

# **Evzio™**

(naloxone HCl injection)  
0.4 mg auto-injector

# **FACT SHEET**

## **What is EVZIO?**

- EVZIO is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.<sup>1</sup>
- EVZIO is the first and only naloxone auto-injector intended for immediate administration by family members or caregivers for suspected opioid overdose in settings where opioids may be present.
- EVZIO uses voice and visual cues to assist in guiding users through the injection process. EVZIO is about the length and width of a credit card and the thickness of a small cell phone.

## **How does EVZIO work?**

- Each EVZIO delivers 0.4 mg naloxone hydrochloride injection (0.4 mL). Each EVZIO prescription includes two pre-filled auto-injectors and one trainer.
- Once a caregiver or family member suspects an opioid overdose emergency, they remove EVZIO from its outer case and the automatic voice instructions begin. EVZIO instructs a user to pull off its red safety guard, place the auto-injector against the patient's outer thigh and to press and hold to activate (while EVZIO counts down for 5 seconds).
- EVZIO automatically inserts the needle into the outer thigh, through clothing, if necessary. Once the active ingredient in EVZIO, naloxone, is delivered, the needle retracts fully into its housing and EVZIO tells the user to seek emergency medical assistance. The needle is not visible before, during or after the injection.
- Naloxone works by temporarily blocking the effect of an opioid, reversing the potentially life-threatening respiratory depression and allowing the recipient to breathe more regularly.<sup>2</sup> Once the effects of EVZIO wear off, signs and symptoms of an opioid emergency may reappear. If this happens, additional injections using a new EVZIO auto-injector should be administered every 2-3 minutes until emergency medical care arrives.

## **When should EVZIO be used?**

- People experiencing an opioid overdose generally lose consciousness and are therefore most likely unable to self-administer EVZIO. Caregivers, including family and friends, should learn the signs and symptoms of an opioid overdose so they can recognize an overdose if it occurs.
- EVZIO should be used as soon as signs and symptoms of a suspected opioid overdose are observed. These include: very slow or absent breathing, loss of consciousness, extremely small pupils and a slow heartbeat.<sup>3</sup>
- In cases of caregiver uncertainty, if a patient is unresponsive, and an opioid overdose is suspected, EVZIO should be administered as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death.
- EVZIO is not a substitute for emergency medical care. Caregivers should also seek definitive emergency care.

## **How can people get EVZIO?**

- EVZIO is expected to be available to patients and caregivers beginning in summer 2014 via a doctor's prescription.

## Indication

EVZIO is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

EVZIO is intended for immediate administration as emergency therapy in settings where opioids may be present.

EVZIO is not a substitute for emergency medical care.

## Important Safety Information

### The following is important safety information associated with dosing and administration of EVZIO:

- > EVZIO is for intramuscular or subcutaneous use only.
- > Administer EVZIO to adult or pediatric patients into the anterolateral aspect of the thigh, through clothing if necessary.
- > In pediatric patients under the age of one, the caregiver should pinch the thigh muscle while administering EVZIO.
- > Seek emergency medical care immediately after use.
- > The duration of action of most opioids is likely to exceed that of EVZIO resulting in a return of respiratory and/or central nervous system depression. Keep the patient under continued surveillance and repeated doses of EVZIO should be administered every 2 to 3 minutes, as necessary, while awaiting emergency medical assistance.
- > If the electronic voice instruction system does not operate properly, EVZIO will still deliver the intended dose of naloxone hydrochloride when used according to the printed instructions on the flat surface of its label.

### The following precautions should be taken when administering EVZIO:

- > Consider other supportive and/or resuscitative measures while awaiting emergency medical assistance.
- > Reversal of respiratory depression by partial agonists or mixed agonists/antagonists such as buprenorphine and pentazocine, may be incomplete or require higher doses of naloxone.
- > Use in patients who are opioid dependent may precipitate acute abstinence syndrome.
- > In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated.
- > Patients with pre-existing cardiac disease or patients who have received medications with potential adverse cardiovascular effects should be monitored in an appropriate healthcare setting.
- > EVZIO should be used with caution in patients known to be hypersensitive to naloxone hydrochloride.

### Opioid Withdrawal:

Abrupt reversal of opioid effects in persons who were physically dependent on opioids has precipitated signs and symptoms of opioid withdrawal including: body aches, fever, sweating, runny nose, sneezing, piloerection, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, tachycardia. In the neonate, opioid withdrawal signs and symptoms also included: convulsions, excessive crying, hyperactive reflexes.

### Use in Post-Operative Settings:

The following adverse reactions have been identified during use of naloxone hydrochloride in the post-operative setting: hypotension, hypertension, ventricular tachycardia and fibrillation, dyspnea, pulmonary edema, and cardiac arrest. Death, coma, and encephalopathy have been reported as sequelae of these events. Excessive doses of naloxone hydrochloride in post-operative patients have resulted in significant reversal of analgesia and has caused agitation.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088. For full prescribing information, visit [www.EVZIO.com](http://www.EVZIO.com).

## References

1. EVZIO Prescribing Information. Richmond, VA: kaleo Inc.; 2014.
2. Leavitt, S. Practical Pain Management. "Intranasal Naloxone for At-Home Opioid Rescue." Oct 2013.
3. SAMHSA. Opioid Overdose Prevention Toolkit: Safety Advice for Patients and Family Members. 2013.

