

MEDGUIDE

MEDICATION GUIDE

Temazepam Capsules, USP C-IV

Read the Medication Guide that comes with temazepam 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?

After taking temazepam, 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. 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.

Important:

1. Take temazepam exactly as prescribed

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

2. Do not take temazepam if you:

- drink alcohol
- 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 with your other medicines
- cannot get a full night’s sleep

What is temazepam?

Temazepam is a sedative-hypnotic (sleep) medicine. Temazepam is 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 is not for children.

Temazepam is a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep temazepam in a safe place to prevent misuse and abuse. Selling or giving away temazepam 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?

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

Temazepam may not be right for you. Before starting temazepam, 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 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?

- Take temazepam exactly as prescribed. Do not take more temazepam than prescribed for you.
- **Take temazepam right before you get into bed.**
- **Do not take temazepam 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 much temazepam or overdose, call your doctor or poison control center right away, or get emergency treatment.

What are the possible side effects of temazepam?

Possible serious side effects of temazepam 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?")
- **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.

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.

The most common side effects of temazepam are:

- drowsiness

- headache
- tiredness
- nervousness
- dizziness
- nausea
- “hangover” feeling the day after taking temazepam
- You may still feel drowsy the next day after taking temazepam. **Do not drive or do other dangerous activities after taking temazepam until you feel fully awake.**
- You may have withdrawal symptoms if you stop taking temazepam 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 slowly.

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

How should I store temazepam?

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

General Information about temazepam

- Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.
- Do not use temazepam for a condition for which it was not prescribed.
- Do not share temazepam 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. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about temazepam that is written for healthcare professionals.

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

What are the ingredients in temazepam capsules?

15 mg or 30 mg Capsules

Active Ingredient: temazepam USP

15 mg Capsules

Corn starch, colloidal silicon dioxide, D&C yellow #10, FD&C green #3, FD&C yellow #6 (Sunset Yellow), gelatin, magnesium stearate, microcrystalline cellulose, silicon dioxide, sodium lauryl sulfate, titanium dioxide.

30 mg Capsules

Corn starch, colloidal silicon dioxide, gelatin, magnesium stearate, microcrystalline cellulose, silicon dioxide, sodium lauryl sulfate, titanium dioxide.

Rx only

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

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