NeuroFX
Changing Minds

SLEEP AND NEURODIVERGENCE · 12.6

Melatonin in Children: What the UK Evidence and Licensing Says

Melatonin for paediatric sleep sits in a confusing space. In the US it is sold over the counter; in the UK it is prescription-only. The licensing, the evidence and the conversation are different here.

FOR
Parents considering melatonin for a child with sleep difficulty

AUDIENCE AGE
6–17

REVIEWED
18 May 2026

PART OF
The NeuroFX resource library

info@neurofx.co.uk · 0333 533 3303 · neurofx.co.uk

IN SUMMARY

Melatonin in Children: What the UK Evidence and Licensing Says

The UK position

- **Prescription-only, not over-the-counter.** Parents who have read US parenting media sometimes arrive at the pharmacy expecting to buy melatonin gummies. The UK position is closer to most of Europe: a medicine, prescribed by a clinician, at doses that match the evidence.
- **Slenyto is the specifically licensed option in autism.** Slenyto (paediatric prolonged-release melatonin) is licensed in the UK for autistic children and adolescents aged 2 to 18 (and Smith-Magenis syndrome) where sleep hygiene measures have been insufficient.
- **Off-label use is common and supported.** Off-label paediatric melatonin is used in ADHD, delayed sleep phase, jet lag, and other neurodevelopmental contexts. Off-label means outside the specific licence; this is legal, common in paediatrics, and supported by the BNFc framework.

What the safety evidence says

- **Short-term safety is good.** Common side effects include headache, daytime sleepiness and morning grogginess; serious adverse events are rare.
- **Medium-term safety to 24 months is reasonable.** Maras 2018 open-label extension trial in autistic children followed up to 24 months with sustained sleep benefit, no signal on growth or pubertal development across that period.
- **The puberty question has theoretical basis but no clear human signal.** Boafo 2019 review of available human evidence found no clear signal of harm to puberty timing, but the data is limited and the question is not fully settled. Worth raising with the prescriber for long-term use.
- **Drug interactions are limited but real.** Fluvoxamine and some other medications affect melatonin metabolism. The prescriber will consider this.
- **Works best alongside, not instead of, the wider sleep approach.** Melatonin works for sleep onset; it does little for sleep maintenance. The wider environmental and behavioural work continues to matter.

How we can help

- **GP or paediatrician for the conversation.** Specifically: have we tried environmental work thoroughly? Is Slenyto appropriate (autism) or off-label immediate-release (other pictures)? What is the dose, the review plan, the long-term plan?
- **NeuroFX paediatric prescribing.** Our paediatric prescribing clinicians can address melatonin for patients in our paediatric service where clinically appropriate.
- **SleepFX for structured behavioural support.** NeuroFX's sister product SleepFX offers structured paediatric sleep programmes for neurodivergent children alongside or in advance of any medication conversation.

WHEN TO SPEAK TO A PROFESSIONAL

Speak to your GP or paediatrician if you have tried behavioural and environmental sleep work thoroughly and the picture has not shifted, particularly if your child is autistic (where Slenyto is licensed) or has another neurodevelopmental picture. For NHS routes specifically, your child's existing paediatric team is usually the right first call. NeuroFX paediatric prescribing clinicians can address melatonin for patients in our paediatric service where clinically appropriate. SleepFX offers structured paediatric sleep programmes for neurodivergent children alongside or in advance of any medication conversation.

SOURCES

BNFc; Maras 2018; Bruni 2018 JCPP; Goldman 2014; Boafo 2019; MHRA; NICE Slenyto

NEXT STEPS

Speak to NeuroFX

Private ADHD and autism assessment for adults and children aged 6 and upwards. CQC-registered. Bedford Consulting Rooms, 4 Goldington Road, Bedford MK40 3NF.

neurofx.co.uk · info@neurofx.co.uk · 0333 533 3303