NALOXONE HYDROCHLORIDE- naloxone hydrochloride spray
Advanced Rx of Tennessee, LLC

Naloxone HCl Nasal Spray

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

Keep out of reach of children.

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** • **CALL 911**immediately after giving the 1st dose

	**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
	**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

Warning

When using this productsome 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

NDC: 80425-0409-01

Naloxone HCl Nasal Spray 4 mg

Emergency Treatment of Opioid Overdose

Original Prescription Strength

Easy to Use

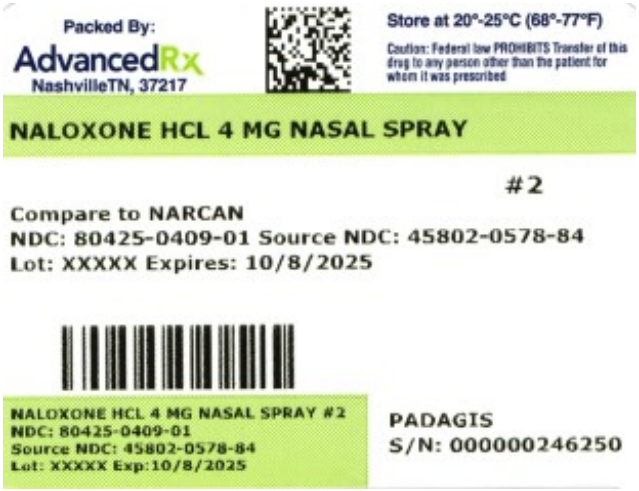
Can Save a Life

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



NALOXONE HYDROCHLORIDE

naloxone hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80425-0409(NDC:45802-578)
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	Marketing	Marketing

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0409-1	2 in 1 CARTON	06/27/2024	
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	06/27/2024	

Labeler - Advanced Rx of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx of Tennessee, LLC		117023142	repack(80425-0409)

Revised: 6/2024 Advanced Rx of Tennessee, LLC