LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Voquily
(melatonin)

SE/H/1995/01/DC

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Summary Public Assessment Report

Voquily
melatonin

Oral solution, 1 mg/ml

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

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

What is Voquily and what is it used for?

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

Voquily is used in the treatment of:

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

How does Voquily work?

Voquily contains the active substance melatonin, which is a hormone produced naturally by the body. This hormone helps regulate the body's day- and night rhythm.

How is Voquily used?

The pharmaceutical form of Voquily is oral solution.

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 Voquily have been shown in studies?

As melatonin is a well-known substance, and its use in the treatment mentioned above (please see section "What is Voquily 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 above-mentioned treatment.

What are the possible side effects from Voquily?

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 Voquily approved?

The Swedish Medical Products Agency decided that Voquily's 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 Voquily?

A risk management plan has been developed to ensure that Voquily 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 Voquily, 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 Voquily

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

This summary was last updated in 2022-06.