

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014			Intro	duction Type:	New Item			Final Version		Date:		
PRODUCT INFORMATION						SPECIAL HAI	NDLING AND ST	FORAGE REQU	IREMENTS*			
Company Name: AuroMedics Pharma LLC Application: ANDA					a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANDA/BLA, Med Device:			207358				I. Freezer – between -25 and -10 C (-13° – 14° F)					
DUNS:	,		1					II Cold - betwee	an 2 and 8 C (36	° – 46° F)		
			njection 6gm/30mL (200mg	a/mL)			II. Cold – between 2 and 8 C (36° – 46° F) III. Cool – between 8 and 15 C (46° – 59° F)					
				355150259304			IV. Controlled Ro	· ·	,	– 77° F)		
CVX Code:				MVX Code:				allows for exc	ursions between	15 and 30 C (59	9° – 86° F)	
Description:	Acetylcysteine Injection	on 6gm/30mL (200	0mg/mL)					V. Avoid Excess	ive Heat – above	e 40 C (>104° F)		
•		0	0 /					VI. Other Tempe				
Active ingredients:								(write in)				
							VII. No Requiren	nent				
URL for Additional Produ	uct Information:	www.auromedic	cs.com									
Address:	6 Wheeling Road			Address 2:				or temperature e	excursion quest	ions:		
City:	Dayton			State: NJ Zip: 08810			Name: Steve Lucas					
Key Contact: Phone Number:	888-238-7880		Email: Fax:	732-355-9449			Numbe			n ian?	No	
Phone Number:	000-230-7000							duct to be shipped				-
		FOR						duct to be shipped			No	-
I. Orange Book Rating:	AP		II. Brand Name:	Acetadote								
III. Generic Equivalent fo		acetylcysteine					c. Special re	gulations for pr	oduct in certain	states?	No	-
	DRU	IG SUPPLY CHA	IN SECURITY ACT (DSCS	SA) INFORMATI	ION		Special re	urns requirement	ts for this produc	t?	No	_
Does supplier meet DSC	SA definition of manu	facturer?	Yes									
Is product exempt from I	DSCSA?	No				d. Store product (unit of sale) upright?			No			
If yes, select exemption	n:		_			Protect product (unit of sale) from light? No			_			
Other exemption - Wri										-		
Is product repackaged?		No	If Yes, was origina	al product purcl	hased direct from mfr?		e. Shelf life:	24	Months			
Is product repackaged? Is product sold by manu	facturer's exclusive di	No stributor?	If Yes, was origina No	al product purcl	hased direct from mfr?		e. Shelf life:	24 Initial shelf I	Months ife at launch (if	different):		Months
		stributor?	-		hased direct from mfr?		e. Shelf life:			different):		Months
Is product sold by manu		stributor? le?	No	If yes, attach			e. Shelf life:	Initial shelf I] Months
Is product sold by manu		stributor? le?	No No	If yes, attach	documentation from FDA			Initial shelf li ITEM AND	ife at launch (if	ORMATION	Volume	<u>-</u>
Is product sold by manu Are any waivers granted	for product ID/barcod	stributor? le?	No No	If yes, attach	documentation from FDA		e. Shelf life: Weight Lb:	Initial shelf li ITEM AND	Fe at launch (if PACKING INF	ORMATION	Volume (Cube)] Months # Pieces:
Is product sold by manu Are any waivers granted Is the Product Legend Device? State Control?	for product ID/barcod	stributor? le? ADDITIONAL P 	No No PRODUCT INFORMATION Unit of Sale Bottle	If yes, attach ORDER INFOR What is the N 4 Vials in one	documentation from FDA RMATION IDC selling unit? Carton. The Carton NDC No. is			Initial shelf li ITEM AND Din	D PACKING INFO	ORMATION smts.)		<u>-</u>
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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	Hazardous Waste Identification					
c. Contact Hazard?						
d. Does this product require special clean-up instructions?						
(If yes, attach SDS with special instructions.)						
e. Does the product contain DEHP?						
Is this product regulated for shipment by the DOT?	(if yes, answer a-d below and provide SDS)					
	a. DOT Hazard Class					
Is this a reportable quantity?	b. UN/ID Number					
RQ Threshold:	c. Packing Group					
Is this a marine pollutant?	d. Inhalation Hazard?					
Is this product shipped utilizing an authorized DOT exception or Special Permit?						
(if yes, identify method below)						
Limited Quantity	ADDITIONAL PRODUCT INFORMATION - Serialization					
Consumer Commodity, ORM-D	Level How? GTIN-14					
Small Quantity (49 CFR 173.4)	Serialized? Item 2D Linear RFID 10355150259301					
Special Permit; DOT-SP	If not, when? Box/Carton 2D Linear RFID 10355150259301					
Special Provision (listed in Column 7 of 49 CFR 172.101);	Items aggregated to case? Case 2D Linear RFID 50355150259309					
SP#	Pallet 2D Linear RFID 70355150259303					
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS					
Passenger	Is there a REMS on this product?					
Cargo	If Yes, is it managed with a pharmacy registry? Website URL:					
Passenger & Cargo	Website UKL:					
ADD'L STORAGE INFORMATION	Comments / Details: (For example, iPledge program?)					
Please check as appropriate for this product.						
Organic Inorganic						
Antineoplastic Steroid/Androgen						
Corrosive Oxidizer						
Aerosol Class; Identify NFPA Storage Level:	RETURN INSTRUCTIONS					
Aerosol Class, Identily INFFA Storage Level.						
	Contact tel. # if product received damaged:					
	Is product returnable for credit:					
Listed Chemical (List I or II) (Indicate or Write-in below):	URL/Link to returns policy:					
Ephedrine	Special regulations or returns requirements for this product in certain states?					
Pseudoephedrine	If so, which states? Other requirements? Comments?					
Phenylpropanolamine						
lodine (≥2.2%)						
Other:						
CLASS OF TRADE RESTRICTION:	ADDITIONAL INFORMATION					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	If Unit Dose NDC, indicate NDC here:					
Restricted to retail pharmacy only:	MISCELLANEOUS NOTES and/or Image of Product Barcode:					
Restricted to hospital, clinics, and physician offices only:						
Restricted from US territories? (explain in comments)						
Comments:						



Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNAT	ED DROP	SHIP PRODUCT	ONLY - if not a	designated	drop ship, d	o not con	nple	te.

Order Meth	hod for Designated Drop Ship Product	Standard Order Receipt and Processing			
Purchase orders may be accepted by: a. EDI b. Autofax	Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:			
c. Fax	Fax Number:	Shipping lead time of PO: Hours Days			
d. Phone only	Phone No.:				
e. Supplier Web Site only	Site Address:	Ships same day for next day receipt:			
Minimum Order Quantity:		Ships for second day receipt:			
Supplier's Customer Service Number: Contracted 3PL company / contact #: Nar	mo	Ships regular ground for 3-10 days receipt:			
	one:	-			
	Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing			
	Charges of Other Designated Drop Ship Fees.				
Expedited freight fees billed with each order:		Overnight receipt available:			
Drop Ship service fee billed with each order:		PO Receipt cut off time:			
Drop Ship miscellaneous fees billed:		Days of week overnight is available: Monday			
Comments:		Tuesday Wednesday Thursday Friday			
		Priority Overnight receipt available:			
	Class of Trade Restriction:	PO Receipt Cut off time:			
No restriction: Select YES if sold to retail pharma	acy, hospitals, clinics and physician offices	Saturday Overnight receipt available:			
Restricted to retail pharmacy only:		PO Receipt Cut off time:			
Restricted to hospital, clinics, and physician office	es only:	Order receipt method: Phone: Phone #:			
Restricted from US territories? (explain in comme	ents)	Fax: Fax #:			
Comments:		EDI:			
		Overnight Fees apply:			
		Other fees apply:			
	REMS or Registry Restrictions	Return Instructions			
REMS:		Contact # if product is received damaged:			
REMS Program Manager Name:	Phone:	Is product returnable for credit:			
Supplier Manages REMS registry exclusiv Wholesale distributor support:		URL/Link to returns policy: Special regulations or returns requirements for this product in certain states?			
Provider Name:		If so, which states? Other requirements? Comments?			
Site Enrollment Number assigned	by Supplier:				
DEA #:		-			
PCPDP #:					
NPI #:					
Comments:		ADDITIONAL INFORMATION			
Registry:					
Registry Program Contact Name:	Phone:	Is product order for scheduled patient procedure?			
Comments		Is product order for restocking purposes?			
	a Information Required to Process PO:	Miscellaneous Notes:			
Patient Procedure Date:					
Physician Name:					
Physician/Clinic Phone #					
Physician State License # Physician/Clinic DEA #:					
Physician/Clinic DEA #.		111			