

Narcan[®] (naloxone) – New over-the-counter approval

- On March 29, 2023, [Emergent BioSolutions announced](#) the [FDA approval](#) of over-the-counter (OTC) [Narcan \(naloxone\)](#) nasal spray 4 mg, for emergency treatment of opioid overdose (from prescription pain medications or street drugs such as heroin).
 - Previously, brand [Narcan](#) (and generic versions of Narcan) was available as a prescription. The prescription Narcan and generic versions of Narcan are approved for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.
 - Narcan is not a substitute for emergency medical care.
- Narcan is 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.
 - Other formulations and dosages of naloxone will remain available by prescription only.
- In accordance with a process to change the status of a drug from prescription to nonprescription, Emergent BioSolutions 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 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 in individuals who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate, 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.
- Refer to the Narcan OTC label for a complete description of directions for use.
- Emergent BioSolutions plans to launch OTC Narcan in late Summer 2023. Narcan will be packaged as 2 single-dose nasal spray devices (containing 4 mg each).
 - The current prescription product will remain in readily available supply through current access channels, including pharmacies through standing order or co-prescription laws and through community distribution.