LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Pinealin
(melatonin)

SE/H/2311/01-06/DC

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Summary Public Assessment Report

Pinealin
melatonin

Tablet, 0,5 mg, 1 mg, 2 mg, 3 mg, 4 mg, 5 mg

This is a summary of the public assessment report (PAR) for Pinealin. 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 Pinealin 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 in the treatment of:
- 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 attention deficit hyperactivity disorder (ADHD), where other healthy sleeping routines have not worked well enough.

How does Pinealin work?

The active substance of Pinealin, 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 Pinealin used?

The pharmaceutical form 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 Pinealin have been shown in studies?

As *melatonin* is a well-known substance, and its use in the treatment of
- Short term treatment of jet lag in adults.
- Insomnia in children and adolescents aged 6-17 years with attention deficit hyperactivity disorder (ADHD), where sleep hygiene measures have been insufficient.

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 Pinealin?

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 Pinealin 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 Pinealin?

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 Pinealin

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

This summary was last updated in 2024-01.