North Central London
Joint Formulary Committee

Factsheet

Melatonin Preparations

Unlicensed indications approved by the North Central London Joint Formulary Committee:

1. Sleep disorders caused by visual impairment
2. REM sleep behaviour disorders
3. Circadian rhythm disorders
4. Insomnia in children, adolescents, adults with learning disabilities
5. Insomnia for Children (>2 years) and adolescents with neurological or developmental disorders

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FACTSHEET TO FACILITATE PRESCRIBING

PLEASE NOTE THIS IS NOT A SHARED CARE GUIDELINE, NOR IS IT A FULL SUMMARY OF DRUG INFORMATION. ALWAYS REFER TO THE MOST RECENT BNF AND/OR SUMMARY OF PRODUCT CHARACTERISTICS.

Disclaimer

This Fact Sheet is registered at North Central London (NCL) Joint Formulary Committee (JFC) and is intended solely for use by healthcare professionals to aid the treatment of patients within NCL. However, this fact sheet is for guidance only, its interpretation and application remains the responsibility of the individual clinician. If in doubt, contact a senior colleague or expert. Clinicians are advised to refer to the manufacturer's current prescribing information before treating individual patients.

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NCL JFC is funded by and provides advice to Acute Trusts and Clinical Commissioning Groups in NCL.

Indication information

- Melatonin has a licensed indication approved by JFC – *"Insomnia in adults aged ≥55 years (Approved as second line treatment up to 13 weeks after zopiclone, zolpidem or a benzodiazepine)"*. However, this is restricted to secondary care only and should not be transferred to primary care.
- Melatonin has been approved ONLY for the specific unlicensed indications below, following specialist initiation only

Approved unlicensed indication of melatonin	Initiated by	For Continuation in Primary Care
Sleep disorders caused by visual impairment	National Hospital for Neurology and Neurosurgery (NHNN) centre for neuromuscular disease	✓ **Once patients have been initiated and stabilised on treatment**
REM Sleep Behaviour Disorders	Sleep Services UCLH	✓ **Once patients have been initiated and stabilised on treatment**
Circadian Rhythm Disorders	Sleep Services UCLH	✓ **Once patients have been initiated and stabilised on treatment**
Insomnia in children, adolescents, adults with learning disabilities	Specialist	✓ **Once patients have been initiated and stabilised on treatment**
Insomnia for children (>2 years) and adolescents with neurological or developmental disorders*	Specialist	✓ **Once patients have been initiated and stabilised on treatment**

*Treatment may be continued into adulthood if clinically appropriate and is appropriate for ongoing supply in primary care (refer to "adult patients" under "dose and administration section")

The appropriate specialist will:

1. Provide the patient and carers with initial information regarding the treatment, possible adverse effects, and unlicensed use
2. Initiate by prescribing 28 day supply initially
3. Write to the GP to transfer prescribing once the patient have been stabilised
4. Optimise the dose of melatonin if necessary and communicate changes to GP
5. Clinically review the patient by routine clinic follow-ups every 6 months and monitor response to treatment until transfer of care to GP

Dose and Administration[2, 3]

Adult Patients

- As advised by specialist. Typically: Initially 2 to 3mg at night, increased if necessary after 1-2 weeks to 6mg at night. Maximum dose is 12mg at night
- Melatonin 2mg modified-release tablets (Circadin®) are used 'off-label' for the approved unlicensed indications. The tablets should be taken 1-2 hours before bedtime and after food. The tablets can also be halved.
- When the patient is unable to take the tablet formulation, the tablets can be crushed before administration (see 'Preparations' section). In exceptional circumstances, melatonin 5mg/5ml oral solution or oral suspension may be considered (see product choice table). Doses should be taken 30 to 60 minutes before bedtime.
- Treatment should be stopped in those who fail to respond to the maximum dose or experience intolerable side effects
- Melatonin treatment should be reviewed by prescriber every 6 months
- In those requiring long-term treatment, consider a reduction in dose after several months, for patients who have settled into a regular sleep pattern.

Paediatric Patients

- Dose will be initiated by a specialist usually at 2mg at night.
- The modified release preparation of melatonin Circadin® MR 2 mg tablets are used routinely. If necessary they can be crushed (off-label) to aid administration. Exceptionally oral solution can be used and then the starting dose can be 0.5mg, escalating to 1 mg, 2 mg etc.
- The European Medicines Agency (EMA) recommends that patients <6 years old should not exceed 6mg/kg of alcohol. Ensure alcohol free formulations are prescribed for this age group where a liquid preparation is required.
- Immediate release preparations (crushed modified release tablets (Circadin®) off-label, or exceptionally oral solution or suspension, unlicensed) should be given 30 to 60 minutes before bedtime.
- Circadin® should be given 1-2 hours before bedtime and after food
- The dose will be reviewed at least fortnightly and will be escalated to 2 mg, 4 mg, 6 mg, 8 mg, 10 mg if:
    - Child not falling asleep within 1 hour of "lights off" or "snuggling down" at age-appropriate times for the child on three out of five nights; and/or less than 6 hours of continuous sleep on three out of five nights
    - No serious adverse events
    - Child has received at least five of seven doses in the past week

  (Note: if a dose of 6mg is not effective higher doses are unlikely to be effective)
- When children are escalated to the maximum dose, their response is reviewed and, if they have not responded in line with criteria above, melatonin is stopped **or** reduced to the minimum dose that achieves the same change.
- Melatonin treatment should be reviewed every 6 months. If still effective, continue treatment, however advise parents to attempt a trial off treatment annually (see below).

- If after months or years of having been effective, melatonin seems no longer to be effective, then a 2 – 3 week period off followed by re-starting at the lowest dose again can be tried.

Trial off Treatment (Paediatric Patients)

- Children may well outgrow their sleep onset latency (SOL) as they get older. For this reason it is advised that they try 7-14 days off melatonin approximately every 12 months.

- Parents are advised of this when they are initially started on melatonin. Parents can choose a suitable time to do this and do not have to liaise with their GP about the timing however they should inform the GP if the trial is successful and melatonin no longer required. If this break in medication is a success the child can stay off melatonin. If it is not parents should start again at the same dose.

- Many paediatric patients with neurodevelopmental disorders such as autism stay on melatonin for many years.

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

Melatonin is not recommended for use in patients with hepatic impairment[2]. 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.

Discontinuing treatment[4]

Melatonin can be stopped abruptly. No discontinuation effects are documented. Melatonin is not generally considered to produce tolerance, rebound insomnia or dependence.

If side effects are clinically significant or intolerable or if there is no benefit from treatment with melatonin, refer back to specialist for review.

Adverse Effects[2,5]

Melatonin is generally well tolerated and adverse reactions reported are at similar levels to those reported with placebo. The most common adverse reactions were headache, nasopharyngitis, back pain, and arthralgia which was common in both the melatonin and placebo treated groups.

There are no very common (≥1/10) or common (≥1/100 to <1/10) adverse effects reported with melatonin at an equivalent or greater rate than placebo. Uncommon (≥1/1,000 to <1/100) side effects include headache, lethargy, dizziness, irritability, nervousness, restlessness, abnormal dreams, anxiety, asthenias, abdominal pain, dyspepsia, mouth ulceration, nausea, hypertension, glycosuria, dermatitis, rash, weight increase, and abnormal liver function tests.

Other rare side effects (≥1/10,000 to <1/1,000) include leukopenia, thrombocytopenia, electrolyte disturbances , altered mood, syncope, memory impairment, visual acuity reduced, vertigo positional, gastro intestinal disorders, arthritis, angina pectoris, increased heart rate, hot flush, polyuria, priapism and fatigue.

See melatonin summary of product characteristics for full list of adverse effects.

Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Special Warnings and Precautions for Use[2]

- Melatonin may cause drowsiness - driving or other activities that put the patient or others at risk should be avoided if the patient is affected by drowsiness
- Melatonin is not recommended for use in patients with autoimmune diseases or taking immunosuppressants
- The licenced preparation of melatonin, Circadin®, contains lactose. Patients with rare hereditary problems of galactose intolerance, LAPP lactase deficiency or glucose-galactose malabsorption should not take this medicine
- Melatonin may, in rare cases, worsen restless legs syndrome
- An observational cohort study has found that in people aged 45 years and over receiving 3 or more melatonin prescriptions was associated with an increased risk of fracture compared with no use of any hypnotic drugs[6]
- Pregnancy - In view of the lack of clinical data, use in pregnant women and by women intending to become pregnant is not recommended.
- Breastfeeding - Breast-feeding is not recommended in women under treatment with melatonin. Endogenous melatonin was measured in human breast milk thus exogenous melatonin is probably secreted into human milk.
- Toxicity - Non-clinical data revealed no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

Drug Interactions[2]

	Medication Interaction	Clinical Effects	Action
Pharmacokinetic Interactions	***Fluvoxamine** **	*Plasma concentration of melatonin significantly increased*	*Avoid*
	Cimetidine	Plasma concentration of melatonin increased	Review / reduce dose of melatonin
	5 and 8-methoxypsoralen (psoralen)	Plasma concentration of melatonin increased	Review / reduce dose of melatonin
	Oestrogens	Plasma concentration of melatonin may be increased	Review / reduce dose of melatonin
	Ciprofloxacin and other quinolones	Plasma concentration of melatonin may be increased	Monitor. Review / reduce dose of melatonin if prescribed long term
	Carbamazepine and rifampicin	Plasma concentration of melatonin may be decreased	Review / increase dose of melatonin
	Cigarette smoking	Plasma concentration of melatonin may be decreased	Review if there is a change in smoking habit
Pharmacodynamic Interactions	***Sedative antipsychotics e.g. olanzapine, risperidone) **	*Increased sedative effect*	*Review patient for over sedation – Advice and Review*
	Other hypnotics and CNS depressants	Melatonin may enhance the sedative properties of other drugs acting on the CNS e.g. benzodiazepines.	Review patient for over sedation – Advice and Review
	Alcohol	Increased sedative effect - reduces effectiveness of melatonin.	Advice and Review

**** Potentially serious interactions***

Please refer to SPC/BNF for full information on interactions

Monitoring

Treatment with melatonin should be initiated and reviewed by a specialist. There will be some situations where it is appropriate for the specialist to follow-up the patient long-term; the specialist will complete the monitoring requirements but request the GP to continue prescribing. Examples of this include children with Cerebral Palsy at special school, or a child with ADHD and on ADHD medication.

There will be other circumstances where patients stabilised on melatonin can be discharged from the specialist clinic and in the long term followed up by the GP. An example of this is children with Autism Spectrum Disorders, who do not normally remain within the community paediatrics clinic caseload.

The need for continuing therapy should be reviewed every 6 months by the responsible clinician, as well as height and weight. Treatment should be stopped in patients who do not continue to benefit from its use or experience intolerable side effects.

GPs should review their patients as per their normal practice, however patients, their family or carers should be asked to keep a sleep diary http://yoursleep.aasmnet.org/pdf/sleepdiary.pdf. The sleep diary should be considered during the review of melatonin.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

Monitoring (Paediatric Patients)

Monitoring, particularly with regard to growth and pubertal/sexual development, is advised in children during long term administration, especially in those receiving melatonin for periods of a year or more.

GP's role after the care of the child has been transferred and accepted (After discharge from specialist):

1. Monitor the child's overall health and wellbeing, including 6 monthly height and weight
2. Refer children back to the consultant if there is delayed sexual development or failure to gain weight and height for the expected age and familial characteristics
3. Refer children back to the consultant if there are ongoing sleep problems or side effects

Preparations

Circadin®, melatonin modified release tablet, is first line but in exceptional cases other formulations may be necessary to meet individual patient clinical needs (e.g. melatonin 5mg/5ml oral solution or oral suspension sugar-free, or sugar and alcohol free formulation in under 6 year olds).

The licenced preparation currently in the UK is Circadin®, 2mg modified release tablet. The MHRA recommends prescribing licensed preparation where possible. Circadin® can be halved or crushed (off-label) to aid administration[7]. The in vitro release from a crushed or powdered tablet is expected to provide an immediate release profile similar to that from an unlicensed immediate release tablet or (unlicensed) oral liquid. The crushed melatonin tablet can be dissolved in a small amount of water or juice, or given on a spoon of cold soft food e.g. yogurt or jam[8].

There are a wide variety of unlicensed melatonin preparations available. Many products rely on food-grade rather than pharmaceutical grade melatonin and some are very expensive[5]. If the tablet formulation is unavailable or unsuitable, the liquid formulation can be prescribed.

If liquid preparation is prescribed, the melatonin 5mg/5mL oral solution or 5mg/5ml oral suspension are the most cost effective formulations in primary care (refer to Drug Tariff Part VIIIB – specials and imported unlicensed medicines). Ensure that the strength and formulation is prescribed as stated in the product choice table below to ensure the most cost-effective product is selected. The Tariff also covers sugar free and alcohol free formulations and prescribers will be required to endorse the prescription accordingly. It should also be noted that these 'specials' product may have varying and short-dated expiry dates – therefore prescribers will need to take this into consideration for the volumes prescribed.

Product choice

Preparation	Comments
Preferred Product **Circadin®** - 2mg modified release tablets ***Off-label use for unlicensed indications***	This is the preferred formulation Licensed UK medicine
First choice alternative **Circadin®** - 2mg modified release tablets – halved or crushed ***Off-label use***	
Second choice alternative - where crushing Circadin® is not a clinically appropriate option: • melatonin **5mg/5ml** oral solution *(minimum prescribed volume 200ml)* OR • melatonin **5mg/5ml** oral suspension *(minimum prescribed volume 100ml)* **Sugar free and/or alcohol free formulations are available – endorse prescription accordingly** ***Unlicensed 'special'***	Most cost effective special formulation in primary care – refer to Drug Tariff Part VIIIB – specials and imported unlicensed medicines) DO NOT PRESCRIBE BY BRAND IN PRIMARY CARE. 'Special' formulations may have short-dated shelf-life. The EMA recommends that patients <6 years old should not exceed 6mg/kg of alcohol. Prescribe an alcohol free formulation for this age group.

Contact Details

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Sleep Neurology Service
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Patient enquiries
Telephone: 020 3448 8623 / 020 3448 8622

GP enquiries
Telephone: 020 3448 8623 / 020 3448 8622
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Paediatrics – Whittington Health

IFOR ward (paediatrics ward)
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MOSAIC CAMHS

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Telephone: 020 3317 2275

Barnet, Enfield and Haringey Mental Health Trust:

Hospital Switchboard
Telephone: 020 8702 3000

Barnet Service:
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Edgware Community Hospital
Burnt Oak Broadway
Edgware
HA8 0AD
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Enfield Service:
Charles Babbage House
1 Orton Grove
Enfield , Middlesex
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Tel: 0208 379 1520

Haringey Service:
St Ann's Hospital – H Block
St Ann's Road
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N15 3TH
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Background

Melatonin is a hormone secreted by the pineal gland. It is normally secreted at night and its main function is the regulation of circadian rhythm and sleep, playing an important role in setting the correct timing of sleep-wake cycles.

The administration of exogenous melatonin has a rapid, transient, mild sleep inducing effect and it lowers alertness, body temperature and performance for about 3 to 4 hours after the administration of low doses (of immediate release formulations).

Melatonin has been used in the UK as an unlicensed medicine for several years on the advice of hospital specialists, for limited use in the treatment of a variety of sleep disorders.

Evidence

1. **Sleep disorders caused by visual impairment**

By adulthood, most individuals maintain a circadian melatonin cycle, however, the fall in endogenous melatonin levels post puberty may particularly affect adults with visual impairment. Khan S et al (2011)[9]undertook a review to assess the effects of melatonin for non-respiratory sleep disorders in visually impaired children, with regard to improvement in sleep habit, sleep scheduling and sleep maintenance, when compared with placebo or other medication. 127 studies were highlighted as part of the initial search strategy with 9 evaluated in detail, however none of the trials met the inclusion criteria for the following reasons: 2 studies [although of RCT design, were not double-blinded] contained populations extending beyond visual impairment where the data for the cohort of interest could not be extracted; the remaining 7 studies were not of RCT design, largely 'N of 1' series, and did not report consistent outcome parameters in order to draw conclusions. The authors concluded that despite empirical inference across the excluded studies finding melatonin to be effective in the short-term only, due to the lack of high quality data the role of melatonin for this indication is unclear.

2. **REM sleep behaviour disorders**

REM Sleep Behaviour Disorder (RBD) is a rare condition characterised by disruptive behaviours emerging during REM sleep, resulting in injuries to the patient and their bed partners. Due to the rarity of the condition, evidence for the efficacy is limited to three prospective studies and one retrospective review. Melatonin treatment reduced the percentage of REM sleep without atonia and sleep onset latency compared to baseline, though the effect was not statistically significant when compared to placebo. The Clinician's Global Impressions score for patients receiving melatonin was statistically significantly reduced compared to placebo treatment. Melatonin treatment had no impact on other sleep variables. The reduction in amount of sleep with atonia was supported by the open-label studies; the retrospective review reported improvements in "control of their RBD" for 12 of 14 patients treated.

3. **Circadian rhythm disorders**

Circadian Rhythm Disorders (CRD) describes a range of different sleep conditions caused by intrinsic errors affecting the body's regulating clock. A systematic review and meta-analysis of 5 RCTS including adults treated with melatonin in delayed sleep phase disorder (a type of CRD) was discussed. Melatonin treated patients saw an improvement in time to dim-light melatonin onset and sleep-onset. Impact on wake-up time, sleep-onset latency and total sleep time were not statistically significantly impacted by treatment with

melatonin. Two small, single-blind, placebo controlled trials, showed that treatment with melatonin allowed nine of fourteen blind patients with Free Running Disorder (another form of CRD) to synchronise to a normal sleep cycle.

4. **Insomnia in learning disabilities and neurodevelopmental disorders**

The most relevant study included by NICE[1] was Gringras et al (2012)[3]. They conducted a 12-week, randomised, double-blind, placebo controlled study, including 146 children (age 3 years to 15 years 8 months) with neurodevelopmental problem. Melatonin was initiated at 0.5 mg daily, and could be escalated to 12 mg based on response and tolerability. This study measured total sleep time (using a sleep diary) as the primary outcome. Secondary outcomes included total sleep time (actigraphy), sleep onset latency (diaries/actigraphy), and Composite Sleep Disturbance Index (CSDI) and Epworth Sleepiness Scale (ESS).

The total sleep time (sleep diary) increased by mean 40.5 minutes in melatonin treated patients, compared to 12.5 minutes in placebo patients (difference of 28 minutes, adjusted difference 22.4 minutes) ($p=0.04$). Sleep onset latency was statistically significantly lower in the melatonin group compared to placebo group when measured both using sleep diary (-37.5 minutes, $p<0.001$) and actigraphy (adjusted difference -45.3 minutes, $p<0.001$). CSDI and ESS showed a statistically significant improvement for melatonin compared to placebo. CSDI (a 12 point scale) was an additional 1 point lower in the melatonin group compared to placebo (lower score better). The ESS was an additional 1.6 points lower in the melatonin treated group compared to the placebo patients (lower score better). Scores that measured individual behaviours that challenged (e.g. irritability, agitation, hyperactivity) did not differ between melatonin and placebo treated patients.

Appendix 1 **Sleep diary**: http://yoursleep.aasmnet.org/pdf/sleepdiary.pdf

TWO WEEK SLEEP DIARY

INSTRUCTIONS:
1. Write the date, day of the week, and type of day: Work, School, Day Off, or Vacation.
2. Put the letter "C" in the box when you have coffee, cola or tea. Put "M" when you take any medicine. Put "A" when you drink alcohol. Put "E" when you exercise.
3. Put a line (I) to show when you go to bed. Shade in the box that shows when you think you fell asleep.
4. Shade in all the boxes that show when you are asleep at night or when you take a nap during the day.
5. Leave boxes unshaded to show when you wake up at night and when you are awake during the day.

SAMPLE ENTRY BELOW: On a Monday when I worked, I jogged on my lunch break at 1 PM, had a glass of wine with dinner at 6 PM, fell asleep watching TV from 7 to 8 PM, went to bed at 10:30 PM, fell asleep around Midnight, woke up and couldn't got back to sleep at about 4 AM, went back to sleep from 5 to 7 AM, and had coffee and medicine at 7:00 in the morning.

Today's Date	Day of the week	Type of Day Work, School, Off, Vacation	Noon	1PM	2	3	4	5	6PM	7	8	9	10	11PM	Midnight	1AM	2	3	4	5	6AM	7	8	9	10	11AM
sample	Mon.	Work		E					A				I									C M				

week 1

week 2

Appendix 2

Sleep Hygiene and Behavioural Intervention

These are the set of practices/habits that promote good sleep. Some important aspects to consider are…

1. Sleep Environment
   . Use the bed only for sleeping. Avoid other activities such as eating, work, reading and internet/chat on the bed.
   . Quieter bedroom, comfortable temperature and a well made bed are more conductive to sleeping.
   . Bright light and light of shorter wavelength (Green and blue light) suppress melatonin secretion. A less bright bedroom and lights of longer wavelength (red and orange lights) can aid sleep.

2. Sleep Schedule
   . Try to have a regular bed and wake-up time, including the weekend. Most importantly, getting up at the same time each morning – regardless of how poor the previous night's sleep was.
   . Sleep when feeling tired and sleepy, rather than spending too much time I the bed awake.
   . If no sleep after 20-30min in the bed, get off the bed and do something calming or boring e.g. reading a boring book, until sleepy. Avoid doing anything too stimulating or interesting.

3. Sleep Habits and Rituals
   . Having a simple bedtime routine helps to unwind (story time, reading, music etc).
   . Avoid naps during the day. However, naps are important for young children and preferably in the early afternoon.
   . On trips take along the child's pillow or bedding if possible.

4. Food, Drinks and Drugs
   . Hunger causes restless sleep. Heavy meal before bed can interrupt sleep.
   . A light snack (low Protein, high carbohydrate) can help. Foods containing melatonin (rice, corn and oats) or its precursor tryptophan (warm milk, nuts etc) can act as a natural sleep inducer.
   . Avoid caffeine (tea, coffee, colas, chocolate etc), nicotine (cigarettes) and alcohol (fragments and reduce total sleep time) for at least 4-6 hours before going to bed.
   . Certain medications can adversely affect sleep directly (e.g.stimulants) or by interfering with melatonin synthesis (e.g. NSAIDS – aspirin, ibuprofen etc).

5. Exercise
   . Regular exercise aids good sleep. Gentle exercise before bed can help feel relaxed. Strenuous exercise before bedtime is not advisable.
   . Having a warm bath 1-2 hrs before bedtime can be useful. This raises the body temperature and makes people feel sleepy as the body temperature drops again.