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Shared Care Guideline for Melatonin

V1.0

July 2011

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Version Control Table

Date	**Version No**	**Summary of Changes**	**Changes Made by** *(Name and Job Title)*
13/7/11	1.0	Final amendments approved; EIA completed, document published	Mike Wilcock, Head of Prescribing Support Unit, Pharmacy, RCHT

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of issue.

MELATONIN

This shared care guideline sets out details for the sharing of care of children affected by a neurological or neurodevelopmental disorder suffering from severe sleep disturbances prescribed melatonin. These guidelines provide additional limited information necessary to aid in the treatment of these patients. As with all shared care guidelines they highlight relevant prescribing issues but should be used in conjunction with relevant NICE guidance, the BNF-C, ABPI summary of product characteristics and *do not* replace them.

Melatonin is not a licensed product in the UK for this indication. This SCG describes the off label use of the Circadin brand of melatonin and the use of unlicensed products.

INDICATIONS FOR THE PURPOSES OF THIS GUIDELINE

Sleep disturbances in children with neurological or behavioural disorders are very common. There are multiple factors for this that are frequently interrelated and which include delayed brain maturation, malfunction of sensory organs (particularly vision) and abnormalities or malformation of the sleep centres. The different types of sleep disruption experienced include delayed onset, frequent waking, early morning wakening and reversal of the day-night sleep pattern. These children have a variable response to behavioural therapies and the use of traditional hypnotic or sedative drugs can cause adverse reactions and lead to tolerance and dependence. Melatonin is an endogenous hormone produced by the pineal gland in the brain. The aims of melatonin treatment are to improve the onset and duration of sleep and establish a regular nocturnal sleep pattern.

PREPARATIONS AND DOSAGE

Melatonin is available in a range of strengths as standard release and sustained release capsules. The products to be used locally are:- Circadin 2 mg modified release tablets (used off-label in this age group and when there are no swallowing problems). A liquid preparation (Kidnaps) is available as the preferred second line option for patients with swallowing problems. Some patients may already be taking a 2mg standard release capsule for when swallowing a solid dose formulation is a problem. The capsule can be opened and the contents sprinkled into milk or other drinks. Two of these items (the liquid and the 2mg standard release capsule) are sourced as unlicensed products.

The patient will have received at least one month's treatment, been shown to respond to the treatment and the dosage stabilised, before prescribing responsibility is transferred to the GP.

CONTRAINDICATIONS AND PRECAUTIONS

Melatonin will not be prescribed for:

- Patients aged under 1 year.
- Patients who are pregnant or breast-feeding.
- Patients with sleep disturbances due to obstructive apnoea, emotional distress or nocturnal seizures.
- Patients with severe allergies, auto-immune diseases or immune system cancers. Patients taking immunosuppressants.
- Caution should be exercised when melatonin is used in patients with epilepsy (see below under Side Effects).
- Caution should be exercised when prescribed concomitantly with antidepressants, tranquillizers or other sedatives.
- There is a paucity of clinical data regarding drug interaction with melatonin therefore caution is necessary with all medication.

MONITORING

SPECIALIST TEAM:

- Responsible for monitoring of growth and sexual development.

GENERAL PRACTICE:

- There are no specific biochemical monitoring requirements for the GP to undertake.

SIDE EFECTS

- Side-effects are generally unusual and melatonin is generally well tolerated.
- There are some reports of headache, fatigue, confusion, pruritus, hypothermia, tachycardia, nightmares, mild depression, morning grogginess, skin rashes and low sex-drive.
- Other reports suggest that it may cause narrowing of blood vessels in the heart and lungs, especially in patients with underlying heart disease or asthma. Paradoxical wakefulness has been reported. It may also affect serotonin levels.
- In overdose blurred vision and dizziness have been observed and possible nystagmus.
- Based on the known physiological effects of melatonin there could be a potential for inhibition of reproductive functions and delayed puberty. Effects on unborn foetuses or breast-fed children are unknown, but their circadian rhythms could be disturbed.
- There is a known potential for melatonin to affect seizure control in patients with epilepsy. Some reports suggest an improvement, whilst others indicate a worsening of control. The effects of introduction and titration of melatonin in epileptic patients should be closely monitored. There may also be theoretical implications when melatonin is used in conjunction with drugs that lower the seizure threshold.
- Tolerance does not appear to be a problem, but clinicians should remain alert to the possibility.

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

These are suggested ways in which the responsibilities for the management of patients who are prescribed melatonin can be shared between the specialist and the general practitioners. Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and be accepted by them.

In its guidelines on responsibility for prescribing (circular EL(91)127) between hospitals and GPs, the DH has advised that legal responsibility for prescribing lies with the doctor who signs the prescription.

Referral criteria

- A full diagnostic assessment will have taken place under the specialist's care prior to prescribing melatonin. This will include documented neurological or neurodevelopmental disorder and documented severe, and disrupted, sleep disturbances (failure to respond to desired conventional treatments and problems causing family crises) supported by a 24-hour sleep pattern record covering a minimum of 7-10 days.
- The patient will have received at least one month's treatment, been shown to respond to the treatment and the dosage stabilised, before prescribing is transferred to the GP.

Specialist responsibilities:

- Make any necessary diagnoses and communicate these to the GP and other professionals involved in the patient's care
- Discuss the treatment options with the patient, their parent(s) and carer(s), to include explanation of the unlicensed nature of melatonin, obtaining appropriate consent to treatment and to share care with the GP. A patient information leaflet is attached in Appendix 1 of this document.
- Initiate treatment with melatonin if agreed and titrate the dose to a satisfactory effect over a minimum of 8 weeks.
- Request the GP to take over prescribing in a clear letter; this letter should include full clinical details and document that the unlicensed / off label nature of melatonin has been discussed and consent obtained.
- Ensure the patient has at least 4 weeks supply remaining from the date the GP accepts the request to continue prescribing (to allow 2 weeks for the surgery to set up the prescription and provide it to the patient and then 2 weeks for the pharmacy / dispensing surgery to obtain supplies).
- Ensure the patient is fully aware of the need to arrange a further supply from their GP in a timely manner. This supply may be through the Specials Direct Service with the GP ordering directly from RCHT pharmacy on the specials prescription form or an FP10 prescription taken to the patient's chosen community pharmacy / dispensing surgery so that arrangements can be made to obtain stocks.
- Follow up every 6 – 12 months to ensure continuing benefit of melatonin.
- Ensure that the appropriate monitoring (of growth and sexual development is recommended, i.e. to check height, weight and pubertal development progress) is undertaken.
- When appropriate, undertake periodic treatment withdrawals, or advise the GP in writing how and when to undertake them.
- Communicate any changes, recommendations, outcomes or other important information to the GP.
- Provide advice to the GP if they have clinical queries relating to the condition or use of melatonin.
- Take back care of the patient should the GP feel unable to continue to manage the prescribing of melatonin.

General Practitioner responsibilities:

- If the GP agrees to shared care he/she will notify the consultant in writing without undue delay.
- Ensure that the patient, their parent(s) and carer(s) has understood and consented to the off-label / unlicensed use of melatonin. Patient information leaflet is attached in Appendix 1 of this document.
- Accept the request to continue prescribing of melatonin within the boundaries of this shared care protocol – prescribing responsibilities will commence 4 weeks from the date of reply.
- Prescribe appropriate quantities for the patient.
- Carry out further dose titration according to the specified schedule, or discontinue the medication, when necessary or requested.
- If the patient approves, consider ordering the unlicensed preparations (Kidnaps liquid, 2mg standard release capsule) through the Specials Direct Service.
- Communicate any problems to the Consultant looking after the patient.
- Only ask the Consultant to take back the prescribing should unmanageable problems arise and allow an adequate notice period (4 weeks is a suggested minimum).

Patient: and parent / carer responsibilities

- Agree to request prescriptions from the GP in good time; obtain the first GP prescription within 2 weeks of being informed that shared care will be in operation.
- Receive supplies via the GP if ordered direct from RCHT Pharmacy or to take a prescription to one chosen community pharmacy / dispensing surgery. In the latter case, to take prescriptions to the pharmacy / dispensing surgery as soon as possible so that they have adequate time to obtain supplies of this medicine. It may take up to two weeks for melatonin products to arrive from the supplier.
- Report and concerns or adverse effects to the GP, Consultant or Pharmacist.
- Patient information leaflet can be found in Appendix 1 of this document.

Request for other formats

Please ask if you would like to receive this leaflet in large print, braille, on CD or in any other languages. If you would like the leaflet in an alternative format please contact the PALS team on **palsteam@ciospct.cornwall.nhs.uk** or **0845 170 8000.**

Melatonin – Information for patients, parents and carers Appendix 1

Your child has been prescribed melatonin as the hormone has been shown to improve sleep in children with neurological problems.

Melatonin has been used to treat insomnia (difficulty falling asleep and/or staying asleep). There is a small amount of evidence to suggest that melatonin may also be able to prevent sleep disturbance, such as with jet lag or shift working.

What is melatonin?

Melatonin is a hormone made by a part of the brain called the pineal gland. Melatonin is thought to help our bodies know when it's time to go to sleep and when it's time to wake up. Melatonin is now available in the form of tablets, capsules or liquid.

How should melatonin be taken?

Your child should be given their dose of melatonin 30-60 minutes before bedtime. Tablets and capsules should be swallowed whole with a drink. They can be taken with or without food. For patients with swallowing difficulties, a liquid is available. Likewise the capsule may be opened and mixed with soft food or liquid. The powder in the standard release capsules may be mixed with water and flushed down a PEG or NG tube.

The doctor will prescribe an appropriate dose and the dose may be increased at weekly intervals. Most children improve within the first few weeks of treatment.

Does melatonin have any side effects?

Melatonin causes very few side effects. Your child may develop a headache, but this is uncommon.

If your child has epilepsy, your doctor will monitor them carefully.

Does melatonin interact with other medicines?

We don't know if melatonin causes problems when taken with other medicines because this has not been studied.

Does melatonin require a doctor's prescription?

Yes. In the UK, certain melatonin products are only available on a doctor's prescription on a "named-patient" basis. This means that the prescribing doctor takes full and complete responsibility for the use of this product in their patient.

Can I obtain melatonin from my GP?

In principle your GP is able to prescribe the unlicensed / off label melatonin preparations in the same way as your hospital doctor i.e. as a "named-patient" medicine, and most are willing to do so.

However, some GPs may not wish to prescribe unlicensed melatonin as it is not a licensed product in UK. If this is the case, you will need to obtain supplies through your local hospital.

How will the melatonin be supplied?

Your surgery may order supplies of the liquid or 2mg plain preparation direct from RCHT Pharmacy.

If instead a prescription is taken to your local pharmacy / dispensing surgery they will be able to obtain supplies from the company listed below:

2mg S/R preparation is the Circadin brand available via normal routes

2mg plain preparation from Special Products Ltd, Unit 25, Boundary Business Centre, Surrey, GU21 5DH. Tel: 01483 736 950

Kidnaps liquid preparation (sugar free) 1mg in 1ml from Special Products Ltd, Unit 25, Boundary Business Centre, Surrey, GU21 5DH. Tel: 01483 736 950

Please remember to organise further supplies two weeks before you run out, as melatonin products may take several days to arrive from the supplier.

Where can I obtain further information?

You can obtain further information from your consultant.

Name of service, strategy, policy or project (hereafter referred to as *policy)* to be assessed: Shared care guideline for melatonin	
Directorate and service area: Pharmacy	Is this a new or existing *Policy?* Existing
Name of individual completing assessment: Dan Thomas, Pharmaceutical Services Contracting Team, NHC C&IoS	Telephone: 01726 627953
1. Guidelines Aim*	To provide information on prescribing of certain medicines used in dementia to enable General Practitioners to take over prescribing responsibility from secondary care.
2. *Policy* Objectives*	To promote a consistent level of shared care between primary and secondary care (in relation to RCHT catchment area)
3. *Policy* – intended Outcomes*	Confident and competent prescribers, enabling medicines to be access in a primary care setting.
4. How will you measure the outcome?	If the guideline is not well received, publicised and adopted, then some GPs may not enter into shared care arrangements.
5. Who is intended to benefit from the *policy*?	General practitioners, hospital specialists and community pharmacists – from understanding local guidance around use of these medicines. Patients/carers, from being able to access medicines from their GP.
6a. Is consultation required with the workforce, equality groups etc. around this *policy*? b. If yes, have these groups been consulted? c. Please list any groups who have been consulted about this *policy*.	No Cornwall & IoS Prescribing Committee

Equality Group	Positive Impact	Negative Impact	No Impact	Reasons for decision
Age			X	
Disability			X	
Faith and Belief			X	
Gender			X	
Race			X	
Sexual Orientation			X	

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:

- **A negative impact and**

No consultation (this excludes any *policies* which have been identified as not requiring consultation). 8. If there is no evidence that the *policy* promotes equality, equal opportunities or improved relations - could it be adapted so that it does? How?	Full statement of commitment to policy of equal opportunities is included in the policy

Please sign and date this form.

Keep one copy and send a copy to the Human Resources Team, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Lamorna House, Penventinne Lane, Truro, Cornwall, TR1 3LJ
They will arrange for a summary of the results to be published on the Trust's web site.

Signed _____Dan Thomas and Mike Wilcock_____

Date _____April 2011_____