Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Item | **0** Final Version | **Date:** 1/17/2020

PRODUCT INFORMATION

Company Name:	Auromedics Pharma LLC	**Application:**	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	212456		
DUNS:	968961354		
Proprietary Name (If Applicable) and Established Name:	Naloxone Hydrochloride Injection, USP 4 mg/10 mL (0.4 mg/mL) [MDV] (10 Vials)		
Selling Unit NDC:	55150-328-10	**Individual Unit NDC:** 55150-328-10	**UPC:** 355150328109
UDI		**CVX Code:**	**MVX Code:**
Description:	Naloxone Hydrochloride Injection, USP 4 mg/10 mL (0.4 mg/mL) [MDV] (10 Vials)		
Active Ingredient(s):	Naloxone Hydrochloride		
URL for Additional Product Information:			
Address:	279 Princeton-Hightstown Road	**Address 2:**	
City:	East Windsor	**State:** NJ	**Zip:** 08520
Key Contact:		**Email:**	
Phone Number:	888-238-7880	**Fax:**	732-355-9449
Product Therapeutic Classification:	Opioid Reversal Agent		

ADDITIONAL PRODUCT INFORMATION

Is the Product…	
a legend device?	No
reverse numbered?	No
co-licensed?	No
Is the Product…	Direct-Ship Only
Is the Product…	Neither
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose NDC, indicate NDC here:	
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION

Size:	10 vials
Strength:	4 mg/10 mL (0.4 mg/mL)
Dosage Form:	Liquid
Product Shape:	
Product Color:	
Product Imprint:	

FOR GENERIC DRUG PRODUCTS

[ ] Authorized Generic — *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AP

II. Generic Equivalent to What Brand?: Narcan® Injection 4 mg/10 mL (Adapt Pharma Operations Ltd.)

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes	**GLN:**	
Is product exempt from DSCSA?	No		
If yes, select exemption:			
Other exemption - Write in:			
Is product repackaged?	No	**If Yes, was original product purchased direct from mfr?**	
Is product sold by manufacturer's exclusive distributor?	No		
Has FDA granted waiver/exception/exemption for product?	No	**If yes, attach documentation from FDA.**	

GTIN PRODUCT INFORMATION

Serialized? Yes
If not, when?
Items aggregated?

Level	Saleable Unit	2D	Linear	Quantity	GTIN-14
x Item		x 2D		10	00355150328109
x Box/Carton/Bundle/Inner Pack	x	x 2D		60	30355150328100
x Case		x 2D		240	50355150328104
x Pallet		x 2D		10,800	70355150328108
		2D	Linear		
		2D	Linear		
		2D	Linear		
		2D	Linear		

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F

Other Temperature Range Requirement (write in): Store at 20° to 25°C (68° to 77°F).

Is this product to be shipped to customers on ice? No

Is this product to be shipped to customers on dry ice? No

b. Contact for temperature excursion questions:

Name:
Number:
Group E-mail:

c. Special regulations for product in any states? No

Special returns requirements for this product? No

d. Store product (unit of sale) upright? No

Protect product (unit of sale) from light? No

e. Shelf life: 24 **Months**

Initial shelf life at launch (if different): **Months**

ORDER INFORMATION

Unit of Sale

	Bottle
x	Box/Carton
	Ampule
	Glass
	Tube
	Vial Liquid Sgl
	Vial Liquid Multi
	Vial Powder Sql
	Vial Power Multi
	Other: Write In

What is the NDC selling unit?

1 box of 10 Vials

(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

	Each
	Inner/Carton/Pack
1	Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? 10 vials

(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

x	Each
	Gram
	Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	0.30643	5.31	2.36	2.17	27.193572	10 vials
Box/Carton/Bundle/ Inner Pack:	3.0643	13.82	2.99	5.75	237.60035	60 vials
Case:	13.812	14.763	7.3023	12.205	1315.74605	240 vials
Pallet:	654.587	48	41.85	40	80352	10,800 vials
UPC:	**Case:** 50355150328104					
	Carton: 00355150328109					

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	$1,150.00
Federal Excise Tax Per Unit of Sale	
As of date:	

WHOLESALER USE ONLY:

Vendor #:
Whsl. Code #:
Fineline Code:

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

***Please provide any additional information on page 2.**

See new p. 3 for Designated Drop Ship Only.

Signature: Muramreddy Penchalaiah

Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic?	No
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	
Is the product a CA Prop 65 carcinogen?	No
Is the product a CA Prop 65 reproductive toxicant?	No
Does the product label bear a CA Prop 65 warning?	No
c. Contact Hazard?	No
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	No
e. Does the product contain DEHP?	
Is this product regulated for shipment by DOT or IATA? (if yes, answer a-e below and provide SDS)	
a. UN/Identification Number	
b. Proper Shipping Name	
c. DOT Hazard Class	
d. Packing Group	
e. Inhalation Hazard?	

SDS Hazard Classification

- ☐ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Corrosive
- ☐ Oxidizer
- ☐ Contact Hazard
- ☐ Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug? No

If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

Is the product restricted for air shipment? If so, indicate restriction:

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

Is this a reportable quantity?

RQ Threshold:

Is this a marine pollutant?

Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below)

- ☐ Limited Quantity
- ☐ Consumer Commodity, ORM-D
- ☐ Small Quantity (49 CFR 173.4)
- ☐ Special Permit; DOT-SP
- ☐ Special Provision (listed in Column 7 of 49 CFR 172.101);

SP#

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

REMS: No

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #:

PCPDP #:

NPI #:

Comments

Registry:

Registry Program Contact Name: Phone:

Comments

ADD'L STORAGE INFORMATION

Is the Product…

Controlled Substance?	No
Controlled by State(s)?	No
ARCOS Reportable?	No
Schedule No. (inc. N for non-narcotic)	
Controlled Substance Code	
Listed Chemical (List I or II)	No
If yes, indicate which:	
Is it a scheduled listed chemical product?:	No

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 888-238-7880

Is product returnable for credit: Yes

URL/Link to returns policy: http://auromedics.com/policies/return-policy/

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes
Restricted to retail pharmacy only:	No
Restricted to hospital, clinics, and physician offices only:	No
Restricted from US territories? (explain in comments)	

Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:

a. EDI
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:
Supplier's Customer Service Number:
Contracted 3PL company / contact #: Name:
Phone:

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier
Cut off time:

Shipping lead time of PO: Hours Days

Ships same day for next day receipt:
Ships for second day receipt:
Ships regular ground for 3-10 days receipt:

Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order:
Drop Ship service fee billed with each order:
Drop Ship miscellaneous fees billed:
Comments:

Overnight and Priority Overnight PO Processing

Overnight receipt available:
PO Receipt cut off time:
Days of week overnight is available:
Monday
Tuesday
Wednesday
Thursday
Friday

Priority Overnight receipt available:
PO Receipt Cut off time:

Saturday Overnight receipt available:
PO Receipt Cut off time:

Order receipt method: Phone: Phone #: Fax: Fax #: EDI:
Overnight Fees apply:
Other fees apply:

Class of Trade Restriction:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices
Restricted to retail pharmacy only:
Restricted to hospital, clinics, and physician offices only:
Restricted from US territories? (explain in comments)
Comments:

Other Data Information Required to Process PO:

Patient Procedure Date:
Physician Name:
Physician/Clinic Phone #
Physician State License #
Physician/Clinic DEA #:
Physician/Clinic Specialty:

Return Instructions

Contact # if product is received damaged:
Is product returnable for credit:
URL/Link to returns policy:
Special regulations or returns requirements for this product in certain states?
If so, which states? Other requirements? Comments?

Miscellaneous Notes:

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?
Is product order for restocking purposes?

Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2020 | Introduction Type: New Item | [ ] Final Version | Date: 09.FEB.2021

PRODUCT INFORMATION

Company Name:	Auromedics LLC
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	213279
DUNS:	968961354
Proprietary Name (If Applicable) and Established Name:	Naloxone Hydrochloride Injection, USP
Selling Unit NDC:	55150-345-10
Unit of Use NDC:	55150-345-01
UPC:	355150345106
UDI:	
CVX Code:	
MVX Code:	
Description:	Naloxone Hydrochloride Injection, USP (2 mL Single Dose Disposable Prefilled Syringe) 10's Pack
Active Ingredient(s):	Naloxone Hydrochloride
URL for Additional Product Information:	
Address:	279 Princeton-Hightstown Road
Address 2:	
City:	East Windsor
State:	NJ
Zip:	08520
Key Contact:	
Email:	
Phone Number:	888-238-7880
Fax:	732-355-9449
Product Therapeutic Classification:	Opioid Reversal Agent

ADDITIONAL PRODUCT INFORMATION

The product is?	
a legend device?	No
if yes, enter class #	
a product kit?	No
if yes, list NDCs of component parts	
reverse numbered?	No
co-licensed?	No
latex-free?	Yes
preservative-free?	Yes
correctional institution block?	No
opioid?	No
Cannabinoid?	No
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose, indicate NDC here:	
Is the Product...	Direct-Ship Only
Is the Product...	Neither
Orphan Drug Status	
FDA Approval Status	
Allergens Present	
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	

PRODUCT DESCRIPTION INFORMATION

Size:	10 x 2 mL Single Dose Disposable Prefilled
Strength:	2 mg per 2 mL (1 mg/mL)
Dosage Form:	Liquid
Product Shape:	PFS
Product Color:	
Product Imprint:	

FOR GENERIC DRUG PRODUCTS

[ ] Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	Narcan Injection

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
GLN:	
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
If Yes, was original product purchased direct from mfr?	
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
If yes, attach documentation from FDA.	

GTIN AND HIBCC PRODUCT INFORMATION

	Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x	Item/Each	1		00355150345106	
	Box/Carton/Bundle/Inner Pack				
	Case	8		50355150345101	
	Pallet	30		70355150345105	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Notes	Protect from light.
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No

b. Contact for temperature excursion questions:

Name:	Steve Lucas
Number:	732-823-4122
Group E-mail:	slucas@aurobindousa.com

c. Special regulations for product in any states?	No
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	No
Protect product (unit of sale) from light?	Yes
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	24 Months

ORDER INFORMATION

Unit of Sale		What is the NDC selling unit?
	Bottle	1 Carton of 10 Pre-Filled Syringes
x	Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
	Ampule	
	Glass	Minimum order quantity? Yes
	Tube	
	Vial Liquid Sgl	
	Vial Liquid Multi	If Yes, how many of which package type?
	Vial Powder Sql	Each
	Vial Power Multi	Inner/Carton/Pack
	Other: Write In	1 Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?	Rx billing unit to pharmacy:	
10 Pre-Filled Syringes	x	Each
(Write-in, e.g. 1 Vial)		Gram
	x	Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	# Pieces:
Item/Each:	0.704	6.3	4.13	8.07	209.97333	1 pack of 10
Box/Carton/Bundle/ Inner Pack:						
Case:	9.4	18.701	14.37	10.24	2751.8297	8 packs
Pallet:	315.058	48	40	56.18	107865.6	30 Cases

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	$315.00
As of date:	

WHOLESALER USE ONLY:

Vendor #:	
Whsl. Code #:	
Fineline Code:	

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature: Aravinda Kumar A.

Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2020

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):
- a. Cytotoxic? No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
  - Is the product a CA Prop 65 carcinogen? No
  - Is the product a CA Prop 65 reproductive toxicant? No
  - Does the product label bear a CA Prop 65 warning? No
- c. Contact Hazard? No
- d. Does this product require special clean-up instructions? No
  (If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT? No
(if yes, answer a-e below and provide SDS)
- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard? No

Is this product regulated for shipment by IATA? No
(if yes, answer a-e below and provide SDS)
- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard? No

Is the product restricted for air shipment? If so, indicate restriction:
- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

Is this a reportable quantity?
RQ Threshold:
Is this a marine pollutant?
Is this product shipped utilizing an authorized DOT exception or Special Permit?
(if yes, identify method below)
- ☐ Limited Quantity
- ☐ Consumer Commodity, ORM-D
- ☐ Small Quantity (49 CFR 173.4)
- ☐ Special Permit; DOT-SP
- ☐ Special Provision (listed in Column 7 of 49 CFR 172.101);
  SP#

SDS Hazard Classification

- ☐ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Corrosive
- ☐ Oxidizer
- ☐ Contact Hazard
- ☐ Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?
If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:
Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No
If Yes, is it managed with a pharmacy registry?
Website URL:

Med Guide Required
Limited Distribution Requirement
Comments / Details: (For example, iPledge program?)

REMS: No
REMS Program Manager Name: Phone:
Supplier Manages REMS registry exclusively:
Wholesale distributor support:
Provider Name: DEA #:
Site Enrollment Number assigned by Supplier: PCPDP#:
NPI #:
Comments

Registry:
Registry Program Contact Name: Phone:
Comments

ADD'L STORAGE INFORMATION

Is the Product…
- Controlled Substance? No
- Controlled by State(s)? No
- ARCOS Reportable? No
- Schedule No.
- Controlled Substance Code
- Listed Chemical (List I or II) No
- If yes, indicate which:
- Is it a scheduled listed chemical product?: No

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes
Restricted to retail pharmacy only: No
Restricted to hospital, clinics, and physician offices only: No
Restricted from US territories? (explain in comments) No
Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 888-238-7880
Is product returnable for credit: Yes
URL/Link to returns policy: http://auromedics.com/policies/return-policy/

Special regulations or returns requirements for this product in certain states?
If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2020

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:

a. EDI
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:

Supplier's Customer Service Number:

Contracted 3PL company / contact #: Name:

Phone:

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier

Cut off time:

Shipping lead time of PO: Hours Days

Ships same day for next day receipt:

Ships for second day receipt:

Ships regular ground for 3-10 days receipt:

Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order:

Drop Ship service fee billed with each order:

Drop Ship miscellaneous fees billed:

Comments:

Overnight and Priority Overnight PO Processing

Overnight receipt available:

PO Receipt cut off time:

Days of week overnight is available:

- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

Priority Overnight receipt available:

PO Receipt Cut off time:

Saturday Overnight receipt available:

PO Receipt Cut off time:

Order receipt method: Phone: Phone #:

Fax: Fax #:

EDI:

Overnight Fees apply:

Other fees apply:

Class of Trade Restriction:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

Other Data Information Required to Process PO:

Patient Procedure Date:

Physician Name:

Physician/Clinic Phone #

Physician State License #

Physician/Clinic DEA #:

Physician/Clinic Specialty:

Return Instructions

Contact # if product is received damaged:

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?

Miscellaneous Notes:

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?

Is product order for restocking purposes?