NALOXONE HYDROCHLORIDE- naloxone hydrochloride spray
HF Acquisition Co LLC, DBA HealthFirst

ACTIVE INGREDIENT (IN EACH SPRAY)

Naloxone hydrochloride 4 mg

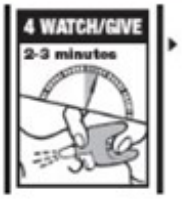
Emergency treatment of opioid overdose

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

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 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

• the product is packaged in individually-sealed blisters.

Do not use if the blister is open or torn, or if the device appears damaged

benzalkonium chloride, edetate disodium, hydrochloric acid, sodium chloride, water

QUESTIONS?

call 1-866-634-9120 or go to www.padagis.com

KEEP OUT OF REACH OF CHILDREN

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 911immediately after giving the 1st dose

Step 4: WATCH & GIVE

• WAIT2-3 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

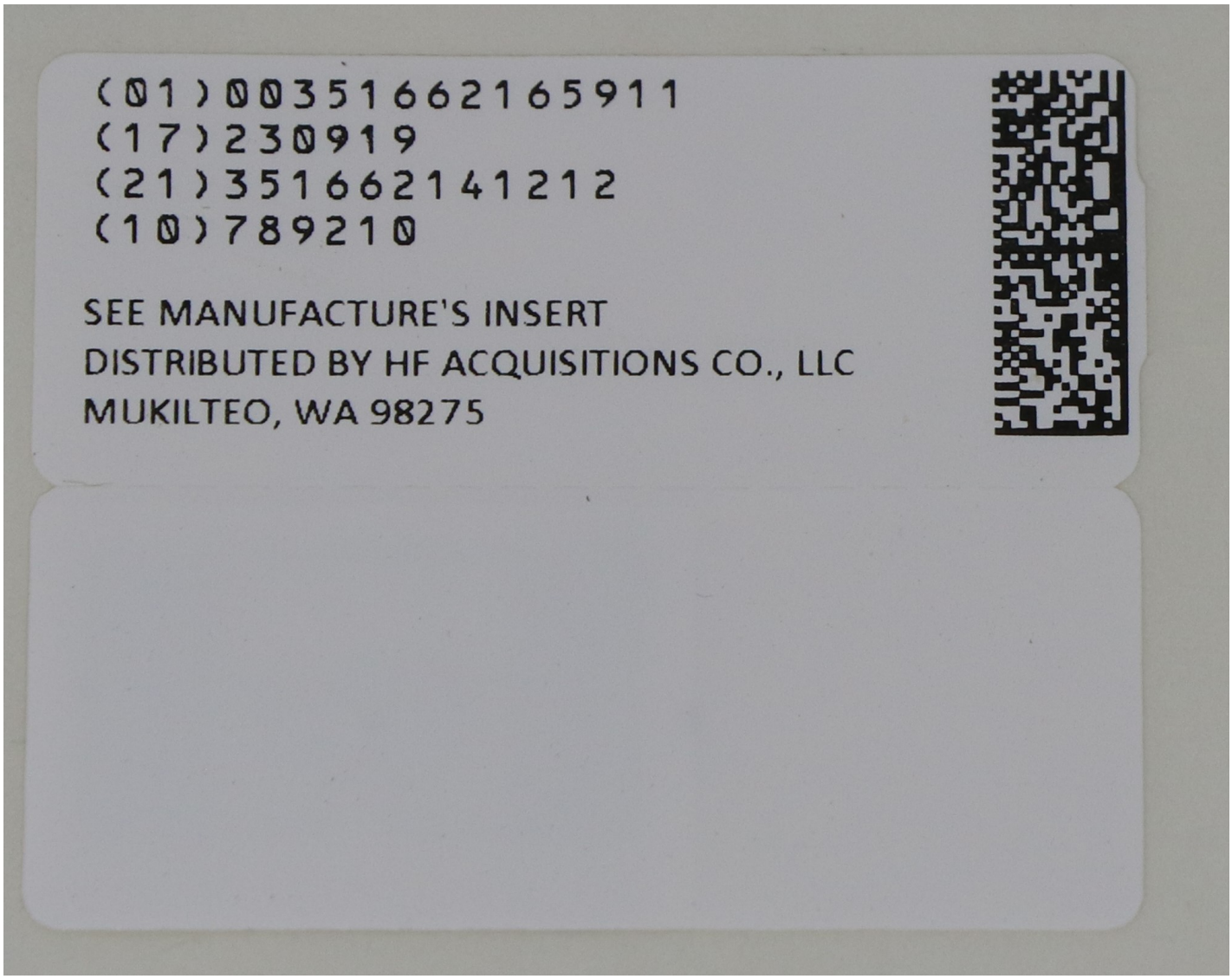
• GIVE another dose if the person becomes very sleepy again

• You may need to give all the doses in the pack

• to “revive” someone during an overdose from many prescription pain medications or street drugs such as heroin

• this medicine can save a life

NDC 51662-1659-1



NDC 51662-1659-2

Drug Facts (continued)

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

Drug Facts (continued)

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 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
- 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, hydrochloric acid, sodium chloride, water

Questions?
call 1-866-634-9120 or go to www.padagis.com

Safe to Use Even if Opioids are Not Present

Padagis.
Manufactured by Padagis®
Yeruham, Israel
www.padagis.com
64QJ8 RT C1
Product of France

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NDC 45802-578-84

Naloxone HCl Nasal Spray 4mg

NDC 45802-578-84

Compare to NARCAN® active ingredient

Naloxone HCl Nasal Spray 4 mg

Emergency Treatment of Opioid Overdose

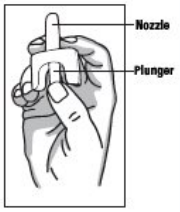
Original Prescription Strength
Easy to Use
Can Save a Life
Designed to Rapidly Reverse the Effects of a Life-Threatening Opioid Emergency

For use in nose only

2 SINGLE-DOSE NASAL SPRAY DEVICES
0.003 FL OZ (0.1 mL) EACH

Padagis®

For use in nose only



Do not test nasal spray device before use

1 nasal spray device contains 1 dose of medicine

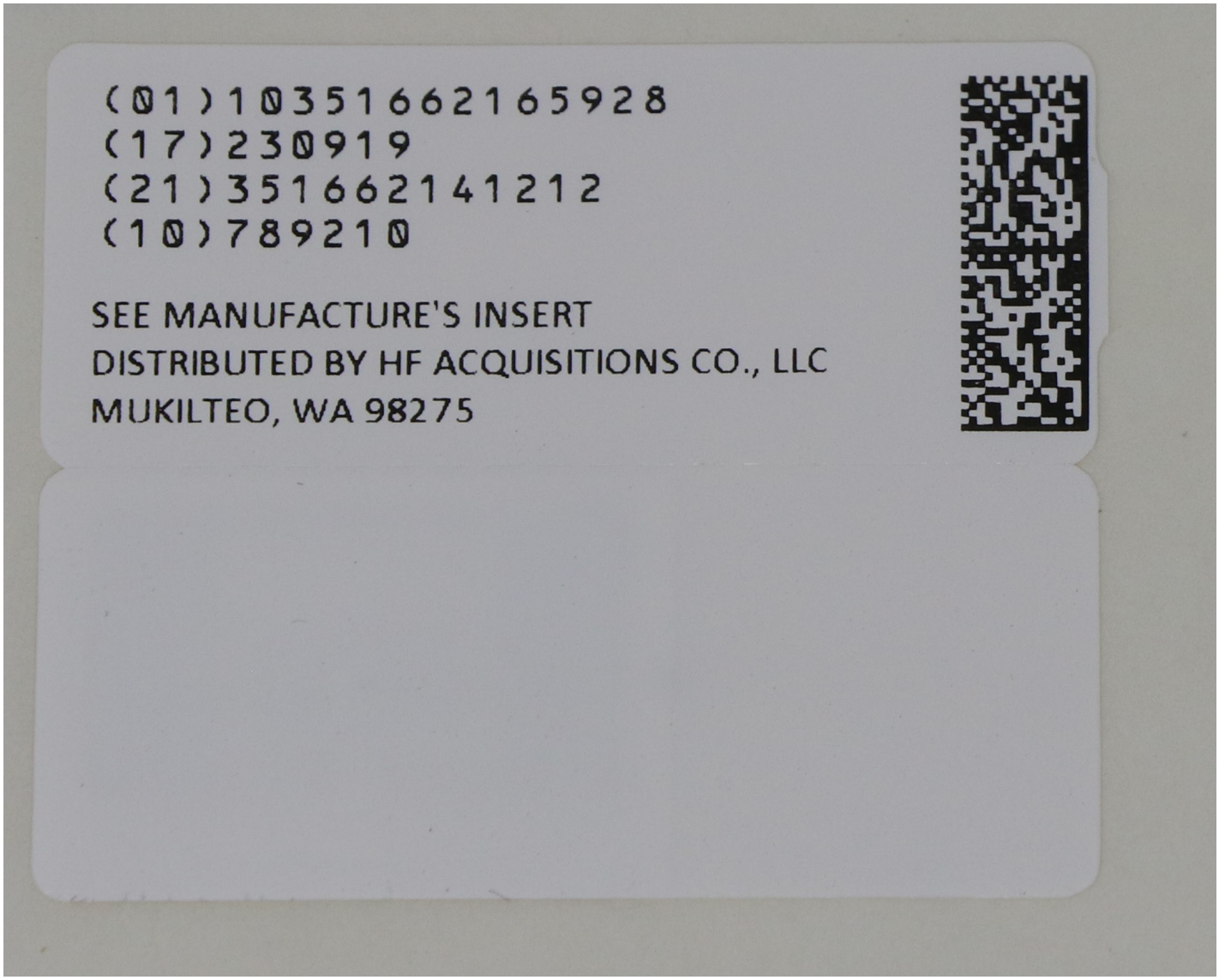
Each device sprays 1 time only

Read Directions Before Use ▶

Drug Facts

Active ingredient (in each spray)	Purpose
Naloxone hydrochloride 4 mg	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 ▶



NALOXONE HYDROCHLORIDE

naloxone hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51662-1659(NDC:45802-578)
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**
WATER (UNII: 059QF0KO0R)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51662-1659-2	2 in 1 CARTON	07/30/2023	
1	NDC:51662-1659-1	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	ANDA211951	07/30/2023	

Labeler - HF Acquisition Co LLC, DBA HealthFirst (045657305)

Registrant - HF Acquisition Co LLC, DBA HealthFirst (045657305)

Establishment

Name	Address	ID/FEI	Business Operations
HF Acquisition Co LLC, DBA HealthFirst		045657305	relabel(51662-1659)

Revised: 5/2024 HF Acquisition Co LLC, DBA HealthFirst