



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

23 April 2015  
EMA/CHMP/239154/2015  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Hetlioz tasimelteon

On 23 April 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Hetlioz, intended for the treatment of non-24-hour sleep-wake disorder in totally blind adults. Hetlioz was designated as an orphan medicinal product on 23 February 2011. The applicant for this medicinal product is Vanda Pharmaceuticals Ltd.

Hetlioz will be available as 20 mg hard capsules. The active substance of Hetlioz is tasimelteon, a psycholeptic (ATC code: N05CH03). Tasimelteon is a melatonin receptor agonist and acts as a circadian regulator that resets the master body clock in the suprachiasmatic nucleus.

The benefit with Hetlioz is its ability to entrain the master body clock in patients with non-24-hour sleep-wake disorder. The most common side effects are headache, somnolence, and nightmares or unusual dreams.

The full indication is: "Hetlioz is indicated for the treatment of non-24-hour sleep-wake disorder (non-24) in totally blind adults".

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.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

