

# Lincolnshire Prescribing and Clinical Effectiveness Bulletin – Melatonin - Recommendation for Prescribers Vol 13 No 8

Optum in association with Lincolnshire Clinical Commissioning Groups, Lincolnshire Community Health Services, United Lincolnshire Hospitals Trust and Lincolnshire Partnership Foundation Trust

## Melatonin- PACEF Recommendation for Prescribers

### Background

The following melatonin preparations have recently been licensed:

- Melatonin prolonged release 1mg and 5mg tablets (Slenyto<sup>®</sup>, Flynn Pharma) are licensed for the treatment of insomnia in children and adolescents aged 2 to 18 years with Autism Spectrum Disorder (ASD) and/or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient. **Approved for inclusion on the formulary as Amber 1**
- Melatonin 3mg film coated tablet and melatonin 1mg/1ml oral solution (Colonis Pharma Ltd). Colonis brands of generic melatonin are licensed for short-term treatment of jet-lag in adults. **Rejected for inclusion on the formulary, Red/Red drug.**

**According to Colonis Pharma Ltd, the safety and efficacy of their melatonin 3mg tablet and 1mg/1ml oral solution in children and adolescents aged 0 – 18 years have not been established and should not be used in children and adolescents due to safety and efficacy concerns.**

Bio-melatonin<sup>®</sup> and other unlicensed melatonin tablets/capsules are no longer recommended where the patient fits the criteria for the licensed alternative preparation. Pharmacies may also return prescriptions for unlicensed preparations unless the prescriber can indicate (by a letter) the special clinical need for the preparation.

This recommendation has been produced to support prescribers with the review of their patients. **The melatonin shared care agreement will be updated in line with this recommendation.**

## Patient Review

1. Review all prescribing of melatonin for adult patients. Lincolnshire does not support prescribing of melatonin for adults in primary care except Circadin<sup>®</sup> MR 2mg tablets for its licensed indication- as monotherapy for the short-term treatment (**13 weeks**) of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over.
2. Do not prescribe melatonin for the management of jetlag on the NHS within Lincolnshire (adults or children).
3. Review all prescribing of melatonin for children and adolescent against the treatment options listed below to ensure licensed products are prescribed where appropriate.

It is recommended that all children and adolescent taking melatonin should be reviewed regularly (every 6 months) and assessed for continued need.

**All reviews should be patient centred and decisions should be made in conjunction with the patient/guardian.**

### **Option A: Prescribed indication meets Slenyto<sup>®</sup> licensed indication and dose:**

Indication: Insomnia in children and adolescents with autism spectrum disorder and/or Smith-Magenis syndrome, where sleep hygiene measures are insufficient.

Dose: 2mg, 5mg or 10mg at night (30-60 minutes before bedtime).

**Switch to equivalent dose of licensed Slenyto<sup>®</sup> MR (1mg or 5mg) tablets.**

**Option B: Prescribed indication does not meet Slenyto<sup>®</sup> licensed indication and dose; and patient can take tablets:**

**Switch to equivalent dose of licensed Circadin<sup>®</sup> MR 2mg tablets (off-label).**

**Option C: Prescribed indication does not meet Slenyto<sup>®</sup> licensed indication and dose; but patient cannot take tablets or Circadin<sup>®</sup> MR tablets:**

**Switch to equivalent dose of “Melatonin 10mg/5ml oral suspension (AF and SF)” [unlicensed];**

**Please add “Alcohol and Sugar Free” to the dose (e.g. 2.5ml ON, alcohol and sugar free)**

**Option D: Patient has been assessed and none of the above three options is deemed to be appropriate; GP to consider contacting the community paediatric service for advice. If a prescription for unlicensed melatonin is required, prescriber may need to provide a letter of “special clinical need” along with the prescription.**

**See the flowchart below**

## Melatonin- PACEF Recommendation for Prescribers

### Review All Prescribing Of Melatonin For Continued Need

Paediatric patients who have been prescribed melatonin continuously for more than 6 months should have a trial discontinuation, to assess for continued need.

Paediatric patients and continued need is confirmed

Adult patients

Does prescribed indication meet Slenyto<sup>®</sup> licensed indication and dose; **and patient can take tablets?**

**Indication:** Insomnia in children and adolescents with autism spectrum disorder and/or Smith-Magenis syndrome, where sleep hygiene measures are insufficient.

**Dose:** 2mg, 5mg or 10mg at night (30-60 minutes before bedtime)

Lincolnshire **does not** support prescribing of melatonin for adults in primary care **except** Circadin<sup>®</sup> MR 2mg tablets for its licensed indication- as monotherapy for the short-term treatment (**13 weeks**) of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over.

**YES**

**(Option A)**

Switch to equivalent dose of licensed **Slenyto<sup>®</sup> MR** (1mg or 5mg) tablets

**NO**

Patient can take tablets

**(Option B)**

Switch to equivalent dose of licensed **Circadin<sup>®</sup> MR** 2mg tablets (off-

Patient cannot take tablets or Circadin<sup>®</sup>

**(Option C)**

Switch to equivalent dose of **Melatonin 10mg/5ml oral suspension** “(Alcohol and Sugar free)” [unlicensed]; Please add “**Alcohol and Sugar Free**” to the dose (e.g. 2.5ml ON, alcohol and sugar free)

None of the other three options is deemed appropriate for patients. **(Option D)**

GP to consider contacting the community paediatric service for advice. If a prescription for unlicensed melatonin is required, prescriber may need to provide a letter of “special clinical need” along with the prescription.

You may refer complex patients to the Community Paediatricians for review.

## References

1. NHSBSA: Drug Tariff, August 2019:  
<https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff>
2. Flynn Pharma, Slenyto<sup>®</sup> 1mg and 5mg modified release tablets SPC, Feb 2019:  
<https://www.medicines.org.uk/emc/search?q=%22Slenyto%22>
3. Colonis Pharm, Melatonin 1mg/1ml oral solution SPC, June 2019:  
<https://www.medicines.org.uk/emc/product/10419/smpc>
4. Colonis Pharm, Melatonin 3mg tablet SPC, April 2019:  
<https://www.medicines.org.uk/emc/product/10405/smpc>
5. Flynn Pharma, Circadin<sup>®</sup> 2mg modified release tablets SPC, May 2018:  
<https://www.medicines.org.uk/emc/product/2809/smpc>
6. Lincolnshire Joint Formulary:  
<http://www.lincolnshirejointformulary.nhs.uk/chaptersSubDetails.asp?FormularySectionID=4&SubSectionRef=04.01.01&SubSectionID=A100&drugmatch=3181#3181>
7. Royal Pharmaceutical Society (RPS), Prescribing Specials, Apr 2016:  
<https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/toolkit/professional-standards---prescribing-specials.pdf>
8. Prescribing data (ePACT2)

Produced by:  
Medicines Management & Optimisation Service  
Optum Health Systems Support  
August 2019



T 020 7121 0560 | E [info@optum.co.uk](mailto:info@optum.co.uk) | [optum.co.uk](http://optum.co.uk)

10th Floor, 5 Merchant Square, Paddington, London, W2 1AS

Optum<sup>®</sup> is a registered trademark of Optum, Inc. in the U.S. and other jurisdictions. All other brand or product names are trademarks or registered marks and the property of their respective owners. Because we are continuously improving our products and services, Optum reserves the right to change specifications without prior notice. Optum is an equal opportunity employer.

© 2017 Optum, Inc. All rights reserved.