Shared Care Protocol for The Use Of Melatonin For Sleep Disorders In Children & Adolescents (Unlicensed Use) in Bedfordshire and Luton ONLY

PATIENT’S NAME: 

DATE OF BIRTH:

PATIENT’S ADDRESS: 

HOSPITAL NAME AND NHS NUMBER / PATIENT IDENTIFIER: 

CONSULTANT’S NAME AND CONTACT DETAILS: 

GP’s NAME: 

What are key elements of the process to ensure good shared care arrangements are in place?

- It is imperative that the GP is contacted to discuss shared care arrangements before treatment is commenced to ensure that they are willing to jointly manage the patient’s therapy.
- It is reasonable to expect the specialist to prescribe if the patient will have to regularly attend hospital for specialist monitoring.
- In addition, CCG policies on clinical effectiveness should be adhered to.
- The general practitioner should have sufficient information on the drug to either allow them to monitor the patient’s response to therapy and adjust dosages as required or know in what circumstances they should refer the patient back to the hospital clinician.
- Where the hospital or community specialist clinician retains responsibility for monitoring drug therapy or making dosage adjustments, the general practitioner must be informed of any dose changes as soon as possible to avoid an incorrect dose being administered. Similarly if the GP changes the patient’s medication then the hospital or community clinician involved in the shared care agreement should be informed of any changes that the GP undertakes.
- If a GP is unhappy to participate in a shared care agreement, the CCG should be asked for assistance in facilitating suitable prescribing arrangements for the patient.
- Informing the patient’s usual community pharmacist of the medication will help ensure that supplies are available.
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1. **Summary of the disease**
Insomnia is a common problem for children with sensory deficits, some learning disabilities and childhood psychiatric disorders such as autistic spectrum disorder and ADHD.

Melatonin is a hormone produced by the pineal gland in a circadian manner, in response to darkness. The link with circadian rhythms has led to its use in the treatment of sleep disorders underpinned by learning disability, autistic spectrum disorders, and ADHD. Melatonin is classified as a medicine in the UK, and is currently unlicensed for these indications in children and adolescents. In contrast, it is readily available to purchase in some countries, e.g. USA.

In practice, the use of melatonin for the treatment of paediatric sleep-wake cycle disorders is widespread. There are a number of published trials, although these are often small and of short duration. As such it is difficult to draw firm conclusions. Children and children with ADHD treated with melatonin have been shown to fall asleep earlier and sleep for longer when compared to controls. Generally no significant change in behaviour or attention has been demonstrated. It would appear that there is wide variability in response. 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.

Circadin® is a sustained release formulation of melatonin that is licensed in the UK for the treatment of primary insomnia in **adults aged 55 years** and over.

- **Diagnosis**
The diagnosis of a sleep disorder in children will be made by specialists in paediatrics, CAMH, and Learning Disabilities.

- **Investigations**
No investigations are required.

2. **Details of the drug therapy**

- **Criteria for patient selection, drug indications and when to stop treatment**
  For use in children of at least 1 year of age with neurodevelopmental disability, autism, 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
  
  - And after failure of sleep hygiene / behavioural measures.

  Children are typically of school age. There may be other causes of these symptoms e.g. depression or anxiety. Other approaches to therapy can be considered. However, melatonin is not known to cause harm.

  Melatonin is only licensed for use in adults aged over 55 years for primary insomnia and so use in children and adolescents is an unlicensed use.

  Specialists should advise GPs on when to stop treatment, e.g. at the end of continuing care typically when children are discharged from the care of the paediatrician.

- **Contra-indications, Special warnings and precautions for use**
  Hypersensitivity to the active substance or to any of the excipients.
Melatonin may cause drowsiness. No clinical data exist concerning the use of melatonin in individuals with autoimmune diseases and so use is not recommended in this group of patients. **Patients with rare heredity problems of galactose intolerance, the LAPP lactase deficiency (this is when the body is unable to digest milk and milk products due to a lack of an enzyme) or glucose-galactose malabsorption should not take this medicine.**

- **Dosage and administration**

<table>
<thead>
<tr>
<th>Age</th>
<th>Oral dose</th>
<th>Maximum dose</th>
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<tbody>
<tr>
<td>1 year onwards</td>
<td>An initial dose of 2-3mg (given 30-60 minutes before bedtime) has been used; in the absence of improvement after 1-2 weeks, the dose is increased to 4-6mg at night.</td>
<td>Usually 10mg per day. (Though 12mg/day has been used).</td>
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**Notes:**
- Each dose is best taken 30 to 60 minutes before bedtime.  
- For children waking during the night, the same dose or a smaller dose can be repeated during the night.  
- A liquid formulation is available for those children with difficulties in swallowing or if administration is via an enteral feeding tube.  
- The contents of the capsule can be added to water, milk or orange juice.  
- Usual dose for Asperger Syndrome 2mg/day  
- Usual dose for autism 9mg/day  
- An annual drug holiday should be introduced to assess the continued need for treatment. This could take place a month before the annual review with the patient and / or the parent keeping a sleep diary.

Treatment may need to be long term. Treatment should be stopped when there is evidence of lack of effect from sleep diary or patient / parent perception.

- **Interactions with other drugs**

From case reports in the literature, clinical experience and theoretical principles it has been suggested that interactions may occur with anticoagulant/ antiplatelet drugs, antidiabetic agents, benzodiazepines/ CNS depressants, carbamazepine and rifampicin, cimetidine, oestrogens (contraceptives or hormone replacement therapy), flumazenil, fluvoxamine, immunosuppressants, nifedipine, quinolones and verapamil. Cigarette smoking may decrease melatonin levels. Interactions for the licensed Circadin™ preparation can be found in its SPC. Further information available in the BNFc/BNF.

- **Product information and Costs**

Circadin® is a licensed version of melatonin and is available as a 2mg prolonged release tablet. It is licensed in the UK for the treatment of primary insomnia in **adults aged 55 years** and over and so use in children and adolescents would be regarded as an off-license use. Circadin® costs 51p per 2mg prolonged release tablet. Circadin®
should be used in preference to preparations licensed outside the UK and “specials”. Appendix 1 contains information about melatonin preparations.

- **Possible side-effects and actions to be taken**
  Melatonin is generally well tolerated, but long term side effects have not been evaluated. It is readily available as a food supplement in the USA. The most commonly reported side-effects are headache, hyperactivity, dizziness and abdominal pain. Increased seizure activity has been reported in patients with epilepsy but there is also anecdotal evidence that seizure activity improves as a result of improved sleep. Much of the clinical trial data with melatonin does not report an increase in seizure frequency, but data must be treated cautiously due to the short term nature, size, and heterogeneous nature of the populations studied. Until more is known prescribers need to approach melatonin use in children with epilepsy highly cautiously and be alert for alterations in seizure activity.

  Concern has been expressed that exogenously administered melatonin could, at least theoretically, adversely affect gonadal development if used in children. Young people up to the age of 20 years produce melatonin endogenously in high levels and levels are inversely related to gonadal development. In the clinical trials included in this review, none reported an association between melatonin and delayed onset of puberty, but most study of melatonin has been short term, and longer term follow-up will be needed to fully address this concern.

  Endogenous serum melatonin concentration is elevated in nocturnal asthmatic patients. Although the clinical trial data presented here do 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 gland. Melatonin from animal sources should be avoided due to the possibility of contamination.

  Adverse events, interactions and precautions for the licensed Circadin™ preparation can be found in its SPC. This is only licensed for (and has only been adequately tested in) adults aged 55 years and above with primary insomnia, therefore the information presented in the SPC cannot be presumed to apply to paediatric patients with neurodevelopmental disorders (NDD).

- **Overdose**
  Administration of daily doses of up to 300 mg of melatonin without causing clinically significant adverse reactions have been reported in the literature. 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.

3. **Back up care available to GP**

   Community paediatricians, Edwin Lobo Centre 01582 700300
   Community paediatricians, Union St. clinic 01234 310071
   Child Development Centre, Hill Rise 01234 310278
   Hospital paediatricians, Bedford Hospital 01234 355122

4. **Written information provided to the patient / carer**

Approved by Medicines management committee/Luton & Beds Joint Prescribing committee May 2013
Appendix 3: Melatonin information leaflet, including how to boost melatonin naturally.

5. Monitoring instructions and responsibilities

SPECIALIST’S RESPONSIBILITIES

- Initiate treatment and continue prescribing until the dose is stabilised, usually 3 to 4 months. Inform GP if a non-standard dose is used.
- Discuss benefits and side effects of treatment with the patient / carer including that the medicine is unlicensed (see appendix 1).
- Supply GP with summary within 14 days of a hospital out-patient review or in-patient stay.
- Ensure the patient is reviewed by a member of the Specialist’s team to monitor response to treatment regularly (at least annually), with trial withdrawal of treatment for a night or so in order to test ongoing need.
- Regularly monitor height, weight, pubertal maturation progress and seizure frequency in epileptic patients
- Advise GPs on when to stop treatment.
- Review the need for continuation treatment annually.
- Report adverse events to the MHRA (yellow card reporting scheme) and inform GP.
- Ensure clear arrangements for GP back-up, advice and support.
- 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.

GP’S RESPONSIBILITIES

- Prescribe melatonin after communication with specialist about the need for treatment.
- Ask patient/carer about side effects and general wellbeing and report back to the Specialist.
- Ask carer about effectiveness.
- 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.
- Report adverse events to the Specialist and MHRA (yellow card reporting scheme).
- Stop treatment on advice of specialist
- Stop or adjust treatment if necessary (e.g. side effects) on discussion with 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.

PATIENT / CARER’S RESPONSIBILITIES

- Contact the GP and community pharmacist to arrange supplies of melatonin in enough time (usually 10 to 14 days before needed) to ensure continuity of treatment.
- Attend appointments.
• Report any adverse effects to the Specialist or GP whilst taking melatonin.
• Share any concerns in relation to treatment with melatonin.
• Report to the Specialist or GP if they do not have a clear understanding of their treatment.
• Keep a sleep diary to assess the effectiveness of therapy if requested.

COMMUNITY PHARMACIST’S RESPONSIBILITIES

• Order the appropriate product from the wholesaler or Quantum Pharmaceutical Services.
• Inform the patient / carer and GP if there is a supply problem.
• Advise the patient / carer / GP as necessary.

6. References

12) Summary of Product Characteristics for Circadin™ (last revised 14/08/2012) http://www.medicines.org.uk/EMC/medicine/25643/SPC/Circadin/
13) Great Manchester Interface Prescribing Group. Shared Care Guideline for Melatonin for Sleep Disorder


17) Personal Communication, Flynn Pharma (manufacturer of Circadin®), 20 March 2013 (data on file).


Appendix 1: Melatonin Preparations and advice

Background
The MHRA want to ensure that the choice of melatonin products is made rationally and takes product quality and safety into consideration. They recognise that it may be necessary to use the non-pharmaceutical products on occasion, especially in patients that may not be able to take solid dosage forms and require liquids or where, for example, they cannot swallow tablets, but can use capsules. There is also the possibility that certain high or low doses may be required, or that capsule contents may be needed for alternative modes of administration. They will consider such cases sympathetically, but will need to know the clinical reason for requiring the product.

MHRA Product Selection Principles
The MHRA specific advice is as follows:

1. Although the MHRA does not recommend “off-label” use of products, if the UK licensed product (Circadin®) can meet the patient’s clinical need, even “off-label”, it should be used. UK licensed products have been assessed for quality, safety and efficacy. If used “off-label” some of this assessment may not apply, but much will still be valid. This is a better risk position than in the use of an un-assessed, unlicensed product.

2. If the UK product cannot meet the patient’s clinical need, then another (imported) pharmaceutical should be considered, which is licensed in the country of origin. For example, there is an immediate release 3mg tablet licensed in Hungary (Bio-Melatonin®, Pharma-Nord), that is manufactured in GMP inspected facilities in Denmark. This is also packed into English language packs in Denmark and may be available in this form from Pharma-Nord, rather than in the Hungarian licensed pack.

3. If option 1 or 2 does not meet the patient’s clinical need, then a completely unlicensed product may have to be used. There are UK manufactured “specials” such as those manufactured by Penn Pharmaceutical Services, which are made in GMP inspected facilities, but which are otherwise unassessed (GMP inspection is not product specific). There are also many US products sold over the counter, but these are not pharmaceuticals and are made to unknown quality standards. They would therefore be classified as a last resort to meet patient’s clinical need.

What is a “special clinical need” letter?
Imported melatonin orders need a letter from the prescriber stating the special clinical need. In other words, why the patient can not take the licensed 2mg modified release tablets, Circadin®.

There are no notification requirements for UK manufactured “specials”. The MHRA are therefore not in a position to routinely review compliance for these products in the manner they can for imports. However, “special clinical need” is still a requirement. Importers and “specials” manufacturers must therefore be able to provide evidence of “special clinical need” for the products they supply. There should be a documented audit trail leading to the prescriber and evidence of the “special clinical need”. The MHRA recommends that the best evidence of “special clinical need” is a letter from the prescriber.

What melatonin preparations are available?
1. UK Licensed preparation (which would be used “off-label”)

Circadin® - Melatonin 2mg prolonged-release tablets is the only melatonin product licensed in the UK. It is licensed for short-term use for insomnia in the over 55s only. However, the MHRA have stipulated that licensed products should be used wherever possible, even if it means using a product “off-label” and outside its licensed indications. Hence, Circadin® 2mg prolonged release is the preferred option for children. Circadin® 2mg prolonged-release tablets £15.39 for 30 x 2mg tablets (March 2013 prices). Tablets should be swallowed whole.

In-vitro dissolution studies show that intact/whole Circadin® tablet releases melatonin in a controlled and prolonged manner over at least 8 hours, although approximately 40% of total dose is released within the first hour and may be regarded as effectively “immediate release”. The tablet broken into quarter fragments provides for melatonin release over approximately 4 hours and an immediate release component of the order 60%. The in-vitro release from a crushed or powdered tablet is expected to provide an immediate release profile similar to that from an unlicensed immediate release tablet or (unlicensed) oral liquid and as such provides a viable alternative to either of these options. The prescriber should be aware that the release characteristics do not match those of the intact tablet and that this may be evident in the clinical effect (when compared to the intact Circadin® tablet). Use in this circumstance would be ‘off-label’ use of a licensed product.

If this formulation, controlled release mechanism or dosage is not suitable then option 2 should be considered.

2. European Licensed preparation

The European licensed immediate release melatonin preparation is called Bio-Melatonin® 3mg Filmtabletta and is made by Pharma Nord.

These 3mg tablets can be crushed and mixed with water if there are swallowing difficulties (information from Bio-Melatonin® patient information leaflet). In accordance with MHRA guidance, a letter confirming “special clinical need” will be required with orders.

Availability
Imported from Denmark (English packaging) may be available from:
local wholesaler, or
PharmaNord (UK), Telford Court
Morpeth
Northumberland
NE61 2DB
Tel: 01670 519989
Fax: 01670 534903
Approximate cost March 2013 (prices may change) = £15.44 +VAT for 60x 3mg tablets + £10.50 carriage charge.
Also available from specials manufacturers such as the specials laboratory
www.specialslab.co.uk/ Bio-Melatonin® 3mg tablets
60 x 3mg tablets approximate cost= £30.88 + VAT (The prices that are included on the list are as of March 2013 and may change. The prices are direct and could therefore change if pharmacies were to order via groups (Mawdsleys/Craig and Hayward etc.).

If preparations in option 1 or 2 are not appropriate for the patient’s clinical need then option 3 should be considered.
3. “Specials” Preparations of Melatonin

Various unlicensed UK Specials and imports, especially from the USA where melatonin is classed as a food supplement and where they may not be made according to good pharmaceutical manufacturing standards, are not recommended.

The following strengths of immediate release capsules, orodispersible tablets and liquid preparations of melatonin are manufactured by Penn Pharmaceutical Services (manufactured under its UK “specials” license 4351) and distributed by Quantum Pharmaceuticals. Prices correct as of March 2013. Contact Quantum Pharmaceuticals to confirm up to date prices.

**Contact Information:**
Penn Pharmaceutical Services, 23/24 Tafarnaubach Industrial Estate, Tredegar, Gwent, NP22 3AA, UK
Tel: 01495 713600, Fax: 01495 713613, e-mail: sales@pennpharm.co.uk
Quantum Pharmaceuticals, Quantum House, Hobson Industrial Estate, Burnopfield, Co Durham, NE 166 EA
Tel: 0800 233 5230, Fax: 0800 233 5250

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>LIST PRICE (+ £12 Carriage charge)</th>
<th>PACK SIZE</th>
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<tbody>
<tr>
<td>Melatonin 1mg capsules</td>
<td>£92.70</td>
<td>100</td>
</tr>
<tr>
<td>Melatonin 2mg capsules</td>
<td>£48.93</td>
<td>60</td>
</tr>
<tr>
<td>Melatonin 2.5mg capsules</td>
<td>£103</td>
<td>100</td>
</tr>
<tr>
<td>Melatonin 3mg tablets</td>
<td>£54.08</td>
<td>60</td>
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<tr>
<td>Melatonin 3mg capsules</td>
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<td>Melatonin 5mg capsules</td>
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<td>Melatonin 5mg capsules</td>
<td>£59.74</td>
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</tr>
<tr>
<td>Melatonin 10mg capsules</td>
<td>£118.45</td>
<td>100</td>
</tr>
<tr>
<td>Oral liquid preparation</td>
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A liquid preparation may be preferable in children with a gastrostomy tube. Melatonin liquid ‘specials’ preparations are listed in the Drug Tariff. The most cost effective preparation is Melatonin 5mg/5ml oral solution (£110.52 for 200ml, March 2013 Drug Tariff)
Appendix 2: Extract from BNF for Children March 2013

Chapter 4.1.1 – Hypnotics

**Melatonin**

Melatonin is a pineal hormone that may affect sleep pattern. Clinical experience suggests that when appropriate behavioural sleep interventions fail, melatonin 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, and learning difficulties. It is also sometimes used before magnetic resonance imaging (MRI), computed tomography (CT), or EEG investigations. Little is known about its long-term effects in children, and there is uncertainty as to the effect on other circadian rhythms including endocrine or reproductive hormone secretion. Treatment with melatonin should be initiated and supervised by a specialist, but may be continued by general practitioners under a shared-care arrangement. The need to continue melatonin therapy should be reviewed every 6 months.

Melatonin is available as a modified-release tablet (Circadin®) and also as unlicensed formulations. Circadin® is licensed for the short-term treatment of primary insomnia in adults over 55 years. Unlicensed immediate-release preparations are available; the manufacturer should be specified in the shared-care guideline because of variability in clinical effect of unlicensed formulations.

**Indications and dose**

**Sleep onset insomnia and delayed sleep phase syndrome** (see notes above)

- **By mouth**
  Child 1 month–18 years initially 2–3 mg daily before bedtime increased if necessary after 1–2 weeks to 4–6 mg daily before bedtime; max. 10 mg daily
APPENDIX 3 Shared Care Guideline - Melatonin information leaflet

Melatonin for the treatment of sleep disorders in children & adolescents - information for patients, parents and carers

What is melatonin?
Melatonin is a natural hormone produced by the pineal gland in the brain. It is produced at night and helps us to fall asleep.

Melatonin has been used to treat jet lag and some sleep problems in adults. The results from a small number of studies in children show that melatonin can help children fall asleep.

When is melatonin used?
Many Specialist doctors (Paediatricians and Child Psychiatrists) are using melatonin to treat severe sleep problems seen in some children with behavioural problems.

Many children with learning disabilities, autism and certain forms of blindness have significant sleep problems. The most common problems are: difficulties settling, waking up repeatedly and waking too early. Sleep problems can cause daytime sleepiness and behavioural problems during the day.

First, we try to change behaviour without any medicines and this can be very successful. However, this does not work for some children. For these patients, we may try a sedative medicine such as alimemazine (the brand name is Vallergan®) or promethazine (the brand name is Phenergan®). These medicines may not work or may have side effects (especially feeling very sleepy the following morning) and can sometimes make sleep problems worse.

Melatonin can help children to fall asleep without feeling very sleepy the next morning.

How is melatonin supplied?
Melatonin is currently an unlicensed medicine in children and adolescents in the UK but can be prescribed by doctors on a prescription.

Melatonin is usually started by a community or hospital Specialist doctor and prescribing can be taken over by your General Practitioner (GP) using our ‘shared care guideline’. This is so you can get supplies from your local pharmacy (chemist) near your home or work. Melatonin has to be specially ordered and it can take 10 to 14 days for your pharmacist (chemist) to get a supply for you - so hand in your prescription before you run out and give them plenty of time.

It is supplied as capsules that can be opened if needed and the contents of the capsule can be mixed in water, milk or orange juice. It is also available as tablets or liquid.

What is the usual dosage?
We usually start on a low dose of between 2mg or 2.5mg and this should be given about 30 to 60 minutes before your child’s regular bedtime. If this does not work or seems to help a little, the dose can be increased slowly up to 10mg, or occasionally, 12mg each night.

Can I boost melatonin naturally for my child?
Exposure to daylight or bright artificial light first thing in the morning and low lighting in the evening can help to boost melatonin production naturally in the brain. Certain foods also provide a naturally rich source of melatonin: oats, sweet corn, rice, ginger, tomatoes and
barley. A banana “smoothie” (banana and milk liquidised together), a cup of tomato soup
or a bowl of corn flakes, made with warm full-cream milk, taken an hour before bedtime
may have a similar effect. Another naturally occurring chemical, tryptophan, is one of the
building blocks of melatonin and foods containing this can also boost melatonin production
in the evening. Foods that are rich in tryptophan include: cottage cheese, instant breakfast
cereals (made with full cream milk), chicken and turkey, nuts (almonds and peanuts), milk,
ice-cream and yoghurt. Foods rich in calcium, magnesium, vitamin B6 and nicotinamide
(B3) can also boost melatonin production.
These can be tried instead of taking melatonin capsules.

What should my child avoid?
Avoid anti-inflammatory drugs (such as aspirin or steroids), caffeine (tea, coffee, cola
drinks and chocolate) and exposure to bright lights before bedtime.
Strong electromagnetic fields from computers, radios, TVs, clocks, baby monitors, electric
blankets, etc. can also reduce melatonin and are best removed from the bedroom or
switched off at the wall socket.

How long should treatment last?
This is a difficult question to answer because there is not much information.
A simple answer is “as long as we believe it is helping and is safe”.
After trying melatonin for one month, your Specialist's team will review whether the
melatonin is helping and whether there have been any problems, like side effects.
If it has not helped then they will discuss increasing the dose or stopping melatonin with
you. If it has helped then they may ask your General Practitioner (GP) to prescribe it so
you can get the melatonin from a pharmacist (chemist) near your home or work.

The Specialist's team will review your child about every 12 months, or earlier if there are
any concerns. Some children can eventually stop taking melatonin and will be able to
sleep normally. But some children will need to take melatonin long term. To see if the
medicine needs to be continued the drug will be stopped once a year, usually a month
before the annual review. You will be asked to keep a sleep diary to see how the treatment
is working. Treatment will be stopped if there is evidence of lack of effect from the sleep
diary or your report a lack of effect.

Sometimes parents forget to give a bedtime dose. If your child sleeps well without the
melatonin then it is a good idea to stop the melatonin and see if this pattern continues for
the next few nights. Tell your doctor of any forgotten doses and how your child slept
without melatonin. Sleep problems in children tend to change so it is very helpful to keep
a sleep diary before and during any treatment to show whether the treatment is working.

Side effects
Melatonin is generally well tolerated. Some patients report they get headaches.
A small number of children may become excitable and agitated and some may have vivid
dreams or nightmares and the melatonin may need to be stopped.
There has been concern about using melatonin in children with epilepsy but for most it is
safe to use. Children suffering from illnesses that affect the immune system (severe
allergies, autoimmune conditions and some forms of immune system cancer) should avoid
melatonin because it may make these illnesses worse.

(This leaflet has been reproduced with the kind permission of Dr D Bramble, Telford &
Whelkin PCT.)