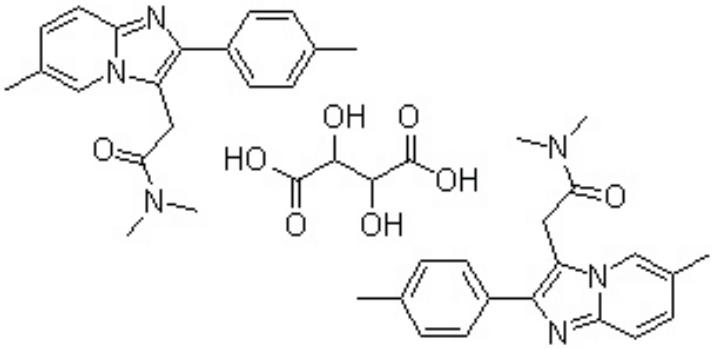
Taj Pharmaceuticals Ltd.

Zolpidem Tartrate

CAS No. : : 99294-93-6

Name Zolpidem tartrate
Synonyms N,N,6-Trimethyl-2-p-tolyl-imidazo (1,2-a)pyridine-3-acetamide L-(+)-tartrate
Molecular Structure :
Zolpidem tartrate, N,N,6-Trimethyl-2-p-tolyl-imidazo 1,2-a)pyridine-3-acetamide L-(+)-tartrate (2:1),
CAS No. : : 99294-93-6
Molecular Formula : 2(C19H21N3O).C4H6O6
Molecular Weight : 764.88



Zolpidem is a prescription medication used for the short-term treatment of insomnia, as well as some brain disorders. It is a short-acting nonbenzodiazepine hypnotic that potentiates gamma-aminobutyric acid (GABA), an inhibitory neurotransmitter, by binding to gamma-aminobutyric acid (GABAA) receptors at the same location as benzodiazepines It works quickly(usually within 15 minutes) and has a short half-life (2–3 hours).ts hypnotic effects are similar to those of the benzodiazepine class of drugs, but it is molecularly distinct from the classical benzodiazepine molecule and is classified as an imidazopyridine. Flumazenil, a benzodiazepine receptor antagonist, which is used for benzodiazepine overdose, can also reverse zolpidem's sedative/hypnotic and memory impairing effects.As an anticonvulsant and muscle relaxant, the beneficial effects start to emerge at 10 and 20 times the dose required for sedation, respectively.[8] For that reason, it has never been approved foreither muscle relaxation or seizure prevention. Such drastically increased doses are more inclined to induce one ormore negative side-effects, including hallucinations and/or amnesia.

Zolpidem tartrateis a non-benzodiazepine hypnotic of the imidazopyridine class and is available in 5 mg and 10 mg strength tablets for oral administration.Zolpidem tartrate is a white to off-white crystalline powder that is sparingly soluble in water, alcohol, and propylene glycol.

INDICATIONS
zolpidem tartrateis indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation.

DOSAGE AND ADMINISTRATION
The doseshould be individualized.
Dosage in adults
The recommended dose for adults is 10 mg once daily immediately before bedtime. The total Ambien dose should not exceed 10 mg per day.
Special populations
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 Ambien in both of these patient populations is 5 mg once daily immediately before bedtime
Use with CNS depressants
Dosage adjustment may be necessary when Ambien is combined with other CNS depressant drugs because of the potentially additive effects

TAJ PHARMACEUTICALS LIMITED

Zolpidem tartrate

Formula C19H21N3O

Cas No. **99294-93-6**

Administration
The effectbe slowed by ingestion with or immediately after a meal.

HOW TO USE

Take this medication by mouth, usually once nightly immediately before bedtime on an empty stomach, or as directed by your doctor. Do not take it with food because the effect of the medication will be delayed.

Dosage is based on your medical condition, age, and response to therapy. Do not take more than 10 milligrams per day.
Although unlikely, this drug can infrequently cause temporary memory loss. To avoid this effect, do not take a dose of this drug unless you have time for a full night's sleep that lasts at least 7-8 hours. For example, do not take zolpidem during an overnight plane flight of less than 8 hours.
SIDE EFFECTS: Dizziness, lightheadedness, headache, upset stomach, diarrhea, and dry mouth may occur. To minimize the risk of falls, remember to get up slowly when rising from a seated or lying position. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

This medication may make you sleepy during the day. Tell your doctor if you have daytime drowsiness. Your dose may need to be adjusted.
Rarely, after taking this drug, people have gotten out of bed and driven vehicles while not fully awake ("sleep-driving"). People have also sleepwalked, prepared/eaten food, made phone calls, or had sex while not fully awake. Often, these people do not remember these events. If you discover that you have experienced any of these events, tell your doctor immediately. A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching, swelling (especially of the face, lips, tongue, or throat), severe dizziness, trouble breathing.

PRECAUTIONS

Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, liver disease, mental/mood problems (e.g., depression), personal or family history of regular use/abuse of drugs/alcohol/other substances, lung/breathing problems (e.g., chronic obstructive pulmonary disease-COPD, sleep apnea), a certain muscle disease (myasthenia gravis).

This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Avoid alcoholic beverages because they may increase the risk of this drug's side effects.

STORAGE

Store at room temperature between 68-77 degrees F (20-25 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children.

PRECAUTIONS

Abnormal thinking and behavioral changes

A variety of abnormal thinking and behavior changes have been reported to occur in association with the use of sedative/hypnotics. Some of these changes may be characterized by decreased inhibition (e.g., aggressiveness and extroversion that seemed out of character), similar to effects produced by alcohol and other CNS depressants. Visual and auditory hallucinations have been reported as well as behavioral changes such as bizarre behavior, agitation and depersonalization. In controlled trials, < 1% of adults with insomnia who received zolpidem reported hallucinations. In a clinical trial, 7.4% of pediatric patients with insomnia associated with attentiondeficit/hyperactivity disorder (ADHD), who received zolpidem reported hallucinations

Note
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Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.
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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs.

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