Melatonin for the management of Sleep – Wake Disorders in Children and Young People

Shared Care Guidance

Introduction

Indication
For the treatment of sleep-wake cycle disorders in children and young people with the aims of improving the onset and duration of sleep and establishing a regular nocturnal sleep pattern where non-pharmacological treatments have failed or are inappropriate.

Treatment with melatonin should be initiated and supervised by a specialist but may be continued by general practitioners under a shared-care arrangement **for an initial period of up to 2 years, before a formal review of treatment is required by secondary care and renewal of shared care agreement.**

Dose
For children and young adults aged 2 to 18 years: **2mg** recommended starting dose - see individual formulation
Dose increases can be made according to clinical response, up to a maximum of **10mg/day**.
Give ~ 1 hour before bedtime.

Duration
If no improvement observed within 3 months, review and consider withdrawing treatment. Further review with specialist every 6-12 months. Melatonin can be stopped suddenly without any side effects.

Formulary Preparations

Status	Preparation	Indication	Comments
First line – for licensed indication only	Slenyto® Melatonin 1mg and 5mg prolonged release tablets	Autism Spectrum Disorder (ASD) and/or Smith-Magenis syndrome only - where sleep hygiene measures have been insufficient. **Licensed use**	Tablets are very small in size (3mm) – can mix whole with yoghurt, orange juice or ice cream to aid swallowing then take immediately

First line -for all other indications	Adaflex ® Melatonin 1mg,2mg,3mg, 4mg and 5mg tablet	Attention deficit hyperactivity disorder (ADHD) in children and adolescents aged 6-17 years where sleep hygiene measures have been insufficient **Licensed use.** All other indications (**off-label use of a licensed product**)	Tablets are licensed to be crushed before administration and taken with water
Second line – only use if crushed tablets have been trialed first and are unsuitable**.**	Melatonin 1mg/1ml oral solution (alcohol-free) *Not suitable for use in under 5's due to propylene glycol content. Consider Slenyto® off label use in this patient group.	**Off label use of a licensed product** in children/young people	Community pharmacies will provide Colonis® brand for a prescription for melatonin liquid, based on the current Drug Tariff.

Please note :
Circadin ® (melatonin MR 2mg) should be used in the following exceptional circumstances- for children and young people who are:

- Currently stabilised on Circadin ® (melatonin MR 2mg) with existing shared care agreements in place, and who are unable or not suitable to switch to an alternative licensed preparation of melatonin
- Administered melatonin via enteral feeding tubes (unlicensed route but accepted practice and supported by The NEWT guidelines for administration of medication to patients with enteral feeding tubes or swallowing difficulties)

Specialist Responsibilities	• Assessing suitability of patients for initial and continuation of treatment • Discuss treatment options with the patient, their parent(s) and carer(s), to include explanation and recording of the off-label nature of melatonin where applicable. See Medicines for Children leaflet: Melatonin for sleep problems http://www.medicinesforchildren.org.uk/melatonin-for-sleep-ddisorders • Ensure that appropriate sleep hygiene measures are established. • If child struggling with sleep onset despite above measures, only then initiate Melatonin. • During first 3 months review effectiveness and adjust dose as necessary to improve sleep onset. • After **3 months**, review efficacy – stop if no benefit • If satisfactory effectiveness is reached and treatment is to continue, arrange shared care with patient's GP • Provide the GP with relevant information for each patient including treatment to be undertaken by GP • Assess and monitor patients' continued response and tolerability to treatment every **6-12 months,** with sleep hygiene advice, giving regular medication breaks to prevent tolerance, consider whether the melatonin dose could be **reduced,** or medication **stopped**. Advise GP on suitable reduction plan if indicated. • Conduct formal review after **2 years** of treatment from initiation and

	request renewal of shared care agreement with GP. Request to include clear rationale for continuing treatment as well as evidence of a least one treatment break trial annually. • Report any suspected ADRs to CSM via Yellow Card system. • Provide contact details of prescriber/specialist team on referral (telephone and email) for access to future advice, where needed
Primary Care Responsibilities	• Prescribe melatonin in line with shared care agreement • Report any adverse effects to specialist and regulatory bodies i.e., CSM via Yellow Card process • Seek advice from specialist team if concerns with the treatment plan • Inform specialist team if treatment is stopped or patient is non-concordant
Adverse Effects, Precautions, Contraindications	**Contraindications** Hypersensitivity to the active substance or to any of the excipients **Precautions** Melatonin may cause drowsiness and should be used with caution if the effects of drowsiness are likely to be associated with a risk to safety. Use with caution in children with epilepsy – monitor seizure frequency. There is a lack of information on use of melatonin in patients with hepatic, renal or autoimmune disorders or the use in patients who are pregnant or breastfeeding. Melatonin can be stopped suddenly without any side effects. **Adverse Effects** Melatonin is **well tolerated** in children but those adverse events that have been reported rarely include daytime drowsiness, headache, and dizziness, a reduction in body temperature, transient depressive symptoms, mild tremor, mild anxiety, abdominal cramps, irritability, confusion, nausea and hypotension.
Common Drug Interactions	Few interactions have been reported including: Cimetidine can increase plasma concentration of melatonin Fluvoxamine can significantly increase plasma concentrations of melatonin - avoid concomitant use Oestrogens can increase the plasma concentration of melatonin Ciprofloxacin and other quinolones - can increase melatonin levels Carbamazepine and rifampicin can reduce the plasma levels of melatonin Other hypnotics and CNS depressants: melatonin may enhance the sedative properties of other drugs acting on the CNS e.g., benzodiazepines
Communication/Contact Details	Prescriber/specialist team contact details will be stated on the shared care agreement.

This information is not inclusive of all prescribing information and potential adverse effects. Please refer to full prescribing data in the Summary of Product Characteristics www.emc.org or the BNF/eBNF

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Melatonin - Shared Care Request/Confirmation

- Specialist Prescriber to complete first section of form and send to patient's GP.
- GP to complete second section of form and return to specialist prescriber within 28 days
- A copy of the full shared care guideline can be viewed at:

http://www.northoftyneapc.nhs.uk/guidance/

https://www.sunderlandccg.nhs.uk/about- us/prescribing/shared-care-green-plus/

Specialist Prescriber				
Department				
Hospital				
Telephone				
Email address				
Patient details (use hospital label if preferred)				
Name				
Address				
Postcode				
NHS Number		**Male / Female**	**DoB**	

Treatment Requested for Prescribing in Accordance with an Approved Shared Care Arrangement			
Drug Information – Melatonin			
Formulation (delete as appropriate)	**Slenyto / Adaflex / Adaflex crushed / Liquid 1mg/ml alcohol free* / Crushed Slenyto*** *confirm Adaflex trialed first* ☐ **/Crushed Circadin ® (melatonin MR 2mg)** *for administration via enteral feeding tube*	**Dose and frequency**	
Indication – For the Management of Sleep – Wake Disorders in Children and Young People **Date of initiation:**			
Other information (if appropriate)			

Signed (Specialist Prescriber)		**Name (Print)**		**Date**	

To be completed by GP	**Please tick one box**
I ACCEPT the proposed shared care arrangement for this patient	❑
I ACCEPT the proposed shared care arrangement with the caveats below	❑
I DO NOT ACCEPT the proposed shared care arrangement for this patient	❑
My caveats/reason(s) for not accepting include:	

Signed		**Name (print)**		**Date**	

N.B. Participation in this shared care arrangement implies that prescribing responsibility is shared between the specialist prescriber and the patient's GP

Private and Confidential

Melatonin - Shared Care Renewal request/confirmation

- **This form is to be used to request extension of shared care after 2 years of initial treatment**
- Specialist Prescriber to complete first section of form and send to patient's GP.
- GP to complete second section of form and return to specialist prescriber within 28 days

A copy of the full shared care guideline can be viewed at:
http://www.northoftyneapc.nhs.uk/guidance/
https://www.sunderlandccg.nhs.uk/about- us/prescribing/shared-care-green-plus/

Specialist Prescriber				
Department				
Hospital				
Telephone				
Email address				
Patient details (use hospital label if preferred)				
Name				
Address				
Postcode				
NHS number		**Male / Female**	**DoB**	

Treatment continuation for Melatonin shared care arrangement (after 2 years initial treatment)					
Rationale for treatment continuation: **Date(s) and duration(s) of treatment breaks:**					
Signed (Specialist Prescriber)		**Name (Print)**		**Date**	

To be completed by GP	**Please tick one box**
I ACCEPT the proposed shared care renewal for this patient	❑
I ACCEPT the proposed shared care renewal with the caveats below	❑
I DO NOT ACCEPT the proposed shared care renewal for this patient	❑
My caveats/reason(s) for not accepting include:	

Signed		**Name (print)**		**Date**	

N.B. Participation in this shared care arrangement implies that prescribing responsibility is shared between the specialist prescriber and the patient's GP