



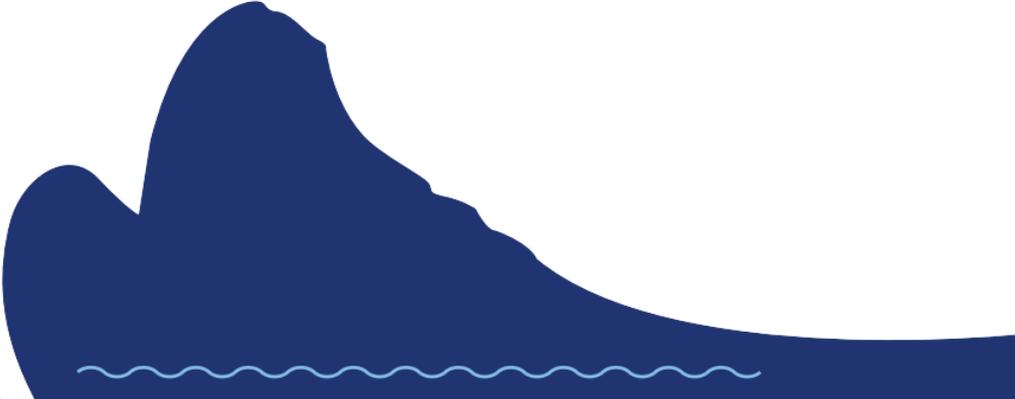
# Your guide to <sup>Pr</sup>LUNESTA<sup>®</sup>

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Your doctor has prescribed LUNESTA, a prescription medicine for the short-term treatment and relief of symptoms of insomnia including difficulty falling asleep, nocturnal awakenings, or early morning awakenings.

Read this carefully before you start taking LUNESTA and each time you get a refill. This brochure 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 LUNESTA.

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# What is insomnia?

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Insomnia is a common sleep problem that can make it hard to fall asleep and stay asleep.

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# What can you do about insomnia?

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The first step in managing your insomnia is to remove anything that may contribute to it, like drinking coffee too late, or using your phone in bed.

These changes might work for some people, but others may still have trouble falling asleep. For them, additional insomnia treatment may involve cognitive behavioural therapy (CBT), or medications.

## **Some simple tips to help with sleep:**

- ✓ Learn techniques to relax
- ✓ Take some time to unwind before bedtime
- ✓ Go to bed only when you are sleepy
- ✓ Get out of bed if you can't fall asleep right away
- ✓ Wake up at the same time every morning
  - even on weekends
- ✓ Limit naps during the day
- ✓ Maintain good sleep hygiene

## What is LUNESTA?

LUNESTA is a prescription treatment used for a short period of time to help you sleep, including helping you fall asleep, stay asleep during the night, and avoid waking up too early.

## How does LUNESTA work?

LUNESTA causes a calming effect in your brain and allows you to sleep.

If you are prescribed sleep medications, you should consider both their benefits and risks.

**Important Risks and Limitations of LUNESTA include:**

- You may become dependent on LUNESTA
- LUNESTA may affect your mental alertness or memory, particularly when not taken as prescribed

# How to take LUNESTA

- ✗ Do not take more than one dose in a single night
- ✓ Make sure you are able to stay in bed a full night (7-8 hours) before you have to be active again
- ✓ Take LUNESTA right before you get into bed, not sooner
- ✓ The recommended starting dose for LUNESTA is 1 mg. Depending on your response, your doctor may increase the dose to 2 mg or 3 mg. The maximum daily dose in adults is 3 mg
- ✗ Do not take a higher dose of LUNESTA than was prescribed by your healthcare professional
- ✗ Do not take LUNESTA if it is not prescribed for you
- ✗ Do not take LUNESTA if you drink alcohol
- ✗ Do not break or crush the LUNESTA tablets
- ✗ LUNESTA is not indicated for patients under 18 years of age. Do not take LUNESTA if you are under 18 years of age
- ✓ LUNESTA may take longer to work if you take it with or right after having a big meal
- ✗ Treatment with LUNESTA should usually not go on for more than 7-10 days. Do not take LUNESTA for more than 7-10 days without first speaking with your doctor

# Important safety information about LUNESTA

Speak to your doctor about your medical conditions and all medicines you are taking before starting with LUNESTA.

## Serious Warnings and Precautions

### **Complex sleep-related behaviours**

There have been reports of people getting out of bed while not fully awake after taking LUNESTA and doing activities they did not know they were doing. The activities you may do in these situations can put you and people around you in danger. Reported activities included driving a car, leaving the house, making and eating food, talking on the phone, etc.

### **Important**

- Do not take more LUNESTA than prescribed.
- Do not take LUNESTA if you drink alcohol.
- Do not take LUNESTA if you have ever experienced behaviours like those described above with any other medication, including LUNESTA.
- Talk to your doctor if you have a condition that affects your sleep, such as Periodic Limb Movement in Sleep or Restless Legs Syndrome.
- Talk to your doctor about all of your medicines, including over-the-counter and herbal medicines.
- You and people close to you should watch for the type of unusual behaviour described above. If you find out, or suspect that you have done any such activities for which you have no memory, you should stop taking LUNESTA and call your doctor immediately.

### **Taking opioids**

Taking LUNESTA with opioid medicines can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

## **Missed Dose**

If you miss a dose, do not take LUNESTA in the middle of the night. You should wait and take the next dose at bedtime the next night, if you need to take a dose.

## **Do not use LUNESTA if you:**

- Have a known allergy to eszopiclone, zopiclone, or to any ingredients in the formulation or components of the container
- Have myasthenia gravis, a condition where the muscles easily tire and become weak

- Have severe breathing problems and/or sleep apnea where you stop breathing for short periods while you sleep
- Are elderly and taking certain antifungals or antibiotics (such as ketoconazole) or you have severe liver problems
- Have ever experienced a complex sleep-related behaviour (such as driving a car, making and eating food, talking on the phone or having sex while not fully awake) after taking LUNESTA or any other medication

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LUNESTA. Talk about any health conditions you might have including if you:**

- Have a history of depression, mental illness, and/or suicidal thoughts or attempts
- Have a history of drug or alcohol abuse or addiction
- Have had unexpected reactions to alcohol or sedative medications in the past
- Have liver or kidney problems
- Have a lung disease or breathing problem
- Have had episodes of sleepwalking in the past, or have a family history of sleepwalking
- Have a condition that affects your sleep, such as Periodic Limb Movement Disorder or Restless Legs Syndrome
- Consume alcohol
- Are taking opioid medicines or other central nervous system depressants such as sedatives or hypnotics, as well as if you are taking any other medicines, including over-the-counter medicines and herbal products
- Are pregnant or planning to become pregnant

**Other warnings you should know about:**

- **Mental Alertness:** LUNESTA may affect your ability to be alert the next day. DO NOT DRIVE A CAR or operate potentially dangerous machinery if you do not feel fully awake or if it has not been at least 12 hours since taking LUNESTA.
- **Memory Problems:** LUNESTA may cause a special type of memory loss (amnesia); you may not recall events that occurred during some period of time, usually several hours, after taking the drug.
- **Dependence and Abuse:** All prescription sleeping pills can cause dependence (addiction), especially when they are used regularly for more than a few weeks or at higher doses.
- **Withdrawal:** Although uncommon, withdrawal symptoms (including stomach pain, headache, increased appetite and insomnia) have been reported after LUNESTA treatment is stopped.
- **Mental and Behavioural Changes:** A variety of abnormal thinking and behavioural changes may occur when you use prescription sleeping pills. Some of these changes include aggressiveness and extroversion which seem out of character. If you develop any unusual, disturbing thoughts or behaviour while using LUNESTA, discuss the matter immediately with your healthcare professional.
- **Worsening of Side Effects:** DO NOT CONSUME ALCOHOL WHILE TAKING LUNESTA. Some medicines may also worsen the side effects that some patients experience with LUNESTA.

- **Risk of Falls:** LUNESTA can cause drowsiness, dizziness, lightheadedness and a decreased level of wakefulness, which could increase your risk of falling. Elderly patients in particular are at an increased risk of falls and fractures. Always take LUNESTA right before bed or once already in bed.
- **Effects on Pregnancy:** Certain sleeping pills have been linked to birth defects when taken during the early months of pregnancy. It is not yet known if LUNESTA could cause similar effects. In addition, sleeping pills taken during the last weeks of pregnancy have been known to sedate the baby and may also cause withdrawal symptoms after birth. Therefore, **DO NOT TAKE LUNESTA** at anytime during pregnancy, it may affect the developing baby.
- **Use in Nursing Mothers:** LUNESTA passes into breast milk. Therefore, if you are breast feeding, this medicine should be avoided. Your healthcare professional will discuss this with you.

### The following may interact with LUNESTA:

- Alcohol
- Other sedative drugs or sleeping pills
- Narcotic analgesics (opioids) (see Serious Warnings and Precautions box)
- Olanzapine used to treat schizophrenia and bipolar disorder
- Ketoconazole an antifungal used to treat fungal infections
- Rifampin an antibiotic used to treat infections

### Possible side effects of LUNESTA are:

- Unpleasant taste, dry mouth
- Nausea, stomach upset
- Back pain
- Headache
- Drowsiness
- Dizziness, lightheadedness
- Nervousness
- Abnormal dreams

Elderly patients are especially susceptible to side effects. Excessive drowsiness in the elderly may result in falls and fractures.

If you experience side effects not listed here, or that become bad enough to interfere with your daily activities, talk to your doctor.

For more information:

- Talk to your doctor or healthcare professional
- See the Patient Medication Information included with LUNESTA



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