



**Final Appraisal Recommendation**  
Advice No: 0321 – March 2021

**Melatonin (Slenyto<sup>®</sup>) 1 mg and 5 mg prolonged-release tablets**

**Resubmission by Flynn Pharma Ltd**

**Recommendation of AWMSG**

**Melatonin (Slenyto<sup>®</sup>) is recommended as an option for use within NHS Wales for the treatment of insomnia in children and adolescents aged 2 to 18 years with autism spectrum disorder and/or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient.**

**This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.**

**Additional note:**

- This advice replaces the previous AWMSG recommendation for melatonin (Slenyto<sup>®</sup>) (AWTTC advice number 1519, published November 2019).

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 4694), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.

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All Wales Medicines Strategy Group Final Appraisal Recommendation – 0321:  
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