East Lancashire Health Economy Medicines Management Board
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# SHARED CARE GUIDELINE

## Drug: Melatonin (Circadin® m/r tablets)
## Treatment of sleep disorders in children aged 2 to 18 years

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| **Introduction** | **Indications For Shared Care:**<br><br>Melatonin is indicated for the treatment of sleep disorders (e.g. sleep onset delay or recurrent night time wakening) in children and young people 2-18 years of age with neurodevelopmental and psychiatric disorders, when behavioural modification and sleep hygiene has been unsuccessful or is very difficult to achieve. Melatonin is unlicensed for this indication. Melatonin is to be only prescribed in patients with:<br><br>• visual impairment,<br><br>• cerebral palsy,<br><br>• attention deficit hyperactivity disorder,<br><br>• epilepsy,<br><br>• autism and learning difficulties<br><br>**N.B. Please see the SPC for detailed information on licensed indications**<br><br>**Please note:**<br><br>**The best interest, agreement and preferences of the patient should be at the centre of any shared care agreement and their wishes followed wherever possible. Patients should be able to decline shared care if, after due consideration of the options, they decide it is not in their best interests.**<br><br>**The provision of shared care prescribing guidelines does not necessarily mean that the GP must agree to and accept clinical and legal responsibility for prescribing; they should only do so if they feel clinically confident in managing that condition.**<br><br>**Referral to the GP should only take place once the GP has agreed to this in each individual case, and the hospital or specialist will continue to provide prescriptions until a successful transfer of responsibilities has occurred. The GP should confirm the agreement and acceptance of the shared care prescribing arrangement and that supply arrangements have been finalised. The secondary/tertiary provider must supply an adequate amount of the medication to cover the transition period. The patient should then be informed to obtain further prescriptions from the GP.** |

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*References: Flynn Pharma Ltd, Circadin® SmPC lasted updated 23.08.2019*

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| | **Background:**<br><br>Melatonin is a pineal hormone which may affect sleep pattern. Production is affected by light exposure detected by the retina; it is thought that this rhythm is disturbed in children with neurodevelopmental disorders or visual disturbance (1-3). Randomised-controlled trials and 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, epilepsy, autism, and learning difficulties. |
| **Form** | Melatonin (Circadin®) 2mg modified release tablets |
| **Dose and administration (please refer to BNFc)** | By mouth Child 2 - 18 years,<br><br>• Initially 2mg once daily (for children 2 to 5 years to start on 1mg), dose to be taken 30-60 minutes before bedtime. If there is no response or an insufficient response after a minimum of 14 days therapy to increase to 4mg once daily. If further increases in dose are needed then these should be made in 2mg increments after a minimum of 14 days on each dose. The normal maximum is 10mg at night<br><br>Sleep hygiene measures should also continue alongside the administration of Melatonin. Written guidance on sleep hygiene measures will be provided to the carers.<br><br>**CRITERIA FOR A BENEFICIAL RESPONSE:**<br><br>The sleep diary to be used and this can be defined as _<br><br>• A consistent shift in sleep pattern towards earlier settling to sleep<br>• An increase in sleep duration by 60 mins or more<br>• The ability to wake in the morning in order to get to school on time.<br>• A reported improvement in daytime functioning. |

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| | **Administration**<br><br>**Tablets**<br><br>**For oral administration,** Melatonin (Circadin) 2mg modified release (m/r) tablets will be used. If prolonged action is required, advise that the tablets should be swallowed whole. Crushing the m/r tablets will result in an immediate release effect. Crushed melatonin can be mixed with water, milk or juice. The contents can also be mixed with soft food such as yoghurt, mashed potato or jam. For a 1mg dose use half a tablet of Circadin®.<br><br>**For enteral tube administration,** Melatonin (Circadin®) 2mg m/r tablets can be used. The tablets can be crushed and the contents mixed with water for administration. Exceptionally there will be a very small group of patients especially on the autistic spectrum of disorders who are very restricted in their oral intake. Only in these significant cases should a liquid preparation be considered.<br><br>**Liquid (expensive and unlicensed) – to be prescribed by hospital only.** |
| **Common Adverse Effects (please refer to BNF / SPCs for full details)** | **Please refer to the SPC or BNF for full list.**<br><br>**Common or very common:** Arthralgia; behavior abnormal; drowsiness; feeling abnormal; headaches; increased risk of infection; mood altered; pain; sleep disorders<br><br>**Uncommon:** Anxiety; asthenia; chest pain; dizziness; dry mouth; gastrointestinal discomfort; hyperbilirubinaemia; hypertension; menopausal symptoms; symptoms; movement disorders; nausea; night sweats; oral disorders; skin reactions; urine abnormalities; weight increased |
| **Contraindications / Cautions (please refer to BNF / SPCs for full details)** | **Contraindications:**<br>• Hypersensitivity to the active substance or any of the excipients listed in section 6.1 of the SPC<br><br>**Cautions:**<br>• Circadin® may cause drowsiness. Therefore the product should be used with caution if the effects of drowsiness are likely to be associated with a risk to safety.<br>• No clinical data exist concerning the use of Circadin® in individuals with autoimmune diseases. Therefore, Circadin® is not recommended for use in patients with autoimmune diseases.<br>• Circadin® contains lactose. Patients with rare hereditary problems of galactose intolerance, the LAPP lactase deficiency or glucose-galactose malabsorption should not take this medicine. |

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| **Potentially Serious Drug Interactions (please refer to BNF / SPCs for full details)** | • Caution should be exercised in patients on fluvoxamine (the combination should be avoided), 5- or 8-methoxypsoralen, cimetidine, oestrogens which increases melatonin levels.<br>• Cigarette smoking may decrease melatonin levels.<br>• Quinolones may give rise to increased melatonin exposure.<br>• Carbamazepine and rifampicin may give rise to reduced plasma concentrations of melatonin.<br>• Alcohol should not be taken with Circadin®, because it reduces the effectiveness of Circadin® on sleep.<br>• Circadin® may enhance the sedative properties of benzodiazepines and non-benzodiazepine hypnotics, such as zaleplon, zolpidem and zopiclone. |
| **Secondary Care Responsibilities** | 1) Give information about sleep disorders and additional support to parents or carers including education and information, parenting strategies, and sleep hygiene measures.<br>2) Record the person's preferences and concerns in their treatment plan. Patients should be able to decline shared care if, after due consideration of the options, they decide it is not in their best interests. Patients should provide explicit consent and this should be recorded in both the patients notes and on the shared care agreement form.<br>3) Provide information about the medication to patients, including common side effects, necessary monitoring, and where that monitoring will take place. Also, to keep the patient informed of the process at all stages to ensure continuity of treatment.<br>4) Titrate the dose against symptoms and adverse effects until dose optimization is achieved, that is reduced symptoms (see criteria for beneficial response above).<br>5) Prescribe and monitor the patient until a stable treatment dose is reached.<br>6) Continue to provide prescriptions until a successful transfer of responsibilities to the GP has occurred. The secondary/tertiary provider must supply an adequate amount of the medication to cover the transition period.<br>7) The patient should then be informed to obtain further prescriptions from the GP after the transition period.<br>8) Conduct an annual face to face medication review for all patients covered by this shared care guidance.<br>9) Contact the GP (in a timely manner) of a patient missing a specialist face to face appointment to advise whether treatment should be withheld<br>10) Accept referrals back from primary care for medication discontinuation.<br>11) Resume prescribing and monitoring of the patient when a decision for managed withdrawal of treatment has been taken.<br>12) Continue to provide emergency appointments where patients are receiving prescriptions from their GP and they feel that a prompt assessment or review of their treatment is required.<br>13) Provide prompt on-going advice to General Practitioners as required without necessarily requiring a new referral.<br>14) Provide advice to the GP as to the changes in parameters that should trigger urgent referral back to the specialist |

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| | 15) Telephone details and (if appropriate) secure email addresses for both Secondary and Primary Care should be exchanged and recorded. This should include out-of-hours contact numbers. Patients and their carers should also be provided with contact details for support and help if required; both in and out of hours. |
| **Primary Care Responsibilities** | **Clinical responsibility for prescribing is held by the person signing the prescription, who must also ensure adequate monitoring.**<br><br>1) To consider requests to prescribe under shared care arrangements and reply in a timely manner<br><br>2) Prescribe melatonin in accordance with the specialist recommendations.<br><br>3) Any ongoing monitoring requirements for individual patients discharged from secondary care will be identified by the specialist service as part of the discharge information to the GP<br><br>4) Stop or adjust treatment on advice of, or in consultation with a specialist.<br><br>5) To report to and seek advice from the specialist on any aspect of patient care which is of concern to the GP and may affect treatment.<br><br>**5)** To refer back to secondary care if withdrawal of treatment might be indicated.<br><br>**Circumstances for discontinuation of treatment in Primary Care**<br><br>1) As a joint decision with specialist team providing specific advice in case of adverse effect pending assessment.<br><br>2) Following non-attendance at annual specialist team review pending that review taking place or if there is failure to engage with the review process. |

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| **Transition to adult services** | **Transition from paediatric services to adult services**<br><br>• If the care of a patient is being transferred from paediatrics to an adult services consultant in a secondary or tertiary care centre then the paediatrician should obtain consent from the new consultant if they are happy to continue prescribing melatonin.<br><br>• If accepted then the GP should be informed of the change including anticipated date of transfer by the paediatrician.<br><br>• The adult consultant will need to communicate to the GP the change in consultant and acceptance of responsibility for melatonin prescribing by the new consultant.<br><br>• If the new consultant declines responsibility for prescribing Melatonin then the paediatrician will need to stop the prescribing of Melatonin prior to transfer after discussion with the patient and family.<br><br>• The GP will need to be informed of the change.<br><br>If the patient is not transferred to a secondary or tertiary care adult consultant and is transferred to the care of the GP, the paediatrician should stop the prescribing of melatonin after discussion with patient/family and inform the GP. |

**Bibliography**


Summary of Product Characteristics. Circadin (melatonin) 2mg prolonged release tablets. Flynn Pharma Ltd. Last updated: 08/2019. [Acessed online: 04/03/2021] Accessed via: https://www.medicines.org.uk/emc/product

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