

FDA NEWS RELEASE

FDA Approves First Over-the-Counter Naloxone Nasal Spray

Agency Continues to Take Critical Steps to Reduce Drug Overdose Deaths Being Driven Primarily by Illicit Opioids

For Immediate Release:

March 29, 2023

Español (<https://www.fda.gov/news-events/press-announcements/la-fda-aprueba-el-primer-aerosol-nasal-de-naloxona-de-venta-libre>)

Today, the U.S. Food and Drug Administration approved Narcan, 4 milligram (mg) naloxone hydrochloride nasal spray for over-the-counter (OTC), nonprescription, use – the first naloxone product approved for use without a prescription. Naloxone is a medication that rapidly reverses the effects of opioid overdose and is the standard treatment for opioid overdose. Today’s action paves the way for the life-saving medication to reverse an opioid overdose to be sold directly to consumers in places like drug stores, convenience stores, grocery stores and gas stations, as well as online.

The timeline for availability and price of this OTC product is determined by the manufacturer. The FDA will work with all stakeholders to help facilitate the continued availability of naloxone nasal spray products during the time needed to implement the Narcan switch from prescription to OTC status, which may take months. Other formulations and dosages of naloxone will remain available by prescription only.

Drug overdose persists as a major public health issue in the United States, with more than 101,750 reported fatal overdoses occurring in the 12-month period ending in October 2022, primarily driven by synthetic opioids like illicit fentanyl.

“The FDA remains committed to addressing the evolving complexities of the overdose crisis. As part of this work, the agency has used its regulatory authority to facilitate greater access to naloxone by encouraging the development of and approving an over-the-counter naloxone product to address the dire public health need,” said FDA Commissioner Robert M. Califf, M.D. **“Today’s approval of OTC naloxone nasal spray will help improve access to naloxone, increase the number of locations where it’s available and help reduce opioid overdose deaths throughout the country. We encourage the manufacturer to make accessibility to the product a priority by making it available as soon as possible and at an affordable price.”**

Narcan nasal spray was first approved by the FDA in 2015 as a prescription drug. In accordance with a [process \(https://www.fda.gov/drugs/drug-application-process-nonprescription-drugs/prescription-nonprescription-rx-otc-switches\)](https://www.fda.gov/drugs/drug-application-process-nonprescription-drugs/prescription-nonprescription-rx-otc-switches) to change the status of a drug from prescription to nonprescription, the manufacturer provided data demonstrating that the drug is safe and effective for use as directed in

its proposed labeling. The manufacturer also showed that consumers can understand how to use the drug safely and effectively without the supervision of a healthcare professional. The application to approve Narcan nasal spray for OTC use was granted priority review status and was the subject of an advisory committee meeting in February 2023, where committee members voted unanimously to recommend it be approved for marketing without a prescription.

The approval of OTC Narcan nasal spray will require a change in the labeling for the currently approved 4 mg generic naloxone nasal spray products that rely on Narcan as their reference listed drug product. Manufacturers of these products will be required to submit a supplement to their applications to effectively switch their products to OTC status. The approval may also affect the status of other brand-name naloxone nasal spray products of 4 mg or less, but determinations will be made on a case-by-case basis and the FDA may contact other firms as needed.

The use of Narcan nasal spray in individuals who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness and increased blood pressure.

“Naloxone is a critical tool in addressing opioid overdoses and today’s approval underscores the extensive efforts the agency has undertaken to combat the overdose crisis,” said Patrizia Cavazzoni, M.D., director of the FDA’s Center for Drug Evaluation and Research. “The FDA is working with our federal partners to help ensure continued access to all forms of naloxone during the transition of this product from prescription status to nonprescription/OTC status. Further, we will work with any sponsor seeking to market a nonprescription naloxone product, including through an Rx to OTC switch, and encourage manufacturers to contact the agency as early as possible to initiate discussions.”

The FDA has taken a series of measures to help facilitate access to naloxone products. In November 2022, the agency [announced \(https://www.fda.gov/news-events/press-announcements/fda-announces-preliminary-assessment-certain-naloxone-products-have-potential-be-safe-and-effective\)](https://www.fda.gov/news-events/press-announcements/fda-announces-preliminary-assessment-certain-naloxone-products-have-potential-be-safe-and-effective) its preliminary assessment that certain naloxone products, such as the one ultimately approved today, have the potential to be safe and effective for over-the-counter use and encouraged sponsors to submit applications for approval of OTC naloxone products. The agency previously [announced \(https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-unprecedented-new-efforts-support-development-over\)](https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-unprecedented-new-efforts-support-development-over) in 2019 that it had designed, tested, and validated a model naloxone Drug Facts Label (DFL) with easy-to-understand pictograms on how to use the drug to encourage manufacturers to pursue approval of OTC naloxone products. The model DFL was used to support the approved application along with the results of a simulated use Human Factors validation study designed to assess whether all the components of the product with which a user would interact could be used safely and effectively as intended.

Through the [FDA Overdose Prevention Framework \(https://www.fda.gov/drugs/drug-safety-and-availability/food-and-drug-administration-overdose-prevention-framework\)](https://www.fda.gov/drugs/drug-safety-and-availability/food-and-drug-administration-overdose-prevention-framework), the agency remains focused on responding to all facets of substance use, misuse, substance use disorders, overdose and

death in the U.S. The framework's priorities include: supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing; encouraging harm reduction through innovation and education; advancing development of evidence-based treatments for substance use disorders; and protecting the public from unapproved, diverted or counterfeit drugs presenting overdose risks.

The FDA granted the OTC approval of Narcan to Emergent BioSolutions.

Related Information

- [FDA Overdose Prevention Framework \(https://www.fda.gov/drugs/drug-safety-and-availability/food-and-drug-administration-overdose-prevention-framework\)](https://www.fda.gov/drugs/drug-safety-and-availability/food-and-drug-administration-overdose-prevention-framework)
- [Information About Naloxone \(https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-naloxone\)](https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-naloxone)
- [Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse \(https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-opioid-misuse-and-abuse\)](https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-opioid-misuse-and-abuse)
- [Consumer Update: Access to Naloxone Can Save a Life During an Opioid Overdose \(https://www.fda.gov/consumers/consumer-updates/access-naloxone-can-save-life-during-opioid-overdose\)](https://www.fda.gov/consumers/consumer-updates/access-naloxone-can-save-life-during-opioid-overdose)

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