NALOXONE HYDROCHLORIDE- naloxone hydrochloride spray, metered
Asclemed USA, 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 1 st 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 1 st dose ▪ 1 nasal spray device contains 1 dose
	**Step 3: CALL** ▪ **CALL 911**immediately after giving the 1 st dose

	**Step 4: WATCH & GIVE** ▪ **WAIT** 2-3 minutes after the 1 st 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

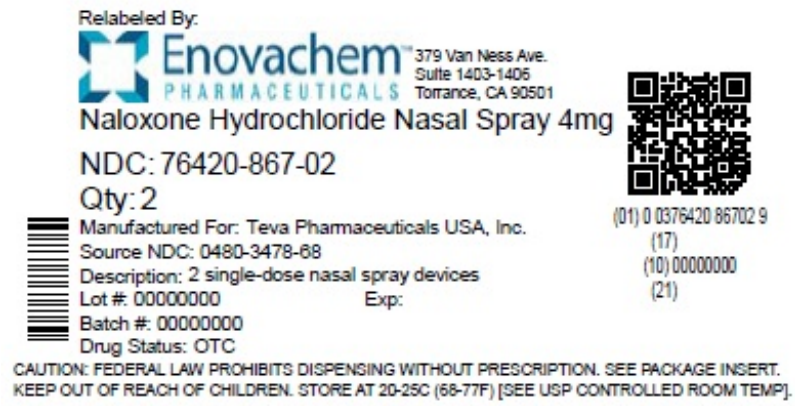
*This product is not affiliated with, manufactured by, or produced by the makers or owners of *NARCAN* ®

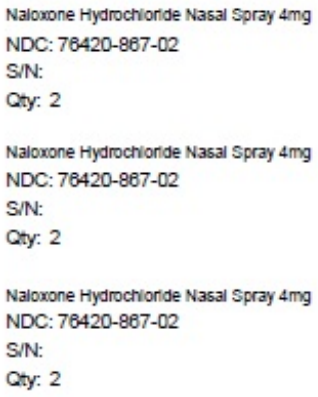
Relabeled by:

Enovachem PHARMACEUTICALS

Torrance, CA 90501

Package/Label Principal Display Panel





NALOXONE HYDROCHLORIDE

naloxone hydrochloride spray, metered

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76420-867(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:76420-867-02	2 in 1 CARTON	10/29/2024	
1		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 - Asclemed USA, Inc. (059888437)

Establishment

Name	Address	ID/FEI	Business Operations
ASCLEMED USA INC. DBA ENOVACHEM		059888437	relabel(76420-867)

Revised: 10/2024 Asclemed USA, Inc.