



Doral is covered on most commercial health insurance plans.

Most commercially insured patients pay \$0 for their Doral prescription. To learn more about the Doral copay program, ask your doctor or visit DoralRx.com to download the copay card. You may also utilize the copay card that is included in this informational brochure.

No insurance? No problem.

Most patients can get Doral even if uninsured or if your insurance does not cover Doral. Doral is available at a low discounted cash price of no more than \$2 per tablet through the Galt Patient Assistance Program, GaltDirect™ and our local Independent Pharmacy Partners.

Galt Patient Assistance Program (PAP)

Galt has partnered with GaltDirect™ Independent Pharmacy Partners to make sure every patient receives the product his/her doctor prescribes. When physician offices work with our network of Independent Pharmacies at GaltDirect™, we strive to make sure every patient receives the product his/her doctor prescribes and will work with you to resolve any issues related to pharmacy availability, copay assistance, cash-price or any other problems getting Doral.

Our GaltDirect™ Helpdesk can be contacted at

1-855-965-2783 | helpdesk@galtrx.com

and will work with you to resolve any issues related to pharmacy availability, copay assistance, patient assistance program or any other problems getting Doral.

INDICATIONS AND USAGE

DORAL is indicated for the treatment of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakenings.

The effectiveness of DORAL has been established in placebo-controlled clinical studies of 5 nights duration in acute and chronic insomnia. The sustained effectiveness of DORAL has been established in chronic insomnia in a sleep lab (polysomnographic) study of 28 nights duration. Because insomnia is often transient and intermittent, the prolonged administration of DORAL Tablets is generally not necessary or recommended. Since insomnia may be a symptom of several other disorders, the possibility that the complaint may be related to a condition for which there is a more specific treatment should be considered.

Important Safety Information (ISI)

WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS

Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death [see Warnings and Precautions (5.1), Drug Interactions (7)]. Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.

Doral is contraindicated in patients with known hypersensitivity to Doral or other benzodiazepines, established or suspected sleep apnea, or pulmonary insufficiency. Doral can produce CNS depressant effects, including daytime impairment. Patients should be cautioned against driving and other activities requiring complete mental alertness. There is an increased risk of next-day psychomotor impairment if Doral is taken with less than a full night of sleep remaining (7-8 hours). The use of Doral and concomitant CNS depressants may require downward dose adjustment and the concomitant use of Doral with other sleep-hypnotics is not recommended. If insomnia worsens or fails to remit after 7 to 10 days of treatment, this might be indication of an underlying illness. Rare cases of severe anaphylactic reactions including angioedema involving the tongue, glottis or larynx and dyspnea have been reported after treatment with Doral and are potentially fatal. Patients experiencing an anaphylactic or anaphylactoid reaction should be treated in an emergency department and should not be rechallenged. Behavior changes and complex behaviors such as “sleep driving” and “sleep eating” can occur with the use of sleep-hypnotics, and Doral should be discontinued if these symptoms occur. Benzodiazepines may worsen depression and consequently, appropriate precautions (e.g., increased monitoring, limiting prescription size) should be considered. Avoid abrupt discontinuation in at-risk patients of benzodiazepine withdrawal syndrome, particularly patients taking higher than recommended doses over an extended time. The most common adverse reactions (>1%) observed with Doral were drowsiness, headache, fatigue, dizziness, dry mouth, and dyspepsia. Doral is classified as a Schedule IV controlled substance and patients treated with Doral should be monitored for tolerance, abuse, and dependence. For a full list of warnings and precautions, please refer to the full prescribing information.



BIN: 610114
PCN: PV
RxGroup: GALTRX
MemberID: Check the back side for instructions on member ID

Pay \$0

On copay up to \$150 for Doral* (You Pay No Copay*)

Visit DoralRx.com for the Full Prescribing Information, including the Boxed Warning and Medication Guide.

* See program rules and requirements on back for more details.

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 depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma and death.**

- 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
- acting 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.

- Do not take DORAL unless you are able to stay in bed a full night (7 to 8 hours) before you must be active again.
- Do not take more DORAL than prescribed.

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 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. 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 over-the-counter medicines, vitamins, and herbal supplements.

Rules & Requirements

Patient Instructions: This coupon is provided to you as a service by Galt Pharmaceuticals, LLC. Redeem this coupon only when accompanied by a valid prescription for Doral (NDC# 61825-0165-10 or NDC# 61825-0165-30) or Quazepam (NDC# 71993-0265-10). Most patients will pay \$0 and this coupon will cover up to \$150 of out-of-pocket expense for Doral or Quazepam for 26 tablets or more and cover up to \$100 of out-of-pocket expense for Doral or Quazepam for 15 – 25 tablets. Minimum 15 tablets required to be eligible for offer. This card is not valid as an insurance card.

Offer valid for patients 18 years or older. Offer not valid for prescriptions reimbursed in whole or in part under Medicaid, a Medicare drug benefit plan or other federal or state programs (such as medical assistance programs or private indemnity or HMO insurance plans that reimburse the patient for the entire cost of their prescription drug). If you are eligible for drug benefits under any such program, you cannot use this coupon. Product dispensed pursuant to program rules and federal and state law. This offer is void where prohibited by law. Not valid in combination with any other offers, discounts, or programs. Card has no cash value. Galt Pharmaceuticals, reserves the right to rescind, revoke or amend this offer without notice.

For Member ID: Pharmacy Initials + 6 digit DOB + Patient Initials.
(Example for Smith's Pharmacy: John Doe born on 01/15/1961 = SP011561JD)

Pharmacist Instructions: Submit the original claim to the primary third-party payer first, then submit the balance due through the copay card as a secondary payer COB (coordination of benefit) with patient responsibility amount.

For any questions regarding use of the copay card, please call the help desk at 1-866-950-9949.



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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 should I avoid while taking DORAL?

- Do not drive, operate machinery, do other dangerous activities or do anything that needs you to be alert until you know how DORAL affects you. You may still feel drowsy the next day after taking DORAL.
- You should not drink alcohol while you are taking DORAL.

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?”
- **Withdrawal symptoms.** You may have withdrawal symptoms if you stop taking DORAL suddenly. Withdrawal symptoms can be serious and include seizures. Mild withdrawal symptoms include a depressed mood and trouble sleeping. Talk to your healthcare provider about slowly stopping DORAL to avoid withdrawal symptoms.
- **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.
- **Depression.** Pre-existing depression may emerge or worsen during use of benzodiazepines including DORAL.
- **Abuse and dependence.** Taking DORAL can cause physical and psychological dependence. Physical and psychological dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.

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:

- 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
- 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.

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