

# NALOXONE HYDROCHLORIDE- naloxone hydrochloride spray

## BluePoint Laboratories

### Naloxone HCl Nasal Spray 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

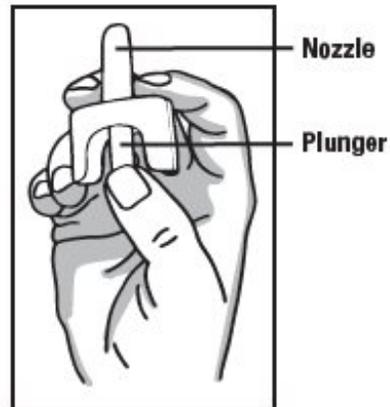
#### Directions

##### 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

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

 <p><b>2 GIVE</b></p>	<p><b>Step 2: GIVE 1st dose in the nose</b></p> <ul style="list-style-type: none"> <li>• <b>HOLD</b> the nasal spray device with your thumb on the bottom of the plunger</li> <li>• <b>INSERT</b> the nozzle into either NOSTRIL</li> <li>• <b>PRESS</b> the plunger firmly to give the 1st dose</li> <li>• 1 nasal spray device contains 1 dose</li> </ul>
 <p><b>3 CALL</b></p>	<p><b>Step 3: CALL</b></p> <ul style="list-style-type: none"> <li>• <b>CALL 911</b> immediately after giving the 1st dose</li> </ul>
 <p><b>4 WATCH/GIVE</b> 2-3 minutes</p>	<p><b>Step 4: WATCH &amp; GIVE</b></p> <ul style="list-style-type: none"> <li>• <b>WAIT</b> 2-3 minutes after the 1st dose to give the medicine time to work</li> <li>• if the person <u>wakes up</u>: Go to Step 5</li> <li>• if the person does <u>not wake up</u>:</li> <li>• <b>CONTINUE TO GIVE</b> doses every 2-3 minutes until the person wakes up</li> <li>• it is safe to keep giving doses</li> </ul>
 <p><b>5 STAY</b></p>	<p><b>Step 5: STAY</b></p> <ul style="list-style-type: none"> <li>• <b>STAY</b> until ambulance arrives: even if the person wakes up</li> <li>• <b>GIVE</b> another dose if the person becomes very sleepy again</li> <li>• You may need to give all the doses in the pack</li> </ul>

**For opioid emergencies, call 911.** For questions on Naloxone HCl Nasal Spray 4 mg, call Padagis<sup>®</sup> at 1-866-634-9120 or go to [www.padagis.com](http://www.padagis.com).

64Q00 RT QS2

## 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

## 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 1-866-634-9120 or go to [www.padagis.com](http://www.padagis.com)

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

NDC 68001-645-45

Naloxone HCl Nasal Spray 4 mg

Emergency Treatment of Opioid Overdose

Original Prescription Strength

Easy to Use

Can Save a Life

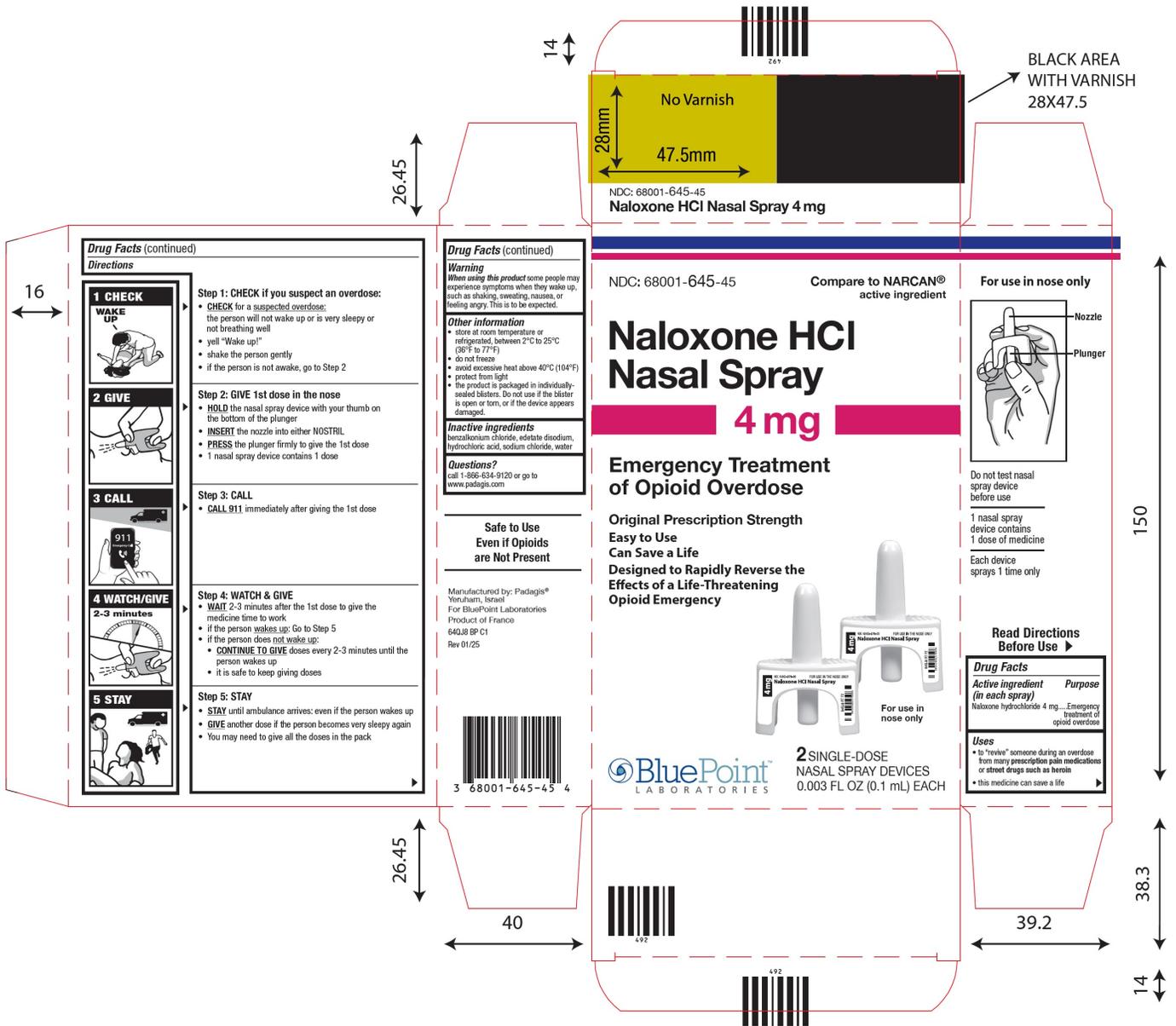
Designed to Rapidly Reverse the Effects of a Life-Threatening Opioid Emergency

For use in nose only

2 SINGLE-DOSE NASAL SPRAY DEVICES

0.003 FL OZ (0.1mL) EACH

Rev 01/2025



NDC 68001-645-45

Naloxone HCl Nasal Spray 4 mg

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Original Prescription Strength

Easy to Use

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

For use in nose only

2 SINGLE-DOSE NASAL SPRAY DEVICES

0.003 FL OZ (0.1mL) EACH

Rev 08/2025

NDC: 68001-645-46  
Naloxone HCl Nasal Spray 4 mg

**Drug Facts (continued)**

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

**Other information**

- Store at room temperature or refrigerate between 2°C to 20°C (36°F to 77°F)
- Do not freeze
- If the container's base shows 40°C (104°F) printed from spray
- The product is packaged in individually sealed blister packs. Do not use if the blister is open or torn, or if the device appears damaged.

**Inactive ingredients**  
benzalkonium chloride, citric acid, dibutyl sebacate, hydrochloric acid, sodium chloride, water

**Questions?**  
Call 1-888-624-6100 or go to [www.podagis.com](http://www.podagis.com)

**Safe to Use Even if Opioids are Not Present**

Manufactured by: Podagis®  
Yonkers, NY  
For: BluePoint Laboratories  
Product of USA  
64618 SP-02  
Rev 08/25



3 68001-645-45 4

NDC: 68001-645-45      Compare to NARCAN® active ingredient

**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



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**      **Purpose**  
Naloxone hydrochloride 4 mg      Emergency treatment of opioid overdose

**Uses**  
• To "wake" someone who has an overdose from drugs such as heroin, fentanyl, or other drugs such as oxycodone  
• This medicine can save a life

**Drug Facts (continued)**

**Directions**

**1 CHECK**  
**WAKE UP**

▶ **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** 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

**3 CALL**

▶ **Step 3: CALL**  
• **CALL 911** immediately after giving the 1st dose

**4 WATCH/GIVE**

▶ **Step 4: WATCH & GIVE**  
• **WAIT** 2-3 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 2-3 minutes until the person wakes up  
• It is safe to keep giving doses

**5 STAY**

▶ **Step 5: STAY**  
• **WAIT** 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



BLACK AREA  
28x47.5  
47.5mm  
28mm  
No Varnish

# NALOXONE HYDROCHLORIDE

naloxone hydrochloride spray

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68001-645
<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>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68001-645-45	2 in 1 CARTON	05/01/2025	
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	ANDA211951	05/01/2025	

**Labeler** - BluePoint Laboratories (985523874)

## Establishment

Name	Address	ID/FEI	Business Operations
Padagis Israel Pharmaceuticals Ltd		600093611	manufacture(68001-645)

Revised: 10/2025

BluePoint Laboratories