

FDA approves 1st generic nasal spray against opioid overdose

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(HealthDay)—The first generic naloxone nasal spray to treat opioid overdose has received approval from the U.S. Food and Drug Administration.

Teva Pharmaceuticals' lifesaving product is also the first generic naloxone nasal spray approved for use by people without medical training. There was already a brand-name spray (Narcan) for emergency use by untrained people, such as family members and bystanders.

The need is urgent. On average, more than 130 Americans die every day from overdoses of opioids—including prescription painkillers such as fentanyl, oxycodone (OxyContin), hydrocodone (Vicodin) and morphine, as well as illegal drugs such as heroin or drugs sold as heroin, the FDA said.

"In the wake of the opioid crisis, a number of efforts are underway to make this emergency overdose reversal treatment more readily available

and more accessible," said Dr. Douglas Throckmorton, deputy center director for regulatory programs in the FDA's Center for Drug Evaluation and Research.

"In addition to this approval of the first generic naloxone nasal spray, moving forward we will prioritize our review of generic drug applications for naloxone," he added.

When someone overdoses on opioids, breathing may become shallow or stop completely, leading to death if no one intervenes. If administered quickly, naloxone can counter the effects within minutes.

Throckmorton said in an agency news release that the FDA is also helping drugmakers pursue approval of an over-the-counter naloxone product, and "exploring other ways to increase availability of naloxone products intended for use in the community."

The FDA is also considering whether naloxone should be routinely prescribed along with all or some opioid prescriptions in order to reduce the risk of overdose.

"All together, these efforts have the potential to put a vital tool for combating opioid overdose in the hands of those who need it most—friends and families of opioid users, as well as first responders and community-based organizations," Throckmorton said.

Nearly 400,000 people in the United States died of opioid overdoses between 1999 and 2017, according to the U.S. Centers for Disease Control and Prevention.

"We're committed to working with other federal, state and local officials, as well as health care providers, patients and communities across the country to combat the staggering human and economic toll created by opioid abuse and

addiction," Throckmorton said in the news release.

More information: The U.S. National Institute on Drug Abuse has more about the [opioid overdose crisis](#).

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