

# **NALOXONE HYDROCHLORIDE- naloxone hydrochloride spray**

## **CVS Pharmacy, Inc**

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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



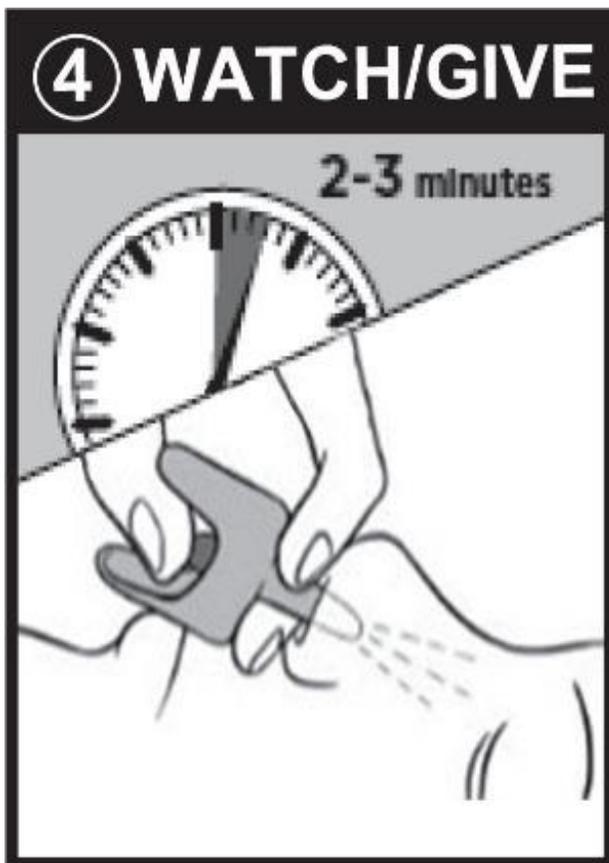
### Step 2: GIVE 1st dose in the nose

- **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



#### 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.

## **Storage**

## **Inactive ingredients**

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

## **Questions**

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

**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
- if the person is not awake, go to Step 2



### Step 2: GIVE 1<sup>st</sup> dose in the nose

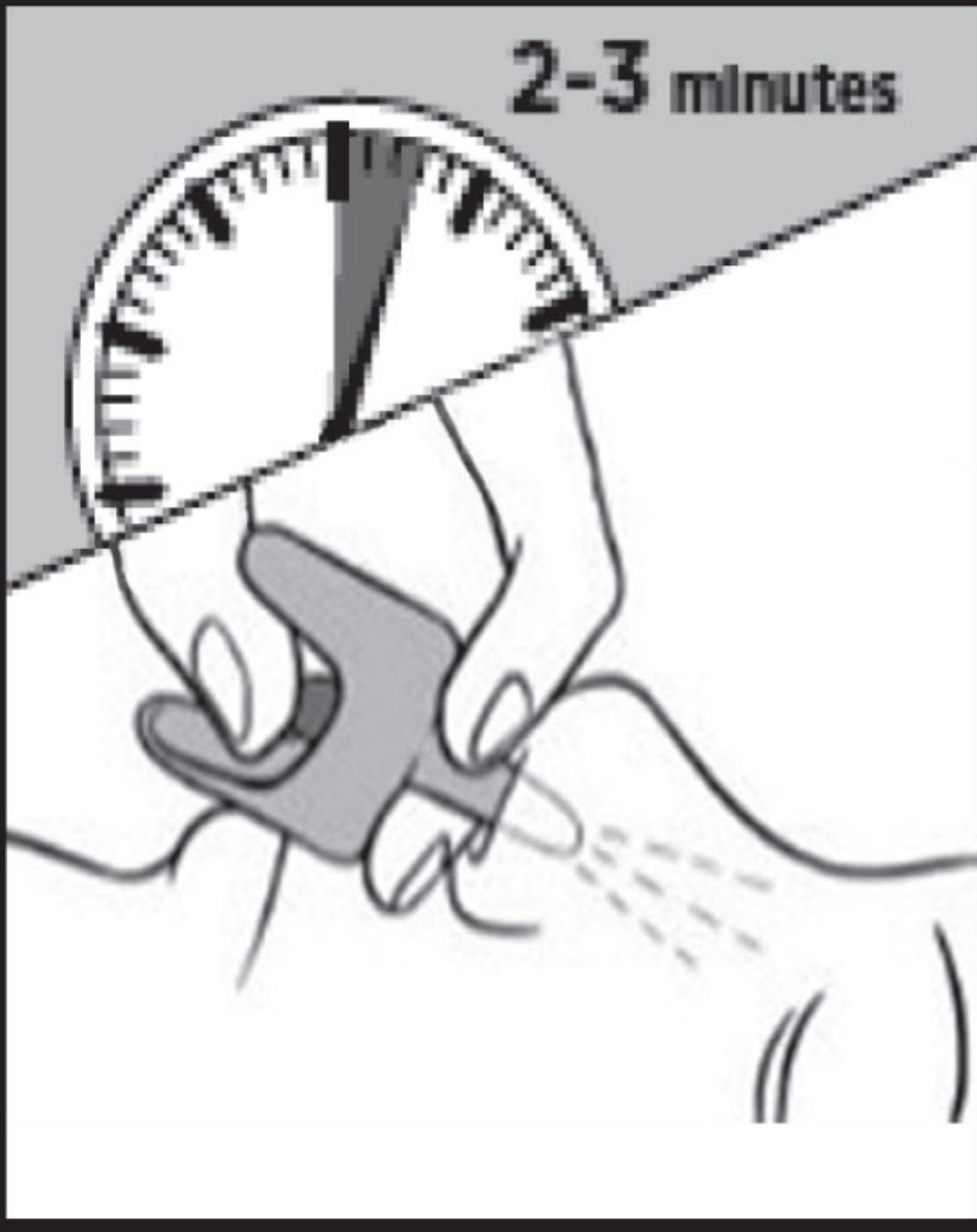
- **HOLD** the nasal spray device with your thumb on the bottom of the plunger
- **INSERT** the nozzle into either NOSTRIL
- **PRESS** the plunger firmly to give the 1<sup>st</sup> dose
- 1 nasal spray device contains 1 dose



### Step 3: CALL 911

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

# ④ WATCH/GIVE



## Step 4: WATCH AND 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**

- **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**

**Drug Facts** (continued)

**Directions**

**1 CHECK**

**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

**2 GIVE**

**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

**3 CALL**

**Step 3: CALL 911**

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

**4 WATCH/GIVE**

**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

**5 STAY**

**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

**Drug Facts** (continued)

**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**

- store at room temperature or refrigerated, between 2°C to 25°C (36°F to 77°F)
- do not freeze
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- 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)

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

**Safe to use even if opioids are not present.**

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V-39542

#616900



0 50428 44395 8 Rev. 06-2023-00

**CVS Health.** Compare to active ingredient in Narcan®  
NDC 51316-210-02

**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
- Can Save a Life
- Easy to Use



**For use in nose only**

**2 SINGLE-DOSE NASAL SPRAY DEVICES**  
0.003 FL OZ (0.1 mL) EACH

**CVS Health.**

**Naloxone HCl Nasal Spray 4 mg**

**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

# NALOXONE HYDROCHLORIDE

naloxone hydrochloride spray

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51316-210
<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:51316-210-02	2 in 1 CARTON	04/24/2024	
1	NDC:51316-210-01	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** - CVS Pharmacy, Inc (062312574)

Revised: 4/2024

CVS Pharmacy, Inc