

FDA DRUG SAFETY COMMUNICATION

Certain Prescription Insomnia Medicines: New Boxed Warning - Due to Risk of Serious Injuries Caused by Sleepwalking, Sleep Driving and Engaging in Other Activities While Not Fully Awake

[Posted 04/30/2019]

ISSUE: 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:

- Lunesta (eszopiclone)
- Sonata (zaleplon)
- Ambien (zolpidem tartrate tablet), Ambien CR (zolpidem tartrate ER tablet), Edluar, Intermezzo (zolpidem tartrate tablet SL), Zolpimist (zolpidem tartrate solution) than other prescription medicines used for sleep.

BACKGROUND: 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.

RECOMMENDATIONS:

If patients experience a complex sleep behavior where they engage in activities while they are not fully awake or if they do not remember activities they have done while taking the medicine they should:

- Stop taking the insomnia medicine.
- Contact their health care professional right away.

Healthcare professionals should not prescribe eszopiclone, zaleplon, or zolpidem to patients who have previously experienced complex sleep behaviors after taking any of these medicines. Healthcare Professionals should advise all patients that:

- Although rare, the behaviors caused by these medicines have led to serious injuries or death.
- To discontinue taking these medicines if they experience an episode of complex sleep behavior.



Following is the link to the full FDA report:

<https://www.fda.gov/safety/medwatch-safety-alerts-human-medical-products/certain-prescription-insomnia-medicines-new-boxed-warning-due-risk-serious-injuries-caused>

Please note that Doctors HealthCare Plans currently has the **generic** formulations of these medications on Formulary with Prior Authorization. **These medications are considered High Risk Medications (HRMs) in the elderly.**

- Sonata (zaleplon)
- Ambien (zolpidem tartrate tablet)
- Ambien CR (zolpidem tartrate ER tablet)
- Intermezzo (zolpidem tartrate tablet SL)

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