General Information

ProSom (estazolam) is a benzodiazepine sedative-hypnotic medication approved for short-term treatment of insomnia. Similar to other benzodiazepines, ProSom has anxiolytic effects (i.e., relieves anxiety), but it is seldom prescribed for this use. It has an intermediate duration of action (i.e., half-life around 16 hours) and no active metabolite. For some patients, a single bedtime dose may lead to daytime sedation and drowsiness. Generally, ProSom should not be used for longer than 1 week. However, longer use occasionally may be necessary for some patients; in such cases, careful monitoring is needed to prevent physical or psychological dependence. As with other benzodiazepines, ProSom is associated with dependence and abuse and is therefore regulated as a controlled substance by federal and state laws.

Dosing Information

The usual dose of ProSom is 1 mg at bedtime. The dose may be increased to 2 mg if needed but should not exceed 2 mg. Seniors may require a lower dose of 1 mg. ProSom should be taken about 1 hour before retiring to allow for the absorption of the medication.

Common Side Effects

The common side effects of ProSom are daytime drowsiness and sedation, especially shortly after initiating therapy. Other frequent complaints are impaired concentration and memory, feeling of dissociation (“spacey”), and impaired coordination.
Adverse Reactions and Precautions

ProSom may affect alertness and coordination the next day after taking a single bedtime dose. Patients should exercise caution when driving or performing other tasks requiring alertness while taking this medication. Seniors may be more adversely affected, because it may affect their coordination and reflexes and lead to falls and injury. Taking ProSom with other central nervous system (CNS) depressants such as alcohol, narcotics, and barbiturates may compound these CNS effects.

Prolonged use of benzodiazepines may lead to dependence. When the medication is abruptly withdrawn, symptoms of withdrawal may occur. Withdrawal symptoms include headache, vomiting, impaired concentration, confusion, tremor, muscle cramps, and seizures. Benzodiazepines are centrally acting depressants, and they can depress respiration. This can affect patients with chronic obstructive pulmonary disease and emphysema by decreasing their “respiratory drive” or their ability to breathe. Patients with sleep apnea—a sleep disorder in which respiration is interrupted by long pauses during the sleep cycle—should not take ProSom or other benzodiazepines. The respiratory depressant effect of benzodiazepines may further suppress the respiratory drive in these patients and put them at risk for respiratory depression.

Benzodiazepines may induce paradoxical reactions in susceptible individuals. Instead of the expected depressant effects, the medication stimulates excitement, aggression, anger, uninhibited behavior, and rage in the susceptible person. These reactions are more likely to occur in seniors, people with brain damage, and individuals with personality and impulse-control disorders.

Possible Drug Interactions

The potential drug interactions with ProSom are summarized in the table below.

<table>
<thead>
<tr>
<th>Central nervous system (CNS) depressants (e.g., alcohol, narcotics, barbiturates, hypnotics) and antihistamines</th>
<th>Combination of ProSom with another CNS depressant may impair coordination and breathing, increase sedation, and produce other CNS depressant effects.</th>
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<td>Tagamet (cimetidine), Serzone (nefazodone), Prozac (fluoxetine), Luvox (fluvoxamine), isoniazid (e.g., INH), Diflucan (fluconazole), Nizoral (ketoconazole), Sporanox (itraconazole), protease inhibitors (e.g., Crixivan, Norvir, Fortovase)</td>
<td>When any of these medications are taken concurrently with ProSom, they can inhibit its metabolism and increase blood levels. This may increase the likelihood of adverse side effects from ProSom (e.g., sedation, drowsiness).</td>
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Patients taking ProSom should not consume alcohol because the combination may increase sedation and drowsiness.

Use in Pregnancy and Breastfeeding: Pregnancy Category X

Benzodiazepines and their metabolites are known to cross the placenta and accumulate in the fetal circulation. Reproduction studies in animals demonstrated that ProSom was absorbed into fetal circulation and increased the occurrence of abnormalities. ProSom should not be used during pregnancy.

Nursing mothers should not take ProSom, because it will pass into breast milk and be ingested by the baby. If stopping the drug is not an alternative, breastfeeding should not be started or should be discontinued.
Overdose

Overdose from oral ingestion of benzodiazepines alone is generally not fatal. Most fatalities reported with benzodiazepines implicate multiple medication ingestion, particularly the combination of a benzodiazepine with CNS depressants, including alcohol, narcotics, and barbiturates.

Mild symptoms of benzodiazepine overdose include drowsiness, confusion, somnolence, tiredness, impaired coordination, clumsiness in walking (ataxia), and slow reflexes. Benzodiazepine overdose, when these agents are taken alone, is rarely fatal. When multiple medications are taken in benzodiazepine overdose, severe symptoms include slowing of respiratory and heart rate, low blood pressure, loss of coordination, and loss of consciousness leading to coma and, potentially, death.

Any suspected overdose should be treated as an emergency. The person should be taken to the emergency department for observation and treatment. The prescription bottle of medication (and any other medication suspected in the overdose) should be brought as well, because the information on the prescription label can be helpful to the treating physician in determining the number of pills ingested.

Special Considerations

- ProSom should only be taken when needed for sleep. Do not take more than the prescribed dose.
- ProSom may cause sedation and drowsiness, especially during initiation of therapy, and impair your alertness. Use caution when driving or performing tasks that require alertness. Avoid alcohol when taking ProSom, because alcohol may intensify these effects.
- Store the medication in its originally labeled, light-resistant container, away from heat and moisture. Heat and moisture may precipitate breakdown of your medication.
- Keep your medication out of reach of children.

*If you have any questions about your medication, consult your physician or pharmacist.*