

RiVIVE- naloxone hydrochloride spray
Harm Reduction Therapeutics, Inc.

RiVive®
Naloxone HCl Nasal Spray 3 mg
Emergency Treatment of Opioid Overdose

Active ingredient (in each spray)

Naloxone hydrochloride 3 mg



Purpose



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

<p>STEP 1 CHECK</p> 	<p>Step 1: CHECK if you suspect an overdose</p> <ul style="list-style-type: none">• CHECK 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
<p>STEP 2 GIVE</p> 	<p>Step 2: GIVE 1st dose in the nose</p> <ul style="list-style-type: none">• Hold nasal spray device with thumb on plunger and a finger on each side of the nozzle• Insert nozzle into one nostril and press plunger firmly• Each nasal spray device contains only one dose of naloxone
	<p>Step 3: CALL 911</p> <ul style="list-style-type: none">• Get medical help <u>immediately</u> after giving the first dose• Call 911 now

<p>STEP 4 WATCH/GIVE</p> 	<p>Step 4: WATCH & GIVE</p> <ul style="list-style-type: none"> • WAIT 2-3 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 does <u>not wake up</u>: <ul style="list-style-type: none"> • <u>Give a second dose of medicine</u> using a new nasal spray device • It is safe to keep giving doses every 2-3 minutes until the person wakes up
<p>STEP 5 STAY</p> 	<p>Step 5: STAY</p> <ul style="list-style-type: none"> • 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

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 20°C to 25°C (68°F to 77°F)
- do not refrigerate
- avoid excessive heat above 40°C (104°F)
- do not use if sealed blister package is torn or opened

Inactive ingredients

hydrochloric acid, purified water, sodium chloride, sodium hydroxide, trisodium citrate dihydrate

Questions?

for more information call toll-free (888)-412-7454 or go to www.RiVive.com

Package/Label Principal Display Panel

RiVive®

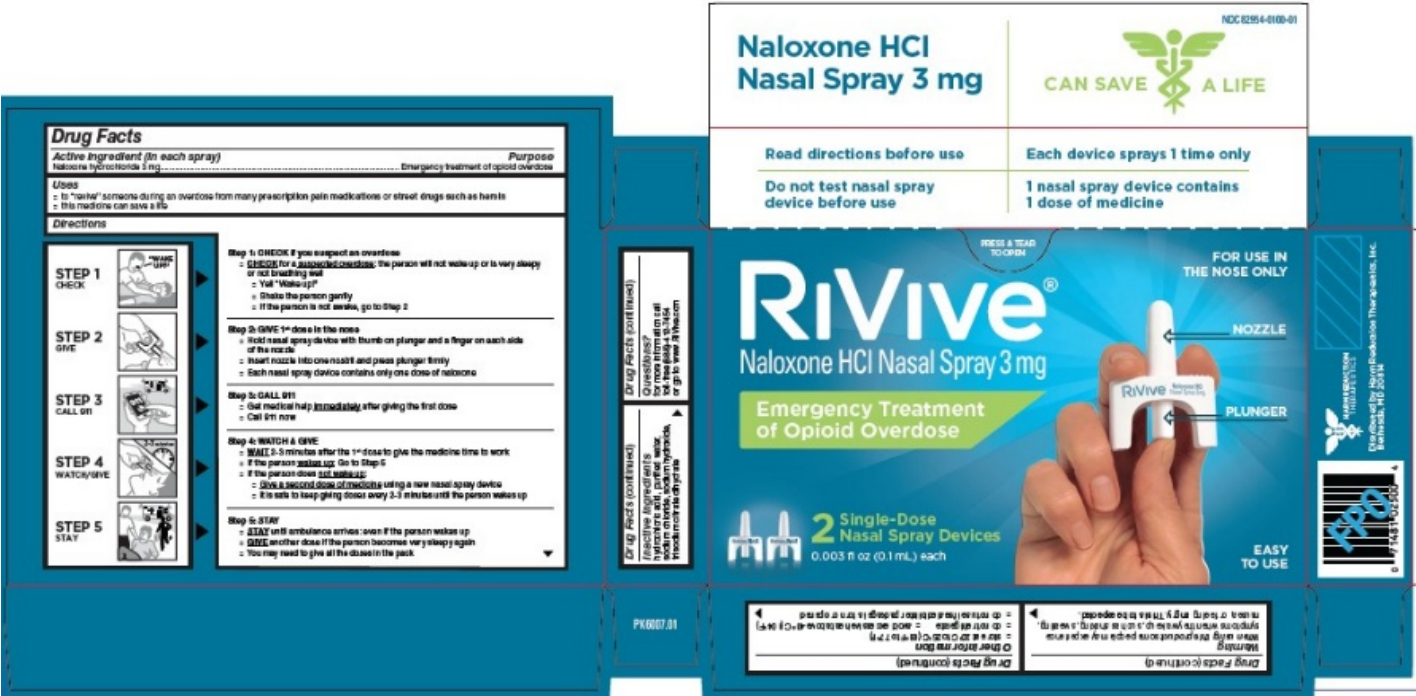
Naloxone HCl Nasal Spray 3 mg

Emergency Treatment of Opioid Overdose

FOR USE IN
THE NOSE ONLY
NOZZLE
PLUNGER
EASY
TO USE

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

HARM REDUCTION
THERAPEUTICS
Distributed by Harm Reduction Therapeutics, Inc.
Bethesda, MD 20814



Label

<div><div>RIVIVE</div><div>naloxone hydrochloride spray</div></div>			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82954-0100
Route of Administration	NASAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
NALOXONE HYDROCHLORIDE (UNII: F850569PQR) (NALOXONE -		NALOXONE	3 mg

UNII:36B82AMQ7N)		HYDROCHLORIDE		in 0.1 mL
Inactive Ingredients				
Ingredient Name				Strength
HYDROCHLORIC ACID (UNII: QTT17582CB)				
WATER (UNII: 059QF0KO0R)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82954-0100-1	2 in 1 CARTON	01/02/2024	
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		NDA217722	01/02/2024	

Labeler - Harm Reduction Therapeutics, Inc. (107812954)