

When the Clock is Ticking, Choose Kloxxado®

Save a life from
opioid overdose.^{1,2}

INDICATION

KLOXXADO® is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult and pediatric patients. KLOXXADO® is intended for immediate administration as emergency therapy in settings where opioids may be present. KLOXXADO® is not a substitute for emergency medical care.

See full ISI on interior spread.



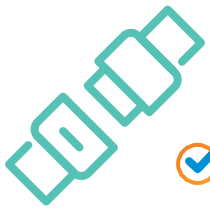
Accidents happen.

Just like a car wreck or house fire, you'll never see it coming.

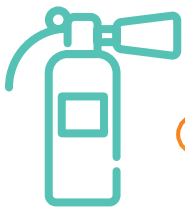
But doing one simple thing may prevent an accidental opioid overdose from being fatal.² Keep yourself, your family and your friends prepared.

Keep KLOXXADO® as part of your first aid kit.

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.¹



 Wear your seat belt



 Keep a fire extinguisher



 Carry KLOXXADO®

This can reverse the effects.¹

The medicine in KLOXXADO® is the same proven medicine that first responders have used for a suspected overdose for more than 50 years.³ Administering naloxone isn't likely to harm someone, but it could save their life.²

For people who are opioid-dependent, withdrawal can occur (body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness and increased blood pressure), but is usually not life threatening.¹

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Be ready with more naloxone.^{1,4}

2x

KLOXXADO® (naloxone HCl) Nasal Spray 8 mg contains twice as much medicine per spray as Narcan® (naloxone HCl) Nasal Spray 4 mg.^{1,4}



78% of opioid overdose reversals involved ≥ 2 doses of naloxone and 30% used ≥ 3 doses.⁵

Ask your doctor about KLOXXADO®.

If you're on an opioid, your risk for accidental opioid overdose could be higher if⁶:

- you're taking a benzodiazepine (certain anxiety, insomnia or seizure medicines)
- you have a respiratory condition like COPD or sleep apnea
- you're currently in recovery for or have a history of substance use disorder (SUD)
- you're being treated for mental illness

“Your doctor is ready to talk about Kloxado®. Trust your doctor. The idea of discussing the risks of opioid overdose may be uncomfortable, but your doctor is ready for it.”

Be prepared. Take action. Save lives.²

When an unintentional, life-threatening overdose happens, use KLOXXADO® to block opioid receptors and to reverse the effects of the drug, then call 911.¹

- KLOXXADO® is ready to use. You do not need to prime or test the device.¹
- Overdoses involving highly potent opioids may require more naloxone to reverse, so KLOXXADO® contains more naloxone per dose.^{1,4,7}
- Keep monitoring the person after giving KLOXXADO®. Some opioids may outlast the reversal effect of KLOXXADO®, so the person may require additional dose(s).¹

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

Pay as
little as **\$0***

With the first ever
manufacturer's savings
card for a naloxone
nasal spray

RxBin: XXXXXX
PCN: XX
Group: XXXXXXXX
Member ID: XXXXXXXXXXXX

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\$0 could save a life⁸

KLOXXADO® is the first naloxone nasal spray to offer a savings card. **Pay as little as \$0 (up to \$40 savings for eligible patients).⁸**

To learn more about KLOXXADO® and download the savings card, please visit **www.kloxxado.com**.

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BRIEF SUMMARY OF SAFETY²

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.

Risk of Recurrent Respiratory & CNS Depression; Risk of limited efficacy with partial agonists or mixed agonist/antagonists; Precipitation of severe opioid withdrawal; Risk of CV effects

See full ISI on interior spread.

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

CONTRAINDICATIONS

- Hypersensitivity to naloxone hydrochloride or to any of the other ingredients in KLOXXADO®

WARNINGS AND PRECAUTIONS

• Risk of Recurrent Respiratory and Central Nervous System Depression

Seek emergency assistance immediately after administration of the first dose and keep the patient under continued surveillance. The duration of action of most opioids may exceed that of KLOXXADO®, resulting in a return of respiratory and/or central nervous system depression after an initial improvement in symptoms. Administer additional doses as necessary if the patient is not adequately responding or responds and then relapses back into respiratory depression.

• Risk of Limited Efficacy With Partial Agonists or Mixed Agonist/Agonists

Reversal of respiratory depression by partial agonists or mixed agonist/antagonists may be incomplete. Larger or repeat doses of naloxone hydrochloride may be required.

• Precipitation of Severe Opioid Withdrawal

Use in patients who are opioid-dependent may precipitate opioid withdrawal characterized by body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness and increased blood pressure. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated and may include convulsion, excessive crying and hyperactive reflexes. Monitor the patient for the development of the signs and symptoms of opioid withdrawal. For more information about management of opioid withdrawal, see the full Prescribing Information.

Abrupt reversal of opioid effects in persons who were physically dependent on opioids has precipitated an acute withdrawal syndrome. In some patients, there was aggressive behavior upon abrupt reversal of an opioid overdose.

Abrupt postoperative reversal of opioid depression after using naloxone hydrochloride may result in nausea, vomiting, sweating, tremulousness, tachycardia, hypotension, hypertension, seizures, ventricular tachycardia and fibrillation, pulmonary edema and cardiac arrest. Death, coma and encephalopathy have been reported as sequelae of these events. These events have primarily occurred in patients who had pre-existing cardiovascular disorders or received other drugs that may have similar adverse cardiovascular effects. Monitor these patients closely in an appropriate healthcare setting.

References

- 1 KLOXXADO® (Naloxone HCl) Nasal Spray [prescribing information]. Columbus, OH: Hikma Specialty USA Inc.; 2021.
- 2 Having Naloxone on Hand Can Save a Life During an Opioid Overdose. Food and Drug Administration. Accessed May 3, 2021. <https://www.fda.gov/consumers/consumer-updates/having-naloxone-hand-can-save-life-during-opioid-overdose>.
- 3 Jordan MR, Morrisonponce D. Naloxone. StatPearls. Accessed March 26, 2021. <https://www.ncbi.nlm.nih.gov/books/NBK441910/>.
- 4 NARCAN® (Naloxone HCl) Nasal Spray [prescribing information]. Plymouth Meeting, PA: Adapt Pharma, Inc.; 2020.
- 5 Abdelal R, et al. Real world study of multiple naloxone administration for opioid overdose reversal among bystanders [abstract F6]. In: Journal of Managed Care & Specialty Pharmacy Meeting Supplement 2021;27(10-a Suppl):S54.
- 6 Naloxone: the opioid reversal drug that saves lives. US Department of Health and Human Services. Accessed March 26, 2021. <https://www.hhs.gov/opioids/sites/default/files/2018-12/naloxone-coprescribing-guidance.pdf>.
- 7 Naloxone. National Institutes of Health. Accessed March 26, 2021. <https://www.drugabuse.gov/publications/drugfacts/naloxone>.
- 8 KLOXXADO® (Naloxone HCl) Nasal Spray Savings Card [terms and conditions]. Columbus, OH: Hikma Specialty USA Inc.; 2021.

ADVERSE REACTIONS

In two pharmacokinetic studies, a total of 47 healthy adult volunteers were exposed to a single dose of KLOXXADO®, one spray in one nostril.

- Adverse reactions were reported in two subjects for each of the following: abdominal pain, asthenia, dizziness, headache, nasal discomfort, and presyncope.
- Signs of nasal inflammation and nasal congestion were observed
- Serious adverse reactions reported: none

The following most frequently reported events (in decreasing frequency) have been identified primarily during post-approval use of naloxone hydrochloride: withdrawal syndrome, vomiting, nonresponsiveness to stimuli, drug ineffective, agitation, somnolence, and loss of consciousness.

USE IN SPECIFIC POPULATIONS

• Pregnancy

Naloxone may precipitate opioid withdrawal in the pregnant woman and fetus. Careful monitoring is needed until the fetus and mother are stabilized.

• Infants

In situations where the primary concern is for infants at risk for opioid overdose, consider the availability of alternate naloxone-containing products.

For more information, please see the full Prescribing Information and Patient Information, which you can find on our website 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.



Distr. by: Hikma Specialty USA Inc.
Columbus, OH 43228

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