NHS Cumbria Clinical Commissioning Group

North Cumbria University Hospitals NHS Trust

University Hospitals of Morecambe Bay NHS Foundation Trust

Cumbria Partnership NHS Foundation Trust

SHARED CARE GUIDELINE

Drug: MELATONIN (CIRCADIN®)

Contact Details	Patient ID Label
Name: _____	**Surname:** _____
Tel ☎: _____	**Forename/s:** _____
Location: _____	**NHS Number:** _____
Date: _____	**Date of Birth:** _____

Introduction

Indication: For use in children over 3 years of age with neuro-developmental disorders including ADHD, autism, visual impairment or neuropsychiatric or chronic sleep disorders or Chronic Fatigue Syndrome/ME where:

	Secondary care to sign below beside reason for request
Documented severe sleep disturbance (usually by sleep diary)	
Failure to respond to behavioural treatments, including sleep hygiene and sleep management	
or	
Urgent need due to severe sleep disturbance and awaiting behavioural treatment	

Also for use in adults with learning disabilities where melatonin was commenced during childhood or adolescence and trial discontinuation has caused behavioural problems.

Licensed: Circadin® tablets 2mg (licensed for adult use). Experience has shown these can be crushed although this would then be unlicensed use.

Unlicensed: Other formulations including melatonin liquid are not for shared care – these may only be prescribed by secondary care Consultant team in CAMHS/Paediatrics for children who cannot tolerate Circadin® but who show clear benefit of treatment, after approval from Children's service or CAMHS clinical director, copied to lead/chief pharmacist.

Background: Insomnia is a common problem in children with neuro-developmental disorders and visual impairment. These children often have disturbed sleep patterns, with delayed onset, fragmentation and frequent nocturnal awakening.

Hypnotics and sedatives are generally effective initially, but tolerance quickly develops.

Melatonin is a synthetic product, identical to a hormone produced in the pineal gland. It is involved in regulation of the body's circadian rhythm associated with the sleep-wake pattern.

Dose & Administration

Recommended starting dose: 2 to 3mg (3mg = one and a half tablets) given before desired sleep time. This dose may be increased if necessary after 1 to 2 weeks to 4 to 6mg. Maximum dose is 10mg. *If prescribing dose which requires half tablet, explain to parent that this is acceptable, although advice in manufacturer leaflet will be not to cut the tablets.*

Secondary Care Responsibilities	1. Assessing the suitability of patient for treatment. 2. Provide written information to child/parents/carers; Information on melatonin is included in cBNF or from the following website: http://www.medicinesforchildren.org.uk/download.php?id=85&type=leaflet 3. Initiation and supply of medicine until dose has been stabilised for one month. 4. Advise parent/carer that if a child was unable to take a tablet formulation then the parent would be advised to crush the Circadin® tablet and suspend in liquid, in this way it could be mixed with food, for example, yoghurt. 5. Assess and monitor patients' response to treatment every 6 months (may be telephone or face-to-face). At review encourage parent/carer to give short break from the melatonin both to see if it is still needed and because there is some evidence that the effect of the melatonin is rejuvenated after a short break. 6. Discuss shared care with patient/parent/carer. 7. Liaise with GP to agree to transfer of prescribing. 8. Report any suspected adverse reactions to the MHRA. 9. Assess the ongoing need for treatment and to advise discontinuation when necessary. 10. Prescribe melatonin liquid if needed, for swallowing difficulties, or for administration in some types of feeding tube, after approval from Children's service/CAMHS clinical director, copied to lead/chief pharmacist. 11. Re-assess need for treatment prior to transition to adult services at 18 years.
Primary Care Responsibilities	1. To continue prescribing once the patients' dose has been stabilised. 2. Liaise with Consultant team in CAMHS/Paediatrics regarding any complications of treatment. 3. Report any suspected adverse reactions to the MHRA.
Monitoring Required in Primary Care	Effectiveness and tolerability.
Adverse Effects	Usually well tolerated. Abdominal pain, constipation, dry mouth, weight gain, drowsiness, dizziness, migraine, asthenia, sleep disorders, restlessness, nervousness, irritability and sweating. *Rarely*: flatulence, halitosis, hypersalivation, vomiting, hypertriglyceridaemia, aggression, agitation, fatigue, leucopenia, thrombocytopenia, muscle cramp and skin reactions.
Cautions	Patients with rare hereditary problems of galactose intolerance, the LAPP lactase deficiency or glucose-galactose malabsorption should not take Circadin®.
Drug Interactions	No known interactions.
Contra-indications	No known contra-indications other than hypersensitivity to the product.
This guidance does not replace the SPC's, which should be read in conjunction with this guidance.	