

# BELSOMRA (SUVOREXANT)

## BELSOMRA for insomnia

### Who might consider taking this drug?

Adults with trouble falling asleep or staying asleep (insomnia) for at least 1 month.

### Who should NOT take it?

- People who fall asleep often at unexpected times (**narcolepsy**).
- If you are **pregnant or breastfeeding**, you should be aware that it is not known if Belsomra might harm your child.

### Precautions

**When to take?** Take Belsomra within 30 minutes of going to bed. Do not take more than **one pill a night** and make sure you have **at least 7 hours before you need to be alert**.

**Limit activities the next day that require clear thinking or mental alertness.** If you take the 20 mg dose of BELSOMRA, **do not drive or do other activities requiring full mental alertness the next day, until you know how the drug affects you.** Lower doses might also make you feel drowsy the next day, so do not drive or do other dangerous activities until you feel fully awake.

**Do not take with other medications that make you sleepy.** Do not take BELSOMRA with other medicines that can also make you sleepy—such as many antidepressants, anxiety drugs, and opioid painkillers—unless your doctor advises otherwise. Make sure your providers know any other medications you take since **mixing BELSOMRA with some drugs is not recommended**; that includes HIV protease inhibitors such as indinavir, and antifungals such as ketoconazole. If these medications are used with BELSOMRA, your doctor should start with the 5 mg dose and never prescribe higher than a 10 mg dose.

**Do not drink alcohol when taking BELSOMRA.** It can increase your chances of experiencing serious side effects.

**People with Chronic Obstructive Pulmonary Disease (COPD) or severe sleep apnea should be cautious** because BELSOMRA can affect breathing. It has not been studied in people with severe COPD or in people with severe sleep apnea.

### What other choices are there?

**Nondrug choices:** Cognitive behavioral therapy, reduce caffeine intake, especially at night, increase exercise, establish a regular bedtime and use the bedroom only for sleep, and avoid daytime naps.

**Other drug choices:** Over-the-counter drugs such as Benadryl, Nytol, or Sominex that contain diphenhydramine or other prescription drugs approved for insomnia such as zolpidem (AMBIEN), zopiclone (LUNESTA), zaleplon (SONATA), ramelteon (ROZEREM), and temazepam (RESTORIL).

## BOTTOM LINE

### BELSOMRA's benefit

At the highest approved doses, BELSOMRA's benefit was modest. BELSOMRA 15 mg and 20 mg helped people stay asleep 16 minutes longer and fall asleep about 6 minutes faster compared to a placebo. The 10 mg dose, tested only in 62 people, had an even smaller effect. The 5 mg dose was not tested in any study, so its effect on sleep is not known.

### BELSOMRA's harm

**Serious side effects** The serious side effects of BELSOMRA include:

- **Sleepiness during the day** This can be so severe that it could impair your ability to drive and carry out other activities. Two out of 28 people taking 20 mg stopped their monitored driving test because they felt too sleepy to drive safely.
- **Memory problems and being unable to think clearly;**
- **Feeling agitated, anxious, confused, upset, or more aggressive** than normal;
- **Sleep-walking** or doing **other activities when you are asleep** like eating, talking, having sex, or driving a car;
- Temporary inability to move or talk (**sleep paralysis**) for up to several minutes while falling asleep or waking up;
- Sudden, temporary weakness in your legs that can happen during the day or at night (**cataplexy**);
- Worsening of **depression** or **suicidal thoughts**.

**Short track record means that new, unexpected side effects are possible.** BELSOMRA was approved by the FDA less than a year ago (August 2014) based on studies that included 1,784 adults—only 555 took the approved doses. As with all new drugs, important side effects may emerge as larger numbers of people, with other conditions and on other medications, take the drug for longer time frames than those in the trials. Since this drug has a different way of acting than other insomnia drugs, the experience with it is particularly limited. The FDA did not require any post-marketing studies to look for harms.

**Do not take more than 20 mg.** The FDA approved doses from 5 mg to 20 mg, for once-a-day use, but did not approve the 30 mg or 40 mg doses. The high doses were only slightly more effective, but resulted in more serious side effects. For example, in one study, 5 percent of those who took a 20 mg dose for a month reported next-day drowsiness, while 12 percent of people who took a 40 mg dose reported the same.

## BELSOMRA Study Findings

The FDA approved BELSOMRA based on the results of two trials that included 1,266 healthy adults. People in the studies had to sleep less than 6.5 hours a night and take more than 30 minutes to fall asleep for at least 3 nights a week during a month or more. Participants were an average age of 56, and 64 percent were women. They were randomly given either BELSOMRA or placebo nightly for 3 months. Here's what happened:

	<b>BELSOMRA</b> (15 mg – 20 mg once a day)	<b>VS.</b>	<b>PLACEBO</b> (No drug)
<b>How did BELSOMRA help people with...</b>			
<b>Sleeping longer?</b>			
BELSOMRA users slept longer (16 minutes longer)	6 hours, 12 minutes		5 hours, 56 minutes
More BELSOMRA users slept at least 15% longer (50 minutes) (8% more people)	50%		42%
<b>Falling asleep faster?</b>			
BELSOMRA users fell asleep faster (6 minutes faster)	46 minutes		51 minutes
More BELSOMRA users fell asleep at least 15% faster (10 minutes) (4% more people)	70%		66%
<b>Improving their insomnia overall?</b>			
More BELSOMRA users rated their insomnia as noticeably better—6 or more points better on a scale from 0 [none] to 28 [most severe insomnia] (13% more people)	56%		42%
<b>What were BELSOMRA'S side effects?</b>			
<b>Serious side effects</b> Based on 1,784 patients taking BELSOMRA at doses of 10 mg to 20 mg for insomnia.			
<b>Driving accidents or traffic tickets</b> (0.6% more people)	2.9%		2.3%
<b>Vivid, disturbing hallucinations when falling asleep or waking up</b> (0.4% more)	0.4%		0%
<b>Sleep paralysis – frightening sense that you can't move or talk when falling asleep or waking up</b> (0.2% more)	0.2%		0%
<b>Trouble staying awake the next day</b> (0.1% more)	0.2%		0.1%
<b>Suicidal thoughts</b> (0.05% more)	0.2%		0.15%
<b>Symptom side effects</b>			
<b>Next-day drowsiness</b> (4% more people)	7%		3%

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