

Side Effects of Sleep Drugs

Eating a little bit of chocolate was a treat that Teresa Wood looked forward to after work. The Fairfax Station, Va., resident allowed herself two small pieces of chocolate candy a day.

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Phototake

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But after taking a drug to help her sleep at night, Wood awoke in the morning to find an empty box on the table in place of a pound of chocolates that had been there the night before.

"I couldn't believe it," says Wood. "I started looking all around the house—I even looked under the bed. I thought for sure someone came into the house during the night and ate them." But she was alone.

A few weeks later, Wood awoke to find a near-full box of chocolates gone again. "I just don't remember eating all that candy," she says.

Complex Sleep-related Behaviors

Wood and her doctor determined that she had been getting up during the night and "sleep eating," an occurrence known as a complex sleep-related behavior. Other behaviors include making phone calls, having sex, and getting into the car and driving while not fully awake. Most people do not remember these events later.

Complex behaviors are a potential side effect of sedative-hypnotic products—a class of drugs used to help a person fall asleep and stay asleep.

"Complex behaviors, such as sleep-driving, could be potentially dangerous to both the patients and to others," says Russell Katz, M.D., Director of the Food and Drug Administration's Division of Neurology Products.

Allergic Reactions

Other rare but potential side effects of sedative-hypnotic drugs are a severe allergic reaction (anaphylaxis) and severe facial swelling (angioedema), which can occur as early as the first

time the product is taken.

"Severe allergic reactions can affect a patient's ability to breathe and can affect other body systems as well, and can even be fatal at times," says Katz. "Although these allergic reactions are probably very rare, people should be aware that they can occur, because these reactions may be difficult to notice as people are falling asleep."

Stronger Warnings

To make known the risks of these products, FDA requested in early 2007 that all manufacturers of sedative-

hypnotic drug products strengthen their product labeling to include warnings about complex sleep-related behaviors and anaphylaxis and angioedema.

"There are a number of prescription sleep aids available that are well-tolerated and effective for many people," says Steven Galson, M.D., M.P.H., Director of FDA's Center for Drug Evaluation and Research. However, after reviewing the available information on adverse events that occurred after the sedative-hypnotic drugs were on the market, FDA concluded that labeling changes were necessary to inform health care providers and consumers about risks, says Galson.

In addition to the labeling changes, FDA has requested that manufacturers of sedative-hypnotic products

- send letters to health care providers to notify them about the new warnings. (Manufacturers sent these letters beginning in March 2007.)
- develop Patient Medication Guides for the products to inform consumers about risks and advise them of precautions that can be taken. (Patient Medication Guides are handouts given to patients, families, and caregivers when a medicine is dispensed. The guides will contain FDA-approved information, such as proper use and the recommendation to avoid ingesting alcohol or other central nervous system depressants.)
- conduct clinical studies to investigate the frequency with which sleep-driving and other complex behaviors occur in association with individual drug products.

Tips for Better Sleep

- Go to bed and get up at the same time each day.
- Avoid caffeine, nicotine, beer, wine, and liquor in the four to six hours before bedtime.
- Don't exercise within two hours of bedtime.
- Don't eat large meals within two hours of bedtime.
- Don't nap later than 3 p.m.
- Sleep in a dark, quiet room that isn't too hot or cold for you.
- If you can't fall asleep within 20 minutes, get up and do something quiet until you feel sleepy.
- Wind down in the 30 minutes before bedtime by doing something relaxing, such as reading or listening to music.

Source: FDA Office of Women's Health

OTC sleep aids are non-habit-forming and do not present the risk of allergic reactions and complex sleep-related behaviors that are known to occur with sedative-hypnotic drugs.

Sleep Facts

- Your brain stays active throughout sleep.
- Not getting enough sleep increases the risk of having high blood pressure, heart disease, and other medical conditions.
- Insomnia—trouble sleeping at night—is more common in
 - females
 - people with depression
 - people older than 60

Source: National Heart, Lung, and Blood Institute

before you start these medications and if you have any questions or concerns.

- Read the Medication Guide, when available, before taking the product.
- Do not increase the dose prescribed by your health care provider. Complex sleep-related behaviors are more likely to occur with higher than appropriate doses.
- Do not drink alcohol or take other drugs that depress the nervous system.
- Do not discontinue the use of these medications without first talking to your health care provider.

How Much Sleep is Enough?

- Most adults need 7–8 hours of sleep each night.
- Newborns sleep between 16 and 18 hours a day.
- Preschool children sleep between 10 and 12 hours a day.
- School-aged children and teens need at least 9 hours of sleep a night.

Source: National Heart, Lung, and Blood Institute

The revised labeling and other actions to make risks known affect these sedative-hypnotic products:

- Ambien, Ambien CR (zolpidem tartrate)
- Butisol sodium
- Carbital (pentobarbital and carbomal)
- Dalmane (flurazepam hydrochloride)
- Doral (quazepam)
- Halcion (triazolam)
- Lunesta (eszopiclone)
- Placidyl (ethchlorvynol)
- Prosom (estazolam)
- Restoril (temazepam)
- Rozerem (ramelteon)
- Seconal (secobarbital sodium)
- Sonata (zaleplon)

Precautions

FDA advises people who are treated with any of these products to take the following precautions:

- Talk to your health care provider

Over-the-Counter Sleep Aids

Not all sleep medications are prescription. FDA has approved over-the-counter (OTC) medications for use up to two weeks to help relieve occasional sleepiness in people ages 12 and older. “If you continue to have sleeping problems beyond two weeks, you should see a doctor,” says Marina Chang, R.Ph., pharmacist and team leader in FDA’s Division of Nonprescription Regulation Development.

OTC sleep aids are non-habit-forming and do not present the risk of allergic reactions and complex sleep-related behaviors that are known to occur with sedative-hypnotic drugs.

But just because they’re available over-the-counter doesn’t mean they don’t have side effects, says Chang. “They don’t have the same level of precision as the prescription drugs. They don’t completely stop working after 8 hours—many people feel drowsy for longer than 8 hours after

taking them.”

Chang advises reading the product label and exercising caution when taking OTC sleep aids until you learn how they will affect you. “They affect people differently,” she says. “They are not for everybody.” [FDA](#)

For more information on prescription sedative-hypnotic products and sleep disorders, visit

www.fda.gov/cder/drug/infopage/sedative_hypnotics/

www.fda.gov/womens/getthefacts/sleep.html

www.nhlbi.nih.gov/health/dci/Diseases/inso/inso_what.html