Prescribing Guidance
MELATONIN FOR SLEEP DISORDERS IN CHILDREN AND ADOLESCENTS WITH NEURODEVELOPMENTAL DISORDERS

Melatonin is an endogenous hormone used in the treatment of persistent sleep onset disorders in children and adolescents (4-17 years inclusive) with a range of neurodevelopmental problems, including Attention Deficit Hyperactivity Disorder (ADHD) and Autism.

Melatonin (3mg to 12mg) is only indicated second-line, where non-pharmacological strategies have been tried, but sleep latency remains a significant problem.

Melatonin is not recommended for the treatment of night time waking.

Melatonin MR tablets (Circadin®) is the product of choice to prescribe in NHS DG&S CCG

The aim of this guidance is to ensure that clinicians have the necessary information available to allow them prescribe melatonin where it would be appropriate to do so and to ensure all prescribers are clear about their responsibilities. The guideline should be used in conjunction with other relevant information and recommendations provided by the consultant or specialist.

The clinician who prescribes the medication legally assumes clinical responsibility for the drug and the consequence of its use. If the prescriber feels they cannot prescribe melatonin, the specialist should be informed as soon as possible to enable appropriate arrangements to be made with the family.

IMPORTANT NOTES

- Parents, carers or older adolescents (if appropriate), may be asked to complete a sleep diary showing significant problems with sleep latency before treatment with melatonin is initiated
- If improvement in symptoms is not observed after one month, melatonin should be discontinued.
- If melatonin has successfully established a good sleep pattern, where appropriate a trial withdrawal of melatonin should be undertaken at the first, subsequent specialist review which will occur 3 to 6 months following initiation. The continuing need for melatonin should be assessed periodically by the specialist by stopping the medicine for up to two weeks each year.
- Melatonin will usually be discontinued by late adolescence (by 18 years) on the recommendation of the specialist.
- Caution is advised in children and adolescents with autoimmune, renal or hepatic disorders due to limited safety data.
AREAS OF RESPONSIBILITY

specialist responsibilities.
1. Ascertain the need for sleep onset treatment in neurodevelopmental disorders.
2. Ensure all relevant investigations are performed.
3. Prescribe melatonin (as Circadin®) as a second line treatment option where non-pharmacological strategies such as provision of sleep hygiene advice (over 3-6 months) have failed, and underlying physical causes are managed. To prescribe melatonin where parent or carer or an older adolescent has been asked to complete a sleep diary over 10 to 14 nights highlighting problems with sleep latency despite a trial of non-pharmacological strategies.
4. After an informed discussion, obtain formal, written consent from the parents or carers regarding treatment with melatonin.
5. Following informed consent, provide a 4 week supply of melatonin at an appropriate dose using Circadin® formulation
6. Contact the patient’s GP to request ongoing prescribing
7. Provide the GP with an initiation letter ideally within 14 days of seeing the patient (which includes diagnosis, relevant clinical information, baseline results, treatment to date and dose of melatonin that the patient is stabilised on, treatment plan, duration of treatment before consultant review).
8. Upon initiation or dose changes, provide parents, carers or patients (if appropriate) with information about melatonin (including potential adverse effects and action to take) in an appropriate format, usually in the form of a written leaflet. Please refer to the link http://www.medicinesforchildren.org.uk/search-for-a-leaflet/melatonin-for-sleep-disorders/ for a leaflet entitled ‘Melatonin for sleep disorders’. Advise and support parents, carers, patients (if appropriate) or older adolescents.
9. Inform the patient of the need to make an appointment with their GP within two weeks of receiving initial supply of melatonin from the specialist for review and assessment of suitability for ongoing melatonin prescriptions.
10. Review patients where appropriate 3-6 months after initiation of melatonin and 6-12 months thereafter in order to assess the benefits of continued treatment. A trial withdrawal should be considered at each medication review. Results of any review must be communicated promptly to the GP.
11. Take back care of the patient should the GP feel unable to continue to manage the prescribing of melatonin.
12. Provide advice to the GP if they have clinical queries relating to the condition or use of melatonin.
13. Notify the GP of the patient’s failure to attend appointments and give advice on stopping the medication.
14. Take responsibility for stopping melatonin or to agree aftercare when the patient reaches 18 years of age.

GP responsibilities
1. Initial referral to secondary care in line with the referral criteria.
2. Inform the specialist, within three weeks of receiving the request to prescribe, if unwilling to do so.
3. Assess the effectiveness of the initial 4 weeks supply of melatonin before providing further repeat prescriptions. (It is recommended that no more than one month’s prescription should be issued at a time). Inform specialist if melatonin is discontinued. 
   Template questions for review are available in Appendix 1.
4. Contact the specialist if there are ongoing sleep problems.
5. Manage adverse reactions or report to the specialist.
6. Act upon recommendations communicated by the specialist, including recommendations on stopping melatonin.

Agreed By NHS DG&S Clinical Committee

Date 12/11/13
Review Date : November 2015
7. Monitor the prescribing rate of melatonin for individual patients and report concerns to the specialist.
8. Review the appropriateness of prescribing for patients who have not been seen by a specialist for over one year.
9. Ensure all relevant staff within the practice are aware of prescribing guidance.

**Patient / Parent / Carer Responsibilities**
1. Attend appointments.
2. Complete a sleep diary if asked to do so before initiation, and during treatment to help evaluate efficacy.
3. Make an appointment with the GP **within two weeks** of receiving initial supply of melatonin from the specialist for review and assessment of suitability for ongoing melatonin prescriptions.
4. After an informed discussion, give formal, written consent regarding treatment with melatonin.
5. Adhere to instructions on the use of melatonin.
6. Inform the GP if health problems arise. To be aware of side effects and report any relevant symptoms to the GP.
7. Any serious reaction should be reported to the Commission of Human Medicines (CHM) by whoever they are highlighted to. Use the Yellow Card System to report adverse drug reactions. Yellow Cards and guidance on its use are available at the back of the British National Formulary or online at [http://yellowcard.mhra.gov.uk/](http://yellowcard.mhra.gov.uk/)

**PRODUCTS TO PRESCRIBE**

<table>
<thead>
<tr>
<th>Name of product</th>
<th>First line</th>
<th>Only if Necessary</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Melatonin 2mg Modified Release tablets (<em>Circadin®</em>)</td>
<td>Melatonin 5mg/5ml solution</td>
</tr>
<tr>
<td>Route of administration</td>
<td>Oral – may be crushed.*</td>
<td>Oral liquid.</td>
</tr>
<tr>
<td>Recommended starting dose</td>
<td>2mg once daily, 1-2 hours before bedtime and after food.</td>
<td>Initially 2-3 mg once daily.</td>
</tr>
<tr>
<td>Titration of dose</td>
<td>Increase by 2mg depending on response every 7-14 days</td>
<td>Increase by 2-3mg depending on response after 7-14 days.</td>
</tr>
<tr>
<td>Maximum dose</td>
<td>8mg</td>
<td>12mg daily but additional benefits from doses above 6 - 9mg are uncertain.</td>
</tr>
<tr>
<td>Adjunctive treatment regimen</td>
<td>Sleep hygiene (advice)</td>
<td>Sleep hygiene (advice)</td>
</tr>
</tbody>
</table>

* When crushed, the modified characteristics of *Circadin®* are lost and it acts an immediate release preparation.
Switching recommendations

It is recommended that an audit of current patients prescribed Melatonin is carried out to ensure treatment is clinically and cost effective and in line with these guidelines.

Current patients prescribed a formulation other than the preferred Circadin product should be reviewed with a view to changing to the more cost effective preferred formulation.

PRESCRIBING INFORMATION.

See Summary of Product Characteristics or product information sheet for further information.

Baseline Data and Routine Monitoring

Monitoring of height and weight is recommended.

Adverse effects

Melatonin is generally well tolerated. Sedation and fatigue, headaches, skin disorders, restlessness, increased pulse, itching and nausea have all been reported as side effects associated with melatonin use.

Cautions

Melatonin should be used with caution in patients with a history of epilepsy, asthma, autoimmune, renal or hepatic disorders.

Contra-indications

Pregnancy and breast feeding. Known hypersensitivity to melatonin or to any of its excipients.

Drug interactions

- It is advisable not to prescribe melatonin if the patient is receiving antipsychotics or antidepressants.
- Concomitant prescribing of melatonin and oral anticoagulants should be avoided.

REFERENCES

## Appendix 1 – Review questionnaire

Review Questionnaire for the effective use of Melatonin.

**Patient Name:** ……………………………

**Date of Birth:** …………………………… **NHS No:** ……………………………

**Date of medication review:** ……………………………

**Date of next medication review:** ……………………………

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>What Melatonin dose is your child taking?</td>
<td></td>
</tr>
<tr>
<td>Is your child taking any other medication to aid sleep?</td>
<td></td>
</tr>
<tr>
<td>How long has your child been taking Melatonin?</td>
<td></td>
</tr>
<tr>
<td>What time is Melatonin given?</td>
<td></td>
</tr>
<tr>
<td>What time does your child fall asleep?</td>
<td></td>
</tr>
<tr>
<td>Where does your child fall asleep?</td>
<td></td>
</tr>
<tr>
<td>Does your child remain asleep for the rest of the night?</td>
<td></td>
</tr>
</tbody>
</table>

**Outcome of Review:**

a)  **Continue the use of Melatonin**  Yes / No

**Rationale:** ……………………………………………………………………………………………
…………………………………………………………………………………………
…………………………………………………………………………………………...
………………………………………………………………………………………….

b)  **Discontinue the use of Melatonin**  Yes / No

**Rationale:** ……………………………………………………………………………………………
…………………………………………………………………………………………
…………………………………………………………………………………………...
………………………………………………………………………………………….
………………………………………………………………………………………….

---

Agreed By NHS DG&S Clinical Committee  Date 12/11/13

November 2015