

Summary Public Assessment Report

Melatonin Aspire (melatonin)

SE/H/2543/01/DC

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Melatonin Aspire
melatonin

Oral solution, 1 mg/ml

This is a summary of the public assessment report (PAR) for Melatonin Aspire. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Melatonin Aspire and what is it used for?

The product is a medicine with 'well-established use'. This means that the medicinal use of the active substance of the product is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Melatonin Aspire is used for:

- Short-term treatment of jet lag in adults. Jet lag refers to the symptoms caused by the time difference when travelling through several time zones.
- Sleep onset insomnia in children and adolescents (6 to 17 years old) with ADHD, where other healthy sleeping routines have not worked well enough.

How does Melatonin Aspire work?

This medicine contains the active substance melatonin. Melatonin is a hormone produced by the body that synchronizes the body's biological day-and-night rhythm.

How is Melatonin Aspire used?

The pharmaceutical form is solution for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Melatonin Aspire have been shown in studies?

As melatonin is a well-known substance, and its use in the treatment of short-term treatment of jetlag in adults and treatment of insomnia in children and adolescents aged 6 - 17 years with ADHD is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of melatonin in the treatment of the above-mentioned indication.

What are the possible side effects from Melatonin Aspire?

For the full list of side effects, see section 4 of the package leaflet.

Why is Melatonin Aspire approved?

The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Melatonin Aspire?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and

the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

The applicant commits to provide updated data to support WEU of the two referenced indications via a post-approval variation application. For more details, please see the full PAR for Melatonin Aspire on the following website: [MRI - Home](#).

Other information about Melatonin Aspire

The full PAR for Melatonin Aspire can be found on the following website: [MRI - Home](#). For more information about treatment with Melatonin Aspire, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-06.