NHS
Kent and Medway

Guideline on the Use of Melatonin for the Management of Sleep Disorders in Children, Adolescents, and Adults

Key Points

Initiation

Melatonin is not recommended for initiation in primary care. It should only be considered for initiation by specialists, where other sleep hygiene methods alone have been unsuccessful.

- The prescribing of melatonin in **CHILDREN / ADOLESCENTS** in Kent and Medway is ONLY supported for children / adolescents with sensory deficits, learning disabilities, an autistic spectrum condition, or living with Attention Deficit Hyperactivity Disorder (ADHD); and where it has been initiated by a specialist.
- Prescribing in **ADULTS** is ONLY supported for the **short-term treatment (up to 13 weeks maximum)** of primary insomnia in patients who are aged 55 or over. Primary i.e. insomnia not attributable to an underlying cause (with the exemption of patients with learning disabilities).
- Melatonin is NOT routinely funded for the management of jet lag within Kent & Medway and in patients with insomnia with Alzheimer's disease.[PRGC PR 2021-01]
- Non-pharmaceutical treatments (e.g. sleep hygiene, CBT) need to be continued if melatonin is started.

Review and Discontinuation

- Review all adults aged 55 years and over on modified-release melatonin after three weeks of treatment and only continue for a further ten weeks if a response is seen. Review and deprescribe melatonin in adults after a total of 13 weeks treatment.
- Review children on melatonin after three months and deprescribe melatonin if there is no clinically relevant treatment effect seen, if appropriate.
- All suitable patients should undergo a two-week drug holiday to assess their need for ongoing treatment. This should take place three months after the commencement of treatment and six monthly thereafter. If sleep improvements are maintained without melatonin, therapy should be stopped.
- If there is a consistent correlation of sleep deterioration during a drug holiday, patients should be advised to continue melatonin without a break unless they are suspected to be a poor metaboliser of melatonin (in which case regular washout with ongoing drug holidays when the benefit wanes, is recommended).
- For patients where caution should be exercised with drug-holidays and deprescribing, refer to the patient's specialist for advice on managing this, including where melatonin is prescribed under a formal shared care arrangement.

Product Choice

Preferred cost-effective product:

- **Melatonin 2mg modified-release (MR) tablets** (generic version of Circadin®).
  Must be prescribed generically as 2mg MR tablets (licensed product, off-label use).
  - For patients with swallowing difficulties melatonin MR 2mg tablets can be halved or divided into four to maintain the prolonged release effect to some extent.
  - For an immediate release effect and for patients with swallowing difficulties, take crushed and mixed with 15-30ml water, orange juice or milk or soft food for example jam or yoghurt (off-label).
- A cost-effective licensed preparation should be selected where possible.
- Review patients prescribed unlicensed melatonin specials and discuss with them whether a change to a licensed alternative is suitable for them.

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- Patients prescribed unlicensed or ‘off-label’ melatonin should be given sufficient information regarding this.

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Aim

This guideline has been designed to support clinicians within primary and secondary care with the management of melatonin prescribing for adults and children with sleep disorders within NHS Kent and Medway.
This guideline will also provide recommendations on the cost-effective prescribing of melatonin by considering product formulations and brand, groups of patients for whom melatonin is indicated, and information around review and discontinuation. Information on drug holidays will also be included. NB: The use of other hypnotics (e.g. benzodiazepines) will not be covered within this guideline.

Background

Melatonin is a naturally-occurring hormone produced in the brain by the pineal gland. It is normally produced in a circadian manner in response to falling light levels, with production starting in the evening and peaking around 2-4am. Its primary function is to induce the physiological changes which prepare the body for sleep, including a hypnotic effect and a fall in body temperature.

Since melatonin production is affected by light exposure detected by the retina; it is thought that this rhythm is disturbed in children with brain damage, neurodevelopmental disorders such as autism or visual disturbance.

Synthetic melatonin is used to promote sleep in a variety of conditions and is considered to have a favourable side-effect profile.

Non-pharmacological Treatment

The interventions stated below should be initiated by the clinician before considering any form of medication to treat the sleep difficulties. A sleep diary (Appendix 1) is recommended before commencing a trial of melatonin in children and adults. This should be completed for at least 2 weeks prior to starting melatonin to determine the baseline sleep pattern and to assess if sleep hygiene measures are being adhered to. Sleep hygiene measures and a sleep diary should continue throughout treatment with melatonin.

Patient response to treatment and the ongoing effectiveness of melatonin should be monitored using sleep diaries and assessment of sleep hygiene measures. Melatonin should only be continued where there is clear evidence of ongoing effectiveness. Prescribing of

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melatonin should be reviewed regularly and treatment breaks are recommended to assess ongoing need.

Sleep hygiene

Advice on sleep hygiene should be offered to those with insomnia. For further information refer to:

- Sleep problems - Every Mind Matters - NHS (www.nhs.uk)
- Sleep hygiene tips - Headspace
- Healthy Sleep Tips for Children: https://www.nhs.uk/live-well/sleep-and-tiredness/healthy-sleep-tips-forchildren/
- Self referral form | With You Kent eReferral | IAPT Portal

Melatonin in Children and Adolescents

Treatment with melatonin should only be initiated by a **specialist clinician**, which may include Paediatric Consultant, Child Psychiatrist or Non-Medical Prescriber with a specialist interest in paediatric sleep disorders, in-line with this prescribing guidance.

Whenever possible the patient (and their parents / guardian) should be involved in the decision making about initiating treatment and should be given information about melatonin in order to make an informed choice. Printable leaflets including information about good sleep hygiene can be found at https://www.nhs.uk/live-well/sleep-and-tiredness/healthy-sleep-tips-for-children/

The prescribing of melatonin in children/adolescents in Kent and Medway is **only** supported for children/adolescents with sensory deficits, learning disabilities, an Autism Spectrum Disorder (ASD) or those living with ADHD.

Melatonin prescribing in children is specialist initiation only – the dose should be stabilised and response to melatonin assessed before prescribing can be continued in primary care. Continued prescribing and monitoring of melatonin will usually be the responsibility of the GP. It will be expected that the specialist initiating melatonin will be responsible for providing advice for deprescribing.

Dosage

Consult the latest edition of the British National Formulary for Children: https://bnfc.nice.org.uk/

Initially 2 mg once daily, increased to 4mg once daily after 5 days if required. The dose should be taken before bedtime.

If treatment at 4mg daily remains ineffective at controlling sleep, advice of a specialist clinician should be sought as daily doses of 6mg and above are rarely required.

Patients and carers should be advised on initiation that treatment with melatonin and the need for continued use, will be reassessed every 6 months via a treatment holiday (see section on review below).

Renal impairment: The effect of any stage of renal impairment on melatonin pharmacokinetics has not been studied. Caution should be used when melatonin is administered to such patients.

Hepatic impairment: There is no experience of the use of melatonin in patients with liver impairment. Published data demonstrates markedly elevated endogenous melatonin levels

during daytime hours due to decreased clearance in patients with hepatic impairment. Therefore, melatonin is not recommended for use in patients with hepatic impairment.

Melatonin in Adults

Treatment with melatonin should only be initiated by a **specialist clinician**, which may include Consultant Psychiatrists, Secondary Care Geriatricians or Non-Medical Prescribers with a specialist interest in sleep disorders, in-line with this prescribing guidance.

For people over 55 years of age with persistent insomnia, treatment with prolonged-release melatonin may be considered. In terms of duration of treatment, the recommended initial duration of treatment is three weeks. If there is a response to treatment, it should be continued for a further ten weeks only, in accordance with the licensed indication (13 weeks total treatment length).

Dose: 2 mg once daily for up to 13 weeks, dose to be taken 1–2 hours before bedtime.

As per NICE guidance on challenging behaviour in patients with learning disability (NG11), if sleep problems persist after a behavioural intervention and following a consultation with a specialist psychiatrist, melatonin can be considered; together with non-pharmacological interventions and regular reviews. This is an off-label use of melatonin in people aged 55 years and under. Treatment should be continued in secondary care.

Review, Drug Holiday, and Discontinuation

There is no routine ongoing monitoring required specifically for melatonin in primary care other than monitoring for possible adverse effects and continued need.

A melatonin drug holiday should be attempted every 6 months as some children/ adolescents will have settled into a regular sleep pattern and may not need to continue at the same dose or may even be able to maintain sleep with no melatonin.

This could be considered during school holidays or over an extended weekend. However, timing of a treatment holiday should be in discussion with the patient / guardian and consider individual circumstances where the impact of potential sleep disruption can be minimised.

If sleep patterns are maintained during the treatment holiday, stopping melatonin permanently should be considered. Or alternatively, if treatment with melatonin is still required, dosing can be reduced by 2mg. If the difficulties recur the original dose should be reinstated, but a further trial reduction / treatment holiday should be attempted 6 months later, and every 6 months thereafter.

Some clinical experience from the National Child and Adolescent Learning Disability Psychiatry Network suggests that the efficacy of melatonin may be lost if prescribed for longer than two years continuously. It suggests that if melatonin is withdrawn prior to this, sensitivity may be re-established, and melatonin successfully re-introduced at a lower dose if still required.

Reinforcement of good sleep hygiene should be discussed at each 6-monthly review and should be continued by the child / adolescent in conjunction with melatonin prescribing.

Individual patients may require additional monitoring based on co-morbidities or interacting medicines. It is likely these patients would remain within secondary care / community services and any primary care monitoring will be agreed on a case-by-case basis.

Children transitioning to adults

Melatonin is not currently recommended across Kent and Medway for adult patients under 55 years old with the exemption of patients with learning disabilities. Young people who are transitioning to adult services or reach 18 years should be reviewed in conjunction with advice from the specialist services where applicable.

If sleep concerns remain, treatment should follow standard guidance for adults with sleep problems.

The expectation is for children's services to be responsible for reviewing and deprescribing melatonin prior to the child turning 18 years old.

NHS Kent and Medway do not support the prescribing of melatonin in adults under 55 years old with the exemption of patients with learning disabilities.

Product choice

Preferred cost-effective product:

- Melatonin 2mg MR tablets (generic version of Circadin®). Must be prescribed generically as 2mg MR tablets *(licensed product, off-label use)*.

For patients with swallowing difficulties:

- Melatonin MR 2mg tablets can be halved or divided into four to maintain the prolonged release effect to some extent.
- For an immediate release effect and for patients with swallowing difficulties, melatonin 2mg MR tablets can be crushed and mixed with water, orange juice, milk, or soft food e.g. jam or yoghurt (off-label) and given immediately, or added to 15-30ml water for administration via enteral feeding tubes.

(Licensed product, off-label use/administration)

Note – the MR properties will be lost once crushed and the product will be equivalent to immediate-release (IR). The tablets are not film-coated.

Restricted use:

Alternatives (ONLY if preferred cost-effective product is not tolerated/suitable e.g. feeding tubes, and indication-specific licensed products needed):

- Adaflex® 1mg, 2mg, 3mg, 4mg, and 5mg standard release tablets. ONLY use if preferred product is not tolerated/suitable, and ONLY in children aged 6-17 years with ADHD. The tablet can be crushed and mixed with water directly before the administration. Must be prescribed by brand name *(licensed product, licensed use).*

- Slenyto® 1mg MR and 5mg MR tablets. ONLY use if preferred product is not tolerated/suitable, and ONLY in children aged 2-18 years with Autism Spectrum Disorder (ASD) and/or Smith-Magenis Syndrome (SMS). Must be prescribed by brand name *(licensed product, licensed use)*.

- Ceyesto 3mg standard release tablets. ONLY use if preferred product is not tolerated/suitable, and ONLY in children aged 6-17 years with ADHD and insomnia, where sleep hygiene measures have been insufficient. Must be prescribed by brand name *(licensed product, licensed use)*.

- Melatonin 1mg/ml oral solution (Colonis Pharma Ltd) – use is restricted only to patients for whom tablets (including crushed tablets) are not tolerated/suitable e.g. feeding tubes, due to higher cost and safety concerns with formulation containing excipients potentially harmful to children (e.g. propylene glycol, sorbitol). Melatonin 1 mg/ ml oral solution is not recommended for use in children younger than 6 years of age. But can be considered as an alternative for administration via fine bore feeding tubes or a very limited number of children who will not tolerate the crushed melatonin 2mg MR tablets

e.g. those with significant feeding difficulties who do not have a feeding tube *(licensed product/administration, off-label use).* Note: Safety concerns are dose dependent.

Patients prescribed unlicensed or 'off-label' melatonin should be given sufficient information informing them of this.

Contraindications and Cautions

For latest information on contraindications and cautions please consult the latest edition of the British National Formulary (BNF or BNFc) https://bnf.nice.org.uk/ or Summary of Product Characteristics (SPC) for individual melatonin products: http://www.medicines.org.uk/emc/

Adverse effects

For latest information on adverse effects please consult the latest edition of the British National Formulary (BNF or BNFc) https://bnf.nice.org.uk/ or Summary of Product Characteristics (SPC) for individual melatonin products: http://www.medicines.org.uk/emc/

Drug Interactions

For latest information on drug interactions please consult the latest edition of the British National Formulary (BNF or BNFc) https://bnf.nice.org.uk/ or Summary of Product Characteristics (SPC) for individual melatonin products: http://www.medicines.org.uk/emc/

Support contact details

KCHFT
kcht.CommunityPaediatrics@nhs.net

MCH
medch.medicinesmanagement@nhs.net
medch.childrenscommunity@nhs.net

NELFT (provides CAMHS services for Kent and Medway – please contact your locality)

East Kent

Canterbury

CanterburyCYPMHSPrescriptions@nelft.nhs.uk

Broadstairs (Thanet)

ThanetPrescriptions@nelft.nhs.uk

South Kent Coast (Folkestone and Dover)

nem-tr.southkentcoast@nhs.net

Ashford

Admin.Lenworth@nelft.nhs.uk

West Kent

westkentcamhs@nhs.net

Telephone numbers

- Medway - 0300 300 1989
- Maidstone - 0300 300 1990
- Tonbridge - 0300 300 1992
- SPA - 0800 011 3474
- Dartford - 0300 300 1986
- Ashford - 0300 300 1982
- Thanet - 0300 300 1983
- Swale - 0300 300 1991
- Canterbury - 0300 300 1984
- South Kent - 0300 300 1988
- All Age Eating Disorders Service - 0300 300 1980

KMPT
Please see details below

COMMUNITY MENTAL HEALTH ADVICE AND SUPPORT CONTACT DETAILS – CMHT & CMHSOP

1. KMPT Community Mental Health Teams (CMHTs) – for adults aged 18-65

For Primary Care colleagues who need advice and guidance regarding their patients' mental health-related medication, please find a list of useful email addresses and contact numbers below.

If your call is unanswered:

- Please state details of your enquiry
- Provide a mobile contact number
- Confirm the best time for a member of the CMHT to call you back
- Your message will be dealt with and **you should expect a call back on the same day**.

Emails are monitored throughout the working day and responses will be sent out within 24 hours.

KMPT Community Mental Health Teams (CMHT) supporting younger adults – aged 18-65

CMHT Location	CMHT Contact details	Time available (Monday – Friday)
Ashford	07798 680210 KAMNASCPT.adminas@nhs.net	12pm – 2pm
Canterbury	07798 680210 Kmpt.admin.canterbury@nhs.net	12pm – 2pm
Dartford, Gravesham, & Swanley	01322 622230 KAMNASCPT.dgscmht@nhs.net	12pm – 2pm
Maidstone	07825 424657 KAMNASCPT.maidstonecmht@nhs.net	1pm – 2pm
Medway	0300 303 3189 kmpt.crsladmin.mit@nhs.net	Part of the Consultant Connect network. GPs have a contact number for the consultant who is oncall
South Kent Coast (Dover, Deal & Shepway)	Mondays & Tuesday 01303 227513 * kmpt.shepwaycmhtadmin@nhs.net Wednesday, Thursday, & Friday 01304 216683** kmpt.dovercmhtadmin@nhs.net	*2.30pm – 3.30pm ** 2pm – 3pm
South West Kent	07464 907407 kmpt.swkadminteam@nhs.net	12pm – 2pm
Swale	01795 418359 KAMNASCPT.swalecmht@nhs.net	Phone line and email staffed by admin team Monday - Friday 9am-5pm; message taken and the psychiatrist will call the GP back same day
Thanet	07798 607635 kmpt.thanetcmht.gpmedicationadvice@nhs.net	Phone line and email staffed by admin team Monday - Friday 9am-5pm; message taken and the psychiatrist will call the GP back same day

Kindly Note:
KMPT has Community Mental Health Teams (CMHTs) located across Kent and Medway. The teams offer support and treatment in the community to adults between the ages of 18-65 who are experiencing a mental illness. The CMHTs provide an assessment of an individual's current needs and provide treatment for service users with moderate to severe mental health needs. This includes a comprehensive assessment of mental health needs and, where required, CMHTs will work alongside social care colleagues in Kent County Council and other external partners within the health care system. The teams include psychiatrists, community mental health nurses, occupational therapists, psychological services and support staff and also work in partnership with social care. Further information about the KMPT CMHTs can be found here.

2. KMPT Community Mental Health Service for Older People (CMHSOP) – for adults aged 65+

For Primary Care colleagues who need advice and guidance regarding their older patients' mental health-related medication, please find a list of useful email addresses and contact numbers below. The lines are open from Monday to Friday from 9am to 5pm and you will be directed to the best member of the team to assist with your query.

If your call is unanswered:

- Please state details of your enquiry
- Provide a mobile contact number
- Confirm the best time for a member of the CMHT to call you back
- Your message will be dealt with and **you should expect a call back within 72 hours**.

Emails are monitored throughout the working day and responses will be sent out within 24 hours.

KMPT Community Mental Health Service for Older People (CMHSOP) – aged 65+

CMHSOP Location	CMHSOP Contact details
Ashford	01233 658125 KAMNASCPT.ashfordOPMH@nhs.net
Canterbury & Coastal	01227 812054 01227 812083 kmpt.canterbury.olderpeople@nhs.net
Dartford, Gravesham, & Swanley	01322 421289 01322 622208 KAMNASCPT.dgscmhsopadmin@nhs.net
Dover & Deal	01304 213364 kmpt.doveranddealcmhtop@nhs.net
Maidstone	01622 726899 kmpt.maidstonecmhsopadmin@nhs.net
Medway	0300 303 3189 KAMNASCPT.medwayCMHSOP@nhs.net
Shepway	01303 228838 kmpt.shepwaycmhsopadmin@nhs.net
South West Kent	01732 228242 01732 228270 kmpt.southwestkentcmhsopadmin@nhs.net
Swale	01795 438446 KAMNASCPT.swalecmhsop@nhs.net
Thanet	01843 267071 KAMNASCPT.thanetcmhtop@nhs.net

KMPT operates a Community Mental Health Service both for older people with mental health needs, which are complicated by age-related needs, and for people of all ages, who have needs related to dementia. The service provides support and advice to professionals, care homes and carers. Service users receive an initial assessment after which a plan will be made in collaboration with the individual concerned as to what the next steps might be. This may involve further appointments with health care professionals, invitations to specialist groups, therapy and neuropsychological assessments. The KMPT team includes consultant psychiatrists, community psychiatric nurses, occupational therapists, psychological services and support staff, Admiral nurses and administrative staff. Further information about the KMPT Community Mental Health Service for Older People can be found here.

References

1. NICE. Clinical Knowledge Summary. Insomnia. https://cks.nice.org.uk/topics/insomnia/
2. Summary of Product Characteristics (SmPC). Circadin 2mg prolonged-release tablets. Flynn Pharma Ltd. https://www.medicines.org.uk/emc/product/2809/smpc#gref
3. Summary of Product Characteristics (SmPC). Adaflex 1, 2, 3, 4, and 5mg tablets. AGB-Pharma AB. https://www.medicines.org.uk/emc/search?q=melatonin
4. Summary of Product Characteristics (SmPC). Slenyto 1mg prolonged-release tablets. Flynn Pharma Ltd. https://www.medicines.org.uk/emc/product/10023/smpc#gref
5. Summary of Product Characteristics (SmPC). Melatonin 1mg/ml oral solution. Colonis Pharma Ltd. https://www.medicines.org.uk/emc/product/10419/smpc#gref
6. NICE. Autism spectrum disorder in under 19s: support and management. Clinical guideline [CG170]. https://www.nice.org.uk/guidance/cg170
7. NICE. Autism spectrum disorder in adults: diagnosis and management. Clinical guideline [CG142]. https://www.nice.org.uk/guidance/cg142/resources/2021-surveillance-of-autism-nice-guidelines-cg128-cg142-and-cg1709140525965/chapter/Surveillance-decision?tab=evidence
8. NHS UK. Health A to Z. Jet Lag. https://www.nhs.uk/conditions/jet-lag/
9. Harman C. Licensed melatonin treatment now available for children with autism. MIMS June 2019. https://www.mims.co.uk/licensed-melatonin-treatment-available-children-autism/learning-disabilities/article/1585967
10. General Medical Council (GMC). Good practice in prescribing and managing medicines and devices: prescribing unlicensed medicines. https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines
11. Department of Health. Drug Tariff. https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff
12. NHS Business Service Authority. DM+D browser. https://services.nhsbsa.nhs.uk/dmd-browser/

Appendix 1: Sleep Diary

Sleep is important for health and wellbeing. This sleep diary will help keep track of your sleeping routine.

It takes just a few minutes to complete each day – some questions need answering at the end of the day, some need answering first thing in the morning.

Please complete every day for 2 weeks. Don't worry too much about giving exact answers, an estimate is ok.

Your completed diary will help us to review your sleep habits and find out how your sleep can be improved.

Name:

Date beginning:

Please write day of the week	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
Questions to answer at the end of the day, before bedtime							
Did you have a nap during the day/evening and for how long?							
How would you rate your mood during the day? (1 - very poor, 5 - very good)							
How tired did you feel during the day from 1-5? (1 – not very tired, 5 – very tired)							
What drinks did you have after 5pm?							
How much exercise/activity have you done today?							
Questions to answer in the morning about:							
Bedtime							
What time did you go to bed last night?							
What did you do in the hour before bedtime?							
What did you do in bed? E.g. read, watch TV							
What time did you turn the lights off?							
How long did it take you to fall asleep?							
During the night							

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After falling asleep, how many times did you wake up in the night?							
How long were you awake during the night in total?							
What disturbed your sleep? E.g. worry, noise, lights							
Morning							
What time did you wake up this morning?							
What time did you get out of bed?							
How would you rate the quality of your sleep last night? (1 - very poor, 5 - very good)							
How do you feel this morning? 1. Refreshed 2. OK 3. Still tired							

What strategies have you tried to help you sleep? Mark each strategy out of 5 (1 – not helpful, 5 - very helpful)

Any other comments?

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