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Volume 65 (Issue 1675)

May 1, 2023

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IN BRIEF

Over-the-Counter *Narcan* Nasal Spray

Note: See addendum

The FDA has approved the over-the-counter (OTC) sale of *Narcan* (Emergent), a nasal spray that delivers 4 mg of the opioid antagonist naloxone. *Narcan* nasal spray has been available by prescription since 2015 for emergency treatment of opioid overdose. Generic formulations of *Narcan* have also been approved; the manufacturers of these products will be required to switch them to OTC status and amend their labeling accordingly.¹ *Kloxxado*, an 8-mg naloxone nasal spray, remains available only by prescription.²

Naloxone is the drug of choice for reversal of opioid overdose. Approval of the OTC sale of *Narcan* was based on data demonstrating that the drug is safe and effective for use as directed in the proposed labeling and that consumers can use it properly without the supervision of a healthcare professional.¹

Every state in the US now has a naloxone access law; in most states, these laws grant both civil and criminal immunity to laypersons who administer naloxone.³ The US Department of Health and Human Services has recommended that certain individuals who are prescribed opioids or are at high risk for an opioid overdose, their caregivers, and persons who are likely to respond to an overdose event carry naloxone nasal spray (see Table 1).⁴

Narcan is not yet available OTC; announcements about its OTC availability and cost are expected in the coming months.¹ ■

Table 1. Persons Who Should Carry Naloxone^{1,2}

Patients prescribed opioids who:

- ▶ Are taking ≥ 50 morphine milligram equivalents (MME) per day
- ▶ Have respiratory conditions such as chronic obstructive pulmonary disease (COPD) or obstructive sleep apnea (regardless of opioid dose)
- ▶ Have been prescribed benzodiazepines (regardless of opioid dose)
- ▶ Have a non-opioid substance use disorder, report excessive alcohol use, or have a mental health disorder (regardless of opioid dose)

Patients at high risk for an opioid overdose, including those:

- ▶ Using heroin or illicit synthetic opioids or misusing prescription opioids
- ▶ Using other illicit drugs such as methamphetamine or cocaine that could potentially be contaminated with illicit synthetic opioids like fentanyl
- ▶ Receiving treatment for opioid use disorder, including medication-assisted treatment with methadone, buprenorphine, or naltrexone
- ▶ With a history of opioid misuse who were recently released from incarceration or other controlled settings and are no longer tolerant to opioids

1. HHS. Naloxone: the opioid reversal drug that saves lives. Available at: <https://bit.ly/3k68NiV>. Accessed April 13, 2023.
2. Includes at-risk individuals, their caregivers, and those likely to respond to an overdose event.

1. FDA News Release. FDA approves first over-the-counter naloxone nasal spray. March 29, 2023. Available at: <http://bit.ly/3mek5Xy>. Accessed April 13, 2023.
2. In brief: Higher-dose naloxone nasal spray (*Kloxxado*) for opioid overdose. *Med Lett Drugs Ther* 2021; 63:151.
3. Legislative Analysis and Public Policy Association. Naloxone: summary of state laws. July 2022. Available at: <https://bit.ly/3ZNK1H9>. Accessed April 13, 2023.
4. HHS. Naloxone: the opioid reversal drug that saves lives. Available at: <https://bit.ly/3k68NiV>. Accessed April 13, 2023.

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ADDENDUM

Over-the-Counter *Narcan* Nasal Spray

Since the publication of our articles entitled Drugs for Opioid Use Disorder and In Brief: Over-the-Counter *Narcan* Nasal Spray earlier this year, *Narcan* (Emergent), a nasal spray that delivers 4 mg of the opioid antagonist naloxone, has become available for sale over the counter (OTC). According to the manufacturer, the retail price for a box containing 2 doses is \$44.99. Some insurance companies have announced plans to cover OTC purchase of the drug for their members.

RiVive (Harm Reduction Therapeutics), a 3-mg naloxone nasal spray recently FDA-approved for OTC sale, is expected to be marketed early next year. ■

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