

## **Patient Indication and Important Safety Information**

### **INDICATION**

#### **What is NALOXONE AUTO-INJECTOR?**

NALOXONE AUTO-INJECTOR 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.

NALOXONE AUTO-INJECTOR 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 NALOXONE AUTO-INJECTOR, even if the person wakes up.

NALOXONE AUTO-INJECTOR 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 NALOXONE AUTO-INJECTOR?**

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

- Use NALOXONE AUTO-INJECTOR 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 NALOXONE AUTO-INJECTOR in an opioid emergency should know where NALOXONE AUTO-INJECTOR is stored and how to give NALOXONE AUTO-INJECTOR before an opioid emergency happens.
- **Get emergency medical help right away after using the first dose of NALOXONE AUTO-INJECTOR.** 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 NALOXONE AUTO-INJECTOR is given. If this happens, give additional injections using new NALOXONE AUTO-INJECTORS every 2 to 3 minutes and continue to closely watch the person until emergency help is received.

#### **Who should not use NALOXONE AUTO-INJECTOR?**

Do not use NALOXONE AUTO-INJECTOR if you are allergic to naloxone hydrochloride or any of the ingredients in NALOXONE AUTO-INJECTOR.

### **What are the ingredients in NALOXONE AUTO-INJECTOR?**

Active ingredient: naloxone hydrochloride

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

### **What should I tell my healthcare provider before using NALOXONE AUTO-INJECTOR?**

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

**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 NALOXONE AUTO-INJECTOR?**

**NALOXONE AUTO-INJECTOR 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 NALOXONE AUTO-INJECTOR 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 NALOXONE AUTO-INJECTOR include dizziness and injection site redness.

These are not all of the possible side effects of NALOXONE AUTO-INJECTOR. 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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.