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Sunosi (*solriamfetol*)

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

What is Sunosi and what is it used for?

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

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. Sunosi is used in patients with or without cataplexy (episodes of severe muscle weakness that can cause collapse).

Obstructive sleep apnoea is repeated interruption of breathing during sleep due to airways becoming blocked. Sunosi 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 the excessive daytime sleepiness.

Sunosi contains the active substance solriamfetol.

How is Sunosi used?

Sunosi can only be obtained with a prescription and treatment should be started by a healthcare professional experienced in treatment of narcolepsy or obstructive sleep apnoea.

Sunosi is available as tablets. The medicine should be taken once a day on waking up and the usual starting dose is 75 mg for narcolepsy or 37.5 mg for obstructive sleep apnoea. Depending on how well the medicine works, the dose may be increased up to a maximum of 150 mg once a day.

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

How does Sunosi work?

Although the way in which the active substance in Sunosi, solriamfetol, works is not fully understood, it is thought to act by increasing the levels of dopamine and noradrenaline in the brain. Dopamine and noradrenaline are neurotransmitters (chemical messengers) that carry signals between brain cells, including those that promote wakefulness.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What benefits of Sunosi have been shown in studies?

Sunosi has been investigated in 2 main studies where it was compared with placebo (a dummy treatment). The main measures of effectiveness were the score on the Epworth sleepiness scale (a standard scale measuring daytime sleepiness ranging from 0 to 24) and the length of time the patient could stay awake in a test called the maintenance of wakefulness test.

In the first study involving 239 adults with narcolepsy, after 12 weeks of treatment, patients taking 75 mg Sunosi had an improvement of around 2.2 points on the Epworth sleepiness scale compared with placebo and patients taking 150 mg had an improvement of 3.8 points. In the maintenance of wakefulness test, patients taking 75 mg Sunosi did not have a significant improvement, while patients taking 150 mg could stay awake for 9.8 minutes longer than they could before treatment started, compared with 2.1 minutes longer for patients on placebo.

In the second study involving 476 adults with obstructive sleep apnoea, after 12 weeks of treatment, patients taking 37.5 mg, 75 mg or 150 mg Sunosi had an improvement of 1.9, 1.7 or 4.5 points, respectively, on the Epworth sleepiness scale compared with placebo. In the maintenance of wakefulness test, patients taking 37.5 mg, 75 mg or 150 mg Sunosi could stay awake for 4.7, 9.1, and 11 minutes longer, respectively, than they could before treatment started, compared with 0.2 minutes longer for patients on placebo.

What are the risks associated with Sunosi?

The most common side effect with Sunosi, which may affect more than 1 in 10 people, is headache. Common side effects, which may affect up to 1 in 10 people, are decreased appetite, anxiety, insomnia (difficulty sleeping), irritability, bruxism (teeth grinding), dizziness, palpitations (a forceful heartbeat that may be rapid or irregular), cough, nausea (feeling sick), diarrhoea, dry mouth, abdominal pain (belly ache), constipation, vomiting, hyperhidrosis (excessive sweating), feeling jittery, chest discomfort and increased blood pressure.

Sunosi must not be used in patients who have uncontrolled hypertension (high blood pressure) or serious heart problems including heart attack in the past year, unstable angina pectoris (chest pain caused by interruptions in blood supply to the heart, that may occur at rest or without an obvious trigger) and serious cardiac arrhythmias (abnormal or irregular heartbeat). It must not be taken at the same time as certain medicines called monoamine oxidase inhibitors (MAOIs) or within 2 weeks of stopping these medicines.

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

Why is Sunosi authorised in the EU?

Sunosi was shown to reduce excessive daytime sleepiness in patients with narcolepsy and obstructive sleep apnoea. The safety profile was as expected for this type of medicine. Because the medicine could cause a harmful rise in blood pressure, patients should be monitored before and during treatment. The European Medicines Agency decided that Sunosi'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 Sunosi?

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

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

Other information about Sunosi

Sunosi received a marketing authorisation valid throughout the EU on 16 January 2020.

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

This overview was last updated in 01-2020.