

Summary Public Assessment Report

Melatonin Unimedic Pharma (melatonin)

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melatonin

Oral solution, 1 mg/ml

This is a summary of the public assessment report (PAR) for Melatonin Unimedic Pharma. It explains how Melatonin Unimedic Pharma 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 Unimedic Pharma.

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

What is Melatonin Unimedic Pharma and what is it used for?

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

Melatonin Unimedic Pharma can be used for:

- 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 (6-17 years of age) with attention deficit hyperactivity disorder (ADHD) where healthy sleeping routines has not worked well enough.

How does Melatonin Unimedic Pharma work?

Melatonin Unimedic Pharma contains the active substance melatonin, which is a hormone produced naturally by the body. The hormone helps regulate the body’s day- and night rhythm.

How is Melatonin Unimedic Pharma used?

The pharmaceutical form of Melatonin Unimedic Pharma is oral 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.

A prescription might be needed for this medicine in Sweden.

What benefits of Melatonin Unimedic Pharma 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 as well as insomnia in children and adolescents (6-17 years of age) with attention deficit hyperactivity disorder (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:

- Short-term treatment of jet lag in adults.
The medicinal product is recommended to adult travellers flying across ≥ 5 time zones, particularly in an easterly direction, and especially if they have experienced jet lag symptoms on previous journeys. Travellers crossing 2-4 time zones can also use it if need be.
- 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 Unimedic Pharma?

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

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

Why is Melatonin Unimedic Pharma approved?

The use of Melatonin Unimedic Pharma in the treatment of short-term treatment of jet lag in adults as well as insomnia in children and adolescents (6-17 years of age) with attention deficit hyperactivity disorder (ADHD) 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 Unimedic Pharma'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 Unimedic Pharma?

A risk management plan has been developed to ensure that Melatonin Unimedic Pharma 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 Unimedic Pharma, 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 Melatonin Unimedic Pharma

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

This summary was last updated in 2022-12.