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# Ozawade (*pitolisant*)

An overview of Ozawade and why it is authorised in the EU

## What is Ozawade and what is it used for?

Ozawade is a medicine used to improve wakefulness and reduce excessive daytime sleepiness in adults with obstructive sleep apnoea.

Obstructive sleep apnoea is the repeated interruption of breathing during sleep due to airways becoming blocked. Ozawade is used when other treatments, such as continuous positive airway pressure (CPAP, use of a ventilator to keep the airways open) have not satisfactorily improved excessive daytime sleepiness or cannot be tolerated by the patient.

Ozawade contains the active substance pitolisant.

## How is Ozawade used?

Ozawade can only be obtained with a prescription. Treatment should be started by a healthcare professional experienced in the treatment of obstructive sleep apnoea and in the management of risks associated with cardiovascular disease (affecting the heart and blood circulation).

Ozawade is available as tablets to be taken once a day in the morning with food. The starting dose is 4.5 mg once a day. Depending on how well the medicine works, the dose may be increased weekly, up to a maximum of 18 mg once a day by week three. Ozawade should always be used at the lowest effective dose.

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

## How does Ozawade work?

The active substance in Ozawade, pitolisant, works by attaching to receptors (targets) 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. Pitolisant also increases levels of the neurotransmitters acetylcholine, dopamine and noradrenaline in the brain. Neurotransmitters are chemical messengers that allow nerve cells to communicate with each other. Since these neurotransmitters are involved in maintaining alertness and arousal, increasing their levels may improve wakefulness.

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## What benefits of Ozawade have been shown in studies?

Ozawade has been found to improve excessive daytime sleepiness in adults with obstructive sleep apnoea in two main studies.

The first study involved 244 patients with obstructive sleep apnoea who were receiving CPAP therapy, but whose excessive daytime sleepiness had not improved satisfactorily. Patients received either Ozawade or placebo (a dummy treatment) in addition to CPAP therapy and excessive daytime sleepiness was measured using a standard daytime sleepiness scale called the Epworth sleepiness scale. After 12 weeks of treatment, daytime sleepiness was reduced by an average of 5.5 points on the Epworth sleepiness scale in patients receiving Ozawade and 2.8 points in those receiving placebo.

The second study, involving 268 patients who could not tolerate or refused CPAP therapy, found that patients receiving Ozawade had an average reduction in daytime sleepiness of 6.3 points on the Epworth sleepiness scale after 12 weeks, compared with 3.6 points in those receiving placebo.

## What are the risks associated with Ozawade?

The most common side effect with Ozawade (which may affect more than 1 in 10 people) is headache. Common side effects (which may affect up to 1 in 10 people) are insomnia (difficulty sleeping), nausea (feeling sick), anxiety, abdominal (belly) pain, vertigo (a spinning sensation) and diarrhoea.

For the full list of side effects of Ozawade, see the package leaflet.

Ozawade must not be used by people who have severely reduced liver function or by women who are breastfeeding.

For the full list of restrictions, see the package leaflet.

## Why is Ozawade authorised in the EU?

Ozawade was shown to improve excessive daytime sleepiness in people with obstructive sleep apnoea, both in those receiving CPAP and in those in whom CPAP did not work well enough or was not tolerated. The side effects of the medicine were mostly mild or moderate. The European Medicines Agency therefore decided that Ozawade's benefits 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 Ozawade?

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

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

## Other information about Ozawade

Ozawade received a marketing authorisation valid throughout the EU on 1 September 2021.

Further information on Ozawade can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ozawade.

This overview was last updated in 09-2021.