

**National PBM
Insomnia Management Updates and Nonpharmacological VA Resources
September 2014**

**VHA Pharmacy Benefits Management Services, VISN Pharmacy Executives, Medical Advisory Panel
And
Center for Medication Safety (VA MEDSAFE)**

Introduction

The purpose of this memo is to summarize recent U.S. Food and Drug Administration (FDA) safety announcements regarding medications taken for insomnia and provide a list of VA non-pharmacologic tools/resources for Cognitive Behavioral Therapy Insomnia (CBT-I), a safe and effective treatment for insomnia.

FDA Labeling and Dosing Changes for Zolpidem (IR and CR) and Eszopiclone

- [January 10, 2013: FDA issued a Drug Safety Communication](#) recommending bedtime doses of immediate and extended-release zolpidem products be lowered because new data showed that the morning after use, blood levels in some patients may be high enough to impair activities that require alertness including driving.
- [May 15, 2014: FDA issued a Drug Safety Communication](#) recommending starting dose for eszopiclone be lowered to 1 mg at bedtime because data showed that 3 mg can cause impairment to driving skills, memory, and coordination that can last more than 11 hours after receiving an evening dose despite patients being unaware there were impaired.

PRODUCT	NEW FDA INITIAL DOSING RECOMMENDATIONS
Ambien, Edluar, Zolpimist (and generic zolpidem)	Women: 5 mg once daily, immediately before bedtime Men: 5 or 10 mg once daily, immediately before bedtime
Ambien CR (and generic zolpidem CR)	Women: 6.25 mg once daily, immediately before bedtime
Lunesta (and generic eszopiclone)	Women and Men: 1mg daily, immediately before bedtime.

Healthcare professionals should prescribe the lowest dose capable of treating patients' insomnia symptoms and caution patients regarding possible impairment in driving and activities that require alertness the next morning, despite feeling fully awake. The FDA is continuing to evaluate the risk of impaired mental alertness with the entire class of sleep aid drugs, including over-the-counter drugs available without a prescription.

Healthcare professionals are reminded to continue to report any adverse reactions with the use of any other drugs for the treatment of insomnia by entering the information into CPRS' Allergies/Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800-FDA-0178, online at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>, or by mail).

Please refer to [National PBM Information Letter: High-dose Zolpidem IR Usage and Tapering Recommendations](#) June 2009; [National PBM Communication](#) January 16, 2013, [National PBM Bulletin](#) May 28, 2014, [Eszopiclone Provider Letter](#), July, 2014, [Eszopiclone Patient Letter](#) July, 2014, for additional information and recommendations.

Non-pharmacological Tools/Resources Available:

[Cognitive Behavioral Therapy-Insomnia \(CBT-I\) SharePoint Site:](#)

https://vaww.portal.va.gov/sites/OMHS/cbt_insomnia/Lists/TrainingOverview/AllItems.aspx

The following information can be found on the CBT-I SharePoint Site:

- [Provider List by VISN](#)
- [CBT-I Patient Brochure](#)
- [CBT-I Fact Sheet for Clinicians](#)
- [Therapy and Assessment Resources](#) (e.g., CBT-I Therapist Manual, Sleep Diary, CBT-I Assessment and Treatment Tools, CBT-I Handouts/Patient Materials)
- [Demonstration Videos](#) demonstrating CBT-I skills and strategies
- [Additional Resources/CBT-I articles](#)

[CBT-i Coach Mobile App](#) is a free mobile app that is designed for use by people having difficulty sleeping to develop good sleep habits and sleep better. It is best used by those participating in CBT-I.

August, 2014

VHA PBM Services

Updated versions may be found at <http://vaww.pbm.va.gov>