Emergent BioSolutions Expands NARCANDirect® to Offer KLOXXADO® (naloxone HCl) Nasal Spray 8 mg and Convenience Kits Amid Changes in Overdose Death Rate

July 2, 2025

Starting July 1, 2025, additional opioid overdose response tools will be available to continue addressing evolving patient and customer needs to combat public health crisis

GAITHERSBURG, Md., July 02, 2025 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) today announced the expansion of its proprietary NARCANDirect® online distribution network to include KLOXXADO® (naloxone HCl) Nasal Spray 8 mg. The platform provides qualified direct purchasers, including emergency medical services, law enforcement, fire departments, government agencies, schools/universities and community-based naloxone distribution programs with streamlined access to opioid overdose response products. This addition complements the existing availability of NARCAN® (naloxone HCl) Nasal Spray 4 mg, increasing access to naloxone across the United States.

In January 2025, Emergent acquired exclusive commercial rights to KLOXXADO® Nasal Spray in the U.S. and Canada in an effort to help save lives by increasing access and availability of life-saving naloxone. By distributing both NARCAN® Nasal Spray 4 mg and KLOXXADO® Nasal Spray 8 mg through Emergent's expansive distribution networks, key stakeholders and communities now have more options in responding to opioid emergencies. KLOXXADO® Nasal Spray is a higher dose prescription emergency treatment for a known or suspected opioid overdose. NARCAN® Nasal Spray is available across the U.S and Canada and continues to be a trusted 4 mg naloxone standard of care in the community setting.

Expanding naloxone tools through NARCANDirect® comes at a pivotal moment in the ongoing fight against the opioid epidemic as provisional data released in May from the Centers for Disease Control and Prevention (CDC) show that drug overdose deaths in 2024 decreased 27 percent, with opioid-related deaths dropping by 34 percent from 2023.[1] Shortly after this initial report, the CDC reported new provisional data available as of June 1, 2025 that found overdose deaths increased by roughly 1,400 in a 12-month period from January 2024 to January 2025.[2,3] This incremental increase demonstrates the persistent and evolving nature of the opioid crisis, further reinforcing the continued need for new tools and ongoing support to ensure widespread opioid emergency preparedness.

"Tremendous progress in the fight against the opioid epidemic has been made since NARCAN® Nasal Spray became available over the counter in 2023, but this most recent uptick in overdose deaths reaffirms that we cannot simply stay the course," says Paul Williams, senior vice president, head of products business, global government & public affairs at Emergent. "Adding KLOXXADO® to our NARCANDirect® distribution is an important step in broadening access to naloxone and saving more lives. We will continue to work with partners across sectors to adopt new approaches and make systemic changes to ensure businesses, communities and individuals nationwide are ready to rescue."

Emergent is also introducing Convenience Kits on NARCANDirect®, which will equip frontline responders and community programs with the requested components of one medical-grade CPR mask and one pair of nitrile examination gloves for overdose response, provided in a durable hard case with internal pockets. To access these new offerings, public interest customers should visit NARCANDirect.com. Consumers, patients and healthcare providers can visit KLOXXADO.com and NARCAN.com to learn how to be prepared in an opioid overdose emergency with life-saving intranasal naloxone.

About NARCAN® Nasal Spray

NARCAN® Naloxone HCl Nasal Spray 4 mg is the first FDA-approved, over-the-counter (OTC) 4 mg naloxone product for the emergency treatment of opioid overdose. NARCAN® Nasal Spray is not a substitute for emergency medical care. Repeat dosing may be necessary. Use as directed.

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

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 **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. You can also contact Hikma Specialty USA Inc. at: us.hikma@primevigilance.com or call 1-877-845-0689 or 1-800-962-8364.

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About Emergent BioSolutions
At Emergent, our mission is to protect and save lives. For over 25 years, we've been at work preparing those entrusted with protecting public health. We deliver protective and life-saving solutions for health threats like smallpox, mpox, botulism, Ebola, anthrax and opioid overdose emergencies. To learn more about how we help prepare communities around the world for today's health challenges and tomorrow's threats, visit our website and follow us on LinkedIn, X, Instagram, Apple Podcasts and Spotify.

Safe Harbor Statement
This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including statements regarding Emergent's ability to market and sell KLOXXADO ® Nasal Spray on the NARCANDirect® online distribution network, are forward-looking statements. We generally identify forward-looking statements by using words like "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "future," "goal," "intend," "may," "plan," "position," "possible," "potential," "predict," "project," "should," "target," "will," "would," and similar expressions or variations thereof, or the negative thereof, but these terms are not the exclusive means of identifying such statements. Forward-looking statements are based on our current intentions, beliefs and expectations regarding future events based on information that is currently available. We cannot guarantee that any forward-looking statements will be accurate. Readers should realize that if underlying assumptions prove inaccurate or if known or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Readers are, therefore, cautioned not to place undue reliance on any forward-looking statements. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, we do not undertake any obligation to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause Emergent's actual results to differ materially from those indicated by any forward-looking statements. Readers should consider this cautionary statement, as well as the risk factors and other disclosures included in Emergent's periodic reports filed with the U.S. Securities and Exchange Commission, when evaluating the company's forward-looking statements.

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1 https://www.cdc.gov/nchs/pressroom/releases/20250514.html

2 https://www.cdc.gov/media/releases/2025/2025-cdc-reports-decline-in-us-drug-overdose-deaths.html

3 https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

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