

Shared Care Guideline

Melatonin for sleep disorders in children and adolescents with neurological or behavioural disorders or chronic fatigue syndrome

Section 1: Agreement for transfer of prescribing to GP

Patient details/addressograph:

Name.....
Address.....
DOB..... Hospital No.....

Drug name and dose:

Diagnosis

<p>Consultant: Address: Contact Number</p>
<p>GP: Address: Contact Number:</p>
<p>Main Carer: <i>parent/guardian</i> Contact Number:</p>
<p>Key Worker if appropriate: Contact Number:</p>

<p>Agreement to shared care, to be signed by GP and Consultant before transfer of prescribing to GP Consultant Signature:</p>
<p>-----</p> <p>Date:</p>
<p>GP Signature:</p>
<p>-----</p> <p>Date:</p>

This shared care agreement outlines suggested ways in which the prescribing responsibilities can be shared between the specialist and GP. GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient's mental health remains with the specialist. If a specialist asks the GP to prescribe, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between specialist, GP and patient.

The prescriber of the medication legally assumes clinical responsibility for the drug and the consequences of its use.

(a) Criteria for use:

- Patients have been assessed by a specialist CAMHS or paediatric consultant
- Traditional non pharmacological sleep hygiene methods have failed
- Patients are stabilised on medication by a consultant. If improvement of symptoms is not observed after appropriate dosage adjustment, the drug should be discontinued by the specialist.
- Regular review is carried out by the consultant

(b) Responsibilities of the Specialist:

- Assessment and decision to initiate treatment
- Explanation to patients' carers of the unlicensed nature of melatonin and obtain appropriate consent.
- Prescribe the medication until the dose is stabilised, the patient has demonstrated a response and the GP agrees to take over responsibility for prescribing
- Stop or modify the dosage as appropriate.
- Notify the GP promptly and in writing of any changes in medication regime and non-attendance at clinic.
- Be available to discuss any problems with the GP and other team members.
- Provide the patient's carers with suitable written and verbal information about the drug benefits and side effects before starting medication.
- Review patient at regular intervals as appropriate, usually 6 monthly, to ensure continued need.
- Keeping the GP informed of monitoring results
- Advise patients of possible delays in supply – it may take up to two weeks for a community pharmacy to obtain supplies

(c) Responsibilities of General Practitioner

- Agree appropriate monitoring with the specialist. Although the responsibility for carrying out monitoring lies with the specialist, the GP must ensure that results are acceptable before generating further prescriptions i.e. there are no concerns regarding side effects or attending clinic for monitoring.
- Issue further prescriptions as requested by the specialist at the appropriate intervals (usually monthly.)
- Contact the specialist for management advice as required.
- Report suspected adverse events to the specialist (& via yellow card reporting if appropriate).
- Advise patients of possible delays in supply; as an unlicensed product it may take up to two weeks for a community pharmacy to obtain supplies

Section 2: Treatment Plan and Shared Care Guideline

(a) Information

Written by: Dr M Tettenborn, Consultant Paediatrician, Dr C Hunter, Dr A Hill-Smith & S Mennear, Hampshire PCT, October 2007

Approved by: Prescribing forum, FPH, January 2008

Review date: January 2010

Sleep disturbances in children with neurological or behavioural disorders are very common. There are many reasons postulated for this including, delayed brain maturation, malfunction of sensory organs (particularly vision) and abnormalities or malformation of the sleep centres.

The types of sleep disruption experienced include delayed onset, frequent waking, early morning wakening and reversal of the day-night sleep pattern.

Sleep disorders can be a major source of stress for the whole family and limited solutions are available. These children have a variable response to behavioural therapies. Hypnotics and sedatives are generally effective initially but tolerance quickly develops and many cause unacceptable adverse effects.

Melatonin is an endogenous hormone produced by the pineal gland in the brain. It has been shown to be important in the regulation of circadian rhythms in humans and animals and a number of studies have shown that exogenous melatonin has beneficial effects on the sleep patterns of these kinds of children.

However melatonin is an unlicensed product in the UK and many GPs are wary of taking on the responsibility for prescribing. When a GP chooses to prescribe an unlicensed product, the product liability passes to the GP. Before prescribing the GP should be confident that a reasonable body of medical opinion would support the use of the product in that way (Bolam principle).

(b) Summary of evidence

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 a 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.

(c) Indications for treatment

For use in children of at least 1 year of age with neurodevelopment 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.

(d) Dose

3mg 20-30mins before desired sleep time. The dose can be increased to 6mg if insufficient response after 7-10 days up to a maximum daily dose of 12mg. The dose is not related to age. Children who continue to have a fragmented sleep pattern may benefit from a sustained release preparation.

Ordinary release capsules can be sprinkled on food or in liquids or administered via a gastrostomy.

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Sometimes sustained release and ordinary release capsules may be mixed to good effect. Some patients may benefit from alternate night, PRN or tapering doses.

(e) Monitoring

Height and weight
Pubertal maturation progress
Seizure frequency in epileptic patients

(f) Cautions

Melatonin has been associated with changes in seizure patterns. Prescribe with caution in epilepsy and monitor seizure frequency, as this may sometimes increase or decrease.

There is little known about long term effects – long term safety has not been established.

A relationship between onset of puberty and decline in melatonin levels is thought to exist. Pubertal maturation should be monitored in prepubertal children.

The ability of melatonin to stimulate the immune system leads to a theoretical risk of developing diseases affecting the immune system: allergy, auto immune conditions and some forms of immune system cancer.

(g) Side effects

Melatonin is generally well tolerated in children. The available literature suggests that melatonin is safe. It is readily available as a food supplement in the USA. In general reviews of melatonin treatment in adults and children, the most commonly documented side effects include reduction in body temperature, sedation, headache, depression, tachycardia and skin rashes/pruritus.

(h) Drug Interactions

Many of the children in whom the use of melatonin is being advocated are on various medications and no problems have been identified.

(i) Treatment length

Once the patient has been sleeping well for a month, melatonin may be withdrawn for a night or so in order to test ongoing need. Blank sleep diary sheets should be provided. However some patients may require long-term treatment. Growth and other developmental parameters should be measured and noted.

Information for patients on melatonin:

<http://www.besttreatments.co.uk/btuk/conditions/1000470098.html>

Sleep diary pages

<http://www.nas.org.uk/content/1/c4/52/72/Appendix%20%2B3.doc>

Preferred Suppliers *

1. Melatonin liquid: 1mg/ml from IDIS made by Special Products called KidNaps. IDIS code MEL196 £21.15 per 200ml

2. Melatonin capsules 3mg: from IDIS made by Life Extension in packs of 60. IDIS code MEL100 £13.00 per 60 ex. VAT.

3. Melatonin capsules 3mg Modified Release: from IDIS made by Life Extension in packs of 60. IDIS code MEL107 £14.60 per 60 ex.VAT

IDIS contact: 01932 824 100

**** As these products are unlicensed in the UK, they are only available on prescription on a named patient basis. Such prescribing incurs increased clinical responsibility and liability on the prescriber for the efficacy, safety and the quality of the product.***

It is therefore recommended that a consistent source of product is prescribed and dispensed.

References

1. Buscemi N, Vandermeer B, Hooton PR, et al. Melatonin for treatment of sleep disorders. Rockville, MD: Agency for Healthcare Research and Quality, 2004. (Evidence report/technology assessment No 108. AHRQ publication No 05-E002-1.)
2. MTRAC: Melatonin Summary Sheet and Verdict, 1996
3. BNF for Children 2007.
4. Shared Care Protocols from Lothian, Berkshire, Telford & Wrekin, and Bolton NHS.