Melatonin

Melatonin treatment is intended to be short-term.[1-4] Patients should be reviewed for the continued need for melatonin. The first licensed melatonin preparations for use in children (Slenyto® 1mg and 5mg tablets) and for the short-term treatment of jet lag in adults (melatonin 3mg tablets, melatonin 1mg/ml oral solution) are reviewed.[1,2,3] Switching patients from unlicensed to licensed melatonin preparations should be considered for safety and quality reasons. Melatonin preparation choice and dose need to be optimised to manage any potential cost increases or safety issues when considering switching melatonin preparations.

Key recommendations

- Do not prescribe melatonin for sleep disorders associated with Attention Deficit Hyperactivity Disorder (ADHD) without a concomitant disorder of Autistic Spectrum Disorder (ASD) or for shift work.
- Do not prescribe melatonin for jet lag on NHS prescription as GPs are not responsible for providing NHS prescriptions for conditions which may arise while abroad or travelling.[5] If wanted, GPs may provide private prescriptions for melatonin in anticipation of jet lag.
- Consider a trial withdrawal of treatment after two years melatonin treatment in children as efficacy and safety data are not available beyond two years treatment; in adults review melatonin and consider a trial withdrawal or stopping treatment after thirteen weeks.[1,4]
- Melatonin 1mg/ml oral solution (Colonis Pharma Ltd) should not be used in children and adolescents due to safety and efficacy concerns.[3]
- Patients with swallowing difficulties should be prescribed the following licensed melatonin preparations off-label, in preference to using an unlicensed melatonin preparation:[6]
  - For an immediate release dose: Halve, quarter or crush Circadin® P/R 2mg tablets, Slenyto® P/R 1mg or 5mg tablets, melatonin 3mg tablets or use melatonin 1mg/ml oral solution.
  - For a prolonged-release melatonin dose: Mix whole Slenyto® P/R 1mg or 5mg tablets with yoghurt, orange juice or ice-cream and take immediately to aid swallowing. Do not break, crush or chew them. If this is not suitable, then change to an immediate release melatonin preparation as above.
- Review patients prescribed unlicensed melatonin preparations for the continued need for melatonin, any adverse effects and then for suitability for a switch to a licensed or off-label use, melatonin preparation.
- Optimise melatonin doses so that use is within licensed doses and also to manage additional cost pressures.
- Be aware that the risks associated with the long-term use of benzodiazepine and 'Z-drug hypnotics have been well recognised for many years. Recent data also suggest a similar safety concern with melatonin. These risks include falls, accidents, cognitive impairment, dependence and withdrawal symptoms, and an increased risk of dementia.[7]
- Monitor children for a possible impact of melatonin on their pubertal development.[8,9]

Costs and savings

The annual spend on melatonin across England and Wales is £30 million for 972,708 items prescribed. £7.8 million of this is for unlicensed melatonin preparations (ePACT2 Feb 2019- April 2019).

Switching from unlicensed melatonin preparations to Circadin® **could save £6 million per year in England and Wales or £9,594 per 100,000 population**. Switching from unlicensed melatonin preparations to Slenyto® **could save £3.1 million per year in England and Wales or £5,009 per 100,000 population**.

A reduction in melatonin prescribing can be achieved by reviewing melatonin prescribing at recommended intervals.

If a 40% reduction in prescribing is achieved by reviewing and stopping melatonin prescribing then the **annual savings would be £12 million, which equates to £19,066 per 100,000 population in England and Wales**.

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Additional resources available	Bulletin	https://www.prescqipp.info/our-resources/bulletins/bulletin-245-melatonin/
	Implementation tools	
	Data pack	https://pdata.uk/#/views/B245_Melatonin/FrontPage?:iid=1

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