LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Zopiclone Grindeks
(zopiclone)

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zopiclone

film-coated tablet, 3.75 mg, 5 mg, 7.5 mg

This is a summary of the public assessment report (PAR) for Zopiclone Grindeks. 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 Zopiclone Grindeks 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 Imovane.

The product is a sleeping tablet with zopiclone as active substance. It is used in adults for various kinds of sleeping problems, e.g., difficulty falling asleep, waking up too early or too many night awakenings. It is used for short-term sleep disorders.

The product will only be prescribed if the sleeping problem is severe, disabling or causing extreme distress if not medicated.

How does Zopiclone Grindeks work?

Zopiclone is a benzodiazepine-like hypnotic agent which belongs to the group of medicines called cyclopyrrolones. Its pharmacological properties are e.g. hypnosis, sedation and muscle relaxation. Zopiclone increases the normal transmission of the neurotransmitter GABA in the central nervous system. It has a rapid onset of action (within about 30 minutes), prolongs sleep duration and reduces the number of awakenings during the night. The amount of REM (rapid eye movement) sleep and deep sleep (stages III and IV) is maintained at the recommended dose.

How is Zopiclone Grindeks 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.

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

What benefits of Zopiclone Grindeks 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, Imovane. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Zopiclone Grindeks?

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 Zopiclone Grindeks approved?

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

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 Zopiclone Grindeks

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

This summary was last updated in 2024-12.