hikma.

Press Release

KLOXXADO® 8mg Naloxone Nasal Spray Shelf-Life Extended from 24 months to 36 months

LONDON, 15 August 2024. Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, announces the shelf-life extension of KLOXXADO® (naloxone HCl) nasal spray 8mg from 24 to 36 months. KLOXXADO® packaging has been updated with 36-month dating, starting with product manufactured in March 2024.

KLOXXADO® contains twice as much naloxone per spray as Narcan® Nasal Spray 4mg in a ready-to-use nasal spray to reverse the effects of opioid overdose, providing an important treatment option in addressing the overdose epidemic.[1,2]

Naloxone has long been recognized as an important, safe and effective treatment in the fight against opioid overdose.[3] With the increasing prevalence of illicitly manufactured synthetic opioids, organizations including the CDC[4] the American Medical Association[5] and others have noted that a higher dose of naloxone may be required to revive a patient experiencing poisoning from illicit fentanyl or other opioids. As a ready-to-use nasal spray that contains twice as much naloxone per spray than Narcan® Nasal Spray 4mg, KLOXXADO® provides an important lifesaving treatment option.[1,2]

"The shelf-life extension is good news for frontline responders and the thousands of people who carry KLOXXADO® and who may need to use it at a moment's notice to reverse an overdose," said Dr. Hafrun Fridriksdottir, President, Hikma Generics. "We have a role to play in the fight against illicit fentanyl and as we approach National Overdose Awareness Day on August 31st , it's gratifying that we are supplying an important medicine that can save lives and help address the deadly overdose epidemic."

About Naloxone
Naloxone hydrochloride is a medicine that rapidly reverses an opioid overdose. It can quickly restore normal breathing in someone experiencing an opioid overdose and should be given to any person who shows signs of an opioid overdose or when an opioid overdose is suspected.[6]

KLOXXADO® is indicated 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.[1] KLOXXADO® is not a substitute for emergency medical care.[1] KLOXXADO® is intended for immediate administration as emergency therapy in settings where opioids may be present.[1]

This product has been approved for marketing in the United States by the US FDA. This product approval does not confer the right on Hikma, or any other party, to market this product outside the United States.

Enquiries
Hikma Pharmaceuticals USA
Media:
Steve Weiss
+1 732 788 8279
uscommunications@hikma.com

[1] https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=ebf0f833-c1c0-487c-8f29-01fa8c61b6cb&type=display
[2] https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=a0ebc83d-2892-40de-bc0a-775ce90b30db&type=display
[3] https://pubmed.ncbi.nlm.nih.gov/28722939/
[4] https://archive.cdc.gov/#/details?url=https://emergency.cdc.gov/han/2020/han00438.asp
[5] https://apnews.com/article/opioids-business-health-government-and-politics-8263d4b147b3c6b104346b4ca31c28a3
[6] https://nida.nih.gov/publications/drugfacts/naloxone

About Hikma

Hikma Pharmaceuticals PLC (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (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

Important Safety Information for 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 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.
- 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, are breastfeeding or plan to breastfeed.
- 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 68°F to 77°F (20°C to 25°C). Do not expose to temperatures below 41°F (5°C) or above 104°F (40°C). 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.

- 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.

Distributed by: Hikma Specialty USA Inc., Columbus, OH 43228.

Document Identification Number: HK-2667-v1

SOURCE Hikma Pharmaceuticals USA Inc.