

PATIENT INFORMATION
EVZIO™ (EVV-zee-oh)
(naloxone hydrochloride injection)
Auto-Injector

You and your caregivers should read this Patient Information leaflet before an opioid emergency happens. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

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.

1. Use EVZIO right away if you or your caregiver think signs or symptoms of an opioid emergency are present 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
2. 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.
3. Get emergency medical help right away after using the first dose of EVZIO.
4. The signs and symptoms of an opioid emergency can return within several minutes after EVZIO is given. If this happens, give additional injections using a new EVZIO auto-injector every 2 to 3 minutes and continue to closely watch the person until emergency help is received.

What is EVZIO?

- EVZIO is a prescription medicine used 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 by a caregiver 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.

Who should not use EVZIO?

Do not use EVZIO if you are allergic to naloxone hydrochloride or any of the ingredients in EVZIO. See the end of this leaflet for a complete list of ingredients in EVZIO.

What should I tell my healthcare provider before using EVZIO?

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 use EVZIO.

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

How should I use EVZIO?

Read the “Instructions for Use” at the end of this Patient Information leaflet for detailed information about the right way to use EVZIO.

- You should use EVZIO exactly as prescribed by your healthcare provider.
- Each EVZIO auto-injector contains only 1 dose of medicine.
- EVZIO should be injected into the muscle or skin of the outer thigh. It can be injected through clothing if needed.
- Caregivers should pinch the thigh muscle while injecting EVZIO into a child under the

age of one.

- A Trainer for EVZIO with a separate “Trainer Instructions for Use” leaflet is included with EVZIO. For additional training information and video instructions go to www.EVZIO.com or call 1-855-773-8946.
 - Practice with the Trainer for EVZIO before an opioid emergency happens to make sure you are able to safely use the real EVZIO in an emergency.
 - The Trainer for EVZIO does not contain a needle or medicine. It can be reused to practice your injection.
 - The red safety guard can be removed and replaced on the Trainer for EVZIO.

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.

These are not all of the possible side effects of EVZIO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store EVZIO?

- Store EVZIO at room temperature between 59°F to 77°F (15°C to 25°C).
- Keep EVZIO in its outer case until ready to use.
- Occasionally check EVZIO through the viewing window of the auto-injector. The solution should be clear. If the EVZIO solution is discolored, cloudy, or contains solid particles, replace it with a new EVZIO.
- Your EVZIO has an expiration date. Replace it before the expiration date.

Keep EVZIO and all medicines out of the reach of children.

General information about the safe and effective use of EVZIO

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use EVZIO for a condition for which it was not prescribed. You can ask your pharmacist or healthcare provider for information about EVZIO that is written for health professionals.

What are the ingredients in EVZIO?

Active ingredient: naloxone hydrochloride

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

EVZIO is not made with natural rubber latex.

Manufactured for kaleo, Inc., Richmond, VA, 23219

For more information, go to www.EVZIO.com or call 1-855-773-8946

This Patient Information has been approved by the U.S. Food and Drug Administration. Issued: 4/2014

Instructions for Use EVZIO (EVV-zee-oh) (naloxone hydrochloride injection) Auto-Injector

Read the Instructions for Use that comes with EVZIO before using it. Talk to your healthcare provider if you or your caregivers have any questions about the use of EVZIO.

Automated voice instructions

EVZIO has a speaker that provides voice instructions to help guide you through each step of the injection. See Figure A. If the voice instructions do not work for any reason, EVZIO will still work. If this happens, use EVZIO as instructed below and follow the written instructions on the EVZIO auto-injector label.

Figure A



How to use EVZIO

Step 1. Pull EVZIO from the outer case. See Figure B.

Figure B

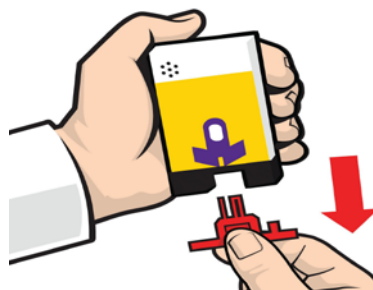


Do not go to Step 2 (Do not remove the **Red** safety guard.) until you are ready to use EVZIO. **If you are not ready to use EVZIO, put it back in the outer case for later use.**

Step 2. Pull off the **Red** safety guard. See Figure C.

To reduce the chance of an accidental injection, do not touch the **Black** base of the auto-injector, which is where the needle comes out.

Figure C



If an accidental injection happens, get medical help right away.

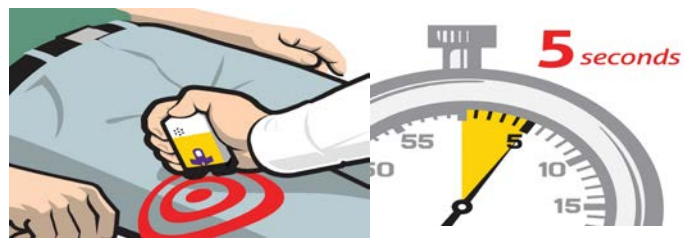
Note: The **Red** safety guard is made to fit tightly. **Pull firmly to remove.**

Do not replace the Red safety guard after it is removed.

Step 3. Place the **Black** end of EVZIO against the outer thigh, through clothing, if needed. **Press firmly** and hold in place for 5 seconds. See Figure D.

If you give EVZIO to an infant less than 1 year old, pinch the middle of the outer thigh before you give EVZIO and continue to pinch while you give EVZIO.

Figure D



Note: EVZIO makes a distinct sound (click and hiss) when it is pressed against the thigh. This is normal and means that EVZIO is working correctly. Keep EVZIO firmly pressed on the thigh for 5 seconds after you hear the click and hiss sound. The needle will inject and then retract back up into the EVZIO auto-injector and is not visible after use.

Step 4. After using EVZIO, get emergency medical help right away.

If symptoms return after an injection with EVZIO, an additional injection using another EVZIO may be needed. Give additional injections using a new EVZIO auto-injector every 2 to 3 minutes and continue to closely watch the person until emergency help is received.

EVZIO cannot be reused. After use, place the auto-injector back into its outer case. Do not replace the **Red** safety guard.

How to know that EVZIO has been used. See Figure E.

- The **Black** base will lock into place.
- The voice instruction system will state that EVZIO has been used and the LED will blink red.
- The **Red** safety guard cannot be replaced.
- The viewing window will no longer be clear. You will see a red indicator.

Figure E



What to do after EVZIO has been used:

- Get emergency medical help right away.
- Put the used EVZIO back into its outer case.
- Do not throw away the EVZIO in household trash. Do not recycle EVZIO.
- Used EVZIO should be taken to a healthcare setting for proper disposal in a sharps container.

There may be local or state laws about how to throw away used auto-injectors.*

*For California Only: This product uses batteries containing Perchlorate Material – special handling may apply. See www.dtsc.ca.gov/hazardouswaste/perchlorate

How should I store EVZIO?

- Store EVZIO at room temperature between 59°F to 77°F (15°C to 25°C).
- Keep EVZIO in its outer case until ready to use.
- Occasionally check EVZIO through the viewing window of the auto-injector. The solution should be clear. If the EVZIO solution is discolored, cloudy, or contains solid particles, replace it with a new EVZIO.
- Your EVZIO has an expiration date. Replace it before the expiration date.

Keep EVZIO and all medicines out of the reach of children.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured for: kaleo, Inc., Richmond, VA 23219

Issued: 4/2014