

**CONTINUING CARE GUIDELINES & INFORMATION FOR STAFF AND
GENERAL PRACTITIONERS**

MELATONIN FOR SLEEP DISORDERS IN CHILDREN

Date of implementation March 2013

Date for review March 2016

Clinical Indication

Treatment of insomnia in children with sleep disorders, to be initiated by specialist secondary care (experienced psychiatrists for CAMHS or experienced paediatricians only)

Introduction

Insomnia is a common problem for children with sensory deficits, some learning disabilities and childhood psychiatric disorders such as autistic spectrum disorder and ADHD.

Melatonin is a hormone produced by the pineal gland in a circadian manner, in response to darkness. The link with circadian rhythms has led to its use in the treatment of sleep disorders underpinned by learning disability, autistic spectrum disorders, and ADHD. Melatonin is classified as a medicine in the UK, and is currently unlicensed for these indications in children and adolescents. In contrast, it is readily available to purchase in some countries, e.g. USA.

In practice, the use of melatonin for the treatment of paediatric sleep-wake cycle disorders is widespread. There are a number of published trials, although these are often small and of short duration. As such it is difficult to draw firm conclusions. Children and children with ADHD treated with melatonin have been shown to fall asleep earlier and sleep for longer when compared to controls. Generally no significant change in behaviour or attention has been demonstrated. It would appear that there is wide variability in response. Melatonin may be most effective in those children whose sleep patterns indicate that their circadian rhythm is disrupted, and in whom sleep hygiene methods have been ineffective.

The Childrens BNF www.bnfc.org 4.1.2 lists Melatonin 2mg SR tablets, and a dose for children 1month to 18years initially 2-3mg before bedtime, increased if necessary after 1-2 weeks to 4-6mg daily, max. 10mg daily.

There are no licensed products of Melatonin in the UK for the treatment of childhood insomnia. Circadin® is a sustained release formulation of melatonin that is licensed in the UK for the treatment of primary insomnia in adults aged 55 years and over.

Indications for use

For use in children of at least 1 year of age with neurodevelopment disability, autism, visual impairment or neuropsychiatric disorders and chronic sleep disturbance, including chronic fatigue syndrome, where both:

- Symptoms of sleep disturbance have been present for at least six months or sleep disturbance is so severe that it is causing significant family disturbance
- Sleep hygiene / behavioural measures had a reasonable trial and failed.

Children are typically of school age. There may be other causes of these symptoms e.g. depression or anxiety. Other approaches to therapy can be considered; however, melatonin is not known to cause harm.

Contra-indications, Special warnings and precautions for use

- Hypersensitivity to the active substance or to any of the excipients.
- Melatonin may cause drowsiness.
- No clinical data exist concerning the use of melatonin in individuals with autoimmune diseases and so use is not recommended in this group of patients.
- Patients with rare heredity problems of galactose intolerance, the LAPP lactase deficiency (this is when the body is unable to digest milk and milk products due to a lack of an enzyme) or glucose-galactose malabsorption should not take this medicine.

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Dosage and administration

Age	Oral dose	Maximum dose
1 year onwards	Initial dose 2mg (given 30-60 minutes before bedtime). In the absence of improvement after 1-2 weeks, the dose is increased by 2mg incrementally according to response. SR Circadin® tablets should be prescribed	12mg/day

- For children waking during the night, the same dose or a smaller dose can be repeated during the night. The 2mg SR Circadin® tablet can be halved using a tablet cutter and it will retain its slow release characteristics¹⁷.
- For children with difficulties swallowing, the tablet 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 administration¹⁸.
- For administration via an enteral feeding tube, the tablet can be crushed to a fine powder and added to 15 - 30ml of water and mixed well. This should be drawn into a 50ml oral syringe and administered taking care to rinse the mortar/tablet crusher with water and administering the rinsings also. The feeding tube should be flushed with 30ml water prior to and post drug administration.
- NOTE: crushing the MR tablet will mean that it is no longer modified release.
- Special order liquid medicines are unlicensed and expensive and should ONLY be used where absolutely necessary. The prescription must state the brand to be used.
- A drug holiday should be introduced at least annually to assess the continued need for treatment. This could take place a month before the annual review with the patient and / or the parent keeping a sleep diary. The outcome of any drug holiday must be recorded in the patient's notes

Withdrawal recommended

Specialists should review the need for continued treatment at each outpatient or community team appointment (at least every 6 months) and advise the GP of continuation, changes or discontinuation of treatment.

Side effects

Melatonin is generally well tolerated, but long term side effects have not been evaluated. It is readily available as a food supplement in the USA. The most commonly reported side-effects are headaches, dizziness, nausea, and drowsiness. Increased seizure activity has been reported in patients with epilepsy but there is also anecdotal evidence that seizure activity improves as a result of improved sleep. Much of the clinical trial data with melatonin does not report an increase in seizure frequency, but data must be treated cautiously due to the short term nature, size, and heterogeneous nature of the populations studied. Until more is known prescribers need to approach melatonin use in children with epilepsy highly cautiously and be alert for alterations in seizure activity.

Concern has been expressed that exogenously administered melatonin could, at least theoretically, adversely affect gonadal development if used in children. Young people up to the age of 20 years produce melatonin endogenously in high levels and levels are inversely related to gonadal development. In the clinical trials included in this review, none reported an association between melatonin and delayed onset of puberty, but most study of melatonin has been short term, and longer term follow-up will be needed to fully address this concern.

Endogenous serum melatonin concentration is elevated in nocturnal asthmatic patients. Although the clinical trial data presented here do not indicate an increase in asthma symptoms, melatonin should be used with caution in this group. Most commercial melatonin is synthesized in the laboratory. However, in rare cases it has been derived from animal pineal gland. Melatonin from animal sources should be avoided due to the possibility of contamination.

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Adverse events, interactions and precautions for the licensed Circadin™ preparation can be found in its SPC. This is only licensed for (and has only been adequately tested in) adults aged 55 years and above with primary insomnia, therefore the information presented in the SPC cannot be presumed to apply to paediatric patients with neurodevelopmental disorders (NDD).

Overdose

Administration of daily doses of up to 300mg of melatonin without causing clinically significant adverse reactions have been reported in the literature.

If overdose occurs, drowsiness is to be expected. Clearance of the active substance is expected within 12 hours after ingestion. No special treatment is required.

Interactions

From case reports in the literature, clinical experience and theoretical principles it has been suggested that interactions may occur with anticoagulant/ antiplatelet drugs, antidiabetic agents, benzodiazepines/ CNS depressants, carbamazepine and rifampicin, cimetidine, contraceptives, flumazenil, fluvoxamine, immunosuppressants, nifedipine, quinolones and verapamil. Cigarette smoking may decrease melatonin levels.

Interactions for the licensed Circadin™ preparation can be found in its Summary of Product Characteristics (SPC). www.medicines.org.uk

Administration and supply

- The patient and carer must be advised that this is an off-label use or an unlicensed product which limits the information that is available about effectiveness and safety
- The patient must be given the Patient Information Leaflet.
- Supply will be by prescription only for the individual patient by a Doctor or non-medical prescriber for the individual patient
- Inpatient prescriptions must be written on the prescription/administration card and ordered in good time by ward staff, particularly for those patients on leave. Discharge planning arrangements must be made for future supply.
- Outpatient prescriptions may be on FP10 HNC prescriptions to be dispensed by a community pharmacy, or on the triplicate NEPFT outpatient form for dispensing at the pharmacy in Chelmsford. There are deliveries twice a day to most NEPFT locations or the parent/carer can collect from the pharmacy at Chelford Court.
- When the patient is stable the specialist should contact the GP to request ongoing prescribing.

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This document outlines ways in which the responsibilities for managing the prescribing of melatonin for children with sleep disorders are shared between the specialist and general practitioner (GP). GPs are requested to participate in this process. If the GP is not confident to undertake these roles initially further advice and support will be available from the Specialist Prescriber. Clinical responsibility lies with the clinician who signs the prescription. **If a specialist asks the GP to prescribe this drug, the GP should reply to this request within two weeks.**

Sharing of care requires communication between the specialist, GP and child/parent or carer. The intention to share care should be explained to the child /parent by the doctor initiating treatment. It is important that parents and children are consulted about treatment and are in agreement with the process.

Responsibilities of the initiating clinician

- Diagnosis. A thorough history should always be taken and a sleep diary used if there is any doubt about the extent of the problem.
- Initiation of treatment by an experienced psychiatrist or paediatrician for CAMHS, Learning Disabilities or paediatrics, who should first discuss the treatment options with the patient, their parent(s) and carer(s), including the unlicensed nature of melatonin, the need for shared care (once dose stabilised), and obtaining appropriate consent to treatment.

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Initiate treatment with melatonin only if agreed.

- Provision of a patient information leaflet (appendix) and a sleep recording chart or sleep diary.
- Advice to the patient and carer to follow sleep hygiene measures (bedtime and wake up routine, avoidance of daytime sleep) and to continue the sleep diary throughout treatment with Melatonin, if practicable.
- The initiating prescriber will continue to prescribe and supply until stability is established (at least 1 month)
- Written notification to the GP when the Melatonin is initiated, and again when the patient is stabilized to ask the GP whether he is willing to participate in the ongoing prescribing and general care as outlined in this continuing care guideline. A copy of the guideline should be sent with the first letter.
- Outpatient appointments at least annually, and regular appointments with the community teams or paediatric support team. At these appointments the efficacy of Melatonin will be reassessed, and discontinued or reviewed as indicated.
- Report any suspected adverse drug reactions (ADRs) to the Medicines and Healthcare products Regulatory Agency (MHRA) via the yellow card scheme. www.mhra.gov.uk/yellowcard
- When appropriate, undertake periodic treatment withdrawals, or advise the GP in writing how and when to undertake them.
- Promptly communicate any changes, recommendations, outcomes or other important information to the GP.
- Provide advice to the GP or patient if they have clinical queries relating to the condition or use of melatonin

Responsibilities of the GP

- The GP is responsible for the general health and well-being of the patient. He/she should only prescribe melatonin if there is some evidence of ongoing efficacy.
- If he/she considers that the patient should be reviewed he/she should contact the initiating prescriber or the CAMHS or paediatric team, but will continue to prescribe until the reassessment has taken place (unless an adverse effect has occurred).
- Continuation of melatonin without specialist review is not recommended.
- Prescribe melatonin once the patient is on a stable dose
- Confirm that the patient, their parent(s) and carer(s) has understood and consented to the off-label or unlicensed use of melatonin.
- Prescribe appropriate quantities for the patient in line with local repeat prescribing policies
- Carry out further dose titration according to response, or discontinue the medication, when necessary or requested
- Communicate any problems to the Specialist looking after the patient
- Only ask the Specialist to take back the prescribing should unmanageable problems arise and allow an adequate notice period (4 weeks is a suggested minimum)
- Ensure compatibility of melatonin with concomitant medication
- Report any suspected adverse drug reactions (ADRs) to the Medicines and Healthcare products Regulatory Agency (MHRA) via the yellow card scheme. www.mhra.gov.uk/yellowcard
- Inform consultant if unable to take on shared care

Patient and/or carer's role

- ***Ensure the parents or carers have a clear understanding of the treatment***
- Take/give the melatonin as directed
- Share any concerns in relation to treatment with the Specialist, GP or pharmacist
- Report any adverse effects or warning symptoms to the Specialist, GP or pharmacist whilst taking/giving the medication
- Attend booked appointments for review and monitoring of therapy

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NHS Cost and choice of product

With the exception of the Circadin® brand, melatonin is not licensed in this country, therefore a prescription for melatonin can be met by any product of any price, at the discretion of the dispensing pharmacy. This could prove to be very expensive. Prescribers are advised to specify a brand or a manufacturer. The MHRA advice is to prescribe in the following order of preference:

- i) If there is a licensed product available it should be used, even if it is for an off-label use. **This means Circadin® 2mg sustained release tablets.** These are in packs of 21, not 28, so prescribe quantities with care
This should be the preparation of choice unless there are clear reasons why it will be inappropriate
- ii) A second choice is an imported product which is licensed in another country with similar standards, and has labelling and patient information in English. Biomelatonin®, Pharma-Nord is a 3mg tablet licensed in Hungary and manufactured in GMP inspected facilities in Denmark. If a medicine is imported the MHRA have advised that the dispensing pharmacy must supply a “special clinical need” letter from the prescriber stating why none of the above options are appropriate.
- iii) If there is a product with a manufacturing licence but not licensed under the Medicines Act. The manufacturer is checked for general standards, but there is not a product-specific GMP inspection. There must be a clear audit trail from the specials manufacturer to the prescriber and the patient. A “special clinical need” letter is recommended.
- iv) There are a number of unlicensed UK specials manufacturers and the import of unlicensed products, particularly from the USA, where melatonin is classed as a food supplement. The standards of manufacture and quality control will be unpredictable. There is likely to be a time delay, and the cost is unspecified. A “special clinical need” letter should still be provided. **This option is not recommended.**

Product	Manufacturer	Strength/form	Pack size	Price (Oct 09)
Licensed product but off-label use TO BE USED UNLESS THERE ARE GOOD REASONS WHY IT WILL BE UNSUITABLE. It can be crushed if necessary (as detailed in dosage & administration)				
Circadin®	Flynn	2mg slow release tab	30	£15.39
Licensed in country of origin but not UK, off-label use				
Bio-melatonin®	Pharma Nord	3mg film-coated tab	60	£15.44
Unlicensed under Medicines Act, but with a manufacturer’s licence				
Melatonin 1mg	Penn pharmaceuticals	1mg capsule	100	£90
Melatonin 2mg	“	2mg capsule	100	£95
Melatonin	“	2mg capsule	60	£47.50
Melatonin	“	2.5mg capsules	100	£100
Melatonin	“	3mg capsules	100	£105
Melatonin	“	3mg capsules	60	£52.50
Melatonin	“	3mg tablets	60	£52.50
Melatonin	“	5mg capsules	100	£115
Melatonin	“	10mg capsules	100	£120
Melatonin oral solution	“	1mg/ml orange flavour (sugar, colour and alcohol-free)	500ml	£95

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Unlicensed under Medicines Act, off-label use, may not be licensed in country of origin or have a manufacturer's licence, price unspecified PLEASE DO NOT PRESCRIBE				
Liquids		See Dose and Administration section for advice on crushing tablets		
Other melatonin products				

Audit

An ongoing audit of Melatonin prescribing must be undertaken to provide more evidence of efficacy and cost-effectiveness for this cohort of children, to be presented to the Mid Essex APC and the NEPFT Clinical Audit Group annually.

Specialist services in North Essex

Mid Essex NEPFT

Dr Anita Anfield, CAMHS, White Lodge, 21 Coggeshall Rd, Braintree Essex CM7 6DB 01376 302 800
 Dr Hannah Bateman, CAMHS, Rannoch Lodge, 146 Broomfield Rd, Chelmsford CM1 1RN 01245 544869
 Both of the above will be moving to the C&E centre, New London Road, in 2013
 Dr Colleen Lyder, Maldon CFCS, Harkenwell, St Peter's Hospital, Spital Rd, Maldon CM9 6EG
 01621 722 900 Moving to the community Clinic Maldon in 2013

Central Essex Community Services paediatric team

Dr L Murtaza, Dr G Kugan and Dr A Band
 Moulsham Grange Children's Centre, Moulsham Street, CHELMSFORD, CM2 9AH Tel. 1-01245 546300
 Dr Cyriac Broomfield Hospital via switchboard

West Essex

Dr Julia Handsides, Dr Bhardwaj Harlow CAMHS, Wych Elm House Harlow CM20 1QR 01279 637 000
 Lionel Bailly, Loughton CAMHS, Whitehills Rd, Loughton IG10 1TS 0208 271 4100

Dr Rudran Viji Jo Jenkins Pharmaceutical Advisor - HCTHerts and Essex Hospital Bishops Stortford CM23 5JH Tel: 01279 827230

East Essex

Dr T Jareonsettasin, Colchester CAMHS, Holmer Court, Essex St., Colchester CO3 3BT 01206 287 212

Dr Mahadevappa Tendring CAMHS, Beech House, 32 Thoroughgood Rd, CLACTON, Essex CO15 6DD 01255 226 100

Advice and useful information

- www.choiceandmedication.nepft.nhs.uk/nepft
- Summary of product characteristics www.medicines.org.uk
- Patient information leaflet www.patient.org.uk
- BNF (current) www.bnf.org
- BNF for children (current) Chapter 4.1.1 www.bnfc.org
- Royal College of Psychiatry www.rcpsych.ac.co.uk
- Maudsley Guidelines 10th edition ISBN-10: 0 415 42416 X
- Psychotropic Directory Steve Bazire ISBN-13 978-0-9569156-0-3
- NHS Direct accessible for patients www.nhsdirect.nhs.uk

Mid Essex Medicines Information Broomfield Tel. 01245 514822 MedicineInfo@meht.nhs.uk
 North East Essex Meds. Info. Colchester General Tel.01206 74 2161
 West Essex Meds. Info. Harlow PAH Tel. 01279 82 7054

Mental Health Specialist Pharmacists, Pharmacy Chelmsford CM1 3AG 01245 315 500
 Associate Director for Pharmacy, NEPFT 01245 315 507 Mob 07506 683179
 Lead pharmacist North East Mob. 07792 209 328
 Lead pharmacist West Mob. 07909 691 981 Tel. 01279 444455 Ext.2811
 Lead pharmacist Mid Mob. 07879 115 278

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Product availability for pharmacies

Pharmacies may purchase from local wholesalers. The following may also be useful
Flynn 01438 727 822
PharmaNord (UK) 01670 519 989 fax 01670 534 903 uksales@pharmanord.co.uk
www.pharmanord.co.uk
Penn pharmaceutical services 01495 713 600 sales@pennpharm.co.uk

Related policies and procedures

Continuing care guidelines process June 09
Procedures for medicines Tab 1 – unlicensed and off-label medicines
Patient information leaflet (NEPFT)

References

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4. Tjon CV et al (2003) Melatonin for treatment of sleeping disorders in children with attention deficit/hyperactivity disorder: a preliminary open label study. *Eur J Pediatr*; 162:554-555
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MELATONIN

Information for children, young people and families

What is Melatonin?

Melatonin is a natural hormone produced by the pineal gland in the brain. It is produced at night and helps to regulate our sleeping patterns; it helps the body to know when to wake up and when to be asleep. The tablets or capsules you have been prescribed contain a manufactured version of this hormone. Melatonin does not have a medicines licence for children, though it can be prescribed, so your psychiatrist/paediatrician will have given careful consideration to prescribing and will have discussed the implications fully with you and your family.

Why has Melatonin been prescribed?

Melatonin has been prescribed for children and young people who have problems with sleeping, when other methods have not worked. These other methods should not stop (good night time routines etc), but should continue alongside the melatonin. The "circadin" slow release 2mg brand is usually prescribed

How should it be taken?

Melatonin should be taken as prescribed and the dose should not be adjusted without the advice of the prescriber. It should be taken as a single dose 30-60 minutes before going to sleep. The capsules or tablets are usually swallowed whole with a whole glass of water. However, if there is a swallowing problem or the tablets are too slow to work the "circadin" tablets can be crushed (crusher available from the pharmacy) and dispersed in a little water, milk or orange juice and then given. The effects of the medication should then be as quick as standard tablets or capsules. If the person awakes at night an **extra dose of melatonin should not be given.**

Does melatonin have any side effects?

Everyone is different and reacts differently to medicines. The side effects mentioned here may not be experienced by everyone. Side effects are fairly uncommon and may include headaches and dizziness. Rare side effects are restlessness, increased heart rate, itching and nausea. Children and young people with epilepsy or asthma will need to be closely monitored whilst on melatonin as there has been different reports about the effect of melatonin on the control of these conditions.

Is it safe to take other medication with melatonin?

It is safe for the child or young person to take the recommended dosage of paracetamol when they are taking melatonin. There are few studies of using other medication with melatonin. If you are discussing other medications with your healthcare professional be sure to tell them that you or your child is taking melatonin.

How long should melatonin be taken for?

For a large number of people melatonin will not have a positive effect on a sleep disorder. The usual starting dose is 2-3mg for all ages, this may be increased to 4-6mg if limited or no improvement is found after one to two weeks. Rarely 9-12mg has been tried but if no benefit is seen after two weeks on the higher dose then the melatonin should be stopped. If it is found to be useful it should be continued for several months. At this point you can discuss with the prescriber how best to reduce the dosage to see if it is still needed.

Can I boost melatonin naturally?

Exposure to strong light in the morning and low lighting in the evening can help to improve melatonin production at night.

Foods like oats, sweetcorn, rice, ginger, tomatoes and barley are a rich source of melatonin. Tryptophan is used by the body to make Melatonin, so foods that contain it like cottage cheese, breakfast cereals with milk, chicken, turkey, some nuts, milk, ice cream and yoghurt may help, and foods that are rich in calcium, magnesium, vitamin B6 and B3 can also boost melatonin production.

What should be avoided

Avoid anti-inflammatory drugs, caffeine and stimulants, and exposure to bright lights near bedtime. Strong electromagnetic fields from computers, televisions, radios, clocks, electric blankets may reduce natural melatonin production. They should be switched off at the wall, not left on standby.

Where can I get more information on Melatonin?

This leaflet covers only some aspects of treatment of sleep disorders with melatonin. Your prescriber will be pleased to discuss it further with you and answer any questions that you may have. You can also speak to a pharmacist who will also be happy to advise you. Contact numbers are as detailed below.

Prescriber details	Pharmacy department
	Medicines Information (MI) service Chelmsford: Monday-Friday 10am-2pm 01245 514822 MedicinesInfo@meht.nhs.uk Colchester: Monday-Friday 9am-5pm 01206 742161. Harlow: Monday-Friday 9am-5pm 01279 827054 NEPFT pharmacy Mon-Fri 9am-5pm 01245 315 500

www.choiceandmedication.org.uk/nepft/

This is a useful website with printable leaflets (including easyread version)