NHS
Newcastle Gateshead
Clinical Commissioning Group

GATESHEAD SHARED CARE GUIDELINE

Melatonin for the Management of Sleep – Wake Disorders in Children

Implementation Date: April 2015
Review Date: April 2017

This guidance has been prepared and approved for use within, Gateshead in consultation within the CCG, Secondary Care Trusts and Local Medical Committees.

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 these treatments within a shared care setting

Approved by:

Committee	Date
Gateshead Medicines Management Committee	11th March 2015
Newcastle Gateshead CCG Optimisation of Medicines, Pathways and Guidelines Committee	16th April 2015

<table>
<tr><th colspan="4">SHARED CARE GUIDELINE</th></tr>
<tr><td>Non-proprietary name</td><td>Melatonin</td><td>Brand name</td><td>Circadin® modified release tables
Also UK specials manufacturers including Penn Pharmaceuticals and Special Products Ltd</td></tr>
<tr><td>Dosage form and strength</td><td>Modified release tablets (Circadin®) 2mg
Oral solution 1mg/ml</td><td>BNF class</td><td>4.1.1 NB: This is an unlicensed use of melatonin</td></tr>
<tr><td>Availability</td><td colspan="3">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 formulary but may be considered on a case by case basis</td></tr>
<tr><td>Indication</td><td colspan="3">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.</td></tr>
<tr><td>Excluded patients</td><td colspan="3">Unstable disease state, patient aged under 1 year, pregnancy or breast-feeding, Sleep disturbances due to obstructive apnoea, emotional distress or nocturnal seizures, Patients with severe allergies, auto-immune diseases or immune system cancers, patients taking immunosuppressant’s.</td></tr>
<tr><td>Eligibility criteria for shared care</td><td colspan="3">Initiated by specialist prescriber and eligible for shared care (AMBER) following dose and drug stabilisation for at least 1 month</td></tr>
<tr><td>Initiation</td><td colspan="3">Initiation of treatment will take place in secondary care</td></tr>
<tr><td>Duration of treatment</td><td colspan="3">May be possible to withdraw the drug after 6 months when a regular sleep pattern has been established</td></tr>
<tr><td>Usual maintenance dos</td><td colspan="3">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.</td></tr>
<tr><td>Maximum dose</td><td colspan="3">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.</td></tr>
<tr><td>Specialist Responsibilities</td><td colspan="3">• Assessing suitability of patients for treatment
• Discuss the treatment options with the patient, their parent(s) and carer(s), to include explanation of the unlicensed nature of</td></tr>
</table>

	melatonin. • Initiation and supply of one month's melatonin after dose has been stabilised to ensure continuity of supply while arranging shared care • Arrange shared care with patient's GP • Assess and monitor patients' response to treatment and the need to continue therapy on a 6-12 monthly basis. • 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 or melatonin if no improvement in symptoms seen after a reasonable trial advising GPs when and how a trial withdrawal of melatonin should be undertaken • Provide GP with any further advice if required
GP Responsibilities	• Prescribe Melatonin • 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
Common 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. 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.
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 might 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 Immunosuppressive therapy: melatonin can stimulate immune function and might interfere with immunosuppressive therapy.
Contra-indications	Known hypersensitivity to the product. Pregnancy (see below) Should be used with caution in children with epilepsy, seizure frequency should be monitored. Liver disease, cerebrovascular disease

Monitoring	Standard monitoring of growth and sexual development is recommended, i.e. to check height, weight and pubertal development progress as expected
Cost 28 days	Based on 2mg/day for 28 days Modified release tablets £15.39 Oral solution £88.28 supplied as 200ml melatonin 1mg/1ml as per Drug Tariff
Communication/Contact Details	For any queries relating to this patient's treatment with melatonin please contact the specialist named below.

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

CONTACTS FOR FURTHER INFORMATION

MON – FRI, 09:00 – 17:00:

Specialist Teams

Newcastle	**Benton House**	**0191 2466913**
Sunderland and Gateshead	**Monkwearmouth Hospital**	**0191-5665500**

Private and Confidential

Shared Care Request/Confirmation

- Consultant 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 day

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 an Approved Shared Care Arrangement

Drug Name	**Dose**	**Frequency**
Indication		
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 ❑

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:

……..

……..

Signed …… **Name (print)** ..... **Date** ……

(Patients GP)

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