Hikma announces Health Canada approval of KLOXXADO® (naloxone HCl) Nasal Spray 8 mg

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Emergent BioSolutions will lead commercial launch efforts to increase access to intranasal naloxone and combat opioid overdose poisonings in Canada

LONDON and GAITHERSBURG, Md., March 20, 2025 (GLOBE NEWSWIRE) -- Hikma Pharmaceuticals PLC (Hikma, Group), the multinational generic pharmaceutical company, announces the approval of KLOXXADO® (naloxone HCl) Nasal Spray 8 mg, by Health Canada for the treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult patients.

KLOXXADO® delivers 8 mg of naloxone hydrochloride per spray in a ready to use nasal spray to reverse the effects of opioid overdose.

“The approval of KLOXXADO ® Nasal Spray will provide Canadian patients, friends and family members – as well as the healthcare and first responder communities – with an important treatment option for victims suffering from opioid overdose,” said Hafrun Fridriksdottir, President, Hikma Generics. “According to distinguished medical and health organizations, widely prescribing and distributing naloxone plays a vital role in the fight against opioid overdose. With the growing threat of stronger, more deadly synthetic opioids like illicit fentanyl, intranasal naloxone is an essential tool in that fight.”

KLOXXADO® Nasal Spray will be marketed and sold in Canada by Emergent BioSolutions (Emergent) under the terms of a recent six-year commercial agreement with Hikma, whereby Emergent will be responsible for all North America product sales and marketing. Hikma will continue producing KLOXXADO® Nasal Spray in its Columbus, Ohio manufacturing facility and will provide it to Emergent as its exclusive commercial partner. Following the approval of KLOXXADO® Nasal Spray, Emergent will engage Canadian agencies, private payers and provincial formularies, and aims to make KLOXXADO® available via prescription as early as 2026.

“Across Canada, 22 innocent lives were lost each day to an opioid overdose fatality in 2023, which is why meeting the needs of our patients, communities and customers is so critical,” said Paul Williams, SVP and products business head, Emergent. “NARCAN ® Nasal Spray has been an important 4 mg naloxone option to reduce opioid poisonings in Canada for years, and we believe KLOXXADO® Nasal Spray 8 mg may be beneficial for those who choose to administer a higher dose of naloxone. We are encouraged by the Health Canada approval and believe broadening our opioid antagonist offerings is a much-needed effort to help save lives from tragic opioid poisonings.”

Recent data reported by Health Canada shows a national decrease in overdose deaths for the third year in a row,[1] with the Minister of Mental Health and Addictions and Associate Minister of Health citing expanded naloxone distribution as one of several factors that could be contributing to this reduction.[2] The availability of naloxone kits has helped to reverse thousands of overdoses across Canada, and now, the approval of KLOXXADO® Nasal Spray will continue to improve access and help save lives. Alongside NARCAN® Nasal Spray, prescription KLOXXADO® Nasal Spray will allow for a tailored approach to opioid overdose reversal treatment for specific patients and communities.

To learn more about Emergent’s commitment in Canada, visit this National Impact Map resource.

About Naloxone

Naloxone hydrochloride is an opioid antagonist that antagonizes opioid effects by competing for the same receptor sites. Administration of naloxone hydrochloride reverses the effects of opioids, including respiratory depression, sedation and hypotension. Naloxone has a long history of safe use as the standard of care in the United States for reversing opioid overdoses.

KLOXXADO® is indicated for the treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult patients. KLOXXADO® is not a substitute for emergency medical care.

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About Hikma

Hikma Pharmaceuticals PLC (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (LEI:549300BNS685UXH4JI75) (rated BBB-/stable S&P and BBB-/positive Fitch)

Hikma helps put better health within reach every day for millions of people around the world. For more than 45 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across North America, the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 9,100 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

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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.

KLOXXADO® is a registered trademark of Hikma Pharmaceuticals USA Inc.
NARCAN® is a registered trademark of Emergent Operations Ireland Limited.

Important Safety Information for KLOXXADO® (naloxone HCl) Nasal Spray 8 mg
Contraindications
Hypersensitivity to naloxone hydrochloride or to any of the other ingredients in KLOXXADO®

Warnings and Precautions

- KLOXXADO® is used in adults to treat an opioid overdose. It can be used to reverse the effects of an
- overdose until medical help arrives. 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 may include:
    - trouble breathing or not breathing
    - extreme drowsiness
    - pale and clammy skin
    - slow or no heartbeat
    - passing out
    - unable to be woken up by touch, shaking of shoulders or shouting
    - Very small pupils, like a pinpoint
- 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.
- **Always seek immediate medical help when using 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, in the other nostril, 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, rapid heartbeat, fever, runny nose, sneezing, goosebumps, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, stomach cramps, weakness and high blood pressure.
- **KLOXXADO® is not indicated for pediatric use.** In an emergency, if KLOXXADO® is administered to an infant because no other options are available, they may experience additional withdrawal symptoms such as: seizures, crying more than usual and overactive reflexes. These symptoms may be life-threatening if not treated right away. **If KLOXXADO® is given to an infant, seek immediate medical help.**
- Tell your doctor about all of your medical conditions before using KLOXXADO®, including if you have heart disease or any other heart problems, are pregnant or think you are pregnant, or are breastfeeding or plan to breastfeed.
- Tell your doctor about all of the medicines you take, including any prescription and over-the-counter medicines, drugs, vitamins, minerals, natural supplements and alternative medicines.

Side Effects
The following side effects are discussed in the full Patient Medication Information for KLOXXADO®:

- Body aches, stomach cramps
- Diarrhea
- Rapid heartbeat
- Fever
- Runny nose, sneezing
- Goosebumps, shivering or trembling
- Sweating
- Yawning
- Nausea or vomiting
- Nervousness
- Restlessness or irritability

- High blood pressure

Infants may have seizures, cry more than normal and have overactive 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 think you are pregnant. Use of KLOXXADO® may cause distress to you and your unborn baby. A healthcare provider should monitor you and your unborn baby right away after you use KLOXXADO®.

Tell your doctor if you are breast-feeding or plan to breastfeed. It is not known if KLOXXADO® passes into breast milk.
If the primary concern is an infant at risk of an overdose, consider whether other naloxone-containing products may be more appropriate.

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 Patient Medication 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 86°F (15°C to 30°C). Do not freeze KLOXXADO®. KLOXXADO® freezes at temperatures below -15°C. If this happens, KLOXXADO® may be thawed by allowing it to sit at room temperature for 15 minutes. It may still be used if it has been thawed after being frozen.

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 and sight 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.

- To report an adverse event or product complaint, please contact us at us.hikma@primevigilance.com or call 1-877-845-0689 or 1-800-962-8364.
- Adverse events may also be reported to the FDA directly at 1-800-FDA-1088 or www.fda.gov/medwatch.

About NARCAN® Nasal Spray
NARCAN® Nasal Spray is a pure opioid antagonist indicated for emergency use to reverse known or suspected opioid overdose, as manifested by respiratory and/or severe central nervous system depression.

While NARCAN® Nasal Spray can be administered by a non-health care professional, it is not intended to be a substitute for professional medical care. Always call 911 as soon as an opioid overdose is suspected, before administering NARCAN® Nasal Spray.

Always read the label and follow the directions for use.

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 in Canada pursuant to the terms of the six-year commercial agreement with Hikma, 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 the company'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 our periodic reports filed with the U.S. Securities and Exchange Commission, when evaluating our forward-looking statements.

[1] https://health-infobase.canada.ca/substance-related-harms/opioids-stimulants/

[2] https://www.canada.ca/en/health-canada/news/2025/03/statement-from-the-minister-of-mental-health-and-addictions-and-associate-minister-of-health-on-the-toxic-illegal-drug-supply-and-overdose-crisis.html

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