

**DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE  
(JAPC)**

**Melatonin information sheet – for the treatment of sleep disorders in  
children with neurodevelopment disorders**

**Taking personalised approaches is a key approach to provide best care.**

- Enabling choice, ensures that patients are aware of their options.
- Shared decision making helps patients to make decisions that are right for them.
- Supporting self-management increases people's knowledge, skills and confidence to manage their own health and care.
- Giving information in a health literate way means that people will understand how to manage their health.

Further information about offering choice, shared decision making and supporting self-care can be found [here](#).

**Melatonin - GREY** after consultant/specialist initiation:

For use in children with neurodevelopment disorders and CAMHs patients  
(including off-label use)

Melatonin is effective in the treatment of sleep disorders in children with neurodevelopment disorders<sup>1</sup>. It is also occasionally used in children, particularly adolescents, who have a reverse sleep pattern in order to re-establish a normal one.

Melatonin should be used in conjunction with sleep hygiene measures, and only when these alone have proved insufficient.

The MHRA has stipulated that a licensed product should be used wherever possible, even if it means using a product off-label and outside its licensed indications<sup>2</sup>. In Derbyshire, **Adaflex** tablets (licensed in children and adolescents aged 6 -17 years, available in 1mg, 2mg, 3mg, 4mg & 5mg strength) and **generic melatonin 2mg MR** tablets are the 1<sup>st</sup> line choice of melatonin for new patients for the treatment of sleep disorders initiated by a specialist in children with neurodevelopment disorders. GPs may be asked to continue to prescriptions and monitoring when the patient is stable.

**Assess response to treatment every 6 months** which should include:

- Ensure patients are complying with their medication
- Enquiring about side effects that may warrant stopping the medication
- Stopping the medication if proving ineffective which may involve liaison with the specialist
- Discuss reduction in dose or stopping if sleeping pattern is re-established
- Monitoring parameters should be agreed with primary care at the point of handover  
Prescriptions for melatonin should be discontinued when patients turn 18 – use in adults under 55 years is unlicensed and rationale to continue in 18 years and over should be made by the current prescriber.
- There is no official guidance around stopping melatonin and it can be abruptly stopped as it is not associated with dependency or withdrawal symptoms. The prescriber may decide to down titrate due to individual patient factors and using professional judgement.

## Dosage

- The usual maximum cumulative (IR and MR) daily dose is 10mg<sup>3</sup>
- For children waking during the night, the same dose or a smaller dose can be repeated during the night. The cumulative dose should not exceed 10mg. An immediate release preparation is preferable in this instance.
- There is little reported benefit of doses in excess of 6mg for both immediate release and modified release preparations. Doses above 6mg can be considered only in certain circumstances and under specialist review
- Doses above 5mg of Adaflex are off license<sup>4</sup>

## Formulation

- Adaflex tablets are used when an immediate release preparation is preferred
  - in children where initiation of sleep is the main difficulty or
  - those with swallowing difficulty (see below) or
  - when melatonin 2mg MR tablets not tolerated/effective.
- Adaflex tablets are lactose free - consider this if lactose free preparation is required.
- If modified release preparation is required, prescribe 2mg MR generically.
- The 2mg MR Circadin® tablet can be halved using a tablet cutter and it will retain its slow release characteristics. Please note crushing the tablet will render it immediate release<sup>5</sup>.
- Generic preparations must be swallowed whole to maintain the slow release characteristics
- **For children with difficulties swallowing-** Adaflex tablets can be crushed and mixed with water directly before the administration<sup>4</sup>. Rinse the glass with water and administer the rinsings as well to ensure the full dose is taken. The prescription should state that the medication is to be crushed prior to administration.
- **For administration via an enteral feeding tube** (local advice as per DHCFT)– crush Adaflex tablets to a fine powder and added to 15 - 30ml of water and mixed well. This should be drawn into a 50ml oral syringe and administered taking care to rinse the mortar/tablet crusher with water and administering the rinsing's also. The feeding tube should be flushed with 30ml water prior to and post drug administration.
- Melatonin 2mg MR tablets are less suitable for use via enteral feeding tube due to the less soluble nature of the tablet coating.
- Melatonin 1mg/ml (Colonis) oral SF solution is classified by JAPC as **Do Not Prescribe (DNP)**
  - Colonis is licensed for sleep onset insomnia in children and adolescents aged 6-17 with ADHD but is not recommended due to cost implications<sup>6</sup>
  - Not suitable for off-label use in children 6 years and under, due to safety concerns regarding propylene glycol content.
  - Adaflex can be crushed and mixed with water prior to administration. This is recommended if a liquid preparation is required. Please seek specialist advice if an alternative liquid preparation is required

### Key Contacts

**Specialist (CAMHS):**

Dr Daniela Tomus – Consultant Psychiatrist/CAMHS clinical director. [Daniela.Tomus3@nhs.net](mailto:Daniela.Tomus3@nhs.net)  
PA's phone number Tel: 0300 7900 264 Ext: 31381

**Consultant Community Paediatrician** – Jehan Labatia, Lead for Neurodevelopment, St Pauls House, DE21 4BB. Secretary- Jane Murphy 03001234586

**Ronnie McKeith Centre** – 01332 785609

**Pharmacist (RDH):** Pharmacist for Women & Children's Services – 01332 785365, bleep 2318

**Pharmacy (Kingsway)** Kate Gupta, Pharmacist for Children's Services, [kate.gupta@nhs.net](mailto:kate.gupta@nhs.net)  
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**Pharmacy (CRH):** 01246 513153

Sleep hygiene resources accessible at:

- <https://www.sleepfoundation.org/sleep-hygiene>
- <https://thesleepcharity.org.uk/>
- National Sleep Helpline: 03303 530 541

Additional resources:

- <https://www.medicinesforchildren.org.uk/wp-content/uploads/sites/8/2021/06/Melatonin-for-sleep-disorders.pdf>

### References

1. Melatonin for the management of sleep problems in children with neurodevelopmental disorders: a systematic review and meta-analysis May 2018
2. MHRA. Off-label or unlicensed use of medicines: prescribers' responsibilities <https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities> [last accessed 11/01/2022]
3. BNF for children accessed online [4/2/2022].
4. SPC Adaflex 3mg tablets. <https://www.medicines.org.uk/emc/product/13630/smpc#gref> [accessed 25/04/2025]
5. Flynn Pharma Kaleigh Marsden Medicines Information [21/8/2012; 21/4/2022] personal communication
6. SPC Colonis 1mg/1mL liquid. [Melatonin 1mg/ml oral solution - Summary of Product Characteristics \(SmPC\) - \(emc\)](#) [accessed 12/02/2025]

Document update	Date
Remove recommendation to mix crushed 3mg tabs with soft food; Cost effective to prescribe melatonin 2mg MR tablets in place of Circadin brand.	April 2022
Circadin brand price change; brand inserted back in	July 2022
Adaflex recommended as preferred brand	Sept 2022
RED classification removed for other licensed/unlicensed preparations. 6yrs and under added to the oral SF solution	Oct 2022
Remove Circadin brand and replace with generic melatonin 2mg MR tablets	June 2023
Consultant contact details updated	June 2024