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Review of zolpidem-containing medicines started

The European Medicines Agency has started a review of zolpidem-containing medicines. Zolpidem is a medicine used for short-term relief of insomnia (inability to sleep). The review follows concerns that some patients may experience drowsiness and slower reactions the day after taking the medicine, which could increase the risk of accidents during activities that require alertness such as driving.

The possibility of drowsiness the day after taking the medicine is a known risk with insomnia medicines, especially if patients do not sleep for long enough after taking the medicine, and in the European Union (EU) the product information for zolpidem already contains a warning of this risk. In June 2013 the Agency's Pharmacovigilance Risk Assessment Committee (PRAC) examined information on reports of problems with driving or road accidents in patients who took zolpidem. Although the Committee considered that no immediate changes to the EU product information were justified, it discussed whether lower doses of zolpidem could reduce the likelihood of reduced mental alertness and impaired driving ability on the following day, and whether a dose reduction should be considered in certain patients. The Committee concluded that a more detailed review and analysis involving additional information on the benefits and risks of zolpidem, including information on its effectiveness at lower doses, was needed to decide this. The Italian Medicines Agency (AIFA) has now requested that such a review be carried out in order to decide if any changes should be made to the marketing authorisations of these products across the EU.

Pending the outcome of the review, patients who have any concerns should speak to their doctor or pharmacist.

More about the medicine

Zolpidem is a medicine used for short-term relief of insomnia in situations where lack of sleep is causing distress or inability to function. It acts by attaching to and stimulating a particular type of receptor on nerve cells called the alpha-1 GABA-A receptor (also called the omega-1 receptor). This receptor is part of a system in the brain that normally responds to a neurotransmitter called gamma-aminobutyric acid (GABA) and which reduces the activity of the brain, causing relaxation and

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sleepiness. A neurotransmitter is a chemical that carries signals between nerve cells. By stimulating the receptor, zolpidem is able to enhance this effect, helping patients to sleep.

Zolpidem has been authorised via national procedures in all Member States of the EU.

More about the procedure

The review of zolpidem-containing medicines has been initiated at the request of Italy, under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. As zolpidem-containing medicines are all authorised nationally, the PRAC recommendation will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. The CMDh is a body representing the EU Member States, responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.