NARCAN® (naloxone HCl) NASAL SPRAY 4 mg

Fact Sheet

FDA-Approved Nasal Naloxone to Treat Opioid Overdose

ADAPT PHARMA

BACKGROUND: THE OPIOID OVERDOSE EPIDEMIC

- Opioid abuse in the United States has reached epidemic proportions, with deaths due to opioid overdose killing Americans every day.[1]
- Naloxone is an antidote that has been used as a pharmaceutical ingredient for more than 40 years as an emergency treatment to rapidly reverse the life-threatening effects of opioid overdose until medical help arrives.[2]
- There is broad consensus across the medical, advocacy and government communities that increased access to naloxone is a critical component of the emergency treatment of opioid overdose.[3,4,5]
- Historically, naloxone has only been approved by the U.S. Food and Drug Administration (FDA) in injectable formulations. However, the FDA recently encouraged innovations in more user-friendly naloxone delivery systems, especially those that can be given by consumers outside of healthcare settings.[6]

WHAT IS NARCAN® NASAL SPRAY?

- NARCAN® Nasal Spray is an FDA-approved, needle-free naloxone treatment. It provides emergency treatment of known or suspected opioid overdose until emergency medical help arrives. **NARCAN® Nasal Spray is not a substitute for emergency care.**
- NARCAN® Nasal Spray rapidly delivers a 4 mg dose of naloxone in a single concentrated 0.1 ml nasal spray from a compact, ready-to-use device.[7] Each package contains two devices.
- NARCAN® Nasal Spray can be readily administered when an opioid overdose occurs and does not require assembly or specialized training.
- **See below for NARCAN® Nasal Spray indications and important safety information.**

HOW DOES NARCAN® NASAL SPRAY WORK?

- In the case of a known or suspected opioid overdose:
  - **Peel** back the tab to remove NARCAN® Nasal Spray from its package.
  - **Place** the device into one nostril.
  - **Press** the device plunger firmly.
  - **Get emergency help right away.**
- While not a substitute for emergency medical care, timely administration of a sufficient dose of NARCAN® Nasal Spray can help rapidly reverse the life-threatening breathing difficulties that an opioid overdose may cause until emergency medical care can be administered.

WHO SHOULD HAVE NARCAN® NASAL SPRAY?

- NARCAN® Nasal Spray will be available in the coming weeks.
- It may be important for the following groups to have NARCAN® Nasal Spray on hand.
  - Anyone who is taking opioids or at risk of an opioid overdose
  - Friends, family members or acquaintances of someone who may be at risk of an opioid overdose
  - Healthcare professionals
  - First responders, including police, firefighters and EMTs
  - Emergency room personnel
  - Hospital and treatment centers

Full Prescribing Information for NARCAN® Nasal Spray is available at www.NarcanNasalSpray.com and the FDA website.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

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.

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.

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.

Precipitation of Severe Opioid Withdrawal: Use in patients who are opioid dependent may precipitate opioid withdrawal and acute withdrawal syndrome. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated. Monitor for 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, musculoskeletal pain, headache, nasal dryness, nasal edema, nasal congestion, and nasal inflammation.

See Instructions for Use and full prescribing information in the use of this product.

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.

Citations

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2 World Health Organization. Naloxone: A Take-home Antidote to Drug Overdose that Saves Lives. 2014. Available at: http://www.who.int/features/2014/naloxone/en/

3 The White House Office of the Press Secretary. FACT SHEET: Obama Administration Announces Public and Private Sector Efforts to Address Prescription Drug Abuse and Heroin Use. 2015. Available at: https://www.whitehouse.gov/the-press-office/2015/10/21/fact-sheet-obama-administration-announces-public-and-private-sector

4 American Medical Association. The American Medical Association Task Force to Reduce Prescription Opioid Abuse. 2015. Available at: http://www.ama-assn.org/ama/pub/advocacy/topics/preventing-opioid-abuse/opioid-abuse-task-force.page

5 Harm Reduction Coalition. American Medical Association, Harm Reduction Coalition and National Safety Council Urge Increased Focus on Overdose Prevention and Treatment. 2014. Available at: http://www.aafp.org/dam/AAFP/documents/advocacy/prevention/risk/LT-NGA-HarmReduction-021915.pdf

6 Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation. Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths. 2015. Available at: http://aspe.hhs.gov/sites/default/files/pdf/107956/ib_OpioidInitiative.pdf

7 Data on file. Naloxone-Ph1a-002 CSR.