LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Meladura
(melatonin)

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melatonin

Prolonged-release tablet, 2 mg

This is a summary of the public assessment report (PAR) for Meladura. 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 Meladura and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Circadin.

Meladura is used on its own for the short-term treatment of primary insomnia (persistent difficulty in getting to sleep or staying asleep, or poor quality of sleep) in patients aged 55 years and older. 'Primary' means that the insomnia does not have any identified cause, including any medical, mental or environmental cause.

How does Meladura work?

The active substance of Meladura is melatonin and it belongs to a natural group of hormones produced by the body. Physiologically, melatonin secretion increases soon after the onset of darkness, peaks at 2-4 am and diminishes during the second half of the night. Melatonin is associated with the control of circadian rhythm and is of importance in the light-dark cycle. It is also associated with a hypnotic effect and increased natural tendency for sleep.

How is Meladura used?

The pharmaceutical form is prolonged-release 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.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Meladura have been shown in studies?

Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Circadin. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Meladura?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

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 Meladura approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Circadin, 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 Meladura?

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 Meladura

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

This summary was last updated in 2024-09.