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Drug Safety Communication: Sleep Behavior Risks with Select Sleep Aids

Eszopiclone, zaleplon, and zolpidem are sedative-hypnotic medications approved for the treatment of insomnia in adults who experience difficulty falling or staying asleep.

On April 30, 2019, the U.S. Food and Drug Administration (FDA) announced they are requiring safety label changes for eszopiclone, zaleplon, and zolpidem because of the risk of complex sleep behaviors, including sleepwalking, sleep driving, and engaging in other activities while not fully awake. While rare, these complex sleep behaviors have resulted in serious injuries and death. Safety label changes include a *Boxed Warning* added to the prescribing information and patient Medication Guides and a *Contraindication* to avoid use of these drugs in patients who have previously experienced a complex sleep behavior with the use of eszopiclone, zaleplon, and zolpidem.

Health care professionals should avoid prescribing eszopiclone, zaleplon, or zolpidem to any patient with a history of even a single episode of complex sleep behavior after the use of these medications. Other recommendations for health care professionals include the following:

- Advise immediate discontinuation in patients who experience an episode of complex sleep behavior, even if it did not result in a serious injury.
- Remind patients that all medications used to treat insomnia could increase the risk for impaired driving and reduce physical and mental alertness, including the following morning.
- Encourage patients to read the Medication Guide every time they fill their prescriptions, and remind them not to combine eszopiclone, zaleplon, and zolpidem with other insomnia medications, alcohol, or central nervous system (CNS) depressants.

The FDA previously communicated the following safety information associated with medications used to treat insomnia:

- [May 2014](#) – lower recommended dose of eszopiclone due to next-day impairment
- [May 2013](#) – avoid driving the day after Ambien CR use; new dosing and label changes for zolpidem
- [January 2013](#) – lower dose recommendations for zolpidem formulations and risk of next-morning impairment

To read the full safety announcement, which includes an overview of cases from the FDA Adverse Event Reporting System (FAERS) database, refer to the “FDA Drug Safety Communication: FDA adds Boxed Warning for risk of serious injuries caused by sleepwalking with certain prescription insomnia medicines” article found on the [Drug Safety and Availability](#) page of the FDA website.