

The Rotherham Medicines Optimisation Group (The Rotherham NHS Foundation Trust, RDaSH and NHS South Yorkshire ICB Shared Care Protocol for the use of melatonin in the treatment of sleep disorders in children and young people (0-19 years old)

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<p>Indications for use of melatonin (NB. some indications are ‘off-label’)</p> <ul style="list-style-type: none"> • Severe sleep disorders in neurodevelopmental or psychiatric disorders. • Sleep difficulties in chronic fatigue syndrome/ myalgic encephalomyelitis (NICE CG53) • Behavioural strategies have had limited or no success. • Significant adverse effects on the child / family prior to work by an appropriate agency (see below). <p>Aims</p> <ul style="list-style-type: none"> • Short term use (6 months) • To aid work on sleep hygiene by health visitor, nursery nurse, school nurse, CAMHS and Early Help <p>A small number of children may need melatonin long term, reviewed every 12 months</p>	
Preparations	
Supply of product	<p>Melatonin 2mg MR tablets were formerly only available in the UK as Circadin® but now is available generically. They are a 2mg prolonged/modified release tablet, licensed for the short-term treatment of primary insomnia in patients aged 55 or over for up to 13 weeks. The MHRA would prefer an ‘off-label’ licensed product to be used if it can meet clinical need, rather than an unlicensed product.</p> <p>If an immediate release melatonin product is required then use Adaflex® tablets. Adaflex® tablets are available in 1/2/3/4 and 5mg strengths. Adaflex® is licensed for insomnia in children and adolescents aged 6-17 years with ADHD, where sleep hygiene measures have been insufficient.</p>
Immediate release	<p>Adaflex® tablets should be used if an immediate release effect is required. These tablets should be swallowed whole or crushed and taken 30 minutes before bedtime. If crushed can be mixed and mixed with water.</p>
Controlled/Modified release	<p>Melatonin 2mg m/r tablet - swallowed whole to maintain the modified release effect. Whole tablets should be taken an hour before bedtime. (these tablets can be halved).</p>

Dose 0-19 years by mouth	Start at 2mg given before going to bed. Adaflex® tablets are given 30 minutes before bed and melatonin 2mg MR tablets are given an hour before bedtime. Increase, if necessary, after 1 - 2 weeks by 2mg to a maximum of 10mg. Initiation and dose titration by consultant. Continuing treatment prescribed by GP under shared care agreement.
Indication	
Sleep initiation	Use Adaflex® tablets swallowed whole.
Sleep maintenance early morning wakening	Use Melatonin 2mg MR tablets swallowed whole.
Sleep initiation + sleep maintenance	Some children may need a combination of immediate release and modified release properties. Use melatonin MR 2mg tablets and Adaflex® tablets in combination with maximum total combined dose of 10mg.
Summary of Product Characteristics: for full details please see Electronic Medicines Compendium-Home - electronic medicines compendium (emc)	
Contra-indications	Hypersensitivity to the active substance or excipients.
Cautions	May cause drowsiness therefore avoid if this could be a risk to safety. Avoid in auto-immune conditions. Patients with rare hereditary problems of galactose intolerance, LAPP lactase deficiency or glucose-galactose malabsorption should not take melatonin. Melatonin has been reported to increase, decrease and have no effect on seizure frequency. Because of the uncertainty of the effect of melatonin on epileptic seizures, some caution should be exercised for use in people with epilepsy.
Side-effects	Well tolerated. Mild headache, sedation, fatigue, skin disorders, restlessness, increased / decreased pulse, itching and nausea. Reduced body temperature in higher doses. Full list of side-effects is given in the Melatonin Summary of Product Characteristics (SmPC) available from: Home - electronic medicines compendium (emc)

Ongoing Treatment	
Interactions with melatonin	Fluvoxamine, cimetidine (and theoretically oestrogens, quinolones) may increase melatonin levels. CYP1A2 inducers e.g. carbamazepine, rifampicin may reduce melatonin levels. Alcohol reduces efficacy. Enhanced effects of sedatives and hypnotics (e.g. benzodiazepines). Interactions with anticoagulants, anti-platelet drugs, anti-diabetic drugs, contraceptives, flumazenil, nifedepine, verapamil, immunosuppressants. If a patient is started on any of these medications GP should contact specialist for advice. The above details are not a complete list and the BNF and the SmPC remain authoritative.
Monitoring	Response to treatment. Monitoring of growth and sexual development with long term use is primarily the responsibility of the child's consultant but the GP should report any concerns. Long term effects have not been fully evaluated in humans but observations from animal models regarding the effect on pituitary hormones necessitate precautionary monitoring. Ensure a drug holiday of 7 days every 6 months has been undertaken and that the sleep diary has been completed to reflect this.
Stopping Treatment	Normally a consultant decision and GP to be informed in writing. The GP should stop treatment immediately after a serious adverse drug reaction. If treatment is discontinued, please notify patient's consultant.

Responsibilities of the GP	Responsibilities of the Consultant
<ul style="list-style-type: none"> • Refer appropriate patients to secondary care for assessment • Respond to the request for shared care as soon as possible. • In the event that the GP is not able to prescribe, or where the SCP is agreed but the consultant is still prescribing certain items the GP will provide the consultant with full details of existing therapy promptly upon request. • Report any adverse reaction to the MHRA and the referring consultant • Continue to prescribe for the patient as advised by the consultant • Inform the consultant if the patient discontinues treatment for any reason • Seek the advice of the consultant if any concerns with the patient's therapy • Conduct an annual medication review and if not seen by consultant in last 12 months refer • Review need for medication 6-12 monthly • Check compliance with drug holidays and diaries. 	<ul style="list-style-type: none"> • Discuss benefits and side-effects of melatonin treatment. • Discuss the requirement for the patient's carer/parent to agree to regular drug holidays from the outset of treatment. • Obtain informed consent. • Initiate Melatonin in appropriate patients and prescribe and titrate to a stable dose. • Arrange for an Information sheet on off label use of medication and a written patient information leaflet to be given by the hospital pharmacy with the first prescription. • Ensure the patient is monitored and reviewed by a member of the specialist team at least annually. Check ongoing need for therapy which will include a review of sleep diaries. • Send request to GP to continue prescribing once patient stabilised on an appropriate dose. • Ask if GP willing to prescribe under shared care, and send copy of pro-forma (TRFT = Appendix 1 or RDaSH = Appendix 2). • Advise the GP regarding duration of treatment. • To discuss any concerns with the GP regarding the patient's therapy • To ensure clear arrangements for GP back- up, advice and support • Report adverse reactions to MHRA.

TRFT: Support, education and information

Community paediatricians via Community Bookings on	01709 426379
CDC paediatricians via CDC admin on	01709 428850
General Paediatricians via paediatric secretaries	01709 424521
Dr McCowen's secretary	01709 427276

Email: rg-h-tr.rotherhampaediatrics@nhs.net

Out of hours and at weekends please contact the Paediatric Registrar on call on
01709 820000

Pharmacy Department:

Medicines Information Pharmacist 01709 304126
Paediatric Pharmacist 01709 820000
Ext 8151

RDASH: CAMHS (Community Services – Rotherham)

Kimberworth Place, Kimberworth Road, Rotherham, S61 1HE

Tel: 03000 215 984

Email: RDASH.Rotherhamcamhsadmin@nhs.net

REFERENCES

1. Jan JE, Espezel H, Appleton RE. Dev Med Child Neurol 1994 Feb;36(2):97-107
2. Wiggs L. J R Soc Med 2001 Apr;94(4):177-9.
3. Quine L. J Ment Defic Res 1991 Aug;35 (Pt 4):269-90.
4. BNF for children on-line [accessed 18.7.23]. Available at [MedicinesComplete — CONTENT > BNF for Children > Drug: Melatonin](#)
5. Smits MG, Nagtegaal EE, van der HJ, Coenen AM, Kerkhof GA. J Child Neurol 2001 Feb;16(2):86-92.
6. Smits MG, van Stel HF, van der HK, Meijer AM, Coenen AM, Kerkhof GA J Am Acad Child Adolesc Psychiatry 2003 Nov;42(11):1286-93.
7. Coppola G, Iervolino G, Mastrosimone M, La TG, Ruiu F, Pascotto A. Brain Dev 2004 Sep;26(6):373-6.
8. Gupta M, Aneja S, Kohli K. Add-on melatonin improves sleep behavior in children with epilepsy: randomized, double-blind, placebo- controlled trial. J Child Neurol 2005 Feb;20(2):112-5.
10. Summary of Product Characteristics – Circadin® [accessed 18.7.23] available at [Circadin 2 mg Prolonged-release Tablets - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#)
11. Summary of Product Characteristics-Adaflex® [accessed 18.7.23] available at: [Adaflex 5 mg Tablets - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#)
12. Brzezinski A. New England Journal of Medicine 1997; 336(3): 186-95.
13. NICE CG53 Aug 2007 Chronic fatigue syndrome Myalgic/ encephalomyelitis (encephalopathy).

APPENDIX 1 - TRFT

Proforma for the use of Melatonin Tablets in the Treatment Of Sleep Disorders In Children and Young People (0-19 years old)

The below patient has been on melatonin for disordered sleep **and is considered stable**. We therefore request this patient is placed on our shared care protocol available on the CCG website under “shared care protocols”

<https://yourhealthrotherham.co.uk/download/shared-care-protocol-for-the-use-of-melatonin-in-the-treatment-of-sleep-disorders-in-children/>

TRFT will continue to monitor the patient and write a letter after annual medication reviews to confirm whether or not dose/form is altered. If we do alter dose/form we will provide the patient with a 1 month’s prescription.

As part of the agreement please could you provide repeat prescriptions as follows:

PATIENT NAME	Prescription details: Melatonin 2mg MR Tablets (modified release) Dose and frequency:..... Adaflex® Tablets (immediate release) Strength: 1mg 2mg 3mg 4mg 5mg (circle) Dose and frequency:.....
NHS No.	
DOB	

Consultant/Specialist Name (Printed):Signature: Date:

To be completed by GP & returned to consultant/specialist to confirm acceptance (email or post)

GP name (Printed):GP signature: Date:

If we do not hear from you within 4 weeks of this letter we will assume that you agree to provide repeat prescriptions. Many thanks.

**Community Bookings, Dept of Paediatrics, The Rotherham NHS Foundation Trust, Rotherham
Hospital, Moorgate Road, Rotherham, S60 2UD Tel: (01709) 424461
Email: rg-h-tr.rotherhampaediatrics@nhs.net**

APPENDIX 2 – CAMHS (RDash)

Proforma for the use of Melatonin Tablets in the Treatment Of Sleep Disorders In Children and Young People (0-19 years old)

The below patient has been on melatonin for disordered sleep **and is considered stable**. We therefore request this patient is placed on our shared care protocol available on the CCG website under “shared care protocols”

<https://yourhealthrotherham.co.uk/download/shared-care-protocol-for-the-use-of-melatonin-in-the-treatment-of-sleep-disorders-in-children/>

RDash will continue to monitor the patient and write a letter after annual medication reviews to confirm whether or not dose/form is altered. If we do alter dose/form we will provide the patient with a 1 month’s prescription.

As part of the agreement please could you provide repeat prescriptions as follows:

PATIENT NAME	Prescription details: Melatonin 2mg MR Tablets (modified release) Dose and frequency:..... Adaflex ® Tablets (immediate release) Strength: 1mg 2mg 3mg 4mg 5mg (circle) Dose and frequency:.....
NHS No.	
DOB	

Consultant/Specialist Name (Printed):Signature: Date:

To be completed by GP & returned to consultant/specialist to confirm acceptance (email or post)

GP name (Printed):GP signature: Date:

RDash: CAMHS (Community Services – Rotherham)
Kimberworth Place, Kimberworth Road, Rotherham, S61 1HE
Tel: **03000 215 984**
Email: RDASH.Rotherhamcamhsadmin@nhs.net