30 January 2025
EMA/CHMP/35017/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Slenyto

melatonin

On 30 January 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Slenyto. The marketing authorisation holder for this medicinal product is RAD Neurim Pharmaceuticals EEC SARL.

The CHMP adopted a new indication to include treatment of insomnia in children and adolescents aged 6-17 years with attention-deficit hyperactivity disorder (ADHD). For information, the full indications for Slenyto will be as follows:[2]

Slenyto is indicated for:

- treatment of insomnia in children and adolescents aged 2-18 with Autism Spectrum Disorder (ASD), and / or neurogenetic disorders with aberrant diurnal melatonin secretion and /or nocturnal awakenings, where sleep hygiene measures have been insufficient.
- **treatment of insomnia in children and adolescents aged 6-17 years with attention-deficit hyperactivity disorder (ADHD) where sleep hygiene measures have been insufficient.**

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR) and made available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold

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