FDA OKs First Non-Opioid Drug Withdrawal Treatment

Lucemyra is approved to treat the symptoms of opioid withdrawal for 14 days.

May 23, 2018 By Benjamin Ryan

The Food and Drug Administration (FDA) has approved Lucemyra (lofexidine hydrochloride), the first non-opioid treatment for abrupt withdrawal from opioids among adults, Medscape reports.

Lucemyra is an oral selective alpha 2-adrenergenic receptor agonist. It works by reducing the release of the neurotransmitter norepinephrine, which is believed to contribute to many symptoms of withdrawal from opioids.

The FDA's Psychopharmacologic Drugs Advisory Committee recommended in March that the agency approve Lucemyra, concluding the drug was safe and effective in lowering the rate of withdrawal symptoms, including diarrhea, nausea, vomiting, anxiety and an overall feeling of sickness.

While Lucemyra may mitigate such symptoms, it does not necessarily eliminate them. It is approved for 14 days of treatment. Research is ongoing into longer periods of use.

The regulatory approval of the treatment was based on a pair of randomized, double-blind placebo-controlled clinical trials of 866 adults dependent on opioids who abruptly stopped taking such drugs. Those who received Lucemyra as opposed to a placebo had lower rates of withdrawal symptoms and were more likely to complete the treatment period.

The most common side effects of the treatment included low blood pressure, bradycardia (abnormally slow rate rate), somnolence (sleepiness), sedation (falling asleep) and dizziness. The drug was also associated with a few cases of syncope (a temporary loss of consciousness following a drop in blood pressure). Upon stopping the treatment, individuals may experience a sudden rise in blood pressure.

The safety and efficacy of Lucemyra has not been established in those younger than 17 years old.

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