Mid Cheshire Hospitals NHS
NHS Foundation Trust

# *Shared Care Agreement Melatonin (Circadin®)*

***Please be advised that the Trust discourages the retention of hard copies of policies and procedures and can only guarantee that the policy on the Trust Intranet is the most up to date version***

| | |
|---|---|
| **Document Type:** | **Protocol** |
| **Version:** | **2** |
| **Date of Issue:** | **January 2018** |
| **Review Date:** | **January 2020** |
| **Lead Director:** | **Medical Director** |
| **Post Responsible for Update:** | **Divisional Pharmacist for Women & Children** |
| **Ratifying Committee:** | **Joint Medicines Management Group** |
| **Ratified by them in the minutes of:** | **JMMG- 20th December 2017** |
| **Distribution to:** | **All Trust and Primary Care staff via the Trust Intranet and CCGs** |

**Contents:**



| **Risk Rating** | | |
|---|---|---|
| Who will be affected by this Procedure? | Trust Employees / Patients / Visitors / General practitioners | |
| Have any existing risk assessments related to this procedure been appropriately updated | No | |
| Is a new risk assessment required by this procedure? | No | |
| Does this procedure require Health and Safety training? | No | |
| Does this procedure require specialist equipment? | No | |
| Name: | Liz Hemingway | Date: 06/2015 |

| | **A Potential Severity (1-5)** | **B Likelihood of Occurrence (1-5)** | **C Risk Rating (A x B = C)** |
|---|---|---|---|
| Raw Risk Rating | 5 | 3 | **15** |
| Final Risk rating | 5 | 2 | **10** |

## 1 INTRODUCTION / PURPOSE

This shared care agreement is to promote the on-going care and support of patients prescribed Melatonin (Circadin®) for sleep disturbance in children with neurological or behavioural disorders when behavioural interventions and implementation of good sleep habits have failed.

These guidelines have been agreed upon by the Joint Medicines Management Committee in consultation with General Practitioners (GPs) and Clinical Commissioning Groups (CCGs).

The guidance is felt to represent a safe level of clinical care for children with neurological or behavioural disorders requiring treatment with Melatonin (Circadin®) for sleep disturbance.

After initial prescribing under hospital supervision, under certain circumstances monitoring and prescribing can be undertaken in general practice.

It is the policy of the Trust that no one will be discriminated against on grounds of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. The Trust will provide interpretation services or documentation in other mediums as requested and necessary to ensure natural justice and equality of access.

## 2 GENERAL DOCUMENT PRINCIPLES

### 2.1 Use of melatonin (Circadin®) in children

**Background**

Sleep disturbances in children with neurological or behavioural disorders are very common. There are multiple factors for this that are frequently interrelated and which include delayed brain maturation, malfunction of sensory organs (particularly vision) and abnormalities or malformations 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. Such children have a variable response to behavioural therapies.

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

When behavioural interventions and implementation of good sleep habits have failed, melatonin may be considered. Melatonin can be initiated on a short term basis alongside good sleep habits and discontinued after a good bedtime routine has been successfully established

## 2.2 Licensed Indication

**Circadin®** has been used and is licensed in the U.K. for patients over 55 years of age many years nationally and internationally. However its use in children is 'off label'.

The following information describing the "off label" status is provided in the information leaflet given to the patient when therapy is started by the community paediatricians

"A drug company must have a licence to advertise and sell a medicine. The licence states what the medicine can be used for and the dose. To get a licence the drug company must prove the drug works and that it is safe to use and publish clinical trial information. When doctors know more about how a medicine works they want to try using it for other groups of patients. If a medicine is used for other age groups not stated in the licence, then it is described as 'off label'.
Because the drug has already been used for sleep disorders in older age groups its quality is assured and therefore it is safer than using unlicensed products."

## 2.3 Exclusions from the shared care protocol

- Children with swallowing difficulties – e.g. tube fed – ( see administration below)
- Autoimmune disease
- Hepatic Impairment: manufacturer advises avoid
- Pregnancy: no information available – manufacturer advises avoid
- Hypersensitivity to the active substance or to any of the excipients.
- Patients with rare hereditary problems of galactose intolerance, the LAPP lactase deficiency or glucose - galactose malabsorption should not take this medicine.

## 2.4 Dose

The recommended dose is initially 2mg once daily, in the evening.

If there has been no beneficial response within 7-14 days, the dose can be increased in 2mg steps every 7-14 days. The usual dosage range is 2 - 6mg, with a maximum of 10mg.

There is no evidence to suggest higher doses provide additional benefits and where patients fail to respond to treatment at the maximum dose stated above, treatment should be discontinued. This can be done abruptly; see below for further information on withdrawal of treatment.

## 2.5 Administration

Tablets should be swallowed whole with a drink. They can be taken with or without food.

It is accepted practice that the tablets can be halved with a tablet cutter, as the modified release matrix should still be intact and this may help children who cannot swallow a whole tablet. However this is outside the product license.

## 2.6 Withdrawal

Where patients benefit from treatment there should be follow up every 6-12 months to assess continued need. These can take the form of treatment holidays, where the melatonin is gradually withdrawn over a period of 3-4 weeks and change in sleeping pattern observed. For some children however withdrawal is not successful and treatment may be necessary long-term.

The specialist will organise this withdrawal and inform the GP to hold prescriptions for that time period, and where necessary to re-start.

## 2.7 Adverse effects

Please see the current edition of the BNFc or the latest SPC for a full list.

Melatonin is generally well tolerated. All possible side effects are unknown due to the small size of trials in children. The most commonly reported side effects are: headache, dizziness, nausea and drowsiness.

Other side effects include: abdominal pain, constipation, fatigue (tiredness), pruritus (itching), hypothermia (severe coldness), tachycardia (fast heart rate), mild depression symptoms, morning lethargy, skin rashes. Melatonin is reported to potentially affect seizure control in patients with epilepsy, so children with epilepsy should be closely monitored for any increased incidence of seizures.

## 2.8 Cautions

Renal Impairment: no information available – manufacturer advises caution

## 2.9 Monitoring requirements

Standard monitoring of growth and sexual development is recommended, i.e. to check height, weight and pubertal development progress as expected.

## 2.10 Preparations available

Circadin® MR 2mg tablets 30 tablet pack

## 2.11 Cost (NHS list price 2015)

CircadinTablets 2mg MR £15.39 for 30 tablet pack. Cost of 12 months treatment between approx. £200 and £950 depending on dose.

Refer to current BNFc for pricing information

# 3 DEFINITIONS

JMMG – Joint Medicines Management Group
CCG – Clinical Commissioning Group
BNFc – BNF for children
SPC – Specific Product Characteristics
SMPG – Safe Medicines Practice Group

## 4 ASSOCIATED DOCUMENTS

Community Paediatric Patient information leaflet for melatonin
MCHFT Medicines Policy

## 5 DUTIES

### 5.1 JMMG

- To develop , disseminate and review this shared care documentation

### 5.2 Community Paediatrician Responsibilities

- Make any necessary diagnosis and communicate this to the GP and any other relevant professionals involved in the patient's care
- Ensure the patient has been given all the required written and verbal information and that they are aware of side effects and any monitoring required
- Discuss treatment options with the patient and their parent(s) or carer(s), including explanation of the off label nature of melatonin. Obtain appropriate consent to treatment. Initiate treatment with melatonin usually for 12 weeks but with a minimum supply of 8 weeks
- Request the GP to enter into a shared care agreement and take over prescribing in a clear letter. The letter should include full care summary including clinical details and doses and document that the "off label" nature of melatonin has been discussed and consent obtained. This should enable safe shared care between the community paediatrician and the GP
- Review the effectiveness and continued need for the medicine at 4-6 months
- Advise on dosage alterations when appropriate
- Follow up every 6-12 months to ensure continuing benefit of melatonin Ensure that the appropriate monitoring is undertaken
- When appropriate, undertake periodic treatment withdrawals, and advise the GP in writing when this is going to happen
- If a treatment withdrawal period is required the specialist will coordinate with the GP to stop prescribing for this time period
- Communicate any changes, recommendations, outcomes or other important information to the GP
- Provide advice to the GP if they have clinical queries relating to the patient's condition or use of melatonin.

### 5.3 GP Responsibilities

- Provide the patient with prescriptions for melatonin (Circadin®) as needed
- Ensure the medicine is added to the GP patient record
- Continue to supply melatonin (Circadin®) according to the schedule suggested by secondary care, or discontinue the medication, when necessary or requested
- Communicate any problems to the community paediatrician looking after the patient.
- If the community paediatrician requests a treatment withdrawal period, the GP would need to put a hold on the prescriptions until they receive confirmation that they are to re-start
- Report any suspected adverse drug reactions to the community paediatrician who

initiated therapy under the shared care agreement, all adverse events should be reported even if causal relationship is not known or if the adverse event is already known about. Report adverse events to the MHRA using yellow card scheme.

### 5.4 Patient and Parent/Carer Responsibilities

- Share any concerns they have in relation to treatment with their drug(s) Report any adverse effects to their community paediatrician or GP whilst taking drug(s)
- Report to the community paediatrician or GP if they do not have a clear understanding of their treatment
- Participate in the monitoring of therapy and the assessment of outcomes, to assist health professionals to provide safe, appropriate treatment.

### 5.5 Contacts

Consultant and medical staff may be available to give advice and can be contacted as detailed in the letterhead or contact Leighton Hospital switchboard and ask for Community Paediatric clinics.

The telephone numbers for the community paediatric team based at Wharton Primary Healthcare Centre are 01606 542538 / 01606 542536 / 01606 542539

The telephone numbers for the community paediatric team based at Leighton Hospital are 01270 278290 / 01270 278292 / 01270 278291 / 01270 278294 / 01270 278287

## 6 CONSULTATION AND COMMUNICATION WITH STAKEHOLDERS

JMMG
General Practitioners

Referred to **Governance.policies@mcht.nhs.uk**

## 7 IMPLEMENTATION

This shared care agreement will be available via MCHFT intranet and the CCG electronic resources. Implementation will be facilitated by the CCG and JMMC members.

## 8 EDUCATION AND TRAINING

This shared care agreement will be made available to secondary care and primary care prescribers when patients are commenced on Melatonin (Circadin®)

## 9 MONITORING AND REVIEW

| Standard/process/issue required to be monitored | Monitoring and Audit | | | |
|---|---|---|---|---|
| | Process for monitoring e.g. audit | Responsible individual /group | Frequency of monitoring | Responsible committee |
| Shared care agreement | Discussion at JMMC and by exception. | JMMG | Ongoing in response to incidents | JMMG |

| | | | | |
|---|---|---|---|---|
| Shared care agreement | Monitoring of medication incidents | SMPG | Monthly | SMPG |

## 10 REFERENCES / BIBLIOGRAPHY

This shared care agreement should be read in conjunction with the Summary of Product Characteristics (SPC, datasheet). The most up to date versions are available at www.emc.medicines.org.uk
British National Formulary for Children – The most up to date version is available at www.bnfc.org Amended from COCH/CWP Shared Care Protocol Melatonin in children

## 11 Appendices

**A** Version Control Document
**B** Communication / Training plan
**C** Equality Impact and Assessment Tool

**APPENIDX A - Control Sheet**

This must be completed and form part of the document appendices each time the document is updated and approved.

| VERSION CONTROL SHEET | | | |
|---|---|---|---|
| **Date dd/mm/yy** | **Version** | **Author** | **Reason for changes** |
| 06/2015 | 1 | Divisional Pharmacist for Women & Children | New Shared Care Agreement |
| 12/2017 | 2 | Divisional Pharmacist for Women & Children | Renewal |
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**APPENDIX B - Training needs analysis**

| **Communication/Training Plan** (for all new / reviewed documents) | |
|---|---|
| **Goal/purpose of the communication/training plan** | To make all relevant staff aware of the shared care agreement |
| **Target groups for the communication/training plan** | Relevant MCHFT staff and GPs |
| **Target numbers** | 250 MCHFT staff |
| **Methodology – how will the communication or training be carried out?** | Through availability of shared care agreement on the Trusts intranet |
| **Communication/training delivery** | Trust Intranet |
| **Funding** | nil |
| **Measurement of success. Learning outcomes and/or objectives** | Shared care agreement in place |
| **Review effectiveness – learning outputs** | Review of shared care agreement |
| **Issue date of Document** | |
| **Start and completion date of communication/training plan** | |
| **Support from Learning & Development Services** | Nil |

For assistance in completing the Communication / Training Plan please contact the MCHT Learning and Development Services

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**APPENDIX C** - Form 1

## Equality Impact Screening Assessment

Please read the Guide to Equality Impact Assessment before completing this form. To be completed and form part of the policy or other document appendices when submitted to governance-policies@mcht.nhs.uk for consideration and approval or to be completed and form part of the appendices for proposals/business cases to amend, introduce or discontinue services.

**POLICY/DOCUMENT/SERVICE – shared care agreement – Low molecular weight heparin**

| | | Yes/ No | Justification and Data Sources |
|---|---|---|---|
| **A** | **Does the document, proposal or service affect one group less or more favourably than another on the basis of:** | | |
| 1 | Race, ethnic origins (including gypsies and travellers) or nationality | N | |
| 2 | Sex | N | |
| 3 | Transgender | N | |
| 4 | Pregnancy or maternity | N | |
| 5 | Marriage or civil partnership | N | |
| 6 | Sexual orientation including lesbian, gay and bisexual people | N | |
| 7 | Religion or belief | N | |
| 8 | Age | N | |
| 9 | Disability - learning disabilities, physical disability, sensory impairment and mental health problems | N | |
| 10 | Economic/social background | N | |
| **B** | **Human Rights – are there any issues which may affect human rights** | | |
| 1 | Right to Life | N | |
| 2 | Freedom from Degrading Treatment | N | |
| 3 | Right to Privacy or Family Life | N | |
| 4 | Other Human Rights (see guidance note) | N | |

**NOTES**

If you have identified a potential discriminatory impact of this document, proposal or service, please complete form 2 or 3 as appropriate.

**Date: 12/2017** **Name: Liz Hemingway**

**Signature: Liz Hemingway** **Job Title: Divisional Pharmacist for Women & Children**

**Date:** **Name:**

**Signature:** **Job Title:**

Mid Cheshire Hospitals NHS
NHS Foundation Trust

Form 2

## Equality Impact Assessment

Please read the Guide to Equality Impact Assessment before completing this form. To be completed when potential impact has been identified, but necessary steps to address that impact have been identified, agreed and included in the document or proposal. If you have identified a potential discriminatory impact of the document or proposal for which actions need to be identified or for which actions are complex in nature, please complete form 3 instead. To form part of the policy or other document appendices when submitted to governance-policies@mcht.nhs.uk for consideration and approval or to form part of the appendices for proposals/business cases to amend, introduce or discontinue services. **Any actions listed in this form should be highlighted in red, with timescales for action and lead responsibility noted.**

**POLICY/DOCUMENT/SERVICE……**

| | | Yes/ No | Justification & data sources. Include nature of impact for which action has been agreed and details of that action. Also record provisions already in place to mitigate impact. |
|---|---|---|---|
| **A** | **Does the document, proposal or service affect one group less or more favourably than another on the basis of:** | | |
| 1 | Race, ethnic origins (including gypsies and travellers) or nationality | | |
| 2 | Sex | | |
| 3 | Transgender | | |
| 4 | Pregnancy or maternity | | |
| 5 | Marriage or civil partnership | | |
| 6 | Sexual orientation including lesbian, gay and bisexual people | | |
| 7 | Religion or belief | | |
| 8 | Age | | |
| 9 | Disability - learning disabilities, physical disability, sensory impairment and mental health problems | | |
| 10 | Economic/social background | | |
| **B** | **Human Rights – are there any issues which may affect human rights** | | |
| 1 | Right to Life | | |
| 2 | Freedom from Degrading Treatment | | |
| 3 | Right to Privacy or Family Life | | |
| 4 | Other Human Rights (see guidance note) | | |

NOTES:

Date…….. Name……..

Signature…… Job Title..…… ……..

Date…….. Name……..

Signature…… Job Title..…….……..

Mid Cheshire Hospitals NHS
NHS Foundation Trust

Form 3

## Equality Impact Assessment

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**POLICY/DOCUMENT/SERVICE……**

**Section A**

| | | Yes/ No | Justification & data sources. Include nature of impact for which action has been agreed and details of that action. Also record provisions already in place to mitigate impact. |
|---|---|---|---|
| **A** | **Does the document, proposal or service affect one group less or more favourably than another on the basis of:** | | |
| 1 | Race, ethnic origins (including gypsies and travellers) or nationality | | |
| 2 | Sex | | |
| 3 | Transgender | | |
| 4 | Pregnancy or maternity | | |
| 5 | Marriage or civil partnership | | |
| 6 | Sexual orientation including lesbian, gay and bisexual people | | |
| 7 | Religion or belief | | |
| 8 | Age | | |
| 9 | Disability - learning disabilities, physical disability, sensory impairment and mental health problems | | |
| 10 | Economic/social background | | |
| **B** | **Human Rights – are there any issues which may affect human rights** | | |
| 1 | Right to Life | | |
| 2 | Freedom from Degrading Treatment | | |
| 3 | Right to Privacy or Family Life | | |
| 4 | Other Human Rights (see guidance note) | | |

NOTES

## Equality Impact Assessment

SECTION B

| | Issues for which action needs to be agreed. | Yes/ No | Justification and data sources. Include nature of impact for which action needs to be agreed. Then complete section C. |
|---|---|---|---|
| **A** | **Does the document, proposal or service affect one group less or more favourably than another on the basis of:** | | |
| 1 | Race, ethnic origins (including gypsies and travellers) or nationality | | |
| 2 | Sex | | |
| 3 | Transgender | | |
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| 9 | Disability - learning disabilities, physical disability, sensory impairment and mental health problems | | |
| 10 | Economic/social background | | |
| **B** | **Human Rights – are there any issues which may affect human rights** | | |
| 1 | Right to Life | | |
| 2 | Freedom from Degrading Treatment | | |
| 3 | Right to Privacy or Family Life | | |
| 4 | Other Human Rights (see guidance note) | | |

NOTES

SECTION C
Please expand tables below as necessary

| SECTION B NUMBER A1-10, B1-4 | NATURE OF IMPACT | EVIDENCE |
|---|---|---|
| | | |
| | | |
| | | |

| SECTION B NUMBER A1-10, B1-4 | STAKEHOLDER INVOLVEMENT | ACTION |
|---|---|---|
| | | |
| | | |
| | | |

| SECTION B NUMBER A1-10, B1-4 | COST | LEAD | TIMESCALE | RISK ASSESSMENT SCORE |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

Date…….. Name……..

Signature…… Job Title..……..

Date…….. Name……..

Signature…… Job Title..……..