

Palmetto State Pharmaceuticals

Patient Drug Education

TEMAZEPAM 15 MG CAPSULE

USES:

This medication is used for the short-term treatment of patients with trouble sleeping (insomnia). It is generally used for 7-10 days. It may help you fall asleep faster and decrease the number of times you awaken during the night. It may also help you sleep for a longer period of time. Temazepam belongs to a class of medications called sedative/hypnotics. It acts on your brain to produce a calming effect.

HOW TO TAKE THIS MEDICATION:

HOW TO USE: Read the Patient Information Leaflet provided by your pharmacist before you start using temazepam and each time you get a refill. If you have any questions regarding the information, consult your doctor or pharmacist. Take this medication by mouth, with or without food, usually once nightly, 30 minutes before bedtime; or take as directed by your doctor. The dosage is based on your medical condition and response to therapy. Do not use this medication if you will need to be alert before getting a full night's sleep (e.g., overnight plane flight of less than 7 hours). Temporary memory loss may occur. This medication may cause dependence, especially if it has been used regularly for an extended period of time, or if it has been used in high doses. In such cases, if you suddenly stop this drug, withdrawal reactions may occur. Such reactions can include unusual depressed/anxious mood, stomach/muscle cramps, vomiting, sweating, or shakiness. Seizures may also occur. Report to your doctor immediately any such reactions. When stopping extended, regular treatment with this drug, gradually reducing the dosage as directed will help prevent withdrawal reactions. Consult your doctor or pharmacist for more details. Although it is very unlikely to occur, this medication can also result in abnormal drug-seeking behavior (addiction/habit forming). Do not increase your dose, take it more frequently or use it for a longer period of time than prescribed. Properly stop the medication when so directed. This will lessen the chances of becoming addicted. 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. Inform your doctor if your condition persists or worsens after 7-10 days.

SIDE EFFECTS:

Dizziness, loss of coordination, or blurred vision may occur. To minimize falls, remember to get up slowly when rising from a seated or lying position. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. This medication may make you sleepy during the day. Tell your doctor if you have daytime drowsiness. Your dose may need to be adjusted. Remember that your doctor has prescribed this medication because the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: confusion, unusual feelings of well-being (euphoria), uncontrolled movements (tremor), restlessness, memory loss, sweating, mental/mood changes (e.g., hallucinations, agitation, anxiety, unusual/disturbing thoughts, depression, rare thoughts of suicide), increased or vivid dreams, vision changes, fainting. Tell your doctor immediately if any of these rare but very serious side effects occur: signs of infection (e.g., fever, persistent sore throat), unusual paleness, unusual tiredness, fast/pounding/irregular heartbeat, yellowing of the eyes/skin, dark urine. A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS:

Before taking temazepam, tell your doctor or pharmacist if you are allergic to it; or to other benzodiazepines (e.g., lorazepam, diazepam); or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease, kidney disease, mental/mood problems (e.g., depression, panic disorder), lung problems (e.g., pulmonary insufficiency, sleep apnea), seizures, personal or family history of regular use/abuse of drugs/alcohol/other substances. This drug may make you dizzy or drowsy, or cause temporary blurred vision. Use caution engaging in activities requiring alertness or clear vision such as driving or using machinery. Avoid alcoholic beverages because they may increase the risk of this drug's side effects. Caution is advised when using this drug in the elderly because they may be more sensitive to the effects of the drug, especially drowsiness, dizziness, loss of coordination, and confusion. Temazepam must not be used during pregnancy. Other medications in this class have caused birth defects when used in the first three months of pregnancy. Other medications in this class have also caused unusual drowsiness, feeding problems, and liver problems in newborns when used at or near the time of delivery, or withdrawal symptoms in newborns when used for a long time during pregnancy. If you are a woman of childbearing age, use an effective form of birth control while taking this drug. If you plan to become pregnant, stop taking this drug before doing so. If you become pregnant or think you may be pregnant, inform your doctor immediately. This medication passes into breast milk and may have undesirable effects on a nursing infant. Breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Your healthcare professionals (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop or change the dosage of any medicine before checking with them first. This drug should not be used with the following medication because very serious interactions may occur: sodium oxybate. If you are currently using the medication listed above, tell your doctor or pharmacist before starting temazepam. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: clozapine, kava. Tell your doctor or pharmacist if you also take drugs that cause drowsiness such as: antihistamines that cause drowsiness (e.g., diphenhydramine), anti-anxiety drugs (e.g., diazepam), anti-seizure drugs (e.g., carbamazepine), other medicines for sleep (e.g., zolpidem), muscle

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relaxants, narcotic pain relievers (e.g., codeine), psychiatric medicines (e.g., phenothiazines such as chlorpromazine, or tricyclics such as amitriptyline), tranquilizers. Check the labels on all your medicines (e.g., cough-and-cold products) because they may contain drowsiness-causing ingredients including alcohol. Ask your pharmacist about the safe use of those products.

NOTES:

Do not share this medication with others. It is against the law. This medication has been prescribed for your current condition only. Do not use it later for another condition unless told to do so by your doctor. A different medication may be necessary in those cases. Laboratory and/or medical tests (e.g., liver and kidney function tests, blood count) may be performed periodically to check for side effects if you use this drug for an extended period of time. Consult your doctor for more details. If you require treatment for more than 7-10 days, laboratory and/or medical tests should be performed to find the cause of your sleep problem. Consult with your doctor for more details. As you get older, your sleep pattern may naturally change and your sleep may be interrupted several times during the night. Consult your doctor or pharmacist for ways to improve your sleep without medication, such as avoiding caffeine and alcohol close to bedtime, avoiding daytime naps, and avoiding going to bed too early each night.

MISSED DOSE:

If you miss a dose, take it as soon as you remember if it is still near bedtime. If it is already the next day, resume your usual dosing schedule that night at bedtime. Do not double the dose to catch up.

STORAGE:

Store the US product at room temperature below 86 degrees F (30 degrees C) away from light and moisture. Store the Canadian product at controlled temperature 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.