

Kloxxado™ (naloxone HCl) nasal spray 8 mg

QUICK INSTRUCTIONS

Use KLOXXADO™ nasal spray for known or suspected opioid overdose in adults and children.

Important: For use in the nose only

Do not remove or test the KLOXXADO™ nasal spray until ready to use

1. IDENTIFY OPIOID OVERDOSE

Check for signs of an opioid overdose:

- Person will not wake up and does not respond to your voice or touch
- Breathing is very slow, irregular, or has stopped
- Center part of their eye is very small, also known as “pinpoint pupils”

Place the person on their back to give a dose of KLOXXADO™ nasal spray.



2. GIVE KLOXXADO NASAL SPRAY

REMOVE KLOXXADO™ nasal spray from the box.

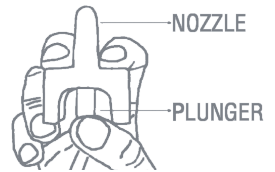
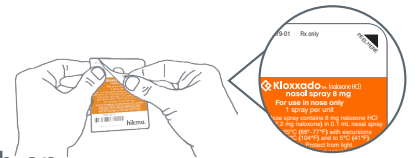
Peel off the back tab with the triangle (▲) to open the KLOXXADO™ nasal spray blister.

HOLD the KLOXXADO™ nasal spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle (**do not apply any pressure until you are ready to give the dose**).

INSERT the tip of the nozzle into one nostril.

- Tilt the person’s head back and provide support under the neck with your hand.
- Gently insert the tip of the nozzle into **one nostril** until your fingers on either side of the nozzle are against the bottom of the person’s nose.

PRESS the plunger firmly to give the dose of KLOXXADO™ nasal spray. Remove the KLOXXADO™ nasal spray from the nostril after giving the dose.



3. CALL FOR EMERGENCY MEDICAL HELP RIGHT AWAY AND WATCH THE PERSON CLOSELY

Get emergency medical help right away. Move the person on their side (recovery position) after giving the KLOXXADO™ nasal spray.

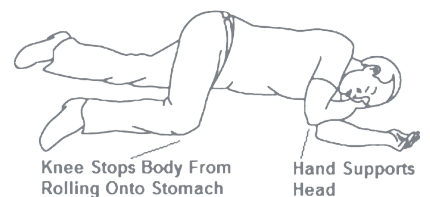
Watch the person closely.

If the person does not respond by waking up, to voice or touch, or start breathing normally, **another dose may be given.**

KLOXXADO™ nasal spray can be dosed every 2 to 3 minutes, if available.

Repeat Step 2 using a new KLOXXADO™ nasal spray to give another dose in the other nostril. If additional KLOXXADO™ nasal sprays are available, repeat Step 2 every 2 to 3 minutes until the person responds or emergency medical help is received.

Caution: In some opioid users, **sudden opioid withdrawal syndromes may occur.** They include but not limited to: agitation, muscle aches, shivering, sweating, goose bumps, yawning, runny nose, and increased heart rate.



KLOXXADO™ (naloxone hydrochloride) Nasal Spray**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.

Across KLOXXADO's™ two PK studies, adverse reactions 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 59F to 77F (15C to 25C). 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 at 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.

Distributed by:

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