

MEDICATION GUIDE
QUAZEPAM tablets, C-IV

What is the most important information I should know about QUAZEPAM?

- **QUAZEPAM 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 the following happens:
 - shallow or slowed breathing
 - breathing stops (which may lead to the heart stopping)
 - excessive sleepiness (sedation)

Do not drive or operate heavy machinery until you know how taking QUAZEPAM with opioids affects you.

- **Risk of abuse, misuse, and addiction.** There is a risk of abuse, misuse, and addiction with benzodiazepines, including QUAZEPAM, 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 QUAZEPAM. These serious side effects may 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.**
 - **Take QUAZEPAM exactly as your healthcare provider prescribed.**
 - Do not share your QUAZEPAM with other people.
 - Keep QUAZEPAM in a safe place and away from children.
- **Physical dependence and withdrawal reactions.** QUAZEPAM can cause physical dependence and withdrawal reactions, especially if you continue to take QUAZEPAM for several days to several weeks.
 - **Do not stop taking QUAZEPAM all of a sudden.** Stopping QUAZEPAM 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, homicidal thoughts, 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.**
 - **Some people who stop QUAZEPAM suddenly 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.
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.
 - Do not take more QUAZEPAM than prescribed or take QUAZEPAM for longer than prescribed.
- After taking QUAZEPAM, 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 QUAZEPAM. Reported activities include:
 - driving a car (“sleep-driving”)
 - having sex
 - making and eating food
 - sleep-walking
 - talking on the phone

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

What is QUAZEPAM?

- QUAZEPAM is a prescription medicine used to treat certain types of insomnia including difficulty falling asleep, waking up often during the night, or waking up early in the morning
- **QUAZEPAM is a federal controlled substance (C-IV) because it contains quazepam that can be abused or lead to dependence.** Keep QUAZEPAM in a safe place to prevent misuse and abuse. Selling or giving away QUAZEPAM 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 QUAZEPAM is safe and effective in children.

Do not take QUAZEPAM if you:

- are allergic to quazepam or any of the ingredients in QUAZEPAM. See the end of this Medication Guide for a complete list of ingredients in QUAZEPAM.
- have had an allergic reaction to other sleep medicines or sedatives such as benzodiazepines Symptoms of a serious allergic reaction can include:
 - swelling of your face, lips, and throat that may cause difficulty breathing or swallowing
 - nausea and vomiting
- have sleep apnea, breathing or lung problems

Before you take QUAZEPAM, 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. It is not known if QUAZEPAM can harm your unborn baby.
- are breastfeeding, or plan to breastfeed. QUAZEPAM can 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 QUAZEPAM.

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

Taking QUAZEPAM with certain other medicines can cause side effects or affect how well QUAZEPAM or the other medicines work.

Do not start or stop other medicines without talking to your healthcare provider.

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

How should I take QUAZEPAM?

- See **“What is the most important information I should know about QUAZEPAM?”**
- Take QUAZEPAM exactly as your healthcare providers tell you to take it.
- QUAZEPAM comes in 15 mg tablets. Your healthcare provider may start your QUAZEPAM dose at 7.5 mg which is half a tablet. Talk to your healthcare provider or pharmacist about your dose schedule.
- If you take too much QUAZEPAM or overdose, get emergency treatment right away.

What are the possible side effects of QUAZEPAM?

QUAZEPAM may cause serious side effects, including:

- See “What is the most important information I should know about QUAZEPAM?”
- **Other conditions.** Call your healthcare provider if your insomnia worsens or is not better within 7 to 10 days. This may mean that there is another condition causing your sleep problem.
- **Severe allergic reactions.** Symptoms include swelling of the tongue or throat, and trouble breathing. Other symptoms may include nausea and vomiting. Get emergency medical help right away if you have these symptoms after taking QUAZEPAM.
- **Abnormal thoughts and behavior.** Symptoms include more outgoing or aggressive behavior than normal, confusion, agitation, hallucinations, worsening of depression, and suicidal thoughts.
- **QUAZEPAM 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 QUAZEPAM affects you.
 - Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking QUAZEPAM without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, QUAZEPAM may make your sleepiness or dizziness much worse
- Depression. Pre-existing depression may emerge or worsen during use of benzodiazepines including QUAZEPAM.

Call your healthcare provider right away if you have any of the above side effects while taking QUAZEPAM.

The most common side effects of QUAZEPAM include:

- drowsiness
- feeling very tired
- dry mouth
- headache
- dizziness
- upset stomach

After you stop taking a sleep medicine, you may have symptoms for the next 1 to 2 days such as:

- trouble sleeping
- lightheadedness
- stomach cramps
- stomach area pain
- nausea
- uncontrolled crying
- panic attack
- flushing
- vomiting
- nervousness

These are not all the possible side effects of QUAZEPAM. 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 QUAZEPAM?

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

General information about the safe and effective use of Quazepam.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use QUAZEPAM for a condition for which it was not prescribed. Do not give QUAZEPAM 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 QUAZEPAM that is written for healthcare professionals.

What are the ingredients in QUAZEPAM?

Active Ingredient: quazepam

Inactive Ingredients: cellulose, corn starch, FD&C Yellow No.6, lactose, magnesium stearate, silicon dioxide, and sodium lauryl sulfate

Distributed by Atland Pharmaceuticals, Sylacauga, AL 35150 USA. If you would like more information, visit www.doralrx.com or call Atland Pharmaceuticals at 1-855-965-2783.