

## Naloxone nasal spray - New drug approval

- On March 8, 2023, <u>Amphastar Pharmaceuticals announced</u> the <u>FDA approval</u> of <u>naloxone nasal spray</u>, for emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult and pediatric patients.
  - Naloxone nasal spray is intended for immediate administration as emergency therapy in settings where opioids may be present.
  - Naloxone nasal spray is not a substitute for emergency medical care.
- Other intranasal formulations of naloxone include <u>Narcan<sup>®</sup></u> (available generically) and <u>Kloxxado<sup>™</sup></u>.
  Both are also approved for the emergency treatment of known or suspected opioid overdose.
- Warnings and precautions for naloxone nasal spray include risk of recurrent respiratory and central nervous system depression; limited efficacy with partial agonists or mixed agonist/antagonists; and precipitation of severe opioid withdrawal.
- The most common adverse reactions with naloxone nasal spray use were oral paraesthesia and headache.
- The recommended initial dose of naloxone nasal spray in adults and pediatric patients is one spray delivered by intranasal administration, which delivers 4 mg of naloxone.
  - For repeat dosing instructions, refer to the naloxone drug label.
- Amphastar Pharmaceuticals' launch plans for naloxone nasal spray are pending. Naloxone nasal spray will be available as a carton containing two unit-dose naloxone nasal spray devices (each delivers a single spray containing 4 mg of naloxone).



At Optum, we help create a healthier world, one insight, one connection, one person at a time. All Optum trademarks and logos are owned by Optum, Inc., in the U.S. and other jurisdictions. All other trademarks are the property of their respective owners. This document contains information that is considered proprietary to Optum Rx and should not be reproduced without the express written consent of Optum Rx. RxNews® is published by the Optum Rx Clinical Services Department.