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EPAR summary for the public

Hetlioz

tasimelteon

This is a summary of the European public assessment report (EPAR) for Hetlioz. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Hetlioz.

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

What is Hetlioz and what is it used for?

Hetlioz is a medicine used to treat totally blind adults with non-24-hour sleep-wake disorder. Non-24-hour sleep-wake disorder is a condition that occurs almost exclusively in people who are completely blind, where patients have sleep patterns that are not synchronised with day and night and often follow a cycle that is longer than the standard 24-hour clock. As a result, patients fall asleep and wake up at unusual times.

Hetlioz contains the active substance tasimelteon.

Because the number of patients with non-24-hour sleep-wake disorder is low, the disease is considered 'rare', and Hetlioz was designated an 'orphan medicine' (a medicine used in rare diseases) on 23 February 2011.

How is Hetlioz used?

Hetlioz is available as 20 mg capsules and can only be obtained with a prescription.

Hetlioz is intended for long-term use. The recommended dose is one capsule per day, taken one hour before bedtime, at the same time every night. The medicine should be taken without food.

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How does Hetlioz work?

A hormone called melatonin plays a key role in co-ordinating the body's sleep-wake cycle. In people with normal perception of light and dark, melatonin is produced in hours of darkness and promotes sleep by acting on melatonin receptors in specific areas of the brain. The active substance in Hetlioz, tasimelteon, acts on the same receptors as melatonin to promote sleep and regulate sleep patterns. By taking it at a suitable time each day it can help to reset the sleep-wake cycle to more standard timing.

What benefits of Hetlioz have been shown in studies?

Hetlioz has been shown to be effective at helping patients adjust to the standard 24-hour clock in 2 main studies.

The first study, which involved a total of 84 totally blind patients with non-24-hour sleep-wake disorder, compared Hetlioz with placebo (a dummy treatment). The main measure of effectiveness was the percentage of patients who were able to adjust to the 24-hour clock, which was calculated by looking at how the amount of melatonin breakdown products changed in the patient's urine over time. 20% of patients who received Hetlioz (8 out of 40) were able to adjust to the 24-hour clock after 1 months of treatment, compared with around 3% of patients on placebo (1 out of 38). Improved results were seen in a subset of patients after 7 months of treatment, which indicate that patients may take weeks or months to respond.

In the second study, 57 patients first received Hetlioz for around 11 weeks. Those patients who were able to adjust to the 24-hour clock (20 patients in total) were then given Hetlioz or placebo for a further 8 weeks to study how well the effect of Hetlioz was maintained. Of the 10 patients who remained on Hetlioz, 9 people remained adjusted to 24-hour clock at the end of the study, compared with 2 of the 10 patients who were switched to placebo.

What are the risks associated with Hetlioz?

The most common side effects with Hetlioz (which may affect more than 3 in 100 people) are headache, somnolence, nausea (feeling sick) and dizziness. These are usually mild or moderate in severity and temporary.

For the full list of all side effects and restrictions with Hetlioz, see the package leaflet.

Why is Hetlioz approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Hetlioz's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP noted that only around 20% of patients would be able to benefit from treatment with Hetlioz, but in view of the lack of approved treatments for non-24-hour sleep-wake disorder, which is a debilitating condition, this modest response was still considered important. However, continued treatment would be necessary to maintain the beneficial effects. Regarding safety, Hetlioz was shown to be well tolerated, causing only few mild side effects.

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

A risk management plan has been developed to ensure that Hetlioz 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 Hetlioz, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Hetlioz

The European Commission granted a marketing authorisation valid throughout the European Union for Hetlioz on 3 July 2015.

The full EPAR and risk management plan summary for Hetlioz can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Hetlioz, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Hetlioz can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 07-2015.