26 July 2018
EMA/CHMP/491031/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Slenyto

melatonin

On 26 July 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Slenyto, intended for the treatment of insomnia in children and adolescents with autism spectrum disorder (ASD) or Smith-Magenis syndrome. The applicant for this medicinal product is RAD Neurim Pharmaceuticals EEC Ltd.

Slenyto will be available as 1-mg and 5-mg prolonged-release tablets. The active substance of Slenyto is melatonin (ATC code: N05CH01), which promotes sleep by activation of melatonin receptors.

The benefits with Slenyto are its ability to increase sleep duration. The most common side effects are somnolence, fatigue and mood swings.

The full indication is: "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, where sleep hygiene measures have been insufficient."

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after 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

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