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

Safety Announcement

[5-15-2014] 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.

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 Web page to find updated information and access the latest labels for insomnia drugs.

Facts about eszopiclone

- A sedative-hypnotic sleep medicine used to treat insomnia in adults
- Marketed under the brand name Lunesta and also as generics
- In 2013, there were approximately 3 million prescriptions dispensed and 923,000 patients who received a dispensed prescription for Lunesta (eszopiclone) from U.S. outpatient retail pharmacies.[1]

Additional Information for Patients

- Patients who take Lunesta (eszopiclone) and other medicines to help them sleep can experience decreased mental alertness the morning after use, even if they feel fully awake.
- Lunesta can cause next-day impairment of driving and other activities that require full alertness.
- The recommended starting dose of Lunesta has been lowered to 1 mg from 2 mg, to be taken once each evening immediately before bedtime. The 1 mg dose can be increased to 2 mg or 3 mg if needed, but the higher doses are more likely to impair next-day driving and other activities that require full alertness.
- Elderly patients and patients with severe liver disease should not take doses of more than 2 mg.
- If you are currently taking Lunesta, continue taking your prescribed dose and contact your health care professional to ask about the most appropriate dose for you. Each patient and situation is unique, and the appropriate dose should be discussed with your health care professional.
- Patients taking a 3 mg dose of Lunesta are cautioned against driving or engaging in other activities that are hazardous or require complete mental alertness the day after use.
- Read the patient Medication Guide that comes with your Lunesta prescription.
- Take all insomnia medicines exactly as prescribed.
- Over-the-counter (OTC) insomnia medicines that are available without a prescription should not be considered safer than prescription insomnia medicines for next-morning alertness and driving.
- Talk to your health care professional if you have any questions or concerns about Lunesta or other insomnia medicines.
- Report any side effects from Lunesta or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Additional Information for Health Care Professionals

- Lunesta (eszopiclone) can cause next-day impairment of driving and other activities that require full alertness.
- The recommended starting dose of Lunesta has been lowered to 1 mg from 2 mg. Dosing can be raised to 2 mg or 3 mg if clinically indicated. The total dose of Lunesta should not exceed 3 mg, once each evening immediately before bedtime.
- Elderly patients and patients with hepatic impairment should not be prescribed doses of more than 2 mg.
- In some patients, the higher morning blood levels of Lunesta following use of the 2 mg or 3 mg doses increase the risk of next-day impairment of driving and other activities that require full alertness.
- Caution patients taking 3 mg of Lunesta against driving or engaging in activities that are hazardous or require complete mental alertness the day after use.
- Encourage patients to read the Medication Guide that comes with their Lunesta prescription.
- For all insomnia drugs, prescribe the lowest dose necessary to treat the patient’s symptoms.

- Inform patients that impairment from insomnia drugs can be present despite feeling fully awake.
- Report adverse events involving Lunesta or other drugs to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Data Summary

In a double-blind study of 91 healthy adults between 25 and 40 years old, the effects of Lunesta 3 mg on psychomotor function were assessed the following morning, between 7.5 and 11.5 hours after dosing. Measures included tests of psychomotor coordination that are correlated with the ability to maintain a motor vehicle in the driving lane, tests of working memory, and subjective perception of sedation and coordination. Compared with placebo, Lunesta 3 mg was associated with next-morning psychomotor and memory impairment that was most severe at 7.5 hours but still present and potentially clinically meaningful at 11.5 hours. Subjective perception of sedation and coordination from Lunesta 3 mg was not consistently different from placebo, even though the subjects were objectively impaired. Lunesta 3 mg had an impairing effect almost as large as zopiclone 7.5 mg, a similar insomnia drug. Zopiclone, which is not approved in the United States, causes consistent psychomotor impairment such that it is often used as a positive control in driving impairment studies.

Reference

1. IMS, National Prescription Audit and IMS, Vector One®: Total Patient Tracker (TPT) Databases. Year 2013. Extracted April 2014.