

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208411Orig1s006

LABELING

NARCAN®

Naloxone HCl Nasal Spray 4 mg

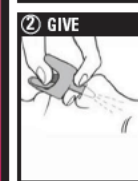


Drug Facts (continued)

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 1-844-4NARCAN (1-844-462-7226) or go to www.narcan.com

Safe to Use
Even if Opioids are Not Present

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Plymouth Meeting, PA 19462 USA

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NDC 69547-627-02



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



Nozzle

Plunger

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

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EXP YYYY-MM-DD



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NARCAN®

Naloxone HCl Nasal Spray 4 mg



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!"
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- Step 3: CALL**
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NDC 69547-627-02



NOT FOR RESALE

FOR NON-RETAIL
DISTRIBUTION

NARCAN®

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



Nozzle

Plunger

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spray device
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1 nasal spray
device contains
1 dose of medicine

Each device
sprays 1 time only

Read Directions Before Use ▶

Drug Facts

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- this medicine can save a life

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EXP YYYY-MM-DD

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NDC 69547-627-02



NARCAN[®]
Naloxone HCl Nasal Spray 4 mg
Emergency Treatment of Opioid Overdose



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- 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
- 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)

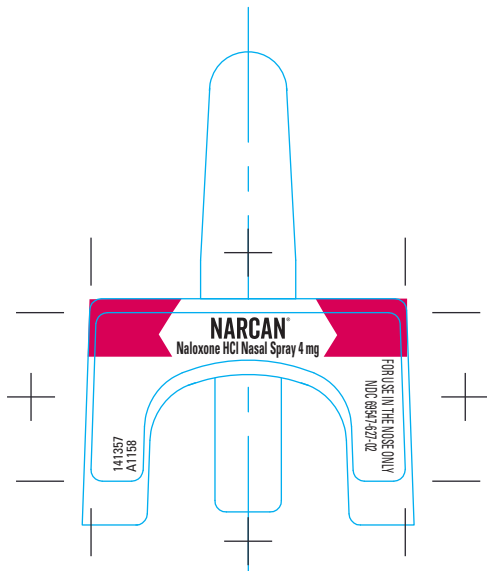
LOT XXXXXX EXP YYYY-MMM-DD

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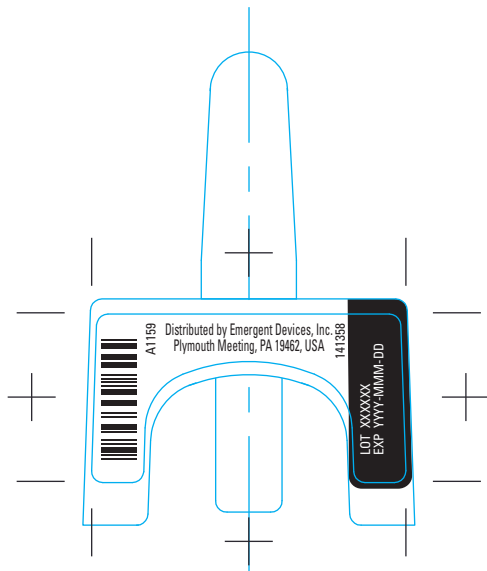
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DIRECTIONS		
NARCAN[®] Naloxone HCl Nasal Spray 4 mg	Emergency Treatment of Opioid Overdose Important: • For use in the nose only • Do not test nasal spray device before use • 1 nasal spray device contains 1 dose of medicine • Each device sprays 1 time only	Nozzle Plunger
1 CHECK WAKE UP!	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	Unfold for Directions
2 GIVE	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	Unfold for Directions 141411
3 CALL	Step 3: Call 911 • CALL 911 immediately after giving the 1st dose	
4 WATCH/GIVE 2-3 minutes	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	
5 STAY	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	
EMERGENT[®] For opioid emergencies, call 911. For questions on NARCAN, call 1-844-4NARCAN (1-844-462-7226) or go to www.narcan.com. ©2023 Emergent Devices Inc. EMERGENT[®] and NARCAN[®] are registered trademarks of Emergent BioSolutions Inc, or its subsidiaries.		
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FRONT



BACK



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/s/

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03/28/2023 10:00:04 PM

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03/29/2023 07:41:36 AM