

**NALOXONE HYDROCHLORIDE- naloxone spray**  
**Amneal Pharmaceuticals NY LLC**

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**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

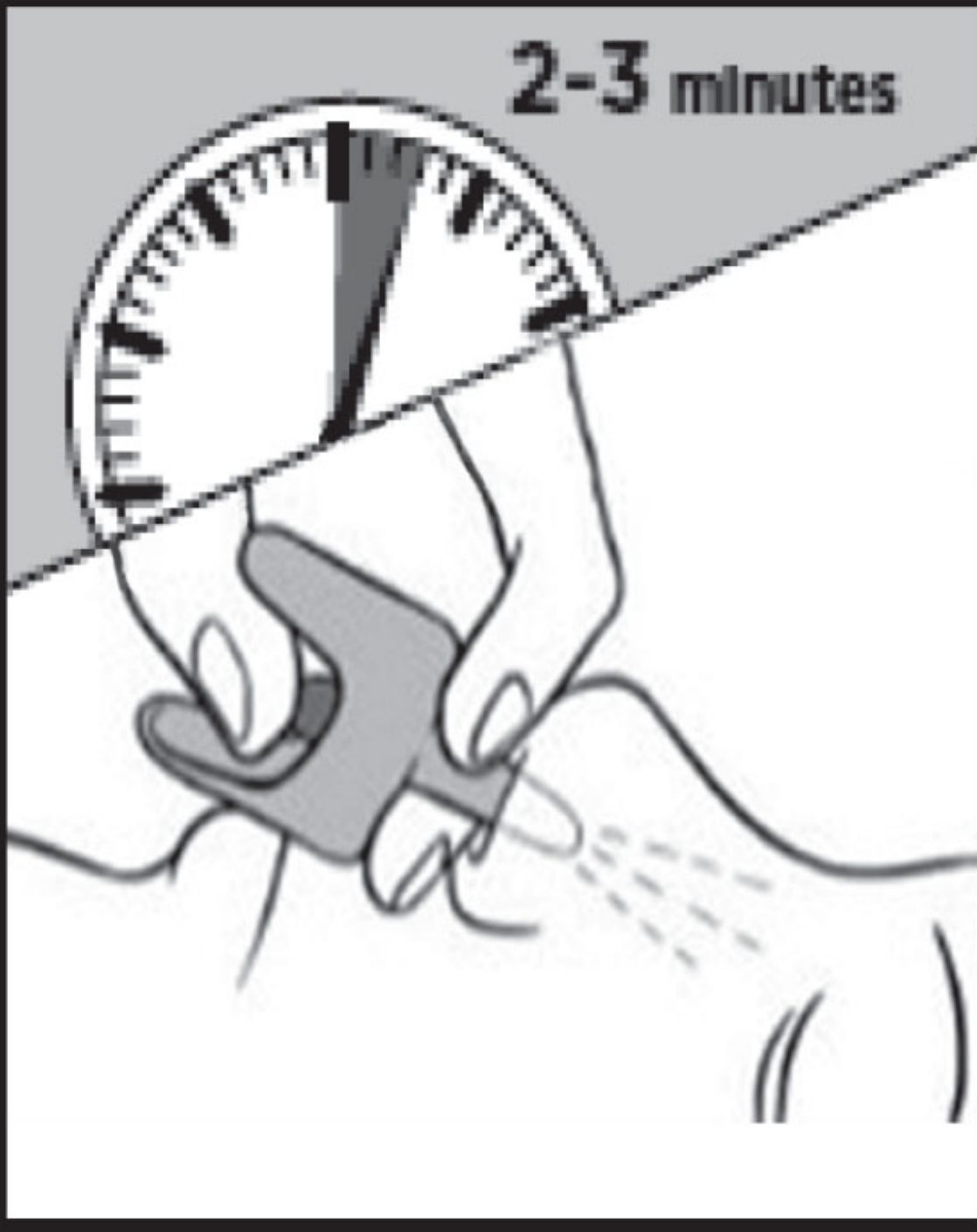
- **HOLD** the nasal spray device with your thumb on the bottom of the plunger
- **INSERT** the nozzle into either NOSTRIL
- **PRESS** the plunger firmly to give the 1st dose
- 1 nasal spray device contains 1 dose



### 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**

#### 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

### **Questions or comments?**

1-877-835-5472 (Mon-Fri, 9AM-5PM EST)

### **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





### 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

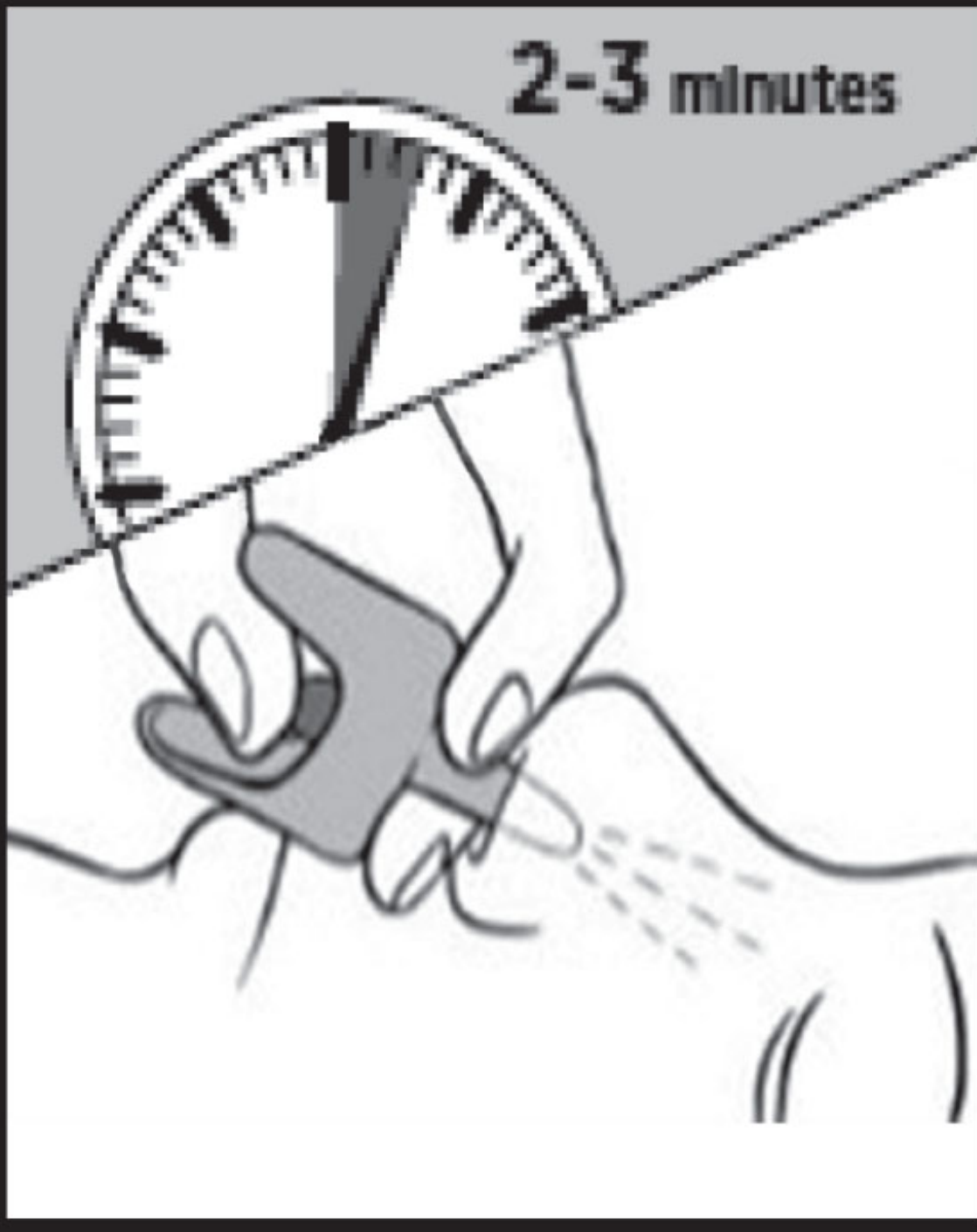
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- **STAY** until ambulance arrives: even if the person wakes up
- **GIVE** another dose if the person becomes very sleepy again
- You may need to give all the doses in the pack

**For opioid emergencies, call 911.** For questions or more information about Naloxone Hydrochloride Nasal Spray, contact Amneal Pharmaceuticals at 1-877-835-5472.

Rev. 07-2023-04

### Principal Display Panel

<p><b>Drug Facts</b> (continued)</p> <p><b>Directions</b></p> <p><b>1 CHECK</b></p> <p><b>Step 1: CHECK if you suspect an overdose</b></p> <ul style="list-style-type: none"> <li>■ CHECK for a suspected overdose: the person will not wake up or is very sleepy or not breathing well</li> <li>■ yell "Wake up!"</li> <li>■ shake the person gently</li> <li>■ if the person is not awake, go to Step 2</li> </ul> <p><b>2 GIVE</b></p> <p><b>Step 2: GIVE 1<sup>st</sup> dose in the nose</b></p> <ul style="list-style-type: none"> <li>■ HOLD the nasal spray device with your thumb on the bottom of the plunger</li> <li>■ INSERT the nozzle into either NOSTRIL</li> <li>■ PRESS the plunger firmly to give the 1<sup>st</sup> dose</li> <li>■ 1 nasal spray device contains 1 dose</li> </ul> <p><b>3 CALL</b></p> <p><b>Step 3: CALL 911</b></p> <ul style="list-style-type: none"> <li>■ CALL 911 immediately after giving the 1<sup>st</sup> dose</li> </ul> <p><b>4 WATCH/GIVE</b></p> <p><b>Step 4: WATCH &amp; GIVE</b></p> <ul style="list-style-type: none"> <li>■ WAIT 2 to 3 minutes after the 1<sup>st</sup> dose to give the medicine time to work</li> <li>■ if the person wakes up: Go to Step 5</li> <li>■ if the person does not wake up: <ul style="list-style-type: none"> <li>■ CONTINUE TO GIVE doses every 2 to 3 minutes until the person wakes up</li> <li>■ it is safe to keep giving doses</li> </ul> </li> </ul> <p><b>5 STAY</b></p> <p><b>Step 5: STAY</b></p> <ul style="list-style-type: none"> <li>■ STAY until ambulance arrives: even if the person wakes up</li> <li>■ GIVE another dose if the person becomes very sleepy again</li> <li>■ You may need to give all the doses in the pack</li> </ul>	<p><b>Drug Facts</b> (continued)</p> <p><b>Warnings</b></p> <p>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.</p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ store at room temperature or refrigerated, between 2°C to 25°C (36°F to 77°F)</li> <li>■ do not freeze</li> <li>■ avoid excessive heat above 40°C (104°F)</li> <li>■ protect from light</li> <li>■ this product is packaged in individually-sealed blisters. Do not use if the blister is open or torn, or if the device appears damaged.</li> </ul> <p><b>Inactive ingredients</b></p> <p>benzalkonium chloride, disodium ethylenediaminetetraacetate, hydrochloric acid, purified water, and sodium chloride</p> <p><b>Questions or comments?</b></p> <p>1-877-835-5472 (Mon-Fri, 9AM-5PM EST)</p> <p><small>*This product is not manufactured or distributed by Emergent, owner of the registered trademark Narcan®.</small></p> <p><b>Safe to Use</b> Even if Opioids are Not Present</p> <p>Manufactured by: <b>CalRx</b> Sacramento, CA 95833</p> <p>Manufactured by: <b>Amneal Pharmaceuticals LLC</b> Branchburg, NJ 08876</p> <p>Rev. 03-2024-00</p>	<p>NDC 60219-2104-7</p> <p><b>Naloxone HCl Nasal Spray, 4 mg</b></p> <p><b>Emergency Treatment of Opioid Overdose</b></p> <p><b>Designed to Rapidly Reverse the Effects of a Life-Threatening Opioid Emergency</b></p> <ul style="list-style-type: none"> <li>• Original Prescription Strength</li> <li>• Easy to Use</li> <li>• Can Save a Life</li> </ul> <p><b>* Compare to active ingredient in NARCAN®</b></p> <p>2 Single-Dose Nasal Spray Devices 0.003 fl oz (0.1 mL) each</p> <p><b>For use in nose only</b></p>	<p><b>For use in nose only</b></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><b>Drug Facts</b></p> <table border="1"> <tr> <td><b>Active ingredient (in each spray)</b></td> <td><b>Purpose</b></td> </tr> <tr> <td>Naloxone hydrochloride 4 mg</td> <td>Emergency treatment of opioid overdose</td> </tr> </table> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>■ to "revive" someone during an overdose from many prescription pain medications or street drugs such as heroin</li> <li>■ this medicine can save a life</li> </ul>	<b>Active ingredient (in each spray)</b>	<b>Purpose</b>	Naloxone hydrochloride 4 mg	Emergency treatment of opioid overdose
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Naloxone hydrochloride 4 mg	Emergency treatment of opioid overdose						

# NALOXONE HYDROCHLORIDE

naloxone spray

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60219-2104
<b>Route of Administration</b>	NASAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	

## Product Characteristics

<b>Color</b>	white (clear, colorless to faintly yellow)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60219-2104-7	2 in 1 CARTON	04/24/2024	
1	NDC:60219-2104-1	0.1 mL in 1 VIAL; 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	04/24/2024	

**Labeler** - Amneal Pharmaceuticals NY LLC (123797875)

## Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals, LLC		079823130	analysis(60219-2104) , label(60219-2104) , manufacture(60219-2104) , pack(60219-2104)

Revised: 4/2024

Amneal Pharmaceuticals NY LLC