Observed reactions include anaphylaxis and angioedema on the other side. Shaped tablets, debossed with "W715" on one side and plain on the other side. Zolpidem tartrate tablets 10 mg are white, film coated, capsule shaped, and are not scored. 

3 DOSAGE FORMS AND STRENGTHS

2.4 Administration

Depressant drugs because of the potentially additive effects. Dosage adjustment may be necessary when zolpidem tartrate tablet is combined with other CNS depressant drugs, including alcohol. Elderly or debilitated patients may be especially sensitive to the effects of zolpidem tartrate. Patients with hepatic insufficiency do not clear the drug as rapidly as normal subjects. The recommended dose of zolpidem tartrate tablets in both of these patient populations is 5 mg once daily immediately before bedtime. 

The recommended initial doses for women and men are different because zolpidem clearance is lower in women. The recommended initial dose is 5 mg for women and 10 mg for men, taken only once per night immediately before bedtime with at least 7 to 8 hours remaining before the planned time of awakening. 

Use the lowest effective dose for the patient. The recommended initial dose is 5 mg for women and 10 mg for men. Use the lowest dose effective for the patient. Do not increase the dose more than 10 mg every 3 to 4 days. 

Severe anaphylactic/anaphylactoid reactions: Angioedema and anaphylaxis have been reported. Do not rechallenge if there is a history of such reactions. 

Instruct patients on correct use. CNS depressant effects: Impairs alertness and motor coordination. Severe injuries: "Sleep-driving" and other complex behaviors while not fully awake. 

The total dose of zolpidem tartrate tablets should not exceed 10 mg. In some patients, the higher morning blood levels following use of the 10 mg dose need to be evaluated. 

Withdrawal: The abrupt discontinuation of zolpidem tartrate tablets, particularly in elderly patients, may be associated with withdrawal symptoms that are usually reversible. 

These highlights do not include all the information needed to use zolpidem tartrate tablets safely and effectively. See full prescribing information for zolpidem tartrate tablets.

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6.1 Clinical Trials Experience

Adverse events reported in clinical studies were similar in nature and incidence to those described for zolpidem tartrate at 10 mg. In clinical studies, the most common adverse events reported were somnolence, dizziness, and headache.

5.1 Discontinuance of Treatment 

Discontinuance of treatment due to an adverse event was reported in approximately 2% of adult patients treated with zolpidem tartrate. The most common reasons for treatment discontinuation were drug intolerance (1% of adult patients) and decreased sleep latency (1% of adult patients). Other reasons for discontinuation included patient discontinuation prior to the end of the study, emergency situations, and other.

5.7 Geriatric Use

Zolpidem tartrate tablets are not recommended for use in patients 65 years of age or older, as the risk of adverse effects may outweigh the benefits of treatment.

5.4 Pregnancy

Zolpidem tartrate tablets are contraindicated in women who are or might become pregnant. Zolpidem tartrate should be used only in women who are not pregnant.

5.8 Nursing Mothers

It is not known whether zolpidem is excreted in human milk. Zolpidem tartrate tablets should be used with caution in breastfeeding women.

5.10 Drug Interactions

Co-administration with other CNS depressants (e.g., hypnotics, opioids, alcohol) has not been studied and is not recommended. Co-administration with other sedative-hypnotics has not been studied and is not recommended. Co-administration with other sedative-hypnotics should be avoided if possible.

5.11 Carcinogenesis, Mutagenesis, Impairment of Fertility

No studies have been performed to evaluate the carcinogenic potential of zolpidem tartrate. Zolpidem tartrate has not been shown to be mutagenic in vitro or in vivo. Zolpidem tartrate has not been shown to impair fertility in male or female rats.

5.12 Other Non-Clinical Pharmacology

Zolpidem tartrate, like other sedative-hypnotic drugs, has central nervous system (CNS) depressant properties. Zolpidem has been shown to produce sedation and impairment of cognitive and psychomotor performance in humans.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of this labeling:

- Somnolence
- Abnormal thinking and behavior changes
- Central and Peripheral Nervous System

6.1 Clinical Trials Experience

In clinical trials, the most common adverse events reported were somnolence, dizziness, and headache.

6.2 Preclinical Development

Zolpidem tartrate has been shown to be effective in animal studies and has been generally well tolerated in clinical trials.

6.3 Clinical Studies

Zolpidem tartrate tablets have been shown to be effective in a variety of controlled clinical trials.

6.4 Special Populations

Zolpidem tartrate tablets have been shown to be effective in special populations, as evidenced by results in clinical studies.

6.5 Postmarketing Experience

Zolpidem tartrate tablets have been monitored for adverse reactions in postmarketing studies.

6.6 Overdose

The effects of zolpidem tartrate overdose have been characterized by sedation and respiratory depression.

6.7 Contraindications

Zolpidem tartrate tablets are contraindicated in patients with a history of drug or alcohol dependence, those with a history of substance abuse, and those with a history of severe sleep-related breathing disorders.

6.8 Warnings and Precautions

Zolpidem tartrate tablets are contraindicated in patients with a history of drug or alcohol dependence, those with a history of substance abuse, and those with a history of severe sleep-related breathing disorders.

6.9 Use in Specific Populations

Zolpidem tartrate tablets are contraindicated in patients with a history of drug or alcohol dependence, those with a history of substance abuse, and those with a history of severe sleep-related breathing disorders.

6.10 Adverse Drug Reactions

The following adverse drug reactions were reported in clinical trials:

- Somnolence
- Abnormal thinking and behavior changes
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- Somnolence
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6.24 Use in Specific Populations

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6.25 Adverse Drug Reactions

The following adverse drug reactions were reported in clinical trials:

- Somnolence
- Abnormal thinking and behavior changes
- Central and Peripheral Nervous System

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6.34 Use in Specific Populations

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The following adverse drug reactions were reported in clinical trials:

- Somnolence
- Abnormal thinking and behavior changes
- Central and Peripheral Nervous System

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6.44 Use in Specific Populations

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6.45 Adverse Drug Reactions

The following adverse drug reactions were reported in clinical trials:

- Somnolence
- Abnormal thinking and behavior changes
- Central and Peripheral Nervous System

6.46 Overdose

The effects of zolpidem tartrate overdose have been characterized by sedation and respiratory depression.

6.47 Contraindications

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6.48 Warnings and Precautions

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6.49 Use in Specific Populations

Zolpidem tartrate tablets are contraindicated in patients with a history of drug or alcohol dependence, those with a history of substance abuse, and those with a history of severe sleep-related breathing disorders.
drugs during pregnancy. Zolpidem tartrate tablets should be used during pregnancy only if the potential benefits justify the potential risks to the fetus. The risk associated with the use of zolpidem tartrate tablets during pregnancy is greater than 1/100 subjects; infrequent adverse events are those occurring in 1/100 to 1/1,000 patients; rare events are those occurring in fewer than 1/1,000 patients.

Adverse event incidence across the entire preclinical and placebo-controlled phase of Zolpidem tartrate tablets were administered to 2164 subjects in clinical trials throughout the U.S., Canada, and Europe. Treatment-emergent adverse events associated with clinical trial procedures were recorded by clinical investigators using terminology of their own choosing. To provide a meaningful estimate of the proportion of individuals experiencing treatment-emergent adverse events, all adverse events reported by patients during the period from the start of dosing through the 8-week postdose period were categorized independently by two investigators as drug-related or not drug-related. The proportion of patients with treatment-emergent adverse events occurring at least once in any 100 subjects is included, except those already listed in the table above as withdrawal adverse events, cases where a drug cause was remote, and those adverse events that were not general as to be uninformative, and those events where a drug cause was remote. It is important to emphasize that, although the events reported did occur during treatment with zolpidem tartrate tablets, they were not necessarily caused by it.

Adverse events that are further classified by body system categories and enumerated below occur in greater than 1/100 subjects; infrequent adverse events are those occurring in 1/100 to 1/1,000 patients; rare events are those occurring in fewer than 1/1,000 patients. There is evidence from dose comparison trials suggesting a dose-related increase in the proportion of subjects reporting adverse events associated with zolpidem use.

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GABA-BZ receptor complex and shares some of the pharmacological properties of the benzodiazepines, barbiturates, or other drugs with known hypnotic properties. It interacts with a Zolpidem, the active moiety of zolpidem tartrate, is a hypnotic agent with a chemical structure unrelated to benzodiazepines or barbiturates.

12.1 Mechanism of Action

Zolpidem tartrate is a gamma-aminobutyric acid (GABA) A agonist of the imidazopyridine class and is considered. The physician may wish to consider contacting a poison control center for up-to-date information.

As with the management of all overdosage, the possibility of multiple drug ingestion should be considered. The physician may wish to consider contacting a poison control center for up-to-date information.

The value of dialysis in the treatment of overdosage has not been determined, although hemodialysis (on a peritoneal) basis. Administration of zolpidem at oral doses of 200 mg has been shown to be effective in the treatment of patients who are not responding to standard therapeutic dosages of benzodiazepines.

The recommended dose of zolpidem tartrate tablets in geriatric patients is 5 mg regardless of gender.

10.2 Recommended Treatment

In postmarketing experience of overdose with zolpidem tartrate alone, or in combination with CNS-depressant drugs, the incidence of adverse events has been generally consistent with those observed in clinical studies. Zolpidem has been administered to a nursing woman.

Zolpidem is excreted in human milk. Caution should be exercised when zolpidem tartrate tablets are administered to a nursing woman.

12.2 Abuse and Delivery

Zolpidem tartrate tablets have no established role in child-feeding, and should be used in children.

8.3 Nursing Mothers

Zolpidem is excreted in breast milk. Caution should be exercised when zolpidem tartrate tablets are administered to a nursing woman.

8.4 Pediatric Use

Zolpidem tartrate tablets are not recommended for use in children and are not recommended for use in children.

In postmarketing experience of overdose with zolpidem tartrate alone, or in combination with CNS-depressant drugs, the incidence of adverse events has been generally consistent with those observed in clinical studies. Zolpidem has been administered to a nursing woman.

9.2 Abuse

Abuse and addiction are important and distinct phenomena at a pathological and behavioral level. Abuse is manifested as misuse of the drug for non-medical purposes, often in combination with 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 failure to reduce use. Drug addiction is a residual disease, using a medical primary approach, and requires continued treatment.

10.4 Dependence

Physical dependence is a state of adaptation that is manifested by a specific withdrawal syndrome that is characterized by motor and/or cognitive performance and unusual sensitivity to sedative/hypnotic drugs (see sewers and Launches (4.4)).

Abuse and addiction are separate and distinct phenomena at a pathological and behavioral level. Abuse is manifested as misuse of the drug for non-medical purposes, often in combination with 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 failure to reduce use.

Drug addiction is a residual disease, using a medical primary approach, and requires continued treatment. Addiction is a primary, chronic, neurobiological disease with genetic, psychosocial, and environmental factors influencing development and manifestation. 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 failure to reduce use. Drug addiction is a residual disease, using a medical primary approach, and requires continued treatment.

Addiction is a primary, chronic, neurobiological disease with genetic, psychosocial, and environmental factors influencing development and manifestation. 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 failure to reduce use. Drug addiction is a residual disease, using a medical primary approach, and requires continued treatment.
12.3 Pharmacokinetics

The pharmacokinetics of zolpidem tartrate is characterized by rapid absorption from the gastrointestinal tract and a short elimination half-life (t1/2) in healthy subjects.

In single-dose studies, elderly subjects administered 5 mg of zolpidem tartrate tablets, the mean peak concentrations (Cmax) were 58 (range: 29 to 113) and 121 (range: 58 to 272) ng/mL, respectively, occurring at a mean time (Tmax) of 1.4 and 2.2 hr for the 5 and 10 mg doses, respectively. Zolpidem tartrate is known to be an active metabolite that is eliminated primarily by renal excretion. Zolpidem tartrate is demonstrated linear kinetics in the dose range of 5 to 30 mg. Final pharmacokinetics were found to be 93.2 ± 6.1% and remained constant, independent of dosage between 10 and 70 mg. Although zolpidem is a metabolite of zolpidem, following nightly dosing with 5 mg of zolpidem tartrate tablets, concentrations remained below the level of quantitation.

In healthy male subjects, the pharmacokinetics of zolpidem tartrate tablets with chronic hepatic insufficiency were compared to results in healthy subjects. Following a single 20 mg oral zolpidem tartrate dose, elderly subjects were administered 5 mg and 10 mg doses and 7 mg and 14 mg doses of zolpidem tartrate tablets, respectively, in two phases of a crossover study. The results of this study showed that elderly subjects had higher plasma concentrations of zolpidem compared to younger adults (2.2 ± 0.4 hr) following a single 20 mg oral dose. Zolpidem tartrate concentrations increased at elderly subjects following multiple dosing of 10 mg for 4 weeks.

Symptomatic

In the elderly, the dose for zolpidem tartrate tablets should be 5 mg (see Warnings and Precautions (5.1) and Dosage and Administration (2)). The recommended doses seen in studies evaluating sleep on the nights following discontinuation of zolpidem tartrate tablets were 5 mg and 10 mg doses of zolpidem tartrate tablets, respectively, observed following a 10 mg dose of zolpidem tartrate tablets given with warfarin in healthy subjects.

A single-dose interaction study with zolpidem tartrate 5 mg and ketoconazole, a potent CYP3A4 inhibitor, significantly reduced the exposure to and the pharmacodynamic effects of zolpidem. Consideration should be given to using a lower dose of zolpidem (70%) compared to zolpidem alone and prolonged the elimination half-life (30%) along with an increase in the pharmacodynamic effects of zolpidem detected on subjective drowsiness, postural sway, or increased blood pressure. There was no evidence of an additive effect in psychomotor performance.

Rifampin, a CYP3A4 inducer, significantly reduced the exposure to and the pharmacodynamic effects of both zolpidem doses. A single-dose interaction study with zolpidem tartrate 10 mg and levamisole, a potent CYP3A4 inducer, reduced the exposure to and the pharmacodynamic effects of zolpidem. Considerations should be given to using a lower dose of zolpidem (70%) compared to zolpidem alone and prolonged the elimination half-life (30%) along with an increase in the pharmacodynamic effects of zolpidem. There was no evidence of an additive effect in psychomotor performance.

Drug-Drug Interaction

CNS-depressants

Co-administration of zolpidem with other CNS-depressants increases the risk of CNS depression (see Warnings and Precautions (5.1)). Zolpidem was evaluated in healthy volunteers in single-dose in three crossover studies to evaluate the effect of zolpidem on psychomotor performance in the presence of ethanol (10 g) or zolpidem (50 mg) or both. In the presence of ethanol, zolpidem was found to significantly increase psychomotor impairment. Both zolpidem and alcohol were found to significantly increase psychomotor performance compared to placebo. A study involving benzodiazepine and zolpidem on the effect of halothane on the pharmacokinetics or pharmacodynamics of zolpidem. The lack of drug interaction between single-dose administration does not predict the absence of interference following chronic administration.

Acute alcohol administration increases the pharmacokinetics and pharmacodynamics of both benzodiazepines and zolpidem. A single-dose interaction study with zolpidem 5 mg and pioglitazone (a PPARγ agonist) resulted in a significant increase in zolpidem exposure. There was no impairment of fertility at the level of the reproductive system and no impairment of the offspring following chronic administration.

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Oral administration of zolpidem base (doses of 4, 20, and 100 mg/kg/day) to rats for 2 years or (doses of 17, 50, and 150 mg/kg/day) to mice for 1 year did not result in any evidence of carcinogenic potential. There was no evidence of an increase in chromosomal aberration (bacterial reverse mutation, mouse lymphoma, and in vitro chromosomal aberration) and no evidence of a clastogenic action in the mouse bone marrow micronucleus test.

Immunotoxicology

Oral administration of zolpidem base to rats (100 mg/kg/day) caused a decrease in total lymphocyte count at the end of the treatment period, accompanied by a decrease in spleen weight and an increase in reactive lymphocytes.

14.1 Clinical Trials

14.1.1 Transient Insomnia

Normal adults experiencing transient insomnia (≥ 80) were treated in a double-blind, parallel group, single-blind trial comparing two doses of zolpidem tartrate tablets (5 mg and 10 mg) and placebo. Both zolpidem doses were superior in patients of sleep latency, sleep duration, and number of awakenings.

In the elderly, the dose for zolpidem tartrate tablets should be 5 mg (see Warnings and Precautions (5.1) and Dosage and Administration (2)). The recommended doses seen in studies evaluating sleep on the nights following discontinuation of zolpidem tartrate tablets were 5 mg and 10 mg doses of zolpidem tartrate tablets, respectively, observed following a 10 mg dose of zolpidem tartrate tablets given with warfarin in healthy subjects.
ZOLPIDEM TARTARTE TABLETS (zole-PI-dem TAR-trate) Tablets C-IV

Distributed by:

Manufactured By:

Zolpidem tartrate tablets have been shown to be effective in the short-term treatment of insomnia in adults (age 18 and older) who have trouble falling asleep, staying asleep, or both, so long as they were able to stay in bed at least 7 to 8 hours before being active again. Zolpidem tartrate tablets are not a substitute for a healthy lifestyle and do not cure your condition. Use zolpidem tartrate tablets only as directed. Do not increase the dose of zolpidem tartrate tablets on your own, and to inform you if they believe the drug "does not work".

Zolpidem tartrate tablets may cause serious side effects, including:

- Tolerance, Abuse, and Dependence
- Impairment of Memory and Judgment

Inform patients that severe anaphylactic and anaphylactoid reactions have occurred with zolpidem. Patients should be counseled to take zolpidem tartrate tablets right before they get into bed and only in situations where they are able to stay in bed a full night (7 to 8 hours) before being active again. Zolpidem tartrate tablets should not be taken with a small amount of food.

Manufactured By:

Zolpidem tartrate tablets may not be right for you. Before starting zolpidem tartrate tablets, tell your healthcare provider about all of your health conditions, including if you:

- Are a woman with a history of postpartum depression
- Have liver disease or kidney disease
- Are taking other medicines that make you sleepy unless your healthcare provider tells you it is safe to use them with zolpidem tartrate tablets. Inform your healthcare provider if you have ever abused or have been dependent on alcohol, prescription medicines or street drugs.

If you think you or another household member is showing symptoms of opioid withdrawal or are using the opioids for nonmedical purposes or taking the opioids to get high or other nonmedical purposes, contact your healthcare provider. Call your healthcare provider right away if you find out that you have done any of the above activities.

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- Tolerance, Abuse, and Dependence
- Impairment of Memory and Judgment

Inform patients that severe anaphylactic and anaphylactoid reactions have occurred with zolpidem. Patients should be counseled to take zolpidem tartrate tablets right before they get into bed and only in situations where they are able to stay in bed a full night (7 to 8 hours) before being active again. Zolpidem tartrate tablets should not be taken with a small amount of food.
You should not take zolpidem tartrate tablets with or right after a meal. Zolpidem tartrate tablets may help you fall asleep faster if you take it on an empty stomach.

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 zolpidem tartrate tablets or overdose, get emergency treatment.

What are the possible side effects of zolpidem tartrate tablets?

Zolpidem tartrate tablets may cause serious side effects, including:
- getting out of bed while not being fully awake and doing an activity that you do not know you are doing.
- abnormal thoughts and behavior. Symptoms include more outgoing or aggressive behavior than usual, confusion, agitation, hallucinations, worsening of depression, and suicidal thoughts or actions.
- memory loss
- allergy reactions. Symptoms include swelling of the tongue or throat, and trouble breathing. Get emergency medical help if you get these symptoms after taking zolpidem tartrate tablets.

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 zolpidem tartrate tablets.

The most common side effects of zolpidem tartrate tablets are:
- dizziness
- drowsiness
- diarrhea
- uncontrolled crying
- vomiting
- stomach cramps
- joint pain
- allergic reactions

These are not all the side effects of zolpidem tartrate tablets. Ask your healthcare provider or pharmacist for more information.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store zolpidem tartrate tablets?

Store at controlled room temperature 20°-25°C (68°-77°F) [see USP].

Keep zolpidem tartrate tablets and all medicines out of reach of children.

General Information about the safe and effective use of zolpidem tartrate tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use zolpidem tartrate tablets for a condition for which it was not prescribed. Do not share zolpidem tartrate tablets 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 zolpidem tartrate tablets. If you would like more information, talk with your healthcare provider.

For more information, call 1-800-346-6854.

What are the ingredients in zolpidem tartrate tablets?

Active Ingredient: Zolpidem tartrate

Inactive Ingredients: lactose, microcrystalline cellulose, sodium starch glycolate, colloidal silicon dioxide, talc, magnesium stearate, hypromellose, polyethylene glycol, and titanium dioxide; the 5 mg tablet also contains iron oxide red.

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

Manufactured By: Wockhardt Limited, Mumbai, India.

Distributed by: Wockhardt USA LLC, 20 Waterview Blvd, Parsippany, NJ 07054, USA.

Rev.031214

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL

DRUG: Zolpidem Tartrate

GENERIC: Zolpidem Tartrate

DOSAGE: Film-coated Tablets

ADMINISTRATION: Oral

NDC: 64679-714-01

STRENGTH: 5 mg

COLOR: Pink

SHAPE: Capsule

SCORE: no score

SIZE: 10 mm

IMPRINT: W714

QTY: 100 tablets

DRUG: Zolpidem Tartrate

GENERIC: Zolpidem Tartrate

DOSAGE: Film-coated Tablets

ADMINISTRATION: Oral

NDC: 64679-715-02

STRENGTH: 10 mg

COLOR: Pink

SHAPE: Capsule

SCORE: no score

SIZE: 12 mm

IMPRINT: W715

QTY: 1000 tablets

ZOLPIDEM TARTRATE

Ingredients

Active Ingredient:

Zolpidem tartrate tablet

Inactive Ingredients:

Lactose, microcrystalline cellulose, sodium starch

glycolate, colloidal silicon dioxide, talc, magnesium

stearate, hypromellose, polyethylene glycol, and
titanium dioxide; the 5 mg tablet also contains iron

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PACKAGE LABEL-PRINCIPAL DISPLAY PANEL
### ZOLPIDEM TARTRATE

**Active Ingredient/Active Moiety**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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</thead>
<tbody>
<tr>
<td>ZOLPIDEM TARTRATE</td>
<td>(UNII: WY6W63843K)</td>
<td>5 mg</td>
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**Inactive Ingredients**

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<tr>
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<tr>
<td>ANHYDROUS LACTOSE</td>
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<tr>
<td>CELLULOSE, MICROCRYSTALLINE</td>
<td>(UNII: OP1R32D61U)</td>
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<td>FERRIC OXIDE RED</td>
<td>(UNII: 1K09F3G675)</td>
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<td>HYPROMELLOSES</td>
<td>(UNII: 3NXW29V3WO)</td>
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<tr>
<td>MAGNESIUM STEARATE</td>
<td>(UNII: 70097M6I30)</td>
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<tr>
<td>POLYETHYLENE GLYCOLS</td>
<td>(UNII: 3WJQ0SDW1A)</td>
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<tr>
<td>SILICON DIOXIDE</td>
<td>(UNII: ETJ7Z6XBU4)</td>
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<tr>
<td>SODIUM STARCH GLYCOLATE TYPE A POTATO</td>
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<td>TALC</td>
<td>(UNII: 7SEV7J4R1U)</td>
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<tr>
<td>TITANIUM DIOXIDE</td>
<td>(UNII: 15FIX9V2JP)</td>
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**Product Characteristics**

- **Color**: Pink (Pink)
- **Score**: no score
- **Shape**: Oval (Capsule-shaped)
- **Size**: 10mm
- **Flavor**: Imprint Code: W714

**Packaging**

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<th>Item Code</th>
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<td>05/15/2007</td>
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<td>64679-714-04</td>
<td>500 in 1 BOTTLE</td>
<td>05/15/2007</td>
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**Marketing Information**

- **Marketing Category**: ANDA
- **Application Number or Monograph Citation**: ANDA078426
- **Marketing Start Date**: 05/15/2007

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### ZOLPIDEM TARTRATE

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**Product Characteristics**

- **Color**: White (White)
- **Score**: no score
- **Shape**: Oval (Capsule-shaped)
- **Size**: 12mm
- **Flavor**: Imprint Code: W715

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**Labeler**: Wockhardt USA LLC

**Registrant**: Wockhardt USA LLC

**Establishment**: 676257570

**Revised**: 12/2017