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# NATIONAL PBM BULLETIN

May 28, 2014

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## DEPARTMENT OF VETERANS AFFAIRS PHARMACY BENEFITS MANAGEMENT SERVICES (PBM), MEDICAL ADVISORY PANEL (MAP), AND CENTER FOR MEDICATION SAFETY (VA MEDSAFE)

### ESZOPICLONE (LUNESTA): LOWERED DOSE RECOMMENDATIONS DUE TO NEXT-DAY IMPAIRMENT

#### I. ISSUE

Eszopiclone at higher doses, especially 3mg before bedtime, can cause next-day impairment of driving and other activities that require full attention/alertness, resulting in new lowered dosing recommendations.

#### II. BACKGROUND

Eszopiclone is a non-benzodiazepine sedative-hypnotic agent that gained FDA-approval in December 2004 for the treatment of insomnia in adults. Eszopiclone is available under the brand name Lunesta as well as in generic form. The recommended starting dose has been lowered to 1 mg from 2 mg, to be taken once each evening immediately before bedtime due to findings from a study that showed higher doses imparting greater next-morning impairment. FDA approved a change to the product labeling to reflect this new information.

#### III. DISCUSSION

A double-blinded study of 91 healthy adults between 25 and 40 years old, evaluated the effects of eszopiclone 3 mg on psychomotor function and dexterity the following morning (up to almost 12 hours after dose administration), specifically with respect to driving skills, memory tests, and subjective perceptions of sedation and coordination. Compared with placebo, results showed next-day psychomotor and memory impairment associated with eszopiclone 3 mg that peaked at 7.5 hours post-dose and persisted through 11.5 hours. Despite these findings, patients did not perceive themselves as impaired.

#### IV. PROVIDER RECOMMENDATIONS

- The new lower recommended starting dose of eszopiclone is 1 mg to be taken once each evening immediately before bedtime. All new patients beginning treatment with eszopiclone should be initiated with no more than 1mg, as tolerated.
- Elderly patients and patients with hepatic impairment should not be prescribed eszopiclone doses of more than 2 mg.
- Patients should be prescribed and maintained on the lowest possible dose that resolves their insomnia symptoms.
- Dose can be increased to 2 mg or 3 mg if needed, but caution patients that even the higher dose of 2 mg taken as prescribed may likely impair next-day driving and other activities that require full alertness.
- Patients taking a 3 mg dose of eszopiclone should be warned not to drive or engage in other activities that are hazardous or require complete mental alertness the day after use.
- Caution patients regarding possible impairment in driving and activities that require alertness the next morning, *despite feeling fully awake*.
- Consider discontinuing the drug or lowering the dose if patients feel drowsy in mornings after using sleeping medications such as eszopiclone.
- Notify patients to watch for morning drowsiness and for any signs of impaired driving (or other activities) when taking any sleeping medication. Providers should re-evaluate patients currently taking eszopiclone for appropriate dose and any side effects associated with treatment.

A provider letter template is available at:

<https://vaww.cmopnational.va.gov/cmop/PBM/Clinical%20Guidance/Patient%20and%20Provider%20Letters/Eszopiclone,%20Provider%20Letter.doc>

A patient letter template is available at:

<https://vaww.cmopnational.va.gov/cmop/PBM/Clinical%20Guidance/Patient%20and%20Provider%20Letters/Eszopiclone,%20Patient%20Letter.doc>

- Continue to report any adverse reactions with the use of eszopiclone (brand or generic) or 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 (by phone: 1-800-FDA-1088, fax: 1-800-FDA-0178, online at: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>), or by mail).

#### V. REFERENCES

FDA Drug Safety Communication: FDA warns of next-day impairment with sleep aid Lunesta (eszopiclone) and lowers recommended dose.

<http://www.fda.gov/Drugs/DrugSafety/ucm397260.htm>. Accessed 05/21/14.

#### ACTIONS

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS and Chief Nurse Executives**: Forward this document to all appropriate providers and health care staff (e.g., **primary care providers, sleep study experts, geriatricians, psychiatrists, including contract providers, etc.**). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D**: Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).