

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use EVZIO safely and effectively. See full prescribing information for EVZIO.

EVZIO (naloxone hydrochloride injection) Auto-Injector for intramuscular or subcutaneous use

Initial U.S. Approval: 1971

INDICATIONS AND USAGE

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. (1)

EVZIO is intended for immediate administration as emergency therapy in settings where opioids may be present. (1)

EVZIO is not a substitute for emergency medical care. (1)

DOSAGE AND ADMINISTRATION

- EVZIO is for intramuscular or subcutaneous use only. (2.1)
- Seek emergency medical care immediately after use. (2.1)
- Administer EVZIO to adult or pediatric patients into the anterolateral aspect of the thigh, through clothing if necessary. (2.2)
- Additional doses may be administered every 2 to 3 minutes until emergency medical assistance arrives. (2.2)
- In pediatric patients under the age of one, the caregiver should pinch the thigh muscle while administering the dose. (2.2)
- **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. (2.1)**

DOSAGE FORMS AND STRENGTHS

Injection: 0.4 mg/0.4 mL naloxone hydrochloride solution in a pre-filled auto-injector. (3)

CONTRAINDICATIONS

Patients known to be hypersensitive to naloxone hydrochloride (4)

WARNINGS AND PRECAUTIONS

- Due to the duration of action, keep the patient under continued surveillance and repeated doses of naloxone should be administered, as necessary, while awaiting emergency medical assistance. (5.1)
- Other supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance. (5.1)
- Reversal of respiratory depression by partial agonists or mixed agonists/antagonists such as buprenorphine and pentazocine, may be incomplete. (5.2)
- Use in patients who are opioid dependent may precipitate acute abstinence syndrome. (5.3)
- 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 (5.3)
- In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated. (5.3)

ADVERSE REACTIONS

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 have caused agitation. (6)

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. (6)

To report SUSPECTED ADVERSE REACTIONS, contact kaleo, Inc. at 1-855-773-8946 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling

Revised: 4/2014

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17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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.

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Instructions

- EVZIO is for intramuscular and subcutaneous use only.
- Because treatment of suspected opioid overdose must be performed by someone other than the patient, instruct the prescription recipient to inform those around them about the presence of EVZIO and the *Instructions for Use*.
- Seek emergency medical care immediately after use. Since the duration of action of most opioids exceeds that of naloxone hydrochloride, and the suspected opioid overdose may occur outside of supervised medical settings, seek immediate emergency medical assistance, keep the patient under continued surveillance, and administer repeated doses of EVZIO as necessary. Always seek emergency medical assistance in the event of a suspected, potentially life-threatening opioid emergency after administration of the first dose of EVZIO.
- Additional doses of EVZIO may be required until emergency medical assistance becomes available.
- Do not attempt to reuse EVZIO. Each EVZIO contains a single dose of naloxone.
- Visually inspect EVZIO through the viewing window for particulate matter and discoloration prior to administration. Do not administer unless the solution is clear and the glass container is undamaged.

The *Instructions for Use* should be read by the patient or caregiver at the time they receive a prescription for EVZIO. Provide the following instructions to the patient or caregiver:

- EVZIO must be administered according to the printed instructions on the device label or the electronic voice instructions (EVZIO contains a speaker that provides voice instructions to guide the user through each step of the injection). **If the EVZIO 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 its label.**
- Once the red safety guard is removed, EVZIO must be used immediately or disposed of properly. Do not attempt to replace the red safety guard once it is removed.

Upon actuation, EVZIO automatically inserts the needle intramuscularly or subcutaneously, delivers 0.4 mg naloxone hydrochloride injection, and retracts the needle fully into its housing. Post injection,

the black base locks in place, a red indicator appears in the viewing window, and electronic visual and audible instructions signal that EVZIO has delivered the intended dose of naloxone hydrochloride and instructs the user to seek emergency medical attention.

2.2 Dosing Information

Administer the initial dose of EVZIO to adult or pediatric patients intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary, and seek emergency medical assistance. Administer EVZIO as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death. The requirement for repeat doses of EVZIO depends upon the amount, type, and route of administration of the opioid being antagonized.

If the desired response is not obtained after 2 or 3 minutes, another EVZIO dose may be administered. If there is still no response and additional doses are available, additional EVZIO doses may be administered every 2 to 3 minutes until emergency medical assistance arrives. Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

Reversal of respiratory depression by partial agonists or mixed agonist/antagonists, such as buprenorphine and pentazocine, may be incomplete or require higher doses of naloxone.

Dosing in Adults and Pediatric Patients over Age One

Instruct patients or their caregivers to administer EVZIO according to the *Instructions for Use*, intramuscularly or subcutaneously.

Dosing in Pediatric Patients under Age One

In pediatric patients under the age of one, the caregiver should pinch the thigh muscle while administering EVZIO.

3 DOSAGE FORMS AND STRENGTHS

Injection: 0.4 mg/0.4 mL naloxone hydrochloride solution in a pre-filled auto-injector. Each EVZIO delivers 0.4 mg naloxone hydrochloride injection (0.4 mL).

4 CONTRAINDICATIONS

EVZIO is contraindicated in patients known to be hypersensitive to naloxone hydrochloride or to any of the other ingredients.

5 WARNINGS AND PRECAUTIONS

5.1 Duration of Effect

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 after an initial improvement in symptoms. Therefore, it is necessary to seek immediate emergency medical assistance after delivering the first dose of EVZIO, keep the patient under continued surveillance, and repeat doses of EVZIO as

necessary. Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

5.2 Limited Efficacy with Partial Agonists or Mixed Agonist/Antagonists

Reversal of respiratory depression by partial agonists or mixed agonist/antagonists such as buprenorphine and pentazocine, may be incomplete. Large doses of naloxone hydrochloride are required to antagonize buprenorphine because the latter has a long duration of action due to its slow rate of binding and subsequent slow dissociation from the opioid receptor. Buprenorphine antagonism is characterized by a gradual onset of the reversal effects and a decreased duration of action of the normally prolonged respiratory depression.

5.3 Precipitation of Severe Opioid Withdrawal

The use of EVZIO in patients who are opioid dependent may precipitate an acute abstinence syndrome characterized by the following signs and symptoms: body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated and may include the following signs and symptoms: convulsions, excessive crying, and hyperactive reflexes.

Abrupt postoperative reversal of opioid depression after using naloxone hydrochloride may result in nausea, vomiting, sweating, tremulousness, tachycardia, hypotension, hypertension, seizures, ventricular tachycardia and fibrillation, pulmonary edema, and cardiac arrest. Death, coma, and encephalopathy have been reported as sequelae of these events. These events have occurred in patients most of whom had pre-existing cardiovascular disorders or received other drugs which may have similar adverse cardiovascular effects. Although a direct cause and effect relationship has not been established, after use of naloxone hydrochloride, patients with pre-existing cardiac disease or patients who have received medications with potential adverse cardiovascular effects should be monitored for hypotension, ventricular tachycardia or fibrillation, and pulmonary edema in an appropriate healthcare setting. It has been suggested that the pathogenesis of pulmonary edema associated with the use of naloxone hydrochloride is similar to neurogenic pulmonary edema, i.e., a centrally mediated massive catecholamine response leading to a dramatic shift of blood volume into the pulmonary vascular bed resulting in increased hydrostatic pressures.

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed elsewhere in the labeling:

- Duration of effect [*see Warnings and Precautions (5.1)*]
- Precipitation of Severe Opioid Withdrawal [*see Warnings and Precautions (5.3)*]

The following adverse reactions have been identified during post-approval use of naloxone hydrochloride in the post-operative setting. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a

causal relationship to drug exposure: 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 have caused agitation [*see Warnings and Precautions (5.3)*].

Abrupt reversal of opioid effects in persons who were physically dependent on opioids has precipitated an acute withdrawal syndrome. Signs and symptoms have included: 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 [*see Warnings and Precautions (5.3)*].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category B

Risk Summary

There are no adequate and well-controlled studies with EVZIO in pregnant women. Animal studies were conducted with naloxone hydrochloride given during organogenesis in mice and rats at doses 4-times and 8-times, respectively, the dose of a 50 kg human given 10 mg/day. These studies demonstrated no embryotoxic or teratogenic effects due to naloxone hydrochloride. Because animal reproduction studies are not always predictive of human response, EVZIO should be used during pregnancy only if clearly needed.

Clinical Considerations

Naloxone hydrochloride crosses the placenta, and may precipitate withdrawal in the fetus as well as in the opioid-dependent mother. The fetus should be evaluated for signs of distress after EVZIO is used. Careful monitoring is needed until the fetus and mother are stabilized.

Data

Animal Data

Naloxone hydrochloride was administered during organogenesis to mice and rats at doses 4-times and 8-times, respectively, the dose of 10 mg/day given to a 50 kg human (when based on body surface area or mg/m²). These studies demonstrated no embryotoxic or teratogenic effects due to naloxone hydrochloride.

8.3 Nursing Mothers

It is not known whether naloxone hydrochloride is present in human milk. Because many drugs are present in human milk, exercise caution when EVZIO is administered to a nursing woman.

8.4 Pediatric Use

The safety and effectiveness of EVZIO (for intramuscular and subcutaneous use) have been established in pediatric patients for known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. Use of naloxone hydrochloride in pediatric patients is supported by evidence from adequate and well-controlled studies of naloxone hydrochloride in adults with additional data from 15 clinical studies (controlled and uncontrolled) in which neonates and pediatric patients received parenteral naloxone in doses ranging from 0.005 mg/kg to 0.01 mg/kg. Safety and effectiveness are also supported by use of other naloxone hydrochloride products in the post-marketing setting as well as data available in the medical literature and clinical practice guidelines.

Absorption of naloxone hydrochloride following subcutaneous or intramuscular administration in pediatric patients may be erratic or delayed. Even when the opiate-intoxicated pediatric patient responds dramatically to naloxone hydrochloride injection, he/she must be carefully monitored for at least 24 hours as a relapse may occur as naloxone is metabolized. In opioid-dependent pediatric patients, (including neonates), administration of naloxone may result in an abrupt and complete reversal of opioid effects, precipitating an acute opioid withdrawal syndrome. Neonatal opioid withdrawal syndrome, unlike opioid withdrawal syndrome in adults, may be life-threatening and should be treated according to protocols developed by neonatology experts [*see Warnings and Precautions (5.3)*].

In neonates and pediatric patients less than 1 year of age, careful observation of the administration site for evidence of residual needle parts and/or signs of infection is warranted [*see Dosage and Administration (2.1)*].

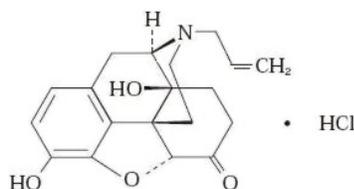
8.5 Geriatric Use

Geriatric patients have a greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy. Therefore, the systemic exposure of naloxone can be higher in these patients.

Clinical studies of naloxone hydrochloride did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

11 DESCRIPTION

EVZIO (naloxone hydrochloride injection, USP) is a pre-filled, single-use auto-injector. EVZIO is not made with natural rubber latex. Chemically, naloxone hydrochloride is the hydrochloride salt of 17-Allyl-4,5 α -epoxy-3,14-dihydroxymorphinan-6-one hydrochloride with the following structure:



$C_{19}H_{21}NO_4 \cdot HCl$

M.W. 363.84

Naloxone hydrochloride occurs as a white to slightly off-white powder, and is soluble in water, in dilute acids, and in strong alkali; slightly soluble in alcohol; practically insoluble in ether and in chloroform.

Each 0.4 mL in EVZIO contains inactive ingredients of 3.34 mg of sodium chloride, hydrochloric acid to adjust pH, and water for injection. The pH range is 3.0 to 4.5.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Naloxone hydrochloride is an opioid antagonist that antagonizes opioid effects by competing for the same receptor sites.

Naloxone hydrochloride reverses the effects of opioids, including respiratory depression, sedation, and hypotension. Also, it can reverse the psychotomimetic and dysphoric effects of agonist-antagonists such as pentazocine.

12.2 Pharmacodynamics

When naloxone hydrochloride is administered intravenously, the onset of action is generally apparent within two minutes. The time to onset of action is shorter for intravenous compared to subcutaneous or intramuscular routes of administration.

The duration of action is dependent upon the dose and route of administration of naloxone hydrochloride.

12.3 Pharmacokinetics

In one pharmacokinetic study in 30 healthy subjects, a single 0.4 mg subcutaneous or intramuscular naloxone injection administered using EVZIO provides equivalent naloxone AUC and 15% greater naloxone C_{max} in comparison to a single 0.4 mg subcutaneous or intramuscular naloxone injection administered using a standard syringe.

Following a single EVZIO injection, the median T_{max} of naloxone was reached at 15 minutes (range 5 minutes to 1.2 hours), with a mean (\pm SD) C_{max} value of 1.24 (\pm 0.64) ng/mL. The mean (\pm SD) plasma half-life of naloxone in healthy adults was 1.28 (\pm 0.48) hours. In the same study, following administration of a single dose of 0.4 mg naloxone injection using a standard syringe, the median T_{max} was 20 minutes (range 5 minutes to 2.03 hours) and the mean (\pm SD) C_{max} value was 1.07 (\pm 0.48) ng/mL. The mean (\pm SD) plasma half-life was 1.36 (\pm 0.32) hours.

Distribution

Following parenteral administration, naloxone is distributed in the body and readily crosses the placenta. Plasma protein binding occurs but is relatively weak. Plasma albumin is the major binding constituent but significant binding of naloxone also occurs to plasma constituents other than albumin. It is not known whether naloxone is excreted into human milk.

Metabolism

Naloxone hydrochloride is metabolized in the liver, primarily by glucuronide conjugation with naloxone-3-glucuronide as the major metabolite.

Elimination

After an oral or intravenous dose, about 25-40% of naloxone is excreted as metabolites in urine within 6 hours, about 50% in 24 hours, and 60-70% in 72 hours. Following a single EVZIO injection, the mean (\pm SD) plasma half-life of naloxone in healthy adults was 1.28 (\pm 0.48) hours. In a neonatal study of naloxone injection, the mean (\pm SD) plasma half-life was observed to be 3.1 (\pm 0.5) hours.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Long-term animal studies to evaluate the carcinogenic potential of naloxone have not been completed.

Mutagenesis

Naloxone was weakly positive in the Ames mutagenicity and in the in vitro human lymphocyte chromosome aberration test but was negative in the in vitro Chinese hamster V79 cell HGPRT mutagenicity assay and in the in vivo rat bone marrow chromosome aberration study.

Impairment of Fertility

Reproduction studies conducted in mice and rats at doses 4-times and 8-times, respectively, the dose of a 50 kg human given 10 mg/day (when based on surface area or mg/m^2), demonstrated no adverse effect of naloxone hydrochloride on fertility.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Carton containing two EVZIO (naloxone hydrochloride injection, USP) 0.4 mg auto-injectors and a single Trainer for EVZIO - NDC 60842-030-01

16.2 Storage and Handling

Store EVZIO in the outer case provided.

Store at controlled room temperature 15°C to 25°C (59°F to 77°F) excursions permitted between 4°C and 40°C (between 39°F and 104°F).

Before using, check to make sure the solution in the auto-injector is not discolored. Replace EVZIO if the solution is discolored or contains a precipitate.

17 PATIENT COUNSELING INFORMATION

Advise the patient and family members or caregivers to read the FDA-approved patient labeling (*Instructions for Use*).

Instruct patients and their family members or caregivers to:

- Become familiar with the following information contained in the carton as soon as they receive EVZIO:
 - EVZIO Instructions for Use
 - Trainer for EVZIO Instructions for Use
 - Trainer for EVZIO
- Practice using the Trainer before EVZIO is needed.
 - Each EVZIO (which is purple and yellow) can only be used one time; however, the Trainer (which is black and white) can be re-used for training purposes and its red safety guard can be removed and replaced.
 - Both EVZIO and the Trainer for EVZIO incorporate the electronic voice instruction system.
- Make sure EVZIO is present whenever persons may be intentionally or accidentally exposed to an opioid to treat serious opioid overdose (i.e., opioid emergencies).

Instruct the patients and their family members or caregivers how to recognize the signs and symptoms of an opioid overdose requiring the use of EVZIO such as the following:

- Extreme sleepiness - inability to awaken a patient verbally or upon a firm sternal rub.
- Breathing problems - this can range from slow or shallow breathing to no breathing in a patient who cannot be awakened.
- Other signs and symptoms that may accompany sleepiness and breathing problems include the following:
 - Extremely small pupils (the black circle in the center of the colored part of the eye) sometimes called “pinpoint pupils.”
 - Slow heartbeat and/or low blood pressure.

Instruct them that when in doubt, if a patient is unresponsive, and an opioid overdose is suspected, administer EVZIO as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death. Instruct them to seek emergency medical assistance after administering the first dose of EVZIO.

Duration of Effect

Instruct patients and their family members or caregivers that since the duration of action of most opioids may exceed that of naloxone, seek immediate emergency medical assistance, keep the patient under continued surveillance, and administer repeated doses of EVZIO as necessary.

Limited Efficacy for/with Partial Agonists or Mixed Agonist/Antagonists

Instruct patients and their family members or caregivers that the reversal of respiratory depression by partial agonists or mixed agonist/antagonists such as buprenorphine and pentazocine, may be incomplete.

Precipitation of Severe Opioid Withdrawal

Instruct patients and their family members or caregivers that the use of EVZIO in patients who are opioid dependent may precipitate an acute abstinence syndrome characterized by the following signs and symptoms: body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. In neonates, opioid withdrawal may be life threatening if not recognized and properly treated, and may include the following signs and symptoms: convulsions, excessive crying, and hyperactive reflexes.

Administration Instructions

Instruct patients and their family members or caregivers about the following important information:

- EVZIO is user actuated and may be administered through clothing [e.g., pants, jeans, etc.] if necessary.
 - Inject EVZIO while pressing into the anterolateral aspect of the thigh. In pediatric patients less than 1 year of age, pinch the thigh muscle while administering EVZIO.
 - Upon actuation, EVZIO automatically inserts the needle intramuscularly or subcutaneously, delivers the naloxone, and retracts the needle fully into its housing. The needle is not visible before, during, or after injection.
 - Each EVZIO can only be used one time.
 - If the electronic voice instruction system on EVZIO does not work properly, EVZIO will still deliver the intended dose of naloxone hydrochloride when used according to the printed instructions on its label.
 - The electronic voice instructions are independent of activating EVZIO and are not required to wait for the voice instructions to be completed prior to moving to the next step in the injection process.
 - Post-injection, the black base locks in place, a red indicator appears in the viewing window and electronic visual and audible instructions signal that EVZIO has delivered the intended dose of naloxone hydrochloride.
 - EVZIO's red safety guard should not be replaced under any circumstances. However, the Trainer is designed for re-use and its red safety guard can be removed and replaced.
 - It is recommended that patients and caregivers become familiar with the training device provided and read the *Instructions for Use*; however, untrained caregivers or family members should still attempt to use EVZIO during a suspected opioid overdose while awaiting definitive emergency medical care.
 - Periodically visually inspect the naloxone solution through the viewing window. If the solution is discolored, cloudy, or contains solid particles, replace it with a new EVZIO.
 - Replace EVZIO before its expiration date.
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Manufactured for:

kaleo, Inc.

Richmond, VA 23219

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