HERPC
Hull & East Riding Prescribing Committee

Prescribing Framework for Melatonin in sleep disorders

Patient's Name:……..… NHS Number: ……

Patient's Address:……..……(Use addressograph sticker)

GP's Name:……..

Communication

We agree to treat this patient within this Prescribing Framework

Specialist Prescriber's Name…… Prof Reg. No. ……

Specialist Prescriber's Signature…… Date:…….

Where prescriber is not a consultant:

Consultant's Name: …… GMC No ……..

Consultant's Signature ……..... ……. Date:……

GP's Signature:…… Date:……..

GP's Name (if different from listed above)……..

The front page of this form should be completed by the specialist and the form sent to the patient's general practitioner.
The patient's GP should sign and **send back to specialist**, to confirm agreement to enter into shared care arrangement. If the General Practitioner is **unwilling** to accept prescribing responsibility for the above patient the specialist should be informed within two weeks of receipt of this framework and specialist's letter.

Full copy of framework can also be found at: http://www.hey.nhs.uk/amber.htm

1. Background

These guidelines aim to provide a framework for the prescribing of Melatonin by GPs and to set out the associated responsibilities of GPs and hospital specialists who enter into the shared care arrangements.

Melatonin is a pineal hormone which regulates circadian rhythms and influences sleep. Clinical experience and limited evidence suggests that it may be of value for treating sleep disorders associated with behavioural or neurological disorders. It is the preferred agent over benzodiazepines and antihistamines in this group of patients to aid sleep as there are fewer interactions and less "hangover effect". Contrary to other sedative therapies, there is no evidence of tolerance or addiction to melatonin.

This document should be read in conjunction with the guidance "Responsibility for prescribing between Primary & Secondary/Tertiary Care" https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf

2. Indication (all unlicensed)

Treatment of sleep disorders in patients with

- visual impairment
- cerebral palsy
- attention deficit hyperactivity disorder
- autism
- learning disability and epilepsy.
- Parkinson's disease with associated REM sleep disorder
- behavioural and psychological symptoms in dementia

3. Dose and formulation

Initially 2mg daily. Increased if necessary after 1-2 weeks to 4-6mg (In some cases the dose may be increased incrementally up to a maximum of 10mg).

Formulation

- Wherever possible the licensed form of modified release melatonin, melatonin m/r (Circadin®) should be used. It should be taken 1-2 hours before bedtime, and after food.
- Where patients cannot swallow tablets, the modified release tablets may be crushed and dispersed in water [unlicensed indication].They should be taken 30-60 mins before bedtime, and after food.
- Melatonin Oral Solution 5mg/5ml 200ml may be prescribed for patients requiring enteral administration and for children with autism, characterised by heightened sensory sensitivities (recommended preparation should be Alcohol Free [AF}, Sugar Free [SF], see Drug Tariff Part VIIIB for more information).
  It should be taken 30-60 minutes before bedtime, after food.

Formulation will be advised by the specialist.

Melatonin should be combined with strict environmental sleep structuring. Specific information will be provided to the GP on dose modifications required throughout treatment.

4. Duration of treatment

Specific advice will be provided to the GP on length of treatment required. If no benefit is seen after 2 to 4 weeks of a higher dose then melatonin should be stopped.

5. Contraindications and cautions

Contraindicated in hepatic impairment, endocrine disorders, pregnancy, breast-feeding;

Use with caution in patients with depression (see Section 6) and renal impairment – no information available.
While rarely an increase in seizure activity had been reported, its use is not contraindicated in children with epilepsy or other neurological disorders.

6. Adverse effects
General: Drowsiness, fatigue, headache, confusion, reduced body temperature, restlessness, pruritus and nausea.
Cardiovascular: Tachycardia has been reported rarely.
CNS: Increased dysphoria with major depression

7. Interactions
Levels of melatonin may be increased by fluvoxamine, 5-methoxyl-psoralen, cimetidine and quinolones. Carbamazepine and rifampicin may reduce the plasma concentration of melatonin Blood pressure control may be affected in patients maintained with nifedipine. Melatonin may also enhance the sedative properties of benzodiazepine and non-benzodiazepine hypnotics.
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Details of contraindications, cautions, drug interactions and adverse effects listed above are not exhaustive. For further information always check with BNF www.bnf.org.uk or SPC (www.medicines.org.uk).

8. Information to Patients or patient's carers
The specialist is responsible for ensuring that the patient or patient's carers are aware that melatonin is unlicensed (by indication and for oral solution/ immediate release capsules by preparation). Patients should be provided with a patient information leaflet

9. Responsibilities of Clinicians involved

Stage of Treatment	Hospital Specialist	General Practitioner
Initiation	-Select patients appropriate for treatment. -Inform patient that use/preparation is unlicensed -Initiate treatment and when on a stable dose ask the GP to prescribe	Accept shared care prescribing when patient on a stable dose.
Monitoring treatment	Inform GP of any relevant changes to monitoring requirement and dose adjustments	Monitor patient for adverse effects and Inform specialist where appropriate.

Contact information:

During office hours:
- Contact the relevant consultants secretary via the appropriate switchboard
- Paediatric Specialist Pharmacist (HRI): 01482 675558
- Neurology Specialist Pharmacist (HRI): 01482 674411
- Medicines Management Pharmacist Humber Teaching NHS Foundation Trust (01482 301724)

Out of Hours:
- HUTH - On call Registrar for Neurology or Paediatrics via HRI switchboard 01482 8754875
- HTFT- Victoria House and ask for on-call CAMHS consultant 01482 223191

APPROVAL PROCESS

Written by:	***Marie Miller, Interface Pharmacist***
Consultation process:	**Specialist Neurology and Paediatric teams, HUTH CAHMS team, HTFT**
Approved by:	**MMIG Sep 2014**
Ratified by:	***HERPC Updated April 2019***
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