Abbott
200 Abbott Park
Abbott, Illinois 60064
1-800-663-9110

Dear Health Care Provider:

After careful consideration, Abbott has made the decision to discontinue ProSom™ (estazolam, Abbott). Abbott took this action for commercial reasons, availability of generic estazolam and available alternative therapies.

If you are aware of a patient receiving ProSom, please notify the prescribing health care provider (if someone other than yourself) and the patient regarding this information. The prescribing health care provider should initiate steps to convert ProSom-treated patients to a generic estazolam product or an alternate therapy.

Abbott will no longer distribute ProSom; however, ProSom will remain available through pharmacies and wholesalers until supplies are exhausted. Health care providers should consider transitioning patients to alternative therapies, as soon as practical. After pharmacy and wholesaler supplies of ProSom are exhausted, no additional product will be available.

Should you or your colleagues have any questions or concerns, our Medical Information department may be contacted at 1-800-633-9110.

Important Indication and Safety Information

ProSom is indicated for the short-term management of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakenings.[1] Because insomnia is often transient and intermittent, the prolonged administration of ProSom is generally neither necessary nor recommended. Since insomnia may be a symptom of several other disorders, the possibility that the complaint may be related to a condition for which there is a more specific treatment should be considered.

ProSom is contraindicated in pregnant women and in patients receiving ketoconazole and itraconazole.

ProSom, like other benzodiazepines, has CNS depressant effects. For this reason, patients should be cautioned against engaging in hazardous occupations requiring complete mental alertness, such as operating machinery or driving a motor vehicle, after ingesting the drug, including potential impairment of the performance of such activities that may occur the day following ingestion of ProSom. Patients should also be cautioned about possible combined effects with alcohol and other CNS depressant drugs.

Withdrawal symptoms similar to those noted with sedatives/hypnotics and alcohol have occurred following the abrupt discontinuation of drugs in the benzodiazepine class. The symptoms can range from mild dysphoria and insomnia to a major syndrome that may include abdominal and muscle cramps, vomiting, sweating, tremors, and convulsions.

Although withdrawal symptoms are more commonly noted after the discontinuation of higher than therapeutic doses of benzodiazepines, a proportion of patients taking benzodiazepines chronically at therapeutic doses may become physically dependent on them. Available data, however, cannot provide a reliable estimate of the incidence of dependency or the relationship of the dependency to dose and duration of treatment. There is some evidence to suggest that gradual reduction of dosage will attenuate or eliminate some withdrawal phenomena. In most instances, withdrawal phenomena are relatively mild and transient; however, life-threatening events (eg, seizures, delirium, etc.) have been reported.

Gradual withdrawal is the preferred course for any patient taking benzodiazepines for a prolonged period. Patients with a history of seizures, regardless of their concomitant antiseizure drug therapy, should not be withdrawn abruptly from benzodiazepines.

Individuals with a history of addiction to or abuse of drugs or alcohol should be under careful surveillance when receiving benzodiazepines because of the risk of habituation and dependence to such patients. Please see the enclosed full prescribing information.

Sincerely,

Robert Hoff M.D.

Robert Hoff, MD
Senior Medical Director
Medical Communications

Reference:

1. Prosom™ (estazolam) [package insert]. Abbott Park, Ill: Abbott.

Enclosure:

Prosom™ [package insert]. Abbott Park, Ill: Abbott.

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A Promise for Life