Product information of Zolpidem to be updated with new advice to minimise the risk of next-morning impaired driving ability and mental alertness

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Information on zolpidem

Zolpidem is a medicine used for the short-term treatment of insomnia. It acts by stimulating a particular type of receptor on nerve cells called the alpha-1 GABA-A receptor. This receptor is part of a system that when activated reduces the activity of the brain, causing relaxation and sleepiness. By stimulating the receptor, zolpidem is able to enhance this effect, helping patients to sleep. Zolpidem products are authorised in Malta as in the table below;

Therapeutic Class	ATC Code	Active Ingredients	Product Name	Pharmaceutical Form	Authorisation Number	Licence Holder Name
PSYCHOLEPTICS	N05CF02	Zolpidem 10mg	Nytamel 10mg Film-coated Tablets	FILM-COATED TABLET	AA912/00401	Pharma MT
PSYCHOLEPTICS	N05CF02	Zolpidem tartrate 10mg	Stilnox 10 mg, film-coated, scored tablets	FILM-COATED TABLET	MA082/04801	Sanofi-Aventis Malta Ltd.
PSYCHOLEPTICS	N05CF02	Zolpidem Tartrate 5mg	Zolpidem Aurobindo 5 mg film-coated tablets	FILM-COATED TABLETS	MA807/07801	Aurobindo Pharma (Malta) Ltd.
PSYCHOLEPTICS	N05CF02	Zolpidem Tartrate 10mg	Zolpidem Aurobindo 10 mg film-coated tablets	FILM-COATED TABLETS	MA807/07802	Aurobindo Pharma (Malta) Ltd.

Information from European Medicines Agency (EMA) about the safety concern

A review of zolpidem was initiated at the EMA after reports of impaired driving or road accidents the morning after patients took the medicine. It is well known that medicines containing 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 Pharmacovigilance Risk Assessment Committee with the EMA 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.

Medicines Authority
203 Level 3, Rue D'Argens, Gzira, GZR 1368 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 www.medicinesauthority.gov.mt

The PRAC recommendation will now be sent to the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) for consideration at its meeting in April 2014.

In Malta

For Healthcare Professionals

- The PRAC considered that the recommended daily dose should remain at 10 mg of zolpidem, and this dose must not be exceeded.
- If individual clinical assessment of a patient leads to a starting dose of 5mg, patients should be told to take this 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.

Advice for Patients

- 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.

For more information please visit **www.ema.europa.eu**

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Zolpidem containing medicinal products. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form or online at **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Prof John J Borg PhD (Bristol)
Post-licensing Director

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Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

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