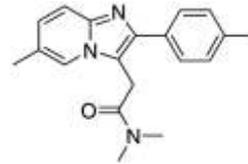


Rx **ZOLPIDEM**
(It is used for the short-term treatment of insomnia)



Zolpidem is a sedative, also called a hypnotic. It affects chemicals in your brain that may become unbalanced and cause sleep problems (insomnia).

Zolpidem is used for the short-term treatment of insomnia (difficulty falling or staying asleep). This medication causes relaxation to help you fall asleep.

Zolpidem may also be used for purposes other than those listed in this medication guide.

GENERIC NAME: zolpidem

Zolpidem belongs to a class of drugs called sedatives or hypnotics. Zolpidem shares some characteristics of a family of sedatives called benzodiazepines. Benzodiazepines cause sedation, muscle relaxation, act as anti-convulsants (anti-seizure medications), and reduce anxiety. Zolpidem has selectivity in that it has little of the muscle relaxant and anti-seizure effects and more of the sedative effect. Therefore, it is used primarily as a medication for sleep. The oral spray form of zolpidem, Zolpimist, has more rapid absorption than the tablet form because it is absorbed through the lining of the mouth. The FDA approved zolpidem in December 1992.

PRESCRIPTION: Yes

GENERIC AVAILABLE: Yes

PREPARATION: Tablets: 5 and 10 mg. Tablet (extended release): 6.25 mg and 12.5 mg. Oral spray: 5 mg/spray

PRESCRIBED FOR:

Zolpidem is used for treating insomnia. Conventional tablets are used for short-term treatment of insomnia associated with difficulty falling asleep. Long acting tablets are used for treating insomnia associated with difficulty falling asleep or staying asleep. Zolpidem improves initiation of sleep and keeps patients asleep longer.

DRUG INTERACTIONS

Alcohol has an additive effect with zolpidem and the two should not be combined. Zolpidem should not be combined with other sedative drugs because of the additive effects. Itraconazole (Sporanox) and ketoconazole (Nizoral, Extina, Xolegel, Kuric) may increase the blood concentration of zolpidem by reducing the activity of the enzymes that breakdown zolpidem in the liver. Conversely, rifampin may reduce the concentration of zolpidem by increasing the activity of the enzymes that breakdown zolpidem.

USES

This medication is used to treat patients with trouble sleeping (insomnia). It helps you fall asleep faster and sleep longer through the night. Zolpidem is a sedative/hypnotic which acts on the brain and nerves (central nervous system) to produce a calming effect. It works by enhancing the effects of a certain natural chemical (gamma-aminobutyric acid - GABA) in the body. This medication is usually limited to short-term treatment periods of 1-2 weeks or less.

HOW TO USE

Since this medication takes effect quickly, take it by mouth immediately before bedtime on an empty stomach, or as directed by your doctor. Use this medication exactly as prescribed. Do not increase your dose, take it more frequently or use it for a longer period of time than prescribed because this drug can be habit-forming. If this drug is used for an extended period of time, do not suddenly stop using it without your doctor's approval. Some conditions may become worse when the drug is abruptly stopped. Your dose may need to be gradually decreased. When used for an extended period, this medication may not work as well and may require different dosing. Talk with your doctor if this medication stops working well. You may experience trouble sleeping the first few nights after you stop taking this medication. This is called rebound insomnia and it is normal. It will usually go away after 1-2 nights. If this effect continues, contact your doctor. Read the Patient Information Leaflet available from your pharmacist. Inform your doctor if your condition persists or worsens.

SIDE EFFECTS

The most common side effects of zolpidem are drowsiness, dizziness, and a "drugged" feeling, which probably reflect the action of the drug. Other side effects include confusion, insomnia, euphoria, ataxia (balance problems),

and visual changes. Zolpidem can cause withdrawal symptoms (muscle cramps, sweats, shaking, and seizures) when the drug is abruptly discontinued. Zolpidem can cause abnormal behavior with confusion, paradoxical insomnia or "complex sleep-related behaviors," which may include sleep-driving (driving with no memory of having done so). If these side effects occur, zolpidem should be discontinued.

PREGNANCY

There are no adequate studies of zolpidem use in pregnant women.

PRECAUTIONS

Before taking zolpidem, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, liver disease, depression, drug or alcohol dependency, lung/breathing problems (e.g., chronic obstructive pulmonary disease-COPD, sleep apnea). This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Avoid alcoholic beverages because they may increase the risk of this drug's side effects. To minimize dizziness and lightheadedness, get up slowly when rising from a seated or lying position. Caution is advised when using this drug in the elderly because they may be more sensitive to its effects, which may lead to an increased risk of falling. This medication should be used during pregnancy only if clearly needed. Discuss the risks and benefits with your doctor. A small amount of this medication passes into breast milk. Consult your doctor before breast-feeding.

DOSING

The recommended adult dose of zolpidem is 10 mg as conventional tablets or spray or 12.5 mg as extended-release tablets. In elderly patients, an initial dose of 5 mg as conventional tablets or 6.25 mg as extended-release tablets is recommended because elderly patients have decreased ability to eliminate zolpidem from the body, and accumulating zolpidem may cause side effects.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include slowed breathing or a deep sleep from which you cannot be awakened.

MISSED DOSE

Take your dose at or near bedtime. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature between 68-77 degrees F (20-25 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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