



Naloxone in the District of Columbia A Training for Pharmacists

Health Regulation and Licensing Administration
Board of Pharmacy

DC | **HEALTH**

Milken Institute School
of Public Health

THE GEORGE WASHINGTON UNIVERSITY



GEORGETOWN UNIVERSITY

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More resources available at the
DC Center for Rational Prescribing

dchealth.dc.gov/dcrx

COURSE FACULTY

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No course faculty disclosed any financial conflicts of interest.

IMPORTANT INFORMATION



The slides will progress at their own pace.



Do not attempt to speed up the video.



The post test will only unlock after viewing the entire video.



The video can be paused and resumed later.

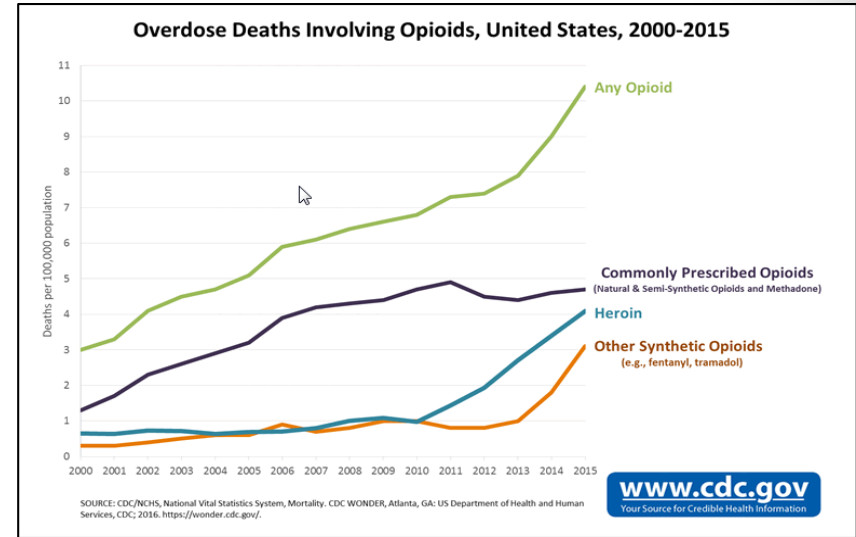
AT THE END OF THIS TRAINING, PARTICIPANTS WILL BE ABLE TO

- Describe the scope of the opioid epidemic
- Appropriately screen a patient to determine if he/she is at risk of an opioid-related overdose
- Explain the mechanism of action of opioid antagonists and demonstrate how to properly administer an opioid antagonist to reverse an overdose
- List and describe the training and counseling requirements for dispensing naloxone in the District of Columbia
- Understand the immunity from civil or criminal liability when dispensing naloxone in the District of Columbia

SCOPE OF THE OPIOID EPIDEMIC

HOW BIG IS THE PROBLEM OF OPIOID OVERDOSE?

- Drug overdose deaths and opioid-involved deaths continue to increase in the United States.
- The majority of drug overdose deaths (more than six out of ten) involve an opioid.
- Since 1999, the number of overdose deaths involving opioids (including prescription opioids and heroin) quadrupled.

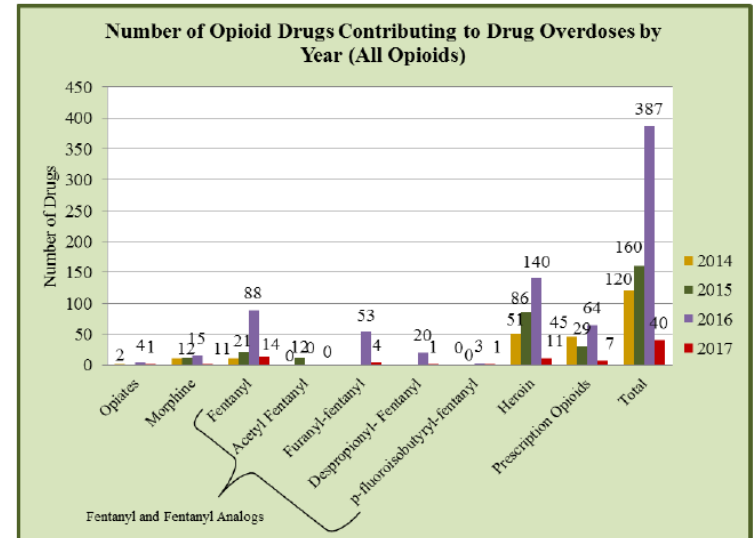


Understanding the Epidemic. Centers for Disease Control and Prevention (CDC). <https://www.cdc.gov/drugoverdose/epidemic/index.html>

Opioid Data Analysis: Centers for Disease Control and Prevention (CDC). <https://www.cdc.gov/drugoverdose/data/analysis.html>

HOW BIG IS THE PROBLEM OF OPIOID OVERDOSE IN DC?

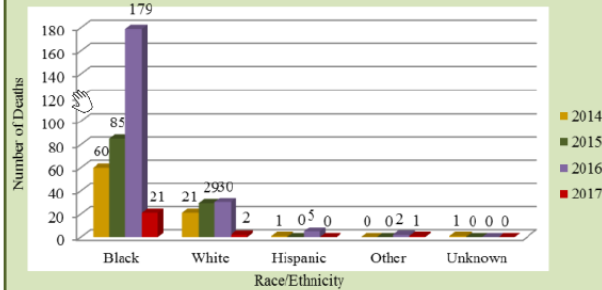
- The DC Office of the Chief Medical Examiner investigated a total of 437 deaths due to the use of opioids from January 1, 2014 through February 28, 2017
 - 83 deaths in CY 2014
 - 114 deaths in CY 2015
 - 216 deaths in CY 2016
 - 24 deaths in CY 2017 (until February 28, 2017)
- There was a 142% increase in the total number of fatal overdoses from 2015 to 2016 that were caused by opioids



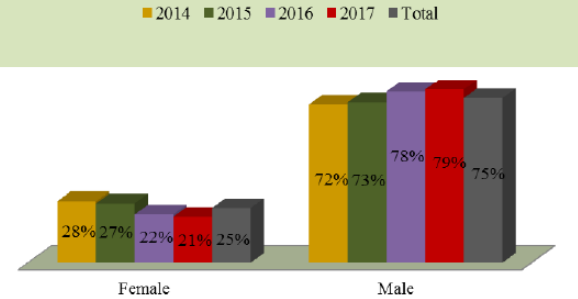
Office of the Chief Medical Examiner. Opioid-related Fatal Overdoses: January 1, 2014 to February 28, 2017. Report date: April 19, 2017.
https://ocme.dc.gov/sites/default/files/dc/sites/ocme/Opioid%20related%20Overdoses%20Deaths_04.19.17.pdf

HOW BIG IS THE PROBLEM OF OPIOID OVERDOSE IN DC?

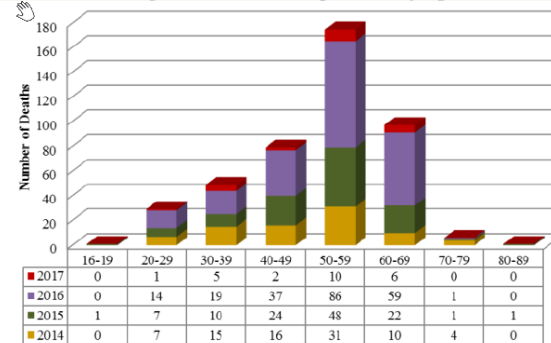
Number of Drug Overdoses due to Opioid Use by Race/Ethnicity and Year



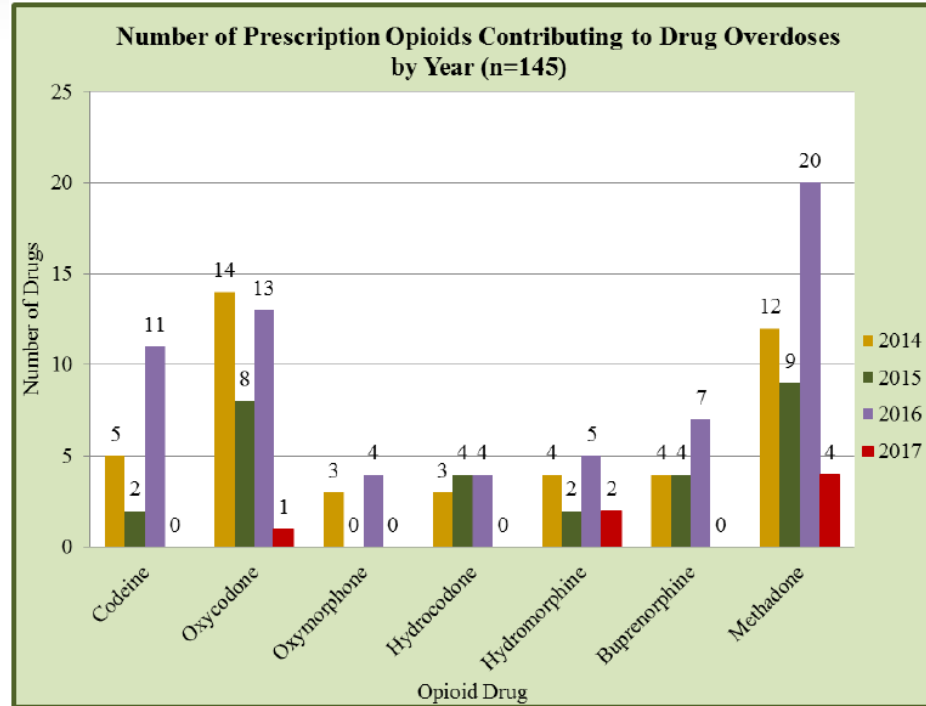
Percentage of Drug Overdoses due to Opioid Use by Gender and Year



Drug Overdoses due to Opioid Use by Age



HOW BIG IS THE PROBLEM OF PRESCRIPTION OPIOID OVERDOSE IN DC?



Office of the Chief Medical Examiner. Opioid-related Fatal Overdoses: January 1, 2014 to February 28, 2017. Report date: April 19, 2017.

https://ocme.dc.gov/sites/default/files/dc/sites/ocme/Opioid%20related%20Overdoses%20Deaths_04.19.17.pdf

HOW TO SCREEN A PATIENT FOR BEING AT RISK OF AN OPIOID-RELATED OVERDOSE

PATIENTS AT RISK OF AN OPIOID-RELATED OVERDOSE

- **People who:**

- Use prescription opioids, especially those taking higher doses;
- Use opioids in combination with other sedating substances;
- Use opioids and have medical conditions such as HIV or liver or lung disease, or who suffer from depression; and
- Inject opioids

- **People with:**

- Household members in possession of opioids;
- Opioid dependence and reduced tolerance following detoxification, release from incarceration, or cessation of treatment; and
- A suspected or confirmed history of substance abuse, dependence or non-medical use of prescription or illegal opioids.

Information sheet on opioid overdose. World Health Organization (WHO). © 2017 Available at: http://www.who.int/substance_abuse/information-sheet/en/

DETERMINING THE NEED TO ADMINISTER OPIOID ANTAGONIST FOR AT-RISK PERSONS

SIGNS OF AN OPIOID OVERDOSE

- Unresponsive to outside stimulus
 - No response if you yell their name or vigorously rub middle of chest hard
- Breathing is slow, irregular, or has stopped
- Pulse is slow, erratic or absent
- Gasping for air, choking or gurgling sounds
- Limp body, pale clammy skin
- Blue lips or fingertips
- Pinpoint pupils

Guide to Developing and Managing Overdose Prevention and Take Home Naloxone Project. Harm Reduction Coalition. © 2012. Available at: <http://harmreduction.org/issues/overdose-prevention/tools-best-practices/manuals-best-practice/od-manual/>

Recognizing Opioid Overdose. Harm Reduction Coalition. Available at: <http://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/recognizing-opioid-overdose/>

HIGH SUSPICION OF OPIOID OVERDOSE

- Steps to take IMMEDIATELY
 - Check for a pulse
 - ❖ If you are able to detect a pulse, begin rescue breathing
 - ❖ If you cannot detect a pulse, begin chest compressions
 - Rate = 100 times per minute
 - Place the person on their back and administer naloxone
 - CALL 911
 - ❖ Continue CPR until the person is responsive
 - ❖ Place the person in the recovery position

Guide to Developing and Managing Overdose Prevention and Take Home Naloxone Project. Harm Reduction Coalition. © 2012. Available at: <http://harmreduction.org/issues/overdose-prevention/tools-best-practices/manuals-best-practice/od-manual/>

Recognizing Opioid Overdose. Harm Reduction Coalition. Available at: <http://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/recognizing-opioid-overdose/>

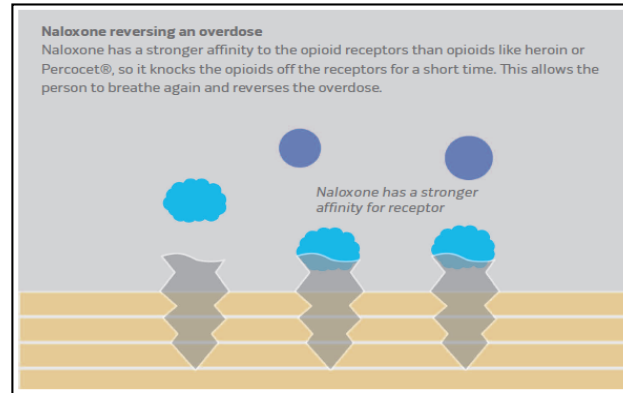
Overdose prevention and response instructions – American Society of Anesthesiologists.



OPIOID ANTAGONISTS AND PROPER ADMINISTRATION TO REVERSE AN OPIOID OVERDOSE

NALOXONE'S MECHANISM OF ACTION

- Naloxone antagonizes opioid effects by competing for the same receptor sites. It has a higher affinity for the receptor site and will remove the opioid from the receptor, thus reversing the effects of the opioid



- Wears off in 30 to 90 minutes
- Ineffective in a person who has not taken opioids

EVZIO Package Insert. Kaleo, Inc. Available at <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=df501ed0-c0f4-11e3-8a33-0800200c9a66&type=display>
Guide to Developing and Managing Overdose Prevention and Take Home Naloxone Project. Harm Reduction Coalition. © 2012. Available at: <http://harmreduction.org/issues/overdose-prevention/tools-best-practices/manuals-best-practice/od-manual/>

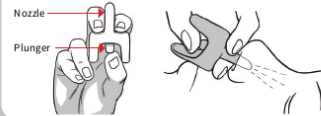
AVAILABLE NALOXONE FORMULATIONS

- Intranasal Administration
 - Naloxone 4 mg Nasal Spray (Narcan)
 - Naloxone 2 mg/2 mL pre-filled syringes with nasal atomizer
- Intramuscular Administration
 - Naloxone 2 mg/0.4 mL auto-injector (EVZIO)
 - Naloxone 0.4 mg/1 mL single-dose vial + one 3 mL syringe and a 23-gauge, 1" needle

HIGH LEVEL OVERVIEW OF HOW TO ADMINISTER AVAILABLE NALOXONE FORMULATIONS

Nasal spray

This nasal spray needs no assembly and can be sprayed up one nostril by pushing the plunger.



Auto-injector

The naloxone auto-injector needs no assembly and can be injected into the outer thigh, even through clothing. It contains a speaker that provides step-by-step instructions.



Nasal spray with assembly

This requires assembly. Follow the instructions below.

- 1 Take off yellow caps.
- 2 Screw on white cone.
- 3 Take purple cap off capsule of naloxone.
- 4 Gently screw capsule of naloxone into barrel of syringe.
- 5 Insert white cone into nostril; give a short, strong push on end of capsule to spray naloxone into nose: **ONE HALF OF THE CAPSULE INTO EACH NOSTRIL.**
Push to spray.
- 6 If no reaction in 3 minutes, give second dose.

Injectable naloxone

This requires assembly. Follow the instructions below.

- 1 Remove cap from naloxone vial and uncover the needle.
- 2 Insert needle through rubber plug with vial upside down. Pull back on plunger and take up 1 ml.
- 3 Inject 1 ml of naloxone into an upper arm or thigh muscle.
- 4 If no reaction in 3 minutes, give second dose.

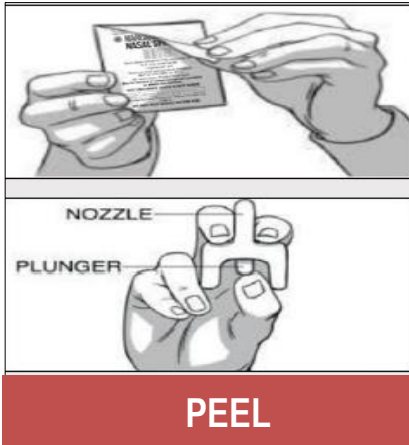
Picture adapted from Naloxone Fact Sheet. San Francisco Department of Public Health 2016. Available at: http://www.pharmacy.ca.gov/publications/naloxone_fact_sheet.pdf

NARCAN NASAL SPRAY

- Availability
 - Naloxone 4 mg/0.1 mL
 - Each carton contains 2 blister-packed, single-use nasal sprays
 - ❖ No assembly, priming requirements
- Storage
 - Original packing, room temperature, protected from light
 - ❖ Do NOT keep in car glove compartment or refrigerator
 - ❖ Keep away from children
 - Remove from blister pack immediately before use
 - Replace before expiration date on packaging

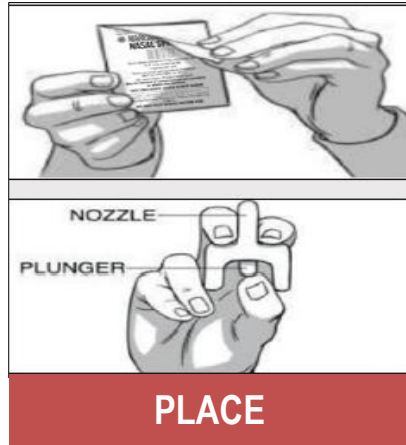


ADMINISTERING NARCAN NASAL SPRAY



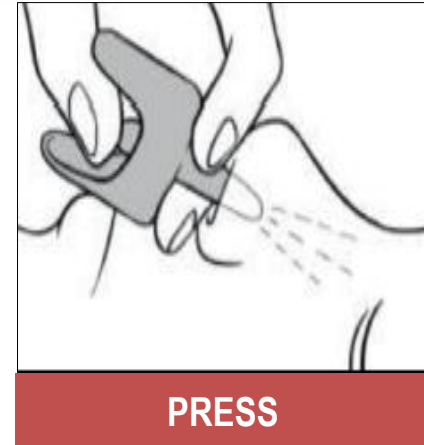
PEEL

- Remove Narcan Nasal Spray from the box
- Peel back the tab to remove the device from the packaging
- Hold the Narcan Nasal Spray with your thumb on the bottom, middle and index finger on either side of the nozzle



PLACE

- Tilt the person's head back and support their neck with your hand
- Insert the tip of the nozzle into 1 nostril, until your fingers on either side of the nozzle are against the bottom of the person's nose



PRESS

- Press the plunger firmly to give the dose of Narcan Nasal Spray
- Remove Narcan Nasal Spray from the nostril
- Call 911 and place the person in the recovery position
- Repeat the dose using the 2nd nasal spray in 2 to 3 minutes in the other nostril if the person does not respond

NARCAN NASAL SPRAY – QUICK START

NARCAN[®] (naloxone HCl) **NASAL SPRAY**

QUICK START GUIDE Opioid Overdose Response Instructions

Use NARCAN Nasal Spray (naloxone hydrochloride) for known or suspected opioid overdose in adults and children.

Important: For use in the nose only.

Do not remove or test the NARCAN Nasal Spray until ready to use.

1 Identify Opioid Overdose and Check for Response

Ask person if he or she is okay and shout name.

Shake shoulders and firmly rub the middle of their chest.

Check for signs of opioid overdose:

- Will not wake up or respond to your voice or touch
 - Breathing is very slow, irregular, or has stopped
 - Center part of their eye is very small, sometimes called "pinpoint pupil"
- Lay the person on their back to receive a dose of NARCAN Nasal Spray.



2 Give NARCAN Nasal Spray

Remove NARCAN Nasal Spray from the box.

Peel back the tab with the circle to open the NARCAN Nasal Spray.



Hold the NARCAN nasal spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle.



Gently insert the tip of the nozzle into either nostril.

- Tilt the person's head back and provide support under the neck with your hand. Gently insert the tip of the nozzle into one nostril, with your fingers on either side of the nozzle are against the bottom of the person's nose.



Press the plunger firmly to give the dose of NARCAN Nasal Spray.

- Remove the NARCAN Nasal Spray from the nostril after giving the dose.



3 Call for emergency medical help, Evaluate, and Support

Get emergency medical help right away.

Move the person on their side (recovery position) after giving NARCAN Nasal Spray.

Watch the person closely.

If the person does not respond by waking up, to voice or touch, or breathing normally another dose may be given. NARCAN Nasal Spray may be dosed every 2 to 3 minutes, if available.


Repeat Step 2 using a new NARCAN Nasal Spray to give another dose in the other nostril. If additional NARCAN Nasal Sprays are available, repeat step 2 every 2 to 3 minutes until the person responds or emergency medical help is received.



ADAPT PHARMA

For more information about NARCAN Nasal Spray, go to www.narcannasalspray.com, or call 1-844-4NARCAN (1-844-462-7226).

©2013 ADAPT Pharma, Inc. NARCAN[®] is a registered trademark licensed to ADAPT Pharma Corporation Limited, AD000-01.



NARCAN[®] (naloxone HCl)
NASAL SPRAY 4mg

Use NARCAN[®] Nasal Spray for known or suspected opioid overdose in adults and children.

Important: For use in the nose only.
Do not remove or test the NARCAN[®] Nasal Spray until ready to use.

This box contains two (2) 4-mg doses of naloxone HCl in 0.1 mL of nasal spray.

Two Pack

CHECK PRODUCT EXPIRATION DATE BEFORE USE.

OPEN HERE FOR QUICK START GUIDE Opioid Overdose Response Instructions

1 Identify Opioid Overdose and Check for Response

ASK person if he or she is okay and shout name.

Check for signs of opioid overdose:

- Will not wake up or respond to your voice or touch
- Breathing is very slow, irregular, or has stopped
- Center part of their eye is very small, sometimes called "pinpoint pupil"

Lay the person on their back to receive a dose of NARCAN[®] Nasal Spray.

2 Give NARCAN[®] Nasal Spray

Remove NARCAN[®] Nasal Spray from box.

Peel back the tab with the circle to open the NARCAN[®] Nasal Spray.

Hold the NARCAN[®] Nasal Spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle.

Press the plunger firmly to give the dose of NARCAN[®] Nasal Spray.

Remove the NARCAN[®] Nasal Spray from the nostril after giving the dose.

3 Call for emergency medical help, Evaluate, and Support

Gently insert the tip of the nozzle into either nostril.

- Tilt the person's head back and provide support under the neck with your hand. Gently insert the tip of the nozzle into one nostril, with your fingers on either side of the nozzle are against the bottom of the person's nose.

Get emergency medical help right away.

Move the person on their side in recovery position after giving NARCAN[®] Nasal Spray.

Watch the person closely.

If the person does not respond by waking up, to voice or touch, or breathing normally another dose may be given. NARCAN[®] Nasal Spray may be dosed every 2 to 3 minutes, if available.

Repeat Step 2 using a new NARCAN[®] Nasal Spray to give another dose in the other nostril. If additional NARCAN[®] Nasal Sprays are available, repeat step 2 every 2 to 3 minutes until the person responds or emergency medical help is received.

Quick Start Guide and video instructions available on manufacturer's website:

- <http://www.narcannasalspray.com/pdf/NARCAN-Quick-Start-Guide.pdf>
- <http://www.narcannasalspray.com/helpful-resources>

EVZIO (AUTOINJECTOR)

- Availability
 - Naloxone 2 mg/0.4 mL*
 - Each carton contains two (2) single-use 2 mg auto-injectors
 - ❖ No assembly or priming requirements
 - Voice instruction system
 - Training (placebo) device included
 - ❖ Can be reused more than 1,000 times!
- Storage
 - Original packing, room temperature
 - ❖ Do NOT keep in car glove compartment or refrigerator
 - ❖ Keep away from children
 - Replace before expiration date on packaging
 - 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

**EVZIO 0.4 mg/0.4 mL is no longer manufactured*

EVZIO Package Insert. Kaleo, Inc. Available at <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=df501ed0-c0f4-11e3-8a33-0800200c9a66&type=display>

EVZIO. Kaleo, Inc. Available at: <https://evzio.com/patient/about-evzio/index.php#using-evzio>

EVZIO 2 mg



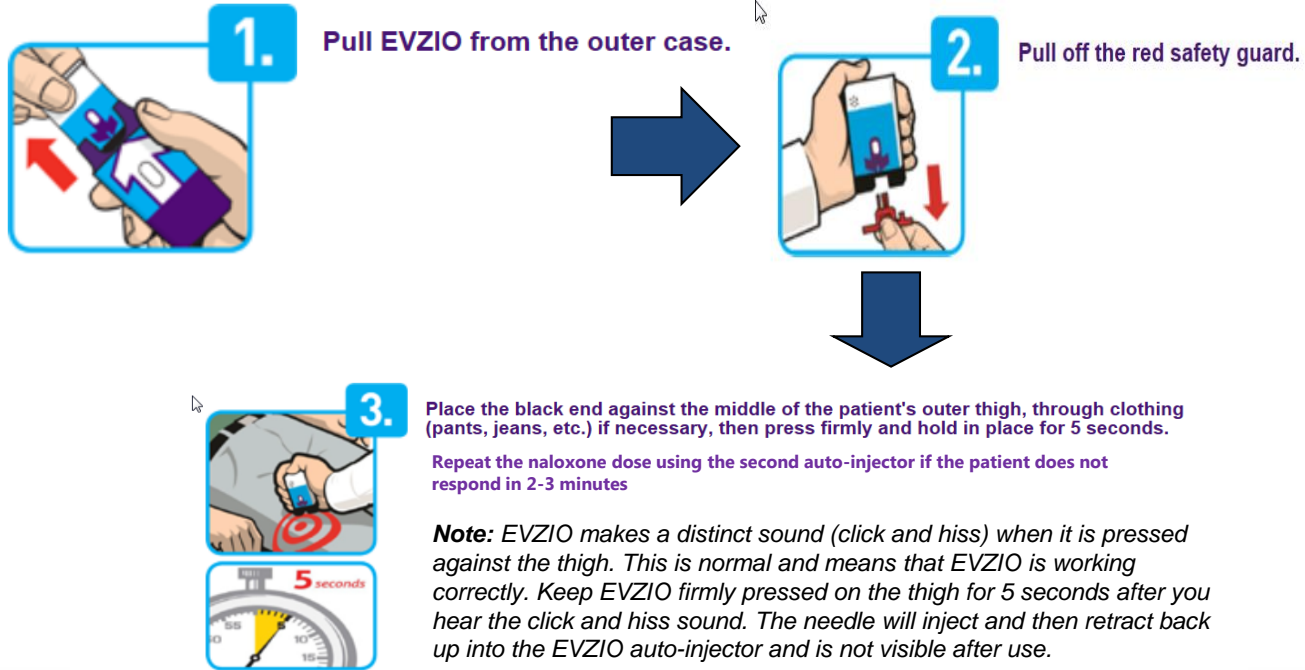
EVZIO 2 mg EVZIO 2 mg Outer Case

Trainer for EVZIO



Trainer Trainer Outer Case

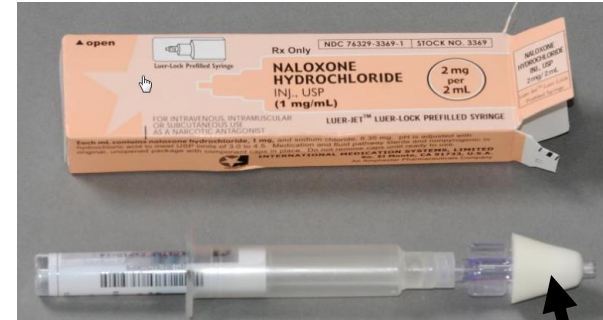
ADMINISTERING EVZIO



EVZIO Package Insert. Kaleo, Inc. Available at <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=df501ed0-c0f4-11e3-8a33-0800200c9a66&type=display>
EVZIO. Kaleo, Inc. Available at: <https://evzio.com/patient/about-evzio/index.php#using-evzio>

NALOXONE VIA NASAL ATOMIZER

- Availability
 - Naloxone 2 mg / 2 mL Luer-Lock prefilled syringes
 - Nasal atomizer
- Storage
 - Store room temperature
 - Protect from light
 - Store in carton until contents have been used

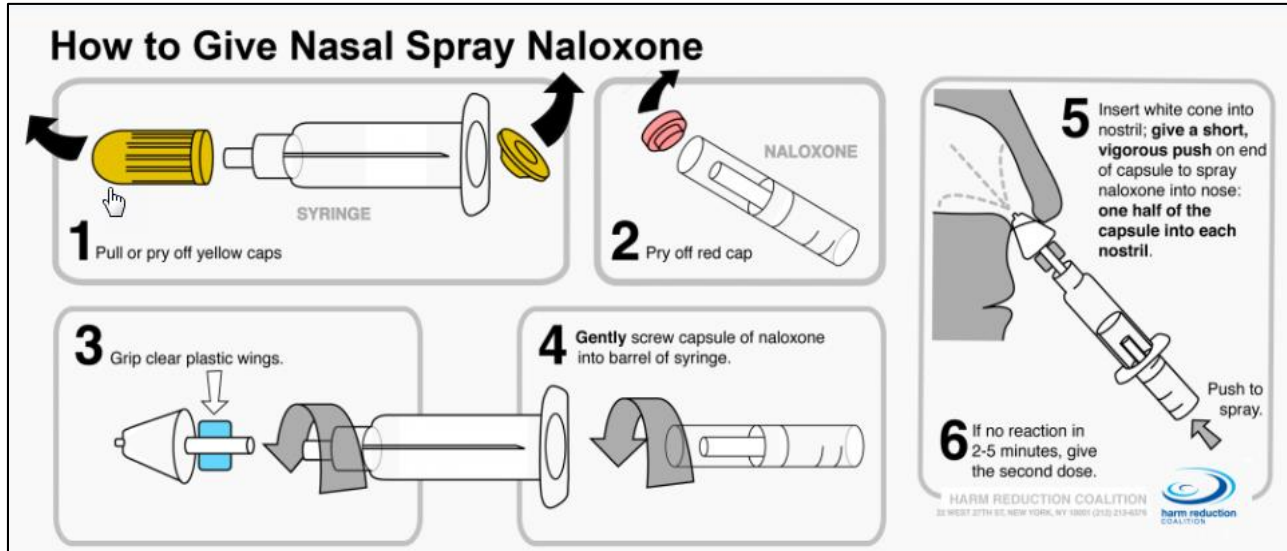


nasal
atomizer

Naloxone HCl. Package insert. International Medication Systems, Limited. Available at:
<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=236349ef-2cb5-47ca-a3a5-99534c3a4996>

ADMINISTERING NALOXONE VIA NASAL ATOMIZER

- Requires assembly!



Naloxone Kit Materials. Harm Reduction Coalition. <http://harmreduction.org/wp-content/uploads/2014/10/IN-instructions-and-kit-assembly.pdf>

NALOXONE VIAL AND SYRINGE

- Availability
 - Naloxone 0.4 mg/1 mL single-dose vial
 - One 1" inch 23 gauge needle and syringe (3mL) for intramuscular injection
- Storage
 - Store room temperature
 - Protect from light



<http://www.chimedsupply.com/Narcan-Naloxone-Injection-1mL-0.4-mg-mL-Single-Dose-Vial.html>

ADMINISTERING NALOXONE VIA VIAL AND SYRINGE

- Requires assembly!
 - Step 1: remove vial cap
 - Step 2: insert needle through rubber stopper
 - Step 3: draw entire contents of vial into syringe (1 mL)
 - Step 4: inject naloxone into deltoid (shoulder) or quadriceps (thigh) muscle (may inject through clothing)
- If no response in 3-5 minutes, give 2nd dose of naloxone

IMPORTANT COUNSELING POINTS FOR THE PERSON ADMINISTERING NALOXONE

- Seek medical care for the person experiencing an opioid-related overdose **immediately** after administering naloxone even if the person appears to be getting better because:
 - Naloxone is only temporary (wears off in 30 to 90 minutes)
 - The individual may need additional doses of naloxone
 - They may have other health problems or complications
 - It may be a non-opioid overdose or combination drug overdose

PRECAUTIONS, WARNINGS AND POTENTIAL ADVERSE REACTIONS WITH OPIOID ANTAGONIST ADMINISTRATION

PRECAUTIONS, WARNINGS AND POTENTIAL ADVERSE REACTIONS WITH NALOXONE ADMINISTRATION

- Administration of naloxone causes the release of catecholamines, which may precipitate acute withdrawal or unmask pain in those who regularly take opioids
- Symptoms of acute withdrawal in opioid-dependent patients may include:
 - Central Nervous System (CNS): pain, fever, sweating, agitation, and irritability
 - Cardiovascular (CV): tachycardia, hypertension,
 - Gastrointestinal (GI): abdominal cramps, diarrhea, nausea, vomiting

Naloxone. Lexi-Comp. © 2017 Wolters Kluwer Clinical Drug Information, Inc.

CONTRAINDICATIONS TO THE ADMINISTRATION OF NALOXONE

- Naloxone **should not be used** if the patient is not experiencing the signs of an overdose, if the overdose is not due to an opioid and if the patient is hypersensitive or allergic to naloxone.

SUBSTANCE ABUSE TREATMENT SERVICES

SUBSTANCE ABUSE TREATMENT SERVICES

- The District's Department of Behavioral Health (DBH) recommends calling or visiting the Assessment and Referral Center (the ARC) for substance-use disorder treatment services.
 - Assessment and Referral Center (the ARC)
 - ❖ Address: 75 P Street NE, Washington, DC 20002
 - ❖ Ph: (202) 727 8473
 - National Treatment Referral Helpline
 - ❖ 1-800-662-HELP (4357) or 1-800-487-4889 (TDD — for hearing impaired)
 - National Substance Abuse Treatment Facility Locator:
 - ❖ Search by state, city, county, and zip code.
 - Available at: <http://www.findtreatment.samhsa.gov/TreatmentLocator>

IMMUNITY FROM CIVIL OR CRIMINAL LIABILITY

IMMUNITY FROM CIVIL OR CRIMINAL LIABILITY

- A pharmacist who dispenses or distributes an opioid antagonist in accordance L21-0186 shall be immune from civil or criminal liability for the subsequent use of the opioid antagonist, unless the pharmacist's actions with regard to dispensing or distributing the opioid antagonist constitute recklessness, gross negligence, or intentional misconduct.
- The immunity granted shall apply whether or not the opioid antagonist is administered by or to the person for whom it was dispensed or distributed.

COUNSELING REQUIREMENTS

- Upon dispensing or distributing an opioid antagonist, the pharmacist shall provide the following education and training to the recipient:
 1. How to identify an opioid-related overdose;
 2. How to properly administer the prescribed opioid antagonist and circumstances under which administration is contraindicated;
 3. Precautions, warnings, and potential adverse reactions related to administration of the prescribed opioid antagonist;
 4. How opioid antagonists operate to stop an opioid-related overdose;
 5. The importance of seeking medical care for the person experiencing the opioid-related overdose immediately after the opioid antagonist is administered; and
 6. Information on how to access substance abuse treatment services.

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- **Presenters:**
 - Daphne Bernard, PharmD, RPh, Board of Pharmacy Chair
 - Lyndsy Beckman, PharmD, MS, CPPS, Pharmacy Quality and Patient Safety Chief, Kaiser Permanente
- **District of Columbia Board of Pharmacy Legislative and Regulatory Committee:**
 - James Appleby, BSP Pharm, MPH, Board Member
 - Alan Friedman, RPh, Board Committee Chair
 - Benjamin Miles, PharmD, RPh, BCPS, Board Member
 - Carla Williams, Assistant General Counsel
 - Shauna White, PharmD, RPh, MS, Board Executive Director



More resources available at the
DC Center for Rational Prescribing

dchealth.dc.gov/dcrx