

MEDICATION GUIDE

DORAL® (DOOR-al)

(quazepam)

tablets, C-IV

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

- **DORAL 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 DORAL with opioids affects you.

- **Risk of abuse, misuse, and addiction.** There is a risk of abuse, misuse, and addiction with benzodiazepines, including DORAL, 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 DORAL.** 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.**
 - **You can develop an addiction even if you take Doral as prescribed by your healthcare provider.**
 - **Take DORAL exactly as your healthcare provider prescribed.**
 - Do not share your DORAL with other people.
 - Keep DORAL in a safe place and away from children.
- **Physical dependence and withdrawal reactions.** DORAL can cause physical dependence and withdrawal reactions.
 - **Do not suddenly stop taking DORAL.** Stopping DORAL 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.**
 - **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. 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 DORAL than prescribed or take DORAL for longer than prescribed.
- After taking DORAL, 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 DORAL. 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 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
- **DORAL is a federal controlled substance (C-IV) because it contains quazepam that 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.
- It is not known if DORAL is safe and effective in children.

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 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 DORAL, 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.
 - Taking DORAL late in pregnancy may cause your baby to have symptoms of sedation (breathing problems, sluggishness, low muscle tone), and/or withdrawal symptoms (jitteriness, irritability, restlessness, shaking, excessive crying, feeding problems).
 - Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with DORAL.
 - There is a pregnancy registry for women who take DORAL during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. If you become pregnant during treatment with DORAL, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychiatric Medications. You can register by calling 1-866-961-2388 or visiting <https://womensmentalhealth.org/pregnancyregistry/>.
- are breastfeeding, or plan to breastfeed. DORAL can pass through your breast milk
 - Breastfeeding during treatment with DORAL may cause your baby to have sleepiness, feeding problems, and decreased weight gain.
 - 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 over-the-counter medicines, vitamins, and herbal supplements.

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

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

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

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.
- 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.
- 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:

- **See “What is the most important information I should know about DORAL?”**
- **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 DORAL.
- **Abnormal thoughts and behavior.** Symptoms include more outgoing or aggressive behavior than normal, confusion, agitation, hallucinations, worsening of depression, and suicidal thoughts.
- **DORAL 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 DORAL affects you.**
 - **Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking DORAL without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, DORAL may make your sleepiness or dizziness much worse.**
- **Depression.** Pre-existing depression may emerge or worsen during use of benzodiazepines including DORAL.

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

The most common side effects of DORAL include:

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

These are not all the possible side effects of DORAL. 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 give DORAL 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 DORAL that is written for healthcare professionals.

What are the ingredients in DORAL?

Active Ingredient: quazepam

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

Distributed by Galt Pharmaceuticals, Atlanta, GA 30339 USA. If you would like more information, call Galt Pharmaceuticals at 1-855-965-2783 or visit www.doralrx.com.