

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

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


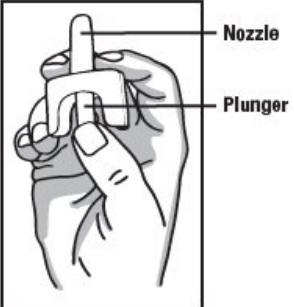



1 nasal spray device contains 1 dose of medicine

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>Step 2: GIVE 1st dose in the nose</p> <ul style="list-style-type: none"> • 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 	
	<p>Step 3: CALL</p> <ul style="list-style-type: none"> • CALL 911 immediately after giving the 1st dose 	
	<p>Step 4: WATCH & GIVE</p> <ul style="list-style-type: none"> • WAIT 2-3 minutes after the 1st dose to give the medicine time to work • if the person <u>wakes up</u>: Go to Step 5 • if the person does <u>not wake up</u>: <ul style="list-style-type: none"> • CONTINUE TO GIVE doses every 2-3 minutes until the person wakes up • it is safe to keep giving doses 	
	<p>Step 5: STAY</p> <ul style="list-style-type: none"> • 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 Naloxone HCl Nasal Spray 4 mg, call Padagis® at 1-866-634-9120 or go to 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

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

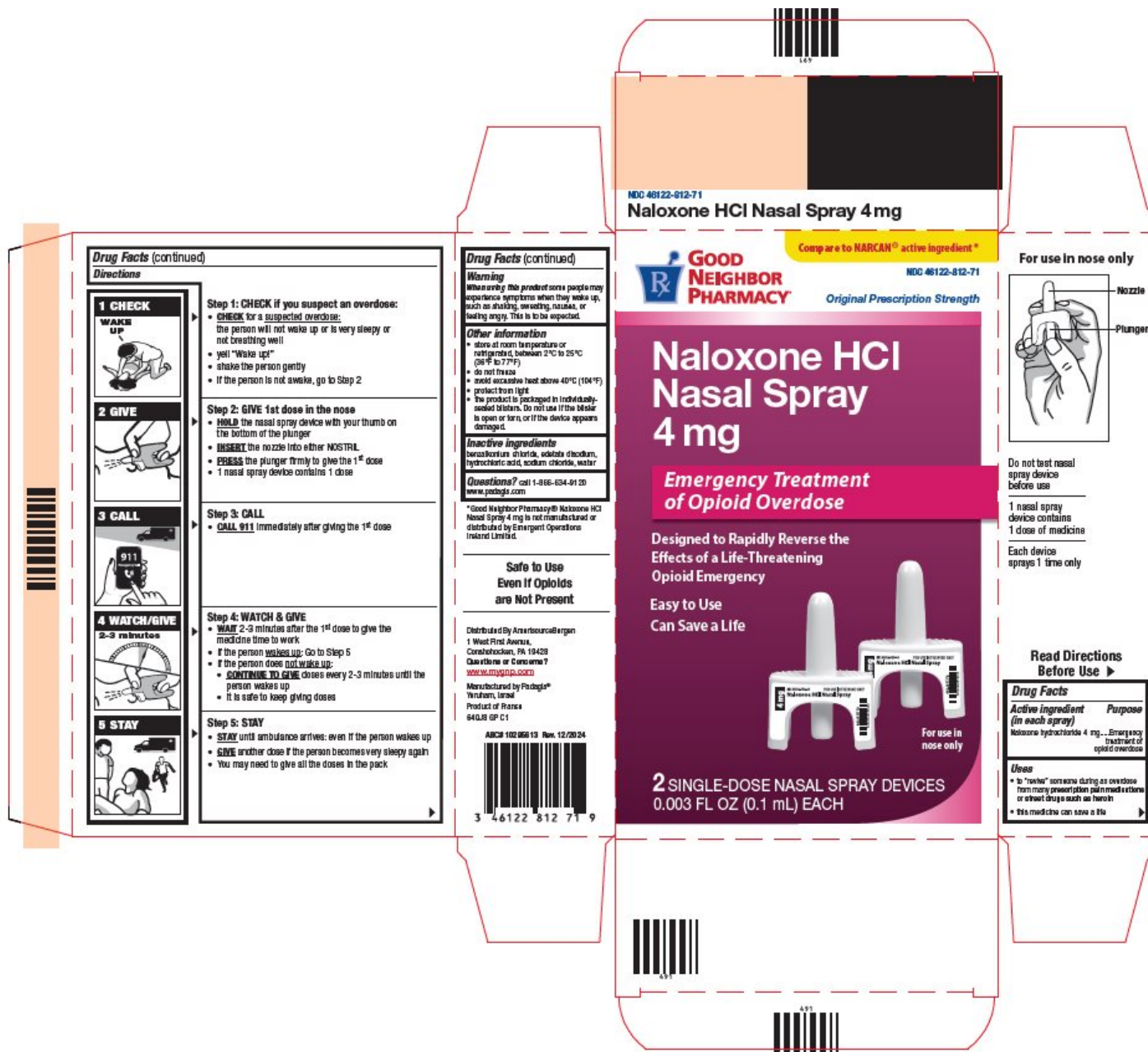
Manufactured by Padagis®

Yeruham, Israel

Product of France

64QJ8 GP C1

64Q00 RT QS2



NALOXONE HYDROCHLORIDE

naloxone hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-812
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)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (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: 3/2025

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