

Perhaps the Worst Thing to Do if You Can't Sleep

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✓ Fact Checked

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STORY AT-A-GLANCE

- › April 30, 2019, the U.S. Food and Drug Administration (FDA) announced it will require sedative-hypnotics – a class of sleep medication used to treat insomnia – to carry a black box warning stating drug side effects may include dangerous behaviors done while sleeping, such as eating, walking, driving or engaging in a range of activities in your sleep that can lead to injury or death
- › These potentially dangerous behaviors are more common with eszopiclone (Lunesta), zaleplon (Sonata), and zolpidem (Ambien, Ambien CR, Edluar, Intermezzo, Zolpimist) than other prescription sleep aids
- › Over the past 26 years, there have been 66 documented reports of “complex sleep behaviors” occurring in patients on these drugs, 20 of which were fatal
- › Several studies have also found sleeping pills increase your risk of death. In one study, fewer than 18 doses per year increased risk of death by 360%
- › Many studies have also shown sleeping pills increase sleep time by mere minutes, typically in the range of five to 30 minutes at the most

This article was previously published May 16, 2019, and has been updated with new information.

If you have trouble sleeping, you're not alone. According to SleepHealth.org, 70% of American adults say they get insufficient sleep at least one night per month, and 11% struggle to get sufficient sleep on a nightly basis.¹ As noted by this organization:

"Sleepiness affects vigilance, reaction times, learning abilities, alertness, mood, hand-eye coordination, and the accuracy of short-term memory. Sleepiness has been identified as the cause of a growing number of on-the-job accidents, automobile crashes and multi-modal transportation tragedies."

However, reaching for a sleeping pill may be just as dangerous as not getting enough sleep.

Sleep Drugs Safety Announcement

April 30, 2019, the U.S. Food and Drug Administration announced² it will require sedative-hypnotics – a class of sleep medication used to treat insomnia – to carry a black box warning stating drug side effects may include dangerous behaviors done while sleeping, such as eating, walking, driving or engaging in a range of activities in your sleep that can lead to injury or death. According to the FDA:³

"These behaviors appear to be more common with eszopiclone (Lunesta), zaleplon (Sonata), and zolpidem (Ambien, Ambien CR, Edluar, Intermezzo, Zolpimist) than other prescription medicines used for sleep.

As a result, we are requiring a Boxed Warning, our most prominent warning, to be added to the prescribing information and the patient Medication Guides for these medicines.

We are also requiring a Contraindication, our strongest warning, to avoid use in patients who have previously experienced an episode of complex sleep behavior with eszopiclone, zaleplon, and zolpidem.

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."

Patients who experience an episode of activity while not fully awake, or find they cannot recall an activity that occurred while taking the medicine, are advised to stop taking the drug immediately and to contact their doctor.

Popular Sleep Drugs Linked to Accidental Fatalities

Over the past 26 years, there have been 66 documented reports of "complex sleep behaviors" occurring in patients on these drugs, the FDA says, 20 of which were fatal. These reports included:⁴

Accidental drug overdose	Falls
Burns	Near drowning and drowning
Exposure to extreme cold, resulting in amputation of a limb	Hypothermia
Carbon monoxide poisoning	Car accidents, where sleeping patient was driving
Self-inflicted gunshot wounds	Unintentional suicide attempts

Research⁵ has also shown that those who take hypnotic sleep aids (including zolpidem, temazepam, eszopiclone, zaleplon, benzodiazepines, barbiturates and sedative antihistamines) on a regular basis are significantly more likely to die over the course of 2.5 years than nonusers, and the link is dose dependent.

Patients prescribed 0.4 to 18 doses per year raised their risk of death by 360%; those taking 18 to 132 doses per year had a 443% greater risk, while those taking in excess of 132 doses were 5.36 times (536%) more likely to die. Heavy users were also found to have a higher risk of cancer.

As noted by the authors, "Receiving hypnotic prescriptions was associated with greater than threefold increased hazards of death even when prescribed [less than] <18 pills/year." Other studies have reached similar conclusions. For example:

- A Norwegian study⁶ published in 2007, which included data from 14,451 men and women aged 40 to 42 who were followed for 18 years, found frequent use of sleeping pills increased men's risk of death by 150% and women's risk by 170%, after adjusting for confounding factors.
- A 2009 Swedish study,⁷ which followed a cohort of 3,523 men and women aged 30 to 65 for 20 years, found regular use of hypnotics raised all-cause mortality by 454% in men and 203% in women.

According to the authors, "With regard to cause-specific mortality, regular hypnotic usage in men was a risk factor for coronary artery disease death, cancer death, suicide and death from "all remaining causes." In women it was a risk factor for suicide."

- A 2010 Canadian study⁸ of 14,117 people between the ages of 18 and 102 found those who used sleeping pills were 1.36 times (136%) more likely to die than nonusers.

Sleeping Pills Provide Little or No Benefit

Considering the risks of these drugs, it's important to realize that the benefit you receive from them is negligible at best. In 2010, after a decade-long delay, the FDA finally got around to analyzing an industry-sponsored study submitted to the agency in 1995.

The study in question evaluated the effectiveness of over-the-counter sleep aids such as Tylenol PM and Excedrin PM. The drugs, which are a combination of acetaminophen (a painkiller) and diphenhydramine citrate (a sleep aid), were found to work only slightly better than a placebo.⁹

In a February 16, 2010, letter to the Consumer Healthcare Products Association (which represents makers of nonprescription drugs), Dr. Charles Ganley, director of the FDA's Office of Specialty Medicine,¹⁰ stated:¹¹

"There is an insufficient basis to support the combination of acetaminophen and diphenhydramine as a nighttime sleep aid for relief of occasional sleeplessness when associated with minor aches and pains."

Many other studies have produced abysmal results, raising serious questions about the value of sleeping pills. For example, an investigation by two drug safety experts commissioned by Consumer Reports revealed the sleep aid Belsomra helps you fall asleep just six minutes sooner, on average, compared to placebo, and extends sleep by about 16 minutes.¹²

Belsomra users also complained of drowsiness the following day, and were involved in a slightly greater number of car accidents. According to the Institute for Safe Medication Practices' (ISMP) 2015 report¹³ for the first and second quarter of that year, Merck's own tests showed a 40 milligram (mg) dose of Belsomra increased sleep time by a modest 23 minutes longer than placebo.

A dose of 10 mg, which FDA insisted on as an initial dose due to concerns about impaired driving the next day, prolonged sleep just five minutes longer than placebo. What's more, between February and July 2015 – the year the drug launched – a whopping 1,016 consumer complaints against Belsomra were filed with the FDA.^{14,15}

A majority, 42%, complained it didn't work; 32% reported sleep disturbances, including nightmares, hallucinations, sleep paralysis and sleepwalking; 28% reported next-day drowsiness, headache, dizziness, fatigue, amnesia and memory impairment; 22% reported agitation, anxiety, tremors, restless leg syndrome and muscle spasms; 5% reported depression, suicidal thoughts and attempted suicide. According to Consumer Reports:¹⁶

"Some drugs have even less benefit. For example, studies show that, on average, people taking ramelteon fall asleep 9 minutes faster than those taking

a placebo; those taking suvorexant got only 10 minutes more shut-eye than those who took a placebo."

The best performing sleep drug in Consumer Reports' "Best Buy Drugs Report," zolpidem, (which is one of the drugs slated to receive a black box warning), allowed patients to fall asleep 20 minutes faster and sleep 34 minutes longer on average, compared to placebo.^{17,18}

Similarly, a 2012 meta-analysis¹⁹ of data from 13 studies submitted to the FDA found so-called Z drugs (non-benzodiazepine hypnotics) decreased the time it took to fall asleep by 11 to 33 minutes (average 22 minutes) compared with placebo.

What Actually Works?

You'd be far better off putting your money toward authentic solutions to help you sleep, like installing black-out drapes in your bedroom, than on sleeping pills, as they may actually make it more difficult for you to get a good night's rest naturally.

One supplement that can be helpful, however, is melatonin. A 2015 systematic review²⁰ of the efficacy and safety of three types of over-the-counter sleep aids – antihistamines (diphenhydramine and/or doxylamine), melatonin and valerian – for occasional disturbed sleep or insomnia, showed that:

"[M]elatonin, especially prolonged-release formulations in older individuals with diagnosed insomnia, demonstrated the most consistent beneficial effects (vs placebo) on sleep measures, specifically sleep onset and sleep quality, with favorable tolerability. In contrast, the clinical trial data for diphenhydramine, immediate-release melatonin, and valerian suggested limited beneficial effects."

Another paper²¹ published in 2015, "Pharmacological Treatment of Insomnia," which reviews the mechanisms of action and effects of a range of sleep medications, cited the following research findings:

"In a randomized, double-blind, placebo-controlled study, a prolonged-release formulation of melatonin was associated with improvements in sleep and daytime parameters, including sleep latency, sleep quality, and morning alertness, after three weeks of treatment in adults with primary insomnia. The improvements were maintained in a subset of patients who continued treatment for a total of six months.

In another short-term (one week), randomized, double-blind, placebo-controlled investigation, a physiological dose of melatonin (0.3 mg) restored sleep efficiency and elevated plasma melatonin levels to normal in adults with insomnia ..."

Beware: Many Sleep Aids Will Leave You Impaired the Next Day

Lastly, it's also important to realize that many sleep drugs have long half-life – i.e., the time it takes for the drug's bioavailability in your blood to be reduced by half – which can leave you feeling groggy and not quite awake the following morning. As noted in the featured FDA safety announcement:²²

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

For example, as reported by ISMP,²³ Belsomra has a half-life of 12 hours and accumulates with repeated use. After taking 40 mg of Belsomra for seven days, the drug's half-life rose from 12 to 17 hours in older men, and from 12 to 20 hours in older women.

"Many patients on a 40-mg dose might experience a therapeutic effect for the entire 24-hour period, potentially leading to daytime sleepiness," ISMP warns. Similarly, sleep aids that contain Benadryl (diphenhydramine) can have a half-life of 2.4 to 9.3 hours in healthy adults.²⁴

As noted by Mental Health Daily,²⁵ you can "estimate that Benadryl will be 100% eliminated from systemic circulation between 13.2 hours and 2.13 days after your final dose." Until then, you may experience cognitive deficits and be more prone to accidents.

Optimize Your Health by Improving Your Sleep

Considering the virtually insignificant benefit sleeping pills provide – say an extra 15 minutes at best – are they really worth the potential risks? Small adjustments to your daily routine and sleeping area can go a long way toward ensuring you uninterrupted, restful sleep, without the added hazards. To get you started, check out the suggestions listed in the table below.

If you're even slightly sleep-deprived I encourage you to implement some of these suggestions, as high-quality sleep is one of the most important factors in your health and quality of life. As for how much sleep you need for optimal health, a panel of experts reviewed more than 300 studies to determine the ideal amount of sleep, and found that, as a general rule, most adults need right around eight hours per night.

Optimize your light exposure during the day, and minimize light exposure after sunset – Your pineal gland produces melatonin roughly in approximation to the contrast of bright sun exposure in the day and complete darkness at night.

If you're in darkness all day long, your body can't appreciate the difference and will not optimize melatonin production. Make sure you get at least 30 to 60 minutes of outdoor light exposure in the morning or midday to "anchor" your master clock rhythm.

Once the sun sets, minimize artificial light exposure to assist your body in secreting melatonin, which helps you feel sleepy. Alternatively, wear blue-blocking glasses in the evening.

It can be helpful to sleep in complete darkness, or as close to it as possible. If you need navigation light, install a low-wattage yellow, orange or red light bulb. Light in these bandwidths does not shut down melatonin production in the way that white and blue light does. Salt lamps are great for this purpose.

Address mental states that prevent peaceful slumber – A sleep disturbance is always caused by something, be it physical, emotional or both. Anxiety and anger are two mental states that are incompatible with sleep. Feeling overwhelmed with responsibilities is another common sleep blocker. To identify the cause of your wakefulness, analyze the thoughts that circle in your mind during the time you lie awake and look for themes.

Many who have learned the Emotional Freedom Techniques (EFT) find it is incredibly useful in helping them to sleep. One strategy is to compile a list of your current concerns, and then "tap" on each issue. For a demonstration, see the video below.

Keep the temperature in your bedroom below 70 degrees Fahrenheit – Many people keep their homes too warm at night. According to Sleep.org, the recommended room temperature for optimal sleep is between 60 and 67 degrees Fahrenheit,²⁶ and the National Sleep Foundation notes temperatures above 75 degrees F and below 54 degrees will disrupt sleep.²⁷

Avoid watching TV or using electronics in the evening, at least an hour or so before going to bed – Electronic devices emit blue light, which tricks your brain into thinking it's still daytime.

Normally, your brain starts secreting melatonin between 9 p.m. and 10 p.m., and these devices may stifle that process. If you have to watch TV or use your cellphone or computer at night, wear blue-blocking glasses.

Take a hot bath 90 to 120 minutes before bedtime — This raises your core body temperature, and when you get out of the bath it abruptly drops, signaling your body that you're ready for sleep.

Minimize electromagnetic fields (EMFs) in your bedroom — EMFs can disrupt your pineal gland and its melatonin production, and may have other detrimental biological effects. Ideally, turn off any wireless router while you are sleeping. After all, you don't need access to the internet while sleeping.

Develop a relaxing presleep routine — Going to bed and getting up at the same time each day helps keep your sleep on track, but having a consistent presleep routine or "sleep ritual" is also important.

For instance, if you read before heading to bed, your body knows that reading at night signals it's time for sleep. Sleep specialist Stephanie Silberman, Ph.D., suggests listening to calming music, stretching or doing relaxation exercises.²⁸ Tai chi and cognitive behavioral therapy have also been found to produce "clinically meaningful improvements in insomnia."²⁹

Avoid alcohol, caffeine and other drugs, including nicotine — Two of the biggest sleep saboteurs are caffeine and alcohol, both of which also increase anxiety. Caffeine's effects can last four to seven hours. Tea and chocolate also contain caffeine.

Alcohol can help you fall asleep faster, but it makes sleep more fragmented and less restorative. Nicotine in all its forms (cigarettes, e-cigs, chewing tobacco, pipe tobacco and smoking cessation patches) is also a stimulant, so lighting up too close to bedtime can worsen insomnia. Many other drugs can also interfere with sleep.

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