NALOXONE HYDROCHLORIDE- naloxone hydrochloride spray, metered
Teva Pharmaceuticals, Inc.

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 below 77°F (25°C).
- 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, sodium chloride buffered with sodium hydroxide/hydrochloric acid, water

Questions?

1-888-838-2872 between 9 am and 5 pm ET, Monday-Friday.
www.tevausa.com/our-products/tevagenerics

Safe to Use
Even if Opioids are Not Present

*This product is not affiliated with, manufactured by, or produced by

*This product is not affiliated with, manufactured by, or produced by the makers or owners of *NARCAN*®

Manufactured For: Teva Pharmaceuticals USA, Inc.
Parsippany, NJ 07054

Rev. A 1/2024

Package/Label Principal Display Panel – Carton Label

Original Prescription Strength
Easy to Use
Can Save a Life

Compare to the active
ingredient in NARCAN®*

NDC 0480-3478-68

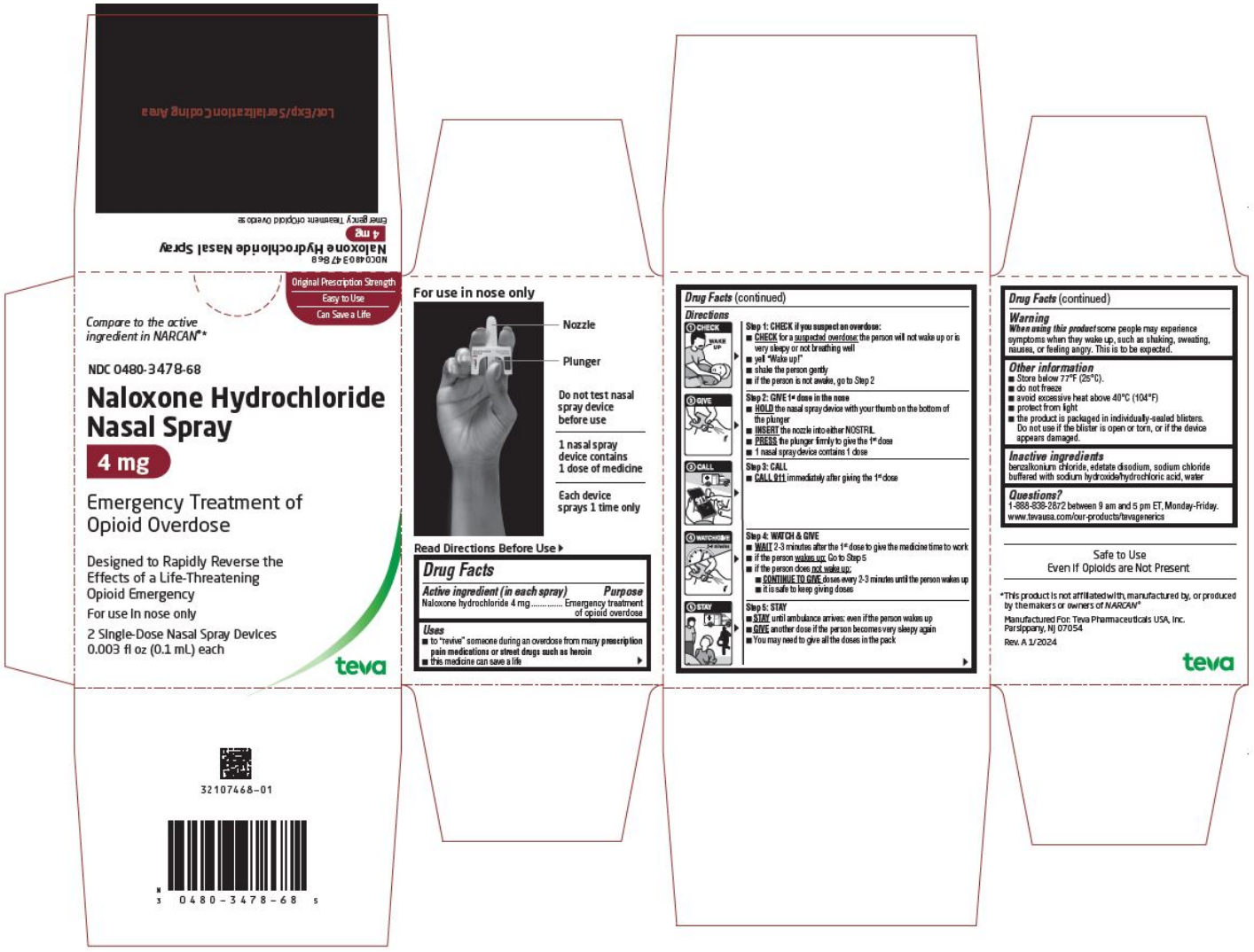
Naloxone Hydrochloride
Nasal Spray
4 mg

Emergency Treatment of
Opioid Overdose

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 (0.1 mL) each



NALOXONE HYDROCHLORIDE

naloxone hydrochloride spray, metered

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0480-3478
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:0480-3478-68	2 in 1 CARTON	09/23/2024	
1	NDC:0480-3478-19	1 in 1 BLISTER PACK		
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	ANDA209522	09/23/2024	

Labeler - Teva Pharmaceuticals, Inc. (022629579)

Revised: 1/2024 Teva Pharmaceuticals, Inc.