FDA Requires Lower Doses for Sleep Medications

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WASHINGTON (AP) — The Food and Drug Administration is requiring makers of Ambien and similar sleeping pills to lower the dosage of their drugs, based on studies suggesting patients face a higher risk of injury due to morning drowsiness.

The agency said Thursday that new research shows that the drugs remain in the bloodstream at levels high enough to interfere with alertness and coordination, which increases the risk of car accidents.

Regulators are ordering drug manufacturers to cut the dose of the medications in half for women, who process the drug more slowly. Doses will be lowered from 10 milligrams to 5 milligrams for regular products, and 12.5 milligrams to 6.25 milligrams for extended-release formulations.

The FDA is recommending that manufacturers apply these lower doses to men as well, though it is not making them a requirement.

The new doses apply to all insomnia treatments containing the drug zolpidem, which is sold under brands including Ambien, Edluar, Zolpimist and in generic forms. It is the most widely prescribed sleeping aid prescribed in the U.S. The changes don't affect other popular sleeping medicines like Lunesta and Sonata, which use different drugs.

FDA officials pointed out that all sleeping drugs carry warnings about drowsiness.

"All sleep drugs have the potential to cause this, so health professionals should prescribe — and patients should take — the lowest dose that is capable of preventing insomnia," said Dr. Ellis Unger, a director in FDA's Office of Drug Evaluation, on a teleconference with reporters.

Unger added that the FDA will begin requiring developers of sleep drugs to conduct driving simulation studies going forward.

Ambien has been blamed for several recent high-profile driving accidents in the past year, including Tom Brokaw in September and Kerry Kennedy in July.

The FDA has received more than 700 reports of driving-related problems connected to zolpidem over the years.

"But in most cases it was very difficult to determine if the driving impairment was actually related to zolpidem," Unger said. "Usually the reports did not contain information about when the accident happened or how much time had lapsed since taking the drug."

The agency decided to take action after recent driving simulation studies showed that, in some patients, drug levels remained high enough to cause difficulty driving. The data came from company studies of Intermezzo, a new form of zolpidem which was approved in 2011 for people who wake late at night and can't get back to sleep.

The data showed that 33 percent of women and 25 percent of men taking extended-release zolpidem had enough of the drug in their blood to interfere with driving as much as eight hours later.

When the dose was cut in half only 15 percent of women and 5 percent of men had those same drug levels.

FDA analysis was unable to determine why women metabolize zolpidem so much more slowly than men. According to FDA staff, the difference cannot be accounted for by usual factors like size and weight.

For now, patients should continue taking their currently prescribed dose until they can talk to their doctor about the best way to proceed.

"We really don't want people to change the dose they're on. We want them to talk to their health care provider," Unger said.

Ambien is marketed by Sanofi, Intermezzo by Purdue Pharma LP and Zolpimist by NovaDel Pharma Inc.

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