# Melatonin

Large-scale, high-quality evidence to demonstrate the cost-effectiveness, and long-term efficacy and safety of melatonin for insomnia is lacking.[1] Regular drug holidays are recommended to ensure ongoing benefit beyond three months of treatment, and treatment should be discontinued when it is no longer indicated.[2] Many melatonin preparations are unlicensed "specials"[3] or their use is off-label for various conditions and age-groups, which increases both prescriber responsibility and medico-legal risk.

## Key recommendations

- The risk of falls and fractures associated with melatonin should be considered before commencing treatment and at each review in patients aged 45 years or over.
- All patients prescribed melatonin for the following indications should have their treatment discontinued:
  - Jet lag (not recommended on the NHS due to the limited and conflicting evidence of benefit)
  - Insomnia with Alzheimer's disease.
- Where melatonin is being considered and before treatment is started, all patients:
  - Under the age of 19 with autism spectrum disorder should have a consultation with a specialist paediatrician or psychiatrist with expertise in the management of autism or paediatric sleep medicine.
  - With challenging behaviour and learning disabilities should have a consultation with a psychiatrist (or a specialist paediatrician for a child or young person) with expertise in melatonin use in people with a learning disability.
- Melatonin should be used together with non-pharmacological interventions.
- Review children on melatonin after three months and deprescribe melatonin if there is no clinically relevant treatment effect seen.
- Review all adults aged 55 years and over on modified-release melatonin after three weeks of treatment and only continue for a further 10 weeks if a response is seen. Review and deprescribe melatonin in adults after a total of 13 weeks treatment.
- All suitable patients should undergo a two-week drug holiday to assess their need for ongoing treatment. This should take place three months after the commencement of treatment and six-monthly thereafter. If sleep improvements are maintained without melatonin, therapy should be stopped.
- If there is a consistent correlation of sleep deterioration during a drug holiday, patients should be advised to continue melatonin without a break unless they are suspected to be a poor metaboliser of melatonin (in which case regular washout with ongoing drug holidays when the benefit wanes, is recommended).
- For patients where caution should be exercised with drug-holidays and deprescribing, refer to the patient's specialist for advice on managing this, including where melatonin is prescribed under a formal shared care arrangement.
- A cost-effective licensed preparation should be selected where possible.
- Review patients prescribed unlicensed melatonin specials and melatonin used "off-label" and discuss with them whether a change to a licensed alternative is suitable for them. For patients prescribed unlicensed or 'off-label' melatonin, where there is no suitable licensed alternative, they should be given sufficient information regarding this.

## Costs and savings*

A 25% reduction in the prescribing of melatonin preparations (excluding melatonin 1mg, 2mg, 3mg, 5mg capsules, and melatonin 1mg/ml oral solution sugar free preparations) **could release savings of approximately £10.9 million per annum across England, Wales and Scotland. This equates to £15,402 per 100,000 patients. A 25% reduction in unlicensed melatonin specials could save £334,360 annually across England and Wales.**

Switching 80% of patients on melatonin 1mg, 2mg, 3mg, or 5mg capsules to the respective strength tablet **would save £2.5 million per annum in England and Wales and £1.1 million in Scotland. This equates to £5,240 per 100,000 population.**

Switching 50% of patients from melatonin 1mg/ml oral solution sugar free to Adaflex® tablets which can be crushed and mixed with water directly before administration **could save £6 million per annum in England and Wales and £850,364 in Scotland and Wales. This equates to £9,586 per 100,000.**

***Based on prescribing data from NHSBSA (England and Wales Jul-Sept22) and Public Health Scotland (Scotland Jun-Aug22).**

## References


1. CADTH Health Technology Review. Melatonin for the Treatment of Insomnia: A 2022 Update. Canadian Journal of Health Technologies 2022; 2(5): 1-53. https://www.cadth.ca/sites/default/files/pdf/htis/2022/RC1422%20Melatonin%20for%20Insomnia%20Final.pdf
2. North of Tyne, Gateshead and North Cumbria Area Prescribing Committee. Melatonin Deprescribing Guideline for Adults in Primary Care. March 2022. http://www.northoftyneapc.nhs.uk/wp-content/uploads/sites/6/2022/04/Melatonin-Deprescribing-Guideline-March-2022.pdf.
3. Department of Health. Drug Tariff. January 2023. https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff


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| Additional resources available | Bulletin | https://www.prescqipp.info/our-resources/bulletins/bulletin-318-melatonin/ |
| | Tools | |
| | Data pack | https://data.prescqipp.info/?pdata.u/#/views/B318_Melatonin/FrontPage?:iid=1 |

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