT FOR PRESCRIBING IN GLOUCESTERSHIRE

(Oct 2019 v2.1)

### KEY POINTS

1. Sleep Hygiene measures are essential to be tried before prescribing. If ineffective alone, they must continue as well as any agreed further treatment.
2. Evidence of beneficial effect is limited. Melatonin is expensive. Consider cost vs benefit carefully before commencing prescribing.
3. First prescribing choice should be Circadin®, either whole (MR) or crushed (immediate release or swallowing issues).
4. Any liquid melatonin prescribed will be more expensive than solid dosage form.
5. 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®). **NOT recommended for use in Gloucestershire.**
  - Colonis 3mg tablets and liquid 1mg/ml. **NOT recommended for use in Gloucestershire.**
- 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 Gloucestershire 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 in primary care will lead to Colonis liquid being dispensed as it is the only licensed liquid available.
  - If an unlicensed melatonin liquid is required, some 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 Circadian](#) is encouraged to be used where immediate release characteristics are required, or where swallowing difficulties are identified.
  - In Gloucestershire, 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 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/2gether/generate/handyfactsheetsleephygiene.pdf](http://www.choiceandmedication.org/2gether/generate/handyfactsheetsleephygiene.pdf)
- A sleep workbook is available from [https://g-care.glos.nhs.uk/pathway/571/resource/7#chapter\\_7079](https://g-care.glos.nhs.uk/pathway/571/resource/7#chapter_7079)
- If someone has a diagnosis of dementia and has a sleep problem, refer them to your local community dementia nurse. [2gnft.CDN-Inbox@nhs.net](mailto:2gnft.CDN-Inbox@nhs.net)
- 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.
- Some 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>

## EVIDENCE FOR EFFECTIVENESS

- Is limited for melatonin and prescribing costs are significant ([www.cks.nice.org.uk/insomnia](http://www.cks.nice.org.uk/insomnia)).
- In 2018, around £500,000 was spent in Gloucestershire. 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](http://www.nice.org.uk/advice/esuom2/chapter/Key-points-from-the-evidence)

## CAUTIONS AND CONTRAINDICATIONS

- See SmPC [www.medicines.org.uk/emc](http://www.medicines.org.uk/emc)

## TYPICAL DOSES

- Recommended starting dose (adults): 2mg once daily, ½ - 1 hour before bedtime and after food.
  - Specialists may recommend higher doses.
- Sleep hygiene is essential. Ask the patient, family or carers to use it alongside the melatonin.
- Usual response time: 7 days.

## 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](http://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 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	For all other patients
<ul style="list-style-type: none"><li>• Review at 3 weeks.</li><li>• If effective at that point, melatonin can be continued for a further 10 weeks then stopped.</li><li>• If diagnosis of dementia, refer to community dementia nurse for review and possible sleep hygiene techniques. <a href="mailto:2gnft.CDN-Inbox@nhs.net">2gnft.CDN-Inbox@nhs.net</a></li><li>• In patients with dementia, it would not be expected that melatonin would be prescribed for longer than 4 months.</li></ul>	<ul style="list-style-type: none"><li>• First review should occur within 3 months, and stop if no clinical benefit. Then review at least once every year.</li><li>• 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 not be restarted.</li></ul>

- **If patients are able to use sleep hygiene measures but choose not to, then melatonin should not continue to be prescribed.**

## REFERENCES

1. [www.medicines.org.uk/emc/product/2809/smpc](http://www.medicines.org.uk/emc/product/2809/smpc)
2. [www.medicines.org.uk/emc/product/10024/smpc](http://www.medicines.org.uk/emc/product/10024/smpc)
3. [www.cks.nice.org.uk/insomnia](http://www.cks.nice.org.uk/insomnia)
4. Gloucestershire Health Community draft Melatonin Shared Care Guideline for children with neurological and/or behavioural problems.
5. [www.ema.europa.eu/en/medicines/human/EPAR/slenyto](http://www.ema.europa.eu/en/medicines/human/EPAR/slenyto)
6. British Association for Psychopharmacology consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders. *Journal of Psychopharmacology*. 24(11) 1577–1600
7. The Maudsley Prescribing Guidelines. 13<sup>th</sup> Edition./ Abel, KM; Taylor, D; Duncan, D; McConnell, H; Kerwin, R.