City Hospitals Sunderland NHS
NHS Foundation Trust

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Clinical Commissioning Group

SHARED CARE GUIDELINE

Melatonin for the Management of Sleep – Wake Disorders in Children and Young People (CYP)

Implementation Date: November 2017 **Review Date: November 2019**

This guidance has been prepared and approved for use within Sunderland in consultation within the CCG, and Secondary Care Trusts.
The guideline sets out the details of the transfer of prescribing and respective responsibilities of GPs and specialist services within shared care prescribing arrangements. It is intended to provide sufficient information to allow GPs to prescribe this treatment within a shared care setting

Approved by:

Committee	Date
Medicines optimisation and guidelines group	**October 2017**
Sunderland Joint formulary committee	**November 2017**

Instructions for completion:

- ☐ Consultant to counsel patient on medication and ensure patient has been provided with information leaflet
- ☐ Consultant to ensure all clinical details completed on this document
- ☐ Consultant to ensure patient understands proposed monitoring and prescribing arrangements if a shared care agreement is entered into
- ☐ GP to complete final section of form and return to specialist prescriber within 28 days
- ☐ GP to retain copy of document on patient record within surgery

Clinical details:

SHARED CARE GUIDELINE					
Non-proprietary name	Melatonin	Brand name	Circadin® modified release tablets	Licensed Y/N?	N
Dosage form and strength	Available: Modified release tablets (Circadin®) 2mg, Oral solution 1mg/ml Order of choice: 1. Melatonin 2mg Modified Release (MR) tablets 2. For patients who cannot take whole tablets or for patients who require a more immediate effect, the MR tablets should be crushed. These can be administered with a spoonful of milk, yoghurt or jam. Crushing destroys the coating on the tablets and removes their prolonged release properties. NB. Crushing the MR tablets is out with the terms of the product license 3. Consider melatonin oral solution 1mg/ml (as per Drug Tariff) Only for use if the licensed form of melatonin MR (Circadin) cannot meet the clinical needs of the patient as described above. Any other preparation not included in the formulary may be considered on a case by case basis Cost (as per drug tariff May 2017): • 2mg modified release tablets (Circadin) £15.39 per 30 • Oral solution 1mg/ml - £52.40 per 200ml			BNF class	4.1.1 NB: This is an off-label use of melatonin. Licenced in adults aged over 55 yrs.
Indication	For the treatment of sleep-wake cycle disorders in children and young adults. With the aims of improving the onset and duration of sleep and establishing a regular nocturnal sleep pattern.				
Dosage and Administration	• For children aged from 1 to 18 years an initial dose of 2 – 3mg is recommended. • Immediate release preparations (oral solution or crushed modified release tablets) should be taken 30 – 60 minutes before bedtime and modified release tablets should be given after food, 1 – 2 hours before bedtime. • In the absence of improvement after 1 – 2 weeks the dose can be increased to 4 – 6 mg at night. It is often useful to give the patient acceptable dose range for self-titration. • The maximum dose is generally accepted to be 10mg but higher doses have been used. Treatment				

	should be stopped in those that fail to demonstrate a response to the maximum dose. • May be possible to withdraw the drug after 6 months when a regular sleep pattern has been established • Melatonin can be stopped suddenly without any side effects.
Eligibility criteria for shared care	Initiated by specialist prescriber and eligible for shared care (AMBER) following dose and drug stabilisation for at least 1 month.
Excluded patients	• Hypersensitivity to the active substance or to any of the excipients • In adults (≥18 years) Melatonin is a GREEN PLUS drug and so can be prescribed by GPs without specialist involvement.
Initiation	Initiation of treatment will take place in secondary care
Specialist Responsibilities	• Assessing suitability of patients for treatment • Discuss the treatment options with the patient, their parent(s) and carer(s), to include explanation of the off-label use of melatonin in CYP. • Initiation and supply of one month's melatonin to ensure continuity of supply while arranging shared care. • Arrange shared care with patient's GP (suitable dose range to be included in shared care agreement) • Assess and monitor patient's response to treatment and the need to continue therapy on a 6-12 monthly basis. • Discuss and consider a 2 week withdrawal on an annual basis with CYP and family to assess need for ongoing treatment. • Monitor physical health –height, weight and sexual development. • Provide the GP with relevant information for each patient including treatment to be undertaken by GP, monitoring to be undertaken by specialist. • Report any suspected ADRs to CSM via Yellow Card system. • Discontinuation – advise discontinuation of melatonin if no improvement in symptoms seen after a reasonable trial. • Provide GP with any further advice if required
GP Responsibilities	• Prescribe medication after specialist initiation. Medication should be prescribed at lowest effective dose within dose range outlined by specialist • Report any adverse effects to specialist and regulatory bodies i.e. CSM via Yellow Card process • Liaison with consultant regarding any complications of treatment • Ask the specialist to take back the prescribing should unmanageable problems arise
Adverse Effects, Precautions and Contraindications	<u>Adverse effects:</u> No very common or common side effects have been reported. Melatonin is well tolerated in children but those adverse events that have been reported rarely include: daytime drowsiness, unusual dreams, headache, and dizziness, a reduction in body temperature, transient depressive symptoms, mild tremor, mild anxiety, abdominal cramps, irritability, confusion, nausea and hypotension. <u>Contra-indications:</u> Known hypersensitivity to the product. Pregnancy. Breast Feeding. Rare hereditary problems of galactose intolerance, LAPP lactase deficiency or glucose-galactose malabsorption (Circadin contains lactose) <u>Cautions:</u> • Should be used with caution in children with epilepsy, seizure frequency should be monitored. • Hepatic impairment, cerebrovascular disease.
Common Drug Interactions	Few interactions have been reported including: • Fluvoxamine: can significantly increase melatonin levels • Ciprofloxacin and other quinolones: can increase melatonin levels • Other hypnotics and CNS depressants: melatonin may enhance the sedative properties of other drugs acting on the CNS e.g. benzodiazepines • Warfarin: INR may be increased. Melatonin may also increase the anticoagulant effect of other drugs with anticoagulant / antiplatelet properties • Nifedipine: Melatonin can increase BP and HR in patients treated with nifedipine • Herbal remedies: those with anti-coagulant / antiplatelet (eg. ginkgo biloba, ginseng) or sedative properties (eg. St John's Wort, valerian) may also enhance the effects of melatonin
Communication/ Contact Details	Sunderland Royal Hospital - Ask for named consultant - 0191 5656256 Monkwearmouth Hospital – Ask for named consultant - 0191 5665500

This information is not inclusive of all prescribing information and potential adverse effects. Please refer to full prescribing data in the SPC or the BNF.

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Shared Care Request/Confirmation

Private and Confidential

Patient information:

To be completed by specialist prescriber:

Consultant ……	**Patient details (use hospital label if preferred)**
Department ……	**Name** ……
Hospital ……	**Address** ……
	……
	Postcode ..... **Sex** ……..
	NHS or Hosp. Reg. No. …… **DoB** ……..

Treatment Requested for Prescribing in Accordance with Shared Care Arrangement:

To be completed by specialist prescriber:

Drug name	
Dose	
Frequency	
Indication	
Other information	

Name (print)…… Signature (of specialist prescriber)…….…….. Date……..

Acceptance/rejection of treatment under Shared Care Agreement:

To be completed by GP:

Please tick one box

I ACCEPT the proposed shared care arrangement for this patient ❑

or

I ACCEPT the proposed shared care arrangement with the caveats below ❑

or

I DO NOT ACCEPT the proposed shared care arrangement for this patient ❑

My caveats / reason(s) for not accepting include: ……
……

Name (print)…….…. Signature (of GP)…….……..... Date….

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