LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Zopiclone Orion
(zopiclone)

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Film-coated tablet; 3.75 mg, 7.5 mg

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

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

What is Zopiclone Orion and what is it used for?

Zopiclone Orion 7.5 mg is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) containing the same active substance.
Zopiclone Orion 3.75 mg is a 'hybrid medicine'. This means that it is also similar to a 'reference medicine' already authorised in the European Union (EU) containing the same active substance, but available in a different strength.
The reference medicine for both strengths of Zopiclone Orion is Imovane.

Zopiclone Orion is used as treatment of transient and short-term insomnia and, for a limited time, chronic insomnia. It is used in adults as a sleeping drug for various kinds of sleeping problems, e.g. difficulty falling asleep, waking up too early or too many nightly awakenings.

How does Zopiclone Orion work?

Zopiclone Orion is a sleeping tablet with zopiclone as active substance. It is sedative, reduces anxiety and relaxes muscles.

How is Zopiclone Orion used?

The pharmaceutical form of Zopiclone Orion is film-coated 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.

What benefits of Zopiclone Orion have been shown in studies?

Because Zopiclone Orion is a generic/hybrid 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 of Zopiclone Orion?

Because Zopiclone Orion is a generic/hybrid medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Zopiclone Orion approved?

It was concluded that, in accordance with EU requirements, Zopiclone Orion has been shown to have comparable quality and to be bioequivalent to the reference medicine Imovane. Therefore, the Medical Products Agency in Sweden 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 Orion?

A risk management plan has been developed to ensure that Zopiclone Orion 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 Zopiclone Orion, 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 Orion

The marketing authorisation for Zopiclone Orion was granted on 2017-01-13 in Sweden.

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

This summary was last updated in 2017-01.