Shared Care Guideline:
Melatonin

NHS
County Durham and Darlington Area Prescribing Committee

Drug	**Melatonin** **First choice (licensed product):** Melatonin MR 2mg tablets (Circadin) It is recognised, however, that there may be individual patients where the licensed product is not suitable. The following UK manufactured, unlicensed products can also be considered (manufacturers / brands should be stated): **Alternatives:** Melatonin (immediate release) 2mg & 3mg tablets / capsules Liquid: Melatonin 1mg/ml solution (Kidnaps)
Speciality	Children & occasional use in Adults
Indication	Chronic sleep disorders in children & young people with neurodevelopmental disorders. Adults: To improve subjective quality of sleep & daytime function in insomniacs over 55yrs old. (alternative drugs are gabapentin and pregabalin). It is also used in Parkinson's patients where a trial of clonazepam has failed and also REM behavioural disorders. If recommended by a sleep neurologist.
Overview	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**.
Specialist's Responsibilities	**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 **Initial regimen:** An initial dose of 2-3mg (given 30-60 minutes before bedtime). In the absence of improvement after 1 week, dose may be increased to 4-6mg at night. **Clinical monitoring:** Specialist review to ensure continuing benefit and observation of growth parameters & pubertal development **Frequency:** Every 6 months **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 **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 undertaken. For some children however withdrawal is not successful and treatment may be necessary long term. **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 **Documentation:** • 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.

GP's Responsibilities	**Maintenance prescription:** Prescribe melatonin in accordance with the specialist's recommendations. Usual maintenance between 2-6mg (max. 10mg) **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 **Safety monitoring:** Height & Weight **Frequency:** Annual **Duration of treatment:** Stop or adjust treatment on advice of, or in consultation with, a specialist. **Re-referral criteria:** • Failure to attend for review • Intolerance of drugs • Communications failure **Documentation:** Reply to request for shared-care as soon as practical (within 28 days)
Adverse Events	<table><tr><th>Adverse events</th><th>Action</th></tr><tr><td>See below</td><td>Report / discuss with specialist.</td></tr></table>Melatonin is generally well tolerated and no significant adverse effects have been reported with pharmacologically regulated melatonin. Both increased and reduced seizure frequency has been reported in children with epilepsy. Tachycardia, confusion, dysphoria, increased seizure activity, psychosis, gynaecomastia, decreased luteinizing hormone levels, decreased temperature autoimmune hepatitis, elevated liver enzymes, flushing, rashes and withdrawal effects have been reported rarely. 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.
Contra-indications Cautions Drug Interactions	Please refer to the BNF and/or SPC for information. http://www.medicines.org.uk/emc/medicine/25643 Additional contra-indication : sleep disturbance in obstructive sleep apnoea Clinically relevant drug interactions: • Fluvoxamine, caffeine & artemisinin – may increase levels • B-blockers, corticosteroids, NASAID's, cannabiboids, & benzodiazepines – may decrease levels • Antihypertensives - may affect blood pressure control • Warfarin – may increase INR
Other Information	
Contact Details	**Name:** **GMC No:** **Address:** **Telephone:**