FDA APPROVED

# **POWER** TO HELP REVERSE AN OPIOID OVERDOSE



- Concentrated 4 mg dose
- Needle-free; no assembly required
- Designed for ease-of-use in the community setting
- Requires no specialized training\*

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

\*Administer in accordance with Instructions for Use.

## Special pricing discount for public interest groups

## NARCAN® (naloxone hydrochloride) NASAL SPRAY INDICATIONS AND IMPORTANT SAFETY INFORMATION INDICATIONS

NARCAN® 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 on page 6 and accompanying full Prescribing Information.

#### THE OPIOID OVERDOSE CRISIS

In 2015, drug overdose deaths involving an opioid accounted for **33,091 deaths**,<sup>1</sup> and the Centers for Disease Control and Prevention (CDC) reported that 62 people die from prescription opioid-related toxicity in the United States every day.<sup>2</sup> This figure equates to almost **2 deaths every hour**, and 83% of these opioid deaths were unintentional, or at least unanticipated.<sup>3</sup>

### WHAT IS NARCAN® (naloxone HCI) NASAL SPRAY?

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.

NARCAN® Nasal Spray counteracts the life-threatening effects of opioid overdose. Since most accidental overdoses occur in a home setting<sup>4</sup>, it was developed for first responders, as well as family, friends, and caregivers.

Administer in accordance with the Instructions for Use. Repeated doses may be necessary. NARCAN® Nasal Spray is not a substitute for emergency medical care. Always get help immediately, even if the person wakes up, because they may relapse into respiratory depression. The use of NARCAN® Nasal Spray may result in symptoms of acute opioid withdrawal.

Please see Indications and Important Safety Information on these pages in the use of this product.

#### IMPORTANT SAFETY INFORMATION

<u>Risk of Recurrent Respiratory and CNS Depression:</u> 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.

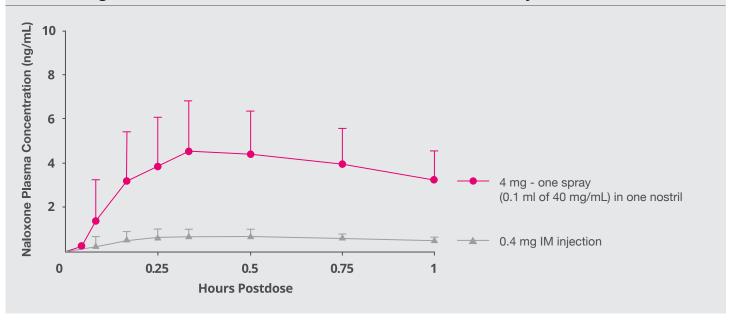
Risk of Limited Efficacy with Partial Agonists or Mixed Agonists/Antagonists: Reversal of respiratory depression caused by partial agonists or mixed agonists/antagonists, such as buprenorphine and pentazocine, may be incomplete. Larger or repeat doses may be required.

<u>Precipitation of Severe Opioid Withdrawal:</u> 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.

## 4 mg NASAL SPRAY DESIGNED FOR EFFECTIVE INTRANASAL DELIVERY

Delivers approximately the same amount of naloxone as a 2 mg dose of IM naloxone.

## Mean ± SD Plasma Concentration of Naloxone, Following Intranasal Administration and Intramuscular Injection<sup>5</sup>



#### Study Results\*

Compared to a 0.4 mg dose of IM naloxone—the historical standard of care in opioid overdose rescue—NARCAN® Nasal Spray 4 mg showed:

- Greater C<sub>max</sub> compared to 0.4 mg IM dose<sup>5</sup>
- Comparable time to maximal plasma concentration (C<sub>max</sub>)
- A longer half-life (T<sub>1/2</sub>)<sup>5</sup>

#### **Study Design**

Open-label, randomized, crossover study, conducted in the United States, in 30 healthy adult volunteers (18-55 years of age). Mean ± SD Plasma Concentration of Naloxone.

A pharmacokinetic study comparing a 4 mg single nasal spray versus 0.4 mg intramuscular injection in healthy volunteers.5

#### **IMPORTANT SAFETY INFORMATION**

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.

Please see Important Safety Information on page 6 and accompanying full Prescribing Information.

<sup>\*</sup>The clinical significance of these results has not been measured and is not known.

#### KEY STEPS TO ADMINISTRATION5\*

## PEEL

Peel back the package to remove the device. Hold the device with your thumb on the bottom of the plunger and 2 fingers on the nozzle.

#### **PLACE**



Place and hold the tip of the nozzle in either nostril until your fingers touch the bottom of the patient's nose.

#### **PRESS**



Press the plunger firmly to release the dose into the patient's nose.

\*Administer in accordance with the Instructions for Use. Repeated doses may be necessary.

Not a substitute for emergency medical care. When administering NARCAN® Nasal Spray, always be sure to call 911 right away, even if the person wakes up. Keep the patient under surveillance or close watch. If breathing does not return to normal or if breathing difficulty resumes, after 2-3 minutes, give an additional dose of NARCAN® Nasal Spray using a new device in the alternate nostril.

### NARCAN® (naloxone HCI) NASAL SPRAY AFFORDABILITY AND ACCESS

ADAPT Pharma recognizes the urgency of the opioid epidemic and is increasing affordability and accessibility of NARCAN® Nasal Spray 4 mg to help reverse an opioid overdose.

#### **ADAPT Pharma offers Public Interest Pricing**

Wi	holesale Acquisition Cost (WAC) <sup>†</sup>	Public Interest Price (Qualified purchasers)	WAC Discount
	\$125 per carton	\$75 per carton (\$37.50 per dose)	40%

†WAC is the list price paid by a wholesaler, distributor and other direct accounts for drugs purchased from the wholesaler's supplier. Generally, it is the price listed by the manufacturer before any rebates, discounts, allowances or other price concessions are offered by the supplier of the product.

#### **Qualified purchasers include:**

- First responder, state or local government agency, school, or community-based organization
- Government-funded organization
- An entity that has received a grant for the purchase of the Product
- An entity that is purchasing the Product on behalf of a government entity or community members by acting as a naloxone distribution program or community-based organization

None of the above-described entities shall seek insurance reimbursement for the Product.

To find out more about our Public Interest Pricing, please call ADAPT Customer Service at 1-844-4NARCAN (1-844-462-7226), or visit https://www.narcan.com/direct-purchasers for more information and to complete in-take forms.

#### **IMPORTANT SAFETY INFORMATION**

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.

Please see Important Safety Information on page 6 and accompanying full Prescribing Information.

## STANDING ORDERS AND COLLABORATIVE PRACTICE AGREEMENTS

NARCAN® Nasal Spray is a prescription product. However, in many states, residents can purchase directly from a pharmacist under a Standing Order or Collaborative Practice Agreement (CPA). Collaborative Practice Agreements create a formal practice relationship between a pharmacist and another healthcare provider, and specify additional patient care services that can be provided by the pharmacist. Patient care services can include<sup>6</sup>:

- Modification of current drug therapy
- Initiation of new therapy
- Ordering of labs
- Physical assessment of the patient

#### INSURANCE COVERAGE FOR NARCAN® NASAL SPRAY

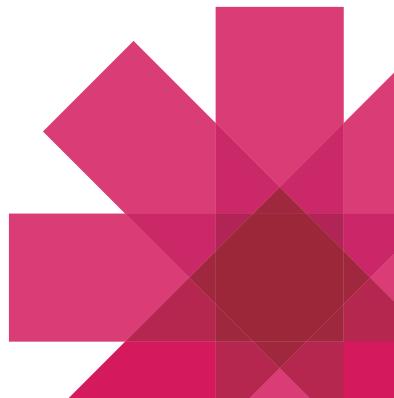
- 94% of insured lives in the U.S. have coverage for NARCAN® Nasal Spray\*
- Nearly 73% of prescriptions for NARCAN® Nasal Spray have a co-pay of \$10 or less§

Please have patients and family members contact their health insurance provider to find out coverage and co-pay requirements for NARCAN® Nasal Spray.

\*MMIT Formulary Analytics. Accessed March 2017 \$IMS Health, NPA Extended Insights Audit. Accessed March 2017

### **COMMUNITY PARTNERSHIPS**

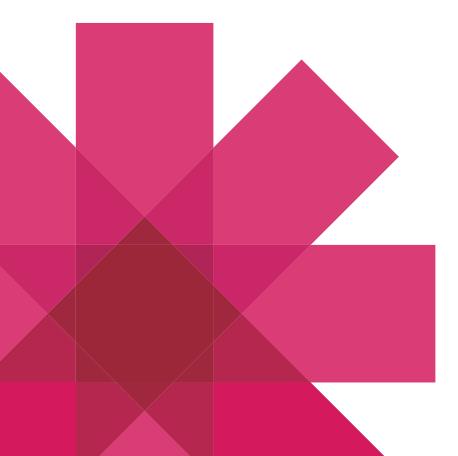
In response to the growing opioid overdose crisis in communities across the nation, ADAPT Pharma partners with state and local communities and organizations to support efforts in educating people about curbing opioid abuse and the appropriate use of opioid prescription medications, and efforts to implement scaled-up naloxone access and distribution policies.



### SUPPORT FOR SCHOOLS

ADAPT Pharma understands the crucial role that high schools, colleges and universities, in addition to other organizations, can play to change the course of the opioid overdose epidemic. To this end, ADAPT Pharma has provided grants to professional and community-based organizations for educational efforts about opioid abuse and the risks of opioid medications in the community. ADAPT will work with each State Department of Education and Health or individual school to help prepare high schools, colleges and universities across the country for an opioid overdose emergency by providing NARCAN® Nasal Spray.

ADAPT will provide access to 1 carton of NARCAN® Nasal Spray to high schools throughout the country and up to 4 cartons for a Title IV degree-granting college and university at no cost.



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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.

**References: 1.** Rudd RA, Seth P, David F, et al. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. Morbidity and Mortality Weekly Report. Centers for Disease Control and Prevention Website. 2016; 65(50-51);1445–1452. **2.** Centers for Disease Control and Prevention. Opioid Data Analysis. https://www.cdc.gov/drugoverdose/data/analysis.html. Accessed May 2017. **3.** 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. Accessed May 2017. **4.** Data on file. Adapt Pharma, Inc. Radnor, PA. 2017. **5.** NARCAN® Nasal Spray Prescribing Information. Adapt Pharma, Inc. Radnor, Pa. 2017. **6.** Pharmacy Association: Policy 101: Collaborative practice empowers pharmacists to practice as providers. https://www.pharmacist.com/policy-101-collaborative-practice-empowers-pharmacists-practice-providers. Accessed May 2017.

## To order or for more information:

**Call: 1-844-4NARCAN** 

Visit: NARCAN.com





