

PATIENT INFORMATION
NARCAN (nar´ kan)
(naloxone hydrochloride)
Nasal Spray

You and your family members or caregivers should read this Patient Information leaflet before an opioid emergency happens. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about NARCAN 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.

What is NARCAN Nasal Spray?

- NARCAN Nasal Spray is a prescription medicine used for the treatment of an opioid emergency such as an overdose or a possible opioid overdose with signs of breathing problems and severe sleepiness or not being able to respond.
- NARCAN Nasal Spray is to be given right away and does not take the place of emergency medical care. Get emergency medical help right away after giving the first dose of NARCAN Nasal Spray, even if the person wakes up.
- NARCAN Nasal Spray is safe and effective in children for known or suspected opioid overdose.

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. See the end of this leaflet for a complete list of 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.

How should I use NARCAN Nasal Spray?

Read the “Instructions for Use” at the end of this Patient Information leaflet for detailed information about the right way to use NARCAN Nasal Spray.

- Use NARCAN Nasal Spray exactly as prescribed by your healthcare provider.
- Each NARCAN Nasal Spray contains only 1 dose of medicine and cannot be reused.
- NARCAN Nasal Spray comes in a 2 mg and 4 mg strength. Your healthcare provider will prescribe the one that is right for you.

- Lay the person on their back. Support their neck with your hand and allow the head to tilt back before giving NARCAN Nasal Spray.
- NARCAN Nasal Spray should be given into one nostril.
- If additional doses are needed, give NARCAN Nasal Spray in the other nostril.

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
 - sneezing
 - nervousness
 - diarrhea
 - goose bumps
 - restlessness or irritability
 - increased heart rate
 - sweating
 - shivering or trembling
 - fever
 - yawning
 - stomach cramping
 - runny nose
 - nausea or vomiting
 - 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 FDA at 1-800-FDA-1088.

How should I store NARCAN Nasal Spray?

- Store at room temperature 68°F to 77°F (20°C to 25°C).
- Avoid exposing Narcan Nasal Spray to excessive heat above 104°F (40°C).
- Do not freeze.
- Keep NARCAN Nasal Spray in its box until ready to use. Protect from light.
- Replace NARCAN Nasal Spray before the expiration date on the box.

Keep NARCAN Nasal Spray and all medicines out of the reach of children.

General information about the safe and effective use of NARCAN Nasal Spray.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use NARCAN Nasal Spray for a condition for which it was not prescribed. You can ask your pharmacist or healthcare provider for information about NARCAN Nasal Spray that is written for health professionals.

What are the ingredients in NARCAN Nasal Spray?

Active ingredient: naloxone hydrochloride

Inactive ingredients: benzalkonium chloride (preservative), disodium ethylenediaminetetraacetate (stabilizer), sodium chloride, hydrochloric acid to adjust pH and sterile water

NARCAN Nasal Spray is not made with natural rubber latex.

Distributed by Adapt Pharma, Inc., Plymouth Meeting, PA 19462 USA.

For more information, go to www.narcannasalspray.com or call 1-844-4NARCAN (1-844-462-7226).

This Patient Information has been approved by the U.S. Food and Drug Administration.

Issued: 03/2020