FDA Grants Nalmefene Injection Approval for Emergency Treatment of Opioid Overdose

The injection adds an additional option to address emergency known or suspected opioid overdoses.

The FDA announced that they have approved nalmefene auto-injector (Zurnai; Purdue Pharma) for the emergency treatment of known or suspected opioid overdose that is induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older, according to a news release from Purdue Pharma.[1]

The injection is a single dose auto-injector that can deliver 1.5 mg of nalmefene hydrochloride per actuation. It is intended for immediate administration as an emergency therapy in settings where opioids may be present. Importantly, the injection is not a substitute for emergency medical treatment.[1]

“We are pleased to gain approval of Zurnai, the nalmefene auto-injector for use by health care professionals or anyone in the community,” Craig Landau, president and CEO of Purdue, said in the news release. “Zurnai can be an important new tool to save lives in critical moments.”[1]

In 2022, the FDA approved Purdue’s abbreviated new drug application for their nalmefene hydrochloride injection, which differs from the newly-approved auto-injector in strength—the previous injection was approved for 2mg/mL—and in mechanism, as the previous approval was not for an auto-injector.[2]

The previous injection is intended for use by health care professionals in emergency departments. Purdue Pharma has been distributing these injections to these departments at no profit.[2]

Nalmefene is the longest-acting opioid antagonist approved for opioid overdose reversal. Key to its effectiveness is that the injection can be administered by anyone in the community, including first responders and health care professionals but also bystanders and family members.[1]

For a 12-month period ending in February 2024, provisional data indicates that approximately 90% of opioid overdose deaths were from synthetic opioids, primarily fentanyl. The newly-approved nalmefene auto-injector can help mitigate these deaths by targeting both prescription opioids and illicitly-manufactured synthetic opioids.[1]

Additionally, opioid overdose deaths among teens have more than doubled recently, with about 22 high-school-age adolescents dying each week from overdoses. These overdoses have been primarily driven by fentanyl-laced prescription pills.[1]

Commonly reported adverse events, occurring in less than 5% of patients, included feeling hot, headache, nausea, dizziness, chills, vomiting, feeling abnormal, and irritability, among others.[1]

Mechanisms to address opioid overdose have been increasing in availability and approvals in recent times. In April, the FDA approved OTC naloxone nasal spray for the treatment of opioid overdoses.[3]

OTC naloxone is available in a variety of locations, including pharmacies, grocery stories, gas stations, convenience stores, and online. The increase in options for opioid overdose should lead to better outcomes for patients and a reduction in overdose deaths across the country.[3]

References

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2. Gallagher A. FDA approves Purdue Pharma's nalmefene hydrochloride injection to treat opioid overdoses. Pharmacy Times. Published March 3, 2022. Accessed August 8, 2024. https://www.pharmacytimes.com/view/fda-approves-purdue-pharma-s-nalmefene-hydrochloride-injection-to-treat-opioid-overdoses

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