

TYPE: DRUG WARNING

FDA warns of next-day impairment with sleep aid and lowers recommended dose

Drug Name: **Lunesta (eszopiclone)**

Audience: Patient

Date: **05/15/2014**



ISSUE

The U.S. Food and Drug Administration (FDA) is warning that the insomnia drug Lunesta (eszopiclone) can cause next-day impairment of driving and other activities that require alertness. As a result, we have decreased the recommended starting dose of Lunesta to 1 mg at bedtime. Health care professionals should follow the new dosing recommendations when starting patients on Lunesta. Patients should continue taking their prescribed dose of Lunesta and contact their health care professionals to ask about the most appropriate dose for them.

A study of Lunesta found that the previously recommended dose of 3 mg can cause impairment to driving skills, memory, and coordination that can last more than 11 hours after receiving an evening dose (see Data Summary). Despite these driving and other problems, patients were often unaware they were impaired. The new lower recommended starting dose of 1 mg at bedtime will result in less drug in the blood the next day.

Women and men are equally susceptible to impairment from Lunesta, so the recommended starting dose of 1 mg is the same for both. The 1 mg dose can be increased to 2 mg or 3 mg if needed, but the higher doses are more likely to result in next-day impairment of driving and other activities that require full alertness. We caution patients taking a 3 mg dose against driving or engaging in other activities that require complete mental alertness the day after use.

We have approved changes to the Lunesta prescribing information and the patient Medication Guide to include these new recommendations. The drug labels for generic eszopiclone products will also be updated to include these changes.

RECOMMENDATION

We are 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, and will update the public as new information becomes available. Health care professionals and patients can refer to our [Sleep Disorder \(Sedative-Hypnotic\) Drug Information](#)² Web page to find updated information and access the latest labels for insomnia drugs.

This information is provided through www.drugs.com and is researched for verification and accuracy by our clinical staff. ProCare Rx takes no responsibility for the accuracy or thoroughness of the data presented in this warning, nor any consequences to clients, patients or others from the recommendation noted.