

Temazepam (tem az e pam) Capsules, USP CIV

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

- **Temazepam capsule is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system (CNS) depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma and death.** Get emergency help right away if any of the following happens:
 - o shallow or slowed breathing
 - o breathing stops (which may lead to the heart stopping)
 - o excessive sleepiness (sedation)

Do not drive or operate heavy machinery until you know how taking temazepam capsules and opioids affects you.

- o **Risk of abuse, misuse, and addiction.** There is a risk of abuse, misuse, and addiction with benzodiazepines including temazepam capsules which can lead to overdose and serious side effects including coma and death. **Serious side effects including coma and death have happened in people who have abused or misused benzodiazepines, including temazepam capsules.** These serious side effects may also include delirium, paranoia, suicidal thoughts or actions, seizures, and difficulty breathing. **Call your healthcare provider or go to the nearest hospital emergency room right away if you get any of these serious side effects.**
- o **You can develop an addiction even if you take temazepam capsules as prescribed by your healthcare provider**
- o **Take temazepam capsules exactly as your healthcare provider prescribed.**
- o Do not share your temazepam capsules with other people.
- o Keep temazepam capsules in a safe place and away from children.
- **Physical dependence and withdrawal reactions.** Temazepam capsules can cause physical dependence and withdrawal reactions.
 - o **Do not suddenly stop taking temazepam capsules.** Stopping temazepam capsules suddenly can cause serious and life-threatening side effects, including, unusual movements, responses, or expressions, seizures, sudden and severe mental or nervous system changes, depression, seeing or hearing things that others do not see or hear, an extreme increase in activity or talking, losing touch with reality, and suicidal thoughts or actions. **Call your healthcare provider or go to the nearest hospital emergency room right away if you get any of these symptoms.**
 - o **Some people who suddenly stop benzodiazepines have symptoms that can last for several weeks to more than 12 months,** including, anxiety, trouble remembering, learning, or concentrating, depression, problems sleeping, feeling like insects are crawling under your skin, weakness, shaking, muscle twitching, burning or prickling feeling in your hands, arms, legs or feet, and ringing in your ears.
 - o Physical dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical dependence and drug addiction.
 - o Do not take more temazepam capsules than prescribed or take temazepam capsules for longer than prescribed.
- 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:
 - o driving a car (“sleep-driving”)
 - o making and eating food
 - o talking on the phone
 - o having sex
 - o sleep-walking

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

What is temazepam capsule?

- Temazepam capsule is a prescription sleep medicine. Temazepam capsule 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 and waking up often during the night.
- **Temazepam capsule is a federal controlled substance (C-IV) because it contains temazepam that 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 healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.
- It is not known if temazepam capsule is safe and effective in children.
- It is not known if temazepam capsule is safe and effective for use longer than 2 weeks.

Do not take Temazepam capsules if you

- are allergic to temazepam or any of the ingredients in temazepam capsules. See the end of this Medication Guide for a complete list of ingredients in temazepam capsules.

Before you take temazepam capsules, tell your healthcare provider about all of your medical 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 lung disease or breathing problems
- are pregnant or plan to become pregnant. Temazepam capsules may cause birth defects or harm your unborn baby.
- are breastfeeding, or plan to breastfeed. Temazepam may pass through your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take temazepam capsules.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking temazepam capsules with certain other medicines can cause side effects or affect how well temazepam capsules or the other medicines work. Do not start or stop other medicines without talking to your healthcare provider.

Do not take temazepam capsules with other medicines that can make you sleepy unless your healthcare provider tells you to.

How should I take temazepam capsules?

- **See “What is the most important information I should know about temazepam capsules?”**
- Take temazepam capsules exactly as your healthcare providers tell you to take it. 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.
- If you take too much temazepam capsules or overdose, get emergency treatment right away.

What are the possible side effects of temazepam capsules?

Temazepam capsules may cause serious side effects, including:

- **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.
- **Severe allergic reactions.** Symptoms include swelling of the tongue or throat, trouble breathing, and nausea and vomiting. Get emergency medical help right away if you have these symptoms after taking temazepam capsules.
- **Temazepam capsules can make you sleepy or dizzy and can slow your thinking and motor skills.**
 - Do not drive, operate heavy machinery, or do other dangerous activities until you know how temazepam capsules affects you.
 - **Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking temazepam capsules talking to your healthcare provider.** When taken with alcohol or other drugs that cause sleepiness or dizziness, temazepam capsules may make your sleepiness or dizziness much worse.

The most common side effects of temazepam capsules include:

- drowsiness
- headache
- tiredness
- nervousness
- dizziness
- nausea

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.**

These are not all the possible side effects of temazepam capsules. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store temazepam capsules?

- Store temazepam capsules at 25° (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
- **Keep temazepam capsules and all medicines out of the reach of children.**

General information about the safe and effective use of 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 give temazepam capsules to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about temazepam capsules that is written for healthcare professionals.

What are the ingredients in temazepam capsules?

Active Ingredient: temazepam

Inactive Ingredients:

7.5 mg Capsules: lactose monohydrate, croscarmellose sodium, microcrystalline cellulose, sodium lauryl sulphate, magnesium stearate, FD&C Blue 1, D&C Red 28, FD&C Red 40, titanium dioxide, gelatin.

15 mg Capsules: lactose monohydrate, croscarmellose sodium, microcrystalline cellulose, sodium lauryl sulphate, magnesium stearate, FD&C Blue 1, FD&C Red 40, titanium dioxide, gelatin.

22.5 mg Capsules: lactose monohydrate, croscarmellose sodium, microcrystalline cellulose, sodium lauryl sulphate, magnesium stearate, FD&C Blue 1, D&C Red 28, titanium dioxide, gelatin.

30 mg Capsules: lactose monohydrate, croscarmellose sodium, microcrystalline cellulose, sodium lauryl sulphate, magnesium stearate, FD&C Blue 1, FD&C Red 40, D&C Red 28, gelatin, titanium dioxide.

The printing ink contains shellac, propylene glycol, potassium hydroxide and iron oxide black.

For more information call Alembic Pharmaceuticals Limited at 1-866-210-9797.

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

Medication Guide available at <http://www.alembicusa.com/medicationguide.aspx> or call 1-866-210-9797.

Manufactured by:

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Revised: 07/2021

20034023