

## MEDICATION GUIDE

### QUAZEPAM

#### TABLETS, USP (C-IV)

Read the Medication Guide that comes with QUAZEPAM TABLETS 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 healthcare provider about your medical condition or treatment.

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

QUAZEPAM TABLETS may cause serious side effects that you may not know are happening to you. These side effects include:

- sleepiness during the day
- not thinking clearly
- act strangely, confused, or upset
- “sleep-walking” or doing other activities when you are asleep like:
  - eating
  - talking
  - having sex
  - driving a car

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

What is QUAZEPAM TABLETS?

QUAZEPAM TABLETS 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.

It is not known if QUAZEPAM TABLETS is safe and effective in children.

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

Who should not take QUAZEPAM TABLETS?

Do not take QUAZEPAM TABLETS if you:

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

Talk to your healthcare provider before taking this medicine if you have any of these conditions.

What should I tell my healthcare provider before taking QUAZEPAM TABLETS?

QUAZEPAM TABLETS may not be right for you. Before taking QUAZEPAM TABLETS, tell your healthcare provider 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 lung disease or breathing problems
- are pregnant or plan to become pregnant. It is not known if QUAZEPAM TABLETS can harm your unborn baby.
- are breastfeeding, or plan to breastfeed. QUAZEPAM TABLETS 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 TABLETS.

Tell your healthcare provider about all 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 QUAZEPAM TABLETS with other medicines that can make you sleepy unless your healthcare provider tells you to.

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

How should I take QUAZEPAM TABLETS?

- See “What is the most important information I should know about QUAZEPAM TABLETS?”
- Take QUAZEPAM TABLETS exactly as your healthcare providers tell you to take it.
- Do not stop taking QUAZEPAM TABLETS without talking to your healthcare provider, drug withdrawal symptoms can happen.
- QUAZEPAM TABLETS comes in 15 mg tablets. Your healthcare provider may start your QUAZEPAM TABLETS dose at 7.5 mg which is half a tablet. Talk to your healthcare provider or pharmacist about your dose schedule.
- You should not drink alcohol while you are taking QUAZEPAM TABLETS.
- 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.
- If you take too much QUAZEPAM TABLETS or overdose, get emergency treatment right away.

What are the possible side effects of QUAZEPAM TABLETS?

QUAZEPAM TABLETS may cause serious side effects including:

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

Call your healthcare provider right away if you have any of the above side effects or any other side effects that worry you while using QUAZEPAM TABLETS.

Common side effects of QUAZEPAM TABLETS include:

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

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

- trouble sleeping

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

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of QUAZEPAM TABLETS. Ask your healthcare provider 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 QUAZEPAM TABLETS?

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

General information about the safe and effective use of QUAZEPAM TABLETS.

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

If you would like more information call Thompson Medical Solutions, LLC. at 1-205-314-4780, fax 1-205-314-4701.

What are the ingredients in QUAZEPAM TABLETS?

Active Ingredient: quazepam

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

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

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