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Ask The Pharmacist

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What should I know about new FDA warnings for insomnia medications?

In what may be a sign of the times, trouble sleeping is no stranger to many of us. Longer working hours, shift work, and late night proximity to blue light from electronic devices are among the issues contributing to a growing concern with getting enough sleep. Insomnia is defined to be difficulty falling or staying asleep, the absence of restful sleep, or poor quality of sleep. It is a symptom and not a disease. The most common causes of insomnia are medication side effects, psychological conditions (for example, depression, anxiety), environmental changes (travel, jet lag, or altitude changes), and stressful events or a stressful lifestyle.

A recent Consumer Reports survey indicates that 27 percent of U.S. adults report having trouble falling or staying asleep on most nights and a significantly greater number (68 percent) struggled with sleep at least once a week.[1] Of all who experience insomnia, about 75 percent recover without developing persistent poor sleep or chronic insomnia.[2]

People struggling with insomnia are increasingly turning to a variety of mattresses, pillows, gadgets, and supplements, in addition to over-the-counter (OTC) and prescription medications in search of a restful night's sleep. Americans spent an estimated $41 billion on sleep aids and remedies in 2015 and that is expected to grow to $52 billion by 2020, according to Natana Raj, an analyst with BCC Research in Wellesley, Massachusetts,[1] and according to the Food and Drug Administration (FDA), an estimated 30 million prescriptions for the three most popular sleep aids were filled in the U.S. in 2018.

Prescription medications used to aid in sleep (called sedative-hypnotics) have been approved and marketed for many years. They work by slowing activity in the brain to promote sleep. Among concerns related to the use of these include:

- Some are metabolized differently in men and women, resulting in lower recommended ceiling doses for women.[4]
- Sedative hypnotics have also been noted to cause carryover (next day) sedation, for which particular caution driving or operating equipment is advised.[4]
- Because these medications function as central nervous system (CNS) depressants, their use in combination with other depressants can contribute to sedation, respiratory depression, and overdose risk.

In late April 2019, the FDA advised 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 eszopiclone (Lunesta®), zaleplon (Sonata®), and zolpidem (Ambien®, Ambien® CR, Edluar®, Intermezzo®, and ZolpiMist™) than other prescription medicines used for sleep."[3] The FDA also required that a boxed warning be added to the prescribing information and Patient Medication Guides for these medicines. "Serious injuries and death from complex sleep behaviors have occurred in patients with and without a history of such behaviors, even at the lowest recommended doses, and the behaviors can occur after just one dose. These behaviors 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."[3]

Injured workers should stop taking their insomnia medicine and contact their health care professional right away if they experience a complex sleep behavior (engage in activities while not fully awake) or if they do not remember activities they have done while taking the medicine. Although rare, the behaviors caused by these medicines have led to serious injuries or death.

1. https://www.consumerreports.org/sleep/why-americans-cant-sleep/
2. ScienceDaily. Retrieved May 19, 2019 from www.sciencedaily.com/releases/2018/06/180605154114.htm
3. https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-risk-serious-injuries-caused-sleepwalking-certain-prescription-insomnia
4. https://wayback.archive-it.org/7993/20170404172106/https:/www.fda.gov/Drugs/DrugSafety/ucm334033.htm

Drug of the Month

ZolpiMist™

ZolpiMist is an oral spray formulation of the sedative-hypnotic compound zolpidem, developed by NovaDel Pharma, Inc., a pharmaceutical company specializing in the creation of oral spray formulations for medications. The belief was that oral spray delivery would provide a more rapid onset of therapeutic activity in a convenient product that patients could self-administer. First approved by the FDA in 2008 for the short-term treatment of insomnia characterized by difficulty with sleep initiation, the ZolpiMist approved label is nearly identical to that of immediate-release zolpidem, except for information specifically relating to the oral spray administration.

The FDA-approved labeling for these sections mirrors the content for immediate-release zolpidem tablets and is similar for other benzodiazepine receptor agonist hypnotics; none are specific for ZolpiMist or were derived from the ZolpiMist clinical studies. The most commonly observed adverse reactions for short-term use were drowsiness, dizziness, and diarrhea, and for long-term use were dizziness and drugged feelings.[3]

All formulations of zolpidem and other benzodiazepine receptor agonist hypnotics are classed as Schedule IV controlled substances by the FDA due to their relatively low potential for abuse and dependence. The ZolpiMist FDA-approved labeling suggests that careful monitoring should be performed when zolpidem is prescribed for people with a history of abuse of, or addiction to, drugs or alcohol.[1]

U.S. drug regulators added a strict new warning about prescription sleeping medications. The FDA found 66 examples of patients who took the drugs and engaged in dangerous activities such as sleepwalking or driving while not fully awake, including 20 deaths linked to carbon monoxide poisoning, drowning, fatal falls, hypothermia, car crashes, and apparent suicide. There were 46 reports of serious injuries that weren't deadly, including overdoses, burns, loss of limbs from extreme cold, and self-injuries from gunshot wounds.

The agency also noted that the recommended dosages should be lower for women, because they don't process zolpidem out of their systems as quickly as men.

Questions related to ZolpiMist or any medications requested for your injured worker may be directed to our team of clinical pharmacists at askthepharmacist@cvty.com.

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3630936/
2. NovaDel Pharma Inc. NovaDel Pharma receives FDA approval of ZolpiMist(TM)[press release]2008. December 22www.integratir.com/newsrelease.asp?news=2131022053&ticker=NVD&lang=ENAccessed 2009 Dec 12
3. NovaDel Pharma Inc. ZolpiMist FDA approved labeling. 2008.
4. https://www.washingtonpost.com/national/health-science/fda-issues-warning-about-risks-of-ambien-other-sleeping-aids/2019/05/03/ccda8560-6ced-11e9-be3a-33217240a539_story.html?noredirect=on&utm_term=.49ad7de6f6e8
5. https://www.abc15.com/news/national/fda-strengthens-warning-about-sleeping-pill-dangers

Governmental Activity by State

Find out more about the governmental updates and potential changes currently being proposed in your state

To find out more about the governmental updates and potential changes currently being proposed in your state, visit the Coventry News and Insights Page each month to read our Government Relations Newsletter, or find this month's newsletter here.