FDA: lower ambien's dose to prevent drowsy driving

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Blood levels from nighttime dose of sleep aid can remain too high the next morning, agency says.

(HealthDay)—The U.S. Food and Drug Administration has approved new, lower-dose labeling for the popular sleep drug Ambien (zolpidem) in an effort to cut down on daytime drowsiness that could be a hazard while performing certain tasks such as driving.

The move follows the FDA's request to manufacturers in January that drugs containing zolpidem carry instructions that lower the recommended dose and provide more safety information to patients.

"FDA has approved these changes because of the known risk of next-morning impairment with these drugs," the agency said in a statement released Tuesday on its website.

Sleep medications containing zolpidem include Ambien, Ambien CR, Edluar and Zolpimist, as well as generic versions of Ambien and Ambien CR.

"The purpose of the lowering is to help decrease the risk of next-morning impairment of activities that require alertness," Dr. Ellis Unger, director of the Office of Drug Evaluation I at the FDA's Center for Drug Evaluation and Research, said at the time of the agency's request to manufacturers. "We're particularly concerned about driving. A large fraction of the population drives and driving is an inherently dangerous activity."

Lowering the nighttime dose means there will be less residual drug in the blood by the time the person wakes up. Extended-release forms of the drugs tend to stay in the body longer, the FDA said.

The FDA has told manufacturers that recommended doses for women should be cut in half, from 10 milligrams to 5 milligrams for immediate-release products (Ambien, Edluar and Zolpimist) and from 12.5 mg to 6.25 mg for extended-release products (Ambien CR).

For men, the agency has asked manufacturers to change the labeling to recommend that doctors and other health-care professionals consider prescribing lower doses, meaning 5 mg for immediate-release products and 6.25 mg for extended-release products.

In explaining the different recommendations for men and women, Unger said that "women appear to be more susceptible to risk for next-morning impairment because they eliminate zolpidem from their bodies more slowly."

It's not clear why women eliminate the substance from their bodies more slowly than men.

Although there have been reports of adverse events, including motor vehicle accidents possibly related to zolpidem, the link has not and probably cannot be definitely established, Unger said.

The changes were spurred by new driving-simulation studies showing that currently prescribed levels of drugs containing zolpidem may be high enough to impair alertness the next day, he explained.

The FDA will be requiring driving-simulation studies for new sleep medications, and it is assessing other insomnia medications on the market. Eventually, Unger said, "we want driving data on all sleep medications."

Unger emphasized that next-day impairment is not limited to medications containing zolpidem but to all sleep medications.

"For all sleep medications, doctors should prescribe and patients should take the lowest dose," he said.

People taking any kind of sleep medication should not change their dose without first talking to their health-care professional, he stressed.

More information: Visit the U.S. Food and Drug Administration for more about next-morning impairment from sleep aids.