FDA adds warning for certain insomnia medicines

The Food and Drug Administration (FDA) is advising that rare but serious injuries have happened with certain common prescription insomnia medicines because of sleep behaviors, including sleepwalking, sleep driving, and engaging in other activities while not fully awake. These complex sleep behaviors have also resulted in deaths. These behaviors appear to be more common with eszopiclone (Lunesta), zaleplon (Sonata), and zolpidem (Ambien, Ambien CR, Edluar, Intermezzo, Zolpimist) than other prescription medicines used for sleep.

As a result, the FDA is requiring a Boxed Warning, their most prominent warning, to be added to the prescribing information and the patient Medication Guides for these medicines. They are also requiring a Contraindication, their strongest warning, to avoid use in patients who have previously experienced an episode of complex sleep behavior with eszopiclone, zaleplon, and zolpidem.

Serious injuries and death from complex sleep behaviors have occurred in patients with and without a history of such behaviors, even at the lowest recommended doses, and the behaviors can occur after just one dose. These behaviors can occur after taking these medicines with or without alcohol or other central nervous system depressants that may be sedating such as tranquilizers, opioids, and anti-anxiety medicines.

Eszopiclone, zaleplon, and zolpidem are medicines used to treat insomnia in adults who have difficulty falling asleep or staying asleep. They are in a class of medicines called sedative-hypnotics and have been approved and on the market for many years. These insomnia medicines work by slowing activity in the brain to allow sleep. Quality sleep can have a positive impact on physical and mental health.

Health care professionals should not prescribe eszopiclone, zaleplon, or zolpidem to patients who have previously experienced complex sleep behaviors after taking any of these medicines. Advise all patients that although rare, the behaviors caused by these medicines have led to serious injuries or death. Tell the patient to discontinue taking these medicines if they experience an episode of complex sleep behavior.

Patients should stop taking your insomnia medicine and contact your health care professional right away if you experience a complex sleep behavior where you engage in activities while you are not fully awake or if you do not remember activities you have done while taking the medicine.

The FDA identified 66 cases of complex sleep behaviors occurring with these medicines over the past 26 years that resulted in serious injuries, including death. This number includes only reports submitted to FDA or those found in the medical literature, so there may be additional cases about which we are unaware. These cases included accidental overdoses, falls, burns, near drowning, exposure to extreme cold temperatures leading to loss of limb, carbon monoxide poisoning, drowning, hypothermia, motor vehicle collisions with the patient driving, and self-injuries such as gunshot wounds and apparent suicide attempts. Patients usually did not remember these events. The underlying mechanisms by which these insomnia medicines cause complex sleep behaviors are not completely understood.
The FDA is also reminding the public that all medicines taken for insomnia can impair driving and activities that require alertness the morning after use. Drowsiness is already listed as a common side effect in the drug labels of all insomnia medicines, along with warnings that patients may still feel drowsy the day after taking these products. Patients who take insomnia medicines can experience decreased mental alertness the morning after use even if they feel fully awake.

The FDA communicated safety information associated with certain insomnia medicines in January 2013 (risk of next-morning impairment with zolpidem), May 2013 (approved lower recommended doses for zolpidem), and May 2014 (risk of next-morning impairment with eszopiclone; lowered recommended dose). The FDA is continuing to monitor the safety of insomnia medicines and will update the public as new information becomes available. To help FDA track safety issues with medicines, report side effects involving Mavyret, Zepatier, Vosevi, or other medicines to the FDA MedWatch program.

Contact FDA
For More Info
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If you have questions, contact AlohaCare Provider Relations at 973-1650 or toll-free at 1-800-434-1002.