

Medicine: prolonged-release melatonin (brand name: Slenyto[®]) for insomnia in children with autism spectrum disorder and/or Smith-Magenis syndrome

Flynn Pharma Ltd

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 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.

What has SMC said?

SMC has not recommended prolonged-release melatonin for the treatment of insomnia in children as described above.



Why has SMC said this?

SMC looks at how well new medicines work compared with current treatments available in Scotland and in relation to how much they will cost to buy and administer (for example, if the medicine has to be given at a clinic or side effects have to be monitored).

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. 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.

To do this SMC consider the following:

- Clinical trial and economic evidence from the company that makes the medicine.
- 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.
- Information from patient groups about the potential impact of the medicine on patients and carers.

After careful consideration, SMC decided the evidence from the company was not strong enough to be certain that prolonged-release melatonin offers value for money to NHSScotland.

What does SMC's decision mean for me?

Prolonged-release melatonin should not normally be prescribed on the NHS in Scotland for use as described above. Your healthcare professional should talk to you about other treatment options available to you/your child. If he or she believes that prolonged-release melatonin would be of benefit, he or she can make a request to prescribe it for you/your child. 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



More information

The organisation below can provide more information and support for people with Smith-Magenis Syndrome. SMC is not responsible for the content of any information provided by external organisations.

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>

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