

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

						Introdu	uction Type:		New Item	]	F	inal Version			Date:	7/10	/2020
			PRODUCT INFORM	IATION								SPECIAL HANDL	ING AND STO	DRAGE REQ	UIREMENTS	;*	
Company Name:	AuroMedics Pharma	LLC					Application	n:	ANDA	a. Temperatu	re – Indica	te the USP temper	ature range f				
Application Number for ND	A/ANDA/BLA (drug);	PMA/510(k)(med dev	ice):	21181	6					]	Temperatu	ure Range		Controlled F	toom – betwe	en 20 and 25	5 C (68° – 77° F
DUNS:	968961354									_	Other Terr	nperature Range Re	equirement				_
Proprietary Name (If Applica		Name: Chlor	rpromazine Hydrochloride Injec				una lanar				(write	e in)		Store at 20°	to 25°C (68°	to 77°F) [see	1
Selling Unit NDC: UDI	55150-318-25		Individual Unit NDC: CVX Code:	55	5150-318-01	мухс		5031825	4	+1	la thia area					Nie	
-						MIVA C	Joue.			<u>.</u>		duct to be shipped t				No	-
Description:	Chiorpromazine Hydr	ocnioride injection, U	SP 25 mg/mL (25 x 2 mL Amp	oules) 1 mL Fill Vo	oiume						Is this pro	duct to be shipped t	to customers of	on dry ice?		No	-
Active Ingredient(s):		Chlorpromazine Hyd	rochloride							b. Contact for		ire excursion ques	stions:				
URL for Additional Product I	Information									-	Name: Number:			Steve Lucas 732-823-412			
Address:	279 Princeton-Hights	town Road				Address 2	:				Group E-r	nail:			obindousa.co	om	
City:	East Windsor				State:	NJ	Zip:	C	8520	1				Ŭ			
Key Contact:					Email:					c. Special reg		or product in any s				No	_
Phone Number:	888-238-7880				Fax:	732-355-94	449			1	Special re	turns requirements	for this produ	ot?		No	-
Product Therapeutic Classifi	ication:	Antipsychotics, Antie	metics									· · · · · · · · · · · · · · · · · · ·				м.	
	AL PRODUCT INFORM				PI		ESCRIPTION I	INFORM	ATION	d. Store prod		sale) upright? roduct (unit of sale	) from light?			No No	-
Is the Product			-			Ковоот В				e. Shelf life:	Frotect pi	ouder (unit of sale	e) nom nync:			24	Months
a legend device?		No								e. Snen me.	Initial she	If life at launch (if	different):			24	Months
reverse numbered?		No	—	Si	ze:	25	5 x 2 mL Ampou	ules					,-				
co-licensed?		No	_	St	trength:	25	5 ma/mL (25 x 2	2 mL Am	ooules) 1 mL Fill Volum			C	ORDER INFO	RMATION			
Is the Product		Direct-Ship Only Neither												\A/h = 4 := 4 h =	NDC selling		
Is the Product		Neither	-	Do	osage Form:	LIC	QUID				Unit of Sa	lle Bottle		1 box of 25	NDC selling	unit?	
Kilek Deers is there has each		ital a comina a										Box/Carton			g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar code	ed to unit dose for nosp	ital scanning?		Pr	roduct Shape	Δr	npoule Pack				ļ	Ampule			-	·	
If Unit Dose NDC, indicate N	IDC here:									Glass		Minimum o	rder quantity	?	Yes		
Country of Origin	Country of Origin India								Гube /ial Liquid Sgl								
							/ial Liquid Multi		If Yes, how	many of wh	ich package	type?					
Is this product covered under the Trade Agreements Act (TAA)? No			Pr	Product Imprint:			Vial Powder Sql Each										
									•	]]		/ial Power Multi			Inner/Cartor	/Pack	
			FOR GENERIC DRUG P	PODUCTS								Other: Write In	-	1	Case		
			TOR GENERIC DRUG P	Roboers						-	L						
					Autho	rized Generi			Generic, other section			PHAR	RMACY ORDE	R / BILL UN	T		
I. Orange Book Rating: AP fields are not applicable					applicable	Rec. sell unit	to custom	er?		Rx billing u	nit to pharm	acy:					
II. Generic Equivalent to What	at Brand?:	Thorazine® Injection	n, 25 mg/mL (GlaxoSmithKline)	:)								25s) carton		x	Each		
		DBUC SU	PPLY CHAIN SECURITY ACT							(Write-in, e.g.	1 Vial)				Gram		
		DRUG SU	PPET CHAIN SECURITY ACT	I (DSCSA) INFOR	MATION					-					Milliliter		
Does supplier meet DSCSA of	definition of manufact	turer?	Yes	GLN:						1		ITEM A	ND PACKING	INFORMAT	ION		
Is product exempt from DSC	SA?		No														
If yes, select exemption: Other exemption - Write in:												Weight Lbs.	Dimei Depth	nsions (US n Height	width	Volume (Cube)	# Pieces:
Is product repackaged?			No	If Yes.	. was origina	l product p	urchased dire	ct		Item:		0 550 /		-		. ,	
Is product sold by manufactu	urer's exclusive distri	butor?	No	from r				-				0.5504	3.43	3.15	3.43	37.059435	25 ampoules
Has FDA granted waiver/exc	ception/exemption for	product?	No	lf yes,	, attach docu	mentation f	rom FDA.			Box/Carton/B	undle/	3.9707	10.67	3.94	7.32	307.731336	of 25) 150 a
			GTIN PRODUCT INFOR							Inner Pack:							.,
			GTIN PRODUCT INFO	Saleable						Case:		8.978	11.614	9.055	8.268	869.502318	s of 25) 300 a
			Level	Unit			Quan	ntity C	GTIN-14	Pallet:		1002.6936	48	58.15	40	111648	(1296 packs
Serialized?	Yes	x			<b>X</b> 2D	Lir	near 25		0355150318254				40	56.15	40	111040	of 25) 32400
If not, when?		x			<b>X</b> 2D		near 150		0355150318255	UPC:		Case:					
Items aggregated?		x			x 2D x 2D		near 300 near 3240		0355150318259 0355150318253		(	Carton:					
		<u>⊢</u> ^		┢──┤┝─	2D 2D		near 3240		000010200		COST II	NFORMATION			WHOLESAL	ER USE ONI	LY:
					2D	Lir	near										
					2D		near			Regular Cost				Vendor #:			
					2D Linear			Invoice Cost (WAC) (\$) \$722.25 Federal Excise Tax Per Unit of Sale			Whsl. Code #: Fineline Code:						
L										As of date:	e lax rer	Unit UI Gale	1	n menne CO	ue.		
											L			1			
			Attach copy of SAFETY DA	ATA SHEET (SDS	6) or non haza	rd letter, PA	CKAGE INSEF	RT, LABE	L AND PHOTO OF PRO	DUCT PACKAGI	NG and BA	RCODE.					
*Please provide any addition	nal information on pag	je 2.		-			o. 3 for Design				Signature				Muramredd	y penchalaiah	ı



# **Standard Pharmaceutical Product Information (Page 2)**

MALERIAL						
	HAZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply):						
a. Cytotoxic? No	SDS Hazard Classification					
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? No					
e. Does the product contain DEHP? No	If yes, indicate which:					
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	Hazardous Waste Identification					
c. DOT Hazard Class	EPA Hazardous Waste Code:					
d. Packing Group						
e. Inhalation Hazard?						
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS					
Passenger	Is there a REMS on this product? No					
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: No					
Limited Quantity	REMS Program Manager Name: 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 #:					
SP#	by Supplier: PCPDP #:					
	NPI #:					
ADD'L STORAGE INFORMATION						
Is the Product	Comments					
Controlled Substance? No						
Controlled by State(s)? No	Registry:					
ARCOS Reportable? No	Registry Program Contact Name: Phone:					
Schedule No. (inc. N for non-narcotic)	Comments					
Controlled Substance Code						
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS					
If yes, indicate which:						
Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 888-238-7880					
CLASS OF TRADE RESTRICTION:	Is product returnable for credit:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: http://auromedics.com/policies/return-policy/					
Restricted to retail pharmacy only: No	Special regulations or returns requirements for this product in certain states?					
Restricted to hospital, clinics, and physician offices only: No	If so, which states? Other requirements? Comments?					
Restricted from US territories? (explain in comments)						
Comments:						
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:					



# **Standard Pharmaceutical Product Information (Page 3)**

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if							
Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing						
Purchase orders may be accepted by:      a. EDI      b. Autofax      c. Fax      d. Phone only      e. Supplier Web Site only      Supplier's Customer Service Number:      Contracted 3PL company / contact #:      Name:      Phone:	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:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order:	Overnight receipt available:						
	Priority Overnight receipt available:						
Class of Trade Restriction:	PO Receipt Cut off time:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:    PO Receipt Cut off time:      Order receipt method:    Phone:    Phone #:      Fax:    EDI:    Fax #:      Overnight Fees apply:    Other fees apply:    Other fees apply:						
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date:	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?						



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

					Intro	duction Type:		New Item	] [	Final Version			Date:	7/10	/2020
			PRODUCT INFORMATION	1						SPECIAL HANDI	ING AND STO	ORAGE REQ	UIREMENTS	;*	
Company Name: AuroMe	edics Pharma LLC					Applicatio	on:	ANDA	a. Temperature –	Indicate the USP tempe	rature range f				
Application Number for NDA/ANDA	VBLA (drug); PMA/510(k	)(med device):		211816					Ter	nperature Range		Controlled F	toom – betwe	en 20 and 25	5 C (68° – 77° F
DUNS: 968961									Oth	er Temperature Range R	equirement				_
Proprietary Name (If Applicable) and		Chlorpromaz	ine Hydrochloride Injection, I							(write in)		Store at 20°	to 25°C (68°	to 77°F) [see	E.
Selling Unit NDC: 55150-3 UDI	-319-25		Individual Unit NDC: CVX Code:	55150-319-01		UPC: '3551 Code:	15031925	1	-	hia unadicatta ha ahinnad	** ********			Nie	
						code.			= 1	his product to be shipped				No	-
Description: Chlorpr	romazine Hydrochioride li	ijection, USP 50 m	ig/2 mL (25 mg/mL) (25 x 2 r	nL Ampoules) 2 mL Fill	voiume				Is t	his product to be shipped	to customers of	on dry ice?		No	-
Active Ingredient(s):	Chlorpron	nazine Hydrochlori	de							perature excursion que	stions:				
										me:		Steve Lucas			
URL for Additional Product Informati Address: 279 Print	tion: inceton-Hightstown Road				Address	2.				mber: oup E-mail:		732-823-412 slucas@aut	22 obindousa.co	m	
City: East W	0			State:	NJ	Zip:	C	8520	Gro	bup E-mail:		siucas@aui	opiniuousa.cu	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
Key Contact:				Email:				c. Special regulat	ions for product in any	states?			No		
	88-7880			Fax:	Fax: 732-355-9449					ecial returns requirements	for this produ	ct?		No	-
Product Therapeutic Classification:	Antipsych	otics, Antiemetics													
	DUCT INFORMATION					DESCRIPTION	NEODIA			unit of sale) upright?				No	_
	DUCTINFORMATION			-	RODUCT	DESCRIPTION	INFORM	ATION		etect product (unit of sal	e) from light?			No	
Is the Product a legend device?		No			Г				e. Shelf life:	ial shelf life at launch (if	different):			24	Months Months
reverse numbered?		No		Size:	2	25 x 2 mL Ampo	oules			iai sheli ille at laulich (il	unierenii).				wontins
co-licensed?		No		Strength:	Ę	50 mg/2 mL (25	mg/mL) (2	25 x 2 mL Ampoules)			ORDER INFO	RMATION			
Is the Product	Direct-Sh	p Only		Strength.	2	2 mL Fill Volume	e								
Is the Product	Neither			Dosage Form	: L	IQUID			Uni	it of Sale			NDC selling	unit?	
					L					Bottle x Box/Carton		1 box of 25 (Write-in_e	g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar coded to unit	t dose for hospital scannir	ig?		Des des tobes		Second Deals				Ampule		(11110 111, 0	g. 1 Dox 01 1	e vicio,	
If Unit Dose NDC, indicate NDC here:				Product Shape: Ampoule Pack				Glass		Minimum o	rder quantity	?	Yes		
	1			Product Color	r:					Tube					
Country of Origin						Vial Liquid Sgl Vial Liquid Multi		If Yes how	many of wh	ich package	type?				
Is this product covered under the Trade Agreements Act (TAA)?			Product Imprint:			Vial Powder Sql Each			type:						
										Vial Power Multi			Inner/Cartor	/Pack	
				1070						Other: Write In		1	Case		
		FU	R GENERIC DRUG PRODL						_						
				Auth	orized Gene	eric *lf Au	uthorized	Generic, other section		PHA	RMACY ORDE	R / BILL UN	Т		
I. Orange Book Rating: AP fields are not applicable					applicable	Rec. sell unit to c	ustomer?		Rx billing u	nit to pharm	acy:				
II. Generic Equivalent to What Brand	I?: Thorazine	® Injection, 25 mg	/mL (GlaxoSmithKline)						Multi Amp	oules (25s) carton		x	Each		
									(Write-in, e.g. 1 V	al)			Gram		
		DRUG SUPPLY C	HAIN SECURITY ACT (DSC	SA) INFORMATION					_				Milliliter		
Does supplier meet DSCSA definition	on of manufacturer?		Yes	GLN:						ITEM A	ND PACKING	INFORMAT	ION		
Is product exempt from DSCSA?		No													
If yes, select exemption: Other exemption - Write in:										Weight Lbs.	Dimer	nsions (US n Height	Width	Volume (Cube)	# Pieces:
Is product repackaged?		No		If Yes, was origin	al product	purchased dire	ect		Item:	0.6054	3.43	3.15	3.43	37.059435	05
Is product sold by manufacturer's ex	xclusive distributor?		No	from mfr?			-			0.6054	3.43	3.15	3.43	37.059435	25 ampoules
Has FDA granted waiver/exception/e	exemption for product?		No	If yes, attach doc	umentation	from FDA.			Box/Carton/Bund	le/ 4.3007	10.67	3.94	7.32	307.731336	of 25) 150 a
		G	TIN PRODUCT INFORMAT	ION	l i i i i i i i i i i i i i i i i i i i				Inner Pack: Case:						
		0	Sale						Case.	9.638	11.614	9.055	8.268	869.502318	s of 25) 300 a
			Level Ui	nit		Quar		GTIN-14	Pallet:	1073.9736	48	58.15	40	111648	(1296 packs
Serialized?	Yes	<b>x</b> Item		<b>( X</b> 2D		Linear 25		0355150319251			40	00.10	40	111040	of 25) 32400
If not, when?			/Carton/Bundle/Inner Pack	x 2D x 2D		Linear 150 Linear 300		0355150319252	UPC:	Case: Carton:					
Items aggregated?		X Cas X Palle		x 2D x 2D		Linear 3240		0355150319250		Carton.					
				2D	1	Linear			C	OST INFORMATION			WHOLESAL	ER USE ONI	LY:
				2D		Linear									
				2D		Linear	_		Regular Cost	C) (\$)	\$007 CO	Vendor #:	<i>#</i> .		
				2D Linear			Invoice Cost (WAC) (\$) \$827.50 Federal Excise Tax Per Unit of Sale			Whsl. Code #: Fineline Code:					
<b>-</b>									As of date:						
		Attac	ch copy of SAFETY DATA S	HEET (SDS) or non haz											
*Please provide any additional inform	mation on page 2.				See new	p. 3 for Desigr	nated Dro	p Ship Only.	Sig	nature:			Muramredd	y penchalaiah	ı



# **Standard Pharmaceutical Product Information (Page 2)**

MALERIAL						
	HAZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply):						
a. Cytotoxic? No	SDS Hazard Classification					
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? No					
e. Does the product contain DEHP? No	If yes, indicate which:					
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	Hazardous Waste Identification					
c. DOT Hazard Class	EPA Hazardous Waste Code:					
d. Packing Group						
e. Inhalation Hazard?						
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS					
Passenger	Is there a REMS on this product? No					
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: No					
Limited Quantity	REMS Program Manager Name: 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 #:					
SP#	by Supplier: PCPDP #:					
	NPI #:					
ADD'L STORAGE INFORMATION						
Is the Product	Comments					
Controlled Substance? No						
Controlled by State(s)? No	Registry:					
ARCOS Reportable? No	Registry Program Contact Name: Phone:					
Schedule No. (inc. N for non-narcotic)	Comments					
Controlled Substance Code						
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS					
If yes, indicate which:						
Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 888-238-7880					
CLASS OF TRADE RESTRICTION:	Is product returnable for credit:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: http://auromedics.com/policies/return-policy/					
Restricted to retail pharmacy only: No	Special regulations or returns requirements for this product in certain states?					
Restricted to hospital, clinics, and physician offices only: No	If so, which states? Other requirements? Comments?					
Restricted from US territories? (explain in comments)						
Comments:						
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:					



# **Standard Pharmaceutical Product Information (Page 3)**

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if							
Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing						
Purchase orders may be accepted by:      a. EDI      b. Autofax      c. Fax      d. Phone only      e. Supplier Web Site only      Supplier's Customer Service Number:      Contracted 3PL company / contact #:      Name:      Phone:	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:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order:	Overnight receipt available:						
	Priority Overnight receipt available:						
Class of Trade Restriction:	PO Receipt Cut off time:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:    PO Receipt Cut off time:      Order receipt method:    Phone:    Phone #:      Fax:    EDI:    Fax #:      Overnight Fees apply:    Other fees apply:    Other fees apply:						
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date:	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?						