NALOXONE HYDROCHLORIDE- naloxone hydrochloride spray
Padagis Israel Pharmaceuticals Ltd

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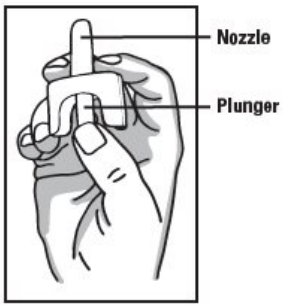
Step 1: CHECK if you suspect an overdose:
• **CHECK** for a suspected overdose: the person will not wake up or is very sleepy or not breathing well
• yell “Wake up!”
• shake the person gently
• if the person is not awake, go to Step 2

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.

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

NDC 45802-578-84

Compare to NARCAN® active ingredient

Padagis

Naloxone

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

2 SINGLE-DOSE NASAL SPRAY DEVICES

0.003 FL OZ (0.1mL) EACH

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

SAFE TO USE EVEN IF OPIOIDS ARE NOT PRESENT

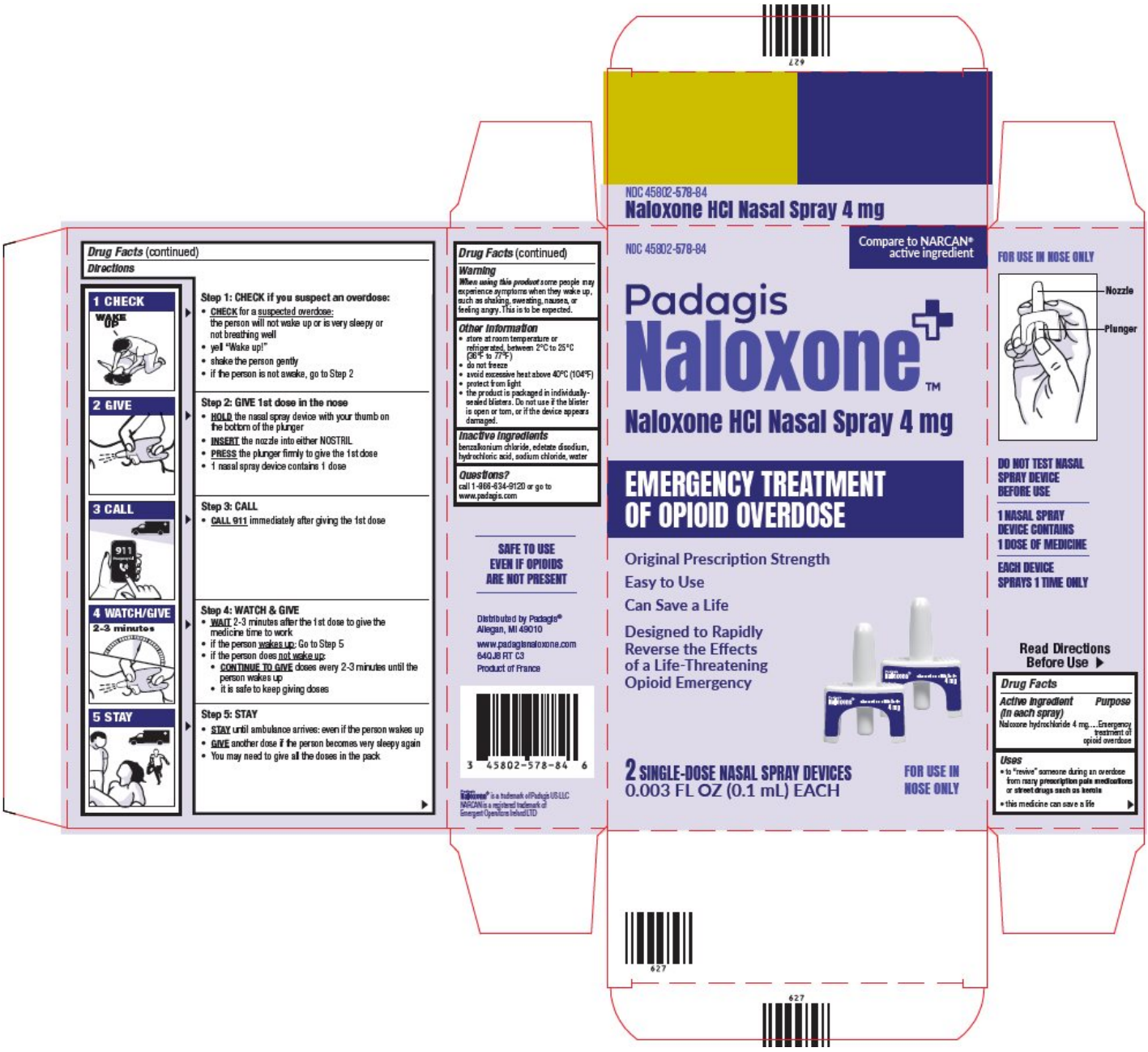
Distributed by Padagis®
Allegan, MI 49010

www.padagis.naloxone.com

64QJ8 RT C3

Product of France

64Q00 RT QS3



NALOXONE HYDROCHLORIDE

naloxone hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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 Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:45802-578-84	2 in 1 CARTON	07/30/2023	
1	NDC:45802-578-00	0.1 mL in 1 VIAL, SINGLE-DOSE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:45802-578-24	24 in 1 CARTON	08/01/2025	
2	NDC:45802-578-00	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	07/30/2023	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 7/2025 Padagis Israel Pharmaceuticals Ltd