Guidance for use of MELATONIN for children with severe sleep disorders

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1. Introduction

Background
Sleep disturbance in children and adolescents is common, especially in those with neurological and/or behavioural disorders (Lin-Dyken and Dyken 2002, Ross, Davies, Whitehouse 2007).

Sleep disturbance may include delayed onset of sleep, frequent waking, early morning waking or day-night reversal of sleep pattern (Jan, Espezel, and Appleion, 2008). The resulting daytime sleepiness and associated cognitive impairment affects learning, behaviour and emotional regulation, it also adds considerably to the burden of care.

Melatonin is a hormone secreted by the pineal gland which has an important role in the regulation of circadian rhythm. Administration of synthetic melatonin promotes the onset of sleep and has been used for the management of sleep difficulties in adults and children.

Melatonin
Melatonin, the hormone of the pineal gland, is normally made in response to dropping light levels at night and after morning exposure to daylight. Production is affected by light exposure detected by the retina; it is thought that this rhythm is disturbed in children with brain damage, neurodevelopmental disorders such as autism or visual disturbance.

When given to humans it has a rapid half-life of half to one hour, producing transient, mild sleep inducing effects (Wassmar and Whitehouse 2006). It lowers alertness, body temperature and performance during the three or four hours after a low dose has been given. Correctly timed, it is able to shift the internal ‘body clock’ both to later and earlier times (BNF for Children 2015).

Melatonin is a hormone reported to improve the onset and duration of sleep in people with Learning Disabilities, in particular those with cortical blindness. It is not licensed for use in children but Circadin® (UK licensed for use in patients aged 55 years and over) is preferred for off-license use in line with Medicine and Healthcare Products Regulatory Agency (MHRA) guidance, April 2009.

Although the evidence base for Melatonin is limited, it is actually more substantial than that available to support the use of any alternative hypnotic (London New Drugs Group 2008).

Melatonin is now an established and routine drug therapy in both paediatric and child psychiatry practice. (NICE Guideline IFPU02 Jan 2013)

2. Purpose
The purpose of these guidelines is to provide a standardised and consistent approach to the medical management of children with sleep disorders within Shropshire Community Health Trust (SCHT). This clinical guideline applies to all medical/clinical healthcare professionals who routinely prescribe melatonin for the treatment of sleep problems in children in their care.
3. Definitions and Glossary

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<thead>
<tr>
<th>BNFC</th>
<th>British National Formulary for Children</th>
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<tr>
<td>CAMHS</td>
<td>Child and Adolescent Mental Health Services</td>
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<td>CHM</td>
<td>Commission on Human Medicines</td>
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<td>CYP</td>
<td>Cytochrome P450</td>
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<td>MHRRA</td>
<td>Medicine and Healthcare Products Regulatory Agency</td>
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<tr>
<td>Off-licence</td>
<td>A licensed medication has been assessed for efficacy, safety and quality and is manufactured to appropriate quality standards. Age appropriate formulations are difficult to develop so are used off-licence. (<a href="http://www.gov.uk">www.gov.uk</a>)</td>
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<td>SCHT</td>
<td>Shropshire Community Health Trust</td>
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<td>SPC</td>
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4. Duties

4.1 Chief Executive
The Chief Executive has ultimate accountability for the strategic and operational management of the Trust, including ensuring there are effective and appropriate processes in place for the medical management of children.

4.2 Director of Nursing & Medical Director
The Director of Nursing & Medical Director have responsibility for ensuring that children are offered appropriate medical management.

4.3 Service Managers
Service Managers are responsible for the day to day operational management and coordination of the medical management.

4.4 All Clinical Staff
Clinical staff are key members in ensuring that children with sleep difficulties are managed appropriately. All clinical staff who prescribe Melatonin are required to comply with this guideline and report any adverse care related issues to their line manager and report any adverse reactions.

5 Indications for Melatonin

5.1 Indications for Therapy
Melatonin is indicated for the treatment of sleep disorders in children and young people with developmental and psychiatric disorders. This is an ‘off-label’ indication.

Randomized-controlled trials and 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, epilepsy, autism, and learning difficulties.

Place in therapy: Patients will have been assessed by a specialist CAMHS or Paediatric Doctor. Melatonin will only be initiated where standard non pharmacological behavioural modification methods have failed, and other medical causes of sleep disturbance such as sleep apnoea, have been excluded i.e. sleep hygiene and advice. Melatonin may be used...
in the context of helping patients to sleep whilst in or recovering from a crisis (bereavement, trauma, abuse, etc.).

5.1.1 Treatment Aims
The aim of treatment is to establish a regular nocturnal sleep pattern. This treatment is of particular benefit when behavioural modification has been unsuccessful or very difficult to achieve, especially in children with severe sleep disturbance.

5.1.2 Sleep Hygiene Methods
Before starting treatment, traditional non pharmacological sleep hygiene methods must have been tried and failed. In exceptional circumstances for example, families in crisis where parents or carers are exhausted e.g. West Syndrome and Tuberous Sclerosis, treatment may be started immediately. However, sleep hygiene measures are required alongside the treatment.

Sleep Hygiene Attachment Appendix 1, 3
Encouraging good sleep habits Appendix 2

5.2 Licensing information
Melatonin has been prescribed for a number of years by Community Paediatrics and Child and Adolescent Mental Health Service for the treatment of sleep disorders in children and adolescents with neurological and/or behavioural problems.

Until fairly recently there were no licensed melatonin preparations in the UK. A licensed modified release melatonin 2mg tablet (Circadin®) has been available since June 2008. Circadin® is only licensed for patients aged 55 years and over, therefore use in children is off-licence.

Following the UK launch of Circadin®, the MHRA issued a letter to healthcare professionals to advise them that unlicensed imports of melatonin products will now only be authorised in the case of a special clinical need.

The MHRA’s concern is that unlicensed medicinal products that have not been manufactured according to Good Manufacturing Practice (e.g. American products, which are classed as supplements) are being used in the UK. The cost of this product is also variable and often very expensive.

The licensed product should therefore be used wherever possible, including off-label use if deemed suitable by the clinician. Circadin® is licensed as monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over; therefore its use in paediatrics will be off-label.

5.2.1 Dosage (by mouth)
Child 1 month–18 years:
Initially 2–3 mg increased if necessary after 1–2 weeks to 4–6 mg; max. 10 mg
The dose should be given 30-60 minutes prior to bedtime. In sleep phase disorders, lower doses (0.5 to 1.0 mg) may be employed initially.
Problems with sleep initiation
Standard release melatonin is indicated for children and adolescents who have problems with sleep initiation. The starting dose is usually 2mg given 30-60 minutes before bedtime. If there is no response or insufficient response after a minimum of 3 days therapy the dose is increased to 6mg. In certain circumstances the dose can be increased up to a maximum dose of 10mg. Very occasionally, higher doses may be effective; there is large individual susceptibility.

Problems with both sleep initiation and sleep maintenance/fragmental sleep/early morning awakening
Ideally Circadin tablets should be swallowed whole when their long acting properties will be at their best Circadin can be crushed. This reduces its delayed absorption. They can however be cut in half and swallowed without chewing, which will cause them to retain their slow release characteristics.

A time period of 7-14 days is usually sufficient to determine if a specific dose is effective, and if ineffective, melatonin can be stopped without the need for gradual withdrawal

5.2.2 Preparations and Availability
Melatonin should be prescribed as Modified release (MR) Circadin 2mg tablets (a licensed UK brand)

It can be cut and crushed as above reducing its modified release characteristics but not its overall efficacy.

For administration by an enteral feeding tube; Circadin can be crushed to a fine powder and mixed with 15-30mls of water for administration

Liquid preparations are likely to be significantly more expensive. Thus should be prescribed;

- Melatonin 5mg in 5mls oral solution.

5.3 Contraindications and Cautions
Melatonin is contraindicated in children less than three months of age.

There is no convincing evidence that melatonin adversely affects seizure control, indeed improved sleep often improves common forms of However when used in patients with epilepsy, it is important to monitor seizure frequency.

The manufacturer of the UK licensed product advises caution in patients with renal disorders and not to use melatonin in patients with liver disorders some rare hereditary glucose tolerance disorders (due to it containing lactose).

5.3.1 Side Effects
Melatonin is generally well-tolerated. Sedation and fatigue, headaches, skin disorders, restlessness, increased pulse, itching and nausea have all been reported as side effects associated with melatonin use.

Melatonin has no predictable effect upon seizure control (see above).

There is no safety data for long term use but it has been used in patients with learning disability throughout their childhoods.
The above details are not a complete list and the BNF and the summary of product characteristics (SPC) remain authoritative. Full list of side effects is given in the Melatonin SPC, available from www.emc.medicines.org.uk

www.medicines for children.org.uk  for parent leaflet see Appendix 4

5.3.2 Interactions
Fluvoxamine and cimetidine has been shown to increase melatonin levels by inhibiting cytochrome P450 (CYP), isoymes CYP1A2 and CYP 2D respectively and these combinations should be avoided. There is a theoretical risk that any CYP1A2 inhibitors could cause an increase in melatonin levels (e.g. oestrogens, quinolones). CYP1A2 inducers such as carbamazepine and rifampicin may give rise to reduced plasma concentrations of melatonin. Alcohol should be avoided as it reduces the effect of melatonin on sleep.

Melatonin may enhance the effects of sedatives and hypnotics (e.g. benzodiazepines).

On initiation of melatonin the specialist will be responsible for checking interactions and making necessary alterations in treatment.

The above details are not a complete list and the BNF and the SPC remain authoritative.

5.3.3 Pregnancy /Lactation
No clinical data on exposed pregnancies are available.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonic /foetal development, parturition or postnatal development. In view of the lack of clinical data, use in pregnant women and by women intending to become pregnant is not recommended.

Endogenous melatonin was measured in human breast milk thus exogenous melatonin is probably secreted into human milk. There are data in animal models including rodents, sheep, bovine and primates that indicate maternal transfer of melatonin to the foetus via the placenta or in the milk. Breast-feeding is not recommended in women under treatment with melatonin.

5.4 Monitoring
During initiation of treatment, sleep patterns should be documented in a sleep diary to monitor efficacy.

In people with epilepsy, monitoring of seizure frequency is advised.

Review patients every six months to ensure that continued treatment with Melatonin is appropriate and effective.

There should be at least an annual trial of cessation of treatment to assess if continued treatment is indicated. Timing of such a trial must take into account individual circumstances where the impact of potential sleep disruption can be minimised.

5.4.1 Toxicity
It has been suggested that melatonin may affect the reproductive system by inhibiting the hypothalamic-pituitary- gonadal axis. Growth and sexual development monitoring is advisable, especially with long-term melatonin use.
This is primarily the responsibility of the Consultant clinician but any concerns from the primary care clinician should be reported to the Consultant clinician.

(Melatonin is monitored intensively by the Commission on Human Medicines (CHM) and MHRA - Please report any adverse reaction to the CHM, using the yellow card system http://yellowcard.mhra.gov.uk )

5.4.2 Efficacy
Prescribers are required to monitor sleep patterns and should review the need to continue treatment every six months and doses adjusted as necessary. A drug holiday of 4-6 weeks can be useful if melatonin stops working, giving time for the melatonin to wash out from receptors before restarting at a low dose.

6. Product information
Modified release products
A licensed melatonin 2mg prolonged release tablet (Circadin®) is available through wholesalers. This product should be used first line.

Circadin tablets 2mg MR
Oral Solution
Melatonin 5 mg in 5 mls

7. Review and Compliance Monitoring
Compliance to guidelines can be audited through the audit cycle within the paediatric department and CAMHS.
Rita O’Brien chief pharmacist monitors all prescribing individuals within the trust. Prescription costs are monitored within each department for as part of their budgeting responsibilities.

8. Consultation
Guideline agreed by Area Prescribing Committee Jan 21st 2015.
(http://www.telfordccg.nhs.uk, Melatonin prescribing information February 2015).
Consultation has occurred with Rita O Brien, Chief pharmacist and her team, who meet with the paediatricians and CAHMS prescribers at the regular monthly consultant meetings.

9. Dissemination and Implementation
Dissemination to all Community Paediatric Doctors and CAHMs doctors who prescribe Melatonin
10. References
BNF for children 2015


11. Associated Documents

SCHT Consent to Examination and Treatment policy

12. Appendices

12.1 Appendix 1 - 10 Steps to a Quiet Night

12.2 Appendix 2 - Good Sleep Habits Booklet, and “helping your child to sleep” booklets.

12.3 Appendix 3 - What is enough sleep? Leaflet

12.4 Appendix 4 - Melatonin for sleep disorders from Medicines for children

12.5 Appendix 5 - Melatonin Information
11. Appendix 1

‘Ten Steps to a Quiet Night’

1. Make the bedroom safe, secure and unstimulating.
2. Set regular bedtime and waking time and stick to it.
3. Avoid stimulating activities (rough play, loud music, TV) in the hour before bedtime.
4. Pre-bedtime settling routine (use symbols and other aids).
5. Rapid settling in bedroom (less than four minutes); use your “magic phrase”; leave bedroom; lights off; door closed.
6. Ignore thereafter (unless physically unwell). Put back without fuss if he/she gets up during the night.
7. Don’t give in – you will only train your child to get worse if you do!
8. Praise and cuddles (if tolerated) once awake in the morning following a good night.
9. Initial worsening of the problem means it is working!
10. Stick to this and your child (children) will learn not to disturb you during the night.

‘Ten Steps to a Quiet Night’ Caveats:

1. Chose a good time (i.e. no holidays or special events pending).
2. Child and parents must be in optimal health.
3. Move bedroom furniture around or change bedrooms.
4. Support and encourage other children.
5. Discuss progress with a friend, Health Visitor &/or teacher.
6. Warn the neighbours of risk temporary disruption.
7. If possible, brief child thoroughly before and throughout treatment.
8. Wavering parents need to back one another up.
9. If illness suspected pause until physically well.
10. Persist and it stands a good chance of working in: 3 to 4 nights!
Appendix 2

Good sleep habits booklet can be downloaded at:

www.Autism.org.uk

Or Contact a Family Information leaflet “helping your child to sleep”

http://www.cafamily.org.uk/
Appendix 3

What is enough sleep?

There is individual variation, but on average:

1 to 2-year-olds need 11-12.5 hours of sleep per night.
3 to 5-year-olds need 10.5-11.5 hours.
6 to 7-year-olds need about 10.5 hours.
7 to 13-year-olds need about 10 hours.
18-year-olds need about 9 hours of sleep each night. Sound impossible? Sometimes it is.

However, the reason it seems impossible usually isn’t because your child wouldn’t benefit from that much sleep, but because by the time you/your spouse arrives home from work, you eat dinner, you do homework, maybe you go to soccer — it is already too late for bedtime.

Life happens, try to structure your routine in a way that would get your children the amount of sleep they will thrive on most of the time. For instance, if your child will sleep an hour later on a weekend, see if you can get on a soccer team on Fridays. If 6 p.m. gymnastics is going to throw your whole family off, give that feedback to the coach. You would be amazed how quickly class times can change, even by 30 minutes, if enough parents give the same feedback.

When should my child give up her nap?
Most 4-year-olds are no longer napping, but some still are. The amount of time a child needs to sleep is spread over a 24-hour period. For this reason, your 4-year-old may go to sleep earlier than your 2-year-old. If your 4-year-old still naps, good for you, but understand that when they are in school this will no longer happen, and bedtime will need to be adjusted.

My child does not seem tired at bedtime.
If your children seem hyper at bedtime, and you are basing bedtime on the recommended average number of hours of sleep, chances are they are overtired. Try to put them to bed 30 minutes earlier tomorrow night, or try to catch them just before the witching hour and start bedtime then. It is counterintuitive that children become hyper when they are overtired, but it often happens. Also, kids will do anything to resist bedtime — they want to stay up and spend more time with you.

My child’s bedtime routine seems to involve 12 stories, elaborate songs and begging.
Think long and hard before integrating a new activity into bedtime routine. Bedtime routine begins either after dinner/at shower or bath/when they are home from their last activity. All activities from this point forward should be quiet and not involve electronics. Stories are great and a great teaching tool — but once you are reading more than 2 or 3 stories, think twice about whether you are spending quality time or reinforcing your child’s stalling.

If you feel the bedtime routine is too long, it is. Think about what to cut out. It helps to have your child use the toilet before they are in bed, and give them a drink of water before lights out as this eliminates stalling tactics.

Sleep associations are key.
This is probably the biggest stumbling block in the way of healthy sleep habits. Your child needs to fall asleep at night with the SAME associations that will be present when he opens his eyes during the night and turns over. We all wake up multiple times a night, but for those
of us without a sleep disorder, this is not even memorable. We grab a pillow, close our eyes, and we are asleep again. However, if you need the TV on to fall asleep — that TV needs to be on during the night for you to be able to fall back to sleep.

So, when the dummy falls out the baby cries. When the toddler falls asleep with his mummy in the room and she is not there during the night — he cries, or screams. When the school-aged child falls asleep watching a movie, and it’s not on when she wakes up, she can’t fall back to sleep. Make sense? Sleep associations matter. So, even if a parent is sharing a room with a child, let the child fall asleep by herself and you come in later. It is fine for siblings to share a room, but the bedtime routine either needs to be the same, or one child needs to go to bed after the other has already fallen asleep. Holidays are special, and while the first night home may be a little difficult, don’t let that stop you from sharing a room on holiday. Also, when children are sick, do what you need for them, but understand once they are well you need to go back to the bedtime routine that works and this may be difficult for a couple nights.

**My child won't go to bed by herself — what do I do?**

Don’t fall for it. Children can and will fall asleep by themselves. If they leave the room, lead them back without speaking to them (remember, don’t give them attention). Do this as many times as you have to. Some children will fall asleep on the other side of the door, sobbing. Some children will vomit. As long as you consistently ignore the behavior while ensuring they stay in their room (by leading them back in each time or closing the door if necessary) none of these behaviors will last that long. However, the behavior will get worse before it gets better — if screaming doesn't work, they may throw something, they may vomit. Rest assured that if those behaviors don’t work to get your attention either, they will stop and soon enough, you will have a household of healthy sleepers.

**My child gets out of her bed during the night and comes in to my room — what do I do?**

As long as children are not sick, bring them back to bed. If you are lucky enough to be a heavy sleeper, put a bell on your door so you hear them come in, and bring them back before they can even get in the bed. Don’t speak to them. Don't sleep with them.

(Appendix 3 complied by Dr Butterworth 2016)
Appendix 4

Medicines for Children information for parents and carers- Melatonin for sleep disorders
Download from www.medicinesforchildren.org.uk

Melatonin Guidelines
Oct 16

Melatonin for sleep disorders

This leaflet has been written specifically for parents and carers about the use of this medicine in children. The information may differ from that provided by the manufacturer. Please read this leaflet carefully. Keep it somewhere safe so that you can read it again.

Name of drug
Melatonin
Common brand: Circadin®
Melatonin is available in a range of branded products.

Why is it important for my child to take this medicine?
Melatonin is mostly used for children with partial or complete blindness, cerebral palsy, attention deficit hyperactivity disorders, autism or learning disabilities. It is unlikely to be used for an otherwise healthy child who has sleep problems. 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?
- Modified-release tablets: Circadin® 5 mg
- Tablets and capsules: from 0.5 to 5 mg can be ordered specially from your pharmacist.
- Liquid medicine: 5 mg per 5 mL (this has to be ordered specially from your pharmacist)

When should I give melatonin?
Melatonin is best given between half an hour and an hour before your child’s agreed bedtime. Give the medicine at 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.
- You will probably start with a low dose and the dose will be increased a little each week until the sleep problems have been improved, or up to an agreed maximum. It is important that your child has the minimum they need to help them get to sleep.
- It is important that you follow your doctor’s instructions about how much to give.

How should I give melatonin?
Tablets should be swallowed with a glass of water, milk or juice. Your child should not chew the tablets.

Capsules should be swallowed with a glass of water, milk or juice. Your child should not chew the capsules.
You can open the capsules and mix the contents with a small amount of soft food such as yogurt, honey or jam. Your child should swallow it all straight away, without chewing.

Liquid medicine: Measure out the right amount using a medicine spoon or oral syringe. 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?
If the medicine is helpful, your child should start to feel sleepy about half an hour after taking a dose.

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.

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
- If your child has a seizure (fit) for the first time, or has more seizures than normal if they have epilepsy, contact your doctor straight away.
- If your child gets a fast heart rate (they may have a fluttering feeling in the chest or feel the heart beating fast), contact your doctor before giving the next evening’s dose.
- If they seem unwell, take them to hospital.

Other side-effects you need to know about
- Your child’s temperature may fall a little after taking melatonin. This is a normal reaction to melatonin.
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.
- Check with your doctor or pharmacist before giving any other medicines to your child. This includes herbal or complementary medicines.

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

- Treatment with melatonin is usually started by a specialist.
- We do not know what effects melatonin may have on a child’s development if it is taken for a long time. Your doctor will review whether your child still needs melatonin every 6 months.
- A specialist may suggest that your child takes just one dose of melatonin before having a CT scan, MRI scan or EEG, when they might be expected 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 ‘best before’ or ‘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. 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.

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 more information from:

NHS Direct (England)
0845 4647 - www.nhsdirect.nhs.uk

NHS 24 (Scotland)
0845 24 24 24 - www.nhs24.com

NHS Direct Wales/Galw Iechyd Cymru
0845 4647 - www.nhsdirect.wales.nhs.uk

NI Direct (Northern Ireland)
www.nidirect.gov.uk
Appendix 5

Patient Information Leaflet for Melatonin

This leaflet provides some important information about Melatonin; please read it carefully before taking this medication. If you have any further questions or there is anything else you do not understand about this treatment, ask your doctor or pharmacist.

What is Melatonin?
Melatonin is a hormone that is produced by the pineal gland in the brain; it is produced naturally by the body during the hours of darkness and is involved in the promotion of sleep and maintenance of the normal sleep pattern.

What is Melatonin used for?
Melatonin is useful for the treatment of sleep problems and especially in the circumstances where there is a marked difficulty in falling asleep. It is also helpful for children with visual impairment, where the brain does not receive cues from the eyes about light levels. But it is less effective for patients who repeatedly wake during the night or those who habitually wake very early.

Melatonin is best reserved for patients who do not respond to standard practical measures that aim to promote a normal and refreshing night’s sleep. A system commonly employed to achieve this is called ‘sleep hygiene’; the components of this are provided in the table at the end of this leaflet. It is possible to manage most common night settling problems with sleep hygiene alone, thus reducing the need for medication.

What is in your medicine?
Although Melatonin is a naturally occurring hormone, the Melatonin in your medicine is produced synthetically. Each brand of this drug contains other chemically inactive substances. You will need to check the information leaflet supplied with your medicine or discuss with your pharmacist any possibility of allergy to the inactive ingredients.

Strength of Melatonin
Melatonin is produced in tablets and capsules ranging from 0.5mg up to 20mg. They are usually manufactured in pack sizes of 60 or 100 items, but may be supplied in smaller quantities according to your doctor’s prescription. Other formulations are available including liquid and longer-acting modified-release preparations.

Dose of Melatonin
Your doctor will decide what dose of Melatonin to start on. This is usually 2–3mg taken at night 30–60 minutes before settling to sleep. If, after two weeks this is ineffective, your doctor may advise you to increase the dose. Always follow the instructions you have been given by your doctor. DO NOT EXCEED THE STATED DOSE.

What if a dose is forgotten?
If your child is asleep, do not wake them to give them a dose. If your child wakes later in the night and has difficulty getting back to sleep, the usual dose can then be given at a later time, but the later the child wakes the less effective it is likely to be. There is no need to ‘catch up’ a missed dose.

What if more than the recommended dose is accidentally given?
Normally, this will not result in any problems because Melatonin is a remarkably safe drug, but do seek medical advice from your GP, community pharmacist or NHS Direct if you are worried.
**What side-effects are experienced with Melatonin?**

Melatonin has been shown to be a very safe drug, with relatively few side-effects. Occasionally reported side effects are: headache; dizziness; nausea; drowsiness. Some other very rarely encountered side-effects include: bedwetting; worsening of nocturnal asthma; worsening of depression; worsening of behaviour difficulties.

All side-effects tend to disappear when the medication is stopped.

There is limited information about the very long-term safety of Melatonin, although it does appear to be a very safe medicine.

**Contraindications**

Melatonin can cause drowsiness and should not be taken if you are operating machinery. Melatonin should not be used during pregnancy.

Inform your doctor if you suffer from: depression, epilepsy, asthma and other allergies or hormonal problems.

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

Melatonin rarely causes problems with other medicines, but contact your specialist or pharmacist if you have any worries. If you are buying medicine over-the-counter from a pharmacy always mention that your child has been prescribed Melatonin. It is safe to give your child ibuprofen or paracetamol with this medicine. Advice should be sought when considering using herbal or homeopathic remedies.

**How should this medicine be given?**

This medicine will usually be supplied as either a tablet or capsule. This is usually swallowed whole with a small amount of water. If your child is unable to swallow tablets or capsules, liquid preparations are available. For short term treatment tablets can be crushed and dissolved in a small amount of water. Equally the contents of a capsule can be sprinkled into water or onto food. Any remaining solution must be discarded.

**When should this medication be stopped?**

You should follow the instructions given by your specialist. It will not do any harm if this medication is stopped suddenly, or an occasional dose is missed. It is important to discuss with your specialist if you decide to stop the medication, or you feel that it is not working. It is now regarded as good medical practice to try to withdraw the treatment periodically with due attention to ‘sleep hygiene’.

**How should it be stored?**

The medicine should be stored at room temperature away from direct sunlight, heat and out of reach of children. Do not take after the expiry date on the packet.

**How can I obtain a further supply?**

If you think you will run out of medication before your next appointment you will need to contact your specialist for a repeat prescription. If your specialist has set up an agreement with your GP to provide repeat prescriptions then you can contact your local surgery instead. It is advisable to give as much notice as possible (10-14 days).