

NALOXONE- naloxone spray
Summit Biosciences Inc.

TRADENAME NASAL SPRAY, 10 MG PACKAGE/LABEL.PRINCIPAL DISPLAY PANEL

TRADENAME
(naloxone HCl)
NASAL SPRAY **10 mg**

QUICK START GUIDE


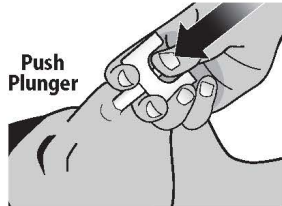


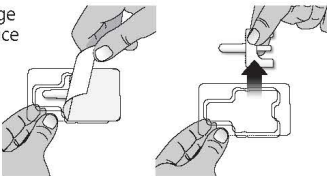

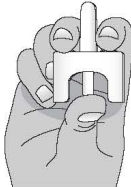

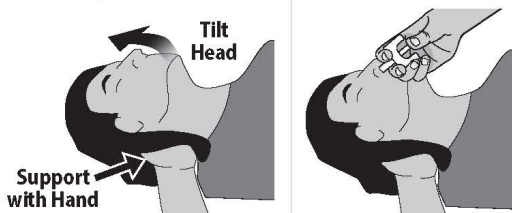

Response Instructions for Opioid Overdose

Use TRADENAME (naloxone hydrochloride) Nasal Spray for known or suspected opioid overdose in adults and children.

Important: For Nasal Use Only.

Do not unpack or test TRADENAME Nasal Spray until ready to use.

Each TRADENAME Nasal Spray device has 1 dose and cannot be reused.

<p>1 Check for Signs of Opioid Overdose</p> <ul style="list-style-type: none">• Unresponsive• Unconscious or unable to wake up• Slow, shallow, irregular breathing• Fingernails or lips turning blue/purple  <p>Check Person for Overdose</p>	<p>6 Give Dose by Pushing the Plunger Hard and All the Way In. Then Remove From Nostril</p>  <p>Push Plunger</p>
<p>2 Lay the Person on Their Back</p> 	<p>7 Call for Emergency Help Right Away</p> 
<p>3 Peel Open Package and Remove Device</p> 	<p>8 Put the Person into the Recovery Position by Turning Them On Their Side</p> <p>Watch Closely for 2 Minutes</p> 
<p>4 Hold Device as Shown</p> 	<p>9 If No Response, Give a 2nd Dose in the Other Nostril With A New Nasal Spray</p> <p>Return the Person to a Recovery Position</p>  <p>Use Other Nostril</p>
<p>5 Tilt the Person's Head Back and Provide Support with Your Hand</p> <p>Insert Nozzle into One Nostril</p>  <p>Tilt Head</p> <p>Support with Hand</p>	<p>10 Throw Away the Used TRADENAME Nasal Spray</p>  <p>Trash</p>

ART: 3 DATE: 11/29/2022 CUSTOMER: Summit

PIN: Naloxone_QSG_10mg_LETTER_PI

Eval#: X5383629

SIZE: 8.4645 x 10.7410

FOLD: 1.6929 x 1.8110

DRWG: 211935



CODE: Type / Decoded Data / Human Readable
128 Code / 5123XX / 5123XX

APPROVED

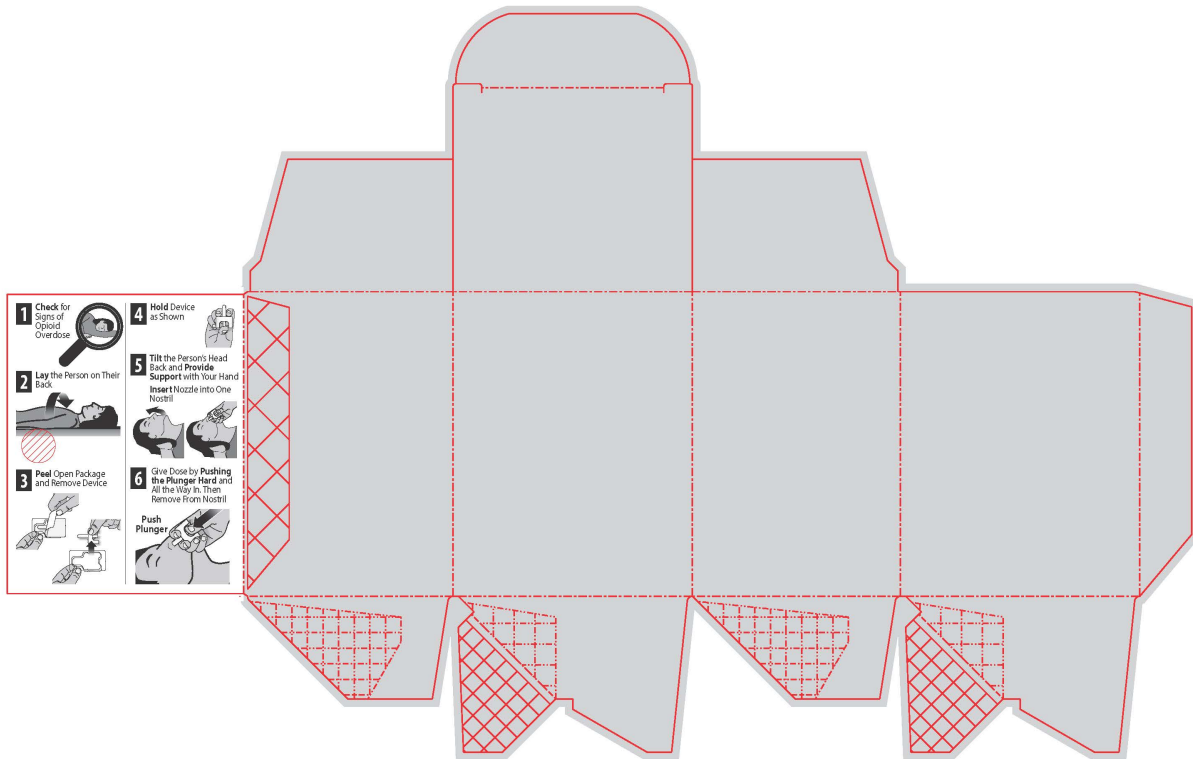
(Signature / Date)

Approval must be sent to ArtFlo and Acct. Manager

CAUTION: Artwork cycles are NOT proofread. Please, proofread BEFORE authorizing Nosco to proceed to final proofing. The ART is to show size, copy placement and color breaks. Actual colors will be matched on press to approved color standards and/or PMS color swatches. *Customer Logos, Brand/Drug names with Superscripts/Subscripts with **9's** and **TM's** is to be a minimum 1/32" high for the TM and bold, and for the **9** 1/32" in circumference and bold. Any deviation to this will be printed as is. **Nosco Glue Flap Barcode:** is for Internal Quality Control Purposes Only and any element in Die color Does NOT Print.

TRADENAME (Naloxone Hydrochloride) Nasal Spray



ART: 6 DATE: 11/29/2022 CUSTOMER: SUMMIT BIOSCIENCES

PIN: TRADENAME_ABCD1234E_10MG_CTN

Eval#: X5383735

SIZE: 2.875 x 2.5 x 3.6814

DRWG: 290887 Rev 3



CODE: Type / Encodation / Human Readable
CODE: UPC / 000000000000 / 000000000000
CODE: 2D / non-printing FPO / NA

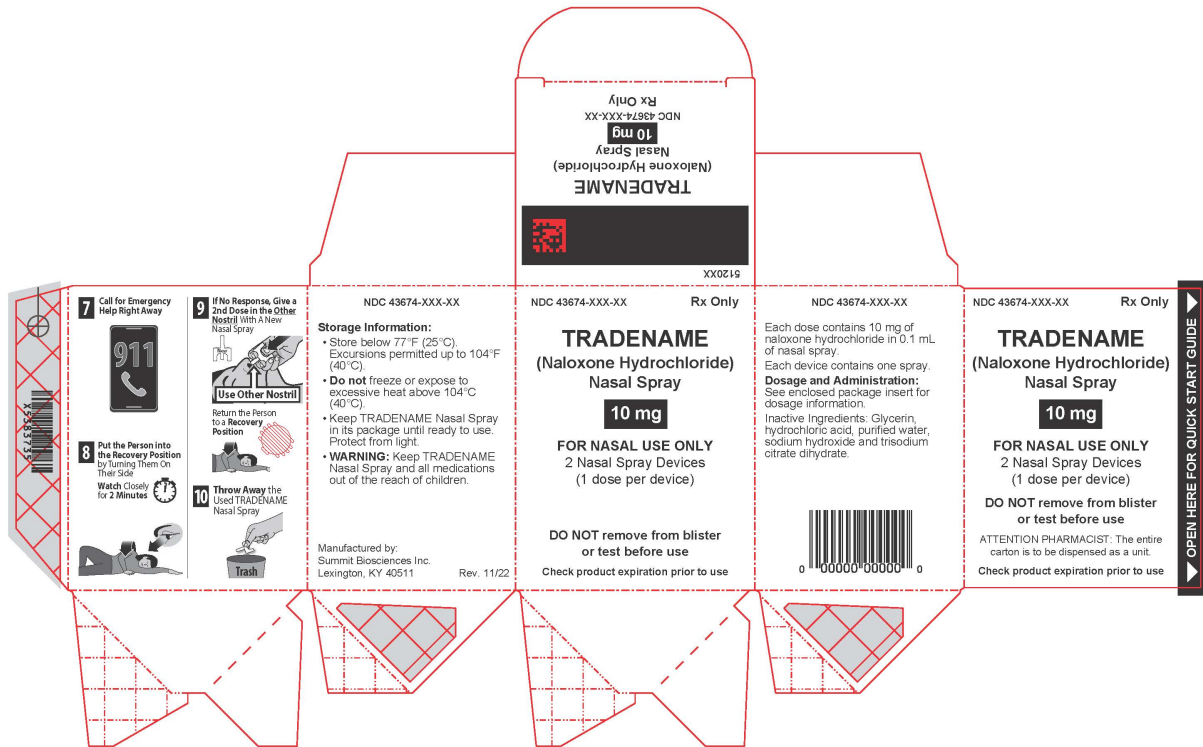
APPROVED

(Signature / Date)

Approval must be sent to ArtFlo and Acct. Manager

CAUTION: Artwork cycles are NOT proofread. Please, proofread BEFORE authorizing Nosco to proceed to final proofing. The ART is to show size, copy placement and color breaks. Actual colors will be matched on press to approved color standards and/or PMS color swatches. *Customer Logos, Brand/Drug names with Superscripts/Subscripts with **9's** and **TM's** is to be a minimum 1/32" high for the TM and bold, and for the **9** 1/32" in circumference and bold. Any deviation to this will be printed as is. **Nosco Glue Flap Barcode:** is for Internal Quality Control Purposes Only and any element in Die color Does NOT Print.



ART: 6 DATE: 11/29/2022 CUSTOMER: SUMMIT BIOSCIENCES Black Green Yellow/Red

PN: TRADENAME_ABCD1234E_10MG_CTN
 Eval#: X5383735
 SIZE: 2.875 x 2.5 x 3.6614
 DRWG: 200007 Rev 3

CODE: Type / Decoded Data / Human Readable
 UPC Code / 000000000000 / 000000000000
 ZD Code / non-printing FPO / NA

APPROVED _____ (Signature / Date)
Approval must be sent by ArtFlo and Acct. Manager

CAUTION Artwork cycles are NOT proofed. Please, proofread BEFORE authorizing Nesco to proceed to final proofing. Nesco will follow this cycle document and color guide. Resolutions will be applied to approved color standards and the color match. Customer Logo, Branding names with Superscript/Underline with ® and TM's to be a minimum 1/8" high before final proof and final color proof. Any deviation to this will be considered a Nesco Blue Flag Barcode is for Internal Quality Control Purposes Only and any element in this color does NOT Print.

NALOXONE

naloxone spray

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:43674-003
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NALOXONE HYDROCHLORIDE (UNII: F850569PQR) (NALOXONE - UNII:36B82AMQ7N)	NALOXONE HYDROCHLORIDE	10 mg in 0.1 mL

Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43674-003-02	2 in 1 CARTON	06/28/2024	
1		1 in 1 BLISTER PACK		
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	NDA215487	06/28/2024	

Labeler - Summit Biosciences Inc. (832920081)

Registrant - Summit Biosciences Inc. (832920081)

Establishment

Name	Address	ID/FEI	Business Operations
Summit Biosciences Inc.		832920081	analysis(43674-003) , label(43674-003) , manufacture(43674-003) , pack(43674-003)

Revised: 12/2023

Summit Biosciences Inc.