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A QUICK READ FOR YOUR OTC NEED!

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OVER-THE-COUNTER AND PRESCRIPTION SLEEP AIDS

Various studies report that anywhere from 30% to 50% of Americans have symptoms of insomnia at some time in their lives. And as many as 15% of persons with sleep difficulty suffer from serious distress or impairment. Insomnia is common but complicated. Because sleep is a natural but complex physiological process, generally speaking, taking a drug to help you sleep is not a good idea. The first-line treatment of chronic insomnia should focus on non-drug interventions. Studies show that medicines are only modestly effective and can result in dependency. "Natural" supplements, like melatonin, are also limited in helping with sleep problems (see below). According to the American Academy of Sleep Medicine, whether you use an over-the-counter (OTC) or prescription drug, research has demonstrated that drugs (when they work) only help patients fall asleep about five to fifteen minutes faster and stay asleep about 30 to 60 minutes longer. Many prescription drugs for insomnia have a potential for dependence. OTC medicines and natural supplements are available but many health professionals don't recommend them claiming poor evidence of effectiveness, even though some patients do find them occasionally useful. Most OTC and prescription sleep medicines are on the list of high-risk drugs for use in the elderly. This is due to side effects, daytime drowsiness, and impaired functioning that can lead to a fall in older persons.

It's an oversimplification, but there are two types of insomnia, primary insomnia, and secondary insomnia. Primary insomnia refers to insomnia not associated with lifestyle habits or a medical or psychiatric cause. It tends to persist throughout a person's life. There is no identifiable cause for primary insomnia. Secondary insomnia is far more common and refers to insomnia caused by temporary conditions that cause anxiety due to precipitating events like retirement, travel/jet lag, shift work, warm sleep temperatures, isolation, loneliness, bereavement, job loss, and divorce. Emotional problems like stress, anxiety, and mood disorders such as depression also are responsible for the inability to sleep. Current classification systems group primary and secondary insomnia together under *insomnia disorder.*

With this overview in mind, consider some of the pros and cons of medicines available to treat sleep disorders.

Non-prescription Antihistamines. *Diphenhydramine* is an antihistamine that causes drowsiness and so is used in sleep aid products like ZzzQuil® and Unisom® SleepMelts. However, morning drowsiness, dizziness, and grogginess are often reported as hangovers in patients who use this drug. The American Academy of Sleep Medicine rates it no better than a placebo in producing *quality sleep* and does not recommend it. *Doxylamine* is another OTC antihistamine used for sleep found in Unisom® Sleep Tabs. The American Geriatrics Society's list of medications to avoid in most older patients recommends that individuals 65 years or older avoid the use of diphenhydramine and doxylamine. One study stated that most people who purchased these drugs used them in combination with a pain reliever, like Aleve® PM and Tylenol® PM. Combining a drug for sleep with a pain reliever is also not a good idea. If temporary pain is keeping you awake, treat the pain with a single-ingredient pain reliever like acetaminophen, ibuprofen, or naproxen. Adding an OTC sleep ingredient just adds side effects. If you do try diphenhydramine or doxylamine alone, use them only short-term or occasionally. Read the label for side effects and drink plenty of water with these drugs.

Natural Supplements. These are products not reviewed by the FDA for safety and effectiveness. Consequently, they cannot make drug claims to *treat or cure* insomnia. That said, many of the names used on these supplements strongly suggest that they will induce sleep. Many people do find natural products soothing and calming before bedtime. If you decide to use a natural medicine just make sure it doesn't interact with any other medicines you are taking by checking with your physician or pharmacist first. The ones listed below are a few that show the most promise for insomnia.

Melatonin. Melatonin is a hormone produced naturally in the brain. It regulates the sleep-wake cycle, among other things. Commercial melatonin sold OTC is made in the laboratory. Melatonin does seem to work for some people with certain kinds of sleep disorders. However, taking melatonin as medicine will cause your body to stop producing it naturally since it works on a feedback mechanism. Stopping the melatonin abruptly may cause rebound insomnia. At least one study demonstrated that using a timed-release melatonin reduces this risk. The bottom line is that melatonin seems safe when used short-term in doses not higher than 8 mg daily for up to 6 months. Melatonin 10 mg daily has been used safely for up to 2 months. If you want to try it, buy the timed-release tablets.

L-Tryptophan. An essential amino acid found in many proteins, L-tryptophan is found as part of a normal diet. Taking L-tryptophan as a medicine might decrease the time it takes you to fall asleep and improve your morning mood when compared with a placebo in healthy people with insomnia. If it works, it is most likely because L-tryptophan is ultimately converted to melatonin in the body. Trying it short-term seems to be safe in a dose of 5 grams for 21 days.

Valerian. Valerian root used as a sedative dates back to the ancient Greeks and Romans. Most research shows valerian to be "possibly effective." Valerian whole root extract in a dose of 300-600 mg daily seems to improve sleep quality, although it might take weeks for it to work. The reason for this is not clear from the studies. While valerian may provide a more restful night, it doesn't help you get to sleep faster or keep you asleep longer.

Stay away from products that combine the above ingredients in a shotgun approach, like Sleep Sana,® since they don't tell you how much of the ingredients are in each dose. Buy them individually to find out which natural supplement works for you.

Prescription (Rx) Medicines. Chronic sleep problems should be discussed with your physician. Prescription medicines for insomnia should be a last resort. Any prescription drug used for insomnia should be used short-term, or in chronic insomnia, intermittently, and closely followed by your physician. All but one of the prescription sleep drugs are controlled substances because they can be abused or lead to dependence. There are numerous brand and generic Rx drugs

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used to treat sleep disorders and only a few examples are mentioned below.

Sedative/Hypnotics. Most prescription drugs used for insomnia are classified as "hypnotics." These are drugs like Restoril® (temazepam) and Halcion® (triazolam). Hypnotic drugs are fraught with side effects and danger, such as impaired driving, falls, and fractures, especially in the elderly. Some hypnotic drugs like Ativan® (lorazepam) and Xanax® (alprazolam) are particularly used for secondary insomnia, but they are what is called "off-label" drugs, meaning that the FDA has *not* approved them for insomnia yet doctors use them for that purpose. Another group of hypnotic drugs that include Lunesta® (eszopiclone), Ambien® (zolpidem), and Sonata® (zaleplon) (referred to as "Z" drugs because of all the Zs in the generic names) have been associated with sleepwalking, sleep driving, and other sleep-related behaviors with amnesia. A couple of the most recent hypnotic drugs for insomnia are Dayvigo® (lemborexant) and Belsomra® (suvorexant). These medicines block a certain protein in the brain that is responsible for wakefulness, and thereby induce sleep. They are approved by the FDA for sleep onset and maintenance. While the manufacturers claim fewer side effects than other drugs on the market for insomnia and no withdrawal or rebound insomnia when stopped, like the others they are controlled substances and have similar warnings and precautions as other older hypnotic drugs.

Antidepressants. These are most effective for insomnia in people with depression and pain. At least one antidepressant, doxepin, is approved by the FDA for insomnia. Others are off-label use, again, because they are not approved specifically for insomnia by the FDA. An example of an off-label antidepressant is the generic antidepressant, trazodone.

Melatonin-like drugs. One prescription drug approved in 2005 that works in a similar way to melatonin is Rozerem® (ramelteon). Its benefit is particularly for insomnia characterized by difficulty in falling asleep. Studies have shown it to decrease the time it takes for you to fall asleep and slightly increase the length of time you sleep. Studies also show it to be better than OTC melatonin. It is not limited to short-term use and has been used for up to six months. Because it is not a sedative or hypnotic drug, it's not a controlled substance and has not been associated with abuse. This drug appears to be safe for use in the elderly and is not on the American Geriatrics Society's list of medicines to avoid in older persons.

Recommendation:

Since almost everyone has trouble sleeping at some time in their life, it is wise to focus on non-drug interventions first. Before any medicine is used, work on improving what health professionals call "sleep hygiene." These are the strategies listed below. Admittedly, given the culture we live in, these things are not easy to do. Do the best you can.

Good Sleep Habits

- Stick to a regular sleep schedule...even on weekends.
- Get regular exercise and avoid exercise in the late evening.
- Go to bed only when you are sleepy.
- Put your worries away when you go to bed.
- Make your bedroom quiet and comfortable.
- Avoid large meals just before bedtime.
- Use you bedroom only for sleep and sexual activity.
- If you do not fall asleep within 15 to 20 minutes, get up and go to another room. Return to bed only when you feel drowsy.
- Remove your clock from sight.
- Do not nap during the day. If you must nap, do so only for 30 minutes in the early afternoon.
- Avoid alcohol, nicotine, and caffeine.
- Avoid frequent use of sedatives.
- Spend time outdoors at the same time each day.
- Have your pharmacist check your medicines in case any of them keep you from sleeping
- Avoid bright lights from the TV, computers, video games, etc. before bedtime. Blue light is especially disruptive to the brain and a relaxing sleep.

Adapted from Pharmacist's/Prescriber's Letter, March 2012

References on file

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