

## **Standard Pharmaceutical Product Information (Rx Product Only)**

					Introduction Ty	рс.	New Item		Final Version			Date:	4/21/2	
			PRODUCT INFORMATION						SPECIAL HANDLI	ING AND STO	RAGE REQU	IREMENTS	•	
Anniination Number for ND	AuroMedics Pharma L	LC			Applic	cation:	ANDA	a. Temperature – Indic	ate the USP tempera	ature range fo	or this produc	ct.		
Application Number for NDA	or NDA/ANDA/BLA (drug); PMA/510(k)(med device):			207739	207739			Temperature Range			Controlled Room – between 20 and 25 C (68° – 77° F			
DUNS:	968961354							Other Te	mperature Range Re	quirement				
Proprietary Name (If Applicate	ne (If Applicable) and Established Name: Fluphenazine Decanoate Injection, USP 125mg/5mL (25mg/mL) (5 mL - MDV)[MONO]								ite in)		Store at 20° t	o 25°C (68°	to 77°F).	
	55150-267-05		Individual Unit NDC:	55150-267-05		35515026705	57							
UDI			CVX Code:		MVX Code:			Is this pro	oduct to be shipped to	o customers o	n ice?		No	
Description:	Fluphenazine Decano	ate Injection, USP 125mg	g/5mL (25mg/mL) (5 mL - MDV)[MON	IO]				Is this pro	oduct to be shipped to	o customers o	n dry ice?		No	
Active Ingredient(s):								b. Contact for tempera	ture excursion ques	tions:	Steve Lucas			
URL for Additional Product In	oformation:	www.auromedics.com						Name: Number:			732-823-412	2		
Address:	279 Princeton-Hightstown Road			Address 2:			Group E-mail:			102 020 4122				
City:	East Windsor			State: NJ Zip: 08520										
Key Contact:				Email:			c. Special regulations t					No		
Phone Number:	888-238-7880			Fax: 732-355-9449			Special re	eturns requirements f	for this produc	t?	,	No		
Product Therapeutic Classific	cation:													
ADDITIONAL	L PRODUCT INFORM	ATION	1		RODUCT DESCRIPTI	ION INFORM	ATION	d. Store product (unit of		\			Yes	
	L PRODUCT INFORM.	ATION		F	RODUCT DESCRIPTI	ION INFORMA	ATION	·	product (unit of sale)	) from light?			No	
Is the Product		N.						e. Shelf life:	-16.1%4.1				24	Months
a legend device? reverse numbered?		No No		Size:	1 x 5 mL Mu	ulti Dose Vial		initiai sn	elf life at launch (if o	aimerent):				Months
co-licensed?		No				(0= ( 1)			0	RDER INFOR	RMATION			
Is the Product		Direct-Ship Only		Strength:	125mg/5mL	(25mg/mL)								
Is the Product				Dosage Form:	LIQUID			Unit of S			What is the I		unit?	
									Bottle		55150-267-0			
If Unit Dose, is item bar coded	d to unit dose for hospi	tal scanning?							Box/Carton Ampule		(Write-in, e.g	j. 1 Box of 10	) Vials)	
If Unit Dose NDC, indicate ND	OC here:			Product Shape	Vial Pack				Glass		Minimum or	der quantity	?	
				Book doors Only					Tube			,		
Country of Origin		India		Product Color:					Vial Liquid Sgl					
									W. W L					
Is this product covered under	the Trade Agreements	Act (TAA)?		Product Imprir	nt:			х	Vial Liquid Multi				ch package ty	ype?
Is this product covered under	the Trade Agreements	Act (TAA)? No		Product Imprir	nt:			X	Vial Powder Sql		1	Each		ype?
Is this product covered under	the Trade Agreements	Act (TAA)?		Product Imprir	nt:				Vial Powder Sql Vial Power Multi		70	Each Inner/Carton		ype?
Is this product covered under	the Trade Agreements	Act (TAA)? No	FOR GENERIC DRUG PRODUCTS		nt:				Vial Powder Sql	1	70	Each		ype?
Is this product covered under	the Trade Agreements	s Act (TAA)? No	FOR GENERIC DRUG PRODUCTS	5					Vial Powder Sql Vial Power Multi Other: Write In	]	70 420	Each Inner/Carton Case		ype?
		Act (TAA)? No	FOR GENERIC DRUG PRODUCTS	5	orized Generic *		Generic, other section		Vial Powder Sql Vial Power Multi Other: Write In PHAR	MACY ORDE	1 70 420 R / BILL UNIT	Each Inner/Carton Case	/Pack	ype?
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	AO	Act (TAA)? No No Prolixin Decanoate	FOR GENERIC DRUG PRODUCTS	5	orized Generic *			Rec. sell unit to custon	Vial Powder Sql Vial Power Multi Other: Write In PHAR	MACY ORDE	1 70 420 R / BILL UNIT	Each Inner/Carton Case  Interest to pharma Each	/Pack	ype?
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I. Orange Book Rating: II. Generic Equivalent to What  Does supplier meet DSCSA d Is product exempt from DSCS If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufactu Has FDA granted waiver/exce  Serialized? If not, when?	AO t Brand?: definition of manufacts SA?	Prolixin Decanoate  DRUG SUPPL  urer?  poutor? product?   X X X X X X X X X X X X X X X X X X	Yes No No No No Saleable Level Unit Item BowCarton/Bundle/Inner Pack Case	INFORMATION GLN:  If Yes, was original mfr?  If yes, attach docu  2D	0355150000005  Il product purchased mentation from FDA.  Linear L	Quantity	GTIN-14 10355150267054 30355150267058 50355150267052	Rec. sell unit to custon (Write-in, e.g. 1 Vial)  Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC:  COST  Regular Cost (WAC) (\$) Federal Excise Tax Per As of date:	Vial Powder Sql Vial Power Multi Other: Write In  PHAR  PHAR  Weight Lbs.  0.0638  5.038  33.07  Sea: 529.096  Air. 694.448  Case: Carton:  INFORMATION  r Unit of Sale 4/21/2018	MACY ORDE    ND PACKING	1 70 420	Each fire to pharma Each Gram Milliliter DN smts.) Width 1.26 9.49 15.945 40	Volume (Cube) 4.222512 454.3812 3403.29713 #VALUE!	# Pieces:  1 one E-Flute book, 6 E-Flute book, 1 Vial in Carton 70



## **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): SDS Hazard Classification a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? No Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard c. Contact Hazard? No Aerosol Class; Identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) Is the product a NIOSH hazardous drug? e. Does the product contain DEHP? No If yes, indicate which: Is this product regulated for shipment by DOT or IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number Hazardous Waste Identification b. Proper Shipping Name c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? Cargo If Yes, is it managed with a pharmacy registry? Passenger & Cargo Website URL: Is this a reportable quantity? RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) REMS: REMS Program Manager Name: Limited Quantity Phone: Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: Small Quantity (49 CFR 173.4) Wholesale distributor support: Special Permit: DOT-SP Provider Name: Special Provision (listed in Column 7 of 49 CFR 172.101); Site Enrollment Number assigned DEA #: by Supplier: PCPDP #: NPI#: ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? Nο Controlled by State(s)? No Registry: ARCOS Reportable? No Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Controlled Substance Code RETURN INSTRUCTIONS Listed Chemical (List I or II) If yes, indicate which: Is it a scheduled listed chemical product?: 888-238-7880 Contact tel. # if product received damaged: **CLASS OF TRADE RESTRICTION:** Is product returnable for credit: Yes URL/Link to returns policy: http://auromedics.com/policies/return-policy/ No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: If so, which states? Other requirements? Comments? Restricted from US territories? (explain in comments) Comments: 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
Purchase orders may be accepted by:  a. EDI  b. Autofax  c. Fax  Fax Number:  Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:  Shipping lead time of PO:  Hours  Days
d. Phone only e. Supplier Web Site only Minimum Order Quantity:  Supplier's Customer Service Number: Contracted 3PL company / contact #:  Name: Phone:	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:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:  Drop Ship miscellaneous fees billed:  Comments:	Overnight receipt available:  PO Receipt cut off time:  Days of week overnight is available:  Monday  Tuesday  Wednesday  Thursday  Friday
	Priority Overnight receipt available:
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:	PO Receipt Cut off time:  Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:  Miscellaneous Notes:	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?