

Summary Public Assessment Report

Melatonin AGB melatonin

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Melatonin AGB
melatonin

Tablet, 1 mg, 2 mg, 3 mg, 4 mg, 5 mg

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

For practical information about using Melatonin AGB, patients should read the package leaflet or contact their doctor or pharmacist.

What is Melatonin AGB and what is it used for?

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

Melatonin AGB is used in the treatment of:

- short-term treatment of jet lag in adults. Jet lag refers to the symptoms caused by the time difference when traveling across several time zones.
- Insomnia in children and adolescents (6 to 17 years old) with ADHD, where other healthy sleeping routines has not worked well enough.

How does Melatonin AGB work?

The active substance of Melatonin AGB, melatonin, belongs to a group of natural hormones produced by the body. The hormone helps regulate the body’s day- and night rhythm.

How is Melatonin AGB used?

The pharmaceutical form of Melatonin AGB is tablets 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 AGB have been shown in studies?

As melatonin is a well-known substance, and its use in the short-term treatment of jet lag as well as in the treatment of insomnia in children and adolescents (6 to 17 years old) with ADHD, where other healthy sleeping routines has not worked well enough, 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 in the short-term treatment of jet lag and in the treatment of insomnia in children and adolescents aged 6-17 years with ADHD, where sleep hygiene measures have been insufficient.

What are the possible side effects of Melatonin AGB?

For the full list of all side effects reported with Melatonin AGB, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Melatonin AGB approved?

The use of Melatonin AGB in the treatment of in the short-term treatment of jet lag as well as in the treatment of insomnia in children and adolescents (6 to 17 years old) with ADHD, where other healthy sleeping routines has not worked well enough is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Melatonin AGB's benefits are greater than its risks and recommended that it be approved for use.

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

A risk management plan has been developed to ensure that Melatonin AGB 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 for Melatonin AGB, 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 has also committed to perform a post authorization safety study (PASS) on long-term safety in prepubertal and pubertal children.

Other information about Melatonin AGB

The full PAR for Melatonin AGB can be found on the following website:
<http://mri.medagencies.org/Human/>. For more information about treatment with Melatonin AGB, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2020-09.