



Kloxxado™ (naloxone) – New drug approval

- On April 30, 2021, the [FDA announced](#) the approval of [Hikma Pharmaceuticals' Kloxxado \(naloxone\)](#), 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.
- Kloxxado delivers 8 mg of naloxone into the nasal cavity. The FDA had previously approved 2 mg and 4 mg naloxone nasal spray products.
- The FDA approved Kloxxado through the 505(b)(2) pathway using safety and effectiveness for naloxone ([Narcan®](#)) to support approval.
- Warnings and precautions for Kloxxado include risk of recurrent respiratory and central nervous system depression, risk of limited efficacy with partial agonists or mixed agonist/antagonists, and precipitation of severe opioid withdrawal.
- The following adverse reactions were reported with Kloxxado in two adult patients each: abdominal pain, asthenia, dizziness, headache, nasal discomfort, and presyncope.
- The recommended initial dose of Kloxxado is one spray delivered by intranasal administration into one nostril, which delivers 8 mg of naloxone hydrochloride to adult or pediatric patients. After administering the first dose of Kloxxado, patients should seek emergency medical assistance as soon as possible.
 - If the desired response is not obtained after 2 or 3 minutes, an additional dose should be administered using a new Kloxxado in alternate nostril. If there is still no response and additional doses are available, additional doses should be administered every 2 to 3 minutes, alternating nostrils and using a new Kloxxado, until emergency medical assistance arrives. The requirement for repeat doses of Kloxxado depends upon the amount, type, and route of administration of the opioid being antagonized.
 - Refer to the Kloxxado drug label for complete dosing and administration recommendations.
- Hikma Pharmaceuticals plans to launch Kloxxado in the second half of 2021. Kloxxado will be available as a 8 mg/0.1 mL single-dose, intranasal spray.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at [optum.com](#).

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2021 Optum, Inc. All rights reserved.