

FDA Approves First Over-the-Counter Naloxone Nasal Spray

June 30, 2023



On March 29, 2023, the U.S. Food and Drug Administration (FDA) announced the approval of 4 milligram (mg) naloxone hydrochloride nasal spray as an over-the-counter (OTC) product for non-prescription use. Naloxone is a lifesaving medication that when administered can rapidly reverse the effects of an opioid overdose. Although naloxone nasal spray has been on the market as a prescription since 2015, the switch to OTC status was identified an important intervention to improve access to naloxone in the community and reduce deaths due to opioid overdose. In order for the FDA to consider authorizing a product for OTC use, the manufacturer is required to submit data that demonstrates the product is safe and effective and that consumers can understand how to use the drug safely and effectively without the supervision of a healthcare professional.

As an OTC drug, the 4 mg naloxone hydrochloride nasal spray can be sold directly to consumers online or purchased locally in pharmacies, gas stations, and grocery stores. Although now approved, [a statement from the manufacturer](#) noted the anticipated timeline for it to be available on U.S. shelves and at online retailers is late summer 2023 due to required manufacturing changes for nonprescription packaging and supply chain modifications. In the meantime, the prescription product, as well as other naloxone formulations which are not yet approved for OTC use, will remain available at the pharmacy by prescription or pharmacist-furnishing, as well as community distribution sites.

For additional information on the approval of naloxone nasal spray for OTC use, refer to the FDA Press Announcement: [FDA Approves First Over-the-Counter Naloxone Nasal Spray](#) located on the News & Events page of the FDA website.