

Ambien, Lunesta, and Sonata Will Get New FDA Black Box Warnings About Potentially Fatal Side Effects

The Food and Drug Administration (FDA) is forcing three popular sleep medications to carry their most prominent warning, the black box warning, about the possible serious or life-threatening behaviors that may result from taking these drugs. The behaviors, which have reportedly caused serious injuries and deaths, include sleepwalking, sleep driving, and other behaviors that can occur while not fully awake such as burns from cooking and gunshot wounds, and drowning. The new black box warning—the strictest label used by the FDA to denote potentially life-threatening side effects—will apply to Ambien, Lunesta, and Sonata.

The FDA's decision was motivated by its recent review of 66 case reports about strange behaviors linked to these drugs. Accidental overdoses, falls, burns, near-drowning, extreme temperature exposures leading to loss of limb, self-inflicted gunshot wounds and suicide attempts were among the 46 non-fatal injuries; 20 deaths occurred due to carbon monoxide poisoning, drowning, falls, hypothermia, car crashes and suicide. There have also been anecdotal reports of people killing others while under the influence of these drugs (specifically Ambien).

These incidents can occur after the first dose of these sleep medicines or after a longer period of treatment, and can occur in patients without any history of these behaviors and even at the lowest recommended doses. Patients usually did not remember these behaviors, and they 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.

These 66 case reports only include reports submitted to FDA or those found in the medical literature. However, the majority of patients may never disclose these behaviors to their doctors or the FDA (in part because they do not remember the behaviors). And in the few cases in which patients do report these behaviors to their doctors, few doctors report the cases to the FDA or publish them in the medical literature. Therefore, the actual number of cases involving these potentially deadly behaviors is very likely to be dramatically more than 66 cases.

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.