MedicalXpress

New opioid approved for use in controlled settings

August 11 2020

Credit: Pixabay/CC0 Public Domain

The opioid Olinvyk (oliceridine) was granted approval for the management of moderate-to-severe acute pain in controlled settings, the U.S. Food and Drug Administration announced Friday.

Olinvyk is indicated for short-term intravenous use in adults with pain that is severe enough to require an intravenous opioid and who are inadequately treated with other alternatives. The drug is approved only for use in hospitals or other controlled settings and is not for at-home use. The maximum recommended daily dose is 27 mg.

Approval was based on phase 3 data from clinical and open-label trials that included a total of 1,535 patients with moderate-to-severe acute pain. Compared with patients randomly assigned to placebo, those who received Olinvyk after bunion or abdominal surgery reported decreased pain.

As with other opioids, common side effects of Olinvyk are nausea, vomiting, dizziness, headache, and constipation. Olinvyk is contraindicated for patients with significant respiratory depression, acute or severe bronchial asthma in an unmonitored setting, gastrointestinal obstruction, or known hypersensitivity to Olinvyk. The drug label includes a boxed warning on the risks for addiction, abuse, and misuse; life-threatening respiratory depression; and neonatal opioid withdrawal syndrome, as well as the risks of taking the drug simultaneously with benzodiazepines or other central nervous system antidepressants. Approval was granted to Trevena.

More information: More Information from the FDA: www.fda.gov/news-events/press- … ed-clinical-settings