# MELATONIN
# Insomnia and Sleep Disorders in Children and Adolescents- Shared Care Agreement

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| Version number : | 10 |
| Consultation Groups | Area Prescribing Group (Luton/Beds including Child Development Centre); CCGs Newham/Tower Hamlets/ City & Hackney/ CAMHS community and inpatients |
| Approved by (Sponsor Group) | Area Prescribing Group/ CCGs/ |
| Ratified by: | Medicines committee ELFT |
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| Name of originator/author: | Iffah Salim (CAMHS Pharmacist) |
| Executive Director lead : | Dr Cathy Lavelle |
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| Next Review date: | September 2024 |

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| Services | Applicable |
| Trustwide | CAMHS service- inpatient/community |
| Mental Health and LD | |
| Community Health Services | |

***DOCUMENT TO BE SCANNED INTO ELECTRONIC RECORDS AND FILED IN NOTES***

| **Patient name:** | **Date of Birth:** | **NHS number:** |
|---|---|---|
| **Patient Address:** | **Referring Consultant/Paediatrician name and contact details:** | **GP name and contact details:** |

## INTRODUCTION

Melatonin is a pineal hormone which affects sleep. It is normally secreted at night and its main function is the regulation of circadian rhythm and sleep. It plays 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.

Clinical experience suggests that it may be of value for treating sleep onset insomnia and delayed sleep phase syndrome in children with conditions such as visual impairment, cerebral palsy, attention deficit hyperactivity disorder, autism spectrum disorder, and learning difficulties. In practice, the use of melatonin for the treatment of paediatric sleep-wake cycle disorders is widespread.

Sleep disorders in children with neurodevelopmental difficulties such as ASD and ADHD are more common then the typically developed population. In ASD sleep problems, particularly insomnia can occur in 40-80% of children and adolescents (Cortesi et al, 2010). With regards to ADHD, within the clinic setting, 25-50% of individuals are reported to have sleep problems (Corkum et al, 1998; Gau et al 2007; Fisher et al, 2014).

Children with and or without co-morbid ADHD treated with melatonin have been shown to fall asleep earlier and sleep for longer when compared to controls. The current systematic reviews and meta-analyses of placebo-controlled, and randomised controlled trials in children with neurodevelopmental disorders, have demonstrated that melatonin significantly improves sleep onset latency and sleep duration compared to controls (Gringras et al., 2012). Melatonin may be most effective in those children whose sleep patterns indicate that their circadian rhythm is disrupted, and in whom sleep hygiene methods have been ineffective. Although it is important to note, in children/ adolescents with neurodevelopmental difficulties response to Melatonin can be variable.

Circadin® MR 2mg tablets are a sustained release formulation of Melatonin which is licensed in the UK as monotherapy for the treatment of primary insomnia in adults aged 55 years and over. Melatonin is not licensed for use in children. However its use off label is preferable to the use of an unlicensed special. The MHRA recommends that a licensed product should be used, even if it is used off label, before considering the use of an unlicensed preparation.

For the purpose of this guidance, the term ‘specialist’ is used to reference to a consultant

paediatrician and child and adolescent mental health (CAMHS) consultant.

**Patient group**

Diagnosis of a sleep disorder in children made by a specialist in paediatrics, CAMHS (ELFT) and Learning Disabilities (LD).

For use in children of at least 1 year of age with neurodevelopment disability, autism spectrum disorder, visual impairment or neuropsychiatric disorders and chronic sleep disturbance, including chronic fatigue syndrome, where:

Symptoms of sleep disturbance have been present for at least six months or sleep disturbance is so severe that it is causing significant family disturbance

Sleep hygiene / behavioural measures, have been tried and either did not work and/ or had limited benefit

## CARE PATHWAY AND RESPONSIBILITY ARRANGEMENTS ACROSS PRIMARY AND SECONDARY CARE

| Specialty | Indication | Duration | Prescribed by | Reviewed by |
|---|---|---|---|---|
| *For recommendation by a specialist and continuation by General Practitioner (GP)* | | | | |
| Paediatric and neurology/ CAMHS (ELFT)/ LD | Insomnia in the above group | Duration of therapy to be agreed by specialist. . | To be initiated by specialist and continuation by GP. | Annual review by the Paediatrician/ Neurologist /CAMHS (ELFT)/ LD team depending on local service provision. -Annual GP review at 6month interval to specialist review |

Patient recommendation/transfer will be done via a letter from the Paediatric Consultant/CAMHS consultant/ LD consultant to the GP.

## DOSE AND ADMINISTRATION

| Age | Oral dose | Maximum dose |
|---|---|---|
| 1 year – 18 years | Initially 2 mg daily. Increase every 1-2 weeks based on response to 4-6mg daily. | Usually 10mg daily |

- Take the Melatonin after food.
- Take dose 30-60 minutes before bedtime.
- For children waking during the night, the same dose or a smaller dose can be repeated during the night (as prescribed by the specialist- to be communicated to the GP in writing).
- Melatonin 2mg MR tablet (Circadin®) can be halved using a tablet cutter and it will retain its slow release characteristics.
- For children with tubes/those with severe swallowing difficulties where all medicines are liquids, a liquid preparation of Melatonin is available (see third line under prescription and supply)
- NOTE: crushing the MR tablet will mean that it is no longer modified release.
- Refer to current BNFc and Summary of Product Characteristics for further information.

The brand of Melatonin should be specified when prescribing. This should be completed by the specialist service starting the formulation. .

## PRESCRIPTION AND SUPPLY

Melatonin MR or IR should be prescribed as per the brand listed below. This is to ensure the correct product is supplied as well as the correct cost applied.

The Circadin® 2mg MR tablets should be labeled with advice to swallow the tablets whole and to avoid crushing.

Patients with difficulty swallowing, who will need to crush the tablets before administering, must be advised to override this instruction. The prescription should state that the medication is to be crushed prior to administration.

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| First line | **Circadin®** (Melatonin) MR 2mg tablets. (Cost 2021: £15.39 for 30 tablets).<br><br>**Circadin®** tablets should be used first line if the appropriate dose can be obtained by either swallowing whole or crushing into water/ soft food.<br><br>**Ceyesto®** (Melatonin 3mg immediate release (IR) tablets) **Ceyesto®** is an additional first line choice option for patients who:-<br>Require an immediate release melatonin product<br>Can swallow tablets and are already prescribed an IR melatonin product, including those on an unlicensed melatonin liquid preparation or melatonin 1mg/1ml oral solution (Colonis Pharma Ltd)<br>Are re on doses of 3mg, 6mg or 9mg daily<br><br>***Please note:***<br>*New patients requiring an IR formulation should be prescribed Ceyesto®*<br>*The decision to switch existing patients to IR based on the above criteria should be based on the patient need and if it is appropriate to switch to Ceyesto®* |
| Second Line | **Circadin®** 2mg MR tablets<br><br>Can be halved without losing modified release characteristics.<br>It can be crushed and mixed with water/juice/soft food for swallowing difficulties.<br>Please note: once crushed it will no longer be modified release. |
| Third line<br><br>**Please note: The oral suspension should only be used in exceptional circumstances.** | Melatonin **10mg/5ml oral suspension SF/AF** is available as an unlicensed special order medicine.<br><br>For children with tubes/those with severe swallowing difficulties where all medicines are liquids<br><br>Please prescribe as: Melatonin 10mg/5ml oral suspension SF AF<br><br>**Please Note:** With/without propylene glycol is optional depending on availability, and should be considered for those young people who clinically require PG free formulations.<br><br>Listed as special in Drug Tariff September 2021: £20.68 x 100ml<br><br>SF- Sugar Free; AF- Alcohol Free<br><br>The specialist prescriber is advised to review use annually in the case of the oral solution. |

Melatonin 1mg/ml oral solution (Colonis Pharma) is a licensed product for the treatment of jet-lag in adults. This product is not suitable for use in children and adolescents due to the excipient content and should not be prescribed for children.

**Refer to current BNFc and Summary of Product Characteristics for further information.**

## ADVERSE EFFECTS

Studies have found melatonin very well tolerated with a side effect profile as of the placebo and so symptoms are likely to be a coincidence. The long term side effects have not been evaluated.

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 abnornmal dreams, lethargy, headache, anxiety, nervousness, , dizziness, restlessness, irritability, 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 thrombocytopenia, leukopenia, altered mood, electrolyte disturbances , syncope, memory impairment, visual acuity reduced, vertigo positional, gastro intestinal disorders, arthritis, angina pectoris, increased heart rate, hot flush, polyuria, priapism and fatigue.

For a full list of side effects refer to the BNF or product SmPC/PIL published online at www.medicine.org.uk or www.mhra.gov.uk.

**Overdose**
Administration of daily doses of up to 300mg of Melatonin without causing clinically significant adverse reactions have been reported in literature. High dose can reduce body temperature and if overdose occurs, drowsiness is to be expected. Clearance of the active substance is expected within 12 hours after ingestion. No special treatment is required.

Discontinuation does not appear to be associated with withdrawal effects. If any persistent and problematic side effects occur discontinue melatonin and refer the patient back to the hospital team

## CAUTIONS

Cautions

- Drowsiness - driving or other activities that put the patient or others at risk should be avoided if the patient is affected by drowsiness
- Patients with rare hereditary problems of galactose intolerance, the LAPP lactase deficiency or glucose- galactose malabsorption should not take Circadin® brand melatonin (contains lactose)
- Patients with renal impairment
- Melatonin may worsen restless legs syndrome
- Melatonin can affect serotonin levels and should be used with caution in conjunction with other serotonin related agents.

There is a known potential for melatonin to affect seizure control in patient with epilepsy hence monitoring of seizure frequency is advised. The effects on initiation and titration of melatonin in epileptic patients should be closely monitored. Some reports suggest an improvement of seizure control whilst others indicate a worsening of control. Additionally poor sleep is known to worsen

seizure control.

Endogenous serum Melatonin concentration is elevated in nocturnal asthmatic patients. Although the clinical trial data presented here does not indicate an increase in asthma symptoms, Melatonin should be used with caution in this group. Most commercial Melatonin is synthesized in the laboratory. However, in rare cases it has been derived from animal pineal glands. Melatonin from animal sources should be avoided due to the possibility of contamination.

Pregnancy and Breast Feeding

There are no known concerns with Melatonin in pregnancy. Where young girls or women taking Melatonin become pregnant, cases should be managed on an individual basis, seeking expert advice from the specialists.

Use in pregnant women and by women intending to become pregnant is not recommended. Breastfeeding is not recommended for women taking Melatonin.

## CONTRAINDICATIONS AND INTERACTIONS

Contraindications

- Hypersensitivity to Melatonin or any excipients
- Patients with hepatic impairment
- Patients with autoimmune diseases or taking immunosuppressants

Drug interactions

Please refer to the most up-to date BNF and SPC for Melatonin for detailed information on interactions.

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| 5 and 8-methoxypsoralen | Use with caution with melatonin, increased melatonin plasma concentration |
| Alcohol | Avoid – reduces effectiveness of melatonin |
| Carbamazepine and rifampicin | May give rise to reduced plasma concentrations of melatonin. |
| Cigarette smoking | May reduce melatonin concentrations |
| Cimetidine | Use with caution with melatonin, increased melatonin plasma concentration |
| Ciprofloxacin and other quinolones | Use with caution with melatonin, increased melatonin plasma concentration |
| Fluvoxamine | Avoid use with melatonin as melatonin plasma concentrations are markedly increased (metabolism inhibited) |
| Nifedipine | May affect blood pressure control |
| Oestrogens | Use with caution with melatonin, increased melatonin plasma concentration |
| Other hypnotics and CNS depressants | Melatonin may enhance the sedative properties of other drugs acting on the CNS e.g. benzodiazepines |
| Warfarin | INR may be increased |

## MONITORING AND REVIEW

No baseline monitoring is required. An annual review of Melatonin therapy should be completed by the specialist with the patient. In addition to this, the GP will review at the 6 month point between the specialist annual review. If possible, the patient and/ or carer should keep a sleep diary a month prior to the appointment which can form part of the review. Prescribers are required to monitor sleep patterns and should review the need to continue treatment every six months and doses adjusted as necessary.

With Melatonin a reduction in efficacy can be noted after a good initial response.. For these patients a 1-2 weeks 'medication holiday' should be trialed to see if it is required. If it is still required then it is more helpful to reintroduce melatonin at a lower dose than increasing the dose. As part of the specialist reviews, a break of 1-2 weeks should be discussed with the parent and young persons. The outcome of any treatment break must be recorded in the patient's notes. Treatment should be stopped when there is a lack of effect based on information from the sleep pattern, melatonin break and patient/ parent perception. The GP should be informed of any changes to Melatonin therapy.

For many patients, the use of melatonin will be a medium term medication to support behavioral interventions. It is unusual for a child to continue melatonin into adulthood. There will be a minority of patients with sleep onset difficulties who will benefit from longer term use of melatonin. It is the responsibility of the referring specialist to decide if it is appropriate to continue for a specific individual. The specialist will then advise the GP on future management.

## ACTION AND ADVICE

If adverse effects are not tolerated, melatonin can be stopped immediately.

**The patient's further therapy should be discussed with the patient's specialist.**

## SHARED CARE

**Shared care guideline*:*** is a document which provides information allowing patients to be managed safely by primary care, secondary care and across the interface. It assumes a partnership and an agreement between a hospital specialist, GP and the patient and also sets out responsibilities for each party. The intention to share care should be explained to the patient and accepted by them. Patients are under regular follow-up and this provides an opportunity to discuss drug therapy. Intrinsic in the shared care agreement is that the prescribing doctor should be appropriately supported by a system of communication and cooperation in the management of patients. The doctor who prescribes the medicine has the clinical responsibility for the drug and the consequence of its use**.**

**Monitoring instructions and responsibilities**

**Specialist**

- The specialist will recommend, initiate and prescribe the initial supply of 28 days of Melatonin.
- Any transfer of prescribing should only happen following a successful initiation and stabilisation period (upto 3 months) and with the agreement and understanding of the patient/carer.
- The specialist should confirm that the patient is optimised on the chosen medication with no further changes anticipated in the immediate future. It is the responsibility of the specialist to decide with the patient and/or carer that a patient is suitable for sharing care of their

medication.

- Ensure the patient/ carer understands their treatment regimen and any monitoring or follow up that is required (using advocacy if appropriate).
- Ensure Melatonin treatment is reviewed annually by a member of the specialist team to monitor response, and to stop if there is lack of efficacy.
- A Melatonin free period should be agreed with the young person/ parent/ carer and the specialist to establish if the patient requires continued Melatonin treatment.
- Any Melatonin free period should be documented and reviewed at an appropriate interval (follow up) as agreed between the specialist/ young person/ parent/ carer.
- Ensure the patient/carer is aware of the off-labelstatus or use of unlicensed preparation.
- Discuss benefits and side effects of treatment with the patient/ carer
- Document consent in the patient notes.
- Clinical supervision of the patient by routine clinic follow-up on a regular basis.
- Specialist should indicate, where relevant, in prescribing instructions that the tablet should be crushed.
- The specialist must supply the GP with a summary of the outpatient appointment within 28 days of initiation of treatment, where there any changes, and where the Melatonin is discontinued.
- The letter to the GP should ensure the correct strength, dose and frequency are stated. This includes any specific instructions on e.g. frequency- repeated dose during the night, if the child wakes up; formulation- crushed or specific administration of liquid for NG.
- To ensure any correspondence to the GP includes the specialist contact details.
- The specialist will provide the GP with reference guidelines for the patient and ensure the patient/carer understands they will need to make an appointment to receive a prescription/further supplies from the GP.
- Inform the GP if a non-standard dose is used and/or the preparation is changed from the agreed choice.
- Evaluate any reported adverse effects by GP or patient.
- Advise GP on review, duration or discontinuation of treatment where necessary.
- Inform GP of patients who do not attend clinic appointments.
- Ensure that backup advice and support is available for patient and GP at all times.
- Review the need for on-going Melatonin treatment for children reaching 18 years of age.
- Advise the GP of the arrangements for the future monitoring of the patient, should the young person need to continue melatonin once they reach adulthood.
- Report adverse events to the MHRA (yellow card reporting scheme) and inform GP.
- Where the off-label (Circadin®) preparation is not appropriate, provide clinical justification for using the alternative or liquid formulation in any correspondence sent to the GP.

**General Practitioner**

- Ensure that the patient/carer understands the nature, effect and potential side effects of the drug before prescribing it as part of the shared care programme and contact the specialist for clarification where appropriate.
- Prescribe Melatonin after communication with the specialist.
- Prescribers should indicate, if relevant as per communication from the specialist, in prescribing instructions that the tablet should be crushed.
- Monitor patient's health and wellbeing, if relevant as advised by specialist, in between specialist review appointments of physical health and well-being.
- Ask parent/ carer about effectiveness.

- Report any changes in physical health/ wellbeing and/ or adverse events to Melatonin to the specialist, where appropriate.
- Report any adverse events to the MHRA, where appropriate. Report adverse events to the Specialist and MHRA (yellow card reporting scheme).
- To seek advice and/ or help in monitoring the response to and/ or adverse effects to Melatonin treatment.
- Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment.
- Stop treatment on advice and/ or correspondence from the specialist
- Stop or adjust treatment if necessary (e.g. side effects) on advice and/ or correspondence from the specialist.
- Continuation without Specialist review is not recommended.
- Continue to support the prescribing of the formulation selected by the specialist where clinical justification has been provided.
- Melatonin treatment should be reviewed by the GP at the 6 month point in between the specialist annual review.

**CCG**

- To provide feedback to trusts via Trust Medicines Committee.
- To support GPs to make the decision whether or not to accept clinical responsibility for prescribing.
- To support trusts in resolving issues that may arise as a result of shared care.

**Patient/Carer**

- Contact the GP and community pharmacist to arrange supplies of melatonin in enough time (usually 7 days before re-supply needed) to ensure continuity of treatment.
- Attend appointments.
- Take medication as directed
- Report any adverse effects to their GP and/or specialist whilst taking Melatonin.
- Share any concerns in relation to treatment with melatonin.
- Ensure they have a clear understanding of their treatment. Report to the Specialist or GP if they do not have a clear understanding of their treatment.
- Report any changes in disease symptoms to GP and/or specialist whilst taking Melatonin.
- Alert GP and/or specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy whilst taking Melatonin.
- If requested, keep a sleep diary to assess the effectiveness of therapy.

**Community Pharmacist's Responsibilities**

- Order the appropriate product from the wholesaler.
- Inform the patient / carer and GP if there is a supply problem.
- Advise the patient / carer / GP as necessary.

Use in adults

*A modified release formulation of melatonin is now licensed and marketed for the short-term treatment of primary insomnia, characterized by poor quality sleep, in patients aged 55 years or over. Its use in this indication is limited to a dose of 2mg at night for no longer than 3 weeks at a time. The use in adults is outside the scope of this guideline and not generally used at the hospital.*

## CONTACT NUMBERS FOR ADVICE AND SUPPORT

| East London Foundation Trust | |
|---|---|
| Iffah Salim , CAMHS Pharmacist | 0207 540 6789 |
| Tabassam Beg Lead Pharmacist – Tower Hamlets | 0208 223 8014 |
| Chinedu Ogbuefi, Lead Pharmacist - Newham | 0207 540 4380 |
| Susana FonteloRojano, Lead Pharmacist – City and Hackney | 020 8510 8401 |
| Natasha Patel - Luton and Bedfordshire | 07940 466861 |
| **Clinical Commissioning Groups (CCG)** | |
| **CCG Tower Hamlets, Newham and City & Hackney** | |
| Barts Health NHS Trust | |
| Consultant via switchboard: Registrar on-call out of hours: | 020 7377 7000- see top of the document Air call via switchboard |
| Specialist Pharmacist | 020 324 60133 |
| Medicines Information (for drug information related queries) | 020 324 60120 |
| **CCG Luton and Bedfordshire** | |
| Community paediatrician, Edwin Lobo Centre | 01582 700300 |
| Community paediatrician, Union St. clinic | 01234 310071 |
| Child Development Centre, Hill Rise | 01234 310278 |
| Hospital paediatrician, Bedford Hospital | 01234 355122 |

A patient information leaflet suitable for children's parents and carers is attached to the end of the shared care. A copy of this leaflet on Melatonin is also available at:

http://www.medicinesforchildren.org.uk/search-for-a-leaflet/melatonin-for-sleep-disorders/

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# Information Leaflet: Melatonin:
## Melatonin for sleep disorders

**This leaflet is about the use of melatonin to help children who have difficulty getting to sleep at the start of the night.**

This leaflet is for parents and carers about how to use this medicine in children. Our information sometimes differs from that provided by the manufacturers, because their information is usually aimed at adults. Please read this leaflet carefully. Keep it somewhere safe so that you can read it again

**Brands:** At the time of producing this leaflet, Melatonin is available as a range of branded products. Some of the products need to be specifically ordered by the pharmacist. It is advised to discuss the brand/ product started with the prescriber.

### Why is it important for my child to take this medicine?

Poor sleep can affect your child's physical health, mood, behaviour and development. Melatonin may help your child to get into a regular sleep pattern.

### What is melatonin available as?

Melatonin is available in various formulations e.g. tablets, capsules and liquid. Please refer to your local guidance or speak to your local pharmacy team for advice on specific formulations.

- **Modified-release tablets** (Circadin): 2 mg
- **Prolonged-release tablets** (Slenyto) 1 mg, 5 mg contains lactose
- **Tablets and capsules** from 0.5 to 5 mg (these have to be ordered specially by your pharmacist)
- **Liquid medicine (available in different strengths):** this has to be ordered specially from your pharmacist

### When should I give melatonin?

Melatonin is given once a day, between half an hour and an hour before your child's agreed bedtime.

Give the medicine at about the same time each day so that this becomes part of your child's daily routine, which will help you to remember.

**How much should I give?**

Your doctor will work out the amount of melatonin (the dose) that is right for *your* child. The dose will be shown on the medicine label.
Your doctor will probably recommend that your child has a low dose to start with. They may then increase the dose until your child's sleep problems have improved. Normally, the dose will not be more than 10 mg per day.

**It is important that you follow your doctor's instructions about how much to give.**

How should I give melatonin?

**Modified-release tablets (Circadin)** should be swallowed whole unless your doctor or pharmacist has told you otherwise. Your child should not chew the tablet.
Sometimes, your doctor or pharmacist may tell you to crush it – this will make it act faster, but the effect will not last as long.

**Prolonged-release tablets (Slenyto**) should be swallowed whole unless your doctor or pharmacist has told you otherwise. Your child should not chew the tablet. The whole tablet can be put into a small amount of soft food such as yogurt or ice-cream. Make sure your child swallows it;straight away, without chewing.

**Other tablets and capsules** should be swallowed with a glass of water, juice or squash. You can crush the tablet or open the capsule, and mix the contents with a small amount of cold or room temperature soft food such as yogurt or jam. Make sure your child swallows it straight away, without chewing.

**Liquid medicine:** Measure out the right amount using an oral syringe or medicine spoon. You can get these from your pharmacist. Do not use a kitchen teaspoon as it will not give the right amount.

**When should the medicine start working?**

Your child should feel sleepy about 30 minutes to an hour after taking a dose of melatonin.

**What if my child is sick (vomits)?**

- If your child is sick less than 30 minutes after having a dose of melatonin, give them the same dose again.
- If your child is sick more than 30 minutes after having a dose of melatonin, you do not need to give them another dose that night.

If your child is sick again, seek advice from your family doctor, pharmacist or hospital.

**What if I forget to give it?**

If you miss a dose and your child is already asleep, wait until the next day and give the normal dose as usual. If your child is still awake, give them the normal dose.

**What if I give too much?**

If you think you may have given your child too much melatonin, contact your doctor or local NHS services (details at end of leaflet). Have the medicine or packaging with you if you telephone for advice.

**Are there any possible side-effects?**

We use medicines to make our children better, but sometimes they have other effects that we don't want (side-effects).

**Side-effects that you must do something about**

Rarely, melatonin can cause problems with your child's heart. If your child develops chest pain or has a fast heart rate (they may have a fluttering feeling in their chest or feel their heart beating quickly), contact your doctor straight away or take your child to hospital.

If your child seems very unwell in any way that is unusual for them and you are concerned, take them to hospital.

**Other side-effects you need to know about**

- Your child may feel dizzy or nervous, or may have stomach pain.
- Your child may develop a rash or itch.

If you are concerned about any of these side-effects contact your doctor.

There may, sometimes, be other side-effects that are not listed above. If you notice anything unusual and are concerned, contact your doctor. You can report any suspected side-effects to a UK safety scheme at http://yellowcard.mhra.gov.uk.

**Can other medicines be given at the same time as melatonin?**

- You can give your child medicines that contain paracetamol or ibuprofen, unless your doctor has told you not to.
- Melatonin should not be taken with some medicines. It is important to tell your doctor and pharmacist about any other medicines your child is taking before starting melatonin.
- Check with your doctor or pharmacist **before** giving any other medicines to your child. This includes herbal and complementary medicines.

**Is there anything else I need to know about this medicine?**

- Treatment with melatonin is usually started by a specialist.
- A specialist may suggest that your child takes melatonin if they need to have a scan that requires them to lie still for a while.

**General advice about medicines**

- Only give this medicine to your child. Never give it to anyone else, even if their condition appears to be the same, as this could do harm.

If you think someone else may have taken the medicine by accident, contact your doctor straight away.

- Make sure that you always have enough medicine. Order a new prescription at least 2 weeks before you will run out.
- Make sure that the medicine you have at home has not reached the 'use by' date on the packaging. Give old medicines to your pharmacist to dispose of.

**Where should I keep this medicine?**

- Keep the medicine in a cupboard, away from heat and direct sunlight.
- You may need to keep liquid medicine in the fridge – check the instructions on the bottle.
- Make sure that children cannot see or reach the medicine.
- Keep the medicine in the container it came in.

**Who to contact for more information**

Your child's doctor, pharmacist or nurse will be able to give you more information about melatonin and about other medicines used to treat sleep disorders.
You can also get useful information from:

- **England: NHS 111**
  Tel 111
  www.nhs.uk
- **Scotland: NHS 24**
  Tel 111
  www.nhs24.scot
- **Wales: NHS Direct**
  Tel 0845 46 47 (2p per minute) or 111 (free)
  www.nhsdirect.wales.nhs.uk
- **Northern Ireland: NI Direct**
  www.nidirect.gov.uk

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The primary source for the information in this leaflet is the British National Formulary for Children. For details on any other sources used for this leaflet, please contact us through our website, www.medicinesforchildren.org.uk

We take great care to make sure that the information in this leaflet is correct and up-to-date. However, medicines can be used in different ways for different patients. It is important that you ask the advice of your doctor or pharmacist if you are not sure about something. This leaflet is about the use of these medicines in the UK, and may not apply to other countries. The Royal College of Paediatrics and Child Health (RCPCH), the Neonatal and Paediatric Pharmacists Group (NPPG), WellChild and the contributors and editors cannot be held responsible for the accuracy of information, omissions of information, or any actions that may be taken as a consequence of reading this leaflet.