15 September 2022
EMA/CHMP/734993/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Melatonin Neurim

melatonin

On 15 September 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Melatonin Neurim, intended for the treatment of insomnia. The applicant for this medicinal product is RAD Neurim Pharmaceuticals EEC SARL.

Melatonin Neurim will be available as a 2 mg prolonged-release tablet. The active substance of Melatonin Neurim is melatonin, a psycholeptic (ATC code: N05CH01). Melatonin is a naturally occurring hormone associated with the control of circadian rhythms and entrainment to the light-dark cycle. It is also associated with a hypnotic effect and increased propensity for sleep.

The benefits of Melatonin Neurim are improvements in sleep latency, quality of sleep and morning alertness, as measured in randomised, placebo-controlled trials. The most common side effects are headache, nasopharyngitis, back pain and arthralgia.

The application for Melatonin Neurim was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Melatonin Neurim is Circadin.

The full indication is:

> Melatonin Neurim is indicated as monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over.

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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