

MEDICATION GUIDE
BELSOMRA® (bell-SOM-rah)
suvorexant
Tablets C-IV

What is the most important information I should know about BELSOMRA?

BELSOMRA may cause serious side effects including:

- **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.

See **"What are the possible side effects of BELSOMRA?"** for more information about side effects.

What is BELSOMRA?

- 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.

BELSOMRA is a federally controlled substance (C-IV) 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.

Who should not take BELSOMRA?

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

What should I tell my doctor before taking BELSOMRA?

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
- 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 problems or breathing problems
- have liver problems
- are pregnant or plan to become pregnant. It is not known if BELSOMRA can harm your unborn baby. Talk to your healthcare provider about the risk to your unborn baby if you take BELSOMRA during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if BELSOMRA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with BELSOMRA.

Tell your doctor about all the medicines you take, including prescription or over-the-counter medicines, vitamins, or herbal supplements. 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.

Know the medicines you take. Keep a list of your medicines with you to show your doctor

and pharmacist each time you get a new medicine.

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.
- 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.

What should I avoid while taking BELSOMRA?

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

What are the possible side effects of BELSOMRA? See “What is the most important information I should know about BELSOMRA?”

BELSOMRA may cause serious side effects including:

- **worsening depression and suicidal thoughts** have happened during treatment with BELSOMRA. Call your healthcare provider right away if you have any worsening depression or thoughts of suicide or dying.
- **complex sleep behaviors** such as sleep-walking, sleep-driving, preparing and eating food, making phone calls, having sex or doing other activities while not fully awake that you may not remember the next morning. Call your healthcare provider 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.

The most common side effects of BELSOMRA include drowsiness the next day after you take BELSOMRA.

The following additional side effects have been reported with BELSOMRA: abnormal dreams.

These are not all the possible side effects of BELSOMRA. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store BELSOMRA?

- Store BELSOMRA at room temperature between 68°F to 77°F (20°C to 25°C).
- Store in the original package until use, to protect from light and moisture.
- **Keep BELSOMRA and all medicines out of reach of children.**

General information about the safe and effective use of BELSOMRA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BELSOMRA for a condition for which it was not prescribed. Do not give BELSOMRA to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about BELSOMRA. You can ask your pharmacist or doctor for information about BELSOMRA that is written for health professionals.

For more information, go to www.BELSOMRA.com or call 1-800-622-4477.

What are the ingredients in BELSOMRA?

Active ingredient: Suvorexant

Inactive ingredients: Croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and polyvinylpyrrolidone/vinyl acetate copolymer (copovidone). The film coating contains: hypromellose, lactose monohydrate, titanium dioxide, and triacetin. The film coating for the 5 mg tablets also contains iron oxide black and iron oxide yellow, and the film coating for the 10 mg tablets also contains FD&C Blue #1/Brilliant Blue FCF Aluminum Lake and iron oxide yellow.

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