North Central London
Joint Formulary Committee

# Factsheet
## Melatonin Preparations

**Indications approved for primary OR secondary care initiation:**

1. Insomnia in adults aged ≥55 years (Approved as second line treatment for up to 13 weeks, after zopiclone, zolpidem or a benzodiazepine)

**Indications approved by the North Central London Joint Formulary Committee for secondary care initiation and primary care continuation:**

1. Sleep disorders caused by visual impairment
2. REM sleep behaviour disorders, including in patients with Parkinson's disease
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
6. Autism Spectrum Disorder (ASD) and/or Smith-Magenis syndrome in children

**Start date: July 2024**
**Review date: July 2027**

| **Document Control** | | |
|---|---|---|
| **Date** | **Version** | **Action** |
| March 2019 | V1 | Factsheet originally produced by David Rogalski (C&I)<br>Agreed by NCL Medicines Optimisation Network: March 2019<br>Ratified by NCL Joint Formulary Committee |
| July 2024 | V2 | Addition of the following approved indications:<br>• REM Sleep Behaviour Disorder in Parkinson's disease<br>• Insomnia in adults aged > 55 years (as second line treatment for up to 13 weeks after zopiclone, zolpidem or a benzodiazepine), for primary or secondary care initiation<br>• Autism Spectrum Disorder (ASD) and/or Smith-Magenis syndrome in children<br><br>Amendment of product choice to include generic melatonin MR preparations, Slenyto®, Adaflex® (immediate release) and Melatonin Consilient Health oral solution<br><br>Modified by Gurpal Grewal (NCL IPMO), Dr Ella Rachamim (Specialist Doctor in Community paediatrics, Barnet), Jay Pang (NCL IPMO), Haroon Hafeez (RFL), Caroline Weaver (NCL ICB) and Niketa Dass (NCL ICB). |

| | | |
|---|---|---|
| August 2025 | V2.1 | Addition of Barnet Central London Community Healthcare NHS Trust (CLCH) Parkinson's Disease Unit as a service provider able to initiate melatonin for REM Sleep Behaviour Disorder in Parkinson's disease (including contact details) |

| | |
|---|---|
| Groups / Individuals who have overseen the development of this guidance: | RFL Clinical Team<br>Community paediatrics (Barnet) clinical team<br>NCL ICB Medicines Optimisation team<br>JFC Support Pharmacists |
| Groups which were consulted and have given approval: | NCL Shared Care Group |
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| Review date: | 18/07/2027 |

**Disclaimer**

Factsheets support GPs in taking ongoing responsibility for continuing a medicine initiated in secondary care. It differs from a shared care agreement where secondary cares retain a proportion of responsibility for ongoing care.

This document is intended for use by healthcare professionals to aid the treatment of patients within NCL. It should not be used for marketing purposes. If you identify information within this document that is inaccurate, please report to admin.ncl-mon@nhs.net.

*Indication information*

- Melatonin is licensed in the UK for the "*short-term treatment of jet-lag in adults*". This has not been considered by NCL JFC and is therefore not on formulary in NCL.

**Melatonin has been approved in NCL ONLY for the specific indications below:**

| Approved indication of melatonin | Initiated by | For Continuation in Primary Care |
|---|---|---|
| Insomnia in adults aged > 55 years (as second line treatment for up to 13 weeks after zopiclone, zolpidem or a benzodiazepine) | Primary or Secondary care | ✓ **Can be initiated in primary care or continued after initiation in secondary care up to a total of 13 weeks** |
| Sleep disorders caused by visual impairment* | National Hospital for Neurology and Neurosurgery (NHNN) | ✓ **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** |
| REM Sleep Behaviour Disorder in Parkinson's disease* | Movement Disorder services @ NHNN, RFL and Barnet CLCH Parkinson's Disease Unit | ✓ **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** |
| Autism Spectrum Disorder (ASD) and/or Smith-Magenis syndrome in children | Children and Young People Services | ✓ **Once patients have been initiated and stabilised on treatment** |

* Off-label indication;
† Some products have a licence in the UK for insomnia related to ADHD, autism spectrum disorders and Smith-Magenis syndrome in paediatrics; use in other indications related to neurological or development disorders is considered off-label
‡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").

**For indications initiated in secondary care, 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 and continue until a stable dose has been reached.
3. Once stabilised, write to the GP to transfer prescribing, and inform the GP of plans for melatonin in the short- and long-term (including information on annual breaks) and contact information for any follow-up queries or advice once the patient is discharged.

**Dose and Administration[2, 3]**

**For information on the most appropriate formulation to prescribe, please see the *"Preparations"* section.**

**Adult Patients**

- For unlicensed indications, melatonin will be initiated by a specialist and a treatment plan provided. 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 should be taken 30 minutes before bed (although taken 1-2 hours before bed **if swallowed whole**).
- Treatment should be stopped in those who fail to respond to the maximum dose or experience intolerable side effects. The decision to stop treatment will be made by the specialist if the patient fails to respond after one week at maximum dose.
- Melatonin treatment should be reviewed by the primary care clinician every 12 months.
- Once patients have settled into a regular sleep pattern for several months, consider a reduction in dose with the aim to cease treatment.

**Paediatric Patients**

- Melatonin will be initiated by a specialist. A treatment plan will be provided to the parents which includes contact details of the specialist.
- Melatonin is usually advised to be taken at least 30 minutes before bed (or in the case of Circadin® only if swallowed whole, at least 1-2 hours before bed) and after food.
- The usual starting dose is 1-2mg at night (depending on the formulation used). The treatment plan will outline the dose escalation required, which is usually escalated by 1-2mg every 5-7 days up to 6mg, 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 regular daily dosing for 5 to 7 days before dose escalation.

  (Note: the maximum dose of melatonin is 10mg daily. If a dose of 6mg is not effective higher doses are unlikely to be effective; the specialist will review and consider whether there is any benefit in trialling doses higher than 6mg on a case-by-case basis)
- The initial prescription of melatonin should at least cover the period of titration and until their following review (at least 2 months supply of melatonin should be supplied on the initial prescription).
- The Specialist will offer a routine review with the patient to ensure they are stable on their medication prior to transferring prescribing responsibility to the GP (usually within 2 months, which can be

conducted virtually).

- 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.

- The melatonin therapies approved by use in NCL are described further in the *"Preparations"* section below.

- If necessary, certain melatonin tablets can be crushed to aid administration to patients who are unable to tolerate the tablets whole. See the "*Preparations*" section for more information.

- Exceptionally melatonin oral solution can be used (e.g., gastrostomy patients, or when halved/crushed tablet formulation is unsuccessful); it also allows for a lower starting dose (e.g., 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. Other excipients also have safety limits, and these are listed in Table 1. Ensure alcohol-free formulations are prescribed for this age group where a liquid preparation is required.

- Melatonin treatment should be reviewed every 12 months by the primary care clinician. If still effective, continue treatment; however, parents will be advised 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 period of 5-7 days off treatment followed by re-starting at the lowest dose again can be tried.

**Annual 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 days off melatonin approximately every 12 months. Melatonin will be stopped completely without a tapering regime, even at the highest dose.

- 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, then the parents may be informed to restart melatonin at the lowest dose and titrate upwards until an effective dose is reached (which may be lower than the previous dose). Patients who are on a stable dose are discharged from the specialist service. The initial transfer of care letter should provide details on the annual break and how the parents will perform it. Parents should feedback on the lowest effective dose to the GP for continued prescriptions.

- 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 to the 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, gastrointestinal disorders, arthritis, angina pectoris, increased heart rate, hot flush, polyuria, priapism, and fatigue.

See the melatonin summary of product characteristics relevant to the chosen formulation and brand for a 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 after consumption - driving or other activities that put the patient or others at risk should be avoided if the patient is affected by drowsiness (this is not expected to last to the morning following a dose taken the night before).

- There have been occasional case reports describing an exacerbation of an autoimmune disease in patients taking melatonin. Melatonin is not routinely recommended for use in patients with autoimmune diseases or taking immunosuppressants.

- All melatonin tablet preparations (MR or IR) with the exception of Adaflex® and Ceyesto® immeditate release tablets contains lactose. Patients with rare hereditary problems of galactose intolerance, LAPP lactase deficiency or glucose-galactose malabsorption should be prescribed a lactose-free formulation, where appropriate.

- 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**

When melatonin is initiated in primary care for its licensed indication, patients should be reviewed to determine effectiveness after the initial prescription. Treatment should be stopped if effectiveness has not been determined. The total treatment course should not exceed 13 weeks.

For unlicensed indications initiated in secondary care, treatment with melatonin will 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; an example of this includes children with cerebral palsy at special school.

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 12 months by the responsible clinician. Treatment should be stopped in patients who do not continue to benefit from its use or experience intolerable side effects.

Further monitoring may be advised in relation to the condition being treated in the child. This should be detailed in the letter to the GP.

GPs should review their patients as per their routine review of patients and in line with the clinical management plan; however, patients, their family or carers should be asked to keep a sleep diary (e.g., http://yoursleep.aasmnet.org/pdf/sleepdiary.pdf). The sleep diary should be considered during the review of melatonin. Further advice can be sought from the Healthier Together website (https://www.what0-18.nhs.uk/parentscarers/sleep).

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.

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

1. Monitor the child's overall health and wellbeing.
2. If there are ongoing sleep problems or side effects:
    a. Ensure behavioural techniques and program is in place and encourage and emphasise importance of adherence.
    b. Monitor, review and encourage medication compliance, and that parents are providing medication as prescribed.
    c. Consider referral to sleep organisations (e.g., sleep charity, SCOPE sleep Right)
    d. Consider discussion with the specialist and make referral back if appropriate. The specialist may also discuss other possible causes prior to referral back, such as nutritional causes or checking ferritin levels.

**Preparations**

The most appropriate product to use can be seen in Table 2 below.

**Modified release tablet preparations**

Modified release tablet preparations are preferred over capsule formulations as the most cost-effective choice.

There are now a number of 2mg modified release tablet preparations available in the UK which are licensed for short term management of primary insomnia in patients aged 55 or over. As these are of significantly lower cost than the original brand Circadin®, ***generic* 2mg modified release tablets** are the first choice melatonin preparation in NCL.

**Slenyto®** (1mg and 5mg modified release tablets) are licensed for patients aged 2-18 years with Autism Spectrum Disorders (ASD) and Smith-Magenis syndrome. **Slenyto®** has been approved by NCL JFC for use within its licensed indication if the patient cannot tolerate 2mg modified release tablets. It may be given whole in yoghurt, orange juice or ice-cream to facilitate swallowing and improve compliance.

**Immediate release melatonin preparations**

Generic modified release 2mg melatonin tablets are preferred as the most cost-effective product choice. Immediate release tablets (Adaflex®) may be considered as:

- FIRST line for:
    - Insomnia in children and adolescents aged 6-17 years with ADHD, where sleep hygiene measures have been insufficient.
- SECOND line to modified release tablets for patients:
    - Where initiation of sleep is the main difficulty which may be helped by a shorter onset of action OR

- Where a lactose free preparation is required

**Novel melatonin formulations** which come to market will be assessed (either upon request or if a significant impact is anticipated) for their comparative efficacy, safety, cost and affordability.

**Crushing solid dosage forms**

The in vitro release from a crushed or powdered tablet is expected to provide an immediate release profile similar to that from an immediate release tablet or 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. Note this is considered off-label use.

**Licensed melatonin solution**

**The brand preferred is Melatonin Consilient Health 1mg/mL**, which is a licensed product.

This product is alcohol free.

Another licensed brand (Colonis oral solution melatonin 1mg/1mL) was not approved by NCL JFC as it did not represent good value for money compared with other standard of care melatonin products.

**Table 1 – Safety limits to be considered prior to initiation of melatonin solution[4]**

| Excipient | Age group | Safety limit (maximum daily dose)* |
|---|---|---|
| Propylene glycol | Child aged 1 month to 4 years | 50mg/kg |
| Propylene glycol | Child aged 5 to 17 years | 500mg/kg |
| Ethanol | Child aged less than 6 years | Blood-alcohol concentration should not exceed 1mg/100mL (a dose of 6mg/kg) |
| Ethanol | Child aged 6 to 12 years | Blood-alcohol concentration should not exceed 12.5mg/100mL (a dose of 75mg/kg) |
| Sorbitol | All children | 140mg/kg/day |

*The licensed melatonin 1mg/mL oral solution (Colonis brand) contains propylene glycol 150.37mg/mL. ethanol 0.00045mg/mL and sorbitol 140mg/mL.

**Other unlicensed melatonin products**

The use of unlicensed/ 'special' liquid or solid dosage forms of melatonin preparations is **NOT** recommended in NCL.

Use of a licensed product should be considered before using a licensed product 'off-label'.

No other unlicensed melatonin products should be routinely used. There are a wide variety of unlicensed melatonin preparations available for purchase. Many products rely on food-grade rather than pharmaceutical grade melatonin and some are very expensive[5]. These are not recommended for use.

**Table 2 – Recommended melatonin formulations for use in NCL**

<table>
<tr><th>Indication</th><th>Age</th><th>If tolerating solid dosage formulation</th><th>Swallowing difficulty impacting use of 1st line agent</th></tr>
<tr><td>• Autism Spectrum Disorder (ASD) and/or Smith-Magenis syndrome</td><td>2-18 years</td><td>1st line: Generic melatonin 2mg modified release tablets</td><td rowspan="3"><u>1st Line – if crushing or splitting tablets are an option</u><br><br>Adaflex® is licensed to be crushed and mixed with water directly before administration<br><u>2nd Line – for patients requiring liquid formulations (e.g., gastrostomy patients)</u><br>Prescribe Melatonin Consilient Health 1mg/mL oral solution (specifying brand on the prescription) <u>only if</u> patient can tolerate the safety limits of excipients (see table 1).</td></tr>
<tr><td rowspan="2"></td><td></td><td>2nd line: Slenyto® (for starting doses less than 2mg and where modified release preparations are not tolerated</td></tr>
<tr><td>≥19 years</td><td>1st line: Generic melatonin 2mg modified release tablets<br>2nd line Adaflex® immediate release tablets – see notes above for IR preparations</td></tr>
<tr><td>• Neurological and developmental disorders other than ASD and/or Smith-Magenis syndrome<br>• Sleep disorders caused by visual disturbances<br>• REM sleep behaviour disorders<br>• REM sleep behaviour disorder in patients with Parkinsons disease<br>• Circadian rhythm disorders<br>• Insomnia aged ≥ 55 years<br>• Insomnia in individuals with learning disabilities</td><td>All ages</td><td>1st line: Generic melatonin 2mg modified release tablets<br>2nd line Adaflex® immediate release tablets – see notes above for IR preparations (may be first line for children with ADHD)– see notes above</td></tr>
<tr><td colspan="4">†Slenyto® for ASD and/or Smith-Magenis syndrome may be given whole in yoghurt, orange juice or ice-cream to facilitate swallowing and improve compliance. Δ There are alternative unlicensed liquid preparations available of varying strengths which should only be requested if an extemporaneous product is required to meet the clinical needs of the patient (e.g. lactose-free).</td></tr>
</table>

**Contact Details**

**Camden and Islington NHS Foundation Trust**
Islington Learning Disabilities Partnership
52D Drayton park
London N5 1NS
Telephone: 020 7527 6600
Email: duty.ildp@islington.gov.uk

Camden Learning Disabilities Service
5 Pancras Square
London
N1XC 4AG
Tel: 020 7974 3737

**Sleep Neurology Service - NHNN**
National Hospital for Neurology and Neurosurgery
Box 29
Queen Square
London, WC1N 3BG

Patient enquiries - Tel: 020 3448 8623 / 020 3448 8622
GP enquiries - Tel: 020 3448 8623 / 020 3448 8622 Fax: 020 3448 8615

**Movement Disorder Service - NHNN**
Box 146
National Hospital for Neurology & Neurosurgery Queen Square
London WV1N 3BG
Telephone for GP/Patient enquiries; 0203 448 8726

**Movement Disorder Service – Barnet CLCH Parkinson's Disease Unit**
Edgware Community Hospital
Burnt Oak Broadway
Edgware
HA8 0AD
Email: clcht.edgwareparkinsons@nhs.net
Tel: 0208 397 7150 / 0208 939 7154

**Paediatrics – Whittington Health**
IFOR ward (paediatrics ward)
Tel: 0207 288 5442

**MOSAIC CAMHS**
Tavistock and Portman NHS Foundation Trust Kentish Town Health Centre
2 Bartholomew Road, London, NW5 2BX
Tel: 020 3317 2275

**Royal Free London**
**Barnet Child Development Team (Edgware Hospital):**
Child Development Team (CDT),
3rd Floor, Westgate House,
Edgware General Hospital,
Burnt Oak Broadway,
HA8 0AD
Email: rf-tr.childdevreferrals@nhs.net
Tel: 0207 794 0500 ext 26457 or 26382

**RFH Community Paediatric Services (in Camden)**
Child Health
Lower Ground Floor
Royal Free Hospital
Pond Street
London NW3 2QG

Email: rf.communitypaediatricsadmin@nhs.net
Tel: 0207 794 0500 ext 35820

**RFL Parkinson's Disease Unit**
Email: rf.neurologyadmin@nhs.net

**Barnet, Enfield and Haringey Mental Health Trust:**
Hospital Switchboard Telephone: 0208 702 3000

**Barnet Service:**
Holly-Oak (Dennis Scott Unit)
Edgware Community Hospital
Burnt Oak Broadway
Edgware
HA8 0AD
Tel: 0208 702 4500

**Enfield Service:**
Charles Babbage House
1 Orton Grove
Enfield, Middlesex
EN1 4TU
Tel: 0208 379 1520

**Haringey Service:**
St Ann's Hospital – H Block
St Ann's Road
Tottenham
London
N15 3TH
Tel: 0208 702 3400 / 0207 025 144

## References


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7. Chua, Hui Ming et al. "Dissolution of Intact, Divided and Crushed Circadin Tablets: Prolonged vs. Immediate Release of Melatonin." Ed. Afzal R. Mohammed. Pharmaceutics 8.1 (2016): 2. PMC. Web. 27 Mar. 2017.
8. Data on file – Flynn Pharma Ltd. July 2012
9. Khan SA et al. Therapeutic options in the management of sleep disorders in visually impaired children: a systematic review. Clinical Therapeutics 2011; 33: 168-180
10. Expert Opinion: Dr Ellen Kriesels. Consultant Community Paediatrician, Whittington Health NHS Trust

**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 | | | | |
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week 1

week 2

A sleep diary app **(SNappD®)** is also available on the Google Play store and Apple App store:

Android

IOS

**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
    - Ensure the patient/parent/carer keeps a sleep diary (see Appendix 1 for more information)
    - 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.

6) Other conditions which may cause sleep disturbance
    - 10-44% of ADHD patients have Restless Leg Syndrome (RLS). The sensation of RLS is difficult to describe, so it is even harder in children. It can often be misdiagnosed as "growing pains" or mislabelled as ADHD.
    - Clinicians may recommend checking ferritin levels and treating with oral iron if ferritin levels <75micrograms/L.
    - Sleep problems can be linked to obstructive sleep apnoea (OSA). The severity of OSA correlates with BMI.
    - Consider an OSA questionnaire in paediatrics (example can be found here: https://media.starship.org.nz/osas-screening-questionnaire/osas_screening_questionnaire.pdf)