

**NALOXONE HYDROCHLORIDE- naloxone hydrochloride 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

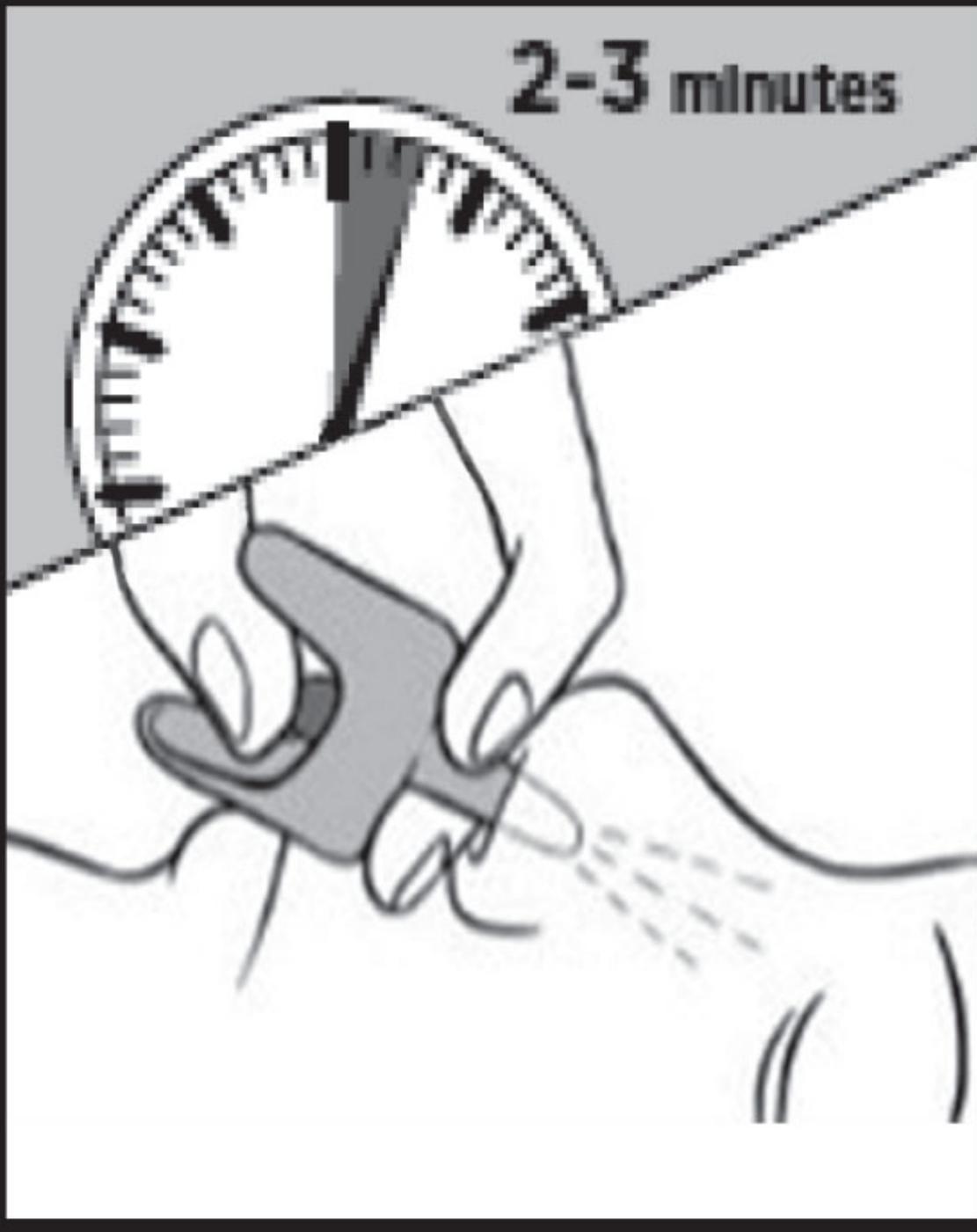
- **HOLD** the nasal spray device with your thumb on the bottom of the plunger
- **INSERT** the nozzle into either NOSTRIL
- **PRESS** the plunger firmly to give the 1st dose
- 1 nasal spray device contains 1 dose



### 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**

- 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**

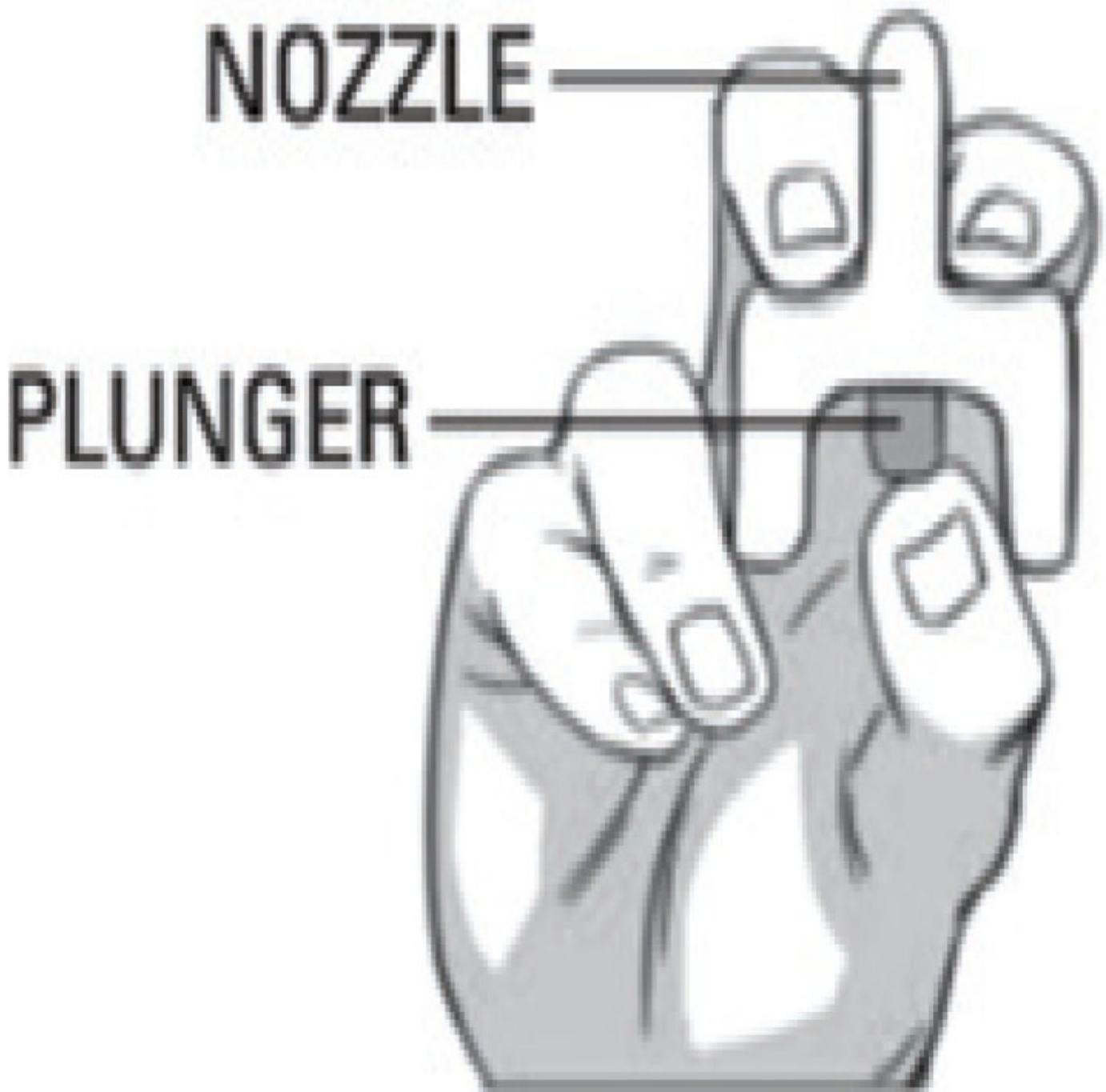
#### **Naloxone Hydrochloride Nasal Spray, 4 mg**

#### **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



**Drug Facts**

**Active ingredient (in each spray) Purpose**

Naloxone hydrochloride 4 mg

.....  
Emergency treatment  
of opioid overdose

**Uses**

- to “revive” someone during an overdose from many **prescription pain**

**medications or street drugs such as heroin**

- this medicine can save a life



### **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!"
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### **Step 2: GIVE 1st dose in the nose**

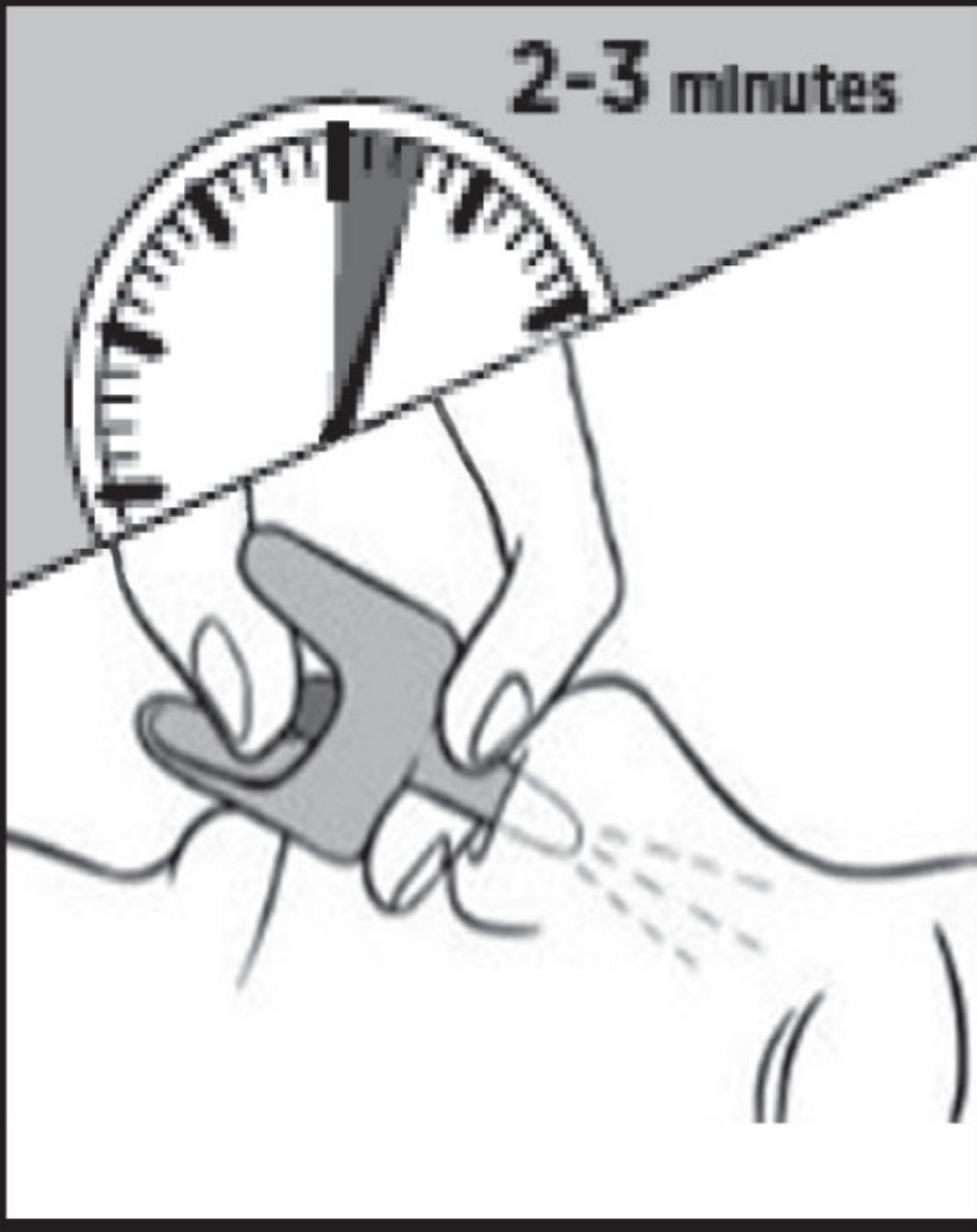
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- 1 nasal spray device contains 1 dose



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# ④ WATCH/GIVE



## Step 4: WATCH & GIVE

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- it is safe to keep giving doses



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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

### **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.

### **Other information**

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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)

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

Rev. 11-2025-05

## Principal Display Panel



# Naloxone HCl Nasal Spray, 4 mg

NDC 69238-2104-7



## Naloxone HCl Nasal Spray, 4 mg

Emergency Treatment of Opioid Overdose

Designed to Rapidly Reverse the Effects of a Life-Threatening Opioid Emergency

- Original Prescription Strength
- Easy to Use
- Can Save a Life



\* Compare to active ingredient in NARCAN®

2 Single-Dose Nasal Spray Devices  
0.003 fl oz (0.1 mL) each

For use in nose only

For use in 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

Read Directions Before Use

### Drug Facts

**Active ingredient (in each spray)** Purpose  
Naloxone hydrochloride 4 mg ..... Emergency treatment of opioid overdose

#### Uses

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

### Drug Facts (continued)

#### 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 1<sup>st</sup> 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 1<sup>st</sup> dose
- 1 nasal spray device contains 1 dose



#### Step 3: CALL 911

- CALL 911 immediately after giving the 1<sup>st</sup> dose



#### Step 4: WATCH & GIVE

- WAIT 2 to 3 minutes after the 1<sup>st</sup> 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

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### Drug Facts (continued)

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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.

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#### 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)  
or go to [amnealnaloxone.com](http://amnealnaloxone.com)

\*This product is not manufactured or distributed by Emergent, owner of the registered trademark Narcan®.

Safe to Use  
Even if Opioids are Not Present

Distributed by:  
Amneal Pharmaceuticals LLC  
Bridgewater, NJ 08807

Rev. 05-2025-06



## NALOXONE HYDROCHLORIDE

naloxone hydrochloride spray

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69238-2104
Route of Administration	NASAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>NALOXONE HYDROCHLORIDE</b> (UNII: F850569PQR) (NALOXONE - UNII:36B82AMQ7N)	NALOXONE HYDROCHLORIDE	4 mg in 0.1 mL
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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: 059QF0KO0R)	
<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:69238-2104-7	2 in 1 CARTON	04/24/2024	
1	NDC:69238-2104-1	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	04/24/2024	

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

Establishment			
Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals, LLC		079823130	analysis(69238-2104) , label(69238-2104) , manufacture(69238-2104) , pack(69238-2104)

Revised: 12/2025

Amneal Pharmaceuticals NY LLC