QUAZEPAM- quazepam tablet
Unit Dose Services

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use QUAZEPAM® safely and effectively. See full prescribing information for QUAZEPAM. QUAZEPAM (quazepam) Tablets for oral use C-IV Initial U.S. Approval: 1985

RECENT MAJOR CHANGES

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

INDICATIONS AND USAGE

QUAZEPAM, a gamma-aminobutyric (GABA) agonist, is indicated for the treatment of insomnia characterized by difficulty falling asleep, frequent nocturnal awakenings, and/or early morning awakenings. ( ) $_A$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 quazepam 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 Questcor Pharmaceuticals, Inc. at 1-800-465-9217 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 QUAZEPAM Tablets to nursing mothers is not recommended as quazepam and its metabolites are excreted in human milk. ( ) 8.3

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 3/2014

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

QUAZEPAM (quazepam) is indicated for the treatment of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakenings. The effectiveness of QUAZEPAM has been established in placebo-controlled clinical studies of 5 nights duration in acute and chronic insomnia. The sustained effectiveness of QUAZEPAM 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 QUAZEPAM 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 QUAZEPAM 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 (QUAZEPAM) on the other.

4 CONTRAINDICATIONS

QUAZEPAM is contraindicated in patients with known hypersensitivity to quazepam 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 QUAZEPAM. 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 QUAZEPAM.

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

5 WARNINGS AND PRECAUTIONS

5.1 CNS-Depressant Effects and Daytime Impairment

QUAZEPAM 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 pharmacodynamic tolerance or adaptation to some adverse depressant effects of QUAZEPAM may develop, patients using QUAZEPAM 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 QUAZEPAM and concomitant CNS depressants should be considered. The potential for adverse drug interactions continues for several days following discontinuation of QUAZEPAM, until serum levels of both active parent drug and psychoactive metabolites decline.

Use of QUAZEPAM with other sedative-hypnotics is not recommended. Alcohol generally should not be used during treatment with QUAZEPAM. The risk of next-day psychomotor impairment is increased if QUAZEPAM 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

5.2 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 QUAZEPAM. 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*

5.3 Need to Evaluate for Co-morbid Disorders

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.

5.4 Severe Anaphylactic or 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 QUAZEPAM. 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 QUAZEPAM should not be rechallenged with the drug.

5.5 Abnormal Thinking and Behavior Changes

Abnormal thinking and behavior changes have been reported in patients treated with sedative-hypnotics including QUAZEPAM. 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 QUAZEPAM 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, QUAZEPAM 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.

5.6 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 Studies 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 clinical practice.

The table shows adverse reactions occurring at an incidence of 1% or greater in relatively short-duration, placebo-controlled clinical trials of QUAZEPAM. 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 actual practice.

	QUAZEPAM 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 quazepam 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

Benzodiazepines, including QUAZEPAM, produce additive CNS depressant effects when co-administered with ethanol or other CNS depressants (e.g. psychotropic medications, anticonvulsants, antihistamines). Downward dose adjustment of QUAZEPAM 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 development dependence, and subsequently withdrawal, during the postnatal period. Although administration of quazepam 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. QUAZEPAM should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Developmental toxicity studies of quazepam 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 quazepam 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

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

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

QUAZEPAM may cause confusion and over-sedation in the elderly. Elderly patients generally should be started on a low dose of QUAZEPAM 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 quazepam 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 QUAZEPAM because of increased risk of abuse and dependence. Benzodiazepine withdrawal symptoms can occur following discontinuation of QUAZEPAM . *[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 QUAZEPAM 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 QUAZEPAM overdose. As with the management of intentional overdose with any drug, the possibility of multiple drug ingestion should be considered.

11 DESCRIPTION

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

Quazepam has the empirical formula C H CIF N S, and a molecular weight of 386.8. It is a white crystalline compound, soluble in ethanol and insoluble in water. Each QUAZEPAM Tablet contains 15 mg of quazepam. The inactive ingredients for QUAZEPAM Tablets include cellulose, corn starch, FD&C Yellow No. 6 Al Lake, lactose, magnesium stearate, silicon dioxide, and sodium lauryl sulfate.

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12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Quazepam, like other central nervous system agents of the 1,4-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: Quazepam is rapidly (absorption half-life of about 30 minutes) and well absorbed from the gastrointestinal tract. The peak plasma concentration of quazepam is approximately 20 ng/mL after a 15 mg dose and occurs at about 2 hours.

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

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

Elimination: Following administration of C-quazepam, 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. [14]

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

Special Populations:

Geriatrics: The pharmacokinetics of quazepam and 2-oxoquazepam 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-oxoquazepam in geriatric patients is about twice that of young adults.

12.4 Drug Interactions

Bupropion (a CYP2B6 substrate): Co-administration of a single dose of 150 mg Bupropion Hydrochloride XL with steady state quazepam 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

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

Mutagenesis

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

Impairment of Fertility

Reproduction studies in mice conducted with quazepam 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 QUAZEPAM was established in placebo-controlled clinical studies of 5 nights duration in acute and chronic insomnia. The sustained effectiveness of QUAZEPAM was established in chronic insomnia in a sleep laboratory (polysomnographic) study of 28 nights duration.

In the sleep laboratory study, QUAZEPAM significantly decreased sleep latency and total wake time,

and significantly increased total sleep time and percent sleep time, for one or more nights. QUAZEPAM 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.

In outpatient studies, QUAZEPAM Tablets improved all subjective measures of sleep including sleep latency, duration of sleep, number of awakenings, occurrence of early morning awakening, and sleep quality. Some effects were evident on the first night of administration of QUAZEPAM (sleep latency, number of awakenings, and duration of sleep).

A double-blind, controlled sleep laboratory study (N=30) in elderly patients compared the effects of quazepam 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

NDC:50436-0405-1 in a BOTTLE of 30 TABLETS

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide).

Inform patients about the benefits and risks of QUAZEPAM, 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 QUAZEPAM 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 QUAZEPAM. Tell patients that daytime impairment may persist for several days following discontinuation of QUAZEPAM.

Withdrawal

Instruct patients to contact you before stopping or decreasing the dose of QUAZEPAM, 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 QUAZEPAM. Describe the signs/symptoms of these reactions and advise patients to seek medical attention immediately if these occur.

Suicide

Tell patients that QUAZEPAM 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

QUAZEPAM.

Pregnancy

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

Tolerance, Abuse, and Dependence

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

Manufactured for: Questcor Pharmaceuticals, Inc. Hayward, CA 94545 USA phone (800) 411-3065
(510) 400-0700 fax (510) 400-0799

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

Under license from Baker Norton Pharmaceuticals, Inc.

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MEDICATION GUIDE

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

Read the Medication Guide that comes with QUAZEPAM 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 QUAZEPAM?

QUAZEPAM 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 yourhealthcare provider right away if you find out that you have done any of the above activities after taking QUAZEPAM.

What is QUAZEPAM?

QUAZEPAM 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 QUAZEPAM is safe and effective in children.

QUAZEPAM is a federally controlled substance (C-IV) because it can be abused or lead to

dependence. Keep QUAZEPAM in a safe place to prevent misuse and abuse. Selling or giving away QUAZEPAM 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 QUAZEPAM?

: **Do not take QUAZEPAM if you**

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

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

including prescription and nonprescription medicines, vitamins and herbal supplements. **Tell your healthcare provider about all of the medicines you take,**

Medicines can interact with each other, sometimes causing serious side effects. **Do not take QUAZEPAM 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 QUAZEPAM?

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

What are the possible side effects of QUAZEPAM?

: **QUAZEPAM may cause serious side effects, including**

- See “ ” **getting out of bed while not being fully awake and doing an activity that you do not know you are doing.What is the most important information I should know about QUAZEPAM?**
- . Symptoms include more outgoing or aggressive behavior than normal, confusion, agitation, hallucinations, worsening of depression, and suicidal thoughts or actions. **abnormal thoughts and behavior**
- **memory loss**
- . Symptoms include swelling of the tongue or throat, and trouble breathing. Get emergency medical help right away if you have these symptoms after taking QUAZEPAM. **severe allergic reactions**

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 QUAZEPAM.

Common side effects of QUAZEPAM include **:**
- drowsiness
- headache
- feeling very tired
- dizziness
- dry mouth
- upset stomach

you may have symptoms for the next 1 to 2 days such as: **After you stop taking a sleep medicine,**
- trouble sleeping
- nausea
- flushing
- lightheadedness
- uncontrolled crying
- vomiting
- stomach cramps
- panic attack
- nervousness
- 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 QUAZEPAM. 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 QUAZEPAM?
- Store at room temperature between 68°F to 77° F (20°C to 25°C).
- **Keep QUAZEPAM and all medicines out of the reach of children**

General information about the safe and effective use of QUAZEPAM.

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

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

What are the ingredients in QUAZEPAM?

quazepam **Active Ingredient:**

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

Distributed by Questcor Pharmaceuticals, Inc.

Hayward, CA 94545 USA This Medication Guide has been approved by the U.S. Food and Drug Administration.

(IS-1500-02 Rev. 04/13)

QUAZEPAM TABLET

QUAZEPAM

quazepam tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:50436-0405(NDC:76218-0405)
Route of Administration	ORAL	**DEA Schedule**	CIV

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
QUAZEPAM (QUAZEPAM)	QUAZEPAM	15 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POWDERED CELLULOSE	
STARCH, CORN	
FD&C YELLOW NO. 6	
LACTOSE	
MAGNESIUM STEARATE	

SILICON DIOXIDE	
SODIUM LAURYL SULFATE	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50436-0405-1	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018708	08/08/2013	

Labeler - Unit Dose Services (831995316)

Registrant - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-0405)

Revised: 8/2013 Unit Dose Services