European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

ZERENE

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Zerene?
Zerene is a medicine that contains the active substance zaleplon. It is available as capsules (white and brown: 5 mg; white: 10 mg).

What is Zerene used for?
Zerene is used for the treatment of adults with insomnia who have difficulty falling asleep. It is used only when the insomnia is severe, disabling or causing extreme distress.
The medicine can only be obtained with a prescription.

How is Zerene used?
Treatment with Zerene should be as short as possible and should last for no more than two weeks. Zerene is taken immediately before going to bed, or after the patient has gone to bed and is having difficulty falling asleep. The recommended dose is 10 mg, except for the elderly and patients with mild or moderate liver disease, who should take 5 mg.
The maximum total daily dose of Zerene is 10 mg. Patients should not take a second dose within a single night. No food should be eaten with or shortly before taking Zerene, because it can reduce the medicine's effects. Zerene must not be taken by children or by patients who have severe liver or kidney problems. For more information, see the Package Leaflet.

How does Zerene work?
The active substance in Zerene, zaleplon, belongs to a group of medicines that are related to the benzodiazepines. Zaleplon is chemically different from the benzodiazepines, but it acts on the same receptors in the brain. It is a gamma-amino butyric acid (GABA) agonist, which means that it attaches to the receptors for the neurotransmitter GABA and activates them. Neurotransmitters such as GABA are chemicals that allow nerve cells to communicate with each other. In the brain, GABA is involved in bringing about sleep. By activating its receptors, zaleplon increases GABA's effects, which encourages sleep.
The powder in Zerene capsules is coloured with an intense dark blue dye, to prevent it being given to someone without their knowledge.

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How has Zerene been studied?
Zerene has been studied in a total of 14 studies, involving nearly 3,500 adults and elderly patients. Five of these studies were comparative: Zerene was compared with placebo (a dummy treatment) or with zolpidem or triazolam (other medicines used in insomnia). The main studies lasted for two to four weeks. The main measure of effectiveness was the time taken to fall asleep. Some studies also looked at the time spent asleep and sleeping patterns.

What benefit has Zerene shown during the studies?
The time taken to fall asleep was reduced in adults taking Zerene 10 mg, and the effects were maintained for up to four weeks.
In elderly patients, the time taken to fall asleep was often decreased with Zerene 5 mg and was always decreased with Zerene 10 mg, when they were compared with placebo in the two-week studies.
Zerene 10 mg was more effective than placebo in decreasing the time taken to fall asleep and increasing time spent asleep during the first half of the night.
Zerene also preserved sleep patterns in the studies that measured the time spent in different stages of sleep.

What is the risk associated with Zerene?
The most common side effects with Zerene (seen in between 1 and 10 patients in 100) are amnesia (memory problems), paraesthesia (unusual sensations like pins and needles), somnolence (sleepiness) and dysmenorrhoea (painful menstruation). For the full list of all side effects reported with Zerene, see the Package Leaflet.
Zerene should not be used in people who may be hypersensitive (allergic) to zaleplon or any of the other ingredients. It must not be used in patients with severe liver or kidney problems, sleep apnoea syndrome (frequent interruption of breathing during sleep), myasthenia gravis (a disease causing muscle weakness) or severe respiratory insufficiency (breathing disorders), or in patients under 18 years of age.

Why has Zerene been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Zerene's benefits are greater than its risks for the treatment of patients with insomnia who have difficulty falling asleep, when the disorder is severe, disabling or subjecting the individual to extreme distress. The Committee recommended that Zerene be given marketing authorisation.

Other information about Zerene:
The European Commission granted a marketing authorisation valid throughout the European Union for Zerene on 12 March 1999. The marketing authorisation was renewed on 12 March 2004 and on 12 March 2009. The marketing authorisation holder is Meda AB.

The full EPAR for Zerene is available here.

This summary was last updated in 03-2009.