E-Scribe #: 2433693

GaltDirect has partnered with Sterling Specialty Pharmacy **for the easiest and most hassle-free Doral® CIV prescribing experience.**

PHONE: 888-618-4126 **FAX: 866-588-0371** **NPI #: 1225548480**
EMAIL: support@sterlingspecialtyrx.com
ADDRESS: 1312 Northland Drive, Suite 500, Mendota Heights, MN 55120

E-Scribe Rx to Sterling Specialty Pharmacy:

STERLING BENEFITS INVESTIGATION:

1. Verify patient's insurance coverage
2. Text or call the patient

IF PATIENT HAS COMMERCIAL COVERAGE:

Copay assistance is applied, patient pays as little as $0 for their prescription of Doral® CIV. Rx is mailed to the patient.*

Rx DENIED OR PATIENT HAS NO COVERAGE:

Rx will be fulfilled by our Patient Assistance Program. Patients will not pay more than $30 for their Doral® CIV prescription. Rx is mailed to the patient.

*Shipping charges may apply.

See the reverse side for important safety information or visit **DoralRx.com** for more details and full prescribing information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.

Benefits of Using GaltDirect:

- Avoid treatment delays
- Increase adherence
- Rx mailed to the patient's home (in all 50 states)
- Reduce the number of phone calls to and from different pharmacies

INDICATIONS AND USAGE

Doral (Quazepam) is indicated for the treatment of insomnia characterized by difficulty 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; ABUSE, MISUSE, AND ADDICTION; and DEPENDENCE AND WITHDRAWAL REACTIONS See full prescribing information for more safety information

- Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. 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 [see Warnings and Precautions (5.1), Drug Interactions (7)].
- The use of benzodiazepines, including DORAL, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Abuse and misuse of benzodiazepines commonly involve concomitant use of other medications, alcohol, and/or illicit substances, which is associated with an increased frequency of serious adverse outcomes. Before prescribing DORAL and throughout treatment, assess each patient's risk for abuse, misuse, and addiction [see Warnings and Precautions (5.2)].
- The continued use of benzodiazepines, including DORAL, may lead to clinically significant physical dependence. The risks of dependence and withdrawal increase with longer treatment duration and higher daily dose. Abrupt discontinuation or rapid dosage reduction of DORAL after continued use may precipitate acute withdrawal reactions, which can be life-threatening. To reduce the risk of withdrawal reactions, use a gradual taper to discontinue DORAL or reduce the dosage [see Dosage and Administration (2.3) and Warnings and Precautions (5.3)].

Contraindications

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 be treated in an emergency department and should not be rechallenged with DORAL.

DORAL is contraindicated in patients with established or suspected sleep apnea, or with pulmonary insufficiency.

Warnings and Precautions

CNS-Depressant Effects and Daytime Impairment: Doral can produce CNS depressant effects, including impaired alertness and motor coordination. Patients should be cautioned against driving and other activities requiring complete mental alertness. Alcohol generally should not be used during treatment with DORAL. Additive effects occur with concomitant use of other CNS depressants. There is an increased risk of next-day psychomotor impairment if higher than the recommended dose is taken, if co-administered with other CNS depressants, or if 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.

Because DORAL can cause drowsiness and a decreased level of consciousness, patients particularly the elderly, are at higher risk of falls.

Need to Evaluate for Co-morbid Diagnoses: If insomnia worsens or fails to remit after 7 to 10 days of treatment, this might be indication of an underlying illness that should be evaluated.

Abnormal Thinking and Behavior Changes: Abnormal thinking, behavior changes, and complex behaviors such as "sleep driving" (i.e., driving while not fully awake, with amnesia for the event) and 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. The risk increases with dose and concomitant CNS depressants and alcohol. As with sleep-driving, patients usually do not remember these events. Some of these changes include decreased inhibition (e.g., aggressiveness and extroversion that seem out of character), bizarre behavior, and depersonalization. Visual and auditory hallucinations have also been reported. Doral should be discontinued if these symptoms occur.

Worsening of Depression: Benzodiazepines may worsen depression and consequently, appropriate precautions (e.g., increased monitoring for suicidal ideation, limiting prescription size) to avoid intentional overdose should be considered.

Adverse Reactions

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.

DORAL contains quazepam, a Schedule IV controlled substance.

Visit www.DoralRx.com for more details and full prescribing information

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