Insomnia medications – Safety communication and updated labeling

- On April 30, 2019, the FDA announced that a *Boxed Warning* will be added to the drug labels of certain common prescription insomnia medications due to rare but serious injuries occurring because of complex 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 (eg, Ambien®, Ambien CR®, Edluar®, Intermezzo®, and Zolpimist™) than other prescription medications used for sleep.
    — The FDA is also requiring an update to the *Contraindication* section of the drug labels, to avoid use of these medications in patients who have previously experienced an episode of complex sleep behavior with eszopiclone, zaleplon, and zolpidem.
    — This information will also be added to the patient Medication Guides.

- Drugs such as eszopiclone, zaleplon, and zolpidem are prescription sedative-hypnotic medications used to treat insomnia in adults who have difficulty falling asleep or staying asleep.

- Patients should stop taking their insomnia medication and contact their health care professional right away if they 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 medication.

- Healthcare professionals should not prescribe eszopiclone, zaleplon, or zolpidem to patients who have previously experienced complex sleep behaviors after taking any of these medications. All patients should be advised that although rare, the behaviors caused by these medications have led to serious injuries or death. Patients should be told to discontinue taking these medications if they experience an episode of complex sleep behavior.

- The FDA identified 62 cases of complex sleep behaviors that resulted in serious injuries or death after taking prescription insomnia medications reported in the FDA Adverse Event Reporting System database between December 16, 1992, and February 27, 2018, and four additional cases reported in the medical literature between December 16, 1992, and March 13, 2018.

    — Of the 66 cases, 20 cases were reported as resulting in fatal outcomes. Forty-six cases reported serious non-fatal injuries; these patients usually did not remember experiencing these complex sleep behaviors. The underlying mechanisms by which these insomnia medications cause complex sleep behaviors are not completely understood.
    — Most of these patients reported using zolpidem (n = 61) when they experienced a complex sleep behavior. The remaining patients took eszopiclone or zaleplon. These data are consistent with the higher number of zolpidem prescriptions dispensed compared to eszopiclone and zaleplon.

- The FDA is also reminding the public that all medications 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 medications, along with warnings that patients may still feel drowsy the day after taking these products. Patients who take insomnia medications can experience decreased mental alertness the morning after use even if they feel fully awake.

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- The FDA communicated safety information associated with certain insomnia medications 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).

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