



Narcan Nasal Spray Approved for OTC Treatment of Opioid Overdose

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The Food and Drug Administration (FDA) has approved Narcan® (naloxone HCl) Nasal Spray as an [over-the-counter \(OTC\) emergency treatment](#) for known or suspected opioid overdose.

[Narcan Nasal Spray](#) is an [opioid](#) antagonist that reverses the effects of opioids, including respiratory depression, sedation, and hypotension. In [2015](#), the FDA approved Narcan Nasal Spray as a prescription medication indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. It is also intended for immediate administration as emergency therapy in settings where opioids may be present.

The approval for nonprescription use is supported by more than 7 years of postmarketing data demonstrating the safety and efficacy of Narcan, along with human factors studies. The Company also demonstrated that consumers are able to understand how to use Narcan safely and effectively without the supervision of a health care professional.

The FDA previously granted [Priority Review](#) to Narcan Nasal Spray for OTC use. Moreover, the FDA's Nonprescription Drugs Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee [unanimously voted in favor](#) of Narcan Nasal Spray for OTC use in February 2023.

Narcan Nasal Spray for OTC use is expected to be available by late summer and will have the same formulation, device design, and 4mg strength as the prescription product. The prescription product will remain available via pharmacies and community distribution.