

## DIRECTIONS FOR USE

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.



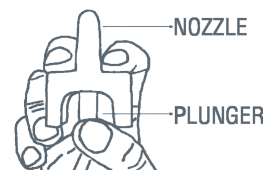
### 2. GIVE KLOXXADO NASAL SPRAY

**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

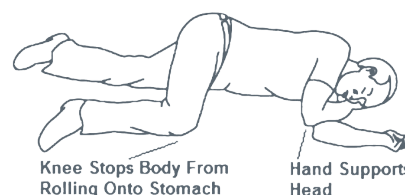
**Get emergency medical help right away. Move the person on their side (recovery position)** after giving the KLOXXADO nasal spray.

**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: Sudden opioid withdrawal symptoms may occur.**

**Please see reverse side for Indication and full Important Safety Information and accompanying full Prescribing Information.**

## INDICATION AND IMPORTANT SAFETY INFORMATION

### What is KLOXXADO® Nasal Spray?

- KLOXXADO® Nasal Spray is a prescription medicine used for the treatment of an opioid emergency such as an overdose or a possible opioid overdose in adults and children with signs of breathing problems and severe sleepiness or not being able to respond.
- KLOXXADO® 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 KLOXXADO® Nasal Spray, even if the person wakes up.

### What is the most important information I should know about KLOXXADO® Nasal Spray?

Get emergency medical help right away after giving the first dose of KLOXXADO® Nasal Spray. The signs and symptoms of an opioid emergency can return after KLOXXADO® Nasal Spray is given. If this happens, give another dose after 2 to 3 minutes using a new KLOXXADO® Nasal Spray and watch the person closely until emergency help is received.

The medicine in KLOXXADO® Nasal Spray is safe to use in people who are not taking opioids. KLOXXADO® Nasal Spray is not intended for self-administration.

### What should I tell my healthcare provider (pharmacist or prescriber) before using KLOXXADO® Nasal Spray?

Before using KLOXXADO® 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 KLOXXADO® 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 KLOXXADO® Nasal Spray.
- are breastfeeding or plan to breastfeed. It is not known if KLOXXADO® Nasal Spray passes into your breast milk.

### What are the possible serious side effects of KLOXXADO® Nasal Spray?

KLOXXADO® Nasal Spray may cause sudden opioid withdrawal symptoms including 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, and 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.

### Who should not use KLOXXADO® Nasal Spray?

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

### What are the most common side effects of KLOXXADO® nasal spray?

The most common side effects of KLOXXADO® Nasal Spray in adults include stomach-area (abdomen) pain, weakness, dizziness, headache, nose (nasal) discomfort, and a feeling like you are going to faint.

These are not all of the possible side effects of KLOXXADO® Nasal Spray. **Please see the accompanying full Prescribing Information, including Patient Information, which includes a more complete discussion of the risks associated with KLOXXADO® Nasal Spray.** Always contact your healthcare provider (pharmacist or prescriber) if you have questions or experience any side effects.

You are encouraged to report negative side effects to the FDA at: 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch). You can also contact Hikma Specialty USA Inc. at: [us.hikma@primevigilance.com](mailto:us.hikma@primevigilance.com) or call 1-877-845-0689 or 1-800-962-8364.

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