

# Writing a 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**

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

# Please see additional Important Safety Information on reverse and enclosed full Prescribing Information.



# (naloxone HCl injection) Writing a Prescription



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### **IMPORTANT SAFETY INFORMATION (continued)**

The following warnings and precautions should be taken when administering EVZIO:

- 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.
- Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.
- Reversal of respiratory depression by partial agonists or mixed agonists/antagonists, such as buprenorphine and pentazocine, may be incomplete.
- Use in patients who are opioid dependent may precipitate acute abstinence syndrome.
- 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.
- In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated.

The following adverse reactions have been identified during use of naloxone hydrochloride in the postoperative 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 postoperative patients have resulted in significant reversal of analgesia and have caused agitation.

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, and tachycardia. In the neonate, opioid withdrawal signs and symptoms also included: convulsions, excessive crying, and hyperactive reflexes.

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 see enclosed full Prescribing Information.