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# EMA recommends authorisation of Melatomed (melatonin, prolonged-release tablets) in the EU

On 11 December 2025, the European Medicines Agency completed a review of Melatomed following a disagreement among EU Member States regarding its authorisation. The Agency concluded that the benefits of Melatomed outweigh its risks, and that the marketing authorisation can be granted in Germany and in the following Member States of the EU where the company has applied for a marketing authorisation: Austria, Denmark and Sweden.

## What is Melatomed?

Melatomed contains the active substance melatonin which belongs to a group of naturally occurring hormones produced by the body. Melatonin is involved in coordinating the body's sleep cycle by acting on cells in specific areas of the brain and helping to bring about sleep.

Melatomed is available as prolonged-release tablets taken by mouth; prolonged-release means that melatonin is released slowly from the tablet over a few hours. The medicine is intended for the short-term treatment of primary insomnia (poor quality of sleep) in people aged 55 years or over. Primary means that the insomnia does not have any identified cause, including any medical, mental or environmental cause.

Melatomed was developed as a generic medicine. This means that Melatomed was developed to contain the same active substance and work in the same way as a 'reference medicine' already authorised in the EU called Circadin.

## Why was Melatomed reviewed?

Fairmed Healthcare GmbH submitted Melatomed to Germany for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance Germany) assesses a medicine with a view to granting a marketing authorisation that will be valid in this country as well as in other Member States (the 'concerned Member States', in this instance Austria, Denmark and Sweden) where the company has applied for a marketing authorisation.

However, the Member States were not able to reach an agreement, and the German medicines agency referred the matter to EMA for arbitration on 07 October 2025.

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The grounds for the referral were concerns raised by the Swedish medicines agency that the data provided by the company did not show that Melatomed is bioequivalent to the reference medicine. Two medicines are considered bioequivalent if the active substances from both medicines are absorbed in the body at the same rate and to the same extent.

As Melatomed is a prolonged-release formulation, the company provided data from two studies, after a single dose of the medicine, one on an empty stomach (fasting) and one after eating. The studies measured how much of the medicine is absorbed in the body over time (based on the area under the curve [AUC] measurement). The Member States looked at the AUC over two different time intervals, including one spanning the first 0 to 3 hours (3.5 hours when taken with food) of taking a single dose and another spanning a longer period after these first few hours (up to 12 or 24 hours of taking the dose). When taken with food, the AUC for the later time intervals was outside the range necessary to show bioequivalence with the reference medicine, although the results from the other time intervals and all the time intervals in the fasting study did meet the criteria for bioequivalence. Based on this, the Swedish medicines agency had concerns that Melatomed may not have the same efficacy and safety as the reference medicine.

## What is the outcome of the review?

Overall, the Agency concluded that the totality of the data provided by the company, including other relevant measures on the amount of the medicine absorbed in the body, was sufficient to demonstrate that Melatomed is bioequivalent to the reference medicine. Melatonin is a naturally occurring hormone whose levels are controlled by the body's natural daily cycle, so they can rise and fall within the same person throughout the day. Although when taken with food, the AUC for the later stage of the dosing interval was outside the range considered acceptable for bioequivalence, it was considered that this was due to variability in each person's daily measurements. The studies were not originally designed to show bioequivalence for the AUCs divided into two intervals, resulting in too few subjects included in the studies to account for the variability (meaning how much a participants AUC levels changed across different time intervals).

The Agency therefore concluded that the benefits of Melatomed outweigh its risks and recommended that the marketing authorisation be granted in the concerned Member States.

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**More about the procedure**

The review started in October 2025. It was initiated at the request of Germany under Article 29(4) of Directive 2001/83/EC.

The review was carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), which is responsible for questions concerning medicines for human use.

A European Commission decision valid throughout the EU will be issued in due course.