NALOXONE HYDROCHLORIDE- naloxone hydrochloride spray
Amneal Pharmaceuticals NY LLC

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

- **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

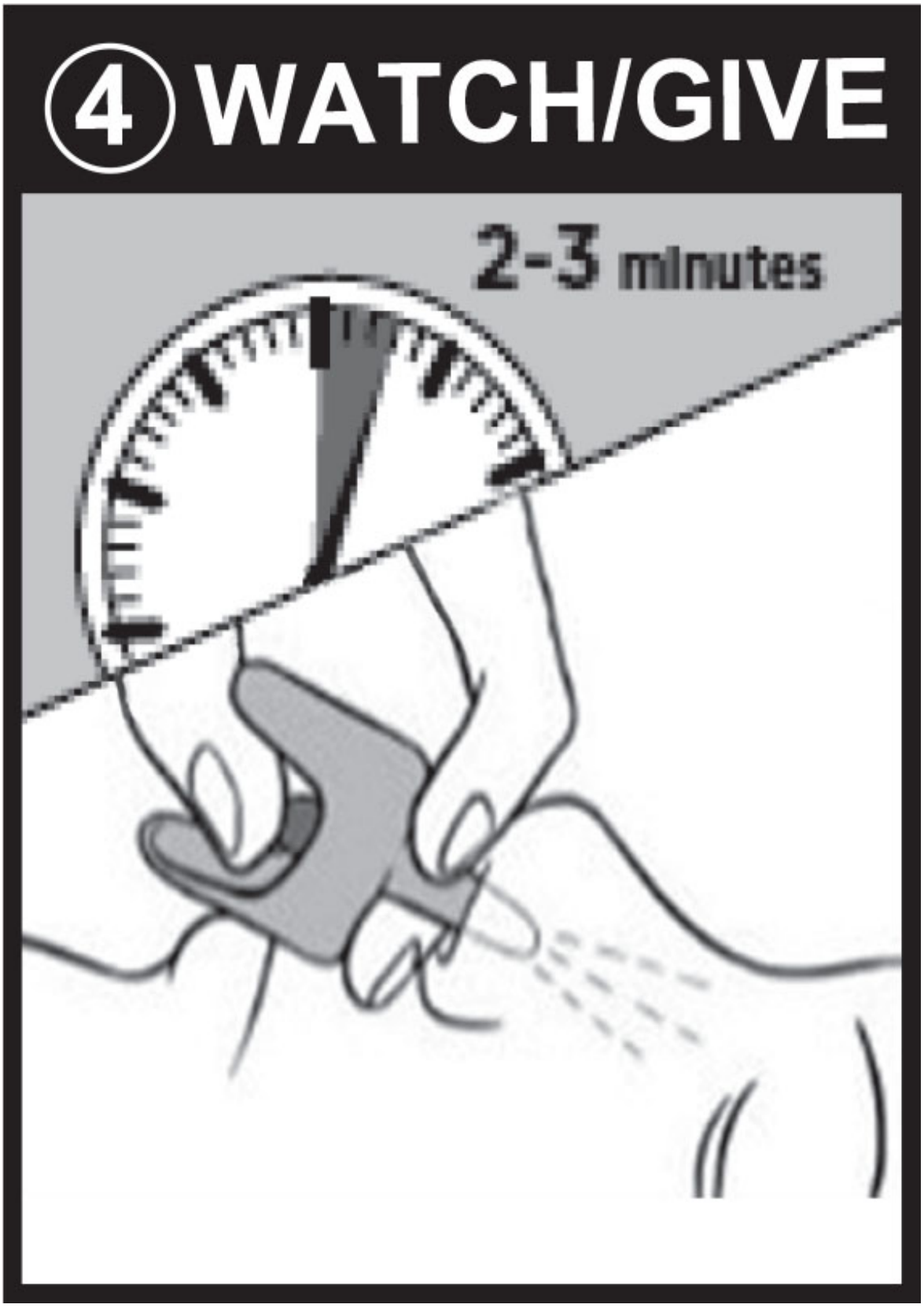
- if the person is not awake, go to Step 2

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 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 wakes up: Go to Step 5
- if the person does not wake up:
- **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

Step 1: CHECK if you suspect an overdose

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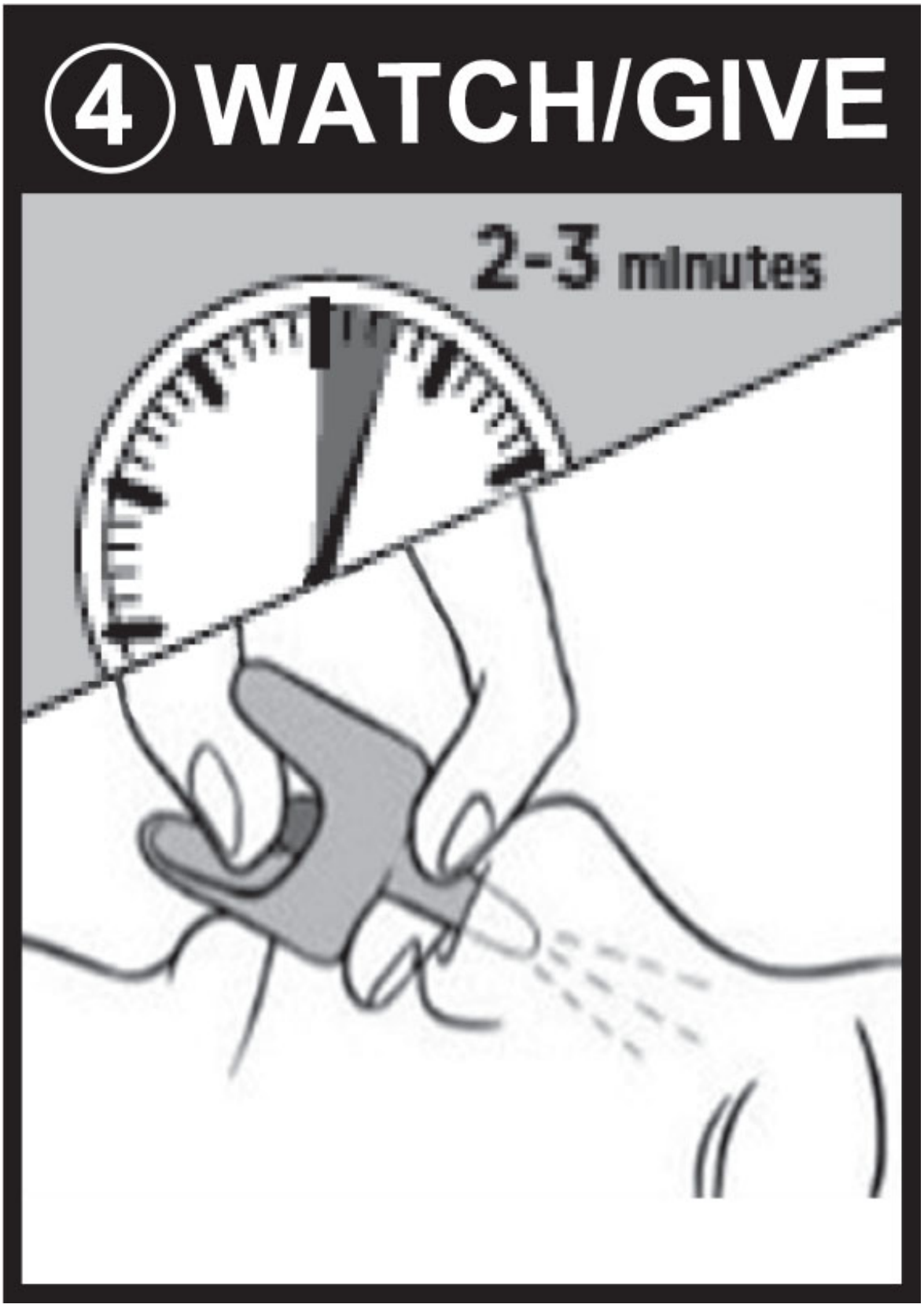

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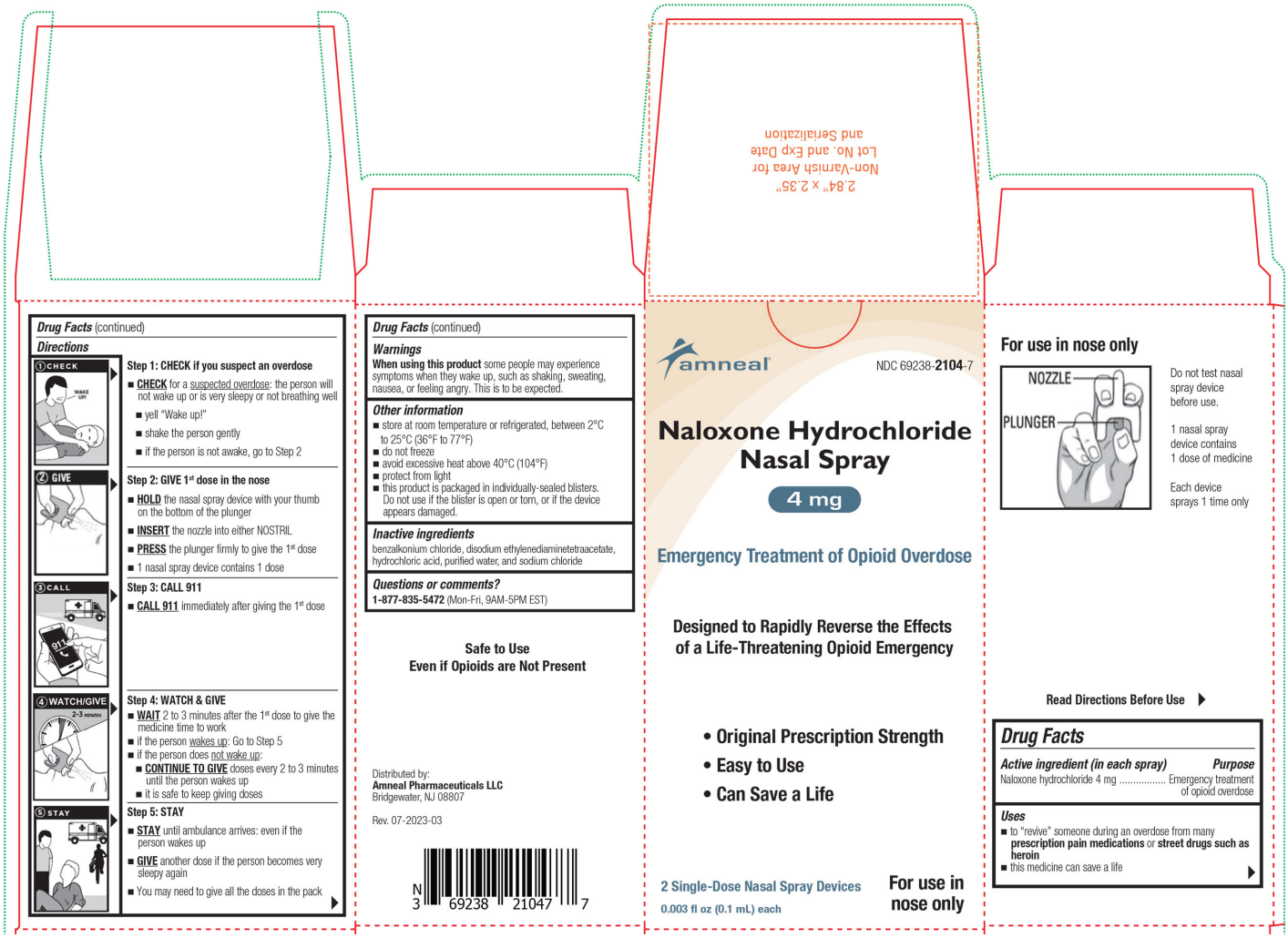
For opioid emergencies, call 911. For questions or more information about Naloxone Hydrochloride Nasal Spray, contact Amneal Pharmaceuticals at 1-877-835-5472.

Rev. 07-2023-04

Principal Display Panel



NALOXONE HYDROCHLORIDE

naloxone hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69238-2104
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69238-2104-7	2 in 1 CARTON	04/24/2024	
1	NDC:69238-2104-1	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	ANDA217992	04/24/2024	

Labeler - Amneal Pharmaceuticals NY LLC (123797875)

Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals, LLC		079823130	analysis(69238-2104) , label(69238-2104) , manufacture(69238-2104) , pack(69238-2104)

Revised: 4/2024 Amneal Pharmaceuticals NY LLC