

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

**PrBELSOMRA™
Suvorexant Tablets**

Read this carefully before you start taking BELSOMRA™ and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about BELSOMRA™.

What is BELSOMRA™ used for?

BELSOMRA™ (suvorexant) is a sleep medication used for the treatment of insomnia in adults who have trouble:

- falling asleep and / or
- staying asleep (waking up too often or for too long during the night or waking up too early, and then not being able to fall back asleep).

BELSOMRA™ is not for use in children under the age of 18 years.

How does BELSOMRA™ work?

Orexin is a chemical that binds to certain receptors in your brain to keep you awake. BELSOMRA™ temporarily blocks these receptors. This may help you fall asleep and stay asleep.

What are the ingredients in BELSOMRA™?

Medicinal ingredient: Suvorexant.

Non-medicinal ingredients: Croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyvinylpyrrolidone/vinyl acetate copolymer (copovidone), titanium dioxide, and triacetin.

The 5 mg tablets also contain: iron oxide black and iron oxide yellow.

The 10 mg tablets also contain: FD&C Blue #1/Brilliant Blue FCF Aluminum Lake and iron oxide yellow.

BELSOMRA™ comes in the following dosage forms:

Film coated tablet: 5 mg, 10 mg, 15 mg, and 20 mg

Do not use BELSOMRA™ if you:

- are allergic to suvorexant, or any of the other ingredients of BELSOMRA™ (see **What are the ingredients in BELSOMRA™?**).
- have narcolepsy (a sleep disorder that causes you to fall asleep often at unexpected times).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BELSOMRA™. Talk about any health conditions or problems you may have, including if you:

- have a history of depression, mental illness, or suicidal thoughts
- have a history of drug or alcohol abuse or addiction
- have had episodes of sleepwalking in the past or if there is a history of sleepwalking in your family
- have conditions known to affect your sleep or cause you to wake up often, such as
 - sleep apnea
 - Periodic Limb Movement Disorder (cramping or jerking of the legs during sleep)
 - Restless Leg Syndrome (the need to move your legs)
- have a history of sudden muscle weakness (cataplexy)
- have a history of falling asleep often at unexpected times (narcolepsy) or daytime sleepiness
- have problems with your lungs or breathing problems
- have problems with your liver
- are pregnant or planning on becoming pregnant. It is not known if BELSOMRA™ can harm your unborn baby. Your doctor will decide whether giving you BELSOMRA™ outweighs the potential risk to the fetus.
- are breastfeeding or planning to breastfeed. It is not known whether BELSOMRA™ can pass into your breastmilk.
- have lactose intolerance

Other warnings you should know about:

Need to check for other existing medical conditions: Sleep problems can be a sign of many physical and mental disorders. Your doctor will need to check your medical history before you start taking BELSOMRA™.

Talk to your doctor if after 7 to 10 days of taking BELSOMRA™ your sleep problems:

- do not stop or do not get better
- get worse or you develop new abnormal thinking or behaviour

This may mean that there is another condition such as a physical or mental illness causing your sleep problem.

Mental alertness, driving and using machines: BELSOMRA™ may affect your ability to be alert the next day.

It can affect how well you drive and you may be at an increased risk of falling asleep while you drive. **Do NOT** drive or use dangerous machinery until you know how BELSOMRA™ affects you the next day.

You can feel less alert the next day:

- even if you take BELSOMRA™ as prescribed
- for several days after you stop taking it

You increase the risk of being less alert the next day if you:

- do not get a full night of sleep (**at least** 7 hours)
- take BELSOMRA™ with other medicines that make you sleepy
- are taking a higher dose

If you notice that you are feeling more sleepy or drowsy during the day that affects your ability to do tasks that require clear thinking or attention, tell your doctor.

Abnormal thinking and behavioural changes: Taking hypnotics such as BELSOMRA™ can cause abnormal thinking and changes to your behaviour. These can include:

- memory loss (amnesia)
- anxiety
- seeing or hearing things that are not there (hallucinations)

Complex sleep-related behaviours: After taking hypnotics such as BELSOMRA™, you may get up out of bed while not being fully awake and do an activity that you do not know you are doing such as:

- sleep-walking
- driving a car (“sleep driving”)
- eating
- making phone calls
- having sex

The next morning, you may not remember that you did anything during the night.

You may have a greater chance for doing these activities while not fully awake if:

- you drink alcohol or
- take other medicines that make you sleepy with BELSOMRA™ or
- have other conditions that affect your sleep and cause you to wake up often during the night (for example, if you have sleep apnea, Periodic Limb Movement disorder or Restless Leg Syndrome)

You should let your family know that BELSOMRA™ can cause you to get out of bed while not being fully awake and do activities without knowing you are doing them.

If you find out that you have done any of these activities after taking BELSOMRA™, call your doctor.

Worsening depression and thoughts of suicide: Thoughts of suicide have been seen in people taking BELSOMRA™. Some people with depression who took hypnotic medications saw their depression get worse. They also had increased thoughts of suicide and actions. If you, your caregiver or your family members notice that your depression is getting worse or that you have increased thoughts of suicide, **call your doctor right away.**

Sleep paralysis, muscle weakness and hallucinations: You may experience the following when taking BELSOMRA™:

- you are not able to move or talk for up to several minutes while you are going to sleep or waking up (sleep paralysis)
- sudden muscle weakness, commonly in the legs, that can last a few seconds to a few minutes. This can happen during the day or at night.
- hallucinations (seeing or hearing things that are not there) while falling asleep or when waking up

If you experience any of these symptoms, call your doctor.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with BELSOMRA™:

Do NOT drink alcohol or take other sedative medications (that can make you sleepy) **or other sleeping pills** while taking BELSOMRA™. It can increase your chances of having serious side effects. Examples of sedative medications are:

- opioids (used to treat pain)
- certain antidepressants (used to treat depression)

You should not take the following medications with BELSOMRA™:

- ketoconazole, itraconazole, and posaconazole (used to treat fungal infections)
- clarithromycin, telithromycin (used to treat bacterial infections)
- ritonavir, saquinavir, nelfinavir, indinavir (used to treat HIV)
- boceprevir, telaprevir (used to treat Hepatitis C Virus (HCV))
- nefazodone (used to treat depression)
- conivaptan (used to treat low sodium levels)

The following medications or products may also interact with BELSOMRA™:

- rifampin, ciprofloxacin, erythromycin, (used to treat bacterial infections)
- fluconazole (used to treat fungal and yeast infections)
- amprenavir, atazanavir, fosamprenavir (used to treat HIV)
- aprepitant (used to treat nausea and vomiting caused by certain anti-cancer medicines)
- imatinib (used to treat certain types of cancer)
- carbamazepine and phenytoin (used to treat convulsions and seizures)
- diltiazem, verapamil (used to treat high blood pressure and chest pain/angina)
- digoxin (used to treat heart failure)
- grapefruit juice

Know the medicines you take. Keep a list of your medicines with you to show your healthcare professional each time you get a new medicine.

How to take BELSOMRA™:

- Take BELSOMRA™ exactly as your doctor tells you to take it. **Do NOT** take more of it than prescribed.
- **Take it only once a night. Do NOT take it at any other time other than bedtime (within 30 minutes of going to bed).**
- **Do NOT take BELSOMRA™ unless you are able to stay in bed for a full night (at least 7 hours) before you must be active again.**
- You can take it with or without meals. However, it may take longer to work if you take it with or right after your meal.
- Call your doctor if your insomnia worsens or is not better within 7 to 10 days. This may mean that there is another condition causing your sleep problems.

When not to take BELSOMRA™:

- **Do NOT** take it if you drank alcohol that evening or before bed.
- **Do NOT** take it with other medicines that make you sleepy.
- **Do NOT** take BELSOMRA™ if you are under the age of 18 years.

What you need to avoid after taking BELSOMRA™:

- driving a car or using dangerous machinery. **Do NOT** do these activities until you know how BELSOMRA™ affects you the next day. Tell your doctor if you experience excessive drowsiness the next day that affects your ability to do tasks requiring clear thinking or attention.

Usual adult dose:

The recommended starting dose: 10 mg once a day (within 30 minutes of going to bed).
The maximum recommended dose: 20 mg once a day (within 30 minutes of going to bed). **Do NOT** take more than 20 mg. It may cause more side effects.

Your doctor may:

- Start you on a lower dose depending on what other medications you are taking
- Change your dose depending on how you respond to BELSOMRA™

Overdose:

If you think you have taken too much BELSOMRA™, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose and

- you **can** get at least 7 hours of sleep before you must be active again, take your dose as usual.
- If you **cannot** get at least 7 hours of sleep before you must be active again: **do NOT** take your dose. Take it the next night at bedtime.

What are possible side effects from using BELSOMRA™?

These are not all the possible side effects you may feel when taking BELSOMRA™. If you experience any side effects not listed here, contact your healthcare professional.

The most common side effect of BELSOMRA™ is:

- Feeling sleepy the next day after taking it.

Other possible side effects of BELSOMRA™ may include:

- Headache
- Feeling dizzy
- Upper respiratory tract infection
- Diarrhea
- Dry mouth
- Having unusual dreams including nightmares
- Cough
- Feeling abnormal
- Anxiety
- Agitation
- Awareness of heartbeat, fast or irregular heartbeat (palpitations, tachycardia)

BELSOMRA™ may also cause serious side effects including those mentioned above in “**Other warnings you should know about**” and the table below.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Excessive sleepiness during the day		✓	
UNCOMMON			
Suicidal thoughts or actions			✓
Worsening of depression		✓	
Sleep paralysis Temporary inability to move or talk for up to several minutes while you are going to sleep or waking up. It may be accompanied by hallucinations or vivid and disturbing perceptions.		✓	
Temporary weakness in the legs that can happen during the day or night.		✓	
Abnormal thoughts and behaviour. Symptoms may include more outgoing or aggressive behaviour than normal, confusion, agitation, hallucinations, anxiety, memory loss.	✓		
VERY RARE			
“Sleep-walking” or doing other activities when you are asleep like eating, talking, having sex, or driving a car		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store

- at room temperature (15°C - 30°C).
- in the original blister package until use, to protect from light and moisture.
- Keep out of reach and sight of children.

Do not use this medicine after the expiry date on the carton.

If you want more information about BELSOMRA™:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website www.merck.ca, or by calling 1-800-567-2594.

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