DRUG APPROVAL

Lunesta™ (eszopiclone)

Lunesta™ (eszopiclone, Sepraco Inc.), formerly known as Estorra, was approved in December 2004 by the U.S. Food and Drug Administration (FDA) for the treatment of insomnia. Lunesta, administered at bedtime, decreases sleep latency and improves sleep maintenance. Lunesta is classified as a C-IV controlled substance. The precise mechanism of Lunesta as a hypnotic agent is not known, but its effect is believed to result from its interaction with GABA-receptor complexes at binding domains located close to or allosterically connected to benzodiazepine receptors. Adverse events with Lunesta therapy may include headache, dry mouth, nausea, dizziness, nervousness, somnolence, infection, unpleasant taste, or dyspepsia. Lunesta is available as 1 mg, 2 mg, and 3 mg tablets.

BACKGROUND

As many as one-third of patients seen in the primary care setting may experience difficulties in sleeping from time to time, and 10 percent of those may have chronic sleep problems. About 30 percent to 40 percent of adults report some level of insomnia within any given year, and about 10 percent to 15 percent report that the insomnia is chronic and/or severe. The prevalence of insomnia increases with age and is more common in women.

DOSAGE AND ADMINISTRATION

Treatment of Insomnia

The dose of Lunesta should be individualized. The recommended starting dose for Lunesta for most non-elderly adults is 2 mg immediately before bedtime. Dosing can be initiated at or raised to 3 mg if clinically indicated, since 3 mg is more effective for sleep maintenance.

The recommended starting dose for Lunesta for elderly patients whose primary complaint is difficulty falling asleep is 1 mg immediately before bedtime. In these patients, the dose may be increased to 2 mg if clinically indicated. For elderly patients whose primary complaint is difficulty staying asleep, the recommended dose is 2 mg immediately before bedtime.

Taking Lunesta with, or immediately after, a heavy, high-fat meal results in slower absorption and would be expected to reduce the effect of Lunesta on sleep latency.

PLACE IN THERAPY

Due to the fact that sleep disturbances may be the presenting manifestation of a physical and/or psychiatric disorder, symptomatic treatment of insomnia should be initiated only after a careful evaluation of the patient. The failure of insomnia to remit after seven days to ten days of treatment may indicate the presence of a primary and/or medical illness that should be evaluated.

Lunesta therapy is not restricted to short-term use.

PREFERRED PROVIDER INFORMATION

Based on currently available data, Caremark recommends for your consideration and at your discretion, coverage of Lunesta when your prescription benefit plan also covers other sedative-hypnotic drugs for the treatment of insomnia.

Clinical programs are available for Lunesta that focus on managing appropriate utilization. Please contact your Caremark account representative for further details.

Caremark will continue to monitor the use of Lunesta to determine if any additional clinical programs are needed.

CONTACT

For more information, call your Caremark account representative.

Please Note: This document provides a brief overview of the subject. Please refer to the manufacturer’s full prescribing information for a complete discussion of the product. This review is provided as a reference only, and is based in part on information derived from third parties.

References

