

**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



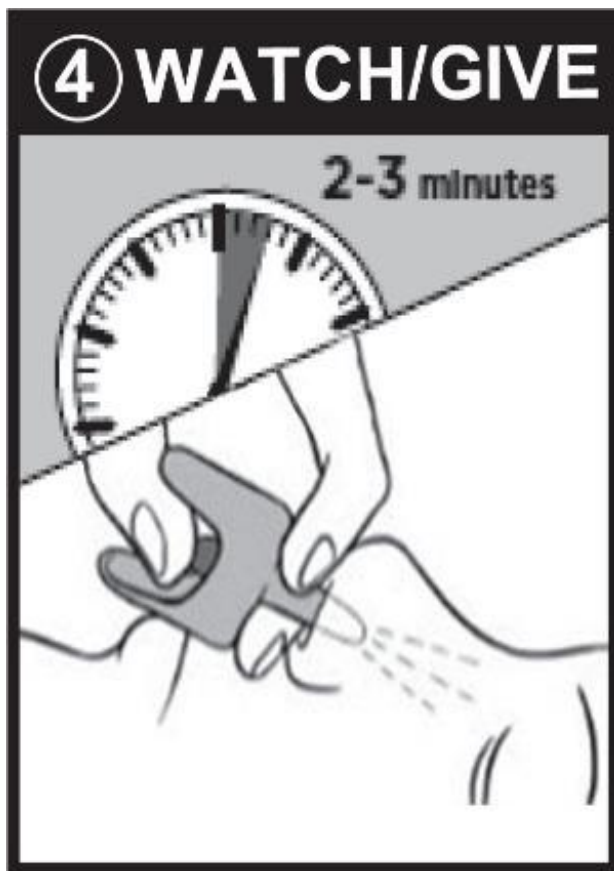
### Step 2: GIVE 1st dose in the nose

- **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**

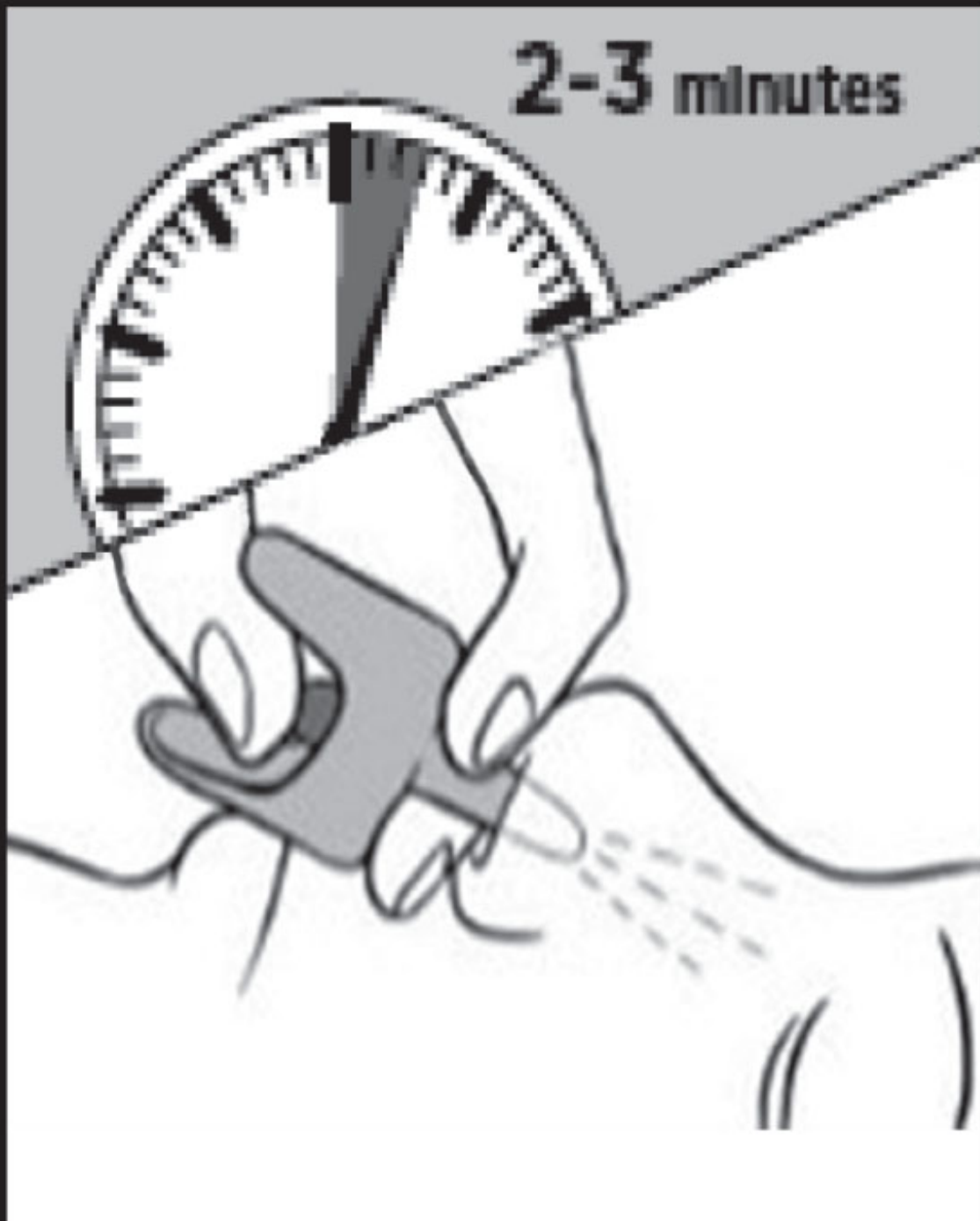
- **HOLD** the nasal spray device with your thumb on the bottom of the plunger
- **INSERT** the nozzle into either NOSTRIL
- **PRESS** the plunger firmly to give the 1<sup>st</sup> dose
- 1 nasal spray device contains 1 dose



### 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

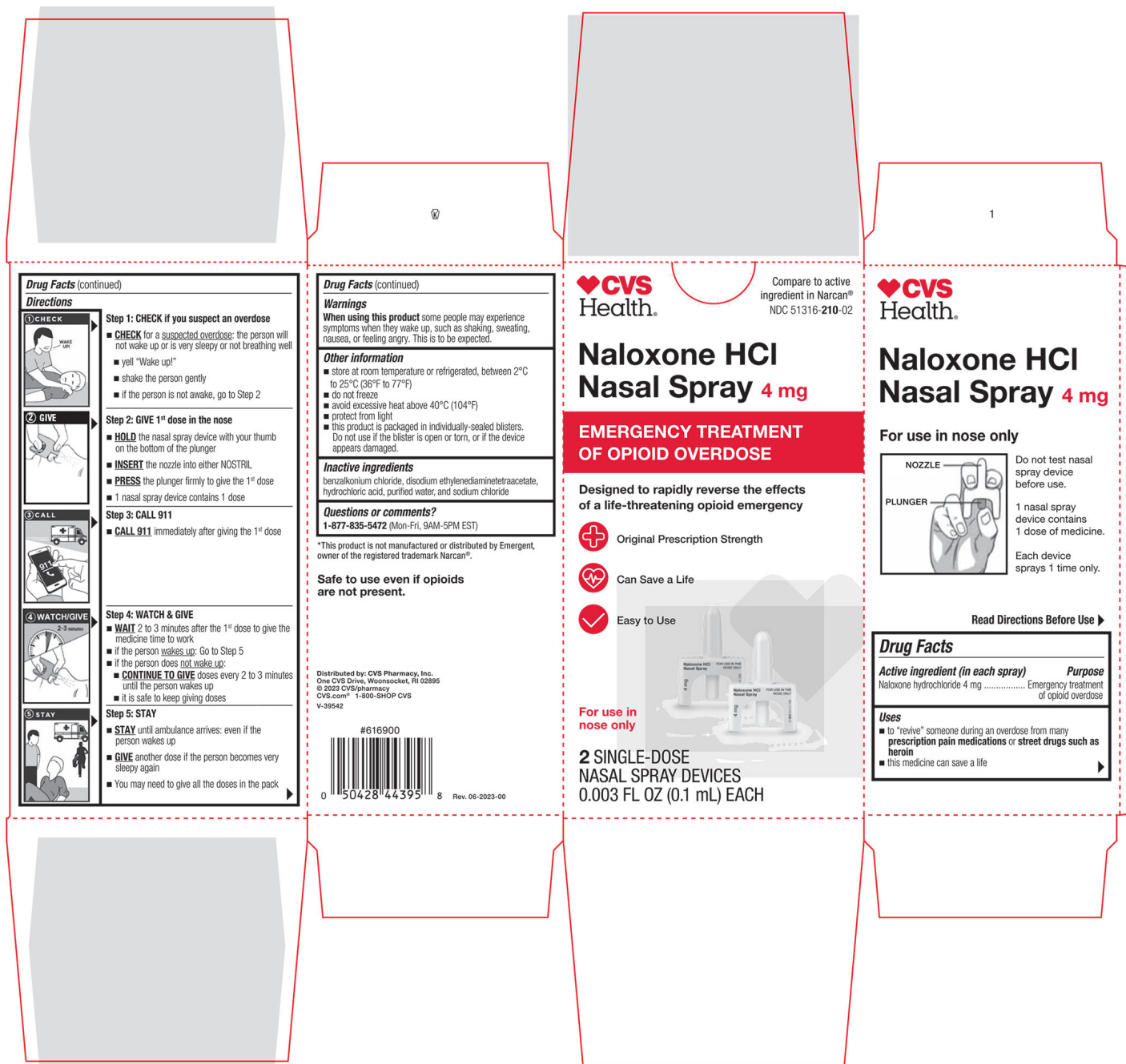
- **STAY** until ambulance arrives: even if the person wakes up
- **GIVE** another dose if the person becomes very sleepy again
- You may need to give all the doses in the pack

**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





## NALOXONE HYDROCHLORIDE

naloxone hydrochloride spray

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:51316-210 |
| 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: 451W47IQ8X)       |          |
| 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: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)