



## Medicine: prolonged-release melatonin (brand name: Slenyto<sup>®</sup>)

### Resubmission

Flynn Pharma Ltd

The Scottish Medicines Consortium (SMC) has assessed prolonged-release melatonin for the treatment of insomnia in children aged 2 to 18 years who have autism spectrum disorder and/ or Smith-Magenis syndrome. Prolonged-release melatonin is used after sleep hygiene measures have not worked. This document summarises the SMC decision and what it means for patients.

### What has SMC said?

After careful consideration, SMC has not recommended prolonged-release melatonin for treating insomnia in children with autism spectrum disorder and/or Smith-Magenis Syndrome as described above.

SMC was unable to accept prolonged-release melatonin because the evidence provided by the company was not strong enough to satisfy the committee that it offers value for money to NHSScotland.

### What does SMC's decision mean for patients?

Prolonged-release melatonin should not normally be prescribed on the NHS in Scotland for use as described above. If a patient's healthcare professional thinks a particular patient would benefit from it, they can make a request to prescribe prolonged-release melatonin. All health boards have procedures in place to consider these requests. For further information see:

Medicines in Scotland: What's the right treatment for me?

[www.healthcareimprovementscotland.org/medicinesbooklet.aspx](http://www.healthcareimprovementscotland.org/medicinesbooklet.aspx)



### What is prolonged-release melatonin used for?

Prolonged-release melatonin is used to treat insomnia in children aged 2 to 18 years who have autism spectrum disorder and/or Smith-Magenis syndrome. Autism spectrum disorder is a condition that affects social interaction, communication, sleep and behaviour. Smith-Magenis syndrome is a rare syndrome which can cause intellectual disability, speech and language delay, sleep disturbances (a reversed body clock) and behavioural problems. Prolonged-release melatonin is used after sleep hygiene measures (such as keeping to a regular bed-time routine) have not worked.

## How does prolonged-release melatonin work?

Melatonin is a hormone produced by a gland in the body called the pineal gland. It is responsible for making us feel sleepy. Levels in the blood should increase when it gets dark, acting on areas of the brain to induce sleepiness. Prolonged-release melatonin given just before bedtime to children with autism spectrum disorder and Smith-Magenis syndrome could help improve their sleep pattern.

## How does SMC make its decision?

SMC carefully considers every new medicine to make sure it benefits patients and is considered to be an acceptable use of the limited resources in NHSScotland.

To do this SMC considers the following:

- Evidence from the company about how well the medicine works compared with current treatments available in Scotland, in relation to how much they will cost to buy and administer.
- Information from patient groups about the potential impact of the medicine on patients and carers.
- Advice from healthcare professionals about any benefits of the new medicine compared to current treatment, along with how the new medicine is likely to be used.

When SMC assesses a medicine it takes account of the needs of all patients in NHSScotland, not just those who may be treated with the medicine under consideration.

You can find more detailed information about the SMC assessment of prolonged-release melatonin by looking at the SMC Detailed Advice Document (SMC2306).

## More information

The organisations below can provide more information and support for people with autism spectrum disorder and/or Smith-Magenis Syndrome and their families. SMC is not responsible for the content of any information provided by external organisations.

### ADHD Parent Support West Glasgow



<http://www.adhdglasgow.org>



[adhdglasgow@outlook.com](mailto:adhdglasgow@outlook.com)

### Smith-Magenis Syndrome Foundation UK



<https://smith-magenis.org>



0300 101 0034

You can find out more about prolonged-release melatonin (Slenyto®) in the European public assessment report (EPAR) summary for the public by searching for the medicine name on the European Medicines Agency (EMA) website.



<http://www.ema.europa.eu>