South Staffordshire and Shropshire Healthcare NHS
NHS Foundation Trust
A Keele University Teaching Trust

Essential Shared Care Agreement:
Melatonin (Circadin®, Bio-Melatonin)

Please complete the following details:

Patient's name, address, date of birth, and either complete when the consultant will review, OR duration of treatment and suggested date for GP review
Consultant's contact details (p.3)
And send One copy to:
-the patient's GP
-put one copy in care plan
-give one copy to the patient

Patient's name:	
Patient's address:	
Patient's Date of Birth:	
Consultant Review:	
Duration of Treatment/ GP Review due:	

Note:
Guidelines will only be written when it has been agreed (at the Medicines Optimisation Committee) that shared care is or maybe an appropriate option in individual cases, and will include a statement of Specialist Unit /GP responsibilities.

Shared Care Guidelines will ensure that all GPs have sufficient information to enable them to undertake responsibility for specialist therapies and other therapies which may affect/interact with specialist therapies. This ESCA is intended to be used to facilitate shared care prescribing for all children and adolescents, and for only adults with a learning disability.

It is not the intention to insist that GPs prescribe such a therapy and any doctor who does not wish to undertake the clinical and legal responsibility for a Shared Care Drug is not so obliged. Acceptance of the Shared Care Guidelines will be endorsed by the medicines management departments of the CCG.

The information contained in this guideline is issued on the understanding that it is the best available from the resources at our disposal at the time of issue. For further information please refer to the trust's Prescribing Guidelines on Melatonin or contact your local Specialist or Drug Information Centre.

Further copies of this guideline may be obtained from:

- South Staffordshire & Shropshire Healthcare Foundation NHS Trust
- CCG Prescribing Advisers.

Produced: May 2016
Review date: May 2018
Replaces: E033

SHARED CARE GUIDELINES FOR MELATONIN

Referral Criteria

- In some cases, prescribing will have been initiated by a GP, and in these cases, shared care is not appropriate, and prescribing responsibility remains with the GP.
- When initiation is by the Trust, and is required immediately, the patient will receive supplies of licensed Melatonin (Circadin®) or unlicensed Melatonin (Bio-Melatonin 3mg tablets) on a hospital or community prescription form until shared care is appropriate and agreed.

Specialist Services Responsibilities

- Assess the patient, establish a diagnosis and determine a management strategy
- Discusses carefully the risks and benefits of treatment with the child/young person and/or their parents, including that either (a) although the medicine is licensed, this indication represents off label use- for Circadin, or (b) although the medicine is unlicensed, this manufacturer operates good manufacturing practice in the UK and is licensed in Europe- Bio-Melatonin 3mg tablets. Use Circadin as the first-line choice
- Initiate treatment and provide at least 28 days supply
- Ask the GP whether he or she is willing to participate in shared care.
- Supply GP with summary within 28 days of a hospital out-patient review or in-patient stay.
- Ensure the patient is reviewed by a member of the specialist team to monitor response to treatment regularly (two weeks after initiation and then at least every 6 months)
- Advise GPs on when to stop treatment.
- Report adverse events to the MHRA
- Ensure clear arrangements for GP back-up, advice, and support.

GP Responsibilities

- Reply to the request for shared care as soon as practicable by faxing back signed form, available from the relevant CCG website
- Prescribe melatonin by BRAND NAME (Circadin) or by branded generic (Bio-Melatonin 3mg tablets) after communication with specialist about the need for treatment.
- Ask patient/carer about side effects and general well being
- Ask carer about efficacy
- 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 specialist and CSM.
- Stop treatment on advice of specialist.
- Inform specialist of all relevant medical information regarding the patient and any changes to the patient's medication irrespective of indication.

Patient/carer's role

- 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.

Back-up advice on the above is available at all times:
South Staffordshire & Shropshire Healthcare Foundation NHS Trust – Contact Details

Contact	**Speciality**	**Available**	☎	
Dr		Mon-Fri 8.30 – 5.00		

SUPPORTING INFORMATION

Indication

Melatonin is indicated for treating sleep disorders in children and adults with neurodevelopment disorders and conditions such as visual impairment, cerebral palsy, attention deficit hyperactivity disorder and autism. It is also sometimes used before EEG investigations.

Licensed Indications

Circadin® 2mg M/R prolonged-release tablets is the only melatonin product licensed in the UK. It is licensed for short-term use in 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 MR is the preferred option.

The next best option is an unlicensed product, which is manufactured according to UK Good Manufacturing Practice and is licensed in Europe; these would be suitable when Circadin is not appropriate, e.g. when a patient cannot swallow tablets NB Bio-Melatonin tablets may be crushed.

Product Information

Circadin 2mg prolonged-release tablets (Lundbeck)
These tablets must be swallowed whole.

The product below is manufactured according to GMP and does not require confirmation of special clinical need.

Bio-Melatonin 3 mg tablets. The tablet may be crushed if required for easier swallowing. Stability data demonstrates the tablet may be crushed and dissolved in up to 200mls of water. The dissolved tablet may be flushed through a percutaneous endoscopic gastrostomy (PEG) tube or nasogastric (NG) tube.

1. The usual starting dose for sleep disorders is 2-4 mg in children above the age of two. The dose may be increased to 4-6 mg if there is insufficient benefit after 1-2 weeks. Doses higher than 10 mg are not considered to be of greater efficacy. If no benefit is seen after 2 weeks, then melatonin should be stopped.

2. It is recommended that melatonin be given on an empty stomach, since the absorption may be delayed when taken with large meals. It should be taken 30-60 minutes before bedtime.

3. The aim is to establish healthy sleep habits with the lowest effective dose. At least six months of an improved sleep pattern should elapse before withdrawal takes place. Withdrawal may occur over a period of 3-4 weeks. For some children however withdrawal is not successful and treatment may be necessary long term.

4. It is recommended that the patients are followed up every six months to ensure continuing benefit of melatonin.

5. The licensed product melatonin 2 mg MR (Circadin®) is to be used first line, for an off-label indication, if clinically appropriate. Once stabilised, shared care is appropriate, in accordance with the ESCA. It is worth noting that Circadin is a modified release tablet, which cannot be crushed