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EPAR summary for the public

Wakix

pitolisant

This is a summary of the European public assessment report (EPAR) for Wakix. 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 Wakix.

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

What is Wakix and what is it used for?

Wakix is a medicine used to treat adults with narcolepsy. Narcolepsy is a long-term sleep disorder which affects the brain's ability to regulate the normal sleep-wake cycle. This leads to symptoms such as an irresistible urge to sleep, even at inappropriate times and places, and disturbed night-time sleep. Some patients also have episodes of severe muscle weakness (cataplexy) that can cause collapse. Wakix is used in patients with or without cataplexy.

Wakix contains the active substance pitolisant. Because the number of patients with narcolepsy is low, the disease is considered 'rare', and Wakix was designated an 'orphan medicine' (a medicine used in rare diseases) on 10 July 2007.

How is Wakix used?

Wakix can only be obtained with a prescription and treatment should be started by a doctor experienced in the treatment of sleep disorders.

Wakix is available as tablets (4.5 and 18 mg). During the first week of treatment, the recommended dose is 9 mg per day, taken in the morning during breakfast. During the second week of treatment, the dose can be increased to 18 mg per day or decreased to 4.5 mg per day. During the third week,

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the dose may be further increased to the maximum dose of 36 mg per day. Wakix should always be used at the lowest effective dose.

In patients with moderately reduced liver function or with kidney problems, the maximum dose should be 18 mg per day.

For more information, see the package leaflet.

How does Wakix work?

The active substance in Wakix, pitolisant, works by attaching to receptors in the brain called 'histamine H3 receptors'. This increases the activity of certain brain cells called 'histamine neurons', which are important for keeping the body awake.

What benefits of Wakix have been shown in studies?

Wakix has been investigated in 2 main studies involving a total of 261 adults with narcolepsy, the majority of whom also had cataplexy. The studies compared Wakix with placebo (a dummy treatment). The main measure of effectiveness was based on how sleepy patients felt during daytime, assessed using the Epworth Sleepiness Scale or ESS. This is a standard scale used in patients with narcolepsy which ranges from 0 to 24.

The first study showed that Wakix was more effective than placebo at reducing daytime sleepiness: patients taking Wakix had an average reduction of 3 points more in the ESS scale than those taking placebo after 8 weeks of treatment. Results from this study also showed a decrease in the number of cataplexy attacks. The second study, however, did not show a difference between Wakix and placebo at reducing sleepiness or cataplexy.

When looking at sleepiness with an objective test called Maintenance of Wakefulness Test or MWT, the results of the two studies together showed that Wakix significantly improved wakefulness compared with placebo.

In a further study in 105 patients with narcolepsy and cataplexy, Wakix was also more effective than placebo at reducing the number of cataplexy attacks per week: the number of cataplexy attacks decreased from around 9 to around 3 per week in patients taking Wakix, while it remained at around 7 per week in patients taking placebo.

What are the risks associated with Wakix?

The most common side effects with Wakix (which may affect up to 1 in 10 people) are insomnia (difficulty sleeping), headache, nausea (feeling sick), anxiety, irritability, dizziness, depression, tremor, sleep disorders, tiredness, vomiting, vertigo (a spinning sensation) and dyspepsia (heartburn). Serious but rare side effects are abnormal loss of weight and spontaneous abortion. For the full list of all side effects reported with Wakix, see the package leaflet.

Wakix must not be used in patients with severely reduced liver function and in women who are breastfeeding. For the full list of restrictions, see the package leaflet.

Why is Wakix approved?

The overall data available demonstrate that Wakix has a positive effect on the two major symptoms of narcolepsy, excessive daytime sleepiness and cataplexy. In addition, Wakix works differently from currently available treatments and therefore offers an alternative treatment option. The safety profile of Wakix is considered acceptable, with no major safety concerns identified.

The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore decided that Wakix's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

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

In addition, the company that markets Wakix will carry out an observational study to collect information on the safety of the medicine when used in medical practice.

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

Other information about Wakix

The European Commission granted a marketing authorisation valid throughout the European Union for Wakix on 31 March 2016.

The full EPAR and risk management plan summary for Wakix 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 Wakix, 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 Wakix can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 03-2016.