

BELSOMRA is a prescription medicine for adults who have trouble falling or staying asleep (insomnia).

It is not known if BELSOMRA is safe and effective in children under the age of 18 years.







Trouble falling asleep?

Trouble staying asleep?

BELSOMRA may help

Selected Risk Information

BELSOMRA may cause decreased awareness and alertness. The morning after you take BELSOMRA, your ability to drive safely and think clearly may be decreased. You may also have sleepiness during the day.

- Do not take more BELSOMRA than prescribed.
- Do not take BELSOMRA unless you are able to stay in bed a full night (at least 7 hours) before you must be active again.
- Take BELSOMRA within 30 minutes of going to bed.

Selected Risk Information continues on the next page.

Understanding insomnia

Sleep and wake pathways under regular conditions



- There are 2 pathways in your brain—a wake pathway and a sleep pathway. Each pathway has many neurotransmitters that send signals to determine whether you are awake or asleep.
- Under regular conditions, sleep occurs when the wake neurotransmitters turn down and sleep neurotransmitters ramp up and take over, allowing you to fall asleep and stay asleep.

Could there be a problem with your wake pathway?



- Both wake and sleep pathways can play a role in insomnia. Wake and sleep pathways don't work well together when you have insomnia.
- Science suggests that when insomnia occurs, your sleep neurotransmitters may be signaling your brain to sleep, but your wake neurotransmitters may not be turning down like they should. When this happens, it can be hard for your brain to transition from the "awake" mode.
- This could be contributing to your insomnia and help explain why you just aren't getting as much sleep as you want.

Selected Risk Information (continued)

BELSOMRA may cause serious side effects, including:

• worsening depression or suicidal thoughts and actions. Call your doctor right away if you have any worsening depression or thoughts of suicide or dying.

What might be contributing to **your insomnia?**

Biological (internal) factors as well as external factors may contribute to insomnia.

These include:







• Stress •

 Certain medications

• Unhealthy sleep habits

 Age-related biological changes

- Brief episodes of not getting enough sleep often get better once the cause subsides.
- If lifestyle changes aren't enough, talk to your doctor about your insomnia.

Selected Risk Information (continued)

- **complex sleep behaviors**, including sleep-walking, sleep-driving or other activities while not fully awake. Call your doctor right away if you experience a complex sleep behavior.
- **temporary inability to move or talk (sleep paralysis)** for up to several minutes while you are going to sleep or waking up.
- **temporary weakness in your legs** that can happen during the day or at night.

Selected Risk Information continues on the next page.



BELSOMRA® (suvorexant) Was studied in adults,

including people 65 years and older.



Selected Risk Information (continued)

Do not take BELSOMRA if you fall asleep often at unexpected times (narcolepsy).

BELSOMRA is a controlled substance because it can be abused or cause dependence.

Before taking BELSOMRA, tell your doctor about all of your medical conditions, including if you:

- have a history of depression, mental illness, or suicidal thoughts
- have a history of drug or alcohol abuse or addiction

In clinical studies with BELSOMRA® (suvorexant):



People fell asleep faster and stayed asleep longer

- People fell asleep faster and stayed asleep longer when using BELSOMRA compared with those taking placebo.
- There was no evidence of physical dependence after prolonged use of BELSOMRA. There were no reported withdrawal symptoms after discontinuation.
- BELSOMRA is a federally controlled substance because it can be abused or cause dependence.
- Keep BELSOMRA in a safe place to prevent misuse and abuse. Selling or giving away BELSOMRA may harm others and is against the law.
- Tell your doctor if you have ever abused or have been dependent on alcohol, prescription medicines, or street drugs.

Selected Risk Information (continued)

- have a history of a sudden onset of muscle weakness (cataplexy)
- have a history of falling asleep often at unexpected times (narcolepsy) or daytime sleepiness
- have lung or breathing problems
- have liver problems
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed

Selected Risk Information continues on the next page.

How BELSOMRA® (suvorexant) may work



Some neurotransmitters send wake signals to other parts of the brain.

Sleep and wake neurotransmitters in your brain

- There are many neurotransmitters within your brain that work together to determine whether you are awake or asleep.
- It is believed orexin is one of the neurotransmitters that promotes wakefulness.

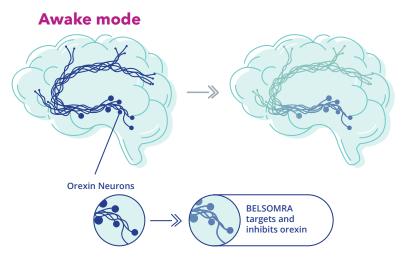
Selected Risk Information (continued)

Medicines can interact with each other, sometimes causing serious side effects. Do not take BELSOMRA with other medicines that can make you sleepy unless your doctor tells you to.

Do not drink alcohol while taking BELSOMRA. It can increase your chances of getting serious side effects.

Do not drive, operate heavy machinery, do anything dangerous, or do other activities that require clear thinking after taking BELSOMRA.

BELSOMRA® (suvorexant) is thought to inhibit the action of orexin



- Orexin is one neurotransmitter involved with sending wake signals to other parts of the brain.
- BELSOMRA is thought to block orexin from sending these wake signals, which could be keeping you from sleeping.

Ask your doctor what might be causing your insomnia

Selected Risk Information (continued)

You may still feel drowsy the next day after taking BELSOMRA. **Do not** drive or do other dangerous activities until you feel fully awake.

The most common side effect of BELSOMRA is sleepiness the next day after you take BELSOMRA.

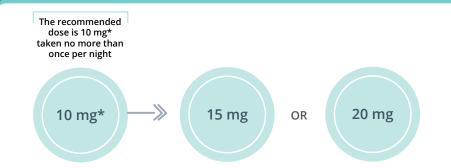
Selected Risk Information continues on the next page.

Please read the accompanying <u>Medication Guide</u> for BELSOMRA and discuss it with your doctor. The physician <u>Prescribing Information</u> also is available. Select links to access.

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Finding the right dose

Your insomnia is as individual as you are and medicines work differently for different people, so BELSOMRA[®] (suvorexant) comes in multiple strengths.



- Your doctor may prescribe the recommended dose of 10 mg.* Tell your doctor if you're still not sleeping well with 10 mg.
- If your current dose is well tolerated and you're not getting the sleep you want, your doctor may increase your dose.
- Do not take more than 20 mg of BELSOMRA in 1 day.
- *5 mg is the recommended dose for certain patients, and these patients should generally not exceed 10 mg.

Selected Risk Information (continued)

How Should I Take BELSOMRA?

- Take BELSOMRA exactly as your doctor tells you to take it.
- Only take BELSOMRA 1 time each night, if needed, within 30 minutes of going to bed.
- Only take BELSOMRA when you can get a full night's sleep (at least 7 hours).
- **Do not** take BELSOMRA if you drank alcohol that evening or before bed.
- BELSOMRA may be taken with or without a meal. However, BELSOMRA may take longer to work if you take it with or right after meals.

How to take BELSOMRA® (suvorexant)

What to expect



Your insomnia is as individual as you are. You and your doctor may need to work together to find the right dosage strength of BELSOMRA for you.

The way you feel when you fall asleep with BELSOMRA may be different from what you've experienced in the past or what you expect. Therefore, it is important to give BELSOMRA an adequate trial period. Try BELSOMRA for a few nights to a week to see how it works for you.

Selected Risk Information (continued)

- Call your doctor if your insomnia (sleep problem) worsens or is not better within 7 to 10 days. This may mean that there is another condition causing your sleep problem.
- If you take too much BELSOMRA, call your doctor right away or get emergency treatment.

Medicines can interact with each other, sometimes causing serious side effects. Do not take BELSOMRA with other medicines that can make you sleepy unless your doctor tells you to.

Selected Risk Information continues on the next page.

Ready to talk insomnia with your doctor?

See the discussion guide on page 8

Belsomra (suvorexant) (V) 5, 10, 15, 20 mg tablets

Patient portrayal

Selected Risk Information (continued)

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Selected Risk Information continues on the next page.



Selected Risk Information (continued)

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- **complex sleep behaviors**, including sleep-walking, sleep-driving or other activities while not fully awake. Call your doctor right away if you experience a complex sleep behavior.

A note to patients and caregivers

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In an insomnia study in people with mild to moderate Alzheimer's disease, people achieved longer total sleep time when taking BELSOMRA® (suvorexant) compared with people taking placebo.

- The most common adverse event in this clinical study with BELSOMRA was drowsiness (4% in patients who took BELSOMRA vs 1% in those who took placebo).
- Because BELSOMRA can cause drowsiness, patients, particularly the elderly, are at higher risk of falls.
- BELSOMRA is a prescription sleep medication with demonstrated efficacy and safety in an insomnia study in patients with mild to moderate Alzheimer's disease (AD).

About BELSOMRA

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Selected Risk Information (continued)

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Discussion Guide

Help your doctor

understand your insomnia

Share your answers to help explain how insomnia affects you.

Do I have trouble falling asleep and/or staying asleep?	Y N
How many nights per week do I have trouble sleeping?	
Do I often think about my sleep issues?	
When I can't sleep at night, I	
Despite lifestyle changes, do I still have trouble falling and/or staying asleep?	
Have I tried any medications or supplements for insomnia?	

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For more information visit BELSOMRA.com



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Having trouble paying for your Merck medicine? Merck may be able to help. Visit <u>merckhelps.com</u>.



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