

Melatonin Paediatric Product Selection Guide

Principles of using this guide:

- IR/MR formulations: MR formulations are not normally required to aid sleep. IR formulations to help with sleep onset are usually preferred. Specialist must specify if an MR formulation is required.
- Switching MR to IR /IR to MR requires discussion with relevant specialist.
- Products may have different licensed indications, but all are covered within the Amber status (may be used outside the terms of the product licence but not to an extent that a GP would not normally be expected to accept clinical responsibility).
- Preferred products may occasionally not be available due to supply chain issues. In these instances, other options can be used.
- Liquid melatonin is more expensive compared with solid dosage forms.
- Products to be administered via PEG tube will be advised by specialist.

1. Preferred First Line Options (all indications)

First Line Choice	Where there are no swallowing difficulties	Where there are swallowing difficulties	Cost per 30 days Based on DT October 2023 Link *BNF accessed online 11/10/2023 Link
If Immediate Release formulation required.	Adaflex® 1mg, 2mg,3mg, 4mg, 5mg (Immediate release) tablets. Please prescribe by brand	Trial of Adaflex® (crushed and mixed with water) before progressing to Table 2.	1mg=£13.30 2mg=£15.30 3mg=£17.60 * 4mg= £20.23 5mg=£23.27
If Modified Release formulation required (MR must be specified by specialist)	Melatonin M/R 2mg tablets.	Progress to Table 2.	2mg=£5.32 4mg=£10.64 6mg=£15.96

2. Products which are recommended for Limited Use Only

Products which are recommended for Limited Use Only	Rationale	Cost per 30days Based on DT October 2023 Link
Slenyto® M/R 1mg, 5mg.	Slenyto® is more expensive than Melatonin MR. Use a trial of Slenyto® ONLY if: <ul style="list-style-type: none"> • M/R is considered essential and patient cannot tolerate swallowing of melatonin M/R 2mg tablets or <ul style="list-style-type: none"> • Adaflex® or Adaflex® (crushed and mixed with water) cannot be used 	1mg=£20.60 2mg =£41.20 3mg =£61.80 4mg =£82.40 5mg=£103 6mg =£123.60
Licensed Melatonin 1mg/ml sugar free oral solution (Consilient Health and Colonis Pharma Ltd). Specify manufacturer to be prescribed/dispensed in e.g. dosage field of prescription. <i>Colonis liquid contains 150mg/ml propylene glycol which makes it unsuitable for under 5 years.</i>	Melatonin liquids are the most expensive ways to give melatonin. Use ONLY if: <ul style="list-style-type: none"> • Adaflex® (crushed and mixed with water) AND Slenyto® are not tolerated. 	1mg =£25.41 2mg =£50.82 3mg =£76.23 4mg =£101.64 5mg =£127.05 6mg =£152.46

3. Products which are not recommended for use.

- Melatonin capsules (as much more expensive than tablets).
- Colonis liquid in children under 5 years (as contains propylene glycol).
- Unlicensed melatonin formulations that are not included in NI paediatric standardised liquid medicines list

4. Additional References

- Melatonin shared care guideline [Link](#)
- GMC prescribing guidance [Link](#)
- MHRA : Off-label or unlicensed use of medicines: prescribers' responsibilities [Link](#)
- NI paediatric standardised liquid medicines list [Link](#)

This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer.