

Melatonin - Paediatric Shared Care Guideline

Specialist Details

Name: _____
Location: _____
Tel: _____

Patient Identifier

Date: _____

Introduction

Melatonin is a hormone produced by the pineal gland. Its release is closely synchronized with the habitual hours of sleep.

The synchronizing effect on the circadian sleep pattern has led to the promotion of orally administered melatonin as a regulator of sleep-wake cycles, and its use for the treatment of sleep disorders in children and adolescents particularly those with behavioural or neurological problems who have chronic sleep disorders where:

Symptoms of sleep disorder have been present for at least six months or where sleep disturbance is very severe and sleep hygiene measures have failed.

Choice of preparation:

Circadin[®] Modified Release is the only melatonin product licensed in the UK although its use in children is off-label. Licensed products (even if used off-label) should be prescribed in preference to unlicensed products or specials where possible as recommended by the Medicines and Healthcare Regulatory Authority (MHRA).

Circadin[®] can be prescribed off-label in children and is the preferred first line choice.

For patients who cannot swallow solid oral dosage forms or where an immediate release effect is required, Circadin[®] tablets may be crushed (see instructions below). This removes the modified release properties and is a cost effective (though off-label) option.

Although modified release preparations are useful in patients with fragmented sleep patterns, immediate release melatonin may be more effective in children who have difficulty in getting to sleep.

Advice on crushing Circadin[®]

Circadin[®] tablets can be crushed to a fine powder and mixed with water or given with cold soft food such as a teaspoon of yoghurt or jam. Use a small amount of food to ensure the full dose is taken. The prescription should state that the medication is to be crushed prior to administration. Administration in this manner is outside the terms of the product license.

In exceptional circumstance, there may be patients for whom it is still necessary to use an unlicensed formulation. These may be expensive and the most appropriate and cost effective product should be chosen, in accordance with the individual needs of the patient. A range of strengths and formulations (including a liquid) of unlicensed melatonin are available from wholesalers / special-order manufacturers but these can vary widely in cost.

BNF for Children advises that the manufacturer of the melatonin product required should be specified because of variability in clinical effect of unlicensed formulations.

Dosage and Administration

Initially 2 - 4mg given 30 - 60 minutes before desired sleep time. If insufficient response after 7 - 10 days, increase to 6mg. In some cases doses of up to 10mg may be tried.

Hospital Specialist Responsibilities (continues overleaf)

- Diagnose the condition and assess if the patient is suitable for treatment with melatonin
- Provide patient/carer with relevant information on use, side effects and need for monitoring of medication
- Arrange shared care with patient's GP
- Provide the GP with relevant information for each patient, including:
 - Treatment to be undertaken by GP (dose, dosage titrations etc.)
 - Details of manufacturer if an unlicensed formulation is required
 - System of monitoring and recording of progress and side effects
- Monitoring of condition: Assess response to treatment and the need to continue therapy by reviewing the patient at regular intervals

Hospital Specialist Responsibilities (continued)

- Drug Monitoring: No specific monitoring is required
- Provide patient with advice and information on crushing Circadin tablets (if applicable)
- Review the treatment regularly, sending a written summary to the GP whenever the patient is reviewed
- Advise discontinuation of melatonin if no improvement in symptoms is seen after 3 months at the maximum tolerated dose
- Discontinue treatment at appropriate intervals under careful supervision – when condition is stable, to assess the need to continue medication
- Provide any other advice or information for the GP if required.

GP Responsibilities

- Prescribe melatonin (specify manufacturer as per specialist recommendation if an unlicensed formulation is required). Continued prescribing is appropriate for patients attending specialist review
- Report any adverse events to the specialist and the usual bodies (e.g. MHRA / CHM).

Adverse Effects, Precautions and Contraindications

Melatonin is well tolerated but those adverse events that have been reported rarely include: daytime drowsiness, headache, dizziness, a reduction in body temperature, transient depressive symptoms, mild tremor, mild anxiety, abdominal cramps, irritability, confusion, nausea and hypotension. May affect performance of skilled tasks (e.g. driving).

Use with caution in epilepsy – monitor seizure frequency.

There is a lack of information on use of melatonin in patients with hepatic, renal or autoimmune disorders. Use in patients who are pregnant or breastfeeding is not recommended.

Melatonin can be stopped suddenly without any side effects.

Common Drug Interactions

Few interactions have been reported including:

- 5 or 8-methoxypsoralen: exercise caution - increases melatonin levels
- Alcohol: should not be taken with melatonin, because it reduces the effectiveness of melatonin on sleep
- Cimetidine: exercise caution - increases melatonin levels
- Fluvoxamine: can significantly increase melatonin levels, the combination should be avoided
- Oestrogens: exercise caution - increases melatonin levels
- Other hypnotics and CNS depressants: melatonin may enhance the sedative properties of other drugs acting on the CNS eg. Benzodiazepines.

Communication

For any queries relating to this patient's treatment with melatonin, please contact the specialist named at the top of this document.

**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**