25 July 2024
EMA/CHMP/321012/2024
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (post authorisation)**

# Slenyto

melatonin

On 25 July 2024, 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 an extension to the existing indication as follows:[2]

> Slenyto is indicated for the treatment of insomnia in children and adolescents aged 2-18 with Autism Spectrum Disorder (ASD) **and / or** ~~Smith-Magenis syndrome~~ **neurogenetic disorders with aberrant diurnal melatonin secretion and /or nocturnal awakenings,** where sleep hygiene measures have been insufficient.

For information, the full indication for Slenyto will be as follows:

> Slenyto is indicated for the 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.

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, removed text as strikethrough

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