



PAN MERSEY AREA PRESCRIBING COMMITTEE

PRESCRIBING POLICY STATEMENT



Pan Mersey

REF: PS152 FINAL

Area Prescribing Committee

FIRST APC BOARD DATE: 12 MAR 2013

LAST APC BOARD DATE: 30 SEP 2015

**MELATONIN modified release tablets 2mg
(Circadin®) 'off – label' use in Adults**

AMBER

The Pan Mersey Area Prescribing Committee recommends the prescribing of MELATONIN 2mg modified release tablets (Circadin®) 'off-label' for adults aged 18 years and over with a learning disability OR who have been transferred from paediatric services, following specialist initiation in childhood for the treatment of persistent chronic sleep disorders

PATIENT RETAINED BY SPECIALIST *

There must be evidence that the patient has a learning disability **OR** has been diagnosed by paediatric services with a persistent chronic sleep disorder (e.g. insomnia or delayed sleep phase syndrome) associated with at least one of the following:

- cerebral palsy
- autistic spectrum disorders
- visual impairment
- global developmental delay / learning disabilities
- acquired brain injury
- chronic pain / fatigue
- epilepsy
- progressive / chronic neurological impairment
- attention deficit hyperactivity disorder (ADHD)

AND has been transferred to an adult clinic and requires continued treatment

Patients will have been stabilised on treatment by the initiating centre before GP prescribing commences. There must be evidence that the patient is being reviewed regularly (at least 6 monthly) by the specialist to ensure continued treatment with melatonin is appropriate and effective.

This statement does not include other forms of melatonin, including liquids, which are unlicensed or are food supplements and remain RED due to the variation in quality and cost to primary care. **If the specialist's clinical judgement is that crushed (Circadin®) is not appropriate for an individual patient, the most appropriate unlicensed preparation should be initiated and prescribing maintained by the specialist.**

Melatonin 2mg modified release tablets (Circadin®) are licensed for the short-term treatment of insomnia in adults over 55 years however, Circadin® for this indication is not recommended in primary care or secondary care (BLACK category).

* **AMBER INITIATED** in Halton CCG

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

MELATONIN modified release tablets 2mg (Circadin®) 'off – label' use in Adults

<p>EFFECTIVENESS</p> <p>Melatonin is a pineal hormone that may affect sleep pattern. Clinical experience suggests that when appropriate behavioural sleep interventions fail, melatonin may be of value for treating sleep onset insomnia and delayed sleep phase syndrome in conditions such as visual impairment, cerebral palsy, ADHD, autism and learning difficulties.¹</p> <p>NICE CG 53 supports its use for the management of chronic fatigue syndrome / myalgic encephalomyelitis in children and young people.²</p> <p>NICE NG 11 states that for children, young people and adults with a learning disability and behaviour that challenges, melatonin should be considered if medication is needed to aid sleep.³</p>	<p>SAFETY</p> <p>Little is known about its long-term effects, and there is uncertainty as to the effect on other circadian rhythms including endocrine or reproductive hormone secretion.¹ The Summary of Product Characteristics (SPC) suggests that melatonin is generally well tolerated and no significant side effects have been reported with pharmacologically regulated melatonin. No case of overdose has been reported. If overdose occurs, drowsiness is to be expected. Melatonin has a short half-life (3.5-4 hours) and clearance of the active substance is expected within 12 hours after ingestion. No special treatment is required.⁴</p> <p>The most commonly reported side effects (other than drowsiness) include headaches, dizziness and nausea.^{1,4}</p> <p>Consult SPC⁴ for full details of contra-indications, side effects and drug interactions: Circadin - Summary of Product Characteristics (SPC) - (eMC)</p>
<p>COST⁶ annual cost per patient</p> <p>Circadin® m/r tablets 2mg at night £184.68</p> <p>Circadin® m/r tablets 4mg at night £369.36</p>	<p>PATIENT FACTORS</p> <p>Treatment with melatonin should be initiated and monitored by a specialist and can be continued by GPs under AMBER criteria.</p> <p>The need to continue melatonin therapy should be reviewed every 6 months for effectiveness and response to treatment.¹ Clinical impression is that during long-term treatment melatonin appears to become less effective so it is worth considering discontinuing for several weeks and then re-starting if necessary.</p>

PRESCRIBING INFORMATION

Circadin® 2mg m/r tablets should be swallowed whole with a drink in those adults who are able to do so. The SPC states that the tablets should be swallowed whole to maintain prolonged release properties and that crushing or chewing should not be used to facilitate swallowing.⁴ However if an adult cannot swallow Circadin® tablets, they may be crushed and dispersed in liquid or soft food before administration or dispersed in water for administration via large bore feeding tubes. The prolonged release properties of Circadin will be lost on crushing and it will revert to immediate release characteristics.⁵

MHRA advice is that although they do not recommend “off-label” use of products, if a UK licensed product can meet a clinical need, even if off-label, it should be used instead of an unlicensed product.⁷

IMPLEMENTATION NOTES

The licensed adult dose is 2mg, 1-2 hours before bed-time and after food. Specialists may advise higher doses.

REFERENCES

1. BNF for Children, February 2016. [Melatonin : BNF for Children](#) accessed 09/03/16
2. NICE Clinical Guideline 53 , August 2007. [Chronic fatigue syndrome/myalgic encephalomyelitis - diagnosis and management in adults and children](#) accessed 26/05/14
3. NICE Guideline 11, May 2015. [Challenging behaviour and learning disabilities: prevention and interventions for people with learning disabilities whose behaviour challenges](#) accessed 25/6/15
4. Flynn Pharma Ltd. Summary of Product Characteristics: Circadin® 2mg M/R tablets. [Circadin - Summary of Product Characteristics \(SPC\) - \(eMC\)](#) accessed 25/06/15
5. Flynn Pharma Ltd. Personal correspondence. Available on request
6. Drug Tariff, March 2016. [Prescription Services Payments and Pricing NHS Business Services Authority](#). Accessed 09/03/16
7. MHRA. Guidance Note 14. [Supply unlicensed medicinal products \(specials\) - Publications - GOV.UK](#) accessed 09/03/16