Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Item | [ ] Final Version | **Date:**

PRODUCT INFORMATION

Company Name: AuroMedics Pharma LLC | **Application:** ANDA
Application Number for NDA/ANDA/BLA, Med Device: 205867
DUNS:
Rx Product/Proprietary Name: DEXMEDETOMIDINE HYDROCHLORIDE INJECTION 200 mcg/ 2 mL (100 mcg/mL)
NDC: 55150-209-02 | **UPC:** 355150209026
CVX Code: | **MVX Code:**
Description: DEXMEDETOMIDINE HYDROCHLORIDE INJECTION 200 mcg/ 2 mL (100 mcg/mL)
Active ingredients:
URL for Additional Product Information: www.auromedics.com

Address: 6 Wheeling Road | **Address 2:**
City: Dayton | **State:** NJ | **Zip:** 08810
Key Contact: | **Email:**
Phone Number: 888-238-7880 | **Fax:** 732-355-9449

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AP | **II. Brand Name:**
III. Generic Equivalent for Brand:

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes
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?
Are any waivers granted for product ID/barcode? | **If yes, attach documentation from FDA**

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

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

- [ ] I. Freezer – between -25 and -10 C (-13° – 14° F)
- [ ] II. Cold – between 2 and 8 C (36° – 46° F)
- [ ] III. Cool – between 8 and 15 C (46° – 59° F)
- [x] IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
- [ ] V. Avoid Excessive Heat – above 40 C (>104° F)
- [ ] VI. Other Temperature Range Requirement (write in)
- [ ] VII. No Requirement

b. Contact for temperature excursion questions:
Name:
Number:
Is this product to be shipped to customers on ice?
Is this product to be shipped to customers on dry ice?

c. Special regulations for product in certain states?
Special returns requirements for this product?

d. Store product (unit of sale) upright?
Protect product (unit of sale) from light?

e. Shelf life: Months
Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION

Is the Product… Direct Ship Item
Legend Device? No
State Control? No
ARCOS reportable? No
Co-Licensed? No
Controlled Substance? No
Schedule No.?
(incl. N for non-narcotic)
Controlled Substance Code:
Hazardous Material/Cytotoxic Agent? No

Is Item...
If Unit Dose, is item bar coded to unit dose for hospital scanning?
Is it reverse numbered?

ORDER INFORMATION

Unit of Sale

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

What is the NDC selling unit?
25 Vials in one Carton
(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?

If Yes, how many of which package type?
Each
48 Inner/Carton/Pack
Case

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Height	Width:	Volume (Cube)	# Pieces:
Item:						
Box/ Carton:	0.54378 (Carton	3.54 (Carton contains 25	1.97 (Carton contains 25	3.54 (Carton contains 25		25 Vials
Case:	29.84	15.944	11.22	12.4		48 Cartons
Pallet:	838.732 (For Sea)	48	38.90 (For Sea)	40		For Sea - 1296
UPC:	**Case:**					
	Carton:	355150209026				

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

- [ ] Each
- [ ] Gram
- [ ] Milliliter

Other Product Information

Size/Strength/Form:
Product Shape:
Product Color:
Product Imprint:

COST INFORMATION

Regular Cost Per Unit of Sale ($)	Invoice Cost (WAC) ($)	Federal Excise Tax Per Unit of Sale
	$800.00	

As of date: 5/26/2016

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:**

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? No

- ☐ Carcinogen
- ☐ Reproductive Toxicant
- ☐ Both
- ☐ Warning appears on label

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

Hazardous Waste Identification

EPA Hazardous Waste Code:

Is this product regulated for shipment by the DOT? No

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

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#

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

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization

	Level			How?			GTIN-14
Serialized?	☐ Item	☐ 2D	☐ Linear	☐ RFID	10355150209023
If not, when?	☐ Box/Carton	☐ 2D	☐ Linear	☐ RFID	10355150209023
Items aggregated to case?	☐ Case	☐ 2D	☐ Linear	☐ RFID	50355150209021
	☐ Pallet	☐ 2D	☐ Linear	☐ RFID	70355150209025

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

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

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

- ☐ Organic
- ☐ Antineoplastic
- ☐ Corrosive
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Oxidizer

☐ Aerosol Class; Identify NFPA Storage Level:

☐ Listed Chemical (List I or II) (Indicate or Write-in below):

- ☐ Ephedrine
- ☐ Pseudoephedrine
- ☐ Phenylpropanolamine
- ☐ Iodine (≥2.2%)
- ☐ Other:

RETURN INSTRUCTIONS

Contact tel. # if product 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?

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:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

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:

REMS or Registry Restrictions

REMS:
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

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?

ADDITIONAL INFORMATION

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

Other Data Information Required to Process PO:

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

Miscellaneous Notes: