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Generic Name:
Solriamfetol
Trade Name:
Sunosi
Company:
Jazz Pharmaceuticals
Notes:

Jazz Pharmaceuticals announced FDA approval of solriamfetol to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA). It is the first dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI) approved for this treatment.

The once-daily drug is approved in doses of 75 mg and 150 mg for patients with narcolepsy and doses of 37.5 mg, 75 mg, and 150 mg for patients with OSA.

Approval of solriamfetol was based on data from the TONES Phase III clinical program, which included four randomized placebo-controlled studies that demonstrated the superiority of solriamfetol relative to placebo. The most common adverse reactions reported in both the narcolepsy and OSA study populations were headache, nausea, decreased appetite, and anxiety. Solriamfetol was evaluated in more than 900 adults with excessive daytime sleepiness associated with narcolepsy or OSA and was shown to maintain its effect relative to placebo after 6 months of use.

In 12 week clinical studies, approximately 68%?74% of people taking solriamfetol at the 75 mg dose and 78%?90% of people taking solriamfetol at the 150 mg dose reported improvement in their overall clinical condition, as assessed by the Patient Global Impression of Change scale.

Although the exact mechanism of action is unknown, the effects of solriamfetol are thought to be mediated through its activity as a DNRI.

In a news release, Jazz Pharmaceuticals cautioned that solriamfetol is not indicated to treat the underlying airway obstruction in OSA. Practitioners should ensure that the underlying airway obstruction is treated with continuous positive airway pressure (CPAP) for at least 1 month before initiating solriamfetol for excessive daytime sleepiness in OSA and continued during treatment.

Medication Monitor Categories:
New Drug Approvals

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