

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

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

Melatonin is effective in the treatment of sleep disorders in children with neurodevelopment disorders⁵. 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 licensed products should be used wherever possible, even if it means using a product off-label and outside its licensed indications. Hence, Circadin[®] MR (off-label) is the 1st line choice for new patients for the treatment of sleep disorder in children with neurodevelopment disorders. Unlicensed generics of melatonin have been re-classified to **RED**.

- In Derbyshire, **Circadin[®] 2mg MR tablets (off-label)** is the 1st line choice of melatonin for new patients for the treatment of sleep disorders initiated by a specialist in children with neurodevelopment disorders.
- Traditionally, melatonin prescriptions were made up using “special medicines” or imported products. In 2008, the MHRA tightened up the rules surrounding the importing of melatonin products and the use of unlicensed products. This means only certain products can be used for melatonin prescriptions^{1,2}.
- Off label use of Circadin (licensed for patients over 55yrs) is the preferred treatment option for use in children with neurodevelopment disorders.
- As it is a licensed product it is available from normal wholesalers which should help to maintain supplies even in the community.
- Doses should normally be prescribed in **multiples of 2mg**.
- Max daily dose is 10mg⁴
- For children waking during the night, the same dose or a smaller dose can be repeated during the night. The 2mg SR Circadin[®] tablet can be halved using a tablet cutter and it will retain its slow release characteristics³.
- **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
- **For children with difficulties swallowing**, the tablet can be **crushed** to a fine powder and **mixed with water or given with cold soft food such as a teaspoon of yoghurt or jam**. Use a small amount of food/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 administration³
- **For administration via an enteral feeding tube**, the tablet can be **crushed** 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 administration³.
- NOTE: **crushing the MR tablet will mean that it is no longer modified release³**.
- NOTE: JAPC does not recommend the use of Melatonin in over 55s for insomnia
- 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

Specialist (RDH): Dr Hani Faza, Consultant Paediatrician
01332 340131 ext. 86828 (sec) 1419 (bleep)

Specialist (CAMHS):

Dr Aislinn Choke – Consultant Psychiatrist / Associate Clinical Director, Temple House, Mill Hill Lane, Derby, DE23 6SA – 03007 900264

Consultant Community Paediatrician – Dr Beth Howman, Kingway Hospital, Kingsway House West Wing, Derby, DE22 3LZ – 01332 623704

Ronnie McKeith Centre – 01332 785609

Pharmacist (RDH): Berglind Palsdottir, Senior Pharmacist for Women & Children's Services – 01332 340131 ext. 85367/85368, 2268 (bleep)

Pharmacy (Kingsway): 01332 623700 ext. 33268/33214

Pharmacy (CRH): 01246 513153

References

1. Derbyshire Shared Care Guideline – Melatonin for the treatment of sleep disorders in children with neurodevelopment disorders, March 2013
2. MHRA Drug procurement advice: Restrictions on the import of unlicensed Melatonin products following the grant of a marketing authorisation for Circadin® 2mg tablets August 2008
3. Flynn Pharma Kaleigh Marsden Medicines Information 21/8/2012 personal communication
4. BNF for children June 2015 accessed online.
5. Melatonin for the management of sleep problems in children with neurodevelopmental disorders: a systematic review and meta-analysis May 2018.

Document update	Date
Melatonin 1mg/ml solution- DNP	August 2019