

# BELSOMRA®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I taking BELSOMRA?

BELSOMRA contains the active ingredient Suvorexant. BELSOMRA is used to help you to go to sleep and stay asleep by temporarily blocking wakefulness, enabling sleep to occur.

For more information, see Section [1. Why am I taking BELSOMRA?](#) in the full CMI.

### 2. What should I know before I take BELSOMRA?

Do not take if you have ever had an allergic reaction to BELSOMRA or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take BELSOMRA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with BELSOMRA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take BELSOMRA?

The recommended dose for:

- Non-elderly adults (younger than 65 years) is one 20 mg tablet.
- Elderly adults (65 years or older) is one 15mg tablet.

BELSOMRA may be taken with or without food. Swallow the tablet whole with a full glass of water.

More instructions can be found in Section [4. How do I take BELSOMRA?](#) in the full CMI.

### 5. What should I know while taking BELSOMRA?

Things you should do	
	<ul style="list-style-type: none"><li>• Call your doctor if your insomnia (sleep problem) worsens or is not better within 7 to 10 days of taking</li></ul>

	<p>BELSOMRA. This may mean that there is another condition causing your sleep problem.</p> <ul style="list-style-type: none"> <li>● If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking BELSOMRA.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not take BELSOMRA if you take other medicines that can make you sleepy. Talk to your doctor about all of your medicines. Your doctor will tell you if you can take BELSOMRA with your other medicines.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● Be careful driving, operating machinery or other activities that require complete alertness until you know how BELSOMRA affects you.</li> <li>● As with other medicines used to treat insomnia, BELSOMRA may cause</li> </ul>

	drowsiness in some people the day after taking it.
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Do not take BELSOMRA if you drank alcohol that evening or before bed.</li> <li>• Alcohol can increase your chances of getting serious side effects with BELSOMRA.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Follow the instructions in the carton on how to take care of your medicine properly</li> </ul>

For more information, see Section [5. What should I know while taking BELSOMRA?](#) in the full CMI.

## 6. Are there any side effects?

Like all medicines, BELSOMRA can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of using BELSOMRA. When you take BELSOMRA, you can have some serious side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# BELSOMRA

**Active ingredient:** *Suvorexant*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about taking BELSOMRA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking BELSOMRA.**

**Where to find information in this leaflet:**

- [1. Why am I taking BELSOMRA?](#)
- [2. What should I know before I take BELSOMRA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take BELSOMRA?](#)
- [5. What should I know while taking BELSOMRA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking BELSOMRA?

**BELSOMRA contains the active ingredient Suvorexant.** BELSOMRA is a medicine called Orexin Receptor Antagonist. BELSOMRA is used to treat a sleep problem called insomnia, which includes problems falling asleep and/or staying asleep.

**BELSOMRA is used to help you to go to sleep and stay asleep by temporarily blocking wakefulness, enabling sleep to occur.**

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

There is no experience with BELSOMRA in children or adolescents under 18 years of age.

**Do not give BELSOMRA to a child or adolescent.**

## **2. What should I know before I take BELSOMRA?**

### **Warnings**

#### **Do not take BELSOMRA if:**

- you fall asleep often at unexpected times (narcolepsy).
- you are allergic to suvorexant, or any of the ingredients listed at the end of this leaflet.
- The packaging is torn or shows signs of tampering.
- The expiry date on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work.

Always check the ingredients to make sure you can take this medicine.

## Check with your doctor if you:

- 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 a history of depression, mental illness, or suicidal thoughts
- have a history of drug or alcohol abuse or addiction. BELSOMRA may be abused or misused.
- have liver disease
- have a lung disease or breathing problems
- take any medicines for any other condition
- are pregnant or plan to become pregnant.
- are breast-feeding.
- have allergies to any other medicines, foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Sleep Walking

After taking 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, eating, talking, or driving a car. The next morning, you may not remember that you did anything during the night.

You have a higher chance for doing these activities if you drink alcohol or take other medicines that make you sleepy with BELSOMRA.

Tell your doctor immediately if you find out that you have done any unusual activities after taking BELSOMRA.

You should contact your doctor if you experience abnormal thoughts and behaviours such as worsening of depression, and suicidal thoughts or actions.

## **Pregnancy**

It is not known if BELSOMRA can harm your unborn baby.

Your doctor will discuss with you the risks and benefits involved.

Check with your doctor if you are pregnant or intend to become pregnant.

## **Breastfeeding**

It is not known if BELSOMRA passes into your breast milk.

Your doctor will discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.



### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Medicines can interact with each other, sometimes causing serious side effects.

BELSOMRA should not be taken with some medicines because it strongly affects the level of either BELSOMRA or the other medicine in the blood.

Medicines that should not be taken with BELSOMRA include but are not limited to clarithromycin, erythromycin, fluconazole, itraconazole, diltiazem, verapamil, and certain medicines to treat HIV.

Do not take BELSOMRA with other medicines that can make you sleepy.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BELSOMRA.**

### **4. How do I take BELSOMRA?**

#### **How much to take**

Take BELSOMRA exactly as your doctor tells you.

For dosage in non-elderly adults (younger than 65 years) and elderly adults (65 years or older):

- The recommended dose for non-elderly adults (younger than 65 years) is one 20 mg tablet.
- The recommended dose for elderly adults (65 years or older) is one 15mg tablet.

These doses should not be exceeded. Higher doses worked similarly, but more side effects were reported.

The safety and effectiveness of BELSOMRA is similar in older and younger patients at the recommended doses.

## **How to take BELSOMRA**

- BELSOMRA may be taken with or without food.
- Swallow the tablet whole with a full glass of water.

## **When to take BELSOMRA**

- Only take BELSOMRA 1 time each night within 30 minutes of going to bed.
- Take BELSOMRA only when you have the opportunity for a full night of sleep (at least 7 hours) before you must be active again.

If you are not sure when to take it, ask your doctor or pharmacist.

## **How long to take BELSOMRA**

Continue to take BELSOMRA for as long as your doctor tells you.

After starting BELSOMRA, your doctor will periodically reassess your need to continue treatment with BELSOMRA.

Ask your doctor or pharmacist if you are not sure how long to take the medicine.

## **If you forget to take BELSOMRA**

If you miss a dose, do not take BELSOMRA unless you have the opportunity to get a full night of sleep (at least 7 hours) before you must be active again. You may continue with your usual dose the following night at bedtime.

If you are not sure what to do, ask your doctor.

## **If you take too much BELSOMRA**

If you think that you have taken too much BELSOMRA, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while taking BELSOMRA?**

### **Things you should do**

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking BELSOMRA.

Tell any other doctors, dentists and pharmacists who treat you that you are taking BELSOMRA.

### **Call your doctor straight away:**

- if your insomnia (sleep problem) worsens or is not better within 7 to 10 days of taking BELSOMRA. This may mean that there is another condition causing your sleep problem.
- If you become pregnant while taking BELSOMRA

### **Things you should not do**

- Do not take BELSOMRA if you take other medicines that can make you sleepy. Talk to your doctor about all of your medicines. Your doctor will tell you if you can take BELSOMRA with your other medicines.
- Do not give BELSOMRA to anyone else, even if they have the same condition as you.

## **Driving or using machines**

**Be careful driving, operating machinery or other activities that require complete alertness until you know how BELSOMRA affects you.**

As with other medicines used to treat insomnia, BELSOMRA may cause drowsiness in some people the day after taking it.

## **Drinking alcohol**

Do not take BELSOMRA if you drank alcohol that evening or before bed.

Alcohol can increase your chances of getting serious side effects with BELSOMRA.

## **Looking after your medicine**

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## When to discard your medicine

If your doctor tells you to stop taking BELSOMRA or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

## Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
Tell your doctor if you notice or have any of the following and they worry you: <ul style="list-style-type: none"><li>• sleepiness</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● tiredness</li> <li>● headache</li> <li>● dizziness</li> <li>● upper respiratory tract infection</li> <li>● diarrhoea</li> <li>● dry mouth</li> <li>● nausea</li> <li>● vomiting</li> <li>● unusual dreams including nightmare</li> <li>● feeling abnormal</li> <li>● anxiety</li> <li>● making mistakes in taking your medicine.</li> <li>● memory loss</li> <li>● temporary weakness in your legs that can happen during the day or at night.</li> <li>● cough</li> <li>● awareness of heartbeat, fast or irregular heartbeat (palpitations, tachycardia)</li> <li>● itching</li> </ul>	

## Serious side effects

Serious side effects	What to do
<p>Stop taking BELSOMRA and tell your doctor immediately if you notice any of the following:</p> <ul style="list-style-type: none"><li>● abnormal thoughts and behaviour. Symptoms include more outgoing or aggressive behaviour than normal, confusion, agitation, hallucinations (including vivid and disturbing perceptions)</li><li>● worsening of depression and suicidal thoughts or actions.</li><li>● temporary inability to move or talk (sleep paralysis) for up to several minutes while you are going to sleep or waking up.</li></ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Other side effects not listed above may also occur in some patients and as with any prescription drug, some side effects may be serious.



**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

### **What BELSOMRA contains**

<b>Active ingredient (main ingredient)</b>	Suvorexant 15 or 20 mg per tablet
<b>Other ingredients (inactive ingredients)</b>	Copovidone Microcrystalline cellulose Lactose monohydrate Croscarmellose sodium

	Magnesium stearate
	Ingredients in film-coating:
	Lactose monohydrate
	Hypromellose
	Titanium dioxide
	Triacetin

BELSOMRA does not contain gluten, sucrose, tartrazine or any other azo dyes.

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What BELSOMRA looks like**

BELSOMRA comes as two strengths of tablets:

15 mg tablet - A white, oval, biconvex, film coated tablet, marked with MSD logo on one side and 325 on the other (AUST R 207709).

20 mg tablet - A white, round, biconvex, film coated tablet, marked with MSD logo and 335 on one side, and plain on the other (AUST R 207712).

A box of BELSOMRA contains 10\* tablets or 30 tablets. BELSOMRA tablets may also be supplied in packs of 3\* tablets to start treatment.

\* Not currently supplied in Australia

## **Who distributes BELSOMRA**

Merck Sharp & Dohme (Australia) Pty Limited  
Level 1, Building A, 26 Talavera Road  
Macquarie Park NSW 2113 Australia

This leaflet was prepared in January 2023.

This leaflet was current at the time of printing. To check if it has been updated, please view our website, ([www.msinfo.com.au/belsomracmi](http://www.msinfo.com.au/belsomracmi)), or ask your pharmacists.

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