

# NALOXONE HYDROCHLORIDE- naloxone hydrochloride spray AMERISOURCE BERGEN

## 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

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#### 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

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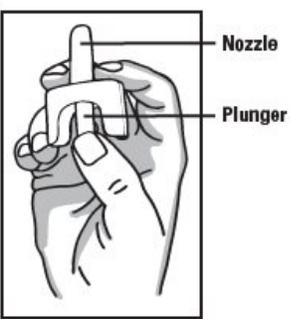
Each device sprays 1 time only

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#### 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>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>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>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 <u>does not wake up</u>: <ul style="list-style-type: none"> <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> </li> </ul>	
	<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® at 1-866-634-9120 or go to [www.padagis.com](http://www.padagis.com).

## 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**

Good Neighbor Pharmacy

NDC 46122-812-71

Original Prescription Strength

Naloxone HCl Nasal Spray 4 mg

Emergency Treatment of Opioid Overdose

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

Easy to Use

Can Save a Life

For use in nose only

2 SINGLE-DOSE NASAL SPRAY DEVICES

0.003 FL OZ (0.1mL) EACH

Safe to Use Even if Opioids are Not Present

\*Good Neighbor Pharmacy® Naloxone HCl Nasal Spray 4 mg is not manufactured or distributed by Emergent Operations Ireland Limited.

Distributed By AmerisourceBergen

1 West First Avenue,

Conshohocken, PA 19428

Questions or Concerns?

[www.mygnp.com](http://www.mygnp.com)

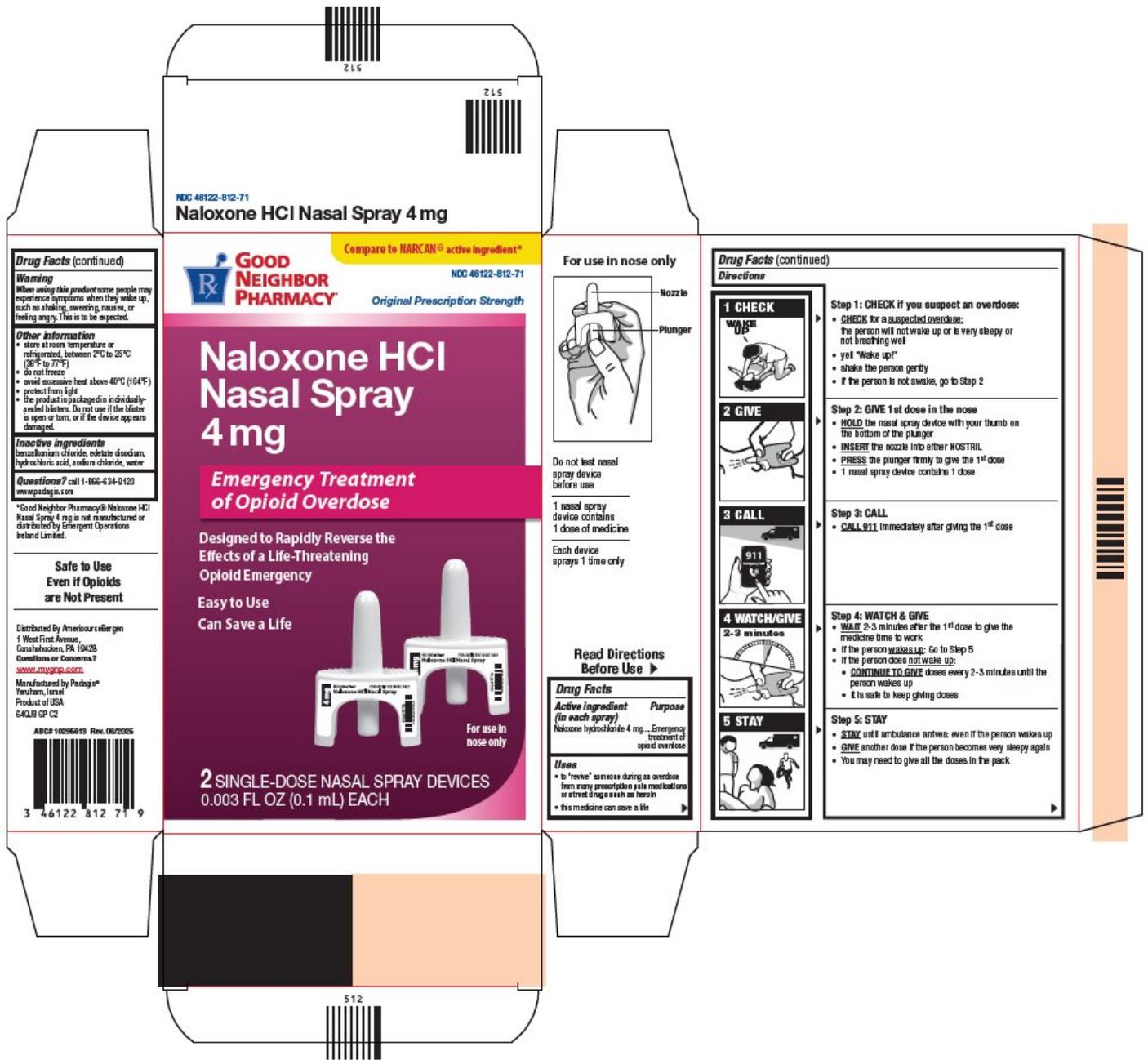
Manufactured by Padagis®

Yeruham, Israel

Product of USA

64QJ8 GP C2

64Q00 RT QS2



## NALOXONE HYDROCHLORIDE

naloxone hydrochloride spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:46122-812
<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:46122-812-71	2 in 1 CARTON	03/12/2025	
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	03/12/2025	

**Labeler** - AMERISOURCE BERGEN (007914906)

Revised: 8/2025

AMERISOURCE BERGEN