

MEDICATION GUIDE

DORAL (DOR-al) (quazepam) Tablets (C-IV)

Read the Medication Guide that comes with DORAL 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 DORAL?

Doral 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 DORAL.

What is DORAL?

DORAL 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 DORAL is safe and effective in children.

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

Do not take DORAL if you:

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

- 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 DORAL?

DORAL may not be right for you. Before taking DORAL, 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 DORAL can harm your unborn baby.
- are breastfeeding, or plan to breastfeed. DORAL 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 DORAL.

Tell your healthcare provider 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 DORAL 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 DORAL?

- See **“What is the most important information I should know about DORAL?”**
- Take DORAL exactly as your healthcare providers tell you to take it.
- Do not stop taking DORAL without talking to your healthcare provider, drug withdrawal symptoms can happen.
- DORAL comes in 15 mg tablets. Your healthcare provider may start your DORAL 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 DORAL.
- 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 DORAL or overdose, get emergency treatment right away.

What are the possible side effects of DORAL?

DORAL 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 DORAL?**”
- **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 have these symptoms after taking DORAL.

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 DORAL.

Common side effects of DORAL 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:

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|-----------------------|---------------------|
| • 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 DORAL. 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 DORAL?

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

General information about the safe and effective use of Doral.

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

If you would like more information, go to <http://www.DORALforsleep.com> or call Questcor Pharmaceuticals at 1-800-411-3065DORAL.

What are the ingredients in DORAL?

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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