

## **IMPORTANT SAFETY INFORMATION**

### **What is the most important information I should know about NARCAN® (naloxone HCl) Nasal Spray?**

NARCAN® Nasal Spray is used to temporarily reverse the effects of opioid medicines. The medicine in NARCAN® Nasal Spray has no effect in people who are not taking opioid medicines. Always carry NARCAN® Nasal Spray with you in case of an opioid emergency.

1. Use NARCAN® Nasal Spray right away if you or your caregiver think signs or symptoms of an opioid emergency are present, even if you are not sure, because an opioid emergency can cause severe injury or death. Signs and symptoms of an opioid emergency may include:
  - unusual sleepiness and you are not able to awaken the person with a loud voice or by rubbing firmly on the middle of their chest (sternum)
  - breathing problems including slow or shallow breathing in someone difficult to awaken or who looks like they are not breathing
  - the black circle in the center of the colored part of the eye (pupil) is very small, sometimes called “pinpoint pupils,” in someone difficult to awaken
2. Family members, caregivers, or other people who may have to use NARCAN® Nasal Spray in an opioid emergency should know where NARCAN® Nasal Spray is stored and how to give NARCAN® before an opioid emergency happens.
3. **Get emergency medical help right away after giving the first dose of NARCAN® Nasal Spray.** Rescue breathing or CPR (cardiopulmonary resuscitation) may be given while waiting for emergency medical help.
4. The signs and symptoms of an opioid emergency can return after NARCAN® Nasal Spray is given. If this happens, give another dose after 2 to 3 minutes using a new NARCAN® Nasal Spray and watch the person closely until emergency help is received.

### **Who should not use NARCAN® Nasal Spray?**

**Do not use NARCAN® Nasal Spray** if you are allergic to naloxone hydrochloride or any of the ingredients in NARCAN® Nasal Spray.

### **What should I tell my healthcare provider before using NARCAN® Nasal Spray?**

Before using NARCAN® Nasal Spray, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems
- are pregnant or plan to become pregnant. Use of NARCAN® Nasal Spray may cause withdrawal symptoms in your unborn baby. Your unborn baby should be examined by a healthcare provider right away after you use NARCAN® Nasal Spray.
- are breastfeeding or plan to breastfeed. It is not known if NARCAN® Nasal Spray passes into your breast milk.

**Tell your healthcare provider about the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

### **What are the possible side effects of NARCAN® Nasal Spray?**

**NARCAN® Nasal Spray may cause serious side effects, including:**

**Sudden opioid withdrawal symptoms.** In someone who has been using opioids regularly, opioid withdrawal symptoms can happen suddenly after receiving NARCAN® Nasal Spray and may include:

- body aches
- diarrhea
- increased heart rate
- fever
- runny nose
- sneezing
- goose bumps
- sweating
- yawning
- nausea or vomiting
- nervousness
- restlessness or irritability
- shivering or trembling
- stomach cramping
- weakness
- increased blood pressure

In infants under 4 weeks old who have been receiving opioids regularly, sudden opioid withdrawal may be life-threatening if not treated the right way. Signs and symptoms include: seizures, crying more than usual, and increased reflexes.

These are not all of the possible side effects of NARCAN® Nasal Spray. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

***Please see the accompanying full Prescribing Information.***

Reference: 1. Data on file. ADAPT Pharma, Inc. Radnor, PA