DORAL- quazepam tablet
Galt Pharmaceuticals LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use DORAL® safely and effectively. See full prescribing information for DORAL.

DORAL (quazepam) for oral use C-IV
Initial U.S. Approval: 1985

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.**

RECENT MAJOR CHANGES

Dosage and Administration (2) 4/2013
Warnings and Precautions (5) 4/2013

INDICATIONS AND USAGE

DORAL, a gamma-aminobutyric (GABAA) agonist, is indicated for the treatment of insomnia characterized by difficulty falling asleep, frequent nocturnal awakenings, and/or early morning awakenings. (1)

DOSAGE AND ADMINISTRATION

Use the lowest dose effective for the patient

- Recommended initial dose is 7.5 mg (2)
- Split the 15 mg tablet along the score line to achieve 7.5 mg dose (2)
- The elderly and debilitated may be more sensitive to benzodiazepines (2)

DOSAGE FORMS AND STRENGTHS

15 mg functionally scored tablet, oral (3)

CONTRAINDICATIONS

- Hypersensitivity to DORAL or other benzodiazepines (4)
- Established or suspected sleep apnea, or chronic pulmonary insufficiency (4)

WARNINGS AND PRECAUTIONS

- CNS depressant effects: Impaired alertness and motor coordination, including risk of daytime impairment. Caution patients against driving and other activities requiring complete mental alertness (5.1)
- Benzodiazepine withdrawal syndrome: avoid abrupt discontinuation in at-risk patients (5.2)
- The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated. (5.3)
- Severe anaphylactic/anaphylactoid reactions: Angioedema and anaphylaxis have been reported. Do not rechallenge if such reactions occur. (5.4)
- Sleep driving and other complex behaviors while not fully awake. Risk increases with dose and concomitant CNS depressants and alcohol. Immediately evaluate any new onset behavioral changes (5.5)
- Worsening of depression or suicidal thinking may occur: Prescribe the least number of tablets feasible to avoid intentional overdose (5.6)

ADVERSE REACTIONS

Most common adverse reactions (>1%): drowsiness, headache, fatigue, dizziness, dry mouth, dyspepsia (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Galt Pharmaceuticals at 1-855-965-2783 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- CNS Depressants: downward dose adjustment may be necessary due to additive effects (7)

USE IN SPECIFIC POPULATIONS

- Pregnancy: Based on animal data, may cause fetal harm (8.1)
- Nursing Mothers: Administration of DORAL Tablets to nursing mothers is not recommended as DORAL and its metabolites are excreted in human milk. (8.3)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 8/2017

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

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.**

1 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.

2 DOSAGE AND ADMINISTRATION

Use the lowest dose effective for the patient, as important adverse effects of DORAL are dose related. The recommended initial dose is 7.5 mg. The 7.5 mg dose can be increased to 15 mg if necessary for efficacy. The 7.5 mg dose can be achieved by splitting the 15 mg tablet along the score line.

2.1 Special Populations

Elderly and debilitated patients may be more sensitive to benzodiazepines.

3 DOSAGE FORMS AND STRENGTHS

Tablets, 15 mg, functionally scored, capsule-shaped, light orange, slightly white speckled tablets, impressed with the product identification number 15 on one side of the tablet, and the product name (DORAL) on the other.

4 CONTRAINDICATIONS

DORAL is contraindicated in patients with known hypersensitivity to DORAL or other benzodiazepines. Rare cases of angioedema involving the tongue, glottis or larynx have been reported in patients after taking the first or subsequent doses of DORAL. Some patients have had additional symptoms such as dyspnea, throat closing, or nausea and vomiting that suggest anaphylaxis. Patients who develop such reactions should not be rechallenged with DORAL.

Contraindicated in patients with established or suspected sleep apnea, or with pulmonary insufficiency.

5 WARNINGS AND PRECAUTIONS

5.1 Risks from Concomitant Use with Opioids

Concomitant use of benzodiazepines, including DORAL, and opioids may result in profound sedation,

respiratory depression, coma, and death. Because of these risks, reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.

Observational studies have demonstrated that concomitant use of opioid analgesics and benzodiazepines increases the risk of drug-related mortality compared to use of opioids alone. If a decision is made to prescribe DORAL concomitantly with opioids, prescribe the lowest effective dosages and minimum durations of concomitant use, and follow patients closely for signs and symptoms of respiratory depression and sedation. In patients already receiving an opioid analgesic, prescribe a lower initial dose of DORAL than indicated in the absence of an opioid and titrate based on clinical response. If an opioid is initiated in a patient already taking DORAL, prescribe a lower initial dose of the opioid and titrate based upon clinical response.

Advise both patients and caregivers about the risks of respiratory depression and sedation when DORAL is used with opioids. Advise patients not to drive or operate heavy machinery until the effects of concomitant use with the opioid have been determined. [see Drug Interactions (7), Patient Counseling (17)].

5.2 CNS-Depressant Effects and Daytime Impairment

DORAL is a central nervous system (CNS) depressant and can impair daytime function in some patients even when used as prescribed. Prescribers should monitor for excess depressant effects, but impairment can occur in the absence of subjective symptoms, and may not be reliably detected by ordinary clinical exam (i.e. less than formal psychomotor testing). While pharmacodynamics tolerance or adaptation to some adverse depressant effects of DORAL may develop, patients using DORAL should be cautioned against driving or engaging in other hazardous activities or activities requiring complete mental alertness.

Additive effects occur with concomitant use of other CNS depressants (e.g., other benzodiazepines, opioids, tricyclic antidepressants, alcohol), including daytime use. Downward dose adjustment of DORAL and concomitant CNS depressants should be considered. The potential for adverse drug interactions continues for several days following discontinuation of DORAL, until serum levels of both active parent drug and psychoactive metabolites decline.

Use of DORAL with other sedative-hypnotics is not recommended. Alcohol generally should not be used during treatment with DORAL. The risk of next-day psychomotor impairment is increased if DORAL is taken with less than a full night of sleep remaining (7 to 8 hours); if higher than the recommended dose is taken; if co-administered with other CNS depressants [see Dosage and Administration (2)].

5.3 Benzodiazepine Withdrawal Syndrome

A withdrawal syndrome similar to that from alcohol (e.g., convulsions, tremor, abdominal and muscle cramps, vomiting, and sweating) can occur following abrupt discontinuation of DORAL. The more severe withdrawal effects are usually limited to patients taking higher than recommended doses over an extended time. Abrupt discontinuation should be avoided in such patients, and the dose gradually tapered. Prescribers should monitor patients for tolerance, abuse, and dependence.

Milder withdrawal symptoms (e.g., dysphoria and insomnia) can occur following abrupt discontinuation of benzodiazepines taken at therapeutic levels for short periods [See Drug Abuse and Dependence (9)].

5.4 Need to Evaluate for Co-morbid Diagnoses

Because sleep disturbances may be the presenting manifestation of a physical and/or psychiatric disorder, symptomatic treatment of insomnia should be initiated only after a careful evaluation of the patient. The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated. Worsening of insomnia or the emergence of new thinking or behavior abnormalities may be the consequence of an unrecognized psychiatric or physical disorder. Such findings have emerged during the course of treatment with

sedative-hypnotic drugs.

5.5 Severe Anaphylactic and Anaphylactoid Reactions

Rare cases of angioedema involving the tongue, glottis or larynx have been reported in patients after taking the first or subsequent doses of sedative-hypnotics, including DORAL. Some patients have had additional symptoms such as dyspnea, throat closing, or nausea and vomiting that suggest anaphylaxis.

Some patients have required medical therapy in the emergency department. If angioedema involves the tongue, glottis or larynx, airway obstruction may occur and be fatal. Patients who develop angioedema after treatment with DORAL should not be rechallenged with the drug.

5.6 Abnormal Thinking and Behavior Changes

Abnormal thinking and behavior changes have been reported in patients treated with sedative-hypnotics including DORAL. Some of these changes include decreased inhibition (e.g., aggressiveness and extroversion that seemed out of character), bizarre behavior, and depersonalization. Visual and auditory hallucinations have also been reported. Amnesia, and other neuro-psychiatric symptoms may occur.

Paradoxical reactions such as stimulation, agitation, increased muscle spasticity, and sleep disturbances may occur unpredictably.

Complex behaviors such as "sleep-driving" (i.e., driving while not fully awake, with amnesia for the event) have been reported with use of sedative-hypnotics. These behaviors can occur with initial treatment or in patients previously tolerant of DORAL or other sedative-hypnotics. Although these behaviors can occur with use at therapeutic doses, risk is increased by higher doses or concomitant use of alcohol or other CNS depressants. Due to risk to the patient and community, DORAL should be discontinued if "sleep-driving" occurs.

Other complex behaviors (e.g., preparing and eating food, making phone calls, or having sex) have been reported in patients who are not fully awake after taking a sedative-hypnotic. As with sleep-driving, patients usually do not remember these events.

5.7 Worsening of Depression

Benzodiazepines may worsen depression. Consequently, appropriate precautions (e.g., limiting the total prescription size and increased monitoring for suicidal ideation) should be considered.

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed in greater detail in other sections of the label:

- CNS-depressant effects and next-day impairment [see Warnings and Precautions (5.1)]
- Benzodiazepine withdrawal syndrome [see Warnings and Precautions (5.2)]
- Abnormal thinking and behavior changes, and complex behaviors [see Warnings and Precautions (5.5)]
- Worsening of depression [see Warnings and Precautions (5.6)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The table shows adverse reactions occurring at an incidence of 1% or greater in relatively short-duration, placebo-controlled clinical trials of DORAL.

	DORAL 15 mg	PLACEBO
NUMBER OF PATIENTS	267	268
	% OF PATIENTS REPORTING	

Central Nervous System		
Daytime Drowsiness	12	3
Headache	5	2
Fatigue	2	0
Dizziness	2	<1
Autonomic Nervous System		
Dry Mouth	2	<1
Gastrointestinal System		
Dyspepsia	1	<1

A double-blind, controlled sleep laboratory study (N=30) in elderly patients compared the effects of DORAL 7.5 mg and 15 mg to that of placebo over a period of 7 days. Both the 7.5 mg and 15 mg doses appeared to be well tolerated. Caution must be used in interpreting this data due to the small size of the study.

7 DRUG INTERACTIONS

The concomitant use of benzodiazepines and opioids increases the risk of respiratory depression because of actions at different receptor sites in the CNS that control respiration. Benzodiazepines interact at GABAA sites and opioids interact primarily at mu receptors. When benzodiazepines and opioids are combined, the potential for benzodiazepines to significantly worsen opioid-related respiratory depression exists. Limit dosage and duration of concomitant use of benzodiazepines and opioids, and monitor patients closely for respiratory depression and sedation.

Benzodiazepines, including DORAL, produce additive CNS depressant effects when co-administered with ethanol or other CNS depressants (e.g. psychotropic medications, anticonvulsants, antihistamines). Downward dose adjustment of DORAL and/or concomitant CNS depressants may be necessary because of additive effects.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

There are no adequate and well-controlled studies in pregnant women. Administration of benzodiazepines immediately prior to or during childbirth can result in a syndrome of hypothermia, hypotonia, respiratory depression, and difficulty feeding. In addition, infants born to mothers who have taken benzodiazepines during the later stages of pregnancy can develop dependence, and subsequently withdrawal, during the postnatal period. Although administration of DORAL to pregnant animals did not indicate a risk for adverse effects on morphological development at clinically relevant doses, data for other benzodiazepines suggest the possibility of adverse developmental effects (long-term effects on neurobehavioral and immunological function) in animals following prenatal exposure to benzodiazepines. DORAL should be used during pregnancy only if the potential benefit justifies the potential risk.

Developmental toxicity studies of DORAL in mice at doses up to 400 times the human dose (15 mg) revealed no major drug-related malformations. Minor fetal skeletal variations that occurred were delayed ossification of the sternum, vertebrae, distal phalanges and supraoccipital bones, at doses approximately 70 and 400 times the human dose. A developmental toxicity study of DORAL in New Zealand rabbits at doses up to approximately 130 times the human dose demonstrated no effect on fetal morphology or development of offspring.

8.3 Nursing Mothers

DORAL and its metabolites are excreted in human milk. Caution should be exercised when administering DORAL to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

DORAL may cause confusion and over-sedation in the elderly. Elderly patients generally should be started on a low dose of DORAL and observed closely. Elderly and debilitated patients may be more sensitive to benzodiazepines, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. A double-blind controlled sleep laboratory study (N=30) compared the effects of DORAL 7.5 mg and 15 mg to that of placebo over a period of 7 days. Both the 7.5 mg and 15 mg doses appeared to be well tolerated. Caution must be used in interpreting this data due to the small size of the study.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

Quazepam is classified as a Schedule IV controlled substance by federal regulation.

9.2 Abuse and Dependence

Addiction-prone individuals (e.g. history of drug addiction or alcoholism) should be under careful surveillance when receiving DORAL because of increased risk of abuse and dependence. Benzodiazepine withdrawal symptoms can occur following discontinuation of DORAL [see Warnings and Precautions (5.2)].

Abuse and addiction are separate and distinct from physical dependence and tolerance. Abuse is characterized by misuse of the drug for non-medical purposes, often in combination with other psychoactive substances. Physical dependence is a state of adaptation that is manifested by a specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug and/or administration of an antagonist. Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug’s effects over time. Tolerance may occur to both the desired and undesired effects of drugs and may develop at different rates for different effects.

Addiction is a primary, chronic, neurobiological disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving. Drug addiction is a treatable disease, utilizing a multidisciplinary approach, but relapse is common.

10 OVERDOSAGE

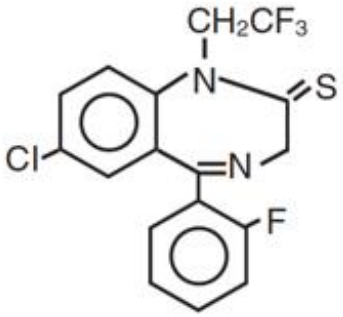
Contact a poison control center for up-to-date information on the management of benzodiazepine overdose.

Manifestations of DORAL overdose include somnolence, confusion, and coma. General supportive measures should be employed, along with immediate gastric lavage. Dialysis is of limited value. Flumazenil may be useful, but can contribute to the appearance of neurological symptoms including convulsions. Hypotension may be treated by appropriate medical intervention. Animal experiments suggest that forced diuresis or hemodialysis are of little value in treating DORAL overdose. As with the management of intentional overdose with any drug, the possibility of multiple drug ingestion should

be considered.

11 DESCRIPTION

DORAL contains DORAL, a trifluoroethyl benzodiazepine hypnotic agent, having the chemical name 7-chloro-5- (o-fluoro-phenyl)-1,3-dihydro-1-(2,2,2- trifluoroethyl)-2H-1,4-benzodiazepine-2-thione and the following structural



DORAL has the empirical formula C17H11ClF4N2S, and a molecular weight of 386.8. It is a white crystalline compound, soluble in ethanol and insoluble in water.

Each DORAL Tablet contains 15 mg of DORAL. The inactive ingredients for DORAL Tablets include cellulose, corn starch, FD&C Yellow No. 6 Al Lake, lactose, magnesium stearate, silicon dioxide, and sodium lauryl sulfate.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

DORAL, like other central nervous system agents of the 14-benzodiazepine class, presumably exerts its effects by binding to stereo-specific receptors at several sites within the central nervous system (CNS). The exact mechanism of action is unknown.

12.3 Pharmacokinetics

Absorption

DORAL is rapidly (absorption half-life of about 30 minutes) and well absorbed from the gastrointestinal tract. The peak plasma concentration of DORAL is approximately 20 ng/mL after a 15 mg dose and occurs at about 2 hours.

Metabolism

DORAL, the active parent compound, is extensively metabolized in the liver; two of the plasma metabolites are 2-oxo DORAL and N-desalkyl-2-oxo DORAL. All three compounds show CNS depressant activity.

Distribution

The degree of plasma protein binding for DORAL and its two major metabolites is greater than 95%.

Elimination

Following administration of 14 C-DORAL, 31% of the dose appeared in the urine and 23% in the feces over five days; only trace amounts of unchanged drug were present in the urine.

The mean elimination half-life of DORAL and 2-oxo DORAL is 39 hours and that of N-desalkyl-2-oxo DORAL is 73 hours. Steady-state levels of DORAL and 2-oxo DORAL are attained by the seventh daily dose and that of N-desalkyl-2-oxo DORAL by the thirteenth daily dose.

Special Populations

Geriatrics: The pharmacokinetics of DORAL and 2-oxo DORAL in geriatric subjects are comparable to those seen in young adults; as with desalkyl metabolites of other benzodiazepines, the elimination half-life of N-desalkyl-2-oxo DORAL in geriatric patients is about twice that of young adults.

Drug Interactions

Bupropion (a CYP2B6 substrate): Co-administration of a single dose of 150 mg Bupropion Hydrochloride XL with steady state DORAL did not significantly affect the AUC and Cmax of bupropion or its primary metabolite, hydroxybupropion.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

DORAL showed no evidence of carcinogenicity in oral carcinogenicity studies in mice and hamsters.

Mutagenesis

DORAL was negative in the bacterial reverse mutation (Ames) assay and equivocal in the mouse lymphoma tk assay.

Impairment of Fertility

Reproduction studies in mice conducted with DORAL at doses equal to 60 and

180 times the human dose of 15 mg produced slight reductions in fertility rate. Similar reductions in fertility rate have been reported in mice dosed with other benzodiazepines, and is believed to be related to the sedative effects of these drugs at high doses

14 CLINICAL STUDIES

The effectiveness of DORAL was established in placebo-controlled clinical studies of 5 nights duration in acute and chronic insomnia. The sustained effectiveness of DORAL was established in chronic insomnia in a sleep laboratory (polysomnographic) study of 28 nights duration. In the sleep laboratory study, DORAL significantly decreased sleep latency and total wake time, and significantly increased total sleep time and percent sleep time, for one or more nights.

DORAL 15 mg was effective on the first night of administration. Sleep latency, total wake time and wake time after sleep onset were still decreased and percent sleep time was still increased for several nights after the drug was discontinued. Percent slow wave sleep was decreased, and REM sleep was essentially unchanged. No transient sleep disturbance, such as “rebound insomnia,” was observed after withdrawal of the drug in sleep laboratory studies in 12 patients using 15 mg doses.

A double-blind, controlled sleep laboratory study (N=30) in elderly patients compared the effects of DORAL 7.5 mg and 15 mg to that of placebo over a period of 7 days. Both the 7.5 mg and 15 mg doses appeared to be effective. Caution must be used in interpreting this data due to the small size of the study.

16 HOW SUPPLIED / STORAGE AND HANDLING

DORAL Tablets, 15 mg, functionally scored, capsule-shaped, light orange, slightly white speckled tablets, impressed with the product identification number 15 on one side of the tablet, and the name (DORAL) on the other.

15 mg Bottles of 100 NDC 61825-165-10

Store DORAL Tablets at controlled room temperature 20°-25°C (68°-77°F).

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide).

Inform patients and caregivers that potentially fatal additive effects may occur if DORAL is used with opioids and not to use such drugs concomitantly unless supervised by a healthcare provider [see Warnings and Precautions (5.1), Drug Interactions (7)]

Inform patients about the benefits and risks of DORAL, stressing the importance of use as directed. Assist patients in understanding the Medication Guide and instruct them to read it with each prescription refill.

CNS depressant Effects and Next-Day Impairment

Tell patients that DORAL can cause next-day impairment, even in the absence of symptoms. Caution patients against driving or engaging in other hazardous activities or activities requiring complete mental alertness when using DORAL. Tell patients that daytime impairment may persist for several days following discontinuation of DORAL.

Withdrawal

Instruct patients to contact you before stopping or decreasing the dose of DORAL, because withdrawal symptoms can occur.

Abnormal thinking and behavior change

Instruct patients that sedative hypnotics can cause abnormal thinking and behavior change, including "sleep-driving" and other complex behaviors while not being fully awake (preparing and eating food, making phone calls, or having sex). Tell patients to call you immediately if they develop any of these symptoms.

Severe Allergic Reactions

Inform patients that severe allergic reactions can occur from DORAL. Describe the signs/symptoms of these reactions and advise patients to seek medical attention immediately if these occur.

Suicide

Tell patients that DORAL can worsen depression, and to immediately report any suicidal thoughts.

Alcohol and other drugs

Ask patients about alcohol consumption, medicines they are taking now, and drugs they may be taking without a prescription. Advise patients that alcohol generally should not be used during treatment with DORAL.

Pregnancy

Instruct patients to inform you if they are nursing or pregnant, or may become pregnant while taking DORAL.

Tolerance, Abuse, and Dependence

Tell patients not to increase the dose of DORAL on their own, and to inform you if they believe the drug "does not work".

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Manufactured by: Meda Pharmaceuticals,
Inc. Somerset, NJ 08873-4120

Printed in USA. IN-04052-02 Rev. 08/2017

MEDICATION GUIDE

DORAL®

(quazepam tablets, USP) /CAPSULES C-IV

Read this Medication Guide before you start taking DORAL and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or treatment. You and your doctor should talk about DORAL when you start taking it and at regular checkups.

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

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")
- making and eating food
- talking on the phone
- having sex
- walking

Important:

1. Take DORAL exactly as prescribed
   - Do not take more DORAL than prescribed.
   - Take DORAL right before you get in bed, not sooner.

2. Do not take DORAL if you:
   - drink alcohol
   - take other medicines that can make you sleepy. Talk to your doctor about all of your medicines. Your doctor will tell you if you can take DORAL with your other medicines
   - cannot get a full night's sleep

3. Call your doctor right away if you find out that you have done any of the above activities after taking DORAL.

What is DORAL?

DORAL is a sleep medicine. DORAL is used in adults for the short-term treatment of the symptom of trouble falling asleep from insomnia. DORAL does not treat other symptoms of insomnia which include waking up too early in the morning and waking up often during the night.

DORAL is not for 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 doctor 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 anything in it. See the end of this Medication Guide for a complete list of ingredients in DORAL.

DORAL may not be right for you. Before starting DORAL, tell your doctor 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 kidney or liver disease
- have a lung disease or breathing problems
- are pregnant, planning to become pregnant, or breastfeeding

Tell your doctor about all of the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Medicines can interact, sometimes causing side effects. Do not take DORAL with other medicines that can make you sleepy.

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

How should I take DORAL?

- Take DORAL exactly as prescribed. Do not take more DORAL than prescribed for you.
- Take DORAL right before you get into bed. Or you can take DORAL after you have been in bed and have trouble falling asleep.
- Do not take DORAL with or right after a meal.
- Do not take DORAL unless you are able to get a full night's sleep before you must be active again.
- 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, call your doctor or poison control center right away, or get emergency treatment.

What are the possible side effects of DORAL?

Serious side effects of DORAL include:

- getting out of bed while not being fully awake and do 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
- anxiety
- severe allergic reactions. Symptoms include swelling of the tongue or throat, trouble breathing, and nausea and vomiting. Get emergency medical help if you get these symptoms after taking DORAL.

Call your doctor 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
- fatigue
- dizziness
- dry mouth
- upset stomach
- You may still feel drowsy the next day after taking DORAL. Do not drive or do other dangerous activities after taking DORAL until you feel fully awake.
- You may have withdrawal symptoms for 1 to 2 days when you stop taking DORAL. Withdrawal symptoms include trouble sleeping, unpleasant feelings, stomach and muscle cramps, vomiting, sweating, shakiness, and seizures.

These are not all the side effects of DORAL. Ask your doctor or pharmacist for more information.

How should I store DORAL?

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

General Information about DORAL

- Medicines are sometimes prescribed for purposes not mentioned 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 condition. 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, talk with your doctor. You can ask your doctor or pharmacist for information about DORAL that was written for healthcare professionals.

If you would like more information, contact Galt Pharmaceuticals at 1-855-965-2783 or visit http://www.doralrx.com

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.

Rx only

Distributed by: Galt Pharmaceuticals, LLC
Marietta, GA 30339

This Medication Guide has been approved by the U.S. Food and Drug Administration.
IS-1500-01 Rev. 08/17

PRINCIPAL DISPLAY PANEL

NDC 61825-165-10
Doral (quazepam tablets, USP)
15 mg
100 Tablets
Rx Only

DORAL

quazepam tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61825-165
Route of Administration	ORAL	**DEA Schedule**	CIV

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
QUAZEPAM (UNII: JF8V0828ZI) (QUAZEPAM - UNII:JF8V0828ZI)	QUAZEPAM	15 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics			
Color	ORANGE (light orange)	**Score**	2 pieces
Shape	CAPSULE	**Size**	12mm
Flavor		**Imprint Code**	15;DORAL
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61825-165-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/19/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018708	07/19/2017	

Labeler - Galt Pharmaceuticals LLC (079214973)

Revised: 8/2017 Galt Pharmaceuticals LLC