Cornwall Partnership
NHS Foundation Trust

Autism Spectrum Disorder Assessment Team (ASDAT)

Cornwall Foundation Trust Information Leaflet

Prescriber Information

Information from CFT prescribers for initiating Melatonin for children with sleep disturbances

Background

There is currently no commissioned specialist sleep service in Cornwall, meaning that a diagnosis of sleep disorder alone does not warrant a referral to specialist services (CAMHs or Community Paediatrics). However there are children with sleep disturbances that may benefit from a trial of melatonin. This guidance explains how treatment is best initiated, monitored and discontinued in primary care.

Overview

Melatonin is a pineal hormone which is used in the management of sleep disturbances. It has both chronobiotic and at higher doses hypnotic properties. Although chronobiotic effects are experienced by all, not all individuals will experience hypnotic effects, meaning that not all children with sleep disturbance will respond to the hypnotic effects of melatonin even at increased doses.

Melatonin is only indicated where non-pharmacological strategies have been tried (i.e. sleep hygiene), but sleep latency remains a significant problem. It is strongly recommended that the parent/carer completes a 24-hour sleep pattern record covering a minimum of 7-10 days prior to commencing treatment.

Melatonin MR tablets 2mg (Circadin®) has always been the first-line melatonin product as it has a UK product license (note its use in children is off-label). An alternative tablet preparation Bio melatonin 3mg (immediate release) has an EU product license may also be prescribed. Melatonin liquid is very expensive and as it is unlicensed there is potential for variation in quality and efficacy so is not recommended. However there is a now a licensed alternative melatonin product launched in 2019 called Slenyto® (melatonin MR tablets 1mg & 5mg) It is licensed for the treatment of insomnia in children and adolescents aged 2-18 with Autism Spectrum Disorder (ASD) and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient. See link to SmPC: https://www.medicines.org.uk/emc/product/10023/smpc

Dosing and Response of Slenyto®

For use in children of 2 years of age with neurodevelopment disability, autism, visual impairment and chronic sleep disturbance, including chronic fatigue syndrome; who have no other reason other than sleep disorder that would require the individual to access CAMHs or Community Paediatric services. Use in children under 2 years would be outside of the product license.

The recommended starting dose is 2mg of Slenyto® (melatonin MR). If an inadequate response has been observed (usually after 1-2 weeks), the dose should be increased to 5mg, with a maximum dose of 10mg.

Slenyto® should be taken once daily, 30 – 60 mins before bedtime and with or after food. Tablets can be put into food or drink such as yoghurt, orange juice or ice-cream to facilitate swallowing and improve compliance. If the tablets are mixed with food or drink, they should be taken immediately and the mixture not stored. If the tablet is broken, crushed or chewed it will lose the prolonged release properties but this is likely to have little significance clinically.

Data are available for up to 2 years' treatment. The patient should be monitored at regular intervals (at least every 6 months) to check that Slenyto® is still the most appropriate treatment. After at least 3 months of treatment, the physician should evaluate the treatment effect and consider stopping treatment if no clinically relevant treatment effect is seen. If a lower treatment effect is seen after titration to a higher dose, the prescriber should first consider a down-titration to a lower dose before deciding on a complete discontinuation of treatment. It is recommended that a drug holiday should be introduced every 6 months to assess the continued need for treatment.

There is evidence that there is little additional benefit at doses over 6mg (MENDS RCT).For children waking during the night, the same dose or a smaller dose can be repeated during the night.

Contra-Indications

- Pregnancy and breastfeeding
- Known hypersensitivity to melatonin or to any of its excipients

Cautions

Melatonin should be used with caution in patients with a history of epilepsy, asthma, autoimmune, renal or hepatic disorders. Slenyto® contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Common adverse effects

The most frequently reported adverse reactions with Slenyto® in clinical studies were somnolence, fatigue, mood swings, headache, irritability, aggression and hangover occurring in 1:100-1:10 children.

Drug Interactions

It is advisable not to prescribe melatonin if the patient is receiving antipsychotics or antidepressants.
Concomitant prescribing of melatonin and oral anticoagulants should be avoided. Combination with benzodiazepines and non-benzodiazepine hypnotics should be avoided.

Monitoring

Baseline Data and Routine Monitoring-monitoring of height and weight is recommended
Monitoring for a delay in puberty is also recommended.

Contact Information

Autistic Spectrum Disorder Assessment Team
Care Management Centre
Children's Care Management Centre
Truro Health Park
Infirmary Hill
Truro
TR1 2JA
01872 221400
Email: cpn-tr.ASDTEAM@nhs.net

Comments and Concerns

We welcome your views, feedback and suggestions and how we can improve the service. Please contact the Patient Advice and Liaison Service (PALS) 01208 834620 or by
Email: cpn-tr.Palscft@nhs.net

To get this information in another format please email: cpn-tr.communications@nhs.net