



# NARCAN<sup>®</sup> (naloxone HCl) NASAL SPRAY 4mg

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## WHAT IS NARCAN<sup>®</sup> NASAL SPRAY?

NARCAN<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Nasal Spray, even if the person wakes up because symptoms may return. Repeat doses may be necessary.

NARCAN<sup>®</sup> Nasal Spray is safe and effective in children for known or suspected opioid overdose.

## WHEN SHOULD NARCAN<sup>®</sup> NASAL SPRAY BE USED?

Use NARCAN<sup>®</sup> 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 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 his/her chest (sternum).
- Breathing problems including slow or shallow breathing in someone difficult to awaken or who looks like he/she is 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.

**Get emergency medical help right away in any cases of known or suspected overdose.** NARCAN<sup>®</sup> Nasal Spray is not a substitute for emergency medical care. Administer in accordance with the Instructions for Use.

## WHO SHOULD NOT USE NARCAN<sup>®</sup> NASAL SPRAY?

Do not use NARCAN<sup>®</sup> Nasal Spray if you are allergic to naloxone hydrochloride (HCl) or any of the ingredients in NARCAN<sup>®</sup> Nasal Spray, which include:

- Benzalkonium chloride (preservative)
- Disodium ethylenediaminetetraacetate (stabilizer)
- Sodium chloride
- Hydrochloric acid (to adjust pH)
- Sterile water

Use in infants with extreme caution.

Please see [Important Safety Information](#) and [full Prescribing Information](#)

## HOW SHOULD I USE NARCAN® NASAL SPRAY?

Read the Instructions for Use at the end of the 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.**
- 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.

## DOES NARCAN® NASAL SPRAY ONLY WORK IN THE NOSE?

Yes, NARCAN® Nasal Spray is for intranasal (in the nose/nostril) use only.

## BEFORE I USE NARCAN® NASAL SPRAY, DO I NEED TRAINING? DO I NEED TO ASSEMBLE NARCAN® OR MEASURE THE MEDICINE?

There is no special training, measuring or assembly required to use NARCAN® Nasal Spray. NARCAN® Nasal Spray comes as a ready-to-use device that contains a single, pre-filled, pre-measured dose of naloxone.

NARCAN® Nasal Spray should be used in accordance with the Instructions for Use contained in the **full Prescribing Information**. The caregiver should familiarize her/himself with these instructions in order to be sure to administer NARCAN® Nasal Spray properly.

## CAN I GIVE MYSELF NARCAN® NASAL SPRAY?

No, treatment of suspected opioid overdose must be performed by someone other than the affected person. If you have or are prescribed NARCAN® Nasal Spray, it's important to tell family, roommates, caregivers, friends, and others around you where you keep NARCAN® Nasal Spray (at home, on your person, in your car, etc.) and how and when to use it. Also, inform them that NARCAN® Nasal Spray should always be given in accordance with the Instructions for Use, which are included in the package.

## HOW DOES NARCAN® NASAL SPRAY WORK?

NARCAN® Nasal Spray is administered in the nostril and does not require evidence of breathing through the nose during administration.

When someone takes an overdose of opioids, the opiates overwhelm certain areas in the brain and interrupt a key part of the body's impulse to breathe. Breathing slows dangerously or stops. Quickly rescuing this person is crucial because prolonged, severe breathing problems can lead to brain injury or death.

## HOW DOES

### NARCAN® NASAL SPRAY WORK? (continued)

Naloxone, the active ingredient in NARCAN® Nasal Spray, competes with opioids to bind with the same receptors in the brain. Usually, it reverses the effects of opioid overdose in 2 to 3 minutes. This buys the opioid-poisoned person time for emergency medical help to arrive. If necessary, a bystander can give an additional dose of NARCAN® Nasal Spray if the patient doesn't respond, doesn't respond enough or relapses into breathing problems while awaiting additional help.

**Get emergency medical help right away in any cases of known or suspected overdose emergency.** NARCAN® Nasal Spray is not a substitute for emergency medical care. Administer in accordance with the Instructions for Use.

## HOW LONG DOES

### NARCAN® NASAL SPRAY TAKE TO WORK?

If the patient does not respond in 2 to 3 minutes or responds and then relapses into respiratory depression, additional doses of NARCAN® Nasal Spray may be given every 2 to 3 minutes until emergency medical assistance arrives.

Each device is a single dose. **If an additional dose is needed, you must use another device.**

**Get emergency medical help right away in any cases of known or suspected overdose emergency.** NARCAN® Nasal Spray is not a substitute for emergency medical care. Administer in accordance with the Instructions for Use.

## CAN I REUSE

### NARCAN® NASAL SPRAY?

No, you cannot reuse NARCAN® Nasal Spray. Each device is single-use, single-dose only. It is intended to be sprayed once, in a nostril, and then discarded.

## IS IT POSSIBLE TO USE ONLY HALF THE CONTENTS?

No, the device is designed and FDA-approved to provide a single 4 mg dose of naloxone. It is intended to be sprayed once, in a nostril, and then discarded.

## HOW LONG DOES NARCAN® NASAL SPRAY WORK? WILL A SECOND DOSE BE NEEDED?

NARCAN® Nasal Spray has been shown in studies to stay in the body for about 2 hours.

A second dose of NARCAN® Nasal Spray may be necessary. One dose of naloxone may not be enough to reverse the effects of an opioid overdose that involves strong opioids or more. Or, sometimes, the naloxone dose can wear off before the opioids—necessitating another dose.

## HOW LONG DOES NARCAN® NASAL SPRAY WORK?

### WILL A SECOND DOSE BE NEEDED? (continued)

Emergency medical services (EMS) will have been called immediately and will hopefully arrive before a second dose is needed. But if help hasn't arrived, bystanders can administer additional doses of NARCAN® Nasal Spray every 2 to 3 minutes in alternating nostrils if the patient doesn't respond, responds insufficiently or relapses back into respiratory depression.

**Get emergency medical help right away in any cases of known or suspected overdose emergency.** NARCAN® Nasal Spray is not a substitute for emergency medical care. Administer in accordance with the Instructions for Use.

## 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 DO YOU ADMINISTER NARCAN® NASAL SPRAY?

Key steps to administering NARCAN® Nasal Spray:

- **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** the tip of the nozzle in either nostril until your fingers touch the bottom of the patient's nose.
- **PRESS** the plunger firmly to release the dose into the patient's nose.

Remove the device from the nostril and, if you haven't already done so, get emergency help right away. Continue to watch the patient. Most patients respond within 2 to 3 minutes.

If help hasn't arrived yet and the patient is not responding after 2 to 3 minutes, or responds and then relapses back into respiratory depression, give another dose. **Make sure to use another device, as each device contains only one dose.**

**Get emergency medical help right away in any cases of known or suspected overdose emergency.** NARCAN® Nasal Spray is not a substitute for emergency medical care. Administer in accordance with the Instructions for Use.

These steps are not comprehensive. See the [Instructions for Use](#) for more information.

**Administer in accordance with the Instructions for Use**

## IS NARCAN® NASAL SPRAY ADDICTIVE?

No, naloxone has no potential for abuse or overdose. It does not work in the absence of opioids.

## 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 less than 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**.

View [full Prescribing Information](#).

## WHAT ARE THE INGREDIENTS IN NARCAN® NASAL SPRAY?

**Active ingredient:** naloxone hydrochloride

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

NARCAN® Nasal Spray is not made with natural rubber latex.

## HOW SHOULD I STORE NARCAN® NASAL SPRAY?

- Store NARCAN® Nasal Spray at room temperature between 59°F to 77°F (15°C to 25°C). NARCAN® Nasal Spray may be stored for short periods up to 104°F (40°C).
- Do not freeze NARCAN® Nasal Spray.
- Keep the 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**

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