

# NARCAN NALOXONE HCL- narcana naloxone hcl spray

## HF Acquisition Co LLC, DBA HealthFirst

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### 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

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

NARCAN®  
Naloxone HCl Nasal Spray 4 mg

<p>Emergency Treatment of Opioid Overdose</p> <p><b>Important:</b></p> <ul style="list-style-type: none"><li>• For use in the nose only</li><li>• Do not test nasal spray device before use</li><li>• 1 nasal spray device contains 1 dose of medicine</li><li>• Each device sprays 1 time only</li></ul>	
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	<p><b>① CHECK</b> Step 1: CHECK if you suspect an overdose:</p> <ul style="list-style-type: none"><li>• <b>CHECK</b> for a <u>suspected overdose</u>; the person will not wake up or is very sleepy or not breathing well<ul style="list-style-type: none"><li>• yell "Wake up!"</li><li>• shake the person gently</li><li>• if the person is not awake, go to Step 2</li></ul></li></ul>
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	<p><b>2) GIVE</b></p> <p>Step 2: Give 1st dose in the nose</p> <ul style="list-style-type: none"> <li>• <b>HOLD</b> the nasal spray device with your thumb on the bottom of the plunger</li> <li>• <b>INSERT</b> the nozzle into either NOSTRIL</li> <li>• <b>PRESS</b> the plunger firmly to give the 1st dose</li> <li>• 1 nasal spray device contains 1 dose</li> </ul>
	<p><b>3) CALL</b></p> <p>Step 3: CALL 911</p> <ul style="list-style-type: none"> <li>• <b>CALL 911</b> immediately after giving the 1<sup>st</sup> dose</li> </ul>
	<p><b>4) WATCH/GIVE</b></p> <p>Step 4: WATCH &amp; GIVE</p> <ul style="list-style-type: none"> <li>• <b>WAIT</b> 2-3 minutes after the 1<sup>st</sup> dose to give the medicine time to work</li> <li>• if the person <u>wakes up</u>: Go to Step 5</li> <li>• if the person does <u>not wake up</u>: <ul style="list-style-type: none"> <li>• <b>CONTINUE TO GIVE</b> doses every 2-3 minutes until the person wakes up</li> <li>• it is safe to keep giving doses</li> </ul> </li> </ul>
	<p><b>5) STAY</b></p> <p>Step 5: STAY</p> <ul style="list-style-type: none"> <li>• <b>STAY</b> until ambulance arrives: even if the person wakes up</li> <li>• <b>GIVE</b> another dose if the person becomes very sleepy again</li> <li>• You may need to give all the doses in the pack</li> </ul>

For opioid emergencies, call 911. For questions on NARCAN, call 1-844-4NARCAN (1-844-462-7226) or go to [WWW.NARCAN.COM](http://WWW.NARCAN.COM).

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#### 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

Call 1-844-4NARCAN (1-844-462-7226) or go to [WWW.NARCAN.COM](http://WWW.NARCAN.COM)

keep out of reach of children

#### **PRINCIPAL DISPLAY PANEL- CARTON LABEL**



**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 1<sup>st</sup> 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<sup>st</sup> dose
- 1 nasal spray device contains 1 dose



**Step 3: CALL**

- **CALL 911** immediately after giving the 1<sup>st</sup> dose



**Step 4: WATCH & GIVE**

- **WAIT** 2-3 minutes after the 1<sup>st</sup> dose to give the medicine time to work
- if the person **gains 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 shivering, sweating, nausea, or feeling angry. This is to be expected.

**Other information**

- store at room temperature or refrigerated, between 2°C to 25°C (32°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 1-844-NARCAN (1-844-463-7228) or go to [www.narcan.com](http://www.narcan.com)

Safe to Use  
Even if Opioids are Not Present

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Ireland Limited.  
NDC 69547-627-02



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110033

**NARCAN®**  
Naloxone HCl Nasal Spray 4 mg



Original Prescription Strength

Easy to Use

Can Save a Life

**NARCAN®**  
Naloxone HCl Nasal Spray 4 mg

Emergency Treatment of Opioid Overdose

Designed to Rapidly Reverse the Effects of a Life-Threatening Opioid Emergency



2 Single-Dose Nasal Spray Devices  
0.003 fl oz (0.1 mL) each

For use in nose only

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**

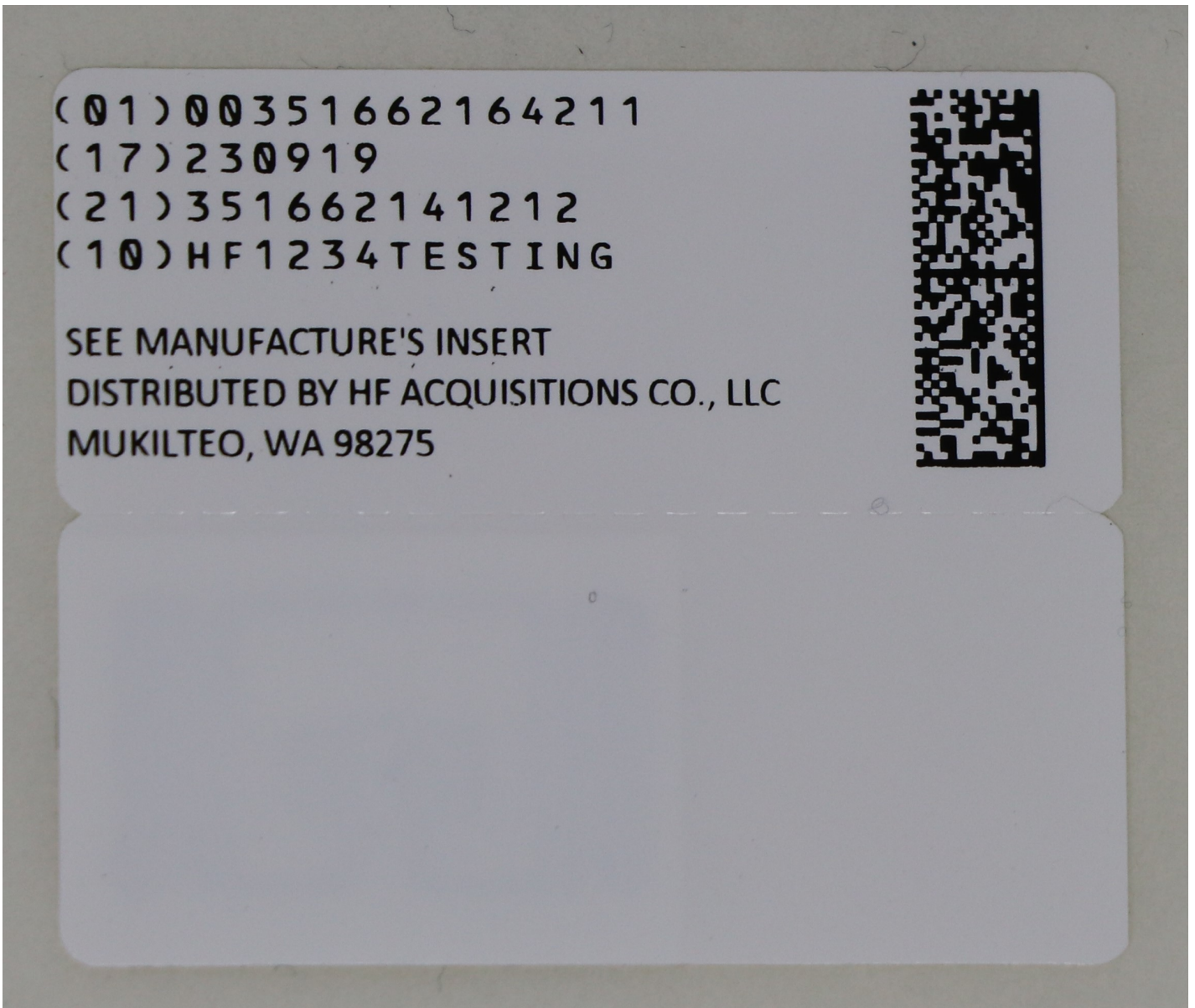
- to "revive" someone during an overdose from many prescription pain medications or street drugs such as heroin
- this medicine can save a life

LOT XXXXXX

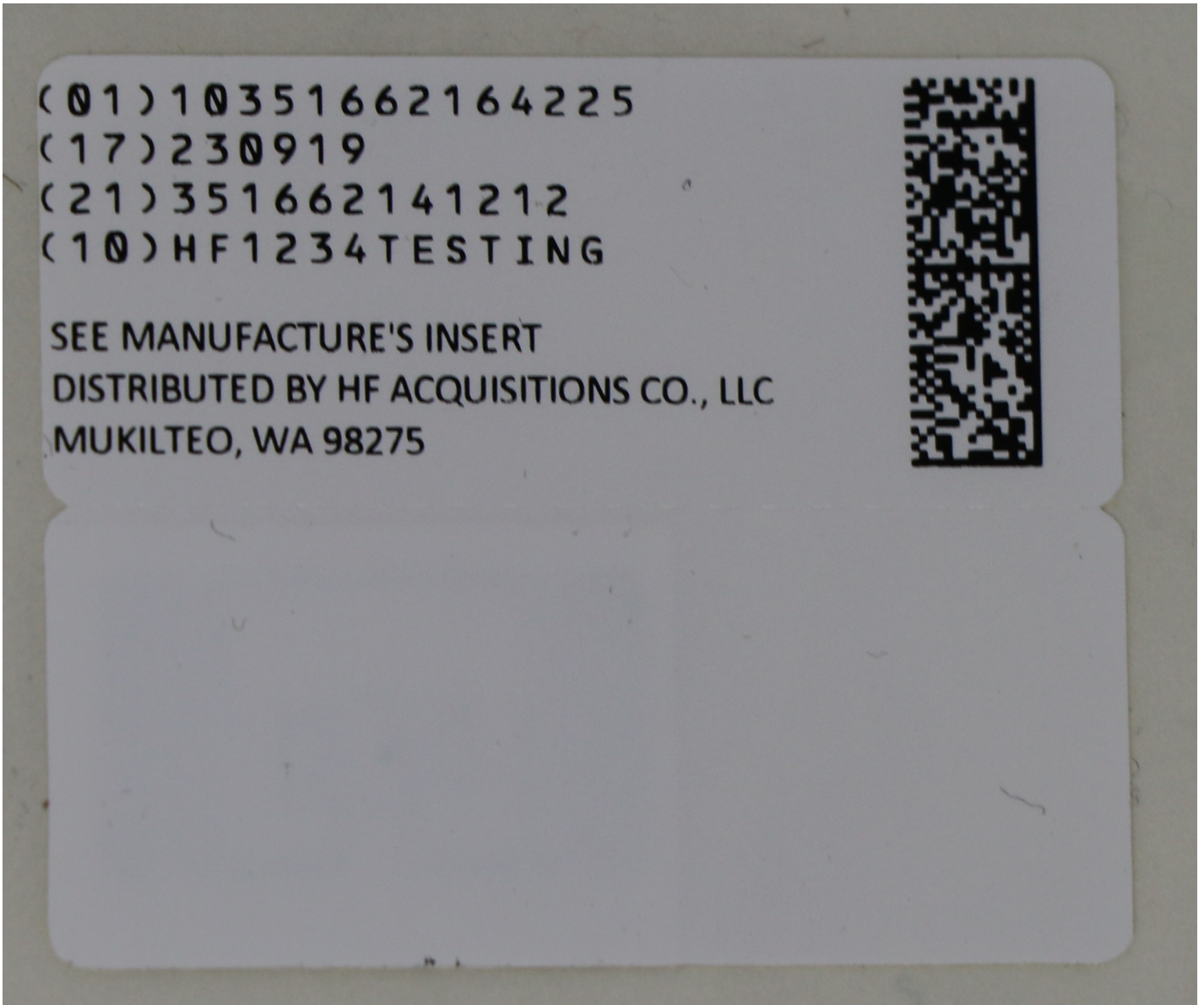
EXP YYY-MM



PRINCIPAL DISPLAY PANEL\_ NDC 51662-1642-1



**PRINCIPAL DISPLAY PANEL- NDC 51662-1642-2**



**NARCAN NALOXONE HCL**

narcn naloxone hcl spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51662-1642(NDC:69547-627)
<b>Route of Administration</b>	NASAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>NALOXONE HYDROCHLORIDE</b> (UNII: F850569PQR) (NALOXONE - UNII:36B82AMQ7N)	NALOXONE HYDROCHLORIDE	4 mg in 0.1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>WATER</b> (UNII: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51662-1642-2	2 in 1 CARTON	08/28/2023	
1	NDC:51662-1642-1	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
NDA	NDA208411	08/28/2023	

**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(51662-1642)