Health and Social Care

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Interface Pharmacist Network
Specialist Medicines

Melatonin - Paediatric Shared Care Guideline

Specialist Details	Patient Identifier
Name: _____	
Location: _____	
Tel: _____	**Date:** _____

Introduction

Melatonin is a hormone produced in the pineal gland and has activity at melatonin receptors involved in the regulation of circadian rhythms and sleep regulation.
Indications: Treatment of sleep disorders in children and adolescents (in conjunction with non-pharmacological interventions) where;
• sleep problems persist despite following the sleep plan (including sleep hygiene measures)
• sleep problems are having a negative impact on the child or young person and their family or carers

Dosage and Administration

Initially 2–3 mg daily, increased if necessary to 4–6 mg daily; maximum 10 mg per day. Should be taken 30–60 minutes before bedtime.

Manufacturers advise that modified-release tablets should be taken with or after food. Licensed immediate-release formulations should be taken on an empty stomach, 2 hours before and 2 hours after food—intake with carbohydrate-rich meals may impair blood glucose control.

Immediate release melatonin is usually preferred and may be more effective in children who have difficulty in getting to sleep. Modified release preparations may be useful in patients with fragmented sleep patterns,

The specialist will advise the most appropriate product for the patient.

See the Northern Ireland melatonin product selection guide

Hospital Specialist Responsibilities (continues overleaf)

- Diagnose the condition and assess if the patient is suitable for treatment with melatonin
- Advise the patient/ carer of their treatment plan and plan for review of this medication
- Provide patient/carer with relevant information on use and side effects of medication (e.g. Melatonin for sleep disorders – Medicines For Children)
- Arrange shared care with patient's GP
- Provide the GP with relevant information for each patient, including:
  - Treatment and product **(see NI product selection guide)** to be prescribed by GP (dose, dosage titrations, etc.)
  - System of monitoring and recording of progress and side effects
- Monitoring of condition: Assess response to treatment by reviewing the patient at regular intervals. Evaluate the ongoing need for melatonin to ensure that the benefits continue to outweigh the side effects and risks. Send a written summary to the GP whenever the patient is reviewed.
- Advise discontinuation of melatonin if no clinically relevant improvement in symptoms is seen after 3 months at the maximum tolerated dose. During ongoing treatment, especially if the treatment effect is uncertain, discontinuation attempts should be done regularly (e.g. once per year) under careful supervision.
- Drug Monitoring: No specific monitoring is required
- Provide any other advice or information for the GP if required.

GP Responsibilities

- Prescribe melatonin as advised by specialist.
- Continued prescribing is appropriate for patients attending specialist review.
- Report any adverse events to the specialist and the usual bodies (e.g. MHRA / CHM).
- Ensure no significant drug interactions with other medicines.

Adverse Effects, Precautions and Contraindications

Cautions: Autoimmune disease, renal impairment, epilepsy, hepatic impairment.

Melatonin is well tolerated; common side effects are: Arthralgia; behaviour abnormal; drowsiness; feeling abnormal; headaches; increased risk of infection; mood altered; pain; sleep disorders

May affect performance of skilled tasks (e.g. driving). The DVANI must be informed if prescribed medication or any side effects of the medication are likely to impair safe driving.

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
- CYP1A2 inhibitors may increase the plasma concentrations of melatonin considerably. Concomitant treatment with melatonin and fluvoxamine should be avoided. Caution should be exercised with ciprofloxacin, norfloxacin and verapamil.
- Oestrogens: exercise caution - increases melatonin levels
- Other hypnotics and CNS depressants: melatonin may enhance the sedative properties of other drugs acting on the CNS e.g. benzodiazepines, alcohol, thioridazine, imipramine.
- CYP1A2 inducers may decrease the plasma concentrations of melatonin. Dose adjustment of melatonin may be needed if given concomitantly with carbamazepine, phenytoin, rifampicin, omeprazole and cigarette smoking.

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 at www.medicines.org.uk or the BNF

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