JLB Sourcing

www.jlbsourcing.com | **Sales@jlbsourcing.com** | (703) 349-3003

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.

JLB Sourcing LLC is proud to introduce the launch of an Oven-The-Counter NALOXONE NASAL SPRAY in the United States

Padagis™

Naloxone HCl Nasal Spray

The country's first over-the-counter (OTC) Naloxone HCl Nasal Spray, generic equivalent to NARCAN®, is now available.

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.

It contains the same active ingredient and same dose of active ingredient as NARCAN® 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.

JLB Sourcing, LLC

Ashburn, Virginia

- 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
- 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
- Availabilty: At Once Inventory, Yes

Quick Start Guide

for the First OTC Naloxone HCI Nasal Spray

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:

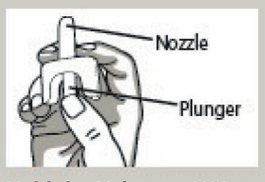
- Will not wake up or respond to your voice ot touch
- Breathing is very slow, irregular, or has stopped
- Center part of their eye is very small, sometimes called "pin-point pupils"

Lay the person on their back to receive a dose of Naloxone HCI Nasal Spray

2 Give Naloxone HCI Nasal Spray

Remove Naloxone HCI Nasal Spray from the box.

Peel back the tab with the circle to open the Naloxone HCI Nasal Spray



Hold the Naloxone HCI 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 HCI Nasal Spray.

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

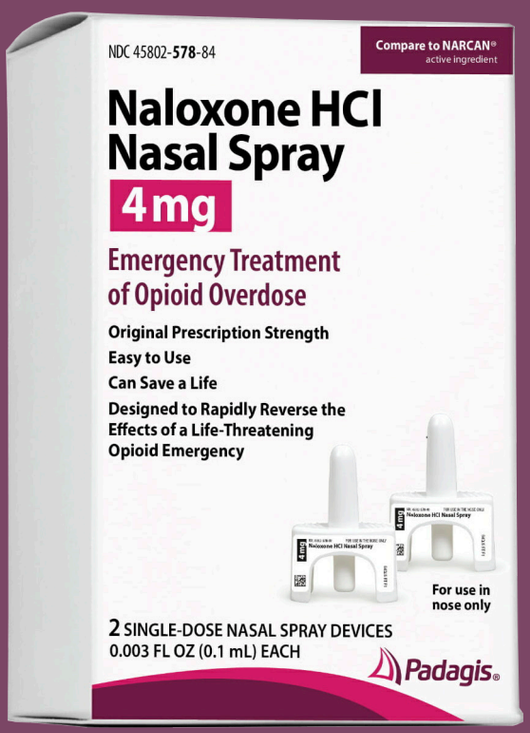
3 Call for emergency medical help, Evaluate, and Support

Get emergency medical help right away.

Move the person on their side (recovery position) after giving Naloxone HCI Nasal Spray. **Watch the person dosely.**

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

Repeat Step 2 using a new Naloxone HCI Nasal Spray to give another dose in the other nostril. If additional Naloxone HCI Nasal Sprays are available, repeat step 2 every 2 to 3 minutes until the person responds or emergency medical help is received.



Product Information

- **PROPRIETARY NAME: NALOXONE**

  Quick start guide available upon request

- **DESCRIPTION**

  Naloxone HCl Nasal Spray, 4 mg
  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)

- **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: 176.02 lbs

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

U.S. FOOD & DRUG ADMINISTRATION

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,

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