

FDA approves nasal spray to reverse narcotic painkiller overdose

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Drug marketed as Narcan offers new treatment option for family members or first responders.

(HealthDay)—A nasal spray that treats narcotic painkiller and heroin drug overdoses has been approved by the U.S. Food and Drug Administration.

The newly approved nasal spray (Narcan) contains the medication naloxone hydrochloride, which can stop or reverse the effects of a narcotic (also called opioid) drug overdose. Narcan is the first approved nasal spray version of the medication and offers an important new easy-to-use treatment option for family members and first responders dealing with a heroin or narcotic painkiller overdose, the FDA said.

Narcotic painkillers include prescription pain drugs such as oxycodone (OxyContin), hydrocodone (when combined with acetaminophen, it's called Vicodin or Percocet) and morphine. Narcan can also reverse the effects of heroin.

Drug overdose deaths are currently the leading cause of injury death in the United States, the FDA said. Every day, 44 Americans die from a prescription narcotic painkiller overdose, according to the U.S. Centers for Disease Control and Prevention.

In narcotic painkiller and heroin overdoses, it can

be difficult to awaken the person. Breathing may become shallow or stop, resulting in death if there is no medical help. When administered quickly, naloxone can counter the overdose effects, usually within two minutes, according to the FDA.

Previously, naloxone was only approved in injectable forms, such as syringes or auto-injectors. However, there was widespread use of unapproved kits that enabled the drug to be delivered nasally.

"Combating the opioid abuse epidemic is a top priority for the FDA," Dr. Stephen Ostroff, FDA acting commissioner, said in an agency news release.

"We cannot stand by while Americans are dying. While naloxone will not solve the underlying problems of the opioid epidemic, we are speeding to review new formulations that will ultimately save lives that might otherwise be lost to drug addiction and overdose," he said.

Clinical trials showed that spraying Narcan in one nostril delivered about the same or higher levels of naloxone as a single dose of a naloxone injection. The drug can be given to adults or children, the FDA said.

However, the FDA cautioned that once the drug has been given, people should seek immediate medical treatment. The drug is not meant to replace medical care.

Dr. Nora Volkow, director of the U.S. National Institute on Drug Abuse, said this new formulation will no doubt save many lives. "While prevention is the ultimate goal, the <u>drug</u>'s successful development illustrates how public/private scientific partnerships can play an important role in responding to a national crisis right now," she said in the news release.

Narcan is marketed by Pennsylvania-based Adapt



Pharma, Inc.

More information: The U.S. Department of Health and Human Services has more about the <u>prescription painkiller and heroin overdose</u> <u>epidemic</u>.

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