Ambien® (imidipine tartrate)

BRIEF SUMMARY

INDICATIONS AND USAGE

Ambien® is indicated for the treatment of insomnia characterized by difficulty falling asleep, short sleep duration, or frequent awakenings and early morning wakening. Ambien® should be used for the short-term treatment of insomnia (no more than 7-10 consecutive days in a month) as needed. Ambien® should not be prescribed for children younger than 12 years of age.

CONTRAINDICATIONS

Ambien® is contraindicated in patients with a history of hypersensitivity to zolpidem or any of the other components of the product. Ambien® should not be used by patients with narrow-angle glaucoma, since zolpidem has been shown to cause dose-related increases in intraocular pressure.

WARNINGS

Zolpidem has been shown to produce dose-related impairment of psychomotor function at recommended doses, including the ability to drive or operate machinery. Patients should be advised to avoid driving or potentially hazardous activities until they are reasonably certain that zolpidem will not affect them adversely. Zolpidem is a controlled substance in schedule IV.

Precautions

Hepatic Impairment

Ambien® is not recommended for use in patients with moderate to severe hepatic impairment (Child-Pugh class B or C) due to a potential risk of serious adverse reactions. Ambien® should be used with caution in patients with mild hepatic impairment (Child-Pugh class A).

Other Drugs

The simultaneous use of Ambien® with other drugs that cause sedation, especially benzodiazepines, alcohol, and the tri cyclic antidepressants, may result in additive effects and an increased risk of adverse reactions. The concomitant use of Ambien® with lithium or other concomitant psychotropic medications may increase the risk of lithium toxicity or other adverse reactions.

Pregnancy

Animal reproduction studies have shown that zolpidem possesses no inherent teratogenic potential. There are no adequate and well-controlled studies in pregnant women. Ambien® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether Ambien® is secreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from zolpidem, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Ambien® is not recommended for use in children under 12 years of age.

ADVERSE REACTIONS

The most common adverse reactions (incidence greater than or equal to 1% and greater than or equal to 5%) associated with Ambien® are: absence of motor responses, amnesia, amnesia/failure to recall, ataxia, anxiety, behavioral changes, breathing irregularities, dizziness, dizziness/light-headedness, dizziness/sleepiness, dizziness/weakness, drowsiness, dry mouth, euphoria, fatigue, headache, hallucinations, headache/migraine, light-headedness, night sweats, nausea, panic attack, paresthesia, sedation, somnolence, somnolence/failure to recall, somnolence/light-headedness, tremor, vomiting, and weakness.

Overdose

In overdose, Ambien® is absorbed in a dose-related manner. The single ingestion of 10 mg of zolpidem has been shown to result in plasma levels of approximately 0.5 nmol/L (6 ng/mL). The single ingestion of 15 mg of zolpidem has been shown to result in plasma levels of approximately 1.0 nmol/L (12 ng/mL). The single ingestion of 20 mg of zolpidem has been shown to result in plasma levels of approximately 1.5 nmol/L (18 ng/mL). The single ingestion of 25 mg of zolpidem has been shown to result in plasma levels of approximately 2.0 nmol/L (24 ng/mL). The single ingestion of 30 mg of zolpidem has been shown to result in plasma levels of approximately 2.5 nmol/L (30 ng/mL). The single ingestion of 40 mg of zolpidem has been shown to result in plasma levels of approximately 3.0 nmol/L (36 ng/mL).

Overdose treatment consists of supportive care, if indicated. Gastric lavage may be considered if performed within 1 hour of ingestion. There is no specific antidote for treatment of overdose. Benzodiazepines and/or barbiturates are used to treat sedation and respiratory depression. Physical restraints should be employed to prevent the victim fromself-injury or harming others. If the patient is unresponsive, intubation should be considered to prevent aspiration of vomiting. Zolpidem, a short-acting benzodiazepine, is metabolized via the cytochrome P450 3A4 enzyme system, so the concomitant use of other drugs that are known to be substrates of this enzyme system (e.g., amiodarone, erythromycin, indinavir, itraconazole, ketoconazole, nefazodone, ritonavir, saquinavir, and tacrolimus) may result in increased plasma levels of zolpidem, further sedation, and a greater risk of adverse reactions. Zolpidem, a short-acting benzodiazepine, is metabolized via the cytochrome P450 3A4 enzyme system, so the concomitant use of other drugs that are known to be substrates of this enzyme system (e.g., amiodarone, erythromycin, indinavir, itraconazole, ketoconazole, nefazodone, ritonavir, saquinavir, and tacrolimus) may result in increased plasma levels of zolpidem, further sedation, and a greater risk of adverse reactions.