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

	**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 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

Naloxone HCl Nasal Spray 4 mg

Emergency Treatment of Opioid Overdose

Original Prescription Strength

Easy to Use

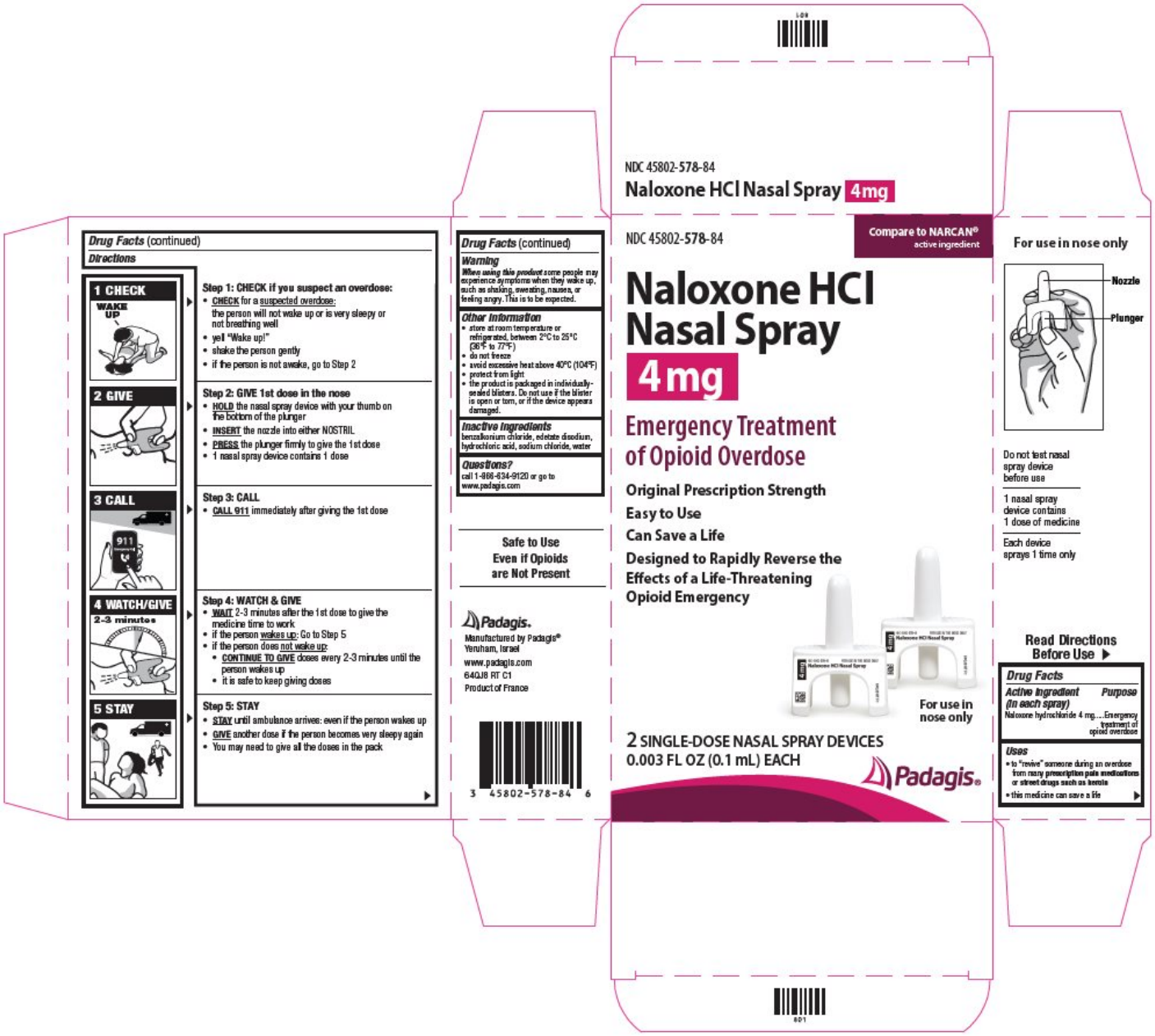
Can Save a Life

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: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.)		

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: 7/2023 Padagis Israel Pharmaceuticals Ltd