

Prescribing Information Document for melatonin in children, adolescents and adults with learning disabilities

- Prescribing of melatonin is limited to those people where sleep problems are seriously affecting quality of life and where other methods of sleep management such as sleep hygiene have failed.
- Regular review should take place because the long term effects of extra melatonin are as yet not totally known.

Licensed Indication

Circadin is indicated as monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over.¹

Unlicensed use: 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 children.²

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, melatonin (circadin®) 2mg modified release (MR) tablets are the preferred option.³

Dosage and administration²

Treatment with melatonin should be initiated and supervised by a specialist, but may be continued by general practitioners. The need to continue melatonin therapy should be reviewed every 6 months.

By mouth using modified release tablets:

Child: Initially 2-3mg daily for 1-2 weeks, then increased if necessary to 4-6mg daily, dose to be taken before bedtime; maximum 10mg daily

Tablets may be crushed to give an 'immediate release' characteristic. Crushed tablets may be mixed with a little water, milk or soft food (such as yoghurt or jam) to aid swallowing ([see patient information on crushing Circadin 2mg MR tablets](#)).

A liquid preparation may be an option when initial treatment with tablets has failed or as an alternative to reduce the tablet burden when prescribing doses of 10mg.

The drug tariff choice in such cases is 10mg/5ml oral SUSPENSION x 100ml.

Note: the drug tariff 1mg/ml oral solution sugar-free IS NOT suitable for this indication as the alcohol content has a cumulative effect in children.

In line with the Scottish Medicines Consortium⁴, Melatonin 1mg and 5mg modified release (Slenyto 1mg and 5mg modified release) are not supported by the local health economy formulary

Adverse effects, Precautions and Contra-indications¹

Contraindications

Known hypersensitivity to melatonin or to any of the excipients (refer to SPC).

Special Precautions

Circadin may cause drowsiness. The product should be used with caution if the effects of drowsiness are likely to be associated with a risk to safety.

Circadin is not recommended for use in patients with autoimmune diseases.

Circadin contains lactose. Patients with galactose intolerance, LAPP lactase deficiency or glucose-galactose malabsorption should not take this medicine

Adverse Effects

The most frequently reported adverse reactions with treatment were: headache, nasopharyngitis, back pain, and arthralgia

See product SPC for full list of possible adverse drug reactions (www.medicines.org.uk)

Drug Interactions

See product SPC for full list of drug interactions (www.medicines.org.uk) or the British National Formulary (www.bnf.org)

Communication

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Bleep:	Fax:	Email address:
Specialist:				
Hospital Pharmacy Dept:				
Other:				

For any queries relating to this patient's treatment with melatonin, please contact the specialist named above.

This information is not inclusive of all prescribing information, potential adverse effects and drug interactions. Please refer to full prescribing data in the Summary of Product Characteristics (www.medicines.org.uk) or the British National Formulary (www.bnf.org).

1. Circadin – Summary of Product Characteristics. Available at www.medicines.org.uk
2. BNF Children – Available at <https://bnfc.nice.org.uk/>
3. Medicines and Healthcare products Regulatory Agency (MHRA)
Refer to appendix 2 of:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/Th_e_supply_of_unlicensed_medicinal_products_specials_.pdf
4. Scottish Medicines Consortium. [Melatonin 1mg and 5mg prolonged-release tablets \(Slenyto®\). Aug 2019.](#)