

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

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

Melatonin is effective in the treatment of sleep disorders in children with neurodevelopment disorders¹. It is also occasionally used in children, particularly adolescents, who have a reverse sleep pattern in order to re-establish a normal one.

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 indications². Hence, locally melatonin 2mg MR tablets (**Circadin**, off-label use) and **Adaflex** tablets (licensed in children and adolescents aged 6-17 years) are recommended for the treatment of sleep disorder in children with neurodevelopment disorders. Other licensed preparations (e.g. 3mg capsules) and unlicensed melatonin preparations are classified **RED**.

In Derbyshire, **Adaflex tablets** (available in 1mg, 2mg, 3mg, 4mg & 5mg strength) and **melatonin 2mg MR tablets** (Circadin) are the 1st line choice of melatonin for new patients for the treatment of sleep disorders initiated by a specialist in children with neurodevelopment disorders.

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

Dosage

- The usual maximum daily dose is 10mg³
- For children waking during the night, the same dose or a smaller dose can be repeated during the night. An immediate release preparation is preferable in this instance.

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.
- 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 release⁴.
- **For children with difficulties swallowing-** Adaflex tablets can be crushed and mixed with water directly before the administration⁵. 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. (Off-label use - to do so is at the discretion of the prescriber)
- **For administration via an enteral feeding tube** - 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)** - not recommended for short-term treatment of jet-lag disorder in adults. Not suitable for off-label use in children due to safety concerns regarding propylene glycol content.

Key Contacts

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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. Flynn Pharma Kaleigh Marsden Medicines Information [21/8/2012; 21/4/2022] personal communication
5. SPC Adaflex 3mg tablets. <https://www.medicines.org.uk/emc/product/13630/smpc#gref> [accessed 14/9/2022]

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