

# How To Recognize An Opioid Overdose Emergency

 **Kloxxado** (naloxone HCl)  
nasal spray 8 mg

kloxxado.com



**40%**

**A bystander was present** for nearly 40% of fatal overdoses.<sup>1</sup>

**You could be that bystander. Are you ready?**

## Signs of an opioid overdose emergency

During an opioid overdose, breathing can decline drastically or stop, causing brain damage and death.<sup>2</sup> Check for the following signs so you can act fast.



Person will not wake up and does not respond to your voice or touch (e.g., rubbing firmly on the middle of their chest).<sup>2</sup>



Breathing is very slow, irregular, or has stopped.<sup>2</sup>



Center part of their eye is very small, also known as “pinpoint pupils.”

## Take action right away

Take action if you suspect an opioid overdose emergency, even if you’re not sure. It could save someone’s life.



### Administer naloxone.<sup>3</sup>

Naloxone is a life-saving medication that can reverse an overdose from opioids.



### Call 911.<sup>3</sup>

Explain that someone is not responsive and not breathing.



### Stay with the person.<sup>3</sup>

Help them feel more comfortable until emergency help arrives. Be prepared to administer a second dose of naloxone after 2 to 3 minutes if they are still unresponsive.

# Opioid overdoses can be dangerous — even fatal. Be ready.

Patients who overdose and spend more time without breathing are at a higher risk of death or complications such as organ damage and/or brain damage.<sup>4</sup> Kloxxado® is a nasally-administered form of naloxone that reverses the effects of opioid overdose. Visit [Kloxxado.com](https://www.kloxxado.com) to find out more.<sup>2</sup>

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**NOTE:** This infographic was not written by a medical professional and is not intended to substitute for the guidance of a physician. These are not Hikma's recommendations, but rather facts and data collected from various reliable medical sources. See below.

## Sources:

<sup>1</sup> CDC, 2020, "Overdose Deaths and the Involvement of Illicit Drugs." <https://www.cdc.gov/drugoverdose/featured-topics/V5-overdose-deaths-illicit-drugs.html>, Accessed September 15, 2021.

<sup>2</sup> KLOXXADO® (naloxone HCl) Nasal Spray [prescribing information]. Columbus, OH: Hikma Specialty USA Inc., 2021.

<sup>3</sup> CDC, "Preventing an Opioid Overdose," <https://www.cdc.gov/stopoverdose/naloxone/index.html>. Accessed March 24, 2022.

<sup>4</sup> NIDA 2021, "Prescription Opioid DrugFacts," <https://www.drugabuse.gov/publications/drugfacts/prescription-opioids>, Accessed June 1, 2021.

## Important Safety Information About KLOXXADO® (naloxone HCl) Nasal Spray 8 mg

### Contraindications

Hypersensitivity to naloxone hydrochloride or to any of the other ingredients

### Warnings and Precautions

- Use KLOXXADO® right away if you suspect an opioid overdose emergency, even if you are not sure, because an opioid overdose emergency can cause severe injury or death. Signs and symptoms of an opioid overdose emergency may include:
  - Unusual sleepiness; 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.
- Family members, caregivers or other people who may have to use KLOXXADO® in an opioid overdose emergency should know where KLOXXADO® is stored and how to give KLOXXADO® before an opioid overdose emergency happens.
- **Get emergency medical help right away after using the first dose of KLOXXADO®.** Rescue breathing or CPR (cardiopulmonary resuscitation) may be needed while waiting for emergency medical help.
- The signs and symptoms of an opioid overdose emergency can return after KLOXXADO® is given. If this happens, give another dose after 2 to 3 minutes, using a new KLOXXADO® device, alternating nostrils, and watch the person closely until emergency medical help arrives.
- Do not use KLOXXADO® if you are allergic to naloxone hydrochloride or any of the ingredients in KLOXXADO®.

- KLOXXADO® can cause sudden and severe opioid withdrawal, the symptoms of which may include body aches, diarrhea, increased heart rate, fever, runny nose, sneezing, goosebumps, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, stomach cramps, weakness and increased blood pressure.
- In infants, opioid withdrawal may be life-threatening if not recognized and properly treated. Infants going through opioid withdrawal may have seizures, cry more than normal, and have increased reflexes.
- Tell your doctor about all of your medical conditions before using KLOXXADO®, including if you have heart problems, are pregnant or plan to become pregnant.
- Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, drugs, vitamins and herbal supplements.

### Side Effects

The following serious side effect is discussed in the full Prescribing Information for KLOXXADO®:

- Sudden and Severe Opioid Withdrawal

Symptoms of sudden and severe opioid withdrawal resulting from the use of KLOXXADO® in someone regularly using opioids include: body aches, diarrhea, increased heart rate, fever, runny nose, sneezing, goosebumps, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, stomach cramps, weakness and increased blood pressure.

Infants may have seizures, cry more than normal and have increased reflexes.

Some people may become aggressive after abrupt reversal of opioid overdose.

In two clinical studies, a total of 47 healthy adult volunteers were exposed to a single dose of KLOXXADO®, one spray in one nostril. Side effects were reported in two subjects for each of the following: abdominal pain, asthenia, dizziness, headache, nasal discomfort, and presyncope.

These are not all of the possible side effects of KLOXXADO®. Contact your doctor for medical advice about side effects.

### Pregnancy, Infancy and Breastfeeding, Children

Tell your doctor if you are pregnant or plan to become pregnant. If you are pregnant and opioid dependent, use of KLOXXADO® may cause withdrawal symptoms in you and your unborn baby. A healthcare provider should monitor you and your unborn baby right away after you use KLOXXADO®.

There is no information regarding the presence of naloxone in human milk, the effects of naloxone on the breastfed infant or on milk production.

If the primary concern is an infant at risk of an overdose, consider whether other naloxone-containing products may be more appropriate.

KLOXXADO® nasal spray is safe and effective in children for known or suspected opioid overdose.

### Dosage and Administration

Do not attempt to prime or test-fire the device. Each KLOXXADO® Nasal Spray contains only 1 dose of medicine and cannot be reused. Read the "instructions for use" at the end of the Prescribing Information and Medication Guide for detailed information about the right way to use KLOXXADO® Nasal Spray.

### Storage and Handling

Store KLOXXADO® at room temperature between 59°F to 77°F (15°C to 25°C). KLOXXADO® may be stored for short periods between 39°F to 104°F (4°C to 40°C). Do not store above 40°C (104°F). Do not freeze KLOXXADO®. Keep KLOXXADO® in its box until ready to use. Protect from light. Replace KLOXXADO® before the expiration date on the box. Keep KLOXXADO® and all medicines out of the reach of children.

**For more information, please see the full Prescribing Information and Medication Guide, which you can find on our website at [www.kloxxado.com](https://www.kloxxado.com).**

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <https://www.fda.gov/medwatch> or call 1-800-FDA-1088.

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