NALOXONE- naloxone spray
Summit Biosciences Inc.

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

TRADENAME
(naloxone HCl)
NASAL SPRAY 10 mg

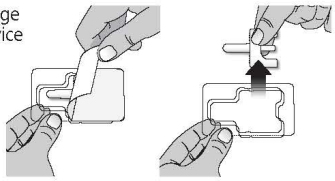
QUICK START GUIDE

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.

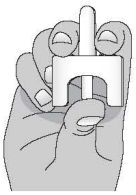
1 **Check** for Signs of Opioid Overdose
- Unresponsive
- Unconscious or unable to wake up
- Slow, shallow, irregular breathing
- Fingernails or lips turning blue/purple

2 **Lay** the Person on Their Back

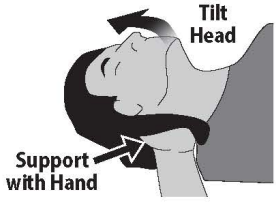
3 **Peel** Open Package and Remove Device



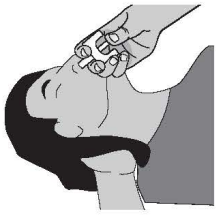
4 **Hold** Device as Shown



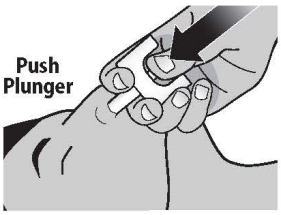
5 **Tilt** the Person's Head Back and **Provide Support** with Your Hand



Insert Nozzle into One Nostril



6 Give Dose by **Pushing the Plunger Hard** and All the Way In. Then Remove From Nostril

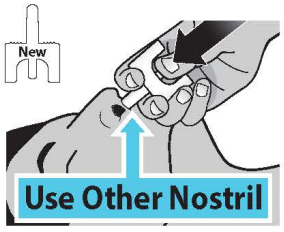


7 **Call for Emergency Help Right Away**

8 **Put the Person into the Recovery Position** by Turning Them On Their Side

Watch Closely for **2 Minutes**

9 **If No Response, Give a 2nd Dose in the Other Nostril** With A New Nasal Spray



Return the Person to a **Recovery Position**

10 **Throw Away** the Used TRADENAME Nasal Spray

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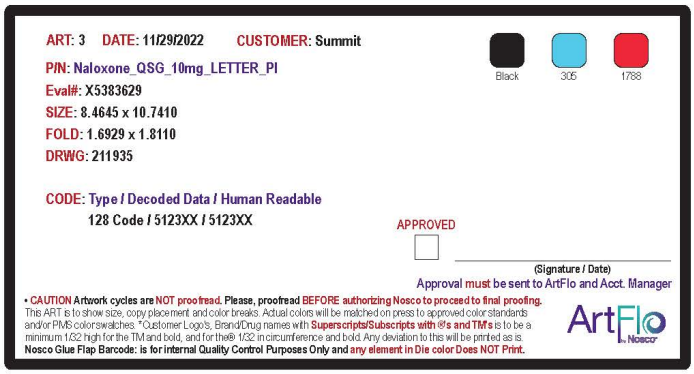
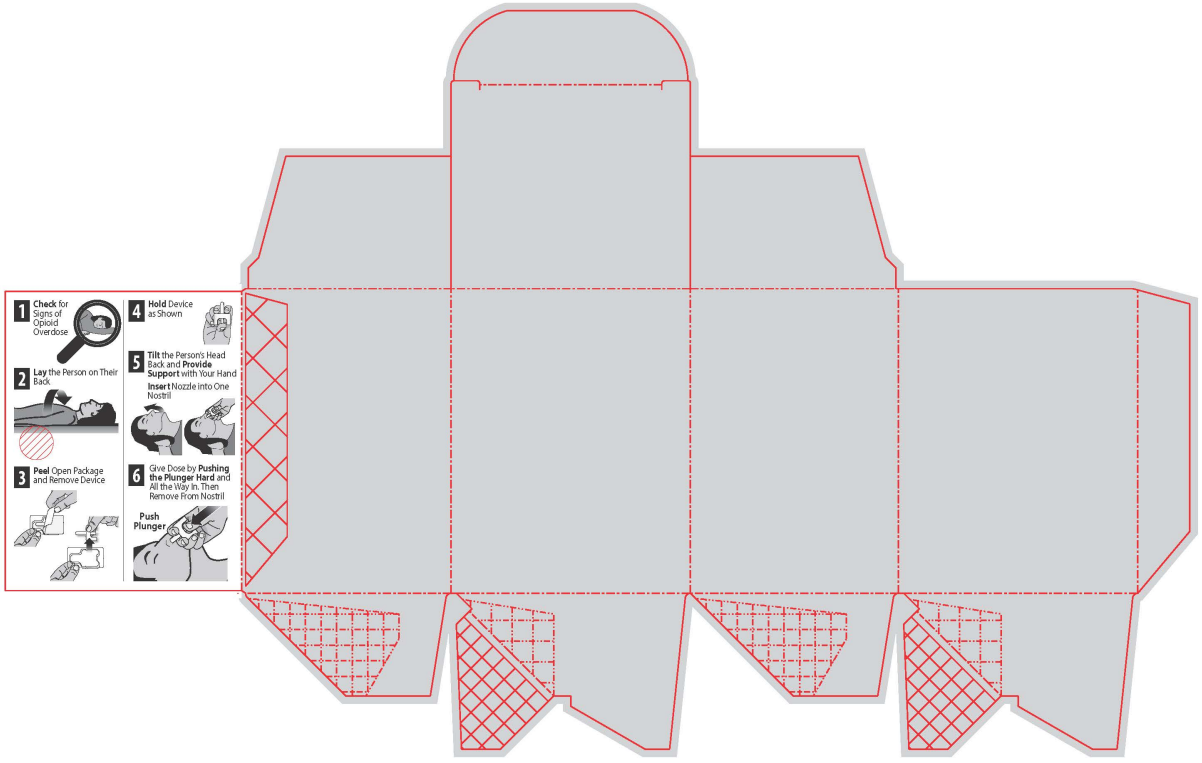
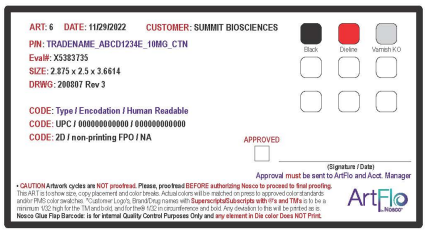
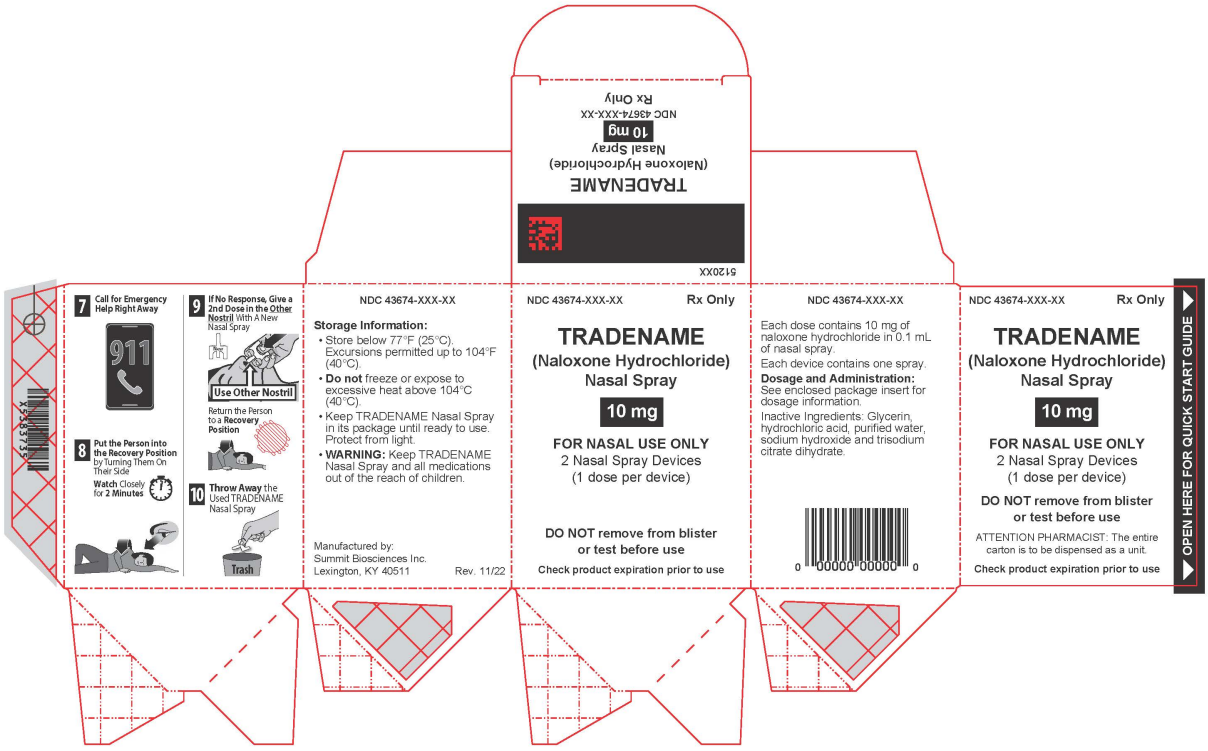
Rev. 11/22

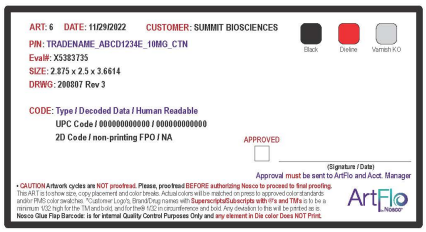


TRADENAME (Naloxone Hydrochloride) Nasal Spray









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.