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Generic Name:

Pitolisant

Trade Name:

Wakix

Company:

Harmony Biosciences

Notes:

On August 15, Harmony Biosciences [announced](#) FDA approval of pitolisant for treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy. It is the first treatment approved for patients with narcolepsy that is not scheduled as a controlled substance by DEA.

WAKIX, a first-in-class medication, is a selective histamine 3 (H₃) receptor antagonist/inverse agonist that works through a novel mechanism of action to increase the synthesis and release of histamine, a wake-promoting neurotransmitter in the brain. The drug is administered orally once daily in the morning upon waking.

Efficacy was evaluated in two multicenter, randomized, double-blind, placebo-controlled studies, HARMONY 1 and HARMONY 1bis. These studies included a total of 261 patients who were randomized to receive pitolisant, placebo, or active control; these patients had a median age of 37 (HARMONY 1) and 40 (HARMONY 1bis). Treatment duration was 8 weeks, with a 3-week dose titration phase followed by a 5-week stable dose phase; 75% to 80% of the patients in these studies had a history of cataplexy.

In both studies, pitolisant demonstrated a statistically significant improvement in EDS as measured by the Epworth Sleepiness Scale (ESS) score. In the placebo-controlled trials conducted in patients with narcolepsy with or without cataplexy, the most common adverse reactions (occurring in 75% of patients and at twice the rate of placebo) were insomnia, nausea, and anxiety.

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