

Should naloxone be part of your first aid kit?

In 2018, fewer than 2 percent of patients at risk of an opioid overdose went home with naloxone.¹ Were you one of them? If you're going to be around opioids, carry Kloxxado™ in case of an emergency. Kloxxado™ contains naloxone HCl,² which is an opioid reversal medication that when given in time, may save a life.³

Use this checklist to determine if you or a family member may be at risk for experiencing or witnessing an opioid overdose. If one or more of the following apply, talk with your doctor or pharmacist about Kloxxado™.^{4, 5}

- You use alcohol or anti-depressants in addition to opioids.

- You're taking a benzodiazepine (anxiety, insomnia or seizure medicines like Ativan®, Xanax®, Valium® or Klonopin®) in addition to opioids.

- You have a respiratory condition such as COPD* or sleep apnea along with taking opioids.

- You take opioids and have been diagnosed with a mental health disorder.

- You have a history of an opioid use disorder.

- You were recently discharged from emergency medical care following an opioid overdose.

- You've recently stopped using opioids, or you're in recovery from opioid use disorder.

- You use drugs such as cocaine or meth (these may be contaminated with opioids).

- You suspect a family member or friend may have a substance use disorder or be misusing opioids.

- You have taken opioids in the past, and were recently discharged from a setting in which you had limited access to opioids (e.g., incarceration).

- You presently are taking an opioid but don't know how "high" your opioid dose is or whether it warrants a prescription for Kloxxado™.

- You feel concerned about opioid misuse in your community and want to be prepared to save a life.

Overdoses can be dangerous—even fatal

Patients who overdose and spend more time without breathing are at a higher risk of life threatening complications such as pulmonary edema, kidney damage, and brain injuries. Keeping naloxone as part of your first aid kit is a simple safety measure to protect yourself or those around you from a potential opioid overdose.

Be ready with Kloxxado™

Kloxxado™ is a nasally-administered form of naloxone,² trusted by healthcare providers for reversing the effects of opioid overdose.⁶ Learn more at Kloxxado.com.

NOTE: This checklist was not written by a medical professional and is not intended to be a 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.

*Chronic obstructive pulmonary disease (COPD)

Sources:

¹ Guy GP Jr, et al. 2019, "Vital signs: pharmacy-based naloxone dispensing – United States, 2012–2018," MMWR. 2019;68(31):679–686.

² KLOXXADO™ (naloxone HCl) Nasal Spray [prescribing information]. Columbus, OH: Hikma Specialty USA Inc., 2021.

³ NIDA. "Naloxone DrugFacts." National Institute on Drug Abuse, Jun. 2021, <https://www.drugabuse.gov/publications/drugfacts/naloxone>.

⁴ Office of the Surgeon General. "U.S. Surgeon General's Advisory on Naloxone and Opioid Overdose." <https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html>.

⁵ 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>.

⁶ Jordan MR, Morrisonponce D. Naloxone. 2021 Jul 13. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan–. PMID: 28722939.

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.

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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