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PRAC recommends product information of zolpidem be updated with new advice to minimise the risk of next-morning impaired driving ability and mental alertness

The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) has completed a review of zolpidem-containing medicines, used for the short-term treatment of insomnia (inability to sleep). The benefit-risk balance of these medicines remains positive, but the PRAC recommended changes to the product information, which are aimed at further minimising the known risks of next-morning impaired driving ability and mental alertness (including somnambulism).

The review of zolpidem was initiated after reports of impaired driving or road accidents the morning after patients took the medicine. It is well known that medicines such as zolpidem may cause 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, and the zolpidem product information already contains a warning of this risk. However, it was considered that a detailed review and analysis involving additional information on the benefits and risks of zolpidem, including information on its effectiveness and risks at lower doses, was needed to decide whether any changes should be made to the marketing authorisations of these products across the EU.

The PRAC has now recommended changes to the product information of zolpidem, including further highlighting the risks of impaired driving and mental alertness and strengthening warnings and precautions aimed at minimising these risks. The PRAC considered that the recommended daily dose should remain at 10 mg of zolpidem, and this dose must not be exceeded. Patients should take the lowest effective dose, in a single intake just before going to bed, and the medicine should not be taken again during the same night. In elderly patients and in patients with reduced liver function, the recommended dose remains 5 mg of zolpidem per day. Furthermore it is recommended not to drive or perform activities that require mental alertness until 8 hours after taking zolpidem. Zolpidem should not be taken together with other medicines that have an effect on the central nervous system (brain and spinal cord). Similarly, alcohol or other substances that affect mental function should not be used when taking zolpidem.

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The PRAC recommendation will now be sent to the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) for consideration at its meeting on 22-24 April 2014[1].

More about the medicine

Zolpidem is a medicine used for the short-term treatment of insomnia. 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 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 was initiated on 4 July 2013 at the request of the Italian Medicines Agency (AIFA) under Article 31 of Directive 2001/83/EC.

The review has been carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), which has made a set of recommendations. As zolpidem-containing medicines are all authorised nationally, the PRAC recommendations 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 regulatory body representing EU Member States, and is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.

If the CMDh position is agreed by consensus, the agreement will be directly implemented by the Member States where the medicines are authorised. Should the CMDh position be adopted by majority vote, the CMDh position will be sent to the European Commission, for the adoption of an EU-wide legally binding decision.

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[1] The companies that market zolpidem have the right to ask for a re-examination of the PRAC recommendation within 15 days of receipt of the PRAC recommendation, which would delay the expected time of finalisation of this review.