

# FDA approves new nasal spray to reverse overdoses

May 23 2023, by Cara Murez

---



The U.S. Food and Drug Administration on Monday approved a second

nasal spray for reversing an opioid overdose.

To be sold as Opvee, the spray contains the medication nalmefene hydrochloride and will be available to Americans aged 12 and older with a prescription, the FDA said.

"The agency continues to advance the FDA Overdose Prevention Framework and take actionable steps that encourage harm reduction by supporting the development of novel [overdose](#) reversal products," FDA Commissioner [Dr. Robert Califf](#) said in an agency [news release](#).

"On the heels of the FDA's recent approval of the first over-the-counter [opioid](#) reversal agent [Narcan], the availability of nalmefene nasal spray places a new prescription opioid reversal option in the hands of communities, harm reduction groups and [emergency responders](#)," Califf added.

Indivior, which will make and sell Opvee going forward, said the spray should be available by October. Indivior bought Opiant Pharmaceuticals, which developed Opvee, in March.

"Opvee's FDA approval represents a significant achievement in the development of new treatment options to address today's era of [opioid overdoses](#) that are driven by powerful synthetic opioids, such as fentanyl," Indivior CEO [Mark Crossley](#) said in a [company news release](#).

"Opvee is an [emergency treatment](#) for the fast reversal of respiratory depression triggered by natural or synthetic opioids, including fentanyl, and we are committed to making this novel rescue medication widely available to those who need it most to help save lives," Crossley added.

Like its predecessor naloxone, which can be used as either a nasal spray or an injection, nalmefene hydrochloride can reverse an overdose. The

difference is that naloxone wears off more quickly. This can avoid longer-lasting withdrawal symptoms, even if naloxone may need to be administered a second time as it wears off, the *Associated Press* reported.

Nalmefene, first approved in the 1990s as an injection but later pulled from the market for a lack of sales, can reverse respiratory depression, sedation and low blood pressure following an overdose, the *AP* reported.

In a study in people who used opioids recreationally, [adverse reactions](#) included nasal discomfort, headache, nausea, dizziness, hot flush, vomiting, anxiety, fatigue, [nasal congestion](#) and throat irritation, pain in the nose, decreased appetite, skin redness and excessive sweating, the FDA said in its approval notice.

Using the medication can also trigger a wide range of opioid withdrawal symptoms, from diarrhea to rapid heart rate to increased blood pressure and more.

That is why some [health care providers](#) prefer the shorter-lasting naloxone, with withdrawal symptoms that last 30 to 40 minutes, even if it needs to be given more than once.

"The risk of long-lasting withdrawal is very real and we try to avoid it," [Dr. Lewis Nelson](#), of Rutgers University in New Jersey, told the *AP*. Nelson is an emergency medicine physician and a former FDA adviser on opioids.

"We're not suffering from a naloxone shortage where we need to use an alternative," Nelson said. "We have plenty of it, and it works perfectly well."

Still, those long-lasting effects were part of the point of the new

medication, U.S. health officials noted.

"The whole aim of this was to have a medication that would last longer, but also reach into the brain very rapidly," [Dr. Nora Volkow](#), director of the U.S. National Institute on Drug Abuse, told the *AP*.

More than 103,000 Americans died in drug overdoses in 2022, according to the FDA.

About two-thirds of fatal overdoses in 2022 were linked to fentanyl and other synthetic opioids. Fentanyl lingers in the body longer than heroin and other opioids, the *AP* said.

The FDA recently [approved](#) Narcan [nasal spray](#), a brand name of naloxone, to be sold over-the-counter.

**More information:** The U.S. Centers for Disease Control and Prevention has more on [drug overdoses and deaths](#).

Copyright © 2023 [HealthDay](#). All rights reserved.

Citation: FDA approves new nasal spray to reverse overdoses (2023, May 23) retrieved 21 November 2023 from

<https://medicalxpress.com/news/2023-05-fda-nasal-spray-reverse-overdoses.html>

<p>This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.</p>
--