



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: ☐ New Item

☐ Final Version

Date:

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
Company Name: <input type="text" value="AuroMedics Pharma LLC"/> Application: <input type="text" value="ANDA"/>		a. Temperature – Indicate the USP temperature range for this product.	
Application Number for NDA/ANDA/BLA, Med Device: <input type="text" value="207358"/>		<input type="checkbox"/> I. Freezer – between -25 and -10 C (-13° – 14° F)	
DUNS: <input type="text"/>		<input type="checkbox"/> II. Cold – between 2 and 8 C (36° – 46° F)	
Rx Product/Proprietary Name: <input type="text" value="Acetylcysteine Injection 6gm/30mL (200mg/mL)"/>		<input type="checkbox"/> III. Cool – between 8 and 15 C (46° – 59° F)	
NDC: <input type="text" value="55150-259-30"/> UPC: <input type="text" value="355150259304"/>		<input checked="" type="checkbox"/> IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)	
CVX Code: <input type="text"/> MVX Code: <input type="text"/>		<input type="checkbox"/> V. Avoid Excessive Heat – above 40 C (>104° F)	
Description: <input type="text" value="Acetylcysteine Injection 6gm/30mL (200mg/mL)"/>		<input type="checkbox"/> VI. Other Temperature Range Requirement (write in) <input type="text"/>	
Active ingredients: <input type="text"/>		<input type="checkbox"/> VII. No Requirement	
URL for Additional Product Information: <input type="text" value="www.auromedics.com"/>		b. Contact for temperature excursion questions:	
Address: <input type="text" value="6 Wheeling Road"/> Address 2: <input type="text"/>		Name: <input type="text" value="Steve Lucas"/>	
City: <input type="text" value="Dayton"/> State: <input type="text" value="NJ"/> Zip: <input type="text" value="08810"/>		Number: <input type="text" value="732-823-4122"/>	
Key Contact: <input type="text"/> Email: <input type="text"/>		Is this product to be shipped to customers on ice? <input type="text" value="No"/>	
Phone Number: <input type="text" value="888-238-7880"/> Fax: <input type="text" value="732-355-9449"/>		Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>	
FOR GENERIC DRUG PRODUCTS			
I. Orange Book Rating: <input type="text" value="AP"/> II. Brand Name: <input type="text" value="Acetadote"/>		c. Special regulations for product in certain states? <input type="text" value="No"/>	
III. Generic Equivalent for Brand: <input type="text" value="acetylcysteine"/>		Special returns requirements for this product? <input type="text" value="No"/>	
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION			
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/>			
Is product exempt from DSCSA? <input type="text" value="No"/>			
If yes, select exemption: <input type="text"/>			
Other exemption - Write in: <input type="text"/>			
Is product repackaged? <input type="text" value="No"/> If Yes, was original product purchased direct from mfr? <input type="text"/>			
Is product sold by manufacturer's exclusive distributor? <input type="text" value="No"/>			
Are any waivers granted for product ID/barcode? <input type="text" value="No"/> If yes, attach documentation from FDA <input type="text"/>			
ADDITIONAL PRODUCT INFORMATION		ITEM AND PACKING INFORMATION	
Is the Product... <input type="text" value="Direct Ship Item"/>		Weight Lbs. <input type="text"/> Dimensions (US msmts.) <input type="text"/> Volume (Cube) <input type="text"/> # Pieces: <input type="text"/>	
Legend Device? <input type="text" value="No"/>		Item: <input type="text"/>	
State Control? <input type="text" value="No"/>		Box/ Carton: <input type="text" value="0.59660 (Carton)"/> <input type="text" value="2.68 (Carton contains 4)"/> <input type="text" value="3.15 (Carton contains 4)"/> <input type="text" value="2.68 (Carton contains 4)"/>	
ARCOS reportable? <input type="text" value="No"/>		Case: <input type="text" value="20.645"/> <input type="text" value="15.748"/> <input type="text" value="9.449"/> <input type="text" value="10.433"/>	
Co-Licensed? <input type="text" value="No"/>		Pallet: <input type="text" value="858.833 (For Sea)"/> <input type="text" value="48"/> <input type="text" value="43.03 (For Sea)"/> <input type="text" value="40"/>	
Controlled Substance? <input type="text" value="No"/>		UPC: <input type="text" value="Case: 355150259304"/> <input type="text" value="Carton: 355150259304"/>	
Schedule No.? <input type="text"/>			
(incl. N for non-narcotic)			
Controlled Substance Code: <input type="text"/>			
Hazardous Material/Cytotoxic Agent? <input type="text" value="No"/>			
Is Item... <input type="text"/>			
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/>			
Is it reverse numbered? <input type="text"/>			
WHOLESALE USE ONLY:		COST INFORMATION	
Vendor #: <input type="text"/>		Regular Cost Per Unit of Sale (\$) <input type="text"/>	
Whsl. Code #: <input type="text"/>		Invoice Cost (WAC) (\$) <input type="text" value="750.00"/>	
Fineline Code: <input type="text"/>		Federal Excise Tax Per Unit of Sale <input type="text"/>	
Rx billing unit to pharmacy: <input type="text"/>		As of date: <input type="text" value="10/6/2016"/>	
<input type="checkbox"/> Each			
<input type="checkbox"/> Gram			
<input type="checkbox"/> Milliliter			
PHARMACY ORDER / BILL UNIT		Other Product Information	
Rec. sell unit to customer? <input type="text"/>		Size/Strength/Form: <input type="text"/>	
<input type="text" value="(Write-in, e.g. 1 Vial)"/>		Product Shape: <input type="text"/>	
Product Color: <input type="text"/>		Product Imprint: <input type="text"/>	
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?
(If yes, attach SDS with special instructions.) ☐ No
- 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)

Is this a reportable quantity?

RQ Threshold:

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

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?	<input type="checkbox"/>	Item	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID 10355150259301
If not, when?	<input type="text"/>	Box/Carton	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID 10355150259301
Items aggregated to case?	<input type="checkbox"/>	Case	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID 50355150259309
		Pallet	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID 70355150259303

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

☐ Aerosol Class; Identify NFPA Storage Level:

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	Standard Order Receipt and Processing
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="text"/></p> <p>b. Autofax <input type="text"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="text"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="text"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="text"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p>
<p>Expedited Freight Charges or Other Designated Drop Ship Fees:</p> <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Overnight and Priority Overnight PO Processing</p> <p>Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p>
<p>Class of Trade Restriction:</p> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input type="text"/></p>	
<p>REMS or Registry Restrictions</p> <p>REMS: <input type="text"/></p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="text"/></p> <p>Wholesale distributor support: <input type="text"/></p> <p>Provider Name: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/></p> <p>DEA #: <input type="text"/></p> <p>PCPDP #: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments: <input type="text"/></p> <p>Registry: <input type="text"/></p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Return Instructions</p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
<p>Other Data Information Required to Process PO:</p> <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>ADDITIONAL INFORMATION</p> <p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p> <p>Miscellaneous Notes:</p> <p><input type="text"/></p>