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Melatonin Neurim (*melatonin*)

An overview of Melatonin Neurim and why it is authorised in the EU

What is Melatonin Neurim and what is it used for?

Melatonin Neurim is a medicine used on its own for the short-term treatment of primary insomnia (poor quality of sleep) in patients aged 55 years or over. 'Primary' means that the insomnia does not have any identified cause, including any medical, mental or environmental cause.

Melatonin Neurim contains the active substance melatonin.

This medicine is the same as Circadin, which is already authorised in the EU. The company that makes Circadin has agreed that its scientific data can be used for Melatonin Neurim ('informed consent').

How is Melatonin Neurim used?

Melatonin Neurim can only be obtained with a prescription.

It is available as tablets; the recommended dose is one tablet a day, taken one to two hours before bedtime and after food. This dose can be continued for up to 13 weeks.

For more information about using Melatonin Neurim, see the package leaflet or contact your doctor or pharmacist.

How does Melatonin Neurim work?

The active substance in Melatonin Neurim, melatonin, is a naturally occurring hormone, which is involved in coordinating the body's sleep cycle. Melatonin levels in the blood normally increase when it gets dark and peak in the middle of the night. Older people may produce less melatonin, leading to the development of insomnia. Melatonin Neurim increases their blood levels of melatonin, helping them to sleep. The active substance in Melatonin Neurim is released slowly over a few hours (prolonged-release tablets) which mimics the natural production of melatonin in the body.

What benefits of Melatonin Neurim have been shown in studies?

Melatonin Neurim was more effective than placebo (a dummy treatment) at improving quality of sleep and the patients' ability to function normally on the following day in three main studies involving a total of 681 patients aged over 55 years with primary insomnia. The patients assessed the severity of

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their symptoms using a standard questionnaire after three weeks of treatment. When the results of all three studies were looked at together, 32% of the patients taking Melatonin Neurim (86 out of 265) reported a significant improvement in symptoms after three weeks, compared with 19% of those taking placebo (51 out of 272).

An additional study showed that Melatonin Neurim was more effective than placebo for at least 13 weeks.

What are the risks associated with Melatonin Neurim?

The most common side effects with Melatonin Neurim (which may affect up to 1 in 100 people) include headache, nasopharyngitis (inflammation of the nose and throat), back pain and arthralgia (joint pain). These side effects were also common in those taking placebo.

For the full list of side effects and restrictions of Melatonin Neurim, see the package leaflet.

Why is Melatonin Neurim authorised in the EU?

The European Medicines Agency decided that the benefits of Melatonin Neurim are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Melatonin Neurim?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Melatonin Neurim have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Melatonin Neurim are continuously monitored. Suspected side effects reported with Melatonin Neurim are carefully evaluated and any necessary action taken to protect patients.

Other information about Melatonin Neurim

Melatonin Neurim received a marketing authorisation valid throughout the EU on 7 November 2022.

Further information on Melatonin Neurim can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/melatonin-neurim.

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