



**BIOLABS  
INTERNATIONAL**  
Factory Direct Distribution

# **NALOXONE HCl NASAL SPRAY**

4mg

Emergency Treatment of Opioid Overdose  
Authorized Distribution



**BIOLABS  
INTERNATIONAL**  
Factory Direct Distribution

**BIOLABS INTERNATIONAL, LLC**

**IS PROUD TO INTRODUCE**

**THE LAUNCH OF AN  
Over-The-Counter**

**NALOXONE NASAL SPRAY  
IN THE UNITED STATES**

[info@biolabsinternational.net](mailto:info@biolabsinternational.net)



**BIOLABS  
INTERNATIONAL**  
Factory Direct Distribution



# NALOXONE HCl NASAL SPRAY 4mg

Emergency Treatment of Opioid  
Overdose.

Original Prescription Strength Easy to Use  
Can Save a Life.

Designed to Rapidly Reverse the Effects of  
a Life-Threat.



## Naloxone HCl Nasal Spray

The country's first over-the-counter (OTC) Naloxone HCl Nasal Spray, generic equivalent to NARCAN<sup>®</sup>, is now available through Biolabs International LLC.

Naloxone is a medication that is designed to rapidly reverse the effects of opioid overdose. It is a life-saving product that, until now, has only been available as a prescription-labeled drug.

Biolabs International LLC is an authorized Distributor of the Product, Now in-stock and ready to ship.



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It contains the same active ingredient and same dose of active ingredient as NARCAN<sup>®</sup> Naloxone HCl Nasal Spray, 4 mg.

Naloxone HCl Nasal Spray, 4 mg, will be available on store shelves and at online retailers so that anyone can purchase it without a prescription.

JV Partnership with Authorized Distributor

**Biolabs International, LLC**

San Diego, California



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- Proprietary Name: Naloxone
- Selling Unit NDC: 45802-0578-84
- Description: Naloxone HCl Nasal Spray 4mg
- Active Ingredients: Naloxone Hydrochloride
- UPC: 345802578846
- Size: 2-Pack
- Strength: 4mg/0.1ML (per dose)
- Dosage Form: Spray
- Product Color: clear, colorless to yellowish solution
- Temperature Range Requirement: 2C to 25C (36F to 77F)
- Note: Avoid excessive heat above 104F
- Is this product to be shipped on ice: No
- Special Regulations: No
- Initial Shelf Life at Launch: 24 Months
- What is the NDC Selling Unit: One carton containing 2 vials
- Box/Carton: 10 Vials
- This Product Is: Latex Free
- Manufacturer: Padagis (U.S.A.)
- Country of Origin: France
- Is this Product Covered Under the Trade Agreements Act (TAA): Yes
- Product Exemption: OTC
- Generic Equivalent to What Brand?: Narcan
- GLN: 0305740000007
- Application Number for NDA/ANDA/BLA (drug; PMA/510(k) (med device): 211951
- Availability: At Once Inventory, Yes

Vista Health LLC

5508 West Plano Parkway, Suite 200, Plano, TX 75093

August 13, 2023

RE: Biolabs International LLC Distributor Status

To Whom It May Concern:

This letter is to confirm that the organization indicated below is an official distributor under contract with Vista Health LLC:

Gino Ajodani  
President  
Biolabs International LLC  
7887 Dunbrook Rd  
Suite: H  
San Diego, Ca 92126  
(800) 440-4580  
(619)-918-5772  
Gino@biolabsinternational.net  
D-U-N-S number: 101361182

Biolabs International LLC is an authorized distributor of the Vista Health LLC products as designated in Addendum A attached to this correspondence.  
Sincerely,

*Craig T. Belling*

Craig Belling CFO.  
Vista Health, LLC  
(949) 304-9970  
cbelling@vistahhealthllc.com



## QUICK START GUIDE

### Opioid Overdose Response Instructions

#### 1 Identify Opioid Overdose and Check for Response



**Ask** person if he or she is okay and shout name.

#### **Check for signs of opioid overdose:**

- Will not wake up or respond to your voice or touch
- Breathing is very slow, irregular, or has stopped
- Center part of their eye is very small, sometimes called "pinpoint pupils"

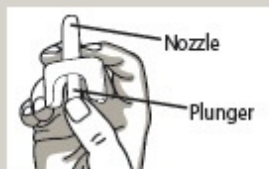
**Lay the person on their back to receive a dose of Naloxone HCl Nasal Spray.**

#### 2 Give Naloxone HCl Nasal Spray

**Remove** Naloxone HCl Nasal Spray from the box.



**Peel** back the tab with the circle to open the Naloxone HCl Nasal Spray.



**Hold** the Naloxone HCl Nasal Spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle.



**Gently insert the tip of the nozzle into either nostril.**

- Tilt the person's head back and provide support under the neck with your hand. Gently insert the tip of the nozzle into one nostril, until your fingers on either side of the nozzle are against the bottom of the person's nose.



**Press the plunger firmly** to give the dose of Naloxone HCl Nasal Spray.

- Remove the Naloxone HCl Nasal Spray from the nostril after giving the dose.

#### 3 Call for emergency medical help, Evaluate, and Support



**Get emergency medical help right away.**

Move the person on their side (recovery position) after giving Naloxone HCl Nasal Spray.

**Watch the person closely.**

**If the person does not respond** by waking up, to voice or touch, or breathing normally another dose may be given. Naloxone HCl Nasal Spray may be dosed every 2 to 3 minutes, if available.

**Repeat Step 2 using a new Naloxone HCl Nasal Spray to give another dose in the other nostril.**

If additional Naloxone HCl Nasal Sprays are available, repeat step 2 every 2 to 3 minutes until the person responds or emergency medical help is received.

# Quick Start Guide

## For The First OTC Naloxone HCl Nasal Spray.

[info@biolabsinternational.net](mailto:info@biolabsinternational.net)



## Product Information

- **PROPRIETARY NAME: NALOXONE**  
Quick start guide available upon request
- **DESCRIPTION**  
Naloxone HCl Nasal Spray, 4mg  
Active Ingredient: Naloxone Hydrochloride  
Product exemption: OTC
- **(2) PACK**  
Strength: 4mg/0.1 ml (per dose)  
Dosage form: Spray  
Shelf life: 24 months  
Product is latex free  
Country of origin: France and is covered under the Trade Agreements Act (TAA)







## Product Information

- **CODES**

NDC Code: 45802-578-84

UPC Code: 345802578846

GLN: 030570000007

- **TEMPERATURE RANGE REQUIREMENTS**

2C to 25C (36F to 77F)

Avoid excessive heat above 104F

- **PRODUCT IS IN-STOCK AND READY TO SHIP**

Pallet: 48D x 40W x 44.24H

Pallet Weight: 176.02lbs

See next page for full detail





# Packing Information

## DIMENSIONS (-US MSMTS.)

	Weight Lbs.	Depth	Width	Height	Volume (Cube)	Saleable# Pieces
Item/Each:	0.099	3.74	1.57	5.91	34.702338	1
Box/Carton/Bundle/ Inner Pack:					0	
Case:	1.544	11.97	7.48	6.54	585.56282	12
Pallet:	176.02	48	40	44.24	84940.8	1,368



ANDA 211951/S-003

**PRIOR APPROVAL SUPPLEMENT  
APPROVAL**

Padagis US LLC  
U.S. Agent for Padagis Israel Pharmaceuticals Ltd.  
3940 Quebec Avenue North  
Minneapolis, MN 55427  
Attention: Anna Voght  
RA Manager

Dear Anna Voght:

This letter is in reference to your supplemental abbreviated new drug application (sANDA) received for review on April 20, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Naloxone Hydrochloride Nasal Spray, 4 mg/spray (OTC).

Reference is also made to any amendments submitted prior to the issuance of this letter.

The sANDA, submitted as "Prior Approval Supplement," provides for a change from prescription marketing status to over-the-counter (OTC) marketing status

We have completed the review of this sANDA, as amended, and it is **approved**.

**COMPENDIAL STANDARDS**

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website as <https://www.uspnf.com/>.

**REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL**

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials,

U.S. Food & Drug Administration  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

ANDA 211951/S-003

Page 2

and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas>.

Sincerely yours,

*{See appended electronic signature page}*

For Rachel Goehe, Ph.D.  
Director  
Division of Labeling Review  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research

U.S. Food & Drug Administration  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)



**BIOLABS  
INTERNATIONAL**  
Factory Direct Distribution

# **Biolabs International LLC is an authorized distributor.**

Due to overwhelming demand,  
We are now taking pre-orders.

**\*\*Please secure your lot by placing your order today.\*\***

## **FOR ALL INQUIRES PLEASE CONTACT US:**

Office: 1-800-440-4580  
[info@biolabsinternational.net](mailto:info@biolabsinternational.net)

Corporate Office:  
7887 Dunbrook Rd Suite H,  
San Diego CA 92126

Sales Inquiries:  
[Sales@biolabsinternational.net](mailto:Sales@biolabsinternational.net)

Join our distribution network:  
[Distributors@biolabsinternational.net](mailto:Distributors@biolabsinternational.net)

Customer Support:  
[Support@biolabsinternational.net](mailto:Support@biolabsinternational.net)