Prescribing Melatonin for Children and Young People under 18 years
Guidance for Primary Care

Introduction

Melatonin is a hormone produced by the pineal gland in the brain, rising at night and falling during the day, helping to regulate the body's circadian rhythm.

Clinical experience suggests that it may be of value for treating sleep onset insomnia and delayed sleep phase syndrome in children with conditions such as visual impairment, cerebral palsy, attention deficit hyperactivity disorder (ADHD), autism spectrum disorder (ASD), and learning difficulties.

Sleep disorders in children with neurodevelopmental difficulties such as ASD and ADHD are more common than the typically developed population. In ASD, insomnia can occur in 40-80% of children and adolescents (Cortesi et al, 2010). In individuals diagnosed with ADHD, 25-50% are reported to have sleep problems (Corkum et al, 1998; Gau et al 2007; Fisher et al, 2014).

Systematic reviews and randomised controlled trials in children with neurodevelopmental disorders, have demonstrated that where sleep hygiene methods have been ineffective, melatonin significantly improves sleep onset latency and sleep duration compared to controls (Gringras et al., 2012), although response to melatonin can be variable.

Purpose

The purpose of these guidelines is to provide primary care clinicians with:

- Guidance on prescribing melatonin for sleep disorders for children and young people aged 2-18 years old with within Frimley ICB.
  - **Melatonin Frimley ICB formulary status amber** - restricted to initiation or recommendation by paediatrics, CAMHS, ADHD services for children and young people under 18 years and for young people prescribed and benefiting from melatonin, transitioning into adult services, where sleep hygiene measures have proved insufficient.
  - **Melatonin Frimley ICB formulary status green** – primary care initiation permitted but restricted to children and young people with an **NHS clinical diagnosis of autism**. (NHS is defined as a provider with an NHS contract).
- Recommendations on cost-effective, evidence-based prescribing of melatonin by considering product formulation and brand, as detailed on the Frimley ICB formulary - Frimley ICS Melatonin Formulary Choices

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Management of poor sleep in children

These guidelines are intended to apply only to children and young people:

- Over 2 years and under 18 years old, with a GP in Frimley ICB.
- With visual impairment, cerebral palsy, attention deficit hyperactivity disorder (ADHD), autism spectrum disorder (ASD), or learning difficulties.
- A suitable trial of non-pharmacological methods has proven ineffective.
- Other potential medical causes for sleep issues, such as sleep apnoea, have been eliminated.

Sleep hygiene measures for children and young people can be found here: Advice for parents / carers on healthy sleep for children (newborn - teenage)

The aim of treatment is to establish a regular nocturnal sleep pattern. The family or carer should be offered a sleep diary which can indicate patterns of sleep difficulty and used as a measure of treatment outcome.

Pharmacological treatment

A sustained release formulation of melatonin (Circadin® MR 2mg tablets) has been available since June 2008, licensed for the treatment of primary insomnia in adults aged 55 years and over, and is now available generically. It wasn't until 2019 that a licensed formulation was available for children with ADHD.

Choice of melatonin

Generic melatonin MR 2mg tablets –generic melatonin MR 2mg tablets - Frimley ICB's first line treatment for children and young people.

This formulation has been prescribed off label to children extensively and safely on the recommendation of a specialist for over 15 years and remains the most cost effective option. When divided into halves, most of the prolonged-release characteristic has shown to be preserved, Dissolution of Intact, Divided and Crushed Circadin Tablets: Prolonged vs. Immediate Release of Melatonin - PMC whereas a quarter-cut or crushed tablet had a more immediate melatonin release profile.

Tablets 1mg, 2mg, 3mg, 4mg, 5mg (Adaflex®), licensed for insomnia in children aged 6-17 years with ADHD, where sleep hygiene measures have been insufficient, (and where generic melatonin M/R 2mg tablets are not suitable). Adaflex tablets can be crushed and mixed with water directly before the administration. Due to a flat pricing structure (same price for every strength) prescribe dose required without adding different strengths together or doubling up.

Tablets M/R 1mg; 5mg (Slenyto®) - Restricted to licensed indications (2-18 years with ASD, and / or neurogenetic disorders with aberrant diurnal melatonin secretion and /or nocturnal awakenings and for children 6-17 years with ADHD, where sleep hygiene measures have been insufficient) and where generic melatonin M/R 2mg or

standard release tablets are not suitable. A Guide for Parents and Caregivers of Children Prescribed Slenyto®

All other capsules / tablets are **non formulary. Liquids are** as per formulary and not initiated in primary care.

Initiation and dosing of melatonin

It is recommended that behavioural sleep therapies are continued alongside medication for at least four weeks, but preferably ongoing, as the combination has been found to be more effective than medication alone. The aim is to establish healthy sleep patterns with the lowest effective dose.

Melatonin for sleep disorders – Medicines For Children, - this leaflet is for parents and carers and describes how to use melatonin in children.

Melatonin MR 2mg tablets dose: Child up to 18 years: Initially 2mg daily for 2 weeks, increased by 2mg every 1-2 weeks up to 4-6 mg for effect. (Note: 10mg is the maximum recommended dose, but if a dose of 6 mg is not effective, higher doses are unlikely to be effective). This should be administered with or after food.

Adaflex® dose: Recommended starting dose 1-2 mg 30-60 minutes before bedtime. The dose of melatonin can be increased by 1 mg every week until effect up to a maximum 5 mg per day, independent of age. It is recommended that food is not consumed 2 h before and 2 h after intake of Adaflex tablets.

Slenyto® dose: Recommended starting dose is 2 mg. If an inadequate response has been observed, increase to 5 mg, with a maximal dose of 10 mg. Take 0.5-1 hour before bedtime, with or after food. Tablets can be put into food such as yoghurt, orange juice or ice-cream to facilitate swallowing and improve compliance but should be taken immediately and the mixture not stored.

Additional information

- Melatonin takes around 1 to 2 hours to work.
- Some people taking melatonin may get a headache, or feel tired, sick or irritable the following day.
- Drinking alcohol or smoking while taking melatonin can reduce its effectiveness.
- Melatonin may enhance the sedative properties of benzodiazepines, hypnotics and some herbal remedies, therefore co-administration should be avoided.

Assessing response to treatment

Significant improvement should be considered based on the following criteria:

- When melatonin results in young person having a reduction in sleep latency of at least 40 minutes and /or
- Increase in total sleep duration of at least 40 minutes or more and/or

- Qualitative improvement in sleep quality where young person wakes up feeling rested and refreshed and/or
- Qualitative positive impact on the quality of life of the young person and positive impact on family life as described by carers.

Monitoring

After four weeks, review to ensure continued treatment with melatonin is appropriate and effective, and at medication review (every 6-12m) thereafter. As children may outgrow sleep onset latency as they get older, a 'treatment holiday' may be considered for all suitable patients in conjunction with the patient or carer to assess the need for ongoing treatment.

If after months or years, melatonin seems no longer effective, a period of 5-7 days off treatment followed by re-starting at the lowest dose again may be tried. If this has not been effective, then consider complete discontinuation of treatment.

Melatonin can be stopped abruptly, even at higher doses. No discontinuation effects are documented. Melatonin is not linked to tolerance, rebound insomnia or dependence.

Contra-indications

Hypersensitivity to the active substance or excipients in each preparation

Cautions

There is no convincing evidence that melatonin adversely affects seizure control, however when used in patients with epilepsy, it is important to monitor seizure frequency. Note - primary care would only initiate melatonin for patients diagnosed with epilepsy on the advice of a specialist.

There is limited information available in prescribing with pre-existing autoimmune conditions; exacerbations have been reported occasionally.

Caution is advised in patients with renal disorders and avoid use in patients with liver disorders and in some rare hereditary glucose tolerance disorders (due to lactose).

Side effects and interactions

Melatonin is generally well-tolerated. Sedation and fatigue, headaches, skin disorders, restlessness, increased pulse, itching and nausea have all been reported as side effects associated with melatonin use. For a complete list of side effects and interactions refer to current BNFc or SPC for each product.

Summary

Note: Non - pharmacological measures are first choice for sleep disorders in adults and children and young people.

Indication	Medication	Licensed for <18 years	Formulary traffic light status
Longer-term sleep problems in children and teenagers under 18 years, where sleep hygiene measures have been insufficient.	Melatonin 2 mg modified-release tablets (generic only)	Off label use	**Amber -** restricted to initiation or recommendation by paediatrics, CAMHS, ADHD services for children and young people under 18 years and for young people prescribed and benefiting from melatonin, transitioning into adult services, where sleep hygiene measures have proved insufficient. **Green** – restricted to initiation in primary care only for children and young people with an NHS clinical diagnosis of autism, where sleep hygiene measures have proved insufficient. Treatment may be initiated after reference to the Frimley ICB Prescribing Melatonin for Children and Young People under 18 years - Guidance for Primary care.
	Tablets 1mg, 2mg, 3mg, 4mg, 5mg (Adaflex®)	6-17 years with ADHD	
	Tablets M/R 1mg; 5mg (Slenyto®)	2-18 years with ASD, and / or neurogenetic disorders with aberrant diurnal melatonin secretion and /or nocturnal awakenings. 6-17 years with ADHD	

This information has been formulated with input from the following people and has been approved by the Frimley Medicines Optimisation Group and ratified by the Frimley ICB Medicines Board (October 2025).

Dawn Best Senior Medicines Optimisation Lead Pharmacist Frimley ICB	Dr Louise Watson Consultant Community Paediatrician - Berkshire Healthcare Designated Dr for Children's Safeguarding Berks East
Dr Alexandra Streeter de Diego GP Partner Farnham Dene Medical Practice Paediatric Clinical Fellow Frimley Park Hospital GP Clinical Lead Frimley ICB Transformation in CYP	Dr Louise Wright Consultant Paediatrician with Interest in Epilepsy and FHFT CYP Mental Health Champion Frimley Health NHS Foundation Trust
Dr Laura Ingenhaag GP Clinical Lead for Mental Health and Neurodiversity for Children and Young People GP Clinical Lead for CYP Gender Identity and Perinatal Mental Health. Frimley Integrated Care Board	

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