

NALOXONE HYDROCHLORIDE- naloxone hydrochloride spray **AvKARE**

Naloxone Hydrochloride Nasal Spray

Active ingredient (in each spray)

Naloxone hydrochloride 4 mg

Purpose

Emergency treatment of opioid overdose

Use(s)

- to “revive” someone during an overdose from many **prescription pain medications** or **street drugs such as heroin**
- this medicine can save a life

Warnings

When using this product

some people may experience symptoms when they wake up, such as shaking, sweating, nausea, or feeling angry. This is to be expected.

Directions



Step 1: CHECK if you suspect an overdose

- **CHECK** for a suspected overdose: the person will not wake up or is very sleepy or not breathing well
- yell “Wake up!”
- shake the person gently
- if the person is not awake, go to Step 2



Step 2: GIVE 1st dose in the nose

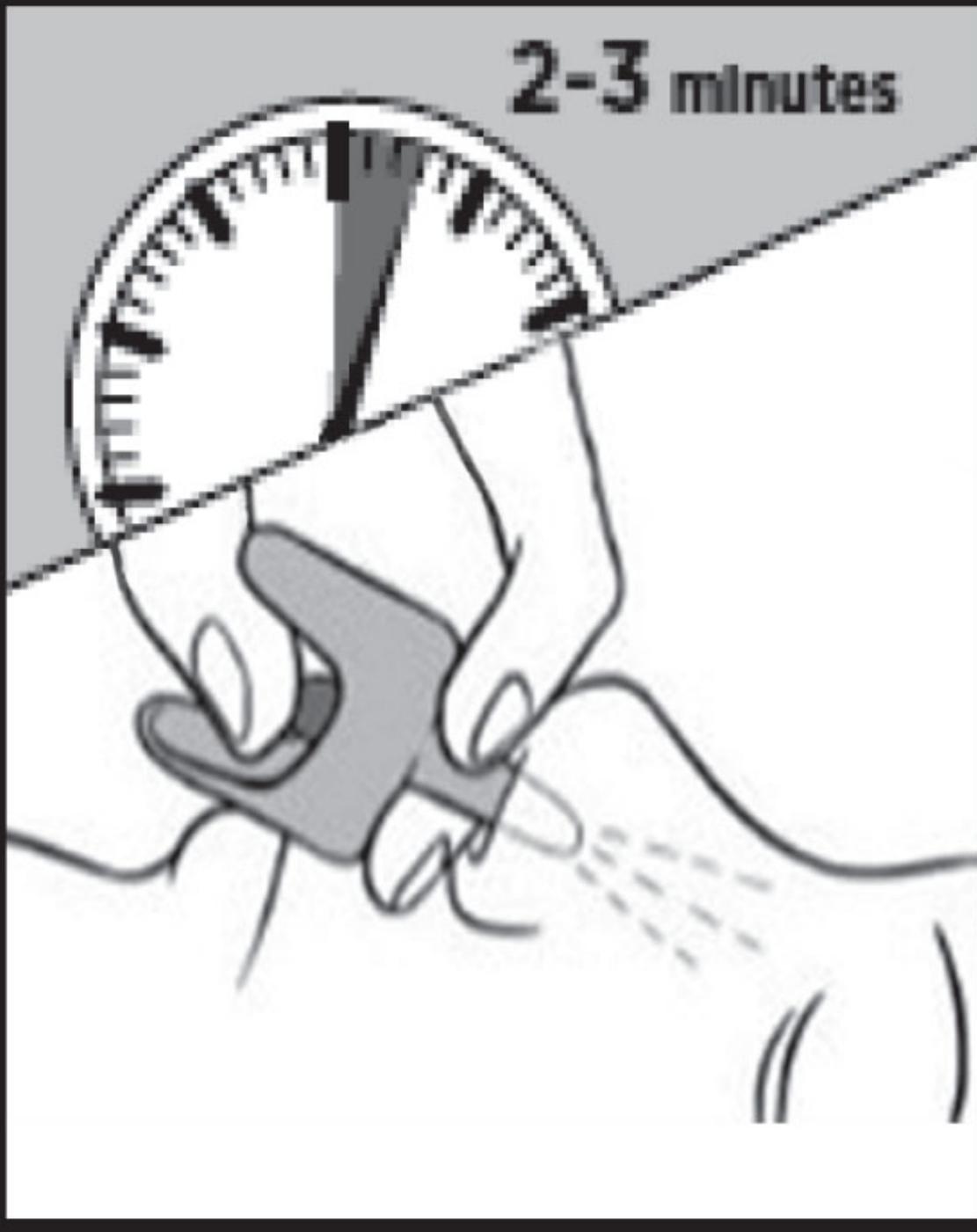
- **HOLD** the nasal spray device with your thumb on the bottom of the plunger
- **INSERT** the nozzle into either NOSTRIL
- **PRESS** the plunger firmly to give the 1st dose
- 1 nasal spray device contains 1 dose



Step 3: CALL 911

- **CALL 911** immediately after giving the 1st dose

④ WATCH/GIVE



Step 4: WATCH & GIVE

- **WAIT** 2 to 3 minutes after the 1st dose to give the medicine time to work
- if the person wakes up: Go to Step 5
- if the person does not wake up:
- **CONTINUE TO GIVE** doses every 2 to 3 minutes until the person wakes up
- it is safe to keep giving doses



Step 5: STAY

- **STAY** until ambulance arrives: even if the person wakes up
- **GIVE** another dose if the person becomes very sleepy again
- You may need to give all the doses in the pack

Other information

- store at room temperature or refrigerated, between 2°C to 25°C (36°F to 77°F)
- do not freeze
- avoid excessive heat above 40°C (104°F)
- protect from light
- this product is packaged in individually-sealed blisters. Do not use if the blister is open or torn, or if the device appears damaged.

Inactive ingredients

benzalkonium chloride, disodium ethylenediaminetetraacetate, hydrochloric acid, purified water, and sodium chloride

DIRECTIONS

Naloxone Hydrochloride Nasal Spray, 4 mg

Emergency Treatment of Opioid Overdose

Important:

- For use in the nose only
- Do not test nasal spray device before use
- 1 nasal spray device contains 1 dose of medicine
- Each device sprays 1 time only

NOZZLE

PLUNGER



Step 1: CHECK if you suspect an overdose

- **CHECK** for a suspected overdose: the person will not wake up or is very sleepy or

not breathing well

- yell “Wake up!”
- shake the person gently
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Step 2: GIVE 1st dose in the nose

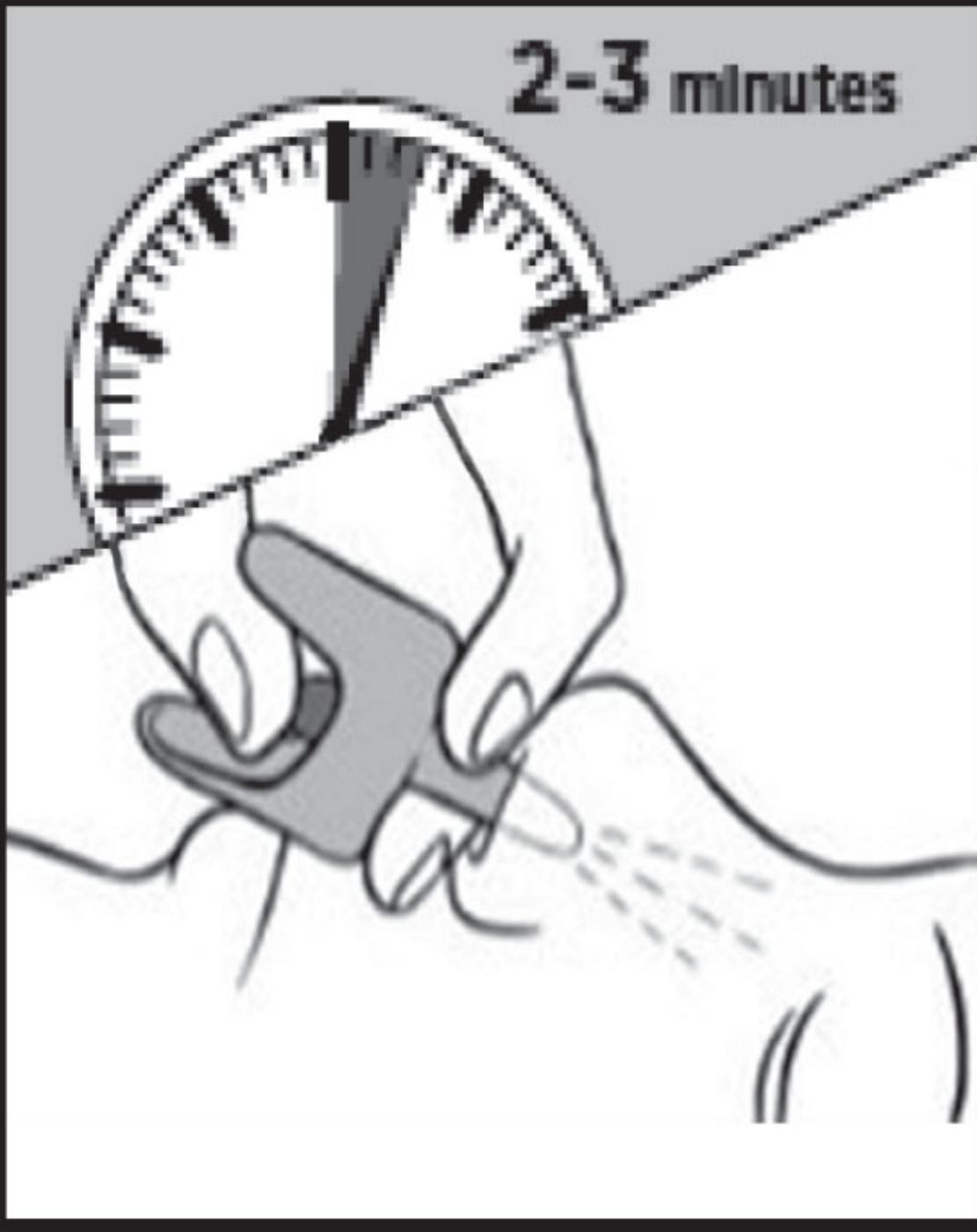
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Step 5: STAY

- **STAY** until ambulance arrives: even if the person wakes up
- **GIVE** another dose if the person becomes very sleepy again
- You may need to give all the doses in the pack

For opioid emergencies, call 911. For questions or more information about Naloxone Hydrochloride Nasal Spray, contact

AvKARE at 1-855-361-3993.

Mfg. Rev. 03-2023-01 AV 05/23

Principal Display Panel

<p>Drug Facts (continued)</p> <p>Directions</p> <p>1. CHECK</p> <ul style="list-style-type: none"> Step 1: CHECK if you suspect an overdose • CHECK for a suspected overdose: the person will not wake up or is very sleepy or not breathing well • yell "Wake up!" • shake the person gently • if the person is not awake, go to Step 2 <p>2. GIVE</p> <ul style="list-style-type: none"> Step 2: GIVE 1st dose in the nose • HOLD the nasal spray device with your thumb on the bottom of the plunger • INSERT the nozzle into either NOSTRIL • PRESS the plunger firmly to give the 1st dose • 1 nasal spray device contains 1 dose <p>3. CALL</p> <ul style="list-style-type: none"> Step 3: CALL • CALL 911 immediately after giving the 1st dose <p>4. WATCH & GIVE</p> <ul style="list-style-type: none"> Step 4: WATCH & GIVE • WAIT 2 to 3 minutes after the 1st dose to give the medicine time to work • if the person does not wake up, go to Step 5 • if the person does not wake up: <ul style="list-style-type: none"> • CONTINUE TO GIVE doses every 2 to 3 minutes UNTIL the person wakes up • if it safe to keep giving doses <p>5. STAY</p> <ul style="list-style-type: none"> Step 5: STAY • STAY until ambulance arrives, even if the person wakes up • GIVE another dose if the person becomes very sleepy again • You may need to give all the doses in the pack 	<p>Drug Facts (continued)</p> <p>Warnings</p> <p>When using this product some people may experience symptoms when they wake up, such as shaking, sweating, nausea, or feeling dizzy. This is to be expected.</p> <p>Other information</p> <ul style="list-style-type: none"> • store at room temperature or refrigerated, between 2°C to 25°C (36°F to 77°F) • do not freeze • avoid excessive heat above 40°C (104°F) • protect from light • this product is packaged in individually-sealed blister packs. Do not use if the blister is open or torn, or if the device appears damaged. <p>Inactive ingredients</p> <p>benzalkonium chloride, disodium ethylenediaminetetraacetate, hydrochloric acid, purified water, and sodium chloride</p> <p>Questions or comments?</p> <p>1-855-361-3993 (Mon-Fri, 9AM-5PM EST)</p> <p>Safe to Use Even if Opioids are Not Present</p> <p>Manufactured for: AvKARE, Pulaski, TN 39478 Manufactured by: Amneal Pharmaceuticals LLC Branzburg, NJ 08876</p> <p>Mfg. Rev. 03-2023-01 AV 05/23</p>	<p>AVKARE NDC 42291-493-02</p> <p>Naloxone Hydrochloride Nasal Spray</p> <p>4 mg</p> <p>Emergency Treatment of Opioid Overdose</p> <p>Designed to Rapidly Reverse the Effects of a Life-Threatening Opioid Emergency</p> <ul style="list-style-type: none"> • Original Prescription Strength • Easy to Use • Can Save a Life <p>2 Single-Dose Nasal Spray Devices 0.009 fl oz (0.1 mL) each</p> <p>For use in nose only</p>	<p>For use in nose only</p> <p>Do not test nasal spray device before use.</p> <p>1 nasal spray device contains 1 dose of medicine</p> <p>Each device sprays 1 time only</p> <p>Read Directions Before Use ▶</p> <p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredient (in each spray)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Naloxone hydrochloride 4 mg</td> <td>Emergency treatment of opioid overdose</td> </tr> </tbody> </table> <p>Uses</p> <ul style="list-style-type: none"> • to "reverse" someone during an overdose from many prescription pain medications or street drugs such as heroin • this medicine can save a life 	Active ingredient (in each spray)	Purpose	Naloxone hydrochloride 4 mg	Emergency treatment of opioid overdose
Active ingredient (in each spray)	Purpose						
Naloxone hydrochloride 4 mg	Emergency treatment of opioid overdose						

NDC 42291-493-01

PEEL HERE

Naloxone Hydrochloride Nasal Spray 4 mg

Emergency Treatment of Opioid Overdose

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Manufactured for: AvKARE, Pulaski, TN 38478
 Manufactured by: Amneal Pharmaceuticals LLC
 Branchburg, NJ 08876
 Mfg. Rev. 03-2023-01 AV 05/23



LOT:

1.15" x 0.75"
 area for Lot and Exp
 printing

EXP:



NALOXONE HYDROCHLORIDE

naloxone hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42291-493
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NALOXONE HYDROCHLORIDE (UNII: F850569PQR) (NALOXONE - UNII:36B82AMQ7N)	NALOXONE HYDROCHLORIDE	4 mg in 0.1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM CHLORIDE (UNII: 451W471Q8X)	
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Product Characteristics

Color	white (clear, colorless to faintly yellow)	Score	
Shape		Size	

Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42291-493-02	2 in 1 CARTON	05/01/2024	
1	NDC:42291-493-01	0.1 mL in 1 VIAL, SINGLE-DOSE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217992	05/01/2024	

Labeler - AvKARE (796560394)