Sleep Aid Eszopiclone Okayed Over 10 Days' Use

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The Food and Drug Administration has approved a new, nonnarcotic therapy for insomnia, eszopiclone. Most sleep aids are approved for only short-term use of a week to 10 days, but eszopiclone can be safely prescribed for longer, according to the FDA.

Formerly known as Estorra and now called Lunesta, eszopiclone is a nonbenzodiazepine hypnotic that is a pyrrolopyrazine derivative of the cyclopyrrolone class. It is manufactured and sold by Sepracor Inc. of Marlborough, Mass. The drug is expected to be available this month.

Eszopiclone was studied in six phase III randomized, double-blind placebo trials, three of which were included in Sepracor's FDA approval package. The drug was superior to placebo in sleep latency and sleep maintenance for transient insomnia and superior in sleep latency and total sleep time in five 6-month studies in chronic insomnia. In two 2-week studies of patients aged 65-86, eszopiclone was also superior to placebo.

There was no major impact on memory or cognitive function in any of the studies, and only about 1% of patients on the highest dose—3 mg—experienced withdrawal signs. In addition, there was very little rebound insomnia.

Patients who do not respond after 7-10 days of treatment may have an underlying psychiatric disorder, warns the label, which adds that the lowest possible effective dose should be used. Eszopiclone will be available in 1-mg, 2-mg, and 3-mg tablets, and it will likely sell for $3.70 a pill, according to Sepracor. The recommended dose is 2-3 mg for adults up to 65 years old and 2 mg for adults over age 65.

Eszopiclone is also in trials as an insomnia therapy for patients with depression, rheumatoid arthritis, perimenopause, and chronic insomnia. ■

Comorbidities Common With Sleep Disorders

SEATTLE — Many adults with obstructive sleep apnea or insomnia also have attention-deficit disorder as well as neuromuscular and psychiatric conditions, results from a detailed analysis suggest.

"The assessment of patients with a sleep disorder and impaired daytime cognition may represent a complex interplay between the sleep disorder and comorbid dual diagnoses," Clifford G. Risk, M.D., said at a press briefing during the annual meeting of the American College of Chest Physicians.

He and his associates at a sleep disorder center in Marlborough, Mass., evaluated 58 patients who presented with sleep apnea or insomnia. They assessed the severity of obstructive sleep apnea, attention deficit problems, depression, and insomnia with a battery of standardized tests.

All patients had treatment, including continuous positive airway pressure (CPAP) for obstructive sleep apnea, cognitive behavior therapy and/or hypnotic medication for insomnia, and psychiatric evaluation and possible medication for primary ADD.

Of the 34 patients who were found to have sleep apnea, 16 had baseline Adult Self-Report Scale (ASRS) symptom checklist scores that suggested moderate or severe impairment of attention. After CPAP treatment, 60% of these patients substantially improved their attention scores. "However, 40% continued to report serious attention deficits following treatment, and required further neuropsychiatric evaluation and specific interventions," said Dr. Risk, who directs the sleep disorder center.

Of the 24 patients who had insomnia, 54% had baseline ASRS scores that suggested moderate or severe impairment of attention. Nine patients suffered from a primary muscular disorder, including fibromyalgia, chronic fatigue, multiple sclerosis, peripheral neuropathy, and postpolio syndrome; 15 suffered from a primary psychological disorder, including depression, bipolar disorder, and anxiety.

Thus there were serious neurologic or rheumatologic diseases causing their insomnia, Dr. Risk said. "If they slept through the night, we found that they were mostly in stage 1 or 2 sleep. They never got to restorative sleep stage 3 or 4. So they had a lack of restorative sleep due to a light or fragmented sleep."

—Doug Brunk