LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Aritonin
(melatonin)

SE/H/2638/001-004/MR

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melatonin

Film-coated tablet, 2 mg, 3 mg, 4 mg, 5 mg

This is a summary of the public assessment report (PAR) for Aritonin. 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 Aritonin 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.

The product is used for:

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

How does Aritonin work?
The active substance in Aritonin, 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 Aritonin used?
The pharmaceutical form is film-coated tablet 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.

A prescription might be needed for this medicine in Sweden.

What benefits of Aritonin have been shown in studies?
As melatonin is a well-known substance, and its use in the approved indications (see What is Aritonin and what is it used for?), 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 Aritonin?
For the full list of side effects, see section 4 of the package leaflet.

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

Why is Aritonin 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 Aritonin?
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.

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

This summary was last updated in 2025-01.