

Drug	<p>Melatonin First line (licensed product): Melatonin MR 2mg tablets (Circadin®) Circadin® can be crushed if unable to swallow tablets, swallowing difficulties or immediate-release action is required (off-label). Second line only if crushing tablets inappropriate: Melatonin 5mg/5ml alcohol free oral solution (200ml) (unlicensed product)</p>
Speciality	Children & occasional use in Adults
Indication	<p>Melatonin is used “off-label” for chronic sleep disturbance resulting in severe stress for the patient and/or family, in children, young people and adults with the following conditions:</p> <ul style="list-style-type: none"> • Neurological or behavioural disorders including: <ul style="list-style-type: none"> ○ Attention Deficit Hyperactivity Disorder ○ Autistic Spectrum Disorders ○ Emotional dysregulation ○ Chronic sleep-onset insomnia • Neurodevelopment disabilities (e.g. delayed brain maturation, sensory dysfunction - especially visual, and dysfunction of sleep centres) • Chronic fatigue syndrome / myalgic encephalomyelitis with associated sleep difficulties (as recommended in NICE clinical guideline 53). <p>It is also used in “off label” in Parkinson’s patients where a trial of clonazepam has failed and also REM behavioural disorders, if recommended by a sleep neurologist.</p> <p>Circadin is not approved on the formulary or included as part of this shared care guideline for its licensed indication as monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over.</p>
Overview	<p>Before starting treatment, traditional non pharmacological methods must have been tried and failed. The aim is to establish healthy sleep habits with the lowest effective dose of melatonin.</p>
Specialist’s Responsibilities	<p>Initial investigations: Assess suitability of patient for treatment. Discuss benefits and side effects of treatment with the patient / parent / carer to include the unlicensed nature of melatonin.</p> <p>Initial regimen: An initial dose of 2 mg (given 30-60 minutes before bedtime). In the absence of improvement after 2 weeks, dose may be increased by 2mg increments up to a maximum dose of 10mg. Most patients respond at doses of 6mg or less. If no response after 2 weeks at maximum dose – stop treatment If response achieved, continue for at least 6 months, then attempt withdrawal over a period of 3-4 weeks, with observation of changes in sleep pattern. If long-term treatment necessary, review every 6 months to assess continuing benefit.</p> <p>Clinical monitoring: Specialist review to ensure continuing benefit and observation of growth parameters & pubertal development.</p> <p>Frequency: Every 6 months to 12 months.</p> <p>Safety monitoring: Monitoring for response and adverse drug reactions (ADRs) during the initiation period. Evaluating ADRs raised by the GP and evaluating any concerns arising from physical checks and reviews undertaken by GP.</p> <p>Prescribing duration: At least six months of an improved sleep pattern should elapse before withdrawal takes place. Advise GP when a trial withdrawal of melatonin should be</p>

	<p>undertaken. For some children however withdrawal is not successful and treatment may be necessary long term.</p> <p>Prescribing arrangements: Titrate the dose of melatonin to a satisfactory effect over a minimum of 8 weeks before transferring to the GP. Write to GP to share the patient's care only when a stable dose has been achieved and proven benefit has been established.</p> <p>Documentation:</p> <ul style="list-style-type: none"> • Obtaining agreement of GP to participate in shared-care arrangement for melatonin therapy (by sending a copy of this document). • Prompt communication with the GP regarding the patient's progress, any reassessment and changes in treatment. Provide additional information and advice to the GP on actions he/she may need to take e.g. on dosage adjustment, other changes in therapy and management of adverse effects, as required. 				
<p>GP's Responsibilities</p>	<p>Maintenance prescription: Prescribe melatonin in accordance with the specialist's recommendations. Usual maintenance between 2-6mg (max. 10mg).</p> <p>Clinical monitoring: To report to and seek advice from the specialist on any aspect of patient care which is of concern to the GP and may affect treatment.</p> <p>Safety monitoring: Height & Weight (children).</p> <p>Frequency: Annual.</p> <p>Duration of treatment: Stop or adjust treatment on advice of, or in consultation with, a specialist.</p> <p>Re-referral criteria:</p> <ul style="list-style-type: none"> • Failure to attend for review • Intolerance of drugs • Communications failure <p>Documentation: Reply to request for shared-care as soon as practical (within 28 days).</p>				
<p>Adverse Events</p>	<table border="1" data-bbox="370 1089 1458 1155"> <thead> <tr> <th data-bbox="370 1089 914 1121">Adverse events</th> <th data-bbox="914 1089 1458 1121">Action</th> </tr> </thead> <tbody> <tr> <td data-bbox="370 1121 914 1155">See below</td> <td data-bbox="914 1121 1458 1155">Report / discuss with specialist.</td> </tr> </tbody> </table> <p>Melatonin is generally well tolerated. Common side effects include headaches, abnormal dreams, nausea and dizziness.</p> <p>All suspected reactions (including those considered not to be serious and even where the causal link is uncertain) should be reported to the specialist and the MHRA.</p>	Adverse events	Action	See below	Report / discuss with specialist.
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<p>Contra- indications Cautions Drug Interactions</p>	<p>Please refer to the BNF and/or SPC for full information. http://www.medicines.org.uk/emc/medicine/25643</p> <p>Contra-indications: hypersensitivity to the active substance or to any of the excipients Cautions: autoimmune disease Clinically relevant drug interactions: Fluvoxamine may increase melatonin exposure</p>				
<p>Other Information</p>	<ul style="list-style-type: none"> • Circadin® can be crushed if unable to swallow tablets, swallowing difficulties or immediate-release action is required (off-label). • For patients with swallowing difficulties, crush tablets and dispersed in water, milk or orange juice immediately prior to administration. • Melatonin 5mg/5ml alcohol free oral solution (200ml) (unlicensed) is the most cost effective oral liquid preparation, but is significantly higher cost than Circadin® tablets. The liquid can be administered via PEG or gastrostomy tube. • Kidnaps® oral solution should not be prescribed as this contains alcohol. 				
<p>Contact Details</p>	<p>Name: _____ GMC No: _____</p> <p>Address: _____</p> <p>Telephone: _____</p>				