Ambien (zolpidem tartrate) - Drug Summary

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Related Drug Information

Ambien (zolpidem tartrate)

THERAPEUTIC CLASS

Imidazopyridine hypnotic

DEA CLASS

CIV

ADULT DOSAGE & INDICATIONS

Insomnia

Difficulties w/ Sleep Initiation:
Initial:
Women: 5mg qhs
Men: 5mg or 10mg qhs
Titrate: May increase to 10mg if the 5mg dose is not effective
Max: 10mg qhs

DOSING CONSIDERATIONS

Concomitant Medications
CNS Depressants: May need to adjust dose of zolpidem

Hepatic Impairment
5mg qhs

Elderly
Elderly/Debilitated: 5mg qhs

ADMINISTRATION

Oral route

Take immediately before hs w/ at least 7-8 hrs remaining before the planned time of awakening
Do not administer w/ or immediately after a meal

HOW SUPPLIED

Tab: 5mg, 10mg

WARNINGS/PRECAUTIONS

Increased risk of next-day psychomotor impairment if taken with less than a full night of sleep remaining (7-8 hrs). May impair mental/physical abilities. Initiate only after careful evaluation; failure of insomnia to remit after 7-10 days of treatment may indicate presence of a primary psychiatric and/or medical illness. Angioedema and anaphylaxis reported; do not rechallenge if such reactions develop. Abnormal thinking, behavior changes, and visual and auditory hallucinations reported. Complex behaviors (eg, sleep-driving) while not fully awake reported; consider discontinuation if a sleep-driving episode occurs. Amnesia, anxiety, and other neuropsychiatric symptoms may occur. Worsening of depression and suicidal thoughts and actions (including completed suicides) reported primarily in depressed patients; prescribe the lowest feasible number of tabs at a time. Caution with compromised respiratory function; prior to prescribing, consider the risk of respiratory depression in patients with respiratory impairment (eg, sleep apnea, myasthenia gravis). Withdrawal signs and

symptoms reported following rapid dose decrease or abrupt discontinuation; monitor for tolerance, abuse, and dependence. May cause drowsiness and a decreased level of consciousness, which may lead to falls and consequently to severe injuries (eg, hip fractures, intracranial hemorrhage).

ADVERSE REACTIONS

Drowsiness, dizziness, headache, diarrhea, drugged feeling, lethargy, dry mouth, back pain, pharyngitis, sinusitis, allergy.

DRUG INTERACTIONS

See Dosage. Increased risk of CNS depression and complex behaviors with other CNS depressants (eg, benzodiazepines, opioids, TCAs, alcohol). Use with other sedative-hypnotics (eg, other zolpidem products) at hs or the middle of the night is not recommended. Increased risk of next-day psychomotor impairment with other CNS depressants or drugs that increase zolpidem levels. May decrease peak levels of imipramine. Additive effect of decreased alertness with imipramine or chlorpromazine. Additive adverse effect on psychomotor performance with chlorpromazine or alcohol. Sertraline and CYP3A inhibitors may increase exposure. Fluoxetine may increase $T_{1/2}$. Rifampin (a CYP3A4 inducer) may reduce exposure, pharmacodynamic effects, and efficacy. Ketoconazole (a potent CYP3A4 inhibitor) may increase pharmacodynamic effects; consider lower dose of zolpidem.

PREGNANCY AND LACTATION

Category C, caution in nursing.

MECHANISM OF ACTION

Imidazopyridine, nonbenzodiazepine hypnotic; interacts with a gamma-aminobutyric acid-BZ receptor complex. Binds the BZ_1 receptor preferentially with a high affinity ratio of the α_1/α_5 subunits.

PHARMACOKINETICS

Absorption: Rapid. C_{max}=59ng/mL (5mg), 121ng/mL (10mg); T_{max}=1.6 hrs (5mg, 10mg). **Distribution:** Plasma protein binding (92.5%); found in breast milk. **Elimination**: Renal; $T_{1/2}$=2.6 hrs (5mg), 2.5 hrs (10mg).

ASSESSMENT

Assess for physical and/or psychiatric disorder, depression, compromised respiratory function, sleep apnea, myasthenia gravis, hepatic impairment, history of drug/alcohol addiction or abuse, hypersensitivity to the drug, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for angioedema, anaphylaxis, emergence of any new behavioral signs/symptoms of concern, respiratory depression, withdrawal signs/symptoms, tolerance, abuse, dependence, drowsiness, decreased level of consciousness, and other adverse reactions.

PATIENT COUNSELING

Inform about the benefits and risks of treatment. Instruct to take only as prescribed; advise to wait at least 8 hrs after dosing before driving or engaging in other activities requiring full mental alertness. Instruct to contact physician immediately if any adverse reactions (eg, severe anaphylactic/anaphylactoid reactions, sleep-driving, other complex behaviors, suicidal thoughts) develop. Advise not to use the drug if patient drank alcohol that pm or before bed. Instruct not to increase the dose and to inform physician if it is believed that the drug does not work.

STORAGE

20-25°C (68-77°F).

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