

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about BELSOMRA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking BELSOMRA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What BELSOMRA is used for

BELSOMRA is a medicine called an Orexin Receptor Antagonist. BELSOMRA is used to treat a sleep problem called insomnia, which includes problems falling asleep and/or staying asleep.

Insomnia

Insomnia is a condition in which patients may have the following symptoms:

- Difficulty falling asleep
- Difficulty staying asleep (waking too often or for too long during the night)
- Waking up too early and then not being able to fall back asleep
- Poor sleep quality

How BELSOMRA works

BELSOMRA helps 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.

Before you take BELSOMRA

When you must not take it

- **Do not take BELSOMRA if you fall asleep often at unexpected times (narcolepsy).**
- **Do not take BELSOMRA if you are allergic to suvorexant or any of the other ingredients of BELSOMRA 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.

If you are not sure whether you should start taking BELSOMRA, talk to your doctor.

Before you start to take it

BELSOMRA may not be right for you. Before starting BELSOMRA, tell your doctor about all of your health conditions, including 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

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.

Tell your doctor or pharmacist if you:

- are pregnant or plan to become pregnant. It is not known if BELSOMRA can harm your unborn baby. Your doctor will discuss with you the risks and benefits involved.
- are breast-feeding. It is not known if BELSOMRA passess into your breast milk. Your doctor will discuss with you the risks and benefits involved.
- **have allergies to any other medicines, foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell him/her before you take any BELSOMRA.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines, vitamins and herbal supplements that you buy without a prescription.

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.

Talk to your doctor about all of your medicines. Your doctor will tell you if you can take BELSOMRA with your other medicines.

How to take BELSOMRA

Follow all directions given to you by your doctor and pharmacist carefully.

If you do not understand the directions, ask your doctor or pharmacist for help.

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 it

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

When to take it

- **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 it

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 it

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 (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131 126), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too

much BELSOMRA. Do this even if there are no signs of discomfort or poisoning.

While you are using BELSOMRA

Things you must do

Call your doctor 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 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.

If you become pregnant while taking BELSOMRA, tell your doctor immediately.

Things you must not do

- **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.
- **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.**

Things to be careful of

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.

Do not drive or do other dangerous activities until you feel fully awake.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking BELSOMRA.

Any medicine may have unintended or undesirable effects, so-called side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice or have any of the following and they worry you:

- sleepiness
- tiredness
- headache
- dizziness
- upper respiratory tract infection
- diarrhoea
- dry mouth
- nausea
- unusual dreams including nightmare
- feeling abnormal
- anxiety

- making mistakes in taking your medicine.
- memory loss
- temporary weakness in your legs that can happen during the day or at night.
- cough

Stop taking BELSOMRA and tell your doctor immediately if you notice any of the following:

- **abnormal thoughts and behaviour.**
Symptoms include more outgoing or aggressive behaviour than normal, confusion, agitation, hallucinations (including vivid and disturbing perceptions)
- **worsening of depression and suicidal thoughts or actions.**
- **temporary inability to move or talk (sleep paralysis) for up to several minutes while you are going to sleep or waking up.**

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 if you notice any other effects.

After using BELSOMRA

Storage

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.

Keep BELSOMRA in a cool dry place where the temperature stays below 25°C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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.

Product description

What it looks like

BELSOMRA comes as two strengths of tablets:

- 15 mg tablet - A white, oval, biconvex, film coated tablet, marked with the MSD logo on one side and 325 on the other.
- 20 mg tablet - A white, round, biconvex, film coated tablet, marked with the MSD logo and 335 on one side, and plain on the other.

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

Ingredients

Active ingredient:

Suvorexant 15 or 20 mg per tablet

Inactive ingredients:

- Copovidone
- Microcrystalline cellulose
- Lactose
- Croscarmellose sodium
- Magnesium stearate

Ingredients of film-coating:

- Lactose
- Hypromellose
- Titanium dioxide
- Glycerol triacetate

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

Supplier

BELSOMRA is supplied in Australia by: Merck Sharp & Dohme (Australia) Pty Limited
Level 1, Building A,
26 Talavera Road
MACQUARIE PARK NSW 2113

Date of Preparation

This leaflet was prepared in December 2017.

Australian Register Numbers:

15 mg tablet - AUST R 207709

20 mg tablet - AUST R 207712

This CMI leaflet was current at the time of printing. To check if it has been updated, please view our website www.msd-australia.com.au or ask your pharmacist. (S-CCPPI-MK4305-T-072017)