NALOXONE HYDROCHLORIDE- naloxone hydrochloride spray Walgreen Co.

Naloxone Hydrochloride Nasal Spray

Active ingredient (in each spray)

Naloxone hydrochloride 4 mg

Purpose

Emergency treatment of opioid overdose

Use(s)

- to "revive" someone during an overdose from many prescription pain medications or street drugs such as heroin
- this medicine can save a life

Warnings

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.

Directions



Step 1: CHECK if you suspect an overdose

- <u>CHECK</u> for a <u>suspected overdose</u>: 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



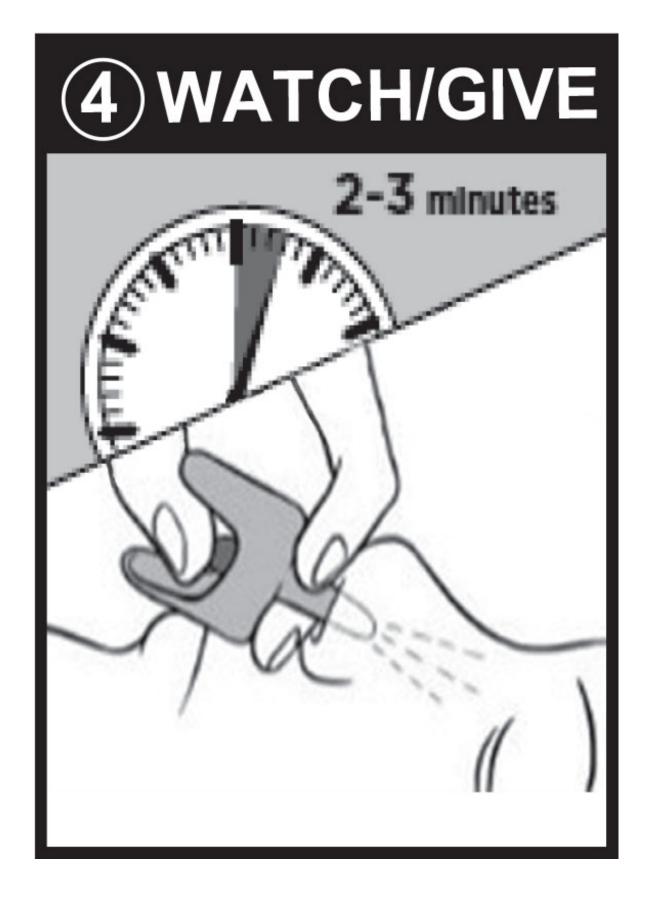
Step 2: GIVE 1st dose in the nose

- **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 911

• **CALL 911** immediately after giving the 1st dose



Step 4: WATCH & GIVE

- **WAIT** 2 to 3 minutes after the 1st dose to give the medicine time to work
- if the person <u>wakes up</u>: Go to Step 5
- if the person <u>does not wake up</u>:
- **CONTINUE TO GIVE** doses every 2 to 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

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
- this 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, disodium ethylenediaminetetraacetate, hydrochloric acid, purified water, and sodium chloride

Questions or comments?

1-877-835-5472 (Mon-Fri, 9AM-5PM EST)

DIRECTIONS

Naloxone Hydrochloride Nasal Spray, 4 mg 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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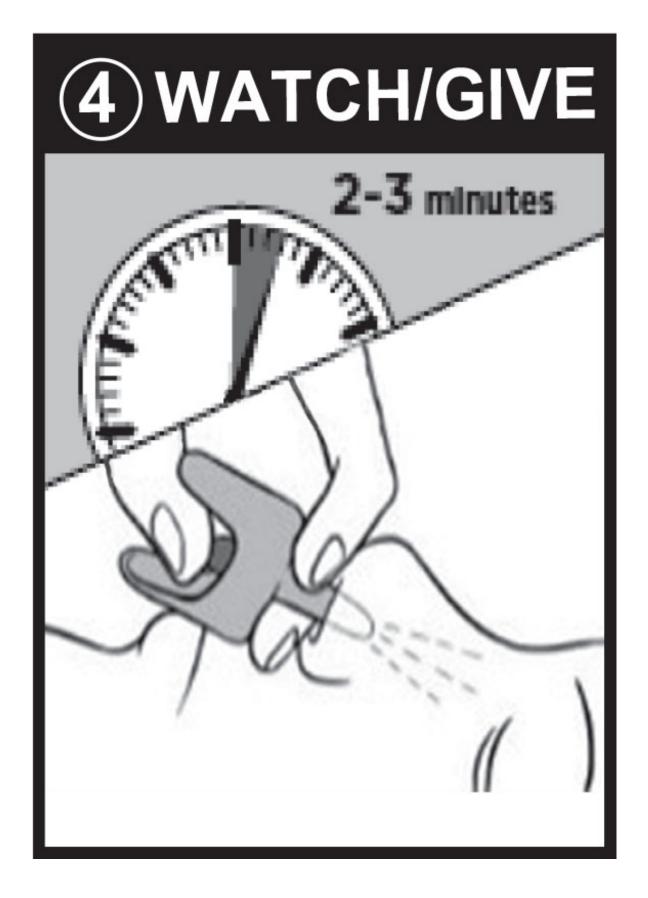
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For opioid emergencies, call 911. For questions or more information about Naloxone Hydrochloride Nasal Spray, contact Amneal Pharmaceuticals at 1-877-835-5472.

Rev. 07-2023-04

Principal Display Panel



NALOXONE HYDROCHLORIDE

naloxone hydrochloride spray

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:0363-2140 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)			
WATER (UNII: 059QF0KO0R)			
HYDROCHLORIC ACID (UNII: QTT17582CB)			

Product Characteristics				
Color	white (clear, colorless to faintly yellow)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

P	Packaging				
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0363- 2140-02	2 in 1 CARTON	04/24/2024		
1	NDC:0363- 2140-01	0.1 mL in 1 VIAL; 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	ANDA217992	04/24/2024		

Labeler - Walgreen Co. (008965063)

Revised: 4/2024 Walgreen Co.