

Suvorexant (Belsomra) for Insomnia

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STEPS new drug reviews cover Safety, Tolerability, Effectiveness, Price, and Simplicity. Each independent review is provided by authors who have no financial association with the drug manufacturer.

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Suvorexant (Belsomra) is labeled for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Unlike other hypnotics, it blocks the binding of neuropeptides (orexin A and B) that promote wakefulness. It is a schedule IV controlled substance.¹

Drug	Dosage	Dose form	Cost*
Suvorexant (Belsomra)	10 mg once daily within 30 minutes of bedtime; may increase to 20 mg once daily	5-, 10-, 15-, or 20-mg tablets	\$305

*—Estimated retail price of one month's treatment based on information obtained at <http://www.goodrx.com> (accessed April 27, 2016).

SAFETY

Suvorexant carries a slight risk of abuse. Events that suggested possible abuse were identified in 3% to 4% of patients in clinical trials.^{2,3} Suvorexant is a central nervous system depressant. Rare side effects include sleep paralysis, hypnagogic hallucinations, and mild cataplexy, consisting of brief periods of leg weakness.² Suvorexant should be avoided in patients with depression because it may worsen symptoms; patients with severe depression were excluded from clinical trials. It should also not be used in patients with narcolepsy, obstructive sleep apnea, or severe chronic obstructive pulmonary disease. It is a U.S. Food and Drug Administration pregnancy category C drug. It is unknown whether suvorexant is excreted in human breast milk.¹

TOLERABILITY

Suvorexant causes significant somnolence in 7% to 11% of patients, and driving performance is impaired in up to 20% of patients, especially at higher doses and when starting the medication. Performance can be affected without the patient being aware.⁴ Taking suvorexant may also impair other mental or physical capabilities. These effects are dose-related and are heightened when suvorexant is combined with other depressants such as alcohol and

opioids. Suvorexant may lead to cognitive and behavioral changes such as neuropsychiatric symptoms and sleep activities (e.g., eating food or driving while not fully awake) with amnesia for the event. Other common effects include dizziness (1.6% to 5.1%), headache (1.6% to 5.1%), and abnormal dreams (1.2% to 4.9%).^{2,3,5} Older adults taking high doses of suvorexant experienced balance impairment upon nighttime awakening compared with those taking placebo.¹ In clinical trials, withdrawal symptoms or rebound insomnia did not occur with abrupt discontinuation.²

EFFECTIVENESS

Suvorexant has been compared with placebo for treatment of chronic insomnia in patients older than 50 years who slept less than 5.5 hours per night on average. Using objective measures, consistent use for one month will decrease the time to fall asleep from an average of 65 to 69 minutes to 32 to 35 minutes, although this change is only eight to 10 minutes less than when using placebo. It will also help patients stay asleep to a greater extent than placebo. Using patient diaries, total sleep time will increase by 39 to 43 minutes per night (vs. 22 to 23 minutes with placebo; $P < .001$). More patients taking suvorexant will report improved sleep and decreased insomnia than ►

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those taking placebo.²⁻⁴ Suvorexant has not been compared with other insomnia therapies and has not been studied for intermittent treatment of insomnia or in shift workers.

PRICE

Suvorexant costs approximately \$305 for a one-month supply of 5-, 10-, 15-, or 20-mg tablets.

SIMPLICITY

The recommended starting dosage of suvorexant is 10 mg once daily. It should be taken within 30 minutes of going to bed with at least seven hours remaining before the planned time of awakening. The dosage may be titrated to 20 mg if needed, although daytime driving impairment increases with higher doses, especially in older and obese patients. Taking suvorexant with food will delay the time to effect. It has been studied for use for up to one year. Suvorexant may be discontinued abruptly without tapering.²

Bottom Line

Suvorexant effectively increases total sleep time and decreases time to sleep onset. Because of its risk of abuse, significant incidence of next-day impairment, and high

cost, it should be reserved for use in patients for whom other insomnia therapies, such as cognitive behavior therapy and lifestyle changes, have failed.

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