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

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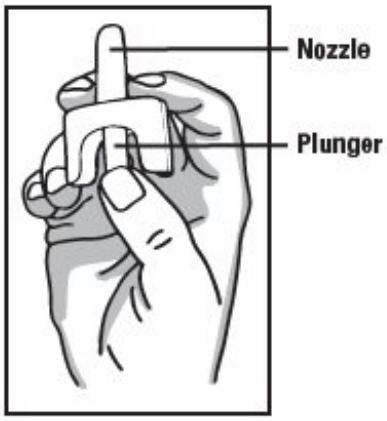


	**Step 1: CHECK if you suspect an overdose:** • **CHECK**for a suspected overdose: the person will not wake up or is very sleepy or not breathing well •yell “Wake up!” •shake the person gently •if the person is not awake, go to Step 2

	**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

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.

64Q00 RT QS2

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 68001-645-45

Naloxone HCl Nasal Spray 4 mg

Emergency Treatment of Opioid Overdose

Original Prescription Strength

Easy to Use

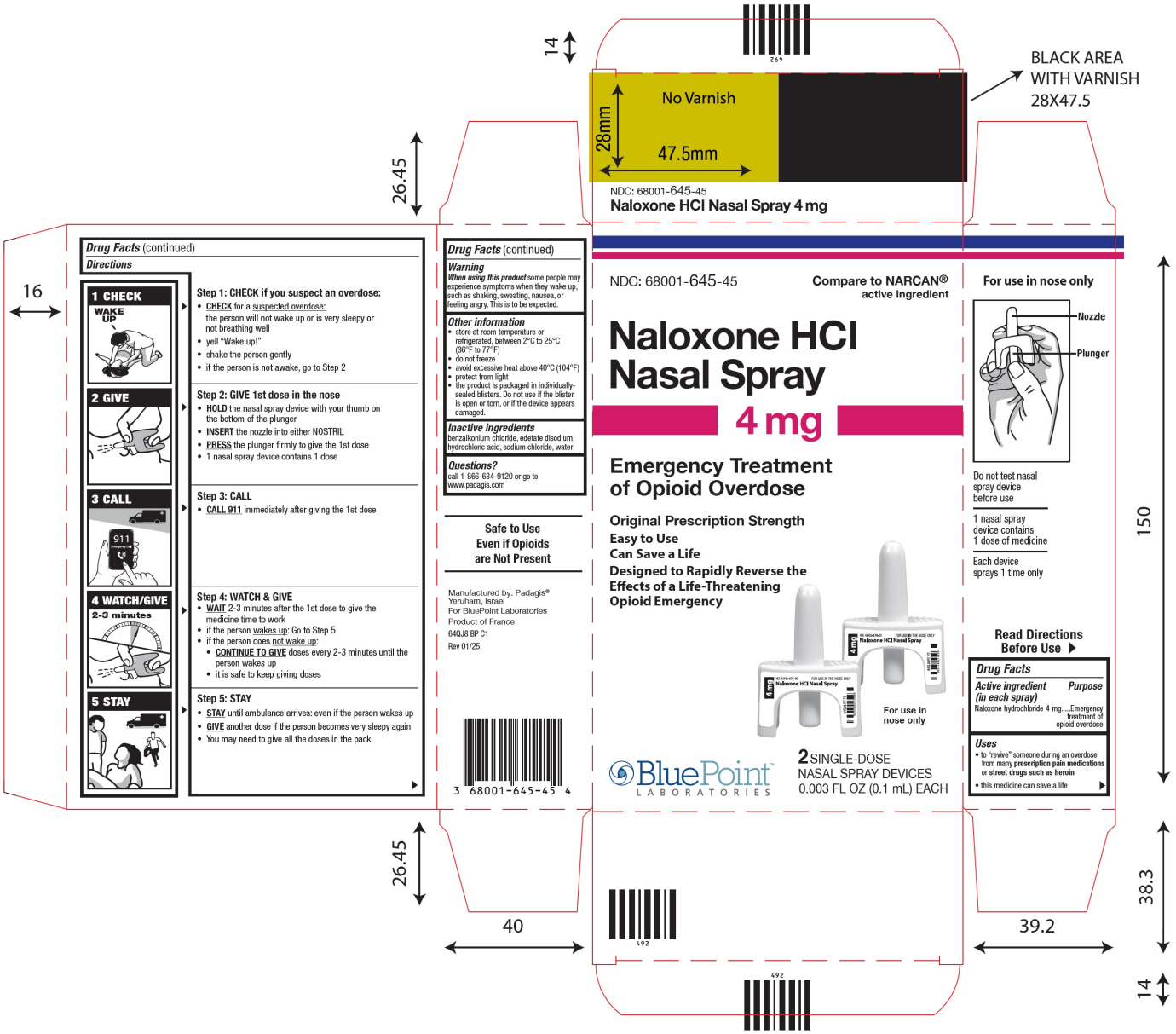
Can Save a Life

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



NALOXONE HYDROCHLORIDE

naloxone hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68001-645
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: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: 4/2025 BluePoint Laboratories