Temazepam is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, there is potential hazard to the fetus. Patients should be instructed to discontinue the drug prior to becoming pregnant.

Benzodiazepines may cause fetal harm when administered to a pregnant woman. An increased risk of congenital malformations and decreased fetal weight have been reported with the use of benzodiazepines during the first trimester of pregnancy. 

Temazepam is not recommended for women who are breast feeding. It is known that many drugs are excreted in human milk. Therefore, caution should be exercised when temazepam is administered to a nursing woman.

CLINICAL PHARMACOLOGY

Elimination Rate of Benzodiazepine Hypnotics and Profile of Common Untoward Effects

The elimination rate of temazepam is characterized by a terminal half-life ranging from 0.4 to 0.6 hours. The mean clearance of temazepam is approximately 0.5 liter/minute. Metabolites were formed with a half-life of 10 hours and excreted with a half-life of approximately 2 hours.

Temazepam is metabolized with the appearance of elimination processes that are distinctive from those observed with the parent compound. The principal intermediate in the formation of temazepam metabolites is temazepam-N-oxide. The ratio of temazepam-N-oxide to temazepam in plasma is approximately 0.2. Therefore, temazepam-N-oxide is the major metabolite of temazepam plasma.

Thus, formation of the major metabolite is the rate limiting step in the biodisposition of temazepam. There is evidence that, when temazepam is administered to subjects with hepatic disease, temazepam is metabolized at a reduced rate.

The elimination rate of temazepam is substantially with larger doses of benzodiazepines in elderly and debilitated patients, 7.5 mg of temazepam was found to be adequate for sleep induction in elderly patients. However, higher doses may be needed for effective sleep maintenance in these patients.

TABLE

<table>
<thead>
<tr>
<th>% Incidence</th>
<th>(n=783)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety</td>
<td>2.2%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>1.7%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>1.7%</td>
</tr>
<tr>
<td>Headache</td>
<td>1.5%</td>
</tr>
<tr>
<td>Euphoria</td>
<td>1.4%</td>
</tr>
</tbody>
</table>

Anxiety

Anxiety may be the consequence of an unrecognized psychiatric or physical disorder. Such disorders should be ruled out by a thorough medical history and physical examination.

Temazepam capsules are a sedative-hypnotic (sleeping pill) medicine. Temazepam capsules are used to help people fall asleep and stay asleep.

Temazepam capsules are not for children.

Temazepam capsules are not for children. Emphysema, bronchitis, and other chronic pulmonary insufficiency, including patients who have chronic pulmonary insufficiency with or without cor pulmonale, or chronic obstructive pulmonary disease (COPD) should not be treated with this medicine.

Temazepam capsules are not for children.
**Administration.**

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

**How to take temazepam capsules.**

Temazepam capsules are not for children.

1. Take temazepam capsules exactly as prescribed.
2. Do not take more temazepam capsules than prescribed.
3. Do not drive or do other dangerous activities after taking temazepam capsules until you feel fully awake.
4. 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?**

Each capsule contains the following inactive ingredients: colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, pregelatinized starch and sodium lauryl sulfate. The capsule shells for all strengths contain FD&C Blue #1, FD&C Red #40, gelatin microcrystalline cellulose, pregelatinized starch and sodium lauryl sulfate. The capsules are supplied as follows:

- Bottles of 10: 0603-5892-10
- Bottles of 1000: 0603-5893-32

**OVERDOSAGE.**

There is one case report of a 29-year-old woman who took an overdose of temazepam capsules. The patient required supportive care, which included ventilation, diuresis, and dialysis. The overdose did not cause any significant harm.

**POSSIBLE SERIOUS SIDE EFFECTS.**

Possible serious side effects of temazepam capsules include:

- Sedation
- Confusion
- Memory loss
- Anxiety
- Mood changes
- Changes in thinking
- Withdrawal symptoms
- Hypersensitivity reaction

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

Some possible side effects of temazepam capsules include:

- Drowsiness
- Headache
- Dizziness
- Anxiety
- Nervousness
- Stomach upset
- Blurred vision
- Muscle twitching
- Dizziness
- Nausea

**How should I store temazepam capsules?**

Store temazepam capsules at room temperature, 68°F to 77°F (20°C to 25°C).

Keep temazepam capsules and all medicines out of reach of children.

**MEDICATION GUIDE.**

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

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

Temazepam capsules are usually prescribed for people who have trouble falling asleep, but it can also be prescribed for people who have trouble staying asleep or waking up in the morning.

**Give temazepam capsules only to people who have trouble falling asleep.**

Temazepam capsules should not be given to people who have trouble staying asleep or waking up in the morning.

**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
- Dizziness
- Anxiety

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

- Sedation
- Confusion
- Memory loss
- Anxiety
- Mood changes
- Changes in thinking
- Withdrawal symptoms
- Hypersensitivity reaction

**Who should not take temazepam capsules?**

You should not take temazepam capsules if you:

- Are allergic to temazepam, any of the inactive ingredients in temazepam capsules, or any of the ingredients in the inactive ingredients in temazepam capsules.
- Have a history of drug or alcohol abuse or addiction.
- Are breastfeeding.
- Are taking other medicines that can make you sleepy. Talk to your doctor about all of your medicines. Your doctor may need to change the dose of your medicines.
- Have a history of sleep problems or breathing problems.
- Have a history of drug or alcohol abuse or addiction.
- Have a history of a serious or severe allergy to other medicines.
- Have a history of a serious or severe allergy to other medicines.

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

The recommended dose of temazepam capsules is 7.5 mg taken right before you go to bed. Do not take temazepam capsules right before you get up out of bed while not being fully awake and do not do any activities after taking temazepam capsules until you feel fully awake.

**Can temazepam capsules cause dependence?**

Temazepam capsules may cause dependence. If you stop taking temazepam capsules suddenly, withdrawal symptoms can be serious and include seizures. Mild withdrawal symptoms include:

- Restlessness
- Nervousness
- Anxiety
- Insomnia
- Sweating
- Nausea

**How should I take temazepam capsules?**

Take temazepam capsules right before you get into bed. Do not take temazepam capsules right before you get up out of bed while not being fully awake. Do not drive or do other dangerous activities after taking temazepam capsules until you feel fully awake.

**How should I store temazepam capsules?**

Store temazepam capsules at room temperature, 68°F to 77°F (20°C to 25°C).

Keep temazepam capsules and all medicines out of reach of children.

**General information about temazepam capsules.**

Temazepam capsules are not for children.

**How should I store temazepam capsules?**

Store temazepam capsules at room temperature, 68°F to 77°F (20°C to 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 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?**

Temazepam capsules contain the following inactive ingredients: colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, pregelatinized starch and sodium lauryl sulfate. The capsule shells contain FD&C Blue #1, FD&C Red #40, gelatin, microcrystalline cellulose, pregelatinized starch and sodium lauryl sulfate. The capsules are supplied as follows:

- Bottles of 10: 0603-5892-10
- Bottles of 1000: 0603-5893-32

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

Temazepam capsules are usually prescribed for people who have trouble falling asleep, but it can also be prescribed for people who have trouble staying asleep or waking up in the morning.

**Give temazepam capsules only to people who have trouble falling asleep.**

Temazepam capsules should not be given to people who have trouble staying asleep or waking up in the morning.

**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
- Dizziness
- Anxiety

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

- Sedation
- Confusion
- Memory loss
- Anxiety
- Mood changes
- Changes in thinking
- Withdrawal symptoms
- Hypersensitivity reaction

**Who should not take temazepam capsules?**

You should not take temazepam capsules if you:

- Are allergic to temazepam, any of the inactive ingredients in temazepam capsules, or any of the ingredients in the inactive ingredients in temazepam capsules.
- Have a history of drug or alcohol abuse or addiction.
- Are breastfeeding.
- Are taking other medicines that can make you sleepy. Talk to your doctor about all of your medicines. Your doctor may need to change the dose of your medicines.
- Have a history of sleep problems or breathing problems.
- Have a history of drug or alcohol abuse or addiction.
- Have a history of a serious or severe allergy to other medicines.
- Have a history of a serious or severe allergy to other medicines.

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

The recommended dose of temazepam capsules is 7.5 mg taken right before you go to bed. Do not take temazepam capsules right before you get up out of bed while not being fully awake and do not do any activities after taking temazepam capsules until you feel fully awake.

**Can temazepam capsules cause dependence?**

Temazepam capsules may cause dependence. If you stop taking temazepam capsules suddenly, withdrawal symptoms can be serious and include seizures. Mild withdrawal symptoms include:

- Restlessness
- Nervousness
- Anxiety
- Insomnia
- Sweating
- Nausea

**How should I take temazepam capsules?**

Take temazepam capsules right before you get into bed. Do not take temazepam capsules right before you get up out of bed while not being fully awake. Do not drive or do other dangerous activities after taking temazepam capsules until you feel fully awake.

**How should I store temazepam capsules?**

Store temazepam capsules at room temperature, 68°F to 77°F (20°C to 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 that 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?**

7.5 mg, 15 mg, 22.5 mg, and 30 mg

**Capsules**

Each capsule contains the following inactive ingredients: colloidal silicon dioxide, sodium phosphate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, and sodium lauryl sulfate. The capsule shells contain FD&C Blue #1, FD&C Red #40, gelatin, and microcrystalline cellulose. In addition, the 7.5 mg, 22.5 mg and 30 mg capsule shells contain FD&C Red #40. The emptying of the capsule body by applying a 1-800-FDA-1088.

**OVERDOSAGE.**

There is one case report of a 29-year-old woman who took an overdose of temazepam capsules. The patient required supportive care, which included ventilation, diuresis, and dialysis. The overdose did not cause any significant harm.

**POSSIBLE SERIOUS SIDE EFFECTS.**

Possible serious side effects of temazepam capsules include:

- Sedation
- Confusion
- Memory loss
- Anxiety
- Mood changes
- Changes in thinking
- Withdrawal symptoms
- Hypersensitivity reaction

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

Temazepam capsules are usually prescribed for people who have trouble falling asleep, but it can also be prescribed for people who have trouble staying asleep or waking up in the morning.

**Give temazepam capsules only to people who have trouble falling asleep.**

Temazepam capsules should not be given to people who have trouble staying asleep or waking up in the morning.

**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
- Dizziness
- Anxiety

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

- Sedation
- Confusion
- Memory loss
- Anxiety
- Mood changes
- Changes in thinking
- Withdrawal symptoms
- Hypersensitivity reaction
### What is the most important information I should know about temazepam capsules?

**Important:**

1. **Take temazepam capsules exactly as prescribed**
   - Do not take more temazepam capsules than prescribed.
   - Take temazepam capsules right before you get in bed, not sooner.

2. **Do not take temazepam capsules 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 capsules with your other medicines.
   - 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
- Cannot get a full night’s sleep.

Temazepam capsules are not for children.

Temazepam capsules may cause birth defects or harm a fetus (unborn baby).

### 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?

1. **Take temazepam capsules exactly as prescribed.**
2. **Do not take more temazepam capsules than prescribed.**
3. **Take temazepam capsules right before you get into bed.**
4. **Do not take temazepam capsules unless you are able to get a full night’s sleep before you must be active again.**
5. **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.**
General information about temazepam capsules

• If you take too much 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.

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 room temperature, 68° to 77°F (20° to 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?

7.5 mg, 15 mg, 22.5 mg, and 30 mg Capsules

Active Ingredient: temazepam, USP

Each capsule contains the following inactive ingredients: colloidal silicon dioxide, edetate disodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch and sodium lauryl sulfate. The capsule shells for all strengths contain FD&C Blue #1, FD&C Red #40, gelatin, and titanium dioxide. In addition, the 7.5 mg, 22.5 mg and 30 mg capsule shells contain D&C Red #3. The imprinting ink may contain butyl alcohol, D&C Yellow #10 Aluminum Lake, FD&C Blue #2, Aluminum Lake, FD&C Blue #2 Aluminum Lake, FD&C Red #40 Aluminum Lake, iron oxide black, propylene glycol, SD-45 alcohol, SDA-3A alcohol and shellac glaze.

Rx only

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

Manufactured for:

QUALITEST PHARMACEUTICALS
Huntsville, AL 35811

R183201
Rev 2/11
R0

What are the possible side effects of temazepam capsules?

Possible serious side effects of temazepam capsules include:

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• 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

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• dizziness

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

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General information about temazepam capsules

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