

EVZIO® (naloxone HCl injection, USP) Auto-Injector Now Available to Patients in Select States Without a Prescription Through Kaléo's New Virtual Standing Order Pilot Program and to Government Agencies at a Direct Purchase Price

-- kaléo announces bold new initiatives in support of U.S. Surgeon General's Advisory on Naloxone and Opioid Overdose --

NEWS PROVIDED BY

Kaléo →

Apr 05, 2018, 08:36 ET

RICHMOND, Va., April 5, 2018 /PRNewswire/ -- Kaléo, a privately-held pharmaceutical company, today announced two new initiatives to help further expand access to EVZIO® (naloxone HCl injection, USP) Auto-Injector in support of the Surgeon General's Advisory on Naloxone and Opioid Overdose emphasizing the importance of naloxone:

- Effective today— Through kaléo's new "Virtual Standing Order" program, those with commercial insurance, **without a prescription**, can receive EVZIO at no cost by calling 1-877-883-8946 to talk to a pharmacist and arrange delivery of naloxone directly to their home. The Virtual Standing Order is now available for patients in six states as part of the initial pilot program: Arizona, California, Colorado, Missouri, Nevada and Ohio. Kaléo plans to expand the Virtual Standing Order program to additional states.

- Also effective today, kaléo is introducing a **direct purchase price of \$180 per auto-injector** of EVZIO (\$360 per pack of two auto-injectors and a trainer) to all federal and state government agencies and tribes who purchase the product directly from kaléo, including those agencies who receive federal grant funding to address the opioid overdose epidemic. To obtain more information, please visit <https://evzio.com/patient/direct-purchase/>.

In addition, commercially-insured patients who are being treated by a healthcare provider and receive a prescription can continue to obtain EVZIO for \$0 out of pocket through kaléo's EVZIO2YOU program. Kaléo will also continue to donate product through the kaléo Cares Product Donation Program, which has donated, free of charge, more than 320,000 EVZIO naloxone auto-injectors nationwide to qualifying non-profits and first responders demonstrating need. For a complete summary of the comprehensive access program (including the terms and conditions) for EVZIO, visit www.evzio.com/patient/evzio2you.

In speaking about naloxone today, the surgeon general stated, "It is time to make sure more people have access to this lifesaving medication, because 77 percent of opioid overdose deaths occur outside of a medical setting and more than half occur at home."

EVZIO—an auto-injector designed to be easy to use—provides simple, on-the-spot **voice and visual guidance** to help those with no medical training administer naloxone during an opioid overdose. EVZIO is not a substitute for emergency medical care.

The two initiatives announced today expand upon kaléo's commitment to help ensure broad access to EVZIO. In 2016, kaléo created a first-of-its-kind access program for EVZIO, which allows the more than 200 million Americans with commercial insurance and a prescription—even those who have high-deductible health plans—to receive EVZIO for \$0 out of pocket. Even in cases where a patient's commercial insurance does not cover EVZIO, kaléo ensures that they can obtain it for absolutely nothing out of pocket. Kaléo stands ready to work with government agencies, physicians, advocacy groups, and managed care organizations to ensure broad, affordable access to EVZIO.

"We are proud to support the Surgeon General's Advisory on Naloxone and Opioid Overdose," said Spencer Williamson, CEO of kaléo. "If we empower more patients to have access to this potentially life-saving medicine, we believe that EVZIO may help reduce the number of tragic

deaths from opioid overdose across the nation."

About kaléo (kuh-LAY-oh)

Kaléo is a pharmaceutical company dedicated to building innovative solutions for serious and life-threatening medical conditions. Our mission is to provide innovative solutions that empower patients to confidently take control of their medical conditions. We believe patients and caregivers are the experts on how their medical condition impacts their lives and are an integral part of our product development process. Each kaléo product combines an established drug with an innovative delivery platform. Kaléo is a privately-held company headquartered in Richmond, Virginia. For more information, visit www.kaleopharma.com.

INDICATION

EVZIO is a prescription medicine used in adults and children for the treatment of an opioid emergency such as an overdose or a possible opioid overdose with signs of breathing problems and severe sleepiness or not being able to respond. EVZIO is to be given right away and does not take the place of emergency medical care. Get emergency medical help right away after the first dose of EVZIO, even if the person wakes up. EVZIO is safe and effective in children for known or suspected opioid overdose.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about EVZIO?

EVZIO is used to temporarily reverse the effects of opioid medicines. The medicine in EVZIO has no effect in people who are not taking opioid medicines. Always carry EVZIO with you in case of an opioid emergency.

Use EVZIO right away if you or your caregiver think signs or symptoms of an opioid emergency are present, even if you are not sure, because an opioid emergency can cause severe injury or death. Signs and symptoms of an opioid emergency may include:

- unusual sleepiness and you are not able to awaken the person with a loud voice or rubbing firmly on the middle of their chest (sternum)
- breathing problems including slow or shallow breathing in someone difficult to awaken or they look 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 EVZIO in an opioid emergency should know where EVZIO is stored and how to give EVZIO before an opioid emergency happens.

Get emergency medical help right away after using the first dose of EVZIO. Rescue breathing or CPR (cardiopulmonary resuscitation) may be given while waiting for emergency medical help.

The signs and symptoms of an opioid emergency can return within several minutes after EVZIO is given. If this happens, give additional injections using new EVZIO auto-injectors every 2 to 3 minutes and continue to closely watch the person until emergency help is received.

Who should not use EVZIO?

Do not use EVZIO if you are allergic to naloxone hydrochloride or any of the ingredients in EVZIO.

What are the ingredients in EVZIO?

Active ingredient: naloxone hydrochloride

Inactive ingredients: sodium chloride, hydrochloric acid to adjust pH, and water

What should I tell my healthcare provider before using EVZIO?

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 EVZIO may cause withdrawal symptoms in your unborn baby. Your unborn baby should be examined by a healthcare provider right away after you are given EVZIO.

Tell your healthcare provider about the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of EVZIO?

EVZIO may cause serious side effects, including:

Sudden opioid withdrawal symptoms. In someone who has been using opioids regularly, opioid withdrawal symptoms can happen suddenly after receiving EVZIO and may include: body aches, fever, sweating, runny nose, sneezing, goose bumps, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, stomach cramping, increased blood pressure, and increased heart rate.

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.

Common side effects of EVZIO include dizziness and injection site redness.

These are not all of the possible side effects of EVZIO. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. Please click here to see the full Prescribing Information and the Patient Information, or visit www.evzio.com.

SOURCE Kaléo

Related Links

<http://www.kaleopharma.com>