Important Clinical News:
New Boxed Warning on Certain Sleep Medications

In April 2019, the U.S. Food and Drug Administration (FDA) announced the addition of a Boxed Warning, the strongest type of warning, to the product labeling for certain prescription sleep medications. The Boxed Warning is regarding the potential for these medications to result in complex sleep behaviors, such as sleepwalking, sleep driving or other activities while the patient is not fully awake. Although these events are rare, in some instances, they have led to serious injuries, including death.

The prescription sleep medications that will have this new warning include:

- eszopiclone (Lunesta®)
- zaleplon (Sonata®)
- zolpidem (Ambien®, Ambien CR®, Edluar®, Intermezzo®, Zolpimist®)

These medications are sedative-hypnotics prescribed to adults with insomnia who have trouble falling or staying asleep. The product labels for these drugs will also be updated to state that the use of these medications should be avoided in patients who have experienced a complex sleep behavior with any of these medications. The corresponding Medication Guide that is required to be provided to the patient also describes the potential risks of these therapies.

These events have occurred in patients taking these medications alone as well as in those who were also drinking alcohol or taking other sedating drugs. Some patients have also exhibited these behaviors after taking the lowest recommended dose. Healthcare providers are instructed not to prescribe these medications to patients with a history of sleep behaviors following the use of these medications.

Patients are instructed to stop taking the insomnia medication and speak with their healthcare provider if a behavior occurs after taking these medications. Insomnia medications can also impair driving and result in drowsiness the following morning. The FDA's monitoring of these medications is ongoing. As a result, patients and healthcare providers are encouraged to report side effects experienced while using these medications to the FDA MedWatch program.

For additional information, view the FDA's Drug Safety Communication, the FDA's News Release, or the FDA's MedWatch.

References:

1. FDA adds Boxed Warnings for risk of serious injuries caused by sleepwalking with certain prescription insomnia medications. FDA Drug Safety Communication. https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-risk-serious-injuries-caused-sleepwalking-certain-prescription-insomnia. Updated April 30, 2019. Accessed May 16, 2019.
2. FDA requires stronger warnings about rare but serious incidents related to certain prescription insomnia medicines. FDA News Release. https://www.fda.gov/news-events/press-announcements/fda-requires-stronger-warnings-about-rare-serious-incidents-related-certain-prescription-insomnia. Updated April 30, 2019. Accessed May 16, 2019.
3. 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. MedWatch Safety Alerts for Human Medical Products. https://www.fda.gov/safety/medwatch-safety-alerts-human-medical-products/certain-prescription-insomnia-medicines-new-boxed-warning-due-risk-serious-injuries-caused. Updated April 30, 2019. Accessed May 16, 2019.