





Prescribing agreement: Melatonin for the treatment of sleep disorders in children and adolescents

Section A: To be completed by the spec	
GP Practice Details:	Patient Details:
Name:	Name:
Address:	Address:
Tel no:	DOB:/ Gender:
Fax no:	Hospital number:
NHS.net e-mail:	NHS number (10 digits):
Consultant/Specialist name:	
Clinic name:	
Contact details:	
Address:	
Tel no: Fax no	
NHS.net e-mail:	
Diagnosis:	Drug name/presentation & dose to be prescribed
_	by GP:
Next hospital/clinic appointment://	
Next nospital/clinic appointment//	·
Dear Dr,	
Your patient was started on	(drug name and dose) for the above
diagnosis on//	(1.9 1.1.1.1)
S/he was reviewed on/ and is now stabilis	ed on therapy.
cine was reviewed on	ou on thorapy.
Lam requesting your agreement to sharing the care	of this patient from/ in accordance with
the (attached) Shared Care Prescribing Guideline (a	
Please take particular note of Section 2 where the a	
patient for this shared care arrangement are detailed	
patient for this shared care affailgement are detailed	u.
Datient information has been given cuttining notantic	al aims and aids affects of this treatment and a clean
	al aims and side effects of this treatment and a sleep
diary, a sleep hygiene leaflet and a melatonin inform	
	at possibly under a shared care prescribing agreement
(with your agreement) and has agreed to comply with	n instructions and follow up requirements.
Section B: To be completed by the GP a	nd returned to the consultant/specialist as
detailed in Section A above	•
Please sign and return your agreement to shared ca	are within 14 days of receiving this request
	the within 14 days of receiving this request
Tick which applies:	ing guideline and above instructions
□ I accept sharing care as per shared care prescribi	
□ I would like further information. Please contact m	
$\ \square$ I am not willing to undertake shared care for this p	Patient for the following reason:
0.0	
GP name:	
OD almost and	Date: 1 /
CP signature:	Date: / /

Date prepared: March 2013 Date approved: 26th July 2013 by Croydon Prescribing Committee Final Version

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Croydon Clinical Commissioning Group

Working in partnership with



SHARED CARE PRESCRIBING GUIDELINE

Melatonin for the treatment of sleep disorders in children and adolescents

NOTES to the GP

The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing this drug.

The questions below will help you confirm this:

- Is the patient's condition predictable or stable?
- Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care prescribing guideline?
- Have you been provided with relevant clinical details including monitoring data?

If you can answer YES to all these questions (after reading this shared care guideline), then it is appropriate for you to accept prescribing responsibility.

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should write to the consultant within 14 days, outlining your reasons for NOT prescribing. If you do not have the confidence to prescribe, we suggest you discuss this with your local Trust/specialist service, who will be willing to provide training and support. If you still lack the confidence to accept clinical responsibility, you still have the right to decline. Your CCG pharmacist will assist you in making decisions about shared care.

It would not normally be expected that a GP would decline to share prescribing on the basis of cost.

The patient's best interests are always paramount

Date prepared: July 2013	Review date: July 2015
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Dr Joy Okpala, Consultant Community Pag	ediatrician (CHS)

Approved by (date approved):

Croydon Prescribing Committee on 26th July 2013

This shared care prescribing guideline has been signed off by the following individuals on behalf of their respective organisations:

Participating CCG	Participating Health Trusts
Croydon CCG	Croydon Health Services
Eileen Callaghan, Chief Pharmacist	Dr Joy Okpala, Consultant Community Paediatrician Louise Coughlan, Chief Pharmacist

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Shared Care Guideline: Melatonin for the treatment of sleep disorders in children and adolescents

CIRCUMSTANCES WHEN SHARED CARE IS APPROPRIATE

- Prescribing responsibility will only be transferred when the consultant and the GP are in agreement that the patient's condition is stable or predictable.
- Patients will only be referred to the GP once the GP has agreed in each individual case and the hospital will continue to provide prescriptions until successful transfer of responsibilities as outlined below.
- The Trust will provide the patient with a minimum initial supply of at least 4 weeks therapy once therapy is stabilised and whilst awaiting agreement from GP.

AREAS OF RESPONSIBILITY

Specialist Clinician

Prior to initiating melatonin the specialist clinician will:

- Assess the patient and establish a diagnosis of sleep disorder.
- > Promote and implement good sleep hygiene practice.
- Ensure parents, carers or older adolescents (if appropriate) complete a sleep diary showing significant problems with sleep latency before treatment with melatonin is initiated. The diary is to be maintained after treatment has been started to establish efficacy.
- Give patient leaflets on sleep hygiene and melatonin information.
- Discuss unlicensed use of melatonin with patient/carer and document discussion in patient's clinical records.
- > Ensure compatibility with any other medication the patient is taking.
- Initiate therapy with melatonin as Circadin® 2mg Prolonged Release tablets within the indications listed in this shared care guideline, and prescribe the medication until the dose has been stabilised.
- Review the patient's response by appointment/ telephone contact with the patient/carer one to two weeks after initiating, including the diary.
- > Titrate the dose in 2mg steps according to response up to a maximum of 10mg.
- Once the patient is on a stabilised dose, write to the GP to ask whether he/she will participate in shared care.
- Once the patient is on a stabilised dose prescribe 4 weeks supply of medication, whilst awaiting confirmation from GP agreement for shared care.

Once shared care has been accepted by patient's GP and written confirmation received, the Specialist Clinician will:

- Provide the GP with appropriate clinical information and individual patient information.
- Follow up every 3-6 months to ensure continuing benefit of melatonin (see review criteria section), and confirm in writing to GP if continuing benefit is seen, annually.
- Undertake periodic treatment withdrawals, or advise the GP in writing how and when to undertake them.
- Determine a management strategy and communicate this to the family & GP.
- Notify the GP if medication is likely to cease or not when adolescent approaches 18 years and confirm by letter the stop date.
- Be available to give advice to GP if the patient's condition changes and to ensure that procedures are in place for prompt specialist review
- Report any adverse drug effects experienced by the patient to the MHRA via the Yellow Card system.



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SHARED CARE PRESCRIBING GUIDELINE - Melatonin for the treatment of sleep disorders in children and adolescents

GP

If the GP has agreed to shared care and he/she should notify the specialist clinician in writing (section B of agreement form) without delay and will:

- Review the patient in accordance with specialist advice.
- Prescribe the melatonin once dose has been stabilised, in line with localised prescribing policies.
- Monitor general health of patient and check adverse effects as appropriate.
- Report any adverse drug effects experienced by the patient to the MHRA via Yellow Card system
- Further titrate the dose, or discontinue the medication if required whilst awaiting specialist review - only under advice of the specialist.
- Check for interactions with melatonin when prescribing new or altering existing concurrent medications.
- · Communicate any problems to the specialist.
- Refer the patient back to the specialist if any unmanageable problems arise, allowing an adequate notice period (minimum 4 weeks suggested).

Note: if GP does not agree to shared care, he/she should notify the specialist clinician in writing outlining the reasons why (section B of agreement form)

Patient and / or carers

- Have a clear understanding of the treatment
- Have read and understood the Trust patient information leaflet and are practising the sleep hygiene methods as recommended by the specialist.
- Will take/give the melatonin as agreed with the specialist or GP.
- Will maintain a sleep diary and bring to appointments with the relevant healthcare professional.
- Will attend booked appointments for review and monitoring of therapy.

COMMUNICATION AND SUPPORT

Contacts:

Croydon Health Services

Community Paediatrician: Dr Joy Okpala, Dr Ide Ojo Tel: (020) 8274 6378

Secretary Tel: (020) 8274 6369

Hospital Paediatricians: Dr T Fenton, Dr J Chang, Dr G Brock.

Secretary Tel: (020) 8401 3397

Pharmacy Department:

Tel: 0208 401 3000 extension 4142

Resources:

- i. BNF for Children (use most up to date)
- ii. NICE Evidence Summary; Unlicensed or Off label medicine- ESUOM2: Sleep disorders in children and young people with attention deficit hyperactivity disorder: melatonin. Published 04/01/2013
- iii. Medicines for Children Website- melatonin information leaflet, accessed via http://www.medicinesforchildren.org.uk/search-for-a-leaflet/melatonin-for-sleep-disorders/
- iv. Summary of Product Characteristics for Circadin® (accessible online via www.medicines.org.uk)

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CLINICAL INFORMATION

Indication(s): Note: these are all unlicensed indications Place in Therapy:	Melatonin is indicated for treating sleep disorders in children/adolescents with neurodevelopment disorders and conditions such as cerebral palsy, attention deficit hyperactivity disorder, learning disabilities and autism - predominantly patients with sleep initiation difficulties (if behavioural and sleep hygiene measures have not proved helpful) who are under a specialist (CAMHS, community/hospital paediatricians or learning disability mental health team). Before starting treatment with melatonin, traditional non-pharmacological sleep hygiene methods must have been tried and failed.
Therapeutic summary:	Melatonin is a naturally occurring hormone produced by the pineal gland in the brain. It is involved in coordinating the body's sleep-wake cycle and helping to regulate sleep.
Dose & route of administration: Dose Titration (by specialist)	Circadin® Prolonged Release Tablets 2mg: Initial dose: children >2 years of age 2mg 30-60 minutes before bedtime If insufficient benefit after 3-4 nights: increase dose to 4mg. If no benefit at new dose, increase dose in 2-4mg steps according to response after 1-2 weeks, to a maximum of 10mg. Higher doses are not considered to be of greater efficacy and may increase side effects.
	 Increases of doses should not be considered when any of the below are present: There have been serious adverse effects or a significant increase in seizure activity (where applicable) Patient falls asleep within one hour of 'lights off' or 'snuggling down to sleep' at age appropriate times for the child in three nights out of five Child having more than 6 hours of continuous sleep in three nights out of five.
Duration of treatment:	If no sleep benefit has been seen after 2 weeks on maximum tolerated dose, then the medicine should be stopped (no withdrawal period required). Where patients do derive benefit from treatment there should be follow up by the specialist clinician every 3-6 months to assess continued need (telephone review is acceptable where sleep diary should be available and discussed).
Review Criteria (specialist to review every 3-6 months and GP as necessary under specialist advice)	Discuss and record the following: Patient/carer should be asked to complete the sleep diary and bring to appointments. Review sleep diary. Ask patient/carer about side effects and general well-being Ask patient/carer about improved sleeping pattern since taken. Any problems with the medication Problems the next day Sleep hygiene – what is patient's routine? Is the room dark? Are there any distractions in the room eg. toys, game, TV, consoles? Do they want to continue with melatonin? If treatment has been stopped (see above), has the sleep pattern altered and if so, how? Consider the following since initiation: Time dose given Time in bed Time patient falls asleep Stop treatment if no benefit seen with the melatonin. GP may wish to discuss with specialist. Specialist to confirm ongoing benefit in writing to GP on an annual basis. The specialist will be responsible for follow up and discontinuing







Withdrawal	In some cases patients may have a natural pause in medication e.g. at weekends/holidays which will help to determine if a benefit is still obtained from taking melatonin. The specialist should communicate to the GP if this is recommended.
	It is suggested that at least six months of an improved sleep pattern should elapse before withdrawal takes place.

Summary of adverse effects

Melatonin is generally well tolerated however the adverse effect profile is unclear because of the relatively small size of the trials supporting its use. Melatonin appeared well tolerated in the RCTs in the short and medium term with only mild and transient adverse effects (for example, headache or dizziness) reported. This included data from children treated for an average of 18 months (range of 1–57 months).

The most common adverse events recognised in the trials to date were dizziness, sleep maintenance insomnia, headache, and hyperactivity, agitation or behaviour changes. Comparing the rate of patients with adverse reactions per 100 patient weeks, the rate was higher for placebo than Circadin®.

Melatonin may have a pro-convulsive effect and should be used with caution in neurologically impaired children. Endogenous serum melatonin concentration is elevated in nocturnal asthmatic patients. Therefore any extra melatonin supplementation may worsen the attacks. Use with caution in this group of patients.

All suspected adverse effects should be reported via the MHRA Yellow Card system.

Uncommon (>1/1000, <1/100): abdominal pain, dyspepsia, dry mouth, mouth ulceration, weight gain, hypertension, chest pain, malaise, dizziness, restlessness, nervousness, irritability, anxiety, migraine, proteinuria, glycosuria, pruritus, rash, dry skin;

Rare: (>1/10,000, <1/1000): thirst, flatulence, halitosis, hypersalivation, vomiting, gastritis, hypertriglyceridaemia, palpitation, syncope, hot flushes, aggression, impaired memory, restless legs syndrome, paraesthesia, mood changes, priapism, increased libido, prostatitis, polyuria, haematuria, leucopenia, thrombocytopenia, electrolyte disturbances, muscle spasm, arthritis, lacrimation, visual disturbances, nail disorder

See summary of product characteristics (SPC) for full list via www.medicines.org.uk

Monitoring Requirements (by specialist):	No specific monitoring is required for melatonin. However, annual growth and height should be measured, for adolescents enquire whether there are any concerns in pubertal development.	
Clinically relevant drug interactions:	Melatonin is metabolised by CYP1A enzymes. Therefore interactions between melatonin and other active substances as a consequence of their effect of CYP1A enzymes are possible.	
	Fluvoxamine	plasma concentration of melatonin increased by fluvoxamine—avoid concomitant use
	Oestrogens	plasma concentration of melatonin can be increased by oestrogens- use with caution
	Cimetidine	plasma concentration of melatonin can be increased by cimetidine- use with caution







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Practical issues:	Circadin® prolonged release 2mg tablets may be swallowed whole with a glass of water, milk or juice, with or without food.
	For patients with swallowing difficulties or who are unable to swallow the tablets, they can be crushed and mixed with water or food such as yoghurt. This will interfere with the prolonged release effect but this is not required for initiating sleep.
	GP should initially only issue a maximum of 4 weeks therapy at a time (to avoid wastage should the drug not be effective). A suggested maximum supply after this is 3 months.
Other formulations:	For patients already taking melatonin in a different formulation (which are unlicensed products) or if patient is not on an equivalent dose of melatonin, eg Biomelatonin 3mg tablets or 2.5mg generic capsules (imported), it is recommended that the specialist switches them to Circadin®, the first choice and only licensed preparation, in agreement with patients and carers. (See Appendix 1 for recommendation of transfer to Circadin® letter). Ideally the dose should be changed to the next nearest lower dose eg. 2.5mg unlicensed melatonin changed to 2mg Circadin® PR tablets.
	If the patient is in the community, the GP may consider the change to Circadin® (as above) after discussion with a specialist.
	For patients unable to swallow whole tablets, a second line choice will be to crush the tablets (see above). As a last line option, melatonin 5mg/5ml oral solution (to be prescribed generically) is available as an unlicensed special (as per drug tariff) for those who are unable to take the crushed tablets.
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Key		
reference	25	-

- NICE Evidence Summary; Unlicensed or Off label medicine- ESUOM2: Sleep disorders in children and young people with attention deficit hyperactivity disorder: melatonin. Published 04/01/2013
- 2. BNF for children 2012/2013
- 3. Summary of Product Characteristics for Circadin, last updated 12/08/2011, accessed via the EMC, www.medicines.org.uk
- 4. Guys' and St Thomas' NHS Foundation Trust Shared Care for melatonin use in Children. March 2013
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- Sweis D. The Uses of Melatonin. Arch Dis Child. Ed. Pract. 2005;90:74-77
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- 9. Braam W, Smits MG, Didden R, Korzilus H, van Geijlswijk M, Curfs LMG. Exogenous melatonin for sleep problems in individuals with intellectual disability: a meta-analysis Dev Med Child Neurol 2009; 51: 340-9.
- 10. Rossignol DA, Frye RE. Melatonin in autism spectrum disorders: a systematic review and meta-analysis. Dev Med Child Neurol doi: 10.1111/j.1469-8749.2011.03980.x. [Epub ahead of print] 19-4-2011.
- 11. Weiss MD, Wasdell MB, Bomben MM, et al. Sleep hygiene and melatonin treatment for children and adolescents with ADHD and initial insomnia. J Am Acad Child Adolesc Psychiatry 2006;45:512–19.
- 12. Van der Heijden KB, Smits MG, Van Someren JW, et al. Effect of melatonin on sleep, behaviour and cognition in ADHD and chronic sleep-onset insomnia. J Am Acad Child Adolesc Psychiatry 2007;46:233–41
- 13. Smits MG, Nagtegaal EE, van der HJ, Coenen AM, Kerkhof GA. Melatonin for chronic sleep onset insomnia in children: a randomized placebo-controlled trial. J Child Neurol 2001 Feb;16(2):86-92.
- 14. Smits MG, van Stel HF, van der HK, Meijer AM, Coenen AM, Kerkhof GA. Melatonin improves health status and sleep in children with idiopathic chronic sleep-onset insomnia: a randomized placebocontrolled trial. J Am Acad Child Adolesc Psychiatry 2003 Nov;42(11):1286-93

APPENDICES

Appendix 1- Letter for transferring from an unlicensed melatonin formulation

Appendix 2- Sleep diary

Appendix 3- Sleep Hygiene Leaflet

Appendix 4- Melatonin Patient Information Leaflet

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Appendix 1

Letter for transferring from an unlicensed melatonin formulation to Circadin® PR

Croydon Health Services NHS
Address
For the attention of the GP
Dear GP,
The following patient
DOB
NHS number
has been transferred from an unlicensed formulation of melatonin to Circadin® 2mg PR tablets at Croydon Health Services NHS Trust on
The patient's Circadin® dose ismg
Circadin® is a licensed formulation recommended for prescribing in Primary and Secondary care by Croydon Prescribing Committee for the treatment of sleep disorders in children and adolescents (unlicensed indication). Please can you prescribe future supplies on an FP10 for your patient to obtain from their chosen chemist, in line with this shared care guideline.
Kind regards,
Dr(Specialist Clinician)
(Sign)
Date:



Time **Monday** Wednesday **Thursday Saturday** Sunday **Tuesday Friday** Time of waking Mood on waking Times of naps during the day Time started preparing for bed What time did the child go to bed? What time did the child get to sleep? Time(s) of waking during the night (e.g. 2am, 5.30am) What did you do to encourage them to fall back asleep? Length of time taken to fall asleep again Total number of hours sleep

Sleep Hygiene

Croydon Health Services NHS Trust

What is Sleep Hygiene?

Sleep hygiene is important for everyone, from childhood through adulthood. A good sleep hygiene routine promotes healthy sleep and daytime alertness. Good sleep hygiene practices can prevent the development of sleep problems and disorders.

Even if your child is taking medication to help them sleep, it is important to ensure good sleep hygiene is followed.

There are some simple things that parents and carers can try to help their child sleep better at night.

During the daytime;

- Make sure your child spends time outside and has regular exercise and activities
- Young children can have a nap as appropriate. Discourage long naps or too many naps

Before bedtime;

- Avoid vigorous and stimulating activities 1-2 hours before bedtime. For young children, try calm activities such as reading a story or listening to soothing music as part of a pre-bedtime routine
- Avoid food or drinks containing caffeine such as chocolate, coffee, tea, or cola in the late afternoon or evening
- Make sure your child is not hungry before going to bed
- Security objects at bedtime are often helpful for children who need a
 transition to feel safe and secure when their parent is not present. Try to
 include a doll, toy or blanket when you cuddle or comfort your child, which
 may help them adopt the object.

Paediatrics Department
Sleep Hygione leaflet Version 1 Final: July

Sleep Hygiene leaflet Version 1 Final: July 2013

• Worry time should not be at bedtime. Children with this problem can try having a "worry time" scheduled earlier when they are encouraged to think about and discuss their worries with a parent.

Bedtime and wake-up time;

- Set a bedtime to be maintained every night that is age appropriate to the child and manageable for the family.
- If your child is never drowsy at the planned bedtime, you can try a temporary delay of bedtime by 30 minute increments until the child appears sleepy, so that they experience falling asleep more quickly once they get into bed. The bedtime should then be gradually advanced earlier until the desired bed time is reached.
- Bedtime and morning waking time should be about the same time, both during school term and holidays or weekends. There should be no more than one hour's difference between a school night, weekend, or a holiday

Bedroom;

- Your child's bedroom should be safe, quiet, dark and comfortable.
- A low level light is appropriate for young children who may be afraid of the dark.
- There should be no TV, internet, or computer games in the child's bedroom. A child can easily develop the habit of needing the TV to sleep. A child cannot relax and sleep easily if he or she is excited after playing computer games before bedtime.
- Avoid using your child's bedroom for 'time out' or punishment.
- When checking on a child at night, checks should be "brief and boring." The purpose is to reassure the child you are present and that they are okay.

Keep a sleep diary to keep track of naps, sleep times and activities to find patterns and target problem areas when things are not working.

References: Sleep problems in children and young people – Help get a better night's sleep by Dr C Yemula (Consultant Community Paediatrician, Bedford)



Melatonin

What is Melatonin?

Melatonin is a hormone found naturally in the body. It helps regulate sleep-wake cycles. Your child has been prescribed melatonin to help them fall asleep at night.

Melatonin is used for treating sleep disorders in children/adolescents with neurodevelopment disorders and conditions such as cerebral palsy, attention deficit hyperactivity disorder and autism.

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 form of melatonin is available at Croydon Health Service NHS Trust?

In Croydon, it has been agreed that the first choice preparation that will be prescribed is Circadin® MR 2mg tablets (melatonin 2mg modified release tablets).

Melatonin only has a licence for use in adults over 55 years old. Your specialist doctor will have explained that melatonin is not licensed specifically for sleep disorder in children, but it is used nationally "off-label" by child specialist doctors for children because it has been found to be effective and safe.

If your child is on another preparation of Melatonin, your doctor will prescribe an appropriate dose of Circadin® MR tablets for your child.

Who will initiate Melatonin for my child?

For those under 18 years, Melatonin will be initiated by a specialist. You may be required to keep a sleep diary before and after treatment is started to establish efficacy. Your child will be given a supply by a specialist, who will review the effect after 4 weeks.

The dose may be changed or melatonin stopped if there has been no benefit.

When should I give melatonin?

Melatonin is best given between half an hour and one hour before your child's agreed bedtime. If the medicine is helpful, your child should start to feel sleepy about half an hour after taking a dose. 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.

Paediatrics Department Melatonin Leaflet Version 1 Final: July 2013

How much should I give?

Your doctor will work out the amount of melatonin (the dose) that is right for **your** child. The dose may be changed according to your child's response.

How should I give melatonin?

Tablets should be swallowed with a glass of water, milk or juice. You may be advised to crush the tablet and give it with water, juice or with some food, such as yoghurt, to help your child take the medication more easily.

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.

What if I forget to give it?

If you miss a dose, wait until the next normal dose. Do not give the missed dose.

What if I give too much?

If you think you may have given your child too much melatonin, contact your doctor or NHS Direct (0845 4647) in England and Wales; 08454 24 24 24 in Scotland. Have the medicine packet with you if you telephone for advice.

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

Check with your doctor or pharmacist before giving any other medicines to your child. This includes herbal or complementary medicines. You can give your child medicines that contain paracetamol or ibuprofen, unless your doctor has told you not to.

Where should I keep this medicine?

Keep the medicine in a cupboard, away from heat and direct sunlight. It does not need to be kept in the fridge. Make sure that children cannot see or reach the medicine. Keep the medicine in the container it came in.

What if I have any questions or concerns?

Contact your local pharmacist or GP. Alternatively the Children's Medical Services (community): 020 8274 6300 or Paediatricians (hospital): 020 8401 3397 / 3626

Reference: http://www.medicinesforchildren.org.uk/ Melatonin