

## **NARCAN- naloxone hydrochloride nasal spray** **Emergent Devices Inc.**

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**NARCAN® Naloxone HCl Nasal Spray 4 mg Drug Facts**

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

Naloxone Hydrochloride 4 mg

### **Purpose**

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

### **Warning**

- **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**

#### **NARCAN®**

Naloxone HCl 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

- **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 1<sup>st</sup> dose



### Step 4: WATCH & GIVE

- **WAIT** 2-3 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 2-3 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 on NARCAN, call 1-844-4NARCAN (1-844-462-7226) or go to [www.narcan.com](http://www.narcan.com).

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### **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
- the 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, edetate disodium, hydrochloric acid, sodium chloride, water

### **Questions?**

Call 1-844-4NARCAN (1-844-462-7226) or go to [www.narcan.com](http://www.narcan.com)

### **Package/Label Principal Display Panel - Carton Label**



**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**

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



**Step 4: WATCH & GIVE**

- **WAIT** 2-3 minutes after the 1<sup>st</sup> dose to give the medicine time to work
- if the person **gains up**, Go to Step 5
- if the person does **not wake up**:
  - **CONTINUE TO GIVE** doses every 2-3 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

**Drug Facts (continued)**

**Warning**

**When using this product** some people may experience symptoms when they wake up, such as shivering, sweating, nausea, or feeling angry. This is to be expected.

**Other information**

- store at room temperature or refrigerated, between 2°C to 25°C (32°F to 77°F)
- do not freeze
- avoid excessive heat above 40°C (104°F)
- protect from light
- the 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, edetate disodium, hydrochloric acid, sodium chloride, water

**Questions?**

call 1-844-NARCAN (1-844-463-7228) or go to [www.narcan.com](http://www.narcan.com)

Safe to Use  
Even if Opioids are Not Present

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NDC 69547-627-02



A101  
110033

**NARCAN®**  
Naloxone HCl Nasal Spray 4 mg



Original Prescription Strength

Easy to Use

Can Save a Life

**NARCAN®**  
Naloxone HCl Nasal Spray 4 mg

Emergency Treatment of Opioid Overdose

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



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

For use in nose only

For use in nose only



Nozzle  
Plunger

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

LOT XXXXXX

EXP YYY-MM



**NARCAN®**  
Naloxone HCl Nasal Spray 4 mg  
Emergency Treatment of Opioid Overdose

Original Prescription Strength

Easy to Use

Can Save a Life

Designed to Rapidly Reverse the Effects of a

Life-Threatening  
Opioid Emergency

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

For use in  
nose only

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NDC 69547-627-02

### Package/Label Principal Display Panel - 4 mg Vial Package



NDC 69547-627-02

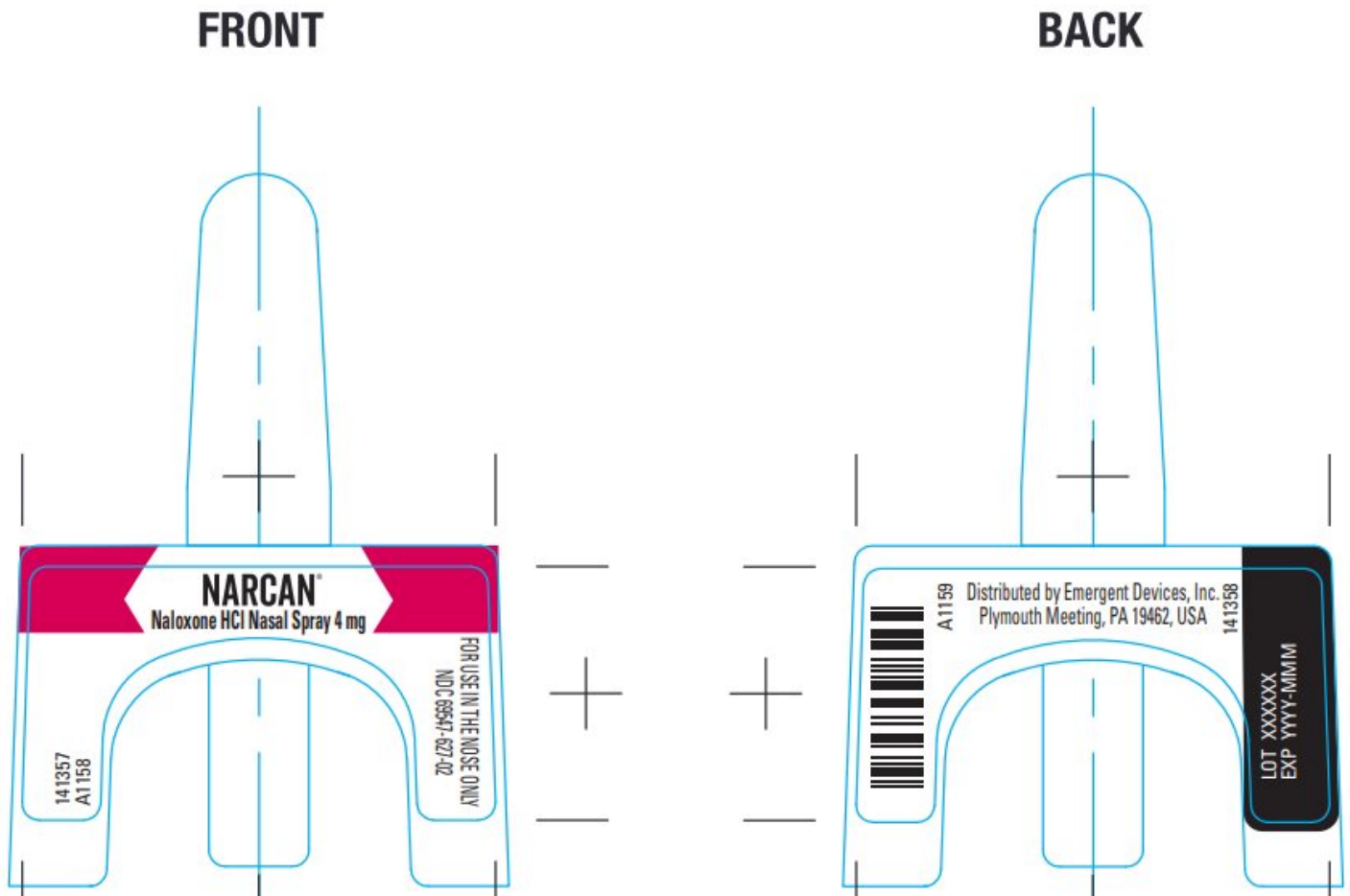
**NARCAN®**  
**Naloxone HCl Nasal Spray 4 mg**  
**Emergency Treatment of Opioid Overdose**

- 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
- 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)

Lot XXXXXX EXP YYYY-MMM

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**Package/Label Principal Display Panel - Front and Back Label**



**NARCAN®**  
**Naloxone HCl Nasal Spray 4 mg**

141357

A1158

FOR USE IN THE NOSE ONLY

NDC 69547-627-02

A1159

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Plymouth Meeting, PA 19462, USA

141358

Lot XXXXXX

EXP YYYY-MMM

## NARCAN

naloxone hydrochloride nasal spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69547-627
<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: 059QF0KO0R)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69547-627-02	2 in 1 CARTON	08/28/2023	
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
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NDA

NDA208411

08/28/2023

**Labeler** - Emergent Devices Inc. (079673287)

Revised: 8/2023

Emergent Devices Inc.