ConsumerReports® Health

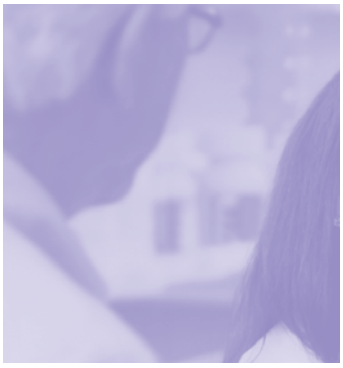
BEST BUY DRUGS™

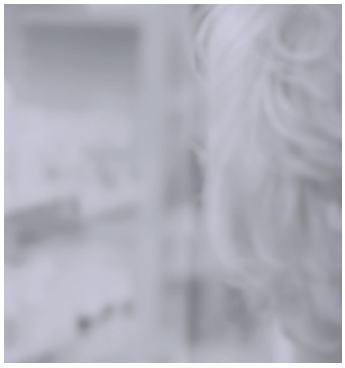
Evaluating Newer Sleeping Pills Used to Treat:

Insomnia

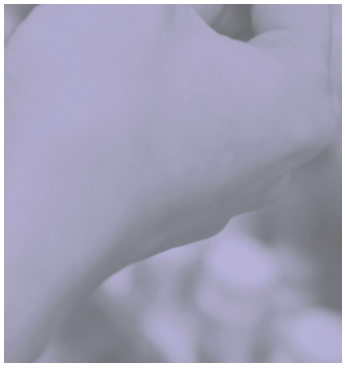
Comparing Effectiveness, Safety, and Price









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Our Recommendations

Four drugs used to treat insomnia—eszopiclone (Lunesta), ramelteon (Rozerem), zaleplon (Sonata and generic) and zolpidem (Ambien, Ambien CR, Edluar, Zolpimist, and generic)—are effective but not necessarily better than behavioral therapy or older, less expensive drugs for many people who need a sleep aid for a night or two.

Nonprescription drugs containing an antihistamine—for example, diphenhydramine (the active ingredient in Benadryl, but also sold as a sleep aid under the brand names Nytol and Sominex and as a generic) or doxylamine (Unisom and generic)—and older prescription sedatives called benzodiazepines, such as estazolam (generic only), flurazepam (Dalmane and generic), and temazepam (Restoril and generic), might work just as well as the newer sleeping pills.

But we recommend that both prescription and nonprescription sleeping pills be used judiciously because research has found that people with mild insomnia sometimes unnecessarily take these medications when they might be able to resolve their sleep issues with nondrug measures.

In addition, all insomnia medicines can cause side effects and dependency, and even worsen your sleeping problems when abused, misused, or taken too often. Possible side effects include daytime sleepiness, dizziness, unsteadiness, and rebound insomnia. Sleep-walking, sleep-driving, sleep-eating, memory lapses, and hallucinations have also been reported.

That said, people with persistent, chronic insomnia—three or more nights a week for months—should seek treatment. We advise cognitive behavioral therapy—a form of psychotherapy—that can improve sleep habits, possibly combined with a cautious use of sleeping pills. Research has found this can help relieve chronic insomnia.

For the average person seeking short-term help—for a few nights—we suggest trying an over-the-counter sleep aid first. If that doesn't work, our comparison of the newer drugs led us to choose zolpidem as a *Best Buy*. This is the less expensive, generic version of the drug Ambien. Fifteen pills cost $27 to $31, depending on the dose and where you buy it.

This report was updated in January 2012.

Welcome

This report compares the effectiveness, safety, and cost of newer sleeping pills used to treat people with insomnia.

There is concern that the newer sleeping pills are overprescribed and inappropriately prescribed. For several years they have been heavily advertised both to doctors and consumers, which may have led to excessive and overly casual use. In addition, media stories and anecdotal accounts suggest there is an emerging "gray market" for the newer sleeping pills, with people getting prescriptions and then selling individual pills.

At the same time, however, studies have found that chronic insomnia is undertreated, with fewer than half of the people who need help getting it.

This report aims to help clarify who might benefit from the newer sleeping pills and who probably shouldn't take them. The report is part of a *Consumer Reports* project to help you find medicines that are safe and effective and give you the most value for your health-care dollar. To learn more about the project and other drugs we've evaluated, or to get price updates, go to CRBestBuyDrugs.org.

Insomnia is defined as having difficulty falling asleep or staying asleep, which can lead to sleepiness and other problems during the daytime. Normal sleep is generally considered getting 7 to 9 hours a night, although this varies from person to person; some might feel fine with as little as 4 hours of sleep while others might need up to 10. Older people often sleep less, on average.

Insomnia can be mild to severe, and the sleep issues vary from person to person. Some people only have trouble falling asleep, while others fall asleep easily but awake during the night, and still others have trouble both falling asleep and staying asleep. These sleep disturbances can lead to daytime drowsiness and feeling irritable and anxious.

Symptoms of Insomnia

- Difficulty falling asleep–tossing and turning for an hour or more
- Waking up during the night and not being able to get back to sleep
- Feeling unrefreshed upon waking
- Daytime sleepiness, irritability, or anxiety

Insomnia is quite common. One in three adults has difficulty falling or staying asleep occasionally, and one in 10 suffers from chronic insomnia, according to the National Heart, Lung, and Blood Institute (NHLBI).

Insomnia can strike people of any age, including children. But women are more likely to suffer from it than men. Older people are also more likely to have trouble sleeping. This is usually because they are more likely to have other illnesses (or just aches and pains) that disrupt sleep, or to be taking medicines that make getting a good night's rest difficult.

African-Americans also face a heightened risk of insomnia, according to the NHLBI. Compared to Caucasians, African-Americans, in general, take longer to fall asleep, don't sleep as well, and tend to take more naps.

Several other factors are also associated with an increased risk of insomnia. They include:

- High level of stress
- Depression or sudden changes in life that cause significant distress, such as divorce or death of someone close
- Working at night
- Traveling to different time zones
- Illnesses or disorders that interfere with sleep
- A sedentary, inactive lifestyle

Relieving insomnia is important because a lack of sleep can have serious consequences. Sleeping difficulties or insufficient sleep have been linked to a higher risk of type 2 diabetes, obesity, and other health conditions. Insomnia can cause daytime sleepiness, which could lead to accidents. Indeed, drowsy drivers are involved in more than 100,000 car crashes each year, according to the NHLBI. Research has also found that insomnia raises the risk of falling, particularly among older women.

In addition, as we previously noted, insomnia can leave you feeling anxious, depressed, or irritable. And due to the drowsiness, you might find it difficult to pay attention, learn, and remember, which can lead to poor performance at work or school.

There are two types of insomnia. The most common is secondary or comorbid insomnia, meaning it is caused by or associated with other conditions, medications, or other substances. More than 8 of 10 people with insomnia suffer from this type. The conditions that can cause insomnia include Alzheimer's disease, anxiety, arthritis, asthma, attention deficit hyperactivity disorder (ADHD), chronic pain, depression, heartburn, heart disease, hyperthyroidism, menopause, Parkinson's disease, post-traumatic stress disorder, prostate enlargement that causes an increase in frequency of nighttime urination, and sleep apnea and other sleep disorders.

Medication that can interfere with sleep includes allergy and cold medicine, beta-blockers, certain pain relievers, steroids, and asthma medicine, such as theophylline. In addition, alcohol, caffeine, and tobacco or other nicotine products can also trigger insomnia.

In many cases, the proper treatment of these illnesses or discontinuing the medication or substance responsible for the insomnia will help resolve the problem without the need for separate treatment. But for millions of people, sleep problems might persist despite treatment and must be managed separately.

A second form of insomnia—affecting a minority of cases—is called primary insomnia. This type isn't related to or precipitated by another illness or medication or other substances. It's cause isn't well understood. Some research suggests that people who have it have a tendency to be more "revved up" physiologically and mentally.

Insomnia can range from short-term (a night or two for up to two weeks) to chronic (difficulty sleeping several nights a week for at least a month). Some people fall in between and have intermittent bouts of insomnia.

Most of us have experienced **short-term insomnia** at some point in our lives. It can be caused by any number of things—stress, work worries, marital strife, jet lag, illness, temporary pain, sleeping in a new place and bed, or a disturbance in normal sleep patterns. It might also be due to poor sleep habits (doctors refer to it as "sleep hygiene"). (See Table 1 on page 9.) But short-term insomnia can also arise for no apparent reason. It can last up to a couple of weeks but usually passes in a few days.

Intermittent short-term insomnia is more bothersome. People with this type are prone to bouts of insomnia from time to time. The episodes might last a few days to a few weeks, sometimes triggered by events, or arise spontaneously. They can be exacerbated by poor sleep habits, such as going to bed at different times each night.

Chronic insomnia is even more serious. People with it have trouble getting to sleep at least three nights a week for at least a month, and usually much longer. If your insomnia has persisted for this long, you should see your doctor for an evaluation. He or she might help you identify an underlying cause, and possibly order blood or other tests such as a sleep study.

Nonmedication treatments are available. Insomnia sufferers can often get relief by treating an underlying illness, stopping a medication that might be causing the insomnia, or making lifestyle changes, such as improving sleep habits (see page 9). Cognitive behavioral therapy—a form of psychotherapy—focused on improving sleep can also help and should be tried first for chronic insomnia. If those don't work, then the best first option for many people is the short-term use of an over-the-counter sleeping aid. If that fails to bring relief, then it might be time to consider a prescription medication.

In this report, we evaluate four currently available prescription sleeping pills. They are:

Generic Name(s)	Brand Name(s)	Available as a Generic?
Eszopiclone	Lunesta	No
Ramelteon	Rozerem	No
Zaleplon	Sonata	Yes
Zolpidem	Ambien	Yes
Zolpidem (extended release)	Ambien CR	Yes
Zolpidem (sublingual tablet)	Edluar	No
Zolpidem (oral spray)	Zolpimist	No

We refer to these drugs as new or newer sleeping pills to distinguish them from an older group of sedatives and anti-anxiety drugs called benzodiazepines. The larger class of benzodiazepines—which includes such drugs as alprazolam (Xanax and generic), diazepam (Valium and generic), and lorazepam (Ativan and generic)—are used primarily to treat anxiety. But the Food and Drug Administration has approved some benzodiazepines to treat insomnia. Those include estazolam (generic only), flurazepam (Dalmane and generic), quazepam (Doral) temazepam (Restoril and generic), and triazolam (Halcion and generic).

The newer drugs we examine in this report have been found to be generally as effective as the benzodiazepines approved for treating insomnia. But it's not clear whether the newer drugs are *more* effective or cause fewer side effects.

Several studies indicate that benzodiazepines cause more day-after sleepiness and grogginess, and are associated with a higher risk of dependency and rebound insomnia (when the insomnia returns after the person stops taking the medication and might even be worse for a few days). But overall, very few studies have directly compared the newer insomnia drugs with benzodiazepines, and many researchers and doctors think it's unclear whether the newer drugs are more effective or safer.

It's also important to note that benzodiazepines remain very useful in some circumstances—specifically when treating people who have an anxiety disorder that also causes sleep problems. In this case, a benzodiazepine may in fact be your doctor's first choice for you. These drugs have the added advantage of being much less expensive since most are now available in generic form.

Indeed, some doctors might even prescribe a benzodiazepine for you first (even if you don't have anxiety symptoms) just because it's much less expensive—and see how you respond. Some people tolerate these medicines well, experience few of the side effects mentioned above, and can use them safely on an intermittent basis.

Other medicines and nondrug therapies are also used to treat insomnia. Among prescription drugs, one antidepressant in particular, trazodone (generic only) is widely prescribed for insomnia even for people who don't have depression. Trazodone is available as an inexpensive, generic drug but it is rarely prescribed these days for depression. For short-term use, studies indicate it helps people with depression fall asleep and stay asleep. Unfortunately, there is very little evidence that it is effective in treating insomnia in people who have not been diagnosed with depression. In the one study to test trazodone against a placebo and a newer sleep drug (Ambien), trazodone came out only slightly better than placebo and was not as helpful as Ambien.

Two other medications—doxepin (Silenor) tablets and low-dose zolpidem (Intermezzo) dissolvable tablets—are approved by the FDA for treating insomnia. Neither were included in the analysis that forms the basis of our report, so we don't know how their effectiveness or safety compares with the other sleeping pills.

Intermezzo is a low-dose of zolpidem, but it has been studied only against a placebo, so it's unclear how it compares with regular-strength zolpidem. Intermezzo's side effects are the same as regular-strength zolpidem. (See pages 13-15 for more about the safety of zolpidem.)

Over-the-counter products and supplements

Several nonprescription products or supplements are often used as sleep aids. Common ones include antihistamines, such as diphenhydramine (Benadryl, Nytol, Sominex, and generic) and doxylamine (Unisom and generic). Diphenhydramine is also contained in combination products such as Advil PM and Tylenol.

Over-the-counter antihistamines do indeed cause sedation and sleepiness, and some are marketed to treat transient or short-term insomnia. People often use them when minor illness, such as a cold, makes sleep difficult. The antihistamine products can be substantially less expensive than prescription medicine.

But just like with prescription sleeping pills, nonprescription antihistamines should not be used over a long period for the management of chronic insomnia. The antihistamine products can cause side effects, including next-day drowsiness, daytime sleepiness, confusion, constipation, dry mouth, and urinary retention.

A few dietary supplements, notably melatonin and valerian, are marketed for insomnia, but studies of both have found mixed results regarding their effectiveness. Some studies suggest that both valerian and melatonin might be better than a placebo at helping people fall asleep or stay asleep. But evaluations that included the studies altogether found that the effect of both products is minimal at best. Also, neither valerian nor melatonin have been compared with benzodiazepines or newer sleep aids. In addition, it's important to note that these supplements are not as closely regulated by the FDA as medications, so there's less assurance of the quality and purity of the available products than with prescription and nonprescription drugs. And there are no safety data on the regular or long-term use of valerian and melatonin as sleep aids.

Table 1. Poor Sleep Habits and How to Correct Them

Watching TV in bed	Don't. TV viewing is not conducive to calming down.
Computer work in bed	Don't work on a computer at all for at least an hour before going to bed.
Drinking alcoholic or caffeinated drinks at night	Don't drink either for at least 3 hours before going to bed.
Taking medicine late at night	A lot of prescription and nonprescription medicine can delay or disrupt sleep. If you take any on a regular basis, check with your doctor about this.
Big meals late at night	Not ideal, especially if you are prone to indigestion or heartburn. Allow at least 3 hours between dinner and going to bed.
Smoking at night	Don't smoke for at least 3 hours before going to bed. (Better yet, quit!)
Lack of exercise	Just do it! Regular exercise promotes healthy sleep.
Exercise late at night	A no-no. Allow at least 4 hours between exercise and going to bed. It revs up your metabolism, making falling asleep harder.
Busy or stressful activities late at night	Another no-no. Stop working or doing strenuous housework at least 2 hours before going to bed. The best preparation for a good night's rest is unwinding and relaxing.
Varying bedtimes	Going to sleep at widely varying times– 10:00 p.m. one night and 1:00 a.m. the next, for example–disrupts optimal sleep. The best practice is to go to sleep around the same time every night, even on the weekends.
Varying wake-up times	Likewise, the best practice is to wake up around the same time every day, with not more than an hour's difference on the weekends.
Spending too much time in bed tossing and turning	Solving insomnia by spending too much time in bed is usually counterproductive; you'll become only more frustrated. Don't stay in bed if you are awake, tossing and turning. Get up and do something else relaxing, such as reading, until you are ready to go to sleep.
Late-day napping	Naps can be wonderful but should not be taken after 3:00 p.m. because they can disrupt your ability to get to sleep at night.
Poor sleep environment	Noise, a room that's too hot or not dark enough, an uncomfortable bed, covers, or pillow–all of those can prevent a good night's sleep. Solve those problems if you have them.

Cognitive Behavioral Therapy

One nondrug treatment has proved to be quite effective in treating insomnia. It's called cognitive behavioral therapy, or CBT. Behavioral therapy involves getting help from a therapist (one trained in CBT) to learn a new set of behaviors regarding sleep. For example, you might be prohibited from watching TV in bed, or be directed to get up at the same time every day. Or you might have your actual time in bed restricted while you "relearn" to associate being in bed with sleep. You might also learn relaxation techniques and mental tricks to help you get to sleep. And behavioral therapy usually involves correcting poor sleep habits. (See Table 1 on page 9.) Generally, CBT involves three to six one-hour sessions with a therapist, who could be a doctor or not, plus lots of direction for at-home activities.

Studies have found behavioral therapy to be effective—it helps 70 to 80 percent of people with chronic insomnia—and several studies have found it *more effective* than sleeping pills alone. In other studies, a combination of the two has helped most. Behavioral therapy also has the advantage of yielding long-lasting benefits, something pills do not (since their effectiveness is limited to when they are being taken). For some people, behavioral therapy might provide a "cure" for insomnia while sleeping pills continue to treat the symptoms but don't address the underlying issues that interfere with sleep.

So behavioral therapy is an appropriate alternative to sleeping pills for people with intermittent or chronic insomnia. If you see a primary-care doctor or therapist for chronic insomnia and they prescribe pills without mentioning behavioral therapy as an option, you should mention it. If they don't know anything about it, we advise finding someone who does. Behavioral therapy costs more than pills in the short-term but probably less in the long run.

The rest of this report focuses primarily on the newer sleeping aids and how they compare with each other.

This report was updated in January 2012.

What Are the Newer Sleeping Pills and Who Needs Them?

Three of the four newer sleeping medications—zolpidem (Ambien and generic), eszopiclone (Lunesta), and zaleplon (Sonata and generic)—work the same way, by affecting a chemical in the brain called gamma-aminobutyric acid, or GABA. The remaining medicine, Rozerem, works differently. It affects the receptor in the brain for the hormone melatonin.

Zolpidem CR contains the same medicine as Ambien but stays active in the body for a longer period. Zolpidem in dissolvable-tablet form (Edluar) and an oral spray (Zolpimist) also contain the same medication as zolpidem but are designed to work more quickly than the other forms.

As mentioned, who should use these medicines and how often they should be used is the subject of significant debate. In the next section we compare the drugs with each other and evaluate their relative strengths and weaknesses.

Our overall recommendation is this: *The newer sleep medicines appear to be overused by millions of people in the U.S., so we recommend that you use caution and try nondrug options first.*

Our advice is based on the following:

(1) Several of these medicines are relatively new and their long-term use has not been well studied. While the newer drugs might produce fewer side effects than older sleeping pills, they still have side effects and safety issues. These include daytime sleepiness, cognitive impairment (which can be difficult to notice), dizziness, unsteadiness and loss of coordination, dependence, and rebound insomnia. Rare but serious side effects include sleep-walking (or sleep-driving), temporary amnesia or memory lapses, and hallucinations. While those side effects appear to be linked to taking excessive doses of the drugs, health authorities and researchers have not yet fully studied the potential for these problems, nor do they know how many people might be taking excessive doses. In addition, some reports of these problems have occurred in people taking recommended doses.

(2) When used only for a night or two, the risk of side effects appears to be minimal, with the benefit of the drug outweighing any potential harm. But when you take one of the newer sleeping pills every night for a week or so, your risk of adverse events, such as a fall or accident, increases. This might be especially true for the elderly.

(3) There are alternatives to these newer pills. For example, people with very mild, transient insomnia may do just as well with a nonprescription antihistamine for a night or two. People with chronic insomnia should look to behavioral therapy, with less use of pills.

To clarify these points a bit further, here's our advice for some specific situations:

- If you don't have insomnia but are tempted to try one of the newer drugs for anticipated sleep problems, such as jet lag, reconsider whether you really need a drug and whether other options might make more sense for your situation. Talk with a physician about it.

- If you have just had a poor night's sleep or two because of stress or travel, and you are worried about losing another night's sleep, a sleeping pill might help. You could try an over-the-counter antihistamine, an older benzodiazepine, or one of the newer pills. All three could help. Try improving your sleep hygiene, too, and see a doctor if your insomnia lasts more than five nights.

- If you have transient or situational insomnia—that is, insomnia because of travel, work or family stress, or a disturbing event-that lasts three nights in a row or three nights during one week—you might benefit from taking a sleeping pill on a short-term basis. But limit it to a maximum of seven days or so, and preferably fewer.

- If you have intermittent insomnia that disrupts your life for several days five or more times a year, you should consider behavioral therapy. You may also want to talk with your doctor

Some Do's and Don'ts About Sleeping Pills	
Do's	**Don'ts**
Take only the dose your doctor and/or pharmacist recommends.	Do not take extra doses to see if that would work better, or extra doses in the middle of the night if you awaken.
Tell your doctor about *all* other medicine you are taking. Many drugs can increase your risk of experiencing side effects from sleeping pills.	Do not mix sleeping pills with alcohol or "recreational" drugs. This can increase the risk of side effects, including sleep-walking, sleep-driving, memory lapses, and hallucinations.
Call your doctor if you think the drug is not helping.	Do not take sedating over-the-counter antihistamines and prescription sleeping pills at the same time. They have addictive effects.
Tell your doctor if you have been depressed or anxious, or diagnosed previously with depression or anxiety, or are taking medicine now to treat these conditions.	Do not use sleeping pills to treat anxiety. They may sedate you, but other medicine is better suited for this purpose.
Take a sleeping pill just as you are about to get into bed.	Do not take sleeping pills during the day or when you must be alert. For example, don't take one on a flight of less than 8 hours if you'll be renting a car or going to work when you land.
Expect to feel very sleepy when you take a sleeping pill.	Do not expect a sleeping pill to put you right to sleep. It might, but more often it will take 15 to 45 minutes.
Explore other ways to improve your sleeping habits.	Do not rely on sleeping pills for long even if your insomnia lasts a week or so.
Be cautious taking any sleeping pill if you are 55 or over.	Do not ignore signs of insomnia that could be reducing your quality of life. Just because you are 55 or older doesn't necessarily mean you need less sleep.
Be explicit when telling your doctor about your sleeping problems and habits, and go online to learn more about sleeping pills.	Do not assume your doctor knows everything he or she should about the risks vs. the benefits of sleeping pills.
Tell your doctor if you start taking a sleeping pill every night for longer than 7 to 10 days, or take one several times a week for weeks or months on end.	Do not count on sleeping pills as a long-term solution to chronic insomnia.

about a prescription for sleeping pills to be used as needed on a short-term basis.

- If you have chronic insomnia, you should be treated with behavioral therapy (in this case, it's probably covered by your insurance plan, but check to make sure). Again, you may also want to talk with your doctor about a prescription for sleeping pills to be used as needed on a short-term basis.

- If you are 55 or older and have chronic insomnia, you should be treated with behavioral therapy and avoid taking sleeping pills unless absolutely necessary and only on a short-term basis. Studies indicate that older people are at higher risk of all the side effects from these medicines.

- If you have been diagnosed with anxiety and also have insomnia, talk with your doctor about trying a benzodiazepine before trying one of the newer sleeping pills.

- If you have been diagnosed with depression and also have insomnia, talk with your doctor about whether you should consider trazodone. You may need another antidepressant and you and your doctor should weigh the pros and cons of taking two drugs at once.

Choosing a Sleeping Pill – Our *Best Buy* Picks

This section presumes you and your doctor have decided that you need sleeping pills.

All of the newer drugs are effective in helping people fall asleep faster. In general, they will help you fall asleep in about 30 to 50 minutes (or 8-20 minutes faster than a placebo). But that can vary widely, depending mostly on the severity of your insomnia.

The evidence on how well these medicines work to *keep* you asleep—what doctors call sleep duration—is less clear. Responses to the drugs vary, with some people having a substantial improvement in how long they sleep without waking and others continuing to wake up during the night.

The drugs have different properties, mostly due to how fast they act and stay active chemically in the body. You and your doctor's choice might be based on these factors, matched against your insomnia symptoms, your overall health status, and your age.

But for the average person needing short-term help for insomnia, we have chosen only one of these drugs—zolpidem—as a *Best Buy*. Zolpidem is the generic version of brand-name Ambien. The generic contains the same active ingredient as the brand-name drug and is much less expensive. At a cost of $12 to $14 for seven pills, depending on dose and strength, zolpidem is less expensive than the other brand-name sleeping pills as well.

Our choice of zolpidem is based not just on this price advantage but also evidence showing that, by some measures, it's more effective than the others. (See Table 2 on page 14.) Thus, if you are getting a first-time prescription for one of the new sleeping pills, or if you have been taking one, we urge you to talk with your doctor about trying generic zolpidem.

The other forms of zolpidem—sustained-release (Ambien CR), dissolvable tablet (Edluar), and the oral mist spray (Zolpimist)—are more expensive and offer little if any advantage to make the higher cost worth it.

So far, the evidence is weak that Ambien CR is any better than zolpidem. While studies have found it increases sleep duration a bit more when compared with regular zolpidem (Ambien), the difference is not that great. And for people whose main problem is getting to sleep, Ambien CR probably offers no advantage at all.

Edluar and Zolpimist are designed to act more quickly than other forms of zolpidem, but there is very little evidence directly comparing these newer drugs with the other insomnia drugs. Edluar has been shown to help people fall asleep more quickly than regular zolpidem tablets. But it does not appear to offer any other advantages.

One study compared a single dose of Edluar with a single dose of zolpidem in people who were monitored in a sleep laboratory. Those who took Edluar fell asleep about 10 minutes faster than those who took zolpidem. But there was no difference between the groups in how long they stayed asleep, or in how long they thought they had slept. There also was no difference between the groups in reports of next-day effects, such as drowsiness.

No studies have compared Zolpimist with the other insomnia drugs. FDA's approval of Zolpimist was based on studies showing that it is bioequivalent to zolpidem—meaning that the drugs are so similar that their effects with regard to efficacy and safety can be expected to be the same.

Table 2 presents some general comparisons of the other drugs, though the numbers come from different studies, making precise comparisons difficult. As you can see, zolpidem (Ambien and generic) and zaleplon (Sonata and generic) tend to act more quickly in the body and thus appear more effective at helping you fall asleep. In one study that directly compared the two drugs in the same group of patients, Sonata was slightly better than zolpidem—by about 17 minutes on average—in bringing sleep about. Other studies, however, have consistently found zolpidem better than Sonata at producing longer duration sleep. Also, people taking zolpidem have reported "better quality" sleep than those taking Sonata.

Regarding zolpidem and sleep duration, there are mixed results. Studies that directly compared zolpidem with a placebo found that the medication did not produce longer sleep. The analysis that forms the basis of our report pooled the results of trials and also found no evidence overall that zolpidem increased sleep duration.

However, three other studies did find longer sleep duration with zolpidem compared with zaleplon and placebo. But these trials were designed to evaluate zaleplon, so it is difficult to conclude from them that zolpidem clearly produces longer sleep duration.

Lunesta acts a bit more slowly in the body and is slightly less effective at helping you get to sleep. While in theory—because of its slower action—Lunesta may be more likely to help you stay asleep, direct comparisons of Lunesta with the other drugs are lacking on this measure. One notable study found Lunesta effective (better than a placebo) and safe for up to six months of use. The other drugs may well produce equal results if six-month studies of them were conducted. But remember, *none* of these medicines—including Lunesta—ought to be used on a regular basis for that long.

Rozerem is a newer drug and there is less evidence available on its effectiveness. It acts differently in the body than the other drugs and appears, based on the available evidence, to be somewhat less effective than the others in helping people fall asleep.

Table 2. Effectiveness and Differences – The Newer Sedative Drugs

Drug and Year it Went on Market	Helps You Fall Asleep?	Average Time to Fall Asleep[1]	How much faster than placebo on average?	Helps You Stay Asleep?	How much longer than placebo on average?	Percent With Next-Day Drowsiness[1]	Risk of Rebound Insomnia?	Risk of Dependency?
Zolpidem (Ambien) (1992)	Yes	33 to 46 minutes	20 minutes	Maybe	34 minutes	2%-3%	Maybe	Yes
Ambien CR (2005)	Yes	33 to 46 minutes	About 10 minutes	Yes	About 30 minutes	15%	Yes	Yes
Lunesta (2004)	Yes	50 minutes	19 minutes	Yes	46 minutes	8%-10%	Yes	Yes
Rozerem (2005)	Yes	75 minutes	8 minutes	No information	3 minutes	5%	No	No
Sonata (1999)	Yes	36 to 55 minutes	14 minutes	Evidence weaker than for zolpidem and Lunesta	19 minutes	5%-6%	No	Yes
Zolpidem sublingual tablet (Edluar)	Yes	20 minutes	6-10 minutes vs regular zolpidem tablets (No comparison to placebo)	Maybe	Not assessed	4%	Maybe	Yes
Zolpidem oral spray mist (Zolpimist)[2]	Yes	33 to 46 minutes	Same as regular zolpidem tablets	Maybe	Same as regular zolpidem tablets	2%-3%	Maybe	Yes

1. As assessed in one major study or, if range given, several studies. Figures are not meant to imply that drugs were necessarily compared to each other in a study with consistent design.
2. Based on studies showing bioequivalence to zolpidem.

Side Effects and Safety

As mentioned, all of the drugs can cause side effects. The three most important are:

- Next-day drowsiness
- Rebound insomnia
- Dependency and abuse

On next-day drowsiness, the evidence is quite clear: Ambien CR and Lunesta both cause more of it than the other drugs. In the few comparison studies to date, fewer people who took zolpidem experienced this side effect.

Rebound insomnia occurred in some people taking zolpidem, Ambien CR, and Lunesta, but not Sonata or Rozerem. But the problem is usually short-term. In studies, it disappeared by the second or third night after the drug was stopped.

It's also not clear how much of a risk of rebound insomnia zolpidem poses. The studies that indicated zolpidem might cause rebound insomnia were actually focused on evaluating zaleplon, and other studies did not find evidence of rebound insomnia in people who took zolpidem.

All of the newer medicines are less likely to cause dependence and abuse problems than benzodiazepines—and that may be their biggest advantage. However, there have been reports of abuse and dependence with zolpidem. Most have occurred among people who had problems with drug or alcohol dependence in the past. So far, there have been fewer similar reports with the other newer sleep drugs. But that could be because Ambien has been available much longer and is used by millions more people than the other drugs. Ambien first became available in 1992, while the next new sleep drug (Sonata) didn't come along until 1999.

Notably, because it works differently, Rozerem is not considered to have the potential for abuse and dependence that the other new insomnia medicines have. That could be an advantage for use in treating people who have dependency problems or a history of drug abuse.

All of the newer sleeping pills cause minor side effects at about the same rate. None offers an advantage over the others in this regard. The most common are headaches and dizziness. But only

Table 3 – Common side effects of newer sleeping pills

	Ambien vs. placebo	Ambien-CR vs. placebo	Lunesta vs. placebo	Rozerem vs. placebo	Sonata vs. placebo
Abdominal pain	2% vs 2%	1% vs 0%	<1%	<1%	6% vs 3%
Cold/Flu	2% vs 0%	3% vs 0%	5% vs 3%	<1%	<1%
Diarrhea	3% vs 2%	1% vs 0%	<1%	<1%	<1%
Dizziness	5% vs 1%	12% vs 5%	5% vs 4%	4% vs 3%	7% vs 7%
Drowsiness/ Somnolence	8% vs 5%	15% vs 2%	10% vs 3%	3% vs 2%	5% vs 4%
Made insomnia/ sleep disorder worse	1% vs 0%	<1%	<1%	3% vs 2%	<1%
Headache	7% vs 6%	19% vs 16%	21% vs 13%	<1%	30% vs 35%
Nausea	<1%	7% vs 4%	5% vs 4%	3% vs 2%	6% vs 7%
Unpleasant taste	<1%	<1%	17% vs 3%	<1%	<1%

about 2 to 6 percent of people stop using the drugs because of these problems.

Sleep-walking, amnesia, and hallucinations appear to be very rare when any of these medicines are taken as they should be. However, the reports of these problems should be a warning that excessive use and especially excessive doses in the middle of the night can raise the risk of serious problems. Combining sleeping pills with alcohol, even just a drink or two, is not a good idea and raises the risk of side effects.

Age, Race, and Gender Differences

The new insomnia medicines are as effective in older adults as they are in younger people. But they cause more side effects in older people. For that reason, older adults should use a lower dose. In general, the recommended starting dose of all the drugs (except Rozerem) in older adults is half the usual dose. Also, studies have shown that all sleeping drugs, not just the new ones, increase the risk of hip fracture in older people, because they can lead to falls.

Table 4. Costs of Insomnia Drugs

Generic Name	Brand Name	Is a Generic Drug?	Average Cost for 7 Doses[1]	Average Cost for 15 Doses[1]
Newer Sedatives				
Zolpidem 10 mg tablet	Ambien	No	$53	$115
Zolpidem 5 mg tablet	Ambien	No	$54	$118
CR BEST BUY Zolpidem 10 mg tablet	Generic	Yes	$12	$27
CR BEST BUY Zolpidem 5 mg tablet	Generic	Yes	$14	$31
Zolpidem 6.25 mg sustained release	Ambien CR	No	$56	$122
Zolpidem 12.5 mg sustained release	Ambien CR	No	$56	$121
Zolpidem 6.25 mg sustained release	Generic	Yes	$41	$89
Zolpidem 12.5 mg sustained release	Generic	Yes	$40	$87
Zolpidem dissolvable tablet 5 mg	Edluar	No	$47	$102
Zolpidem dissolvable tablet 10 mg	Edluar	No	$53	$116
Eszopiclone 1 mg tablet	Lunesta	No	$56	$121
Eszopiclone 2 mg tablet	Lunesta	No	$57	$123
Eszopiclone 3 mg tablet	Lunesta	No	$58	$125
Ramelteon 8 mg tablet	Rozerem	No	$47	$103
Zaleplon 10 mg capsule	Sonata	No	$38	$83
Zaleplon 5 mg capsule	Generic	Yes	$18	$39
Zaleplon 10 mg capsule	Generic	Yes	$17	$36

1. Recommended use is one pill at bedtime. The prices given are based on per pill costs. Prices reflect nationwide retail average for October 2011, rounded to the nearest dollar. Prices are derived by *Consumer Reports Best Buy Drugs* from data provided by Wolters Kluwer Pharma Solutions, which is not involved in our analysis or recommendations.

Talking With Your Doctor

It's important for you to know that the information we present here is not meant to substitute for a doctor's judgment. But we hope it will help you and your doctor arrive at a decision about which sleeping pill is best for you—if one is warranted at all—and which will give you the most value for your health-care dollar.

Bear in mind that many people are reluctant to discuss the cost of medicine with their doctor, and that studies have found that doctors do not routinely take price into account when prescribing medicine. Unless you bring it up, your doctors might assume that cost is not a factor for you.

Many people (including physicians) think that newer drugs are better. While that's a natural assumption to make, it's not necessarily true. Studies consistently find that many older medicines are as good as—and in some cases better than—newer medicines. Think of them as "tried and true," particularly when it comes to their safety record. Newer drugs have not yet met the test of time, and unexpected problems can and do crop up once they hit the market.

Of course, some newer prescription drugs are indeed more effective and safer. Talk with your doctor about the pluses and minuses of newer vs. older medicine, including generic drugs.

Prescription medicines go "generic" when a company's patents on them lapses, usually after about 12 to 15 years. At that point, other companies can make and sell the drug.

Generics are much less expensive than newer brand-name medicine, but they're not lesser-quality drugs. Indeed, most generics remain useful even many years after first being marketed. That's why more than 60 percent of all prescriptions in the U.S. today are written for generics.

Another important issue to talk about with your doctor is keeping a record of the drugs you are taking. There are several reasons for this:

- First, if you see several doctors, each might not be aware of medicine the others have prescribed.
- Second, since people differ in their response to medication, it's common for doctors today to prescribe several before finding one that works well or best.
- Third, many people take several prescription medications, nonprescription drugs, and dietary supplements at the same time. They can interact in ways that can either reduce the benefit you get from the drug or be dangerous.
- Fourth, the names of prescription drugs—both generic and brand—are often hard to pronounce and remember.

For all those reasons, it's important to keep a written list of all the drugs and supplements you are taking and periodically review it with your doctors.

And always be sure that you understand the dose of the medicine being prescribed for you and how many pills you're expected to take each day. Your doctor should tell you this information. When you fill a prescription at a pharmacy or if you get it by mail, check to see that the dose and the number of pills per day on the pill bottle match the amounts your doctor told you.

How We Picked the *Best Buy* Drugs

Our evaluation is primarily based on an independent scientific review of the evidence on the effectiveness, safety, and adverse effects of the newer sleeping pills. A team of physicians and researchers at Oregon Health & Science University Evidence-Based Practice Center conducted the analysis as part of the Drug Effectiveness Review Project, or DERP. DERP is a first-of-its-kind multi-state initiative to evaluate the comparative effectiveness and safety of hundreds of prescription drugs.

A synopsis of DERP's analysis of the insomnia drugs forms the basis for this report. The synopsis was based on DERP's analysis as well as a search for recent trials, systematic reviews, and FDA information. A consultant to *Consumer Reports Best Buy Drugs* is also a member of the Oregon-based research team, which has no financial interest in any pharmaceutical company or product.

The full DERP review of the insomnia drugs is available at http://derp.ohsu.edu/about/final-document-display.cfm. (This is a long and technical document written for physicians.)

The drug costs we cite were obtained from a healthcare information company that tracks the sales of prescription drugs in the U.S. Prices for a drug can vary quite widely, even within a single city or town. All the prices in this report are national averages based on sales of prescription drugs in retail outlets. They reflect the cash price paid for a month's supply of each drug in October 2011.

Consumer Reports selected the *Best Buy* using the following criteria. The drug had to:

- Be approved by the FDA for treating insomnia.
- Be as effective as other insomnia medicines.
- Have a safety record equal to or better than other insomnia medicines.
- Have an average price for a 7- and 15-day supply that was not higher than the other insomnia medicines.

The *Consumers Reports Best Buy Drugs* methodology is described in more detail in the Methods section at CRBestBuyDrugs.org.

Sharing this Report

About Us

Consumers Union, publisher of *Consumer Reports*® magazine, is an independent and nonprofit organization whose mission since 1936 has been to provide consumers with unbiased information on goods and services and to create a fair marketplace. It's website is www.CRBestBuyDrugs.org. The magazine's website is www.consumerreports.org.

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We followed a rigorous editorial process to ensure that the information in this report and on the *Consumer Reports Best Buy Drugs* website is accurate and describes generally accepted clinical practices. If we find an error or are alerted to one, we will correct it as quickly as possible. But *Consumer Reports* and its authors, editors, publishers, licenses, and suppliers can't be responsible for medical errors or omissions, or any consequences from the use of the information on this site. Please refer to our user agreement at CRBestBuyDrugs.org for further information.

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