

## **MEDICATION GUIDE**

### **Temazepam Capsules, USP CIV**

#### **(temaz' e pam)**

Read the Medication Guide that comes with temazepam capsules before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or treatment.

#### **What is the most important information I should know about temazepam capsules?**

**After taking temazepam capsules, you may get up out of bed while not being fully awake and do an activity that you do not know you are doing. 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 temazepam capsules. Reported activities include:

- driving a car (“sleep-driving”)
- making and eating food
- talking on the phone
- having sex
- sleep-walking

**Call your doctor right away if you find out that you have done any of the above activities after taking temazepam capsules.**

#### **Important:**

##### **1. Take temazepam capsules exactly as prescribed**

1. Do not take more temazepam capsules than prescribed.
2. Take temazepam capsules right before you get in bed, not sooner.

##### **2. Do not take temazepam capsules if you:**

3. drink alcohol
4. 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 temazepam capsules with your other medicines
5. cannot get a full night’s sleep

#### **What are temazepam capsules?**

Temazepam capsules are a sedative-hypnotic (sleep) medicine. Temazepam capsules are used in adults for the short-term (usually 7 to 10 days) treatment of a sleep problem called insomnia. Symptoms of insomnia include:

- trouble falling asleep
- waking up often during the night

Temazepam capsules are not for children.

Temazepam capsules are a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep temazepam capsules in a safe place to prevent misuse and abuse. Selling or giving away temazepam capsules may harm others, and is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

#### **Who should not take temazepam capsules?**

**Do not take temazepam capsules if you are pregnant or planning to become pregnant.** Temazepam capsules may cause birth defects or harm a fetus (unborn baby).

**Temazepam capsules may not be right for you. Before starting temazepam capsules, tell your doctor about all of your health conditions, including if you:**

- have a history of depression, mental illness, or suicidal thoughts
- have a history of drug or alcohol abuse or addiction
- have kidney or liver disease
- have a lung disease or breathing problems
- are breastfeeding

Tell your doctor about all of the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Medicines can interact with each other, sometimes causing serious side effects. **Do not take temazepam capsules with other medicines that can make you sleepy.**

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

### **How should I take temazepam capsules?**

- Take temazepam capsules exactly as prescribed. Do not take more temazepam capsules than prescribed for you.
- **Take temazepam capsules right before you get into bed.**
- **Do not take temazepam capsules unless you are able to get a full night's sleep before you must be active again.**
- **Call your doctor if your insomnia worsens or is not better within 7 to 10 days.** This may mean that there is another condition causing your sleep problems.
- If you take too many temazepam capsules or overdose, call your doctor or poison control center right away, or get emergency treatment.

### **What are the possible side effects of temazepam capsules?**

**Possible serious side effects of temazepam capsules include:**

- **getting out of bed while not being fully awake and do an activity that you do not know you are doing.** (See "What is the most important information I should know about temazepam capsules?")
- **abnormal thoughts and behavior.** Symptoms include more outgoing or aggressive behavior than normal, confusion, agitation, hallucinations, worsening of depression, and suicidal thoughts.
- **memory loss**
- **anxiety**
- **severe allergic reactions.** Symptoms include swelling of the tongue or throat, trouble breathing, and nausea and vomiting. Get emergency medical help if you get these symptoms after taking temazepam capsules.

**Call your doctor right away if you have any of the above side effects or any other side effects that worry you while using temazepam capsules.**

**The most common side effects of temazepam capsules are:**

- drowsiness
- headache
- tiredness
- nervousness
- dizziness
- nausea
- "hangover" feeling the day after taking temazepam capsules

- You may still feel drowsy the next day after taking temazepam capsules. **Do not drive or do other dangerous activities after taking temazepam capsules until you feel fully awake.**
- You may have withdrawal symptoms if you stop taking temazepam capsules suddenly. Withdrawal symptoms can be serious and include seizures. Mild withdrawal symptoms include a depressed mood and trouble sleeping. Talk to your doctor to check if you need to stop temazepam capsules slowly.

These are not all the side effects of temazepam capsules. Ask your doctor or pharmacist for more information.

### **How should I store temazepam capsules?**

- Store temazepam capsules at room temperature, 68°-77°F (20°-25°C).
- **Keep temazepam capsules and all medicines out of reach of children.**

### **General Information about temazepam capsules**

- Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.
- Do not use temazepam capsules for a condition for which it was not prescribed.
- Do not share temazepam capsules with other people, even if you think they have the same symptoms that you have. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about temazepam capsules. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about temazepam capsules that is written for healthcare professionals.

### **What are the ingredients in temazepam capsules?**

Active ingredient: temazepam, USP

Inactive ingredients: corn starch, hypromellose, lactose monohydrate, magnesium stearate, and sodium lauryl sulfate. The capsule shells and imprinting inks contain: benzyl alcohol, butylparaben, edetate calcium disodium, gelatin, iron oxide black, methylparaben, potassium hydroxide, propylene glycol, propylparaben, shellac, sodium lauryl sulfate, sodium propionate, strong ammonia solution and titanium dioxide. The 15 mg capsules also contain D&C Yellow #10 and FD&C Blue #1.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 .

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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