RAPID OPIOID COUNTERMEASURE SYSTEM (ROCS)

Naloxone Auto-Injector 10 mg (Naloxone Hydrochloride Injection)



- **Only naloxone product with two indications - post exposure and prophylactic use ahead of mission**
- **Highest FDA-approved dosage of naloxone as countermeasure against high-potency opioids**
- **Gas powered, fully automatic retractable needle system**
- **Auto-injector is about the size of a credit card, thickness of a cell phone, and weighs approximately 58 grams**





DURABLE	Passed all U.S. Department of Defense military durability standards[1]
COMPACT	Approx. 2” W x 3.4” H x 0.54” D | Approx. 5.08 cm W x 8.636 cm H x 1.3716 cm D
RELIABLE	Meets FDA draft guidance standard for 99.999% device reliability[2]

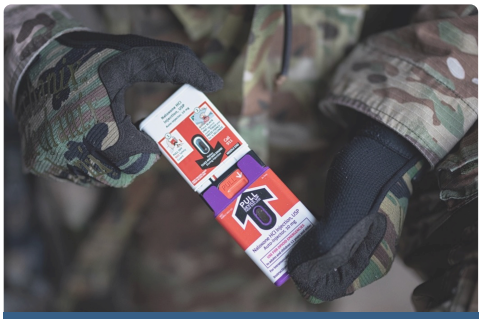
Full Prescribing Information

For More Information

Outside the U.S., allied foreign military services can acquire NAI 10 mg through the U.S. Department of Defense (FMS Sales) or purchase directly via expanded access approval exclusively for government or military use.

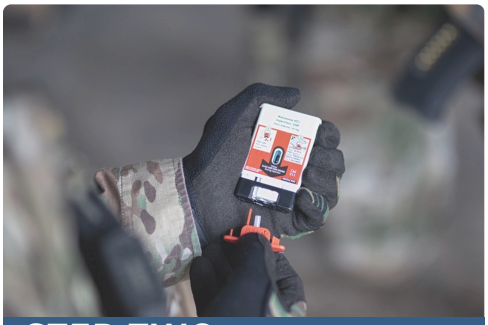
COUNTERMEASURE DESIGNED IN PARTNERSHIP WITH U.S. DEPARTMENT OF DEFENSE TO PROTECT MILITARY, POLICE, AND EMERGENCY RESPONDERS

Instructions for Use[3]



STEP ONE

Firmly pull auto-injector from the outer case.



STEP TWO

Pull off **red** safety guard.



STEP THREE

Place black end of the auto-injector against outer thigh, through clothing, if needed.

IMPORTANT SAFETY INFORMATION

- Contraindications, Warnings, Precautions, and Adverse Events
- Naloxone Auto-Injector 10 mg is contraindicated in individuals with hypersensitivity to naloxone hydrochloride or to any of the other ingredients in Naloxone Auto-Injector 10 mg.
- Use in patients who are opioid dependent may cause abrupt opioid withdrawal. Use of a product that delivers a dose lower than 10 mg of naloxone HCl may be preferable in treatment of a patient with known opioid dependence.
- Due to the duration of action of naloxone HCl relative to the opioid, keep the patient under continued surveillance and administer additional naloxone HCl, as necessary, while awaiting emergency medical assistance.
- The following adverse reactions were observed in more than one subject in clinical studies evaluating NAI: dizziness, feeling hot, headache, and injection site erythema.

To report suspected adverse reactions, contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. For Full Prescribing Information visit www.naloxoneautoinjector.com

1 Naloxone Hydrochloride Injection [Prescribing Information]. Richmond, VA: kaleo, Inc; https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b5463553-b775-47a3-8d10-31e01ca1ec72

2 Data on File; kaleo, Inc.

3 Naloxone Hydrochloride Injection [Instructions for Use. Richmond, VA: kaleo, Inc; https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b5463553-b775-47a3-8d10-31e01ca1ec72

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