NALOXONE HYDROCHLORIDE- naloxone hydrochloride spray, metered
Actavis Pharma, 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

*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

NOT FOR RESALE
FOR NON-RETAIL
DISTRIBUTION

*Compare to the active ingredient in NARCAN®**

NDC 0591-3871-99

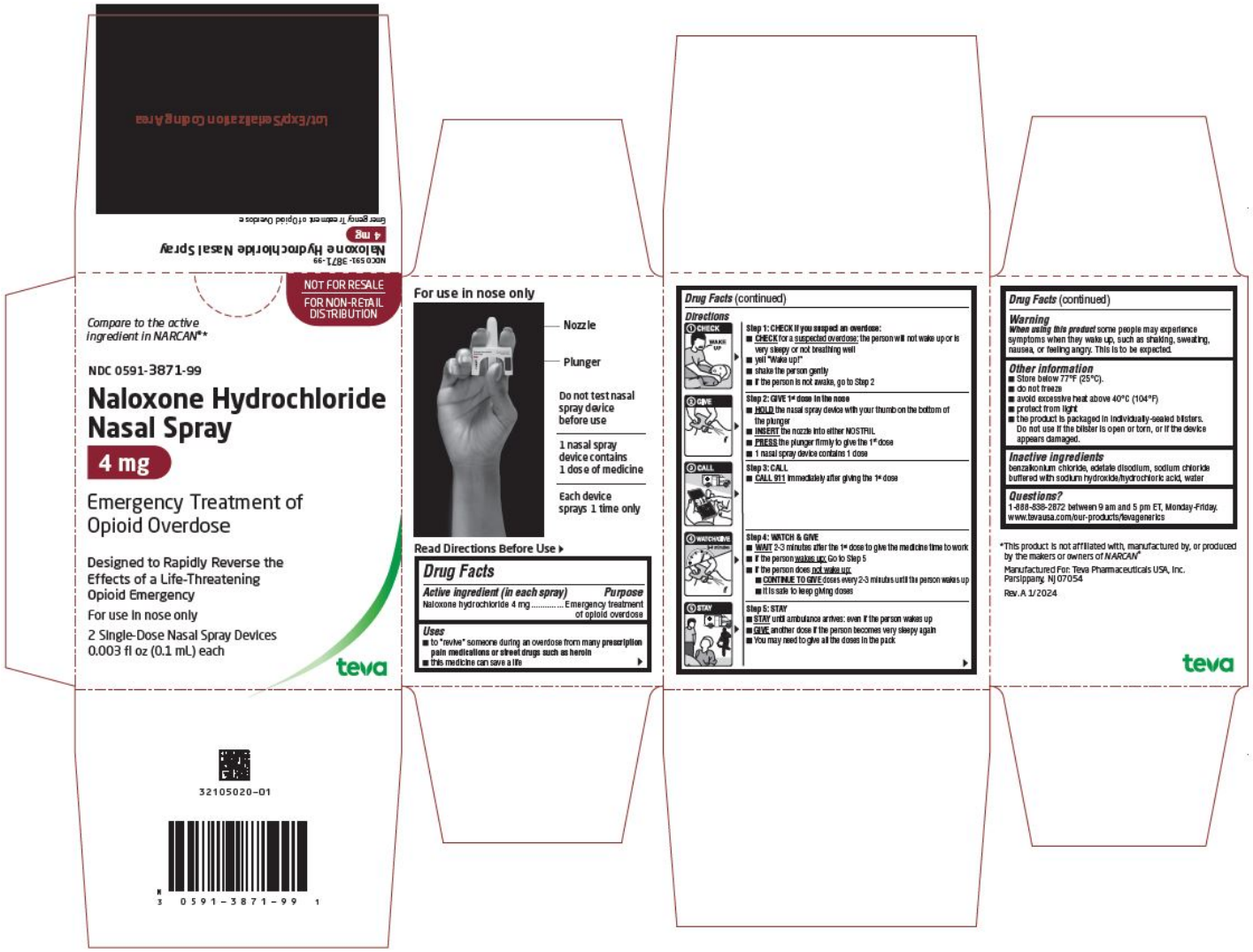
Naloxone Hydrochloride
Nasal Spray
4mg

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:0591-3871
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:0591-3871-99	2 in 1 CARTON	01/17/2025	
1	NDC:0591-3871-54	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	01/17/2025	

Labeler - Actavis Pharma, Inc. (119723554)

Revised: 1/2024 Actavis Pharma, Inc.