

TALKING TO PATIENTS ABOUT LIFE-THREATENING OPIOID-RELATED RISKS

Background Information

LIFE-THREATENING, ACCIDENTAL MISUSE OF OPIOIDS HAS REACHED EPIDEMIC PROPORTIONS.¹

The rate of emergencies from prescription opioid misuse has climbed to over 80%.² Anyone who takes a prescription opioid could be at risk for an overdose, and this risk could even increase for certain patients.³ As a physician who regards the safety of your patients as paramount, the first step is recognizing these at-risk patients in your practice.

This at-risk group includes patients who:

- Use prescription opioids chronically³
- Have a suspected or confirmed history of substance abuse, dependence, or nonmedical use of prescription or illicit opioids³
- Inject opioids³
- Take prescription opioids in higher doses (≥ 20 MME/day)⁴
- Take opioids in combination with other sedating substances, such as benzodiazepines³
- Use opioids and have medical conditions such as HIV, liver disease, sleep apnea, COPD or asthma, kidney disease, or psychiatric disorders^{3,5}
- Keep opioids in their home³

NARCAN[®] Nasal Spray is the first and only FDA-approved nasal form of naloxone for the emergency treatment of a known or suspected opioid overdose. Designed for use in the community, NARCAN[®] Nasal Spray is needle-free and ready to use.⁶

Not a substitute for emergency medical care. Repeated doses may be necessary.

INDICATIONS

NARCAN[®] (naloxone hydrochloride) Nasal Spray is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. NARCAN[®] Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present.

NARCAN[®] Nasal Spray is not a substitute for emergency medical care.

IMPORTANT SAFETY INFORMATION

NARCAN[®] Nasal Spray is contraindicated in patients known to be hypersensitive to naloxone hydrochloride.

Seek emergency medical assistance immediately after initial use, keeping the patient under continued surveillance.

Please see Important Safety Information throughout and accompanying full Prescribing Information.

 **NARCAN[®]** (naloxone HCl)
NASAL SPRAY 4mg

Starting the Conversation

WHILE OPIOIDS HAVE AN APPROPRIATE ROLE IN PAIN MANAGEMENT, PATIENTS MAY NOT REALIZE THAT THEIR OPIOID MEDICATION MAY BE PUTTING THEM AT RISK.

You can discuss how to appropriately take their medication and how to be prepared in case of an opioid-induced emergency (such as a known or suspected overdose as manifested by respiratory and/or CNS depression). Here are some conversation starters that can lead to an open and informative dialogue with patients about their opioid prescription and the role that NARCAN® Nasal Spray can play.



Treating your chronic pain requires opioids. Let's discuss the benefits and risks associated with taking opioids. While opioids can provide effective pain relief, there are risks, such as the possibility for accidental misuse or misdosing.



I see you may be taking sedating drugs called benzodiazepines in addition to your opioid medication, which may have an effect on your body's response to these medications. The combination of these medications may increase your risk for a serious, life-threatening reaction.³



It may be tough to keep track of multiple doses in a day. Have you ever forgotten when you took your last opioid dose?



Too much opioid medicine in your system can affect your breathing, which can be a sign of an opioid overdose.

It is important that we work together to manage your pain with opioids. So as a "just-in-case" safe practice, I would like you to have an emergency treatment used to help reverse the effects of opioids while waiting for emergency medical care to arrive.



Is there a family member, caregiver, or close friend who could help in case of an opioid emergency? Do they know the signs of an opioid-related emergency? Do you have a plan in place, in your home, in case an opioid-related emergency occurs?

IMPORTANT SAFETY INFORMATION (CONTINUED)

Risk of Recurrent Respiratory and CNS Depression: Due to the duration of action of naloxone relative to the opioid, keep the patient under continued surveillance and administer repeat doses of naloxone using a new nasal spray with each dose, as necessary, while awaiting emergency medical assistance.

Please see Important Safety Information throughout and accompanying full Prescribing Information.

Having the Conversation



Even if patients think an opioid overdose can't happen to them, reiterate the importance of being prepared with NARCAN® Nasal Spray. Here are some key points to discuss:

- ✓ Review the signs of an opioid overdose included in the NARCAN® Nasal Spray Patient Brochure
- ✓ Talk to patients about filling/refilling their NARCAN® Nasal Spray prescription and keeping it on hand in case of an opioid emergency
- ✓ Take patients and caregivers through the Instructions for Use
- ✓ Remind patients and caregivers that NARCAN® Nasal Spray is not a substitute for emergency medical care. Repeated doses may be necessary



For additional information on NARCAN® Nasal Spray, visit www.NARCAN.com

IMPORTANT SAFETY INFORMATION (CONTINUED)

Risk of Limited Efficacy with Partial Agonists or Mixed Agonists/Antagonists: Reversal of respiratory depression caused by partial agonists or mixed agonists/antagonists, such as buprenorphine and pentazocine, may be incomplete. Larger or repeat doses may be required.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

Precipitation of Severe Opioid Withdrawal:

Use in patients who are opioid dependent may precipitate opioid withdrawal characterized by body aches, fever, sweating, runny nose, sneezing, goose bumps (piloerection), yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure and increased heart rate (tachycardia). In some patients, there may be aggressive behavior upon abrupt reversal of an opioid overdose. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated and may be characterized by convulsions, excessive crying, and hyperactive reflexes. Monitor for the development of opioid withdrawal.

Risk of Cardiovascular (CV) Effects: Abrupt postoperative reversal of opioid depression may result in adverse CV effects. These events have primarily occurred in patients who had pre-existing CV disorders or received other drugs that may have similar adverse CV effects. Monitor these patients closely in an appropriate healthcare setting after use of naloxone hydrochloride.

The following adverse reactions were observed in a NARCAN Nasal Spray clinical study: increased blood pressure, constipation, toothache, muscle spasms, musculoskeletal pain, headache, nasal dryness, nasal edema, nasal congestion, nasal inflammation, rhinalgia, and xeroderma.

To report SUSPECTED ADVERSE REACTIONS, contact Adapt Pharma, Inc. at 1-844-4NARCAN (1-844-462-7226) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information.

References: **1.** Centers for Disease Control and Prevention. Opioid data analysis. <https://www.cdc.gov/drugoverdose/data/analysis.html>. Updated February 9, 2017. Accessed June 27, 2017. **2.** Elzey MJ, Barden SM, Edwards ES. Patient characteristics and outcomes in unintentional, non-fatal prescription opioid overdoses: a systematic review. *Pain Physician*. 2016;19(4):215-228. **3.** World Health Organization. Management of substance abuse: information sheet on opioid overdose. http://www.who.int/substance_abuse/information-sheet/en. Updated November 2014. Accessed June 27, 2017. **4.** Centers for Disease Control and Prevention. Calculating total daily dose of opioids for safer dosage. www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf. Updated March 14, 2016. Accessed June 27, 2017. **5.** Wilder CM, Miller SC, Tiffany E, et al. Risk factors for opioid overdose and awareness of overdose risk among veterans prescribed chronic opioids for addiction or pain. *J Addict Dis*. 2016;35(1):42-51. **6.** NARCAN[®] Nasal Spray. Prescribing Information. Adapt Pharma, Inc. Radnor, PA; 2017.