



NEWS RELEASE

# Jan7Merck's Insomnia Medicine BELSOMRA® (suvorexant) C-IV, the First and Only Orexin Receptor Antagonist, Now Available in the United States

2/3/2015

Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that BELSOMRA® (suvorexant) is now available at pharmacies in the United States for the treatment of insomnia in adults who have difficulty falling asleep and/or staying asleep. BELSOMRA is the only orexin receptor antagonist approved for the treatment of insomnia in the United States. Orexin is one of the many neurotransmitters in the brain involved in promoting wakefulness, and BELSOMRA selectively blocks orexin receptors. In doing this, BELSOMRA is thought to suppress wake drive in the brain.

"Insomnia is a serious condition that affects millions of Americans," said David Cloud, CEO of the National Sleep Foundation. "With BELSOMRA, healthcare professionals and patients now have an additional option to consider."

The recommended dose of BELSOMRA is 10 mg, taken no more than once per night and within 30 minutes of going to bed, with at least 7 hours remaining before the planned time of awakening. The total dose should not exceed 20 mg once daily.

BELSOMRA is contraindicated in patients with narcolepsy. BELSOMRA contains suvorexant, a Schedule IV controlled substance. BELSOMRA can impair daytime wakefulness. Central nervous system (CNS) depressant effects can last for up to several days after discontinuation.

In the brain's wake/sleep circuitry, two systems work together to regulate wake and sleep. The system that is more

active determines whether a person is awake or asleep. The orexin signaling system is a central promoter of wakefulness. Scientists currently at Tsukuba University, Kanazawa University in Japan, and Stanford University in the United States first discovered orexin in 1998.

“Merck has been conducting research in the sleep field for more than a decade,” said Dr. David Michelson, vice president, Neurosciences, Merck Research Laboratories. “We are proud to be one of the earliest companies to research the role of orexin receptors in insomnia, which ultimately led to the introduction of BELSOMRA in the United States.”

Patients with insomnia should ask their healthcare providers about BELSOMRA. BELSOMRA is available in 5 mg, 10 mg, 15 mg, and 20 mg tablets. Healthcare professionals and patients in the United States can visit [www.belsomra.com](http://www.belsomra.com) to learn more.

Merck is also developing a broad range of resources for patients to help educate them about insomnia and encourage dialogue with their healthcare providers. More information will be available in March 2015.

## About Insomnia

Approximately 30 million Americans suffer from insomnia. People with insomnia may have one or more sleep problems: difficulty falling asleep, difficulty returning to sleep, and/or difficulty staying asleep.

## Indication for BELSOMRA (suvorexant)

BELSOMRA is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.

## Select safety information about BELSOMRA

BELSOMRA is contraindicated in patients with narcolepsy.

BELSOMRA contains suvorexant, a Schedule IV controlled substance.

BELSOMRA can impair daytime wakefulness. Central nervous system (CNS) depressant effects can last for up to several days after discontinuation.

BELSOMRA can impair driving skills and may increase the risk of falling asleep while driving. Caution patients taking BELSOMRA 20 mg against next-day driving and other activities requiring full mental alertness.

Coadministration with other CNS depressants increases the risk of CNS depression. Patients should be advised not to consume alcohol in combination with BELSOMRA due to additive effects. Dosage adjustments of BELSOMRA and of other concomitant CNS depressants may be necessary when administered together because of potentially additive effects. The use of BELSOMRA (suvorexant) with other drugs to treat insomnia is not recommended.

The risk of next-day impairment, including impaired driving, is increased if BELSOMRA is taken with less than a full night of sleep remaining, if a higher than recommended dose is taken, if coadministered with other CNS depressants, or if coadministered with other drugs that increase blood levels of BELSOMRA. Patients should be cautioned against driving and other activities requiring complete mental alertness if taken in these circumstances.

Reevaluate patients for comorbid conditions if insomnia persists after 7 to 10 days of treatment.

A variety of cognitive and behavioral changes (eg, amnesia, anxiety, hallucinations, and other neuropsychiatric symptoms) have been reported with the use of hypnotics such as BELSOMRA. Complex behaviors such as "sleep-driving" (ie, driving while not fully awake after taking a hypnotic) and other complex behaviors (eg, preparing and eating food, making phone calls, or having sex), with amnesia for the event, have been reported in association with the use of hypnotics. Discontinuation of BELSOMRA should be strongly considered for these patients. The use of alcohol and other CNS depressants may increase the risk of such behaviors. These events can occur in hypnotic-naïve as well as hypnotic-experienced persons. Discontinuation of BELSOMRA should be strongly considered for patients who report any complex sleep behavior.

In clinical studies, a dose-dependent increase in suicidal ideation was observed in patients taking BELSOMRA, as assessed by questionnaire. Immediately evaluate patients with suicidal ideation or any new onset behavioral changes. Suicidal tendencies may be present and intentional overdose is more common in this group of patients. Intentional overdose is more common in this group of patients; therefore, the lowest number of tablets that is feasible should be prescribed for the patient at any one time.

The effect of BELSOMRA on respiratory function should be considered.

Sleep paralysis, hypnagogic/hypnopompic hallucinations, and cataplexy-like symptoms can occur. The risk of cataplexy-like symptoms increases with the dose of BELSOMRA.

BELSOMRA is not recommended for patients with severe hepatic impairment or those taking a strong CYP3A inhibitor.

In clinical studies, the most common adverse reaction (reported in 5% or more of patients treated with 15 mg or 20 mg of BELSOMRA and at least twice the placebo rate) was somnolence (BELSOMRA 7%, placebo 3%).

The recommended dose of BELSOMRA is 5 mg in patients receiving moderate CYP3A inhibitors.

Digoxin levels should be monitored, as slight increases were seen with coadministration of BELSOMRA (suvorexant).

## About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit [www.merck.com](http://www.merck.com) and connect with us on **Twitter**, **Facebook** and **YouTube**.

## Forward-Looking Statement

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2013 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

Please see Prescribing Information for BELSOMRA (suvorexant) at [http://www.merck.com/product/usa/pi\\_circulars/b/belsomra/belsomra\\_pi.pdf](http://www.merck.com/product/usa/pi_circulars/b/belsomra/belsomra_pi.pdf) and the Medication Guide for BELSOMRA at [http://www.merck.com/product/usa/pi\\_circulars/b/belsomra/belsomra\\_mg.pdf](http://www.merck.com/product/usa/pi_circulars/b/belsomra/belsomra_mg.pdf).

## RELATED MATERIALS

To download multimedia assets, click [here](#) to view the Multimedia News Release on MultiVu.

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