



*Courtesy of the National Institute on Drug Abuse*

## FDA advises educating families on availability, use of nonprescription naloxone

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The Food and Drug Administration (FDA) is asking health care professionals to discuss the availability and proper use of nonprescription naloxone with all patients when prescribing or renewing opioid analgesics, including its use for children exposed to opioids unintentionally.

“We need to ensure that anyone witnessing an opioid overdose is able to recognize the signs and confidently administer naloxone to any potential victim, regardless of age,” said Marta Sokolowska, Ph.D., deputy center director for substance use and behavioral health in the FDA’s Center for Drug Evaluation and Research.

The FDA recently [approved](#) the first nonprescription naloxone product, Narcan (naloxone hydrochloride) nasal spray, for the emergency treatment of opioid overdose. It is a single-use device containing 4 milligrams of naloxone. Dosing is the same for all ages: one spray given intranasally into one nostril with additional doses administered every two to three minutes until the individual becomes responsive or emergency services arrive.

The FDA first approved Narcan nasal spray in 2015 as a prescription drug for use in adults and children, including neonates. In 1971, naloxone was approved for subcutaneous, intramuscular or intravenous administration.

“Accidental or intentional overdose and death associated with the use, misuse and abuse of illicit or prescription opioids is a public health crisis in the United States, and, unfortunately, children haven’t been spared from this crisis,” Dr. Sokolowska said.

The FDA continues to warn patients, caregivers and health care professionals about the dangers of accidental overdose in children, such as a recent warning about the need to store and dispose of fentanyl patches properly (<https://bit.ly/3rbQYpW>).

Despite these warnings, “we have seen mortality rates for opioid overdose rising sharply for children of all ages,” which is due in part to accidental poisoning, Dr. Sokolowska said. “FDA considers the benefits of having Narcan nasal spray available to adults and children of all ages in the community setting to far outweigh the risks, such as precipitated withdrawal.”

The use of Narcan nasal spray in individuals who are dependent on opioids may result in severe opioid withdrawal characterized by body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness and increased blood pressure. For neonates with known or suspected exposure to maternal opioid use, exposure to naloxone may result in the abrupt precipitation of opioid withdrawal symptoms, including convulsions, excessive crying and hyperactive reflexes.

The switch from prescription to nonprescription use of naloxone did not require new clinical or pharmacologic studies as the drug product did not change and only the labeling changed. The manufacturer provided data demonstrating that the drug is safe and effective when used as directed in the proposed labeling. Consumers as young as age 15 years demonstrated that they understood how to use the drug safely and effectively just by reading the carton and without the guidance of a health care professional.

The FDA reviewed the previous seven years of postmarketing safety data for Narcan nasal spray and found very few serious adverse events in the pediatric population.

Working with other federal agencies, the FDA is helping to ensure continued access to all forms of naloxone for all those at risk, including children, as all formulations of naloxone can save a life.

*The FDA’s Office of Pediatric Therapeutics, Center for Drug Evaluation and Research Office of the Center Director, Office of New Drug’s Division of Pediatrics and Maternal Health, and Office of Nonprescription Drugs contributed to this article.*

#### **Resources**

- [Information for health care professionals on discussing naloxone with patients](#)
- [FDA review of Narcan \(naloxone\) nasal spray for over-the-counter use](#)
- [FDA Overdose Prevention Framework](#)
- [Information on prescription-to-nonprescription switches](#)
- [Information for parents from HealthyChildren.org about using naloxone for opioid overdose](#)